

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Designing, Implementing and Evaluating the Effect of Educational Intervention Program Using Combination of Health Belief Model and Theory of Planned Behavioral on Mammography in Women Referring to Khorramabad Health Centers

#### Protocol summary

##### Study aim

Design, implementation and evaluation of the effect of educational intervention program based on health belief model and theory of planned behavior on performing mammography in women referring to Khorram Abad health centers

##### Design

Clinical trials with randomized control group, with parallel group, randomized

##### Settings and conduct

The present study was an Interventional and experimental study. A randomized sampling method was performed on 140 women aged 50-70 years who referred to Khorramabad health centers in two groups of control and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Being in the age group of 50 to 70 years; Having no history of breast cancer in one person or first-degree relatives (sister, mother, daughter) - Not having a history of mammography over the past year  
Exclusion criteria: Unwillingness to cooperate; No participation in training sessions more than two sessions; No participation in post-test

##### Intervention groups

In the intervention group, the sessions were lecture, group discussion and question and answer sessions, based on the results of the pre-test and not presented in control group

##### Main outcome variables

Performing Mammography, perceived sensitivity, perceived severity, perceived barriers, perceived benefits, self-efficacy, motivation for health, cues to action, attitude, normative belief, perceived behavior control, intention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190407043188N1**

Registration date: **2019-06-19, 1398/03/29**

Registration timing: **retrospective**

Last update: **2019-06-19, 1398/03/29**

Update count: **0**

##### Registration date

2019-06-19, 1398/03/29

##### Registrant information

##### Name

zahra khazir

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 9114

##### Email address

zahrakhazir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-19, 1397/01/30

##### Expected recruitment end date

2018-12-01, 1397/09/10

##### Actual recruitment start date

2018-06-20, 1397/03/30

##### Actual recruitment end date

2019-03-06, 1397/12/15

##### Trial completion date

2019-03-06, 1397/12/15

### Scientific title

Designing, Implementing and Evaluating the Effect of Educational Intervention Program Using Combination of Health Belief Model and Theory of Planned Behavioral on Mammography in Women Referring to Khorramabad Health Centers

### Public title

The effect of educational intervention program on performing mammography in women referring to health centers

### Purpose

Screening

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having ages 50 to 70 years old Not having a mammogram history over the past year Not having a history of breast cancer in one person or first-degree relatives (sister, mother, daughter)

#### Exclusion criteria:

Unwillingness to cooperate No participation in training sessions more than two sessions No participation in training sessions more than two sessions No participation in post-test

### Age

From **50 years** old to **70 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **140**

Actual sample size reached: **140**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Cluster sampling was done on 140 women who referred to health centers in two groups of control and control. Therefore, Four centers were randomly selected and 35 of them each randomly entered the study

### 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

Ethic committee of Shahid Sadoughi University of Medical Sciences

### Street address

Yazd University of Medical Sciences, Safayee St, Alem Square,

### City

Yazd

### Province

Yazd

### Postal code

8915173160

### Approval date

2017-01-25, 1395/11/06

### Ethics committee reference number

IR.SSU.SPH.REC.1395.134

## Health conditions studied

### 1

#### Description of health condition studied

The effect of educational intervention program using combination of health belief model and theory of planned behavior on performing mammography in women referring to health centers

### ICD-10 code

Z12.3

### ICD-10 code description

Special screening examination for neoplasm of breast

## Primary outcomes

### 1

#### Description

perform of mammography

#### Timepoint

Before the intervention and 3 months after the end of the intervention

#### Method of measurement

Questionnaire

### 2

#### Description

perceived Sensitivity and severity

#### Timepoint

Before the intervention and 3 months after the end of the intervention

#### Method of measurement

Questionnaire

### 3

#### Description

perceived Benefits

#### Timepoint

Before the intervention and 3 months after the end of the intervention

#### Method of measurement

Questionnaire

## 4

### **Description**

perceived Barriers

### **Timepoint**

Before the intervention and 3 months after the end of the intervention

### **Method of measurement**

Questionnaire

## 5

### **Description**

perceived Self-efficacy

### **Timepoint**

Before the intervention and 3 months after the end of the intervention

### **Method of measurement**

Questionnaire

## 6

### **Description**

Cues to action

### **Timepoint**

Before the intervention and 3 months after the end of the intervention

### **Method of measurement**

Questionnaire

## 7

### **Description**

Attitude

### **Timepoint**

Before the intervention and 3 months after the end of the intervention

### **Method of measurement**

Questionnaire

## 8

### **Description**

Normative beliefs

### **Timepoint**

Before the intervention and 3 months after the end of the intervention

### **Method of measurement**

Questionnaire

## 9

### **Description**

Perceived behavioral control

### **Timepoint**

Before the intervention and 3 months after the end of the intervention

### **Method of measurement**

Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Using the results of the pre-test, the training classes were considered for this group

#### **Category**

Early detection

### 2

#### **Description**

Control group: There was no intervention for this group. After the collection of post-test information, they were given pamphlets and educational booklet

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Health Center of Army Alley

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

Zahra Hasanvand

##### **Street address**

Golestan Saadi Avenue 10, Health Center of Army Alley

##### **City**

Khorramabad

##### **Province**

Lorestan

##### **Postal code**

6816959436

##### **Phone**

+98 66 3320 9115

##### **Email**

zahrakhazir@gmail.com

### 2

#### **Recruitment center**

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

Health Center of Farzanegan Alley

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

Khatoon Paknejad

##### **Street address**

Sajjad YA60 meter high street, Shahid Nademi Blvd, 1th Farzanegan Alley

##### **City**

Khorramabad

##### **Province**

Lorestan

##### **Postal code**

6819863133

##### **Phone**

+98 66 3323 3894

##### **Email**

Zahrakhazir@gmail.com

### 3

#### Recruitment center

**Name of recruitment center**

Somaye Health Center

**Full name of responsible person**

Hoda Delavar

**Street address**

Shaghayegh Avenue, kazemian Alley

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

6814639519

**Phone**

+98 66 3343 1089

**Email**

Zahrakhazir@gmail.com

### 4

#### Recruitment center

**Name of recruitment center**

Hosseinabad Poshteh Health Center

**Full name of responsible person**

Shahla Beyranvandi

**Street address**

Tayeb Avenue, 3th Pakdasht Alley

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr Masood Mirzaie

**Street address**

Yazd University of Medical Sciences, Alem Square,  
Safayee St.,

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Zahra khazir

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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Yazd University of Medical Sciences, Safayee St.,Alem  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

zahra khazir

**Position**

Ph.D. student health education and promotion

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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zahra khazir@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
zahra khazir  
**Position**  
Ph.D. student health education and promotion  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
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**Province**  
Lorestan  
**Postal code**  
8915173160  
**Phone**  
+98 35 3820 9100  
**Email**

zahra khazir@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

All data, including data before intervention and after intervention

### When the data will become available and for how long

Start the access period 3 months after printing the results

### To whom data/document is available

Researchers and people working in health centers

### Under which criteria data/document could be used

Any use subject to the mention of the source is authorized

### From where data/document is obtainable

email

### What processes are involved for a request to access data/document

It is sent about 21 days after requesting data

### Comments