Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Orem's Self Care training program on quality of life in breast cancer patients undergoing chemotherapy oncology centers in Shiraz

Protocol summary

Summary

The purpose of the study is to determine the application Orem's self-care training program on quality of life for breast cancer patients undergoing chemotherapy. 80 eligible patients were selected by sampling from available target based Shiraz oncology centers, and randomly classified into two test (40) and control (40) groups. The main inclusion criteria: women with breast cancer aged 18 to 69 years, spend at least on course of chemotherapy, self-care ability and exclusion criteria: women with breast cancer were older than 69 years, unwillingness to cooperate and death. Breast cancer quality of life questionnaire and demographic information before the intervention was completed by test and control groups. The training needs of patients in the test groups was obtained through completing the Orem's needs assessment form. The 8-session self-care program based on Orem's pattern during two months for educational counseling was conducted .it was 45-minute discussion lecture for the test group on the patient's needs. At the beginning of the intervention the test group received training booklet and checklist of daily activities. Two weeks after the last session, Breast Cancer Quality of Life Questionnaire again was completed by the two groups. The obtained data before and after the implementation of the program were analyzed in test and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042921425N2**
Registration date: **2016-05-23, 1395/03/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

Name
Shekoofeh Hamzehiekia
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Yasuj University of Medical Science

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-12-06, 1393/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Orem's Self Care training program on quality of life in breast cancer patients undergoing chemotherapy oncology centers in Shiraz

Public title

The effect of education on life of breast cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: women with breast cancer aged 18 to 69 , self-care ability, spend at least on course of chemotherapy, lack of specific mental disorder such as major depression or bipolar disorder and neurological disorder, lack of chronic diseases such as MS, history of other malignancies, Lack of vision and hearing disorders. Exclusion criteria: women with breast cancer were older than 69 years, unwillingness to cooperate and death.

Age
From **18 years** old to **69 years** old

Gender
Female

Phase
N/A

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yasuj University of Medical Science

Street address
Faculty of Nursing and Midwifery, second floor, Yasuj University of Medical Science, next to Emam Sajad hospital, Shahid Jalil boulevard, Yasuj.

City
Yasuj

Postal code
7591741417

Approval date
2014-08-27, 1393/06/05

Ethics committee reference number
93061003

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
Quality of life

Timepoint
Before intervention, two weeks after intervention

Method of measurement
QLQ-BR23, QLQ C30 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
8 sessions self care program based on Orem's model is conduct during two months،once a week for 45 minutes . the training counseling is through lectures and discussion for patients in experimental group based on educational needs

Category
Lifestyle

2

Description
The control group will not received intervention

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Shekoofeh Hamzheekia

Street address
Namazi Hospital, Namazi Square, Zand Ave, Shiraz, Fars

City
Yasuj

2

Recruitment center

Name of recruitment center
Motahari Clinic

Full name of responsible person
Shekoofeh Hamzheekia

Street address
Motahari Clinic, Namazi Square, Zand Ave, Shiraz, Fars
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Yasuj University of Medical Science
Full name of responsible person
Mahmood Naraki
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Vice Chancellor for Research of Yasuj University of Medical Science, ground floor, Center Building of Yasuj University of Medical Sience, Setad, Shahid Motahari Boulevard, Yasuj.
City
Yasuj
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 of Yasuj University of Medical Science
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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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