Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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

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 breast cancer, mammography

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 University of Medical Sciences

City
Bushehr

Province
Boushehr

Postal code
7514633341

Phone
+98 77 3333 0743

Email
hakimehabadi51@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Boushehr University of Medical Sciences

Full name of responsible person
Gholamreza Khamisipour

Street address
Salman Farsi St. Bushehr University of Medical Sciences

City
Bushehr

Province
Boushehr

Postal code
7516433341

Phone
+98 77 2333 1802

Fax
+98 77 2333 1802

Email
khamisipoor@bpums.ac.ir

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

Street address
Salman Farsi St. Bushehr University of Medical Sciences

City
Bushehr

Province
Boushehr

Postal code
7514633341

Phone
+98 917 772 4605

Email
azitanoroozi@yahoo.com

Person responsible for scientific

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

Street address
Salman Farsi St. Bushehr University of Medical Sciences

City
Bushehr

Province
Boushehr

Postal code
7514633341

Phone
+98 917 772 4605

Email
azitanoroozi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Boushehr University of Medical Sciences

Full name of responsible person
Hajar Tamimi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Public Health

Street address
Shahid Jahandideh St. 75693-75671

City
Saadabad

Province
Boushehr

Postal code
7567175693

Phone
+98 917 770 2167

Email
tamimi.h.65@gmail.com

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