

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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 Mahdiah 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

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

Street address

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 scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Azita Tiznobaik

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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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

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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