

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Investigating the effect of sexual mindfulness-based training on sexual function and sexual well-being in women with breast cancer: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of sexual mindfulness-based training on sexual performance and sexual well-being in women with breast cancer

Design

Clinical trial with intervention and control groups, one blind strain, on 30 qualified women with breast cancer who were selected as available and with knowledge of the purpose and method of conducting the study, in two groups of 15 people, are randomly assigned.

Settings and conduct

In the first stage, after obtaining permission from the Ethics Committee of Shahrekord University of Medical Sciences, the researcher will go to the Alla Cancer Prevention and Control Center (Maxa), located in Isfahan city, to collect samples and conduct a targeted sampling of eligible women. In the next step, 30 eligible women with breast cancer were selected as available and after obtaining informed consent from them, they were randomly assigned to two intervention and control groups. The intervention group received sexual mindfulness training in 8 sessions, once a week, and in the meantime, the members of the control group did not receive any intervention. Before, immediately and three months later, both groups were given questionnaires of indicators of sexual performance and well-being. One-way blinding process is possible for this research. Finally, the obtained data will be analyzed with SPSS software version 24.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being sexually active Not having sexual dysfunction before cancer and... Exclusion criteria: major depression

Intervention groups

The members of the intervention group are trained in sexual mindfulness in 8 90-minute sessions by the researcher and with the cooperation of a clinical

psychologist. The control group does not undergo any training in these 8 weeks and only completes the questionnaire.

Main outcome variables

Sexual mindfulness. sexual function. Sexual well-being. breast cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230416057924N1**

Registration date: **2024-02-13, 1402/11/24**

Registration timing: **retrospective**

Last update: **2024-02-13, 1402/11/24**

Update count: **0**

Registration date

2024-02-13, 1402/11/24

Registrant information

Name

Asefeh Shirdashtzadeh kerdabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1272 3993

Email address

st-shirdasht.a@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-02-09, 1402/11/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of sexual mindfulness-based training on sexual function and sexual well-being in women with breast cancer:A Randomized Clinical Trial

Public title
Investigating the effect of sexual mindfulness-based training on sexual function and sexual well-being in women with breast cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least elementary education Iranian citizenship
Definite diagnosis of breast cancer (pathological diagnosis)
Informed consent to participate in the study
Being sexually active
Being single and living with a spouse now and during the study
Not having sexual dysfunction before of cancer
Absence of acute psychiatric disorders and use of related drugs
Passing at least 3 months of conventional cancer treatments

Exclusion criteria:

Failure to participate in 2 or more sessions during the research period
Using consulting services outside of research
Divorce or death of spouse during the study period
Existence of systemic or chronic disorders and any debilitating diseases such as heart disease, diabetes, etc
Any use of sedatives, alcohol, psychotropic substances and drugs
Diagnosing metastasis or disease recurrence
Unwillingness to continue cooperation
major depression

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
One-way blinding process is possible for this research. In this way, in the final analysis, the statistical analyst of the groups
The intervention and control are uninformed and the data of the groups with letters A and B is named

Placebo
Not used

Assignment
Single
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahrekord university of medical sciences

Street address

Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2023-08-15, 1402/05/24

Ethics committee reference number

IR.SKUMS.REC.1402.060

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description

Sexual well-being

Timepoint

Start of the intervention - immediately and three months after the intervention

Method of measurement

Based on the scores obtained from the women's sexual well-being questionnaire:(Fsws scale)

2

Description

Sexual function

Timepoint

Start of the intervention - immediately and three months after the intervention

Method of measurement

(Female Sexual Function Index-FSFI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The members of the intervention group are trained in sexual mindfulness in 8 90-minute sessions by the researcher in collaboration with a clinical psychologist. Meetings are held once a week in person.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

"Iranian Cancer Control Center" (MACSA)

Full name of responsible person

Homayun Naji Esfahani

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No. 29 Amin-o-Doleh Blind Alley, 35th Alley, Motahari St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Elham Raeisi

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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

Shahre-kord University of Medical Sciences

Proportion provided by this source

40

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Asefeh shirdashtzaeh

Position

master of midwifery student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

Midwifery

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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