

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

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3669 3985

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
Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3669 3985

Email

golshiri@hlth.mui.ac.ir

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

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

Faculty of Medicine, Isfahan University of Medical
Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3669 3985

Email

golshiri@hlth.mui.ac.ir

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