

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The effectiveness of health literacy group consultation on self care in women with breast cancer

#### Protocol summary

##### Summary

1) Objectives: Determine the effectiveness of health literacy group consultation on self-care in women with breast cancer(2) Design: It is a randomized trial without blinding.(3) Setting and conduct: Shiraz center (4) Participants: the sample consisted of 64 women with breast cancer who have had a mastectomy. inclusion criteria is: being Iranian women with breast cancer who have had a mastectomy, the first meeting of chemotherapy, no other underlying disease, wanting to take part in the study and exclusion criteria is: no wanting to take part in the study, lack of participation in a maximum of two sessions of consultation, failure to complete or partially completed questionnaires. (5) Intervention: self care consultations. (6) Main outcome: the primary outcome variable is health literacy and second is self care.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017022327728N5**

Registration date: **2017-05-13, 1396/02/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-13, 1396/02/23

##### Registrant information

##### Name

Zohreh Mahmoodi

##### Name of organization / entity

Nursing&Midwifery faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3430 4433

##### Email address

zohrehmahmoodi@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Alborz University of Medical Sciences

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### 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

The effectiveness of health literacy group consultation on self care in women with breast cancer

##### Public title

The effectiveness of health literacy group consultation on selfcare in women with breast cancer

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Iranian women; women with breast cancer who have had a mastectomy; the first meeting of chemotherapy; no other underlying disease; wanting to take part in the study. Exclusion criteria: no wanting to take part in the study; lack of participation in a maximum of two sessions of consultations; failure to complete or partially completed questionnaires.

##### Age

No age limit

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 32

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Alborz University Of Medical Sciences.

##### Street address

ninth floor, Dara building, north Yasmin, east Pune street, 45 Yards of Golshahr, karaj, Iran.

##### City

karaj

##### Postal code

#### Approval date

2017-01-28, 1395/11/09

#### Ethics committee reference number

Abzums.Rec.1395.144

## Health conditions studied

### 1

#### Description of health condition studied

Breast cancer

#### ICD-10 code

C50-C50

#### ICD-10 code description

Malignant neoplasm of breast

## Primary outcomes

### 1

#### Description

Health literacy.

#### Timepoint

At the beginning of the first session, at the end of sessions, three weeks after the intervention

#### Method of measurement

Iranian Health literacy Inventory

## Secondary outcomes

### 1

#### Description

selfcare

#### Timepoint

At the beginning of the first session, at the end of sessions, three weeks after the intervention

#### Method of measurement

self care Inventory

## Intervention groups

### 1

#### Description

1-Intervention group: In this group addition to routine counseling, Consultation with health literacy approach in self-care will offer in sessions. The number of sessions 7 and the duration of each sessions is an hour and a half the content that will be presented in each session is : session 1: meet members and leaders of groups, create positive relationships.Expression rules of the group and motivate active participation and time attendance at meetings ,a description of the nature of the disease and chemotherapy, feeling of sickness.Perceptions of the disease affect the body, and the importance of self-care needs of patients in their care. Session 2: Advice on health related concepts, understand basic information and familiarity with the person's thinking in the field of health care, digestive problems and ways of dealing with it. Session 3: Understand basic information and familiarity with the person's thinking in the field of skin and hair health, ways of dealing with it. Session 4: understand basic information and a familiar with the person's thinking in the field of fatigue, shortness of breath, pain, sexual problems and the proposed solutions to reduce complications. Session 5: Meeting the basic knowledge and a familiar with the person's thinking In the field of Mental Health (stress, depression) .symptoms and consequences, the need to identify, Prevention ways and ways of dealing with it Understanding concepts related to communication skills, understand the impact of family and social support. Session 6: understand basic information and a familiar with the person's thinking in the field of complications of treatments, the need to identify, prevent ways and the ways of dealing with it, and familiarity with the service provider associated with breast cancer. Session 7: Summary of presentations, training in counseling skills, ask questions about the classes held .receive feedback.

#### Category

Prevention

### 2

#### Description

2-Control group: In this group routine counseling sessions and self-care training package offered to control group.

#### Category

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Breast Diseases Research Center

**Full name of responsible person**

Dr, Zohreh Mahmoodi

**Street address**

Shahid Motahari Specialized Treatment Centers,  
Namazi Square, Shiraz, Iran.

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad noori sepehr

**Street address**

Department of Nursing and Midwifery, Alborz  
University of Medical Sciences, Eshteraki street,  
Baghestan, Karaj, Iran.

**City**

Karaj

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Alborz 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**

Alborz University of Medical Sciences

**Full name of responsible person**

Dr Zohreh Mahmoodi

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Department of Nursing and midwifery Alborz  
University of Medical Sciences, Eshteraki Street,  
Baghestan, Karaj, Iran

**City**

Karaj

**Postal code**

**Phone**

+98 26 3430 4433

**Fax**

**Email**

zohrehmahmoodi2011@gmai.com;

zohrehmahmoodi.abzums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Dr Zohreh Mahmoodi

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Department of Nursing and Midwifery of Alborz  
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zohrehmahmoodi 2011@gmail.com

;zohrehmahmoodi.abzums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Alborz university of medical sciences

**Full name of responsible person**

Dr Zohreh Mahmoodi

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**Web page address**

## **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*