

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of theory based educational program on females' health beliefs toward breast cancer screening behaviors.

Protocol summary

Study aim

Determine the effect of the theory-based educational intervention on women's health beliefs about breast cancer screening behavior

Design

In this Randomized clinical trial (RCT) study 100 eligible women will be selected from qualified women referring to health centers. Then, 50 women in the control group and 50 in the intervention group will be randomly assigned. For random assignment of samples, in each center, samples will select cards A and B. People with card A in the intervention group and the B card will be in the control group.

Settings and conduct

Among the comprehensive health centers of Khoy, three centers will be selected from 3 regions of the city with low socioeconomic status, medium and high. The researcher selects 33 women from each center with convenience sampling. After explaining the goals of the study, women who are eligible to enter the study and gaining confidence in their willingness to participate in the research, the questionnaire prepared by them will be completed. Then, 50 people will be randomly assigned to the control group and 50 will be in the intervention group. After performing educational intervention in the intervention group, the questionnaires will be filled in by both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inclination to participate in the study, age over 20 years old, having literacy
Exclusion criteria: having breast cancer, getting instructional materials on breast cancer and its screening behaviors

Intervention groups

Educational intervention based on health belief model to promote women's beliefs about breast cancer screening behaviors that will be performed in the intervention group in 4 sessions and the control group will not receive any intervention.

Main outcome variables

Women's Health Beliefs on Breast Cancer Screening Behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160203026347N9**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

Soheyla Ahangarzade Rezaei

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of theory based educational program on females' health beliefs toward breast cancer screening behaviors.

Public title

The effect of theory based educational program on females' health beliefs toward breast cancer screening behaviors.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire to participate in the study 20 years old Having literacy

Exclusion criteria:

Women with breast cancer Getting educational materials about breast cancer and screening behaviors

Age

From 20 years old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

In each center, in terms of the number of people selected, cards A and B are written to select by samples. People with card A in the intervention group and the B card will be in the control group

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 Urmia University of Medical Sciences

Street address

Urmia university of Medical Sciences, Orghans Alley, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-06-04, 1396/03/14

Ethics committee reference number

IR.UMSU.REC.1396.128

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**

health beliefs

Timepoint

Before intervention, 2 weeks after the last training session

Method of measurement

Champion Health Belief Model Scale

Secondary outcomes**1****Description**

Health beliefs about breast cancer screening behaviors

Timepoint

Before intervention, 2 weeks after the last training session

Method of measurement

Champion Health Belief Model Scale

Intervention groups**1****Description**

Intervention group: The intervention in the intervention group will be held in four sessions of 90 minutes. For educational intervention, combined methods including direct and indirect training methods will be used. Considering the goal of the study, which is to change the health beliefs of women, the use of speech lecture alone will not be effective, but also interactive methods should be used including group discussion and question and

answer.
Category
Prevention

2

Description

Control group: In the control group, no intervention will be performed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Services Center No. 6

Full name of responsible person
Zahra Shaabanloei

Street address
Comprehensive Health Services Center No. 6,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr Iraj Mohebi

Street address
Urmia University of Medical Science (UMSU), UMSU
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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr Soheila Ahangarzade Rezaei

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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Nursery

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City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available