

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Educational Intervention Based on Health Belief Model in Breast Cancer Prevention Behaviors in Women of Reproductive Age

Protocol summary

Study aim

To evaluate the effect of educational program based on Health Belief Model on adopting preventive behaviors of breast cancer in women of reproductive age referring to Qazvin comprehensive health centers.

Design

Clinical trial with control and intervention groups, parallel, blinded, simple randomized groups

Settings and conduct

The study population consisted of women of reproductive age of 18-49 years who were covered by health centers in Qazvin. Samples were entered in a list from lowest to highest score based on the Health Literacy Assessment Tool and then randomly selected 84 individuals (depending on the number of sample size in phase II). The infestation of information is first taken by the control group and entered into the study after the intervention group.

Participants/Inclusion and exclusion criteria

Arrival: literate women of reproductive age (18-49 years) Women residing in Qazvin city Having active file in health community centers. Exclusion: Any Factor That Impairs Women's Participation: Immigration Breast cancer Having mental and physical illnesses

Intervention groups

Intervention group In addition to the current training of the center, they receive educational intervention based on Health Belief Model. The control group received only the current training of the center.

Main outcome variables

Health belief model constructs (Awareness, Perceived severity, Perceived benefits, Perceived barriers, Self-efficacy, Cue for action).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200201046323N1**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **prospective**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Sara Chalambari

Name of organization / entity

Tarbiyat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 6522 7097

Email address

s.chalambari@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Educational Intervention Based on Health Belief Model in Breast Cancer Prevention Behaviors in Women of Reproductive Age

Public title

The effect of education on preventive behaviors of breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Literate women Women residing in Qazvin city Women with active profile in community health centers Women of reproductive age (18-49 years)

Exclusion criteria:

Migration and emigration Experience of Breast Cancer Physical and neurological diseases Suffering Illiteracy

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization gives each woman an equal chance of being selected. In this way, the names of eligible women will be listed and numbered. They are then selected at random. According to the law of probability, the people selected must have the same characteristics as the community from which they are elected.

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 Tarbiat Modares University

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Tehran Jalal AleAhmad Nasr P.O.Box: 14115-111

City

Tehran

Province

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Postal code

1411713116

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.MODARES.REC.1398.203

Health conditions studied**1****Description of health condition studied**

Brest Cancer Preventive Behaviour

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Preventive Behaviors of Breast Cancer

Timepoint

Measurement of behavior before, immediately after intervention, 3 months after educational intervention

Method of measurement

Using a Man-made questionnaire "Effectiveness of Health Education Based on Health Belief Model in Adoption of Preventive Behaviors of Breast Cancer", which was psychometric evaluated by Kalan-FermanFarma et al.in 2014.

Secondary outcomes

empty

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

Intervention group: Women are eligible to receive 10 training sessions (lectures, group discussions) in addition to the routine training provided by the Comprehensive Health Centers. In addition to completing the pre-test questionnaire, the group will complete a questionnaire assessing the effectiveness of educational intervention on preventive behaviors immediately after and three months after the intervention.

Category

Behavior

2**Description**

Control group: Women are eligible to receive no educational intervention program other than routine training provided by comprehensive health centers. In addition to completing the pre-intervention questionnaire, the group will complete a questionnaire assessing the effectiveness of educational intervention on preventive behaviors immediately after and three months after the intervention.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Bolandian Health Center
Full name of responsible person
Sara Chalambari
Street address
End of Shahid Babaei Street ,Next to the Canal
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Faculty of Medical Sciences, Tarbiat Modares University
Full name of responsible person
Dr. Jacob Fathollahi
Street address
Tehran, Jalal Al Ahmad, Nasr, Tarbiat Modarres University
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Aminsh_f@modares.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Medical Sciences, Tarbiat Modares University
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
Faculty of Medical Sciences, Tarbiat Modares University
Full name of responsible person
Ferdinand Amin Shokravi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information is confidential but information about the consequences of awareness, perceived severity, perceived benefits, perceived barriers, self-efficacy, cues to action, and shareable practice

When the data will become available and for how long

One week after receiving the request by email to the principal of the study

To whom data/document is available

Researchers at the scientific and academic institutes of the Ministry of Health

Under which criteria data/document could be used

Vice Chancellors for Health, Universities of Medical Sciences

From where data/document is obtainable

With Dr. Farkhondeh Amin Shokravi in charge of the study by email: Aminsh_f@modares.ac.ir

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

one week after receiving an email by corresponding researcher

Comments