

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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@gmail.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.abzums.ac.ir

Web page address

Person responsible for updating data

Contact

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zohrehmahmoodi 2011@gmail.com

;zohrehmahmoodi.abzums.ac.ir

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