

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The Effect of an Educational Intervention based on Pender's Theory on Quality of Life of Breast Cancer Patients after Mastectomy Surgery

#### Protocol summary

##### Summary

Background: Educational intervention can be effective in improvement of quality of life. The present study aimed to investigate the effect of educational intervention based on Pender's theory on quality of life of patients 6 months after mastectomy. Methods: This randomized pre/posttest clinical trial is conducted in Motehary polyclinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran. The patients are randomly divided in to an intervention (n=70) and a control group (n=70). Both groups are assessed regarding different aspects of quality of life using EORTC QLQ-C30 questionnaire, which consists of 30 questions, at different phases (pretest and posttest). The interventional group are participated in an educational program for 2 months, while the control group only received the polyclinic's routine care. The interventional group is invited to participate in educational intervention in five group of 10 to 15 persons. Educational intervention consisted of three 45 minutes sessions about patients present illness and nutrition, physical activity and methods of stress management. To enhance the effect of intervention the interventional group is asked with self monitoring by using Pender's questionnaire in three aspects such as physical activity, nutrition and stress management. They are asked to report their life aspects by using on the above mentioned questions one researcher is responsible to monitor their reports once every two weeks.

#### General information

##### Acronym

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##### IRCT registration information

IRCT registration number: **IRCT138806172432N1**

Registration date: **2016-06-27, 1395/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-27, 1395/04/07

##### Registrant information

###### Name

Azadeh Amiri

###### Name of organization / entity

Shiraz University Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4254

###### Email address

amirlea@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

##### Expected recruitment start date

2008-07-20, 1387/04/30

##### Expected recruitment end date

2008-09-20, 1387/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of an Educational Intervention based on Pender's Theory on Quality of Life of Breast Cancer Patients after Mastectomy Surgery

##### Public title

The Effect of an Educational Intervention on Quality of Life after Mastectomy Surgery

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria :aging 25-55 years, passage of 6 months from mastectomy surgery, and not suffering from lymphedema and other malignancies. Exclusion criteria:recurrence of the disease and metastasis to other organs.chemoterapy or radiotrappy

## Age

From **25 years** old to **55 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **140**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

random number table

## Secondary Ids

### 1

#### Registry name

.

#### Secondary trial Id

.

#### Registration date

2017-11-21, 1396/08/30

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences, Shiraz, Iran

##### Street address

School of Nursing and Midwifery

##### City

Shiraz

##### Postal code

7193613119

#### Approval date

2008-05-10, 1387/02/21

#### Ethics committee reference number

87-4018

## Health conditions studied

### 1

#### Description of health condition studied

Breast cancer

#### ICD-10 code

c50.9

#### ICD-10 code description

Malignant Neoplasm OFBreast -Breast Unspecified Mass

## Primary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before intervention and two mounths after intervention

#### Method of measurement

QLQ-C30 Quastionaire

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

#### Method of measurement

-

## Intervention groups

### 1

#### Description

Interventional group: The interventional program is carried out through 3 training45 to 60 minutes sessions in three fields of nutrition, physical activity, and stress management. Thus, the intervention group participants take part in the training program in groups of10 to 15, so that group discussion forums become possible. The educational content included information about the disease, its treatment and complications, diet including healthy nutrition for the treatment process, and recovery including healthy food pyramid and foods that are essential for good health. High-risk foods and their low-risk alternatives in the course of treatment are expressed, as well. In addition, healthy cooking method of different food products is emphasized and necessary training is conducted in this area. Also, sports activities, including healthy physical activity pyramid, were emphasized in order to increase mobility at work and home in everyday life. Recommendations are, too, made about performing the activities that the patients can do. Besides, rehabilitation and recovery exercises, including stretching, isotonic, and isometric exercises, are taught to improve shoulder, scapula, and motor muscles movement in the process of treatment and recovery.

Moreover, the patients are trained about and are required to do stress reduction and relaxation techniques, such as diaphragmatic breathing, imagination, and positive thinking, every day. They are also provided with the necessary supports in different fields of the intervention. Furthermore, an educational booklet is prepared and given to the patients. During the study period, the researchers follows the patients by phone calls and ensured about their self-monitoring. In case the patients need assistance about other problems, they are trained individually or, if necessary, are referred to a specialist.

**Category**

Lifestyle

**2****Description**

Control group: control group just will received the routine care of polyclinic.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Motahari polyclinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran

**Full name of responsible person**

Azade Amiri

**Street address**

Namazee Square ,Zand Street, Shiraz

**City**

Shiraz

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

Vice Chancellor for research of Shiraz University of Medical Sciences, Shiraz, Iran

**Full name of responsible person**

Dr Basir Hashemi

**Street address**

Zand Street, Shiraz University of Medical Sciences, Shiraz

**City**

Shiraz

**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 Shiraz University of

Medical Sciences, Shiraz, Iran

**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**

School Of Nursing and Midwifery Of Shiraz University of Medical Sciences,

**Full name of responsible person**

Azadeh Amiri

**Position**

Master of Science In Nursing -Faculty member of School of Nursing and Midwifery, Shiraz University o

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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*