Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of counseling intervention based on good enough sex (GES) model versus control group on the sexual self-esteem and the sexual quality of life among breast cancer survivors: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of counseling intervention based on good enough sex (GES) model versus control group on the sexual self-esteem and the sexual quality of life among breast cancer survivors

Design
This is a randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Mahdieh Diagnostic and Treatment Center in Hamadan city, involving 100 eligible breast cancer survivors. The patients will be randomly assigned to the intervention and control groups through the block randomization. It should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 49 years Married women Definitive diagnosis of breast cancer At least 6 months and a maximum of 5 years have passed since the treatment Being literate Being a Persian speaker Exclusion criteria: Pregnancy or breastfeeding History of participation in sex counseling sessions Psychological or cognitive problems Blindness or deafness

Intervention groups
Intervention group: Routine care plus 60-90-minute counseling sessions with the Good Enough Sex (GES) approach weekly for 4 weeks Control group: Just routine care

Main outcome variables
Primary outcome: Sexual self-esteem Sexual quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N482**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

Registrant information

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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of counseling intervention based on good enough sex (GES) model versus control group on the sexual self-esteem and the sexual quality of life among breast cancer survivors: a randomized clinical trial

Public title
Effect of counseling intervention based on good enough sex (GES) model versus control group on the sexual self-esteem and the sexual quality of life among breast cancer survivors

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 49 years Married women Definitive diagnosis of breast cancer At least 6 months and a maximum of 5 years have passed since the treatment Being literate Being a Persian speaker

Exclusion criteria:
Pregnancy or breastfeeding History of participation in sex counseling sessions Psychological or cognitive problems Blindness or deafness

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2023-08-12, 1402/05/21

Ethics committee reference number
IR.UMSHA.REC.1402.409

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 self-esteem

Timepoint
Before the intervention and 2 months later

Method of measurement
Using Sexual Self-Esteem Inventory- Women (SSEI-W)

2

Description
Sexual quality of life

Timepoint
Before the intervention and 2 months later

Method of measurement
Using Sexual Quality of Life-Female (SQOL-F) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care plus 60-90-minute counseling sessions with the Good Enough Sex (GES) approach weekly for 4 weeks (including: getting to know the anatomy of the body, the reproductive cycle, the importance of sex, the quality of sex, satisfaction and sexual performance, expectations in sex , correction of false beliefs and superstitions about sexual intercourse, the effect of breast cancer and mastectomy on sexual function, nutritional recommendations, sleep hygiene, body examination and conscious attention to different parts of the body, duration of sexual stimulation, enjoying sex , communication skills , skills to create and maintain intimacy)
Category
Treatment - Other

2

Description
Control group: Just routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Diagnostic and Treatment Center in Hamadan city
Full name of responsible person
Samaneh Goudarz
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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Samaneh Goudarz
Position
Midwifery Student
Latest degree
Master
Other areas of specialty/work
Midwifery
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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