

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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 Hamzehiekiea

Name of organization / entity

Yasuj University of Medical Science

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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

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2

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Medical Science

Full name of responsible person

Mahmood Naraki

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Yasuj University of Medical Science, Setad, Shahid
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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**Contact****Name of organization / entity**

Yasuj university of Medical Science

Full name of responsible person

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Position

Master of Medical Surgical Nursing

Other areas of specialty/work**Street address**

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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