Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of the effect of education by compact disc and booklet about breast cancer screening on women's knowledge, breast cancer screening behaviors and health anxiety in attending women to urban healthcare centers.

Protocol summary

Study aim

The aim of the present study is to compare the educational effect of compact disc and booklets on knowledge, the behavior of breast cancer screening and health anxiety in women.

Design

In this study, 53 women will be selected from each of the 3 health centers in Ilam. These 3 centers will be selected randomly and are randomly divided into one of the three groups of compact discs, booklets, and control. Subjects are then selected as the systematic random at each center.

Settings and conduct

First, a preliminary interview will be conducted with the selected women, and a description of the goal of the study will be provided and will be considered as a sample if the individual is satisfied with the research. The questionnaires are given to them to complete. Subsequently, the compact disc (CD)will be provided to eligible women referring to the first center and the booklet will be given to the eligible women referring to another center, as well as eligible attendants to the next center will be considered as a control group.This group will receive no intervention during the study. One week and three months after the intervention, the questionnaires were given by midwives of the three centers to the same sample and will be taken from them after completing. In order to consider the ethical aspects of research, the third group at the end of the study will provide the more effective method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women aged 20 to 70 years with a minimum education, having a computer or a computer for sighting a CD in the respective group, which did not undergo a physical examination during the past year and did not do so despite the mammogram's indication. Exclusion criteria: Poor learning ability or diseases that people can not learn and respond to, current or history of breast cancer.

Intervention groups

First intervention group (receive the CD): First intervention group (Compact disc group): This group were 53 eligible women. After a brief explanation about the goals of the study, the CD will give them and they will be asked to view it. Content of the compact disc were: Breast cancer, Breast Anatomy, Factors Affecting Breast Cancer, Breast Cancer symptoms, Breast Cancer Diagnosis, Breast Imaging Techniques, Breast Cancer Therapy, Important Tips on Breast Examination, Breast Examination Procedures and Techniques, How to Perform Breast Self-Examination. The source of this content is Breast Disease (Harris 2014). In the stages of pre-intervention, one week and three months later, the questionnaires will be completed. When completing the questionnaire at a stage one week later, it will be ensured that the contents of the compact disc are seen by the participants (by a question). Second intervention group (educational booklet): This group has 53 eligible women who will be given a booklet after providing a brief explanation about the goals of the study. The contents of the booklet are the same as the content of the compact disc in writing format. In this group, questionnaires will be completed in the before, one week and three months after the delivery of the booklet. At the stage of one week after the delivery of the booklet, study of the booklet will be ensured (by a question). Control group (without any intervention): This group also includes 53 women who will not receive any intervention. At the beginning of the study, researcher will tell them that they will not receive a CD or booklet during the study, but at the end of the study, the method that will have the greatest impact will be delivered to them. In this group, the questionnaires will be completed simultaneously with other groups, before, one week and

three months after the intervention. receive the booklet receive no intervention

Main outcome variables

Breast cancer screening behavior Health anxiety

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20161126031117N6**
Registration date: **2018-01-08, 1396/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-08, 1396/10/18**
Update count: **0**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of education by compact disc and booklet about breast cancer screening on women's knowledge, breast cancer screening behaviors and health anxiety in attending women to urban healthcare centers.

Public title

A comparison of the effect of education by compact disc and booklet about breast cancer screening on women's knowledge, breast cancer screening behaviors and health anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All women aged 20 to 70 years with a minimum level of education about guidance school having a computer or a CD player for watching compact disc have not been performed breast exam by a physician during the past year despite the indication of mammography, haven’t done it.

Exclusion criteria:

The inability to understand the questions of a questionnaire. the inability to answer questions of a questionnaire, such as blindness and deafness; diseases that prevent people from learning and responding, such as Alzheimer's, mental retardation; current or history of breast cancer.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

First of all 10 health centers in Ilam, three centers will be selected randomly (using random numbers). The type of intervention for each center will also be determined randomly (using the random number table) (ie, in each center, which type of intervention (CD or booklet, or without intervention) will be specified randomly. At each center, a list of qualified individuals will be selected and selected among them in a sample systematical method. That is, from 1 to the digit of classes’ interval, one digit will be selected randomly, that is the first sample in this center. Then, the next samples are selected as the interval between the classes. In the absence of access or reluctance to participate in the study, the next women will be selected from the list.

Blinding (investigator's opinion)

Not blinded

Blinding description

In the pre-intervention phase, the researcher will send questionnaires to the samples in all three centers, but in the process of evaluating the outcomes, midwives will be asked to complete the questionnaire.

Placebo

Not used

Assignment

Parallel

Other design features

Women attending to three healthcare centers (which selected randomly) that will be selected by the method of systematic random.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Comittee of Mazandaran University of Medical Sciences

Street address
Vice-Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square.

City
Sari

Province
Mazandaran

Postal code
4817918479

Approval date
2017-07-11, 1396/04/20

Ethics committee reference number
IR.MAZUMS.REC.96.3156

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50.9

ICD-10 code description
Malignant neoplasm: Breast, unspecified

Primary outcomes

1

Description
Breast cancer screening behavior

Timepoint
Before, one week and three months after the intervention

Method of measurement
Breast Cancer Screening Knowledge and Behavior questionnaire

Secondary outcomes

1

Description
Women's health anxiety

Timepoint
Before, one week and three months after the intervention

Method of measurement
Health Anxiety Questionnaire

Intervention groups

1

Description
Intervention group 1: The compact disk will be taken to 53 eligible Women attending the first center that select randomly. This CD contains comprehensive information on various methods for screening breast cancer which provided by academic Jihad. It's validity approved by 10 specialists of reproductive health, obstetrician and gynecologist, breast surgeon and oncologist.

Category
Prevention

2

Description
Intervention group 2: The educational booklet will be taken to 53 eligible Women attending to the second center that select randomly. This booklet contains comprehensive information on various methods for screening breast cancer. It's validity approved by 10 specialists of reproductive health, obstetrician and gynecologist, breast surgeon and oncologist.

Category
Prevention

3

Description
Control group: Women of this group will not any intervention during the study. The educational booklet will give them at the end of the study.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
urban healthcare center of Ilam city (number 1)

Full name of responsible person
Mrs. NourMaleki

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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
IR.MAZUMS.REC.96.3156
Grant code / Reference number
3156
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
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Full name of responsible person
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Position
assistant professor
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Person responsible for updating data

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Other areas of specialty/work
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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
the article about comparing education through compact disc and booklet on breast cancer screening behavior and health anxiety will be published.

When the data will become available and for how long
one year later

To whom data/document is available
policy makers, Managers, healthcare providers, researchers, educators and general population.

Under which criteria data/document could be used
Vice-chansellor for research of Mazandaran University of Medical Sciences

From where data/document is obtainable
apply to Vice-chansellor for research of Mazandaran University of Medical Sciences in Moallem Square, Sari, Iran

What processes are involved for a request to access data/document
apply to Vice-chansellor for research of Mazandaran University of Medical Sciences, refer to research manager of University, study and answer.

Comments
no comment