# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

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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**

*No information*

**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

### 1

**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

### 1

**Description of health condition studied**

breast cancer

**ICD-10 code**

C50

**ICD-10 code description**

Malignant neoplasm of breast

## Primary outcomes

### 1

**Description**

assessing sexual satisfaction

**Timepoint**

before and one and three months after intervention

**Method of measurement**

using Hudson questionnaire

### 2

**Description**

assessing body image

**Timepoint**

before and one and three months after intervention

**Method of measurement**

using Lam questionnaire

## Secondary outcomes

### 1

**Description**

Nothing

**Timepoint**

Nothing

**Method of measurement**

Nothing

## Intervention groups

### 1

**Description**

Routine care plus consultation with the approach of motivational interview 45 min once a week for 5 weeks.

**Category**

Other

### 2

**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**
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## Sponsors / Funding sources

**1**

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**Name of organization / entity**
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**Full name of responsible person**
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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**
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

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## Person responsible for updating data

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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*