Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Univercity

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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
Street address
Tehran Jalal AleAhmad Nasr P.O.Box: 14115-111
City
Tehran
Province
Tehran
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