

# 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 of 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 a 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 1333 7251

###### Email address

sh.hamzhiekiea@yums.ac.ir

##### 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

+98 74 1333 7251

**Fax**

+98 74 1333 7370

**Email**

Hamzeieki@yahoo.com

**Web page address**

www.yums.ac.ir

**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

**Street address**

Vice Chancellor for Research of Yasuj University of  
Medical Science, ground floor, Center Building of  
Yasuj University of Medical Science, 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****Contact****Name of organization / entity**

Yasuj university of Medical Science

**Full name of responsible person**

Shekoofeh Hamzheekia

**Position**

Master of Medical Surgical Nursing

**Other areas of specialty/work****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

**Phone****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasuj University of Medical Science

**Full name of responsible person**

Dr. Ardashir Afrasyabifar

**Position**

PHD in Nursing

**Other areas of specialty/work****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

**Phone**

+98 74 1333 7251

**Fax**

+98 74 1333 7370

**Email**

Afrasiabifar@yahoo.com

**Web page address**

www.yums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Yasuj University of Medical Science

**Full name of responsible person**

Shekoofeh Hamzheekia

**Position**

Master of Medical Surgical Nursing

**Other areas of specialty/work****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

**Phone**

+98 74 1333 7251

**Fax**

+98 74 1333 7370

**Email**

Hamzeieki@yahoo.com

**Web page address**

www.yums.ac.ir

## **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*