

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of consultation with the approach of motivational interview versus no consultation on sexual satisfaction and body image in women with breast cancer after mastectomy: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of consultation with the approach of motivational interview versus no consultation on sexual satisfaction and body image in women with breast cancer after mastectomy. Design: a randomized clinical trial. Setting and conduct: The eligible patients with breast cancer after mastectomy who will refer to Imam Khomeini Clinic during the study period will be enrolled into the trial. Inclusion criteria: age of 25 to 60 years; stage of I or II of the disease; completion of chemotherapy; having husband; literate; residence of Hamadan; sexual satisfaction score of 30 to 70. Exclusion criteria: Lumpectomy; substance abuse; having chronic diseases. Intervention group: Routine care plus consultation with the approach of motivational interview 45 min once a week for 5 weeks. Control group: Just routine care. Primary outcome: (a) assessing sexual satisfaction before and one and three months after intervention using Hudson questionnaire; (b) assessing body image before and one and three months after intervention using Lam questionnaire. Secondary outcome: Nothing. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608179014N109**
Registration date: **2016-08-19, 1395/05/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-19, 1395/05/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of consultation with the approach of motivational interview versus no consultation on sexual satisfaction and body image in women with breast cancer after mastectomy: a randomized clinical trial

Public title

Effect of consultation with the approach of motivational

interview versus no consultation on sexual satisfaction and body image in women with breast cancer after mastectomy	
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: age of 25 to 60 years; stage of I or II of the disease; completion of chemotherapy; having husband; literate; residence of Hamadan; sexual satisfaction score of 30 to 70. Exclusion criteria: Lumpectomy; substance abuse; having chronic diseases.
Age	From 25 years old to 60 years old
Gender	Female
Phase	2
Groups that have been masked	<i>No information</i>
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Not possible.
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Hamadan University of Medical Sciences
Street address	Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City	Hamadan
Postal code	6517838695
Approval date	2016-07-16, 1395/04/26
Ethics committee reference number	IR.UMSHA.REC.1395.219

Health conditions studied	
<u>1</u>	
Description of health condition studied	breast cancer
ICD-10 code	C50
ICD-10 code description	Malignant neoplasm of breast
Primary outcomes	
<u>1</u>	
Description	assessing sexual satisfaction
Timepoint	before and one and three months after intervention
Method of measurement	using Hudson questionnaire
<u>2</u>	
Description	assessing body image
Timepoint	before and one and three months after intervention
Method of measurement	using Lam questionnaire
Secondary outcomes	
<u>1</u>	
Description	Nothing
Timepoint	Nothing
Method of measurement	Nothing
Intervention groups	
<u>1</u>	
Description	Routine care plus consultation with the approach of motivational interview 45 min once a week for 5 weeks.
Category	Other
<u>2</u>	
Description	Just routine care
Category	Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Clinic

Full name of responsible person

Fatemeh Zanganeh

Street address

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Fatemeh Zanganeh

Position

Midwifery Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

Department of Epidemiology

Full name of responsible person

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Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty