

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation of self-care education program's effect on breast self-examination behaviors in women attending to health care centers

#### Protocol summary

##### Summary

This quasi-experimental intervention study with pretest/post test was conducted to determine the effects of self-care education on performing breast self-exam (BSE) among women referred to health centers. 168 women were entered in the study. Inclusion criteria ; referring to health centers in Nurabad Mamasani; being at most 50 years old for married women and more than 25 years old for single ones; did not have breast cancer; continuous participation in the educational program. Exclusion criteria; being diagnosed with breast cancer based on self-reporting and medical records; being pregnant; breast-feeding. These women were non-randomly divided into intervention and control group. We had not blinding in the study. Main outcome in this study was self-care behavior that was measured by validated researcher-made questionnaire. Inclusion criteria ; referring to health centers in Nurabad Mamasani; being at most 50 years old for married women and more than 25 years old for single ones; did not have breast cancer; continuous participation in the educational program. Exclusion criteria; being diagnosed with breast cancer based on self-reporting and medical records; being pregnant; breast-feeding. The instruments were administered to both groups before intervention and after holding training classes for intervention group; one week and 10 weeks after the intervention the questionnaire were administered to both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012115015N16**

Registration date: **2017-04-25, 1396/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-04-25, 1396/02/05

##### Registrant information

###### Name

Leila Ghahremani

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1725 1001

###### Email address

ghahramanl@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of self-care education program's effect on breast self-examination behaviors in women attending to health care centers

##### Public title

Self-care education programs effect on breast self-examination behaviors

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria ; referring to health centers in Nurabad Mamasani; being at most 50 years old for married women and more than 25 years old for single ones; did not have breast cancer; continuous participation in the educational program. Exclusion criteria; being diagnosed with breast cancer based on self-reporting and medical records; being pregnant; breast-feeding.

### **Age**

From **25 years** old to **100 years** old

### **Gender**

Female

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **168**

### **Randomization (investigator's opinion)**

Not 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**

Vice chancellor for research, Shiraz University of Medical Sciences

##### **Street address**

Shiraz University Of Medical Science, Namazi Square

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2014-04-21, 1393/02/01

#### **Ethics committee reference number**

7259-93

## **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**

Self-care behavior in prevention of breast cancer

#### **Timepoint**

Before intervantion , one week after intervention, ten weeks after intervention

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: For the intervention group, the training program was self-care education on breast cancer. Training program was performed in four weekly 45-minute sessions. In each session lecture delivery and question-answer methods were used to educate participants. The education program included theoretical and practical training material which delivered through direct teaching methods, such as giving lecture, question and answer, breast self-exam (BSE) training videos, slideshows, and flip charts. At the end of the training sessions, educational pamphlets were also distributed among the participants of the intervention group. The questionnaire was administered to the women in both groups one week and 10 weeks after the intervention.

#### **Category**

Prevention

### **2**

#### **Description**

Control group: without any intervention

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Health center city Nurabad Mamasani

##### **Full name of responsible person**

Miss.Zakiye Mosavi

##### **Street address**

Nourabad, Nurabad Mamasani Health Center

##### **City**

Nurabad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Shiraz University of Medical Science

**Full name of responsible person**

Dr. Leila Ghahramani

**Street address**

School of health, Koye Zahra, 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 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Leila Ghahramani

**Position**

Professor

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

School of health, Koye Zahra, Shiraz

**City**

Shiraz

**Postal code****Phone**

+98 930 244 6689

**Fax****Email**

mousavi\_z@sums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Leila Ghahramani

**Position**

Professor

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

School of health, Koye Zahra, Shiraz

**City**

Shiraz

**Postal code****Phone**

+98 71 3725 1005

**Fax****Email**

mousavi\_z@sums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Leila Ghahramani

**Position**

Professor

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

School of health, Koye Zahra, Shiraz

**City**

Shiraz

**Postal code**

00987137251005

**Phone**

+98 71 3725 1005

**Fax****Email**

mousavi\_z@sums.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*