

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigation of Impact of Theoretical- Based Education in Performing Mammography and Self- Breast Examination in Women Consulting Health Care Center in Isfahan in 96-97

#### Protocol summary

##### Study aim

Determining the Effect of the Theory- Based Educational Intervention on Performing Mammogram and Breast Self- Examination in Women Referred to Health Centers in Isfahan

##### Design

Controlled Clinical Trial

##### Settings and conduct

Select Two Health Centers in Isfahan and then Perform an Educational Intervention on One of Them

##### Participants/Inclusion and exclusion criteria

Women 35 Years and Older

##### Intervention groups

Women 35 years of Age and Older Who are Referred to the Health Care Centers that Are Undergoing Training on This Group, and After the Intervention and three months later, the questionnaire will be filled again.

##### Main outcome variables

Attitude; Perceived Barrier and Benefits; perceived Severity and Sensitivity; Efficacy; Screening Behaviors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180830040907N1**

Registration date: **2019-03-23, 1398/01/03**

Registration timing: **retrospective**

Last update: **2019-03-23, 1398/01/03**

Update count: **0**

##### Registration date

2019-03-23, 1398/01/03

##### Registrant information

##### Name

Sakine Ansari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3342 1208

##### Email address

mosakken\_2222@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2018-12-21, 1397/09/30

##### Actual recruitment start date

2018-08-23, 1397/06/01

##### Actual recruitment end date

2018-12-21, 1397/09/30

##### Trial completion date

2018-12-21, 1397/09/30

##### Scientific title

Investigation of Impact of Theoretical- Based Education in Performing Mammography and Self- Breast Examination in Women Consulting Health Care Center in Isfahan in 96-97

##### Public title

Effect of Education in Performing Mammography and Self- Breast Examination

##### Purpose

Screening

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Women Older than 35 Years Ability of Talking Oral

Consent in Control Group and Written Consent in Case Group

**Exclusion criteria:**

Non Iranian people History of malignant breast disease

**Age**

From **35 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

Actual sample size reached: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We will select an area of Isfahan and then select two health centers from that area as a control center and a center as one then randomly selected individuals (from among those who go to the center on a daily basis they do )

**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 Isfahan University of Medical Sciences

**Street address**

Hezarjerib Ave., Isfahan town

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Approval date**

2017-10-18, 1396/07/26

**Ethics committee reference number**

ir.mui.rec.1396.3.565

**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**

Perceived Severity and Sensitivity

**Timepoint**

Before and After the Intervention, and 3 Months later

**Method of measurement**

Answer Sheet

**2****Description**

Breast Cancer Screening Behaviors

**Timepoint**

Before and After the Intervention, and 3 Months later

**Method of measurement**

Answer Sheet

**3****Description**

Efficacy

**Timepoint**

Before and After the Intervention, and 3 Months later

**Method of measurement**

Answer Sheet

**4****Description**

Perceived Benefits and Barriers

**Timepoint**

Before and After the Intervention, and 3 Months later

**Method of measurement**

Answer Sheet

**5****Description**

Attitude

**Timepoint**

Before and After the Intervention, and 3 Months later

**Method of measurement**

Answer Sheet

**6****Description**

Abstract Norm

**Timepoint**

Before and After the Intervention, and 3 Months later

**Method of measurement**

Answer Sheet

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Women 35 and Older Referring to Health Centers Who receive educational intervention. Intervention Contains Booklet and Oral Content with visual pictures

#### Category

Early detection

### 2

#### Description

Control group: Women Over 35 and older Referring to Health Centers Who received no intervention

#### Category

Early detection

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baghe Abrisham Health Care Center

##### Full name of responsible person

Parastoo Golshiri

##### Street address

Isfahan, Abrisham, Baghe Abrisham Health Care Center

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3669 3985

##### Fax

##### Email

golshiri@hlth.mui.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Hasan Abad Health Care Center

##### Full name of responsible person

Parastoo golshiri

##### Street address

Isfahan, Hasan Abad, Hasan Abad Health Care Center

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

#### Phone

+98 31 3669 3985

#### Email

golshiri@hlth.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Deputy of Isfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Hagh Joo Javanmard

##### Street address

Hezar Jereb St., Isfahan University of Medical Sciences and Health Services

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۷۳۴۶۱-۸۱۷۴۶

##### Phone

+98 31 3668 8138

##### Email

sh\_haghjoo@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Research Deputy of Isfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Parastoo Golshiri

##### Position

Associate Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Public Health/Community Medicine

##### Street address

Hezar Jereb St., Isfahan University of Medical Sciences  
and Health Services

**City**

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**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

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**Email**

golshiri@hlth.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Parastoo Golshiri

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**

Faculty of Medicine, Isfahan University of Medical  
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**Province**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Parastoo Golshiri

**Position**

Associate Professor

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Specialist

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+98 31 3669 3985

**Email**

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## 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 Accepting the  
results

**To whom data/document is available**

Researchers and Industry Workers

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

Any Use Subject to the Mention of the Source is Allowed

**From where data/document is obtainable**

Sakine.ansari@gmail.com

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

It will Be Sent About 15 Days After Requesting Data

**Comments**