

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The role of breast cancer risk assessment in educational intervention based on Health Belief Model for mammography performance in women with family history of breast cancer

Protocol summary

breast cancer, mammography

Study aim

Determining the role of breast cancer risk assessment in educational intervention based on health belief model on mammography in women with a family history of breast cancer

Design

A randomized controlled clinical trial with 3 groups with parallel groups of 210 women aged 40 years and older living in Bushehr. Three groups will be assigned

Settings and conduct

In women living in Bushehr, after sampling and contacting people to attend the center and after completing the questionnaires, in the group of educational intervention with a model of health belief and risk assessment, first using the online breast cancer risk assessment program based on the model IBIS risk evaluator Edition 10's lifetime risk is estimated and the results are interpreted for the person, then the delivery of a booklet based on the structures of the health belief model, the person is asked to do within the next 3 months Have a mammogram and repeat it annually

Participants/Inclusion and exclusion criteria

Admission of women 40 years and older with a family history of breast cancer and no mammography during the past two years, literacy, lack of urination and breastfeeding, willingness to participate in the study of no breast cancer or other cancers and living in Bushehr At the time of conducting the study and leaving the study, not reading the educational booklet at the specified time and carrying the sample

Intervention groups

1- Educational intervention group with health belief model and risk assessment, 2- Risk assessment group 3- Control group

Main outcome variables

Perceived sensitivity, perceived severity, perceived benefits, perceived barriers, health motivation, risk of

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048161N1**

Registration date: **2020-08-02, 1399/05/12**

Registration timing: **prospective**

Last update: **2020-08-02, 1399/05/12**

Update count: **0**

Registration date

2020-08-02, 1399/05/12

Registrant information

Name

Hajar Tamimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3483 2188

Email address

tamimi.h.65@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of breast cancer risk assessment in educational intervention based on Health Belief Model for mammography performance in women with family history of breast cancer

Public title

The role of breast cancer risk assessment in educational intervention based on Health Belief Model for mammography performance in women with family history of breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women 40 years and older Having a family history of breast cancer Not having a mammogram for the past two years Literacy for reading and writing Lack of urination and breastfeeding Willingness to participate in the study No person has breast cancer or other cancers Living in Bushehr at the time of the study

Exclusion criteria:

Failure to read the training booklet at the time specified for the participants Getting pregnant during the study

Age

From **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

After preparing the selected samples, individuals will be randomly assigned to three groups (random allocation) to In this way, the names of the people are written on separate sheets and by lottery, the first choice will be assigned to the educational intervention group with the pattern of health belief and risk assessment, the second to the risk assessment group and the third to the control group. It will continue for other people to assign people in groups.

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 Bushehr University of Medical Sciences

Street address

Salman Farsi St. Bushehr University of Medical Sciences

City

Bushehr

Province

Boushehr

Postal code

7514633341

Approval date

2020-07-18, 1399/04/28

Ethics committee reference number

IR.BPUMS.REC.1399.065

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**

Doing and not doing mammography

Timepoint

Before training and three months after training

Method of measurement

View mammography answers

Secondary outcomes

empty

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

Intervention group: In the group of educational intervention with the model of health belief and risk assessment, first using the online program of breast cancer risk assessment based on Gil model edited by IBIS risk evaluator, the 10-year and lifetime risk of the person is estimated and the results are interpreted for the person. Which were based on the structures of the health belief model received.

Category

Prevention

2

Description

Intervention group: In individuals in the risk assessment group, using the online breast cancer risk assessment program based on the Gil model edited by IBIS risk evaluator, the 10-year and lifetime risk is estimated and the results are compared based on the percentage of risk of cancer in the next 10 years. With similar people in terms of age and type of risk of cancer (low risk, moderate risk or high risk) based on what is specified in this online program

Category

Prevention

3

Description

Control group: The control group did not receive any training until the end of the study period (after completing the second stage questionnaires).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Registration Center

Full name of responsible person

Hakimeh Abadi

Street address

Sports Street in front of Mosalla Jomeh, Bushehr
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

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Salman Farsi St. Bushehr University of Medical
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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Azita Norouzi

Position

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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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available