

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The education effect base on health belief model on screening behaviors in high risk women

Protocol summary

Summary

The education effect base on health belief model on screening behaviors in high risk women The aim of this randomized controlled clinical trial is to investigation of breast screening behaviors in high risk women for breast cancer after appropriate educations as target group. 100 participant will be recruited who are high risk for breast cancer according to their family history of breast cancer in their first degree relative(mother, sister or daughter) , but they are not diagnosed for any kind of malignancy such as breast cancer and should be in a healthy condition in order to participate at educational sessions. They will be allocated in experiment and control group. People in experiment group will be educated for breast screening methods in 10-15 people in a class in the radiation ward of Shohada-e-Tajrish Hospital. Participants in control group will not be given any education like the experiment participants. Variables of the present study are: knowledge, perceived severity, perceived usefulness, perceived barriers , perceived susceptibility, self efficacy, breast screening behaviors rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101015525N1**

Registration date: **2011-06-20, 1390/03/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-20, 1390/03/30

Registrant information

Name

Sepidh Hajian

Name of organization / entity

Sharoud Mdical Science University

Country

Iran (Islamic Republic of)

Phone

+98 27 3339 5054

Email address

hajia@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Reproductive health reserch Center of Medical Science of Shahid Beheshti University

Expected recruitment start date

2010-01-10, 1388/10/20

Expected recruitment end date

2010-07-27, 1389/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The education effect base on health belief model on screening behaviors in high risk women

Public title

breast screening behaviors

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: every woman who is at risk of breast cancer (because of family history of breast malignancy in her first degree relative i.e mother,sister, daughter) but has not been diagnosed for any kind of malignancy and /or suspicios pathologic of breast tumor can be rectuited for intervention if she has been not diagnosed for breast cancer . Meanwhile having general well being and health

to attending at indructive sessions . exclusion criteria:
every woman with any kind of malignancy , unabling ti
attending at instuctive sessions due to illness, dwelling
out of Tehran

Age

No age limit

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

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

Reproductive health Research Center of Shahid
Beheshti Medical Sciecne University

Street address

3th floor,Ayatollah Taleghani
Hospital,Parvaneh,st.Yaman
st.Velenjak,Avenue,Tehran,Iran

City

Tehran

Postal code

Approval date

2009-12-20, 1388/09/29

Ethics committee reference number

6114-3141

Health conditions studied

1

Description of health condition studied

breast screening brehaviours

ICD-10 code

c50

ICD-10 code description

c50

Primary outcomes

1

Description

breast self examination

Timepoint

before and 3 months after intervention

Method of measurement

check list and questionnaire

2

Description

clinical examination

Timepoint

before and 3 months after intervention

Method of measurement

check list and questionnaire

3

Description

mamography

Timepoint

before and 3 months after intervention

Method of measurement

check list and questionnaire

Secondary outcomes

1

Description

knowledge

Timepoint

before and 3 months after intervention

Method of measurement

questionnaire

2

Description

perceived severity

Timepoint

before and 3 months after intervention

Method of measurement

questionnaire

3

Description

perceived benefits

Timepoint

before and 3 months after intervention

Method of measurement

questionnaire

4

Description

perceived barriers

Timepoint

before and 3 months after intervention
Method of measurement
questionnaire

5

Description
perceived susceptibility
Timepoint
before and 3 months after intervention
Method of measurement
questionnaire

6

Description
self efficacy
Timepoint
before and 3 months after intervention
Method of measurement
questionnaire

Intervention groups

1

Description
In intervention group all educations will be given based on Health Belief Model in order to behaviour change. The sessions will be held in 10-15 people groups assisting lecture, slide, posters and film presentations and instructive pamphlets will be given to participants.
Category
Early detection

2

Description
In control group we do not give them the instructions in intervention group, however if they want will be guide to health care providers to be educated. Then they will be followed up 3 months later.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e- Tajrish Hospital
Full name of responsible person
Hamid Reza Mirzaei
Street address
Radiation ward-Shohada-e- Tajrish Hospital Tajrish sq. Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Reproductive Health Research Center of Shaid Beheshti Medical Science University
Full name of responsible person
Dr. Seyed Jalil Hoseini
Street address
3th floor, Reproductive Health Research Center, Ayatollah Taleghani Hospital Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Reproductive Health Research Center of Shaid Beheshti Medical Science University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shohada Tajrish Hospital
Full name of responsible person
Hamid Reza Mirzaei
Position
assistant professor of radiation oncology
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Shahroud Medical Science University

Full name of responsible person

Sepideh Hajian

Position

PhD student

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty