Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Designing, implementation and evaluation of educational intervention related to breast cancer screening behaviors in middle-aged women

Protocol summary

Study aim
Designing and determining the effect of educational intervention on breast cancer screening behaviors in middle-aged women

Design
A clinical trial with a control group, with parallel and randomized groups, with the participation of 250 middle-aged women.

Settings and conduct
The study will be conducted in comprehensive health centers under the auspices of two health centers (number one and two) in Isfahan. First, one of the two health centers will be randomly assigned to the intervention group and the other to the control group. Then, from the comprehensive health centers which are dependant to each of them, 5 centers will be randomly selected.Also, samples will be selected from women covered by these centers using convenience sampling method. Regarding the given information, three and 6 months after the intervention time done by the questionnaire, Factors related to the promotion of breast cancer screening behaviors are collected and compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria:1. Middle-aged women who have not experienced breast cancer screening in the past two years. 2- No history of malignant breast diseases in a person or a close relative 3- Having a laptop or smart phone 4-Minimum literacy

Intervention groups
Intervention group: Intervention in this group will be done for eight weeks using effective intervention methods and strategies such as holding a training session, role playing, showing a video, questions and answers, etc in the Sky room and sending files and training packages through Whatsapp channel . Control group: without intervention

Main outcome variables
Motivation; social support; seeking information; Self-care; stress management; anxiety; Breast self-examination; Clinical breast examination ; Mammography

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211119053105N1**
Registration date: **2021-12-15, 1400/09/24**
Registration timing: **prospective**

Last update: **2021-12-15, 1400/09/24**
Update count: **0**

Registration date
2021-12-15, 1400/09/24

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Designing, implementation and evaluation of educational intervention related to breast cancer screening behaviors in middle-aged women

Public title
The effect of educational intervention on breast cancer screening behaviors in women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Middle-aged women who have not had two breast cancer screening methods, including mammography or clinical breast examination, for at least the past two years. Minimum literacy No history of malignant breast disease in the person or close relatives Owning a laptop, mobile phone or tablet with the ability to access the Internet and install software Consent to participate in the study

Exclusion criteria:
Pregnant and breastfeeding women History of participating in training sessions related to breast cancer screening

Age
From **40 years** old to **59 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **250**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method will be used. The randomization scale will be cluster. First, one of the two Isfahan health centers will be randomly assigned to the intervention group and the other to the control group.Then,5 centers will be selected randomly from the comprehensive health centers ,which were their subsets, and among the women who were covered by these centers, considering the inclusion and exclusion criteria and the agreement to participate in the study, 125 people will be opted using convenience sampling method and will enter into the study for each of the intervention and control 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 Isfahan University of Medical Sciences

Street address
Building No. 4, Isfahan University of Medical Sciences, Hezar Jarib Street

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Province
Isfehan

Postal code
8174673461

Approval date
2021-11-15, 1400/08/24

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.343

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
Motivation

Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program

Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

2

Description
social support

Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program

Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

3

Description
Information seeking
Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

4

Description
Self-care
Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

5

Description
stress management
Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

6

Description
Worry
Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

Secondary outcomes

1

Description
Breast self-examination behavior
Timepoint
1- Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

2

Description
Clinical breast examination behavior
Timepoint
1-Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

3

Description
Mammography behavior
Timepoint
1-Before the intervention 2- Three months after the intervention program 3- Six months after the intervention program
Method of measurement
Questionnaire including factors related to the promotion of breast cancer screening behaviors

Intervention groups

1

Description
Intervention group: The intervention will be performed in the following steps: 1- describing the objectives of the study to the participants and obtaining their consent 2- Creating a communication channel (Whats App) to send questionnaires and programs, training packages and reminders Programs 3- Justifying the intervention group regarding the conditions and manner of holding online training sessions, sending the link to enter the sessions via SMS, sending training packages, etc. 4- Providing the necessary instructions regarding the installation of the required programs (for participation in online training classes) on the mobile phone, tablet or laptop of the participant or a family member who lives with him. 5- If necessary, by assigning a specific day and time with the presence of the person participating in the health center, the mentioned programs will be installed on his mobile phone or tablet by the research group.6- Starting educational intervention programs by the participating in 60-80 minute online sessions once a week. These sessions will be held in Skyroom and the presence and absence of people in the sessions will be done in the same way. Sending text, audio and video files and messages reminding sessions and linking classes will be done via SMS and WhatsApp channel. The duration of the intervention is 8 weeks and is as follows, Week 1: Teaching how to work with Skyroom, holding an online session on a trial basis to identify and resolve possible problems of participants in joining the class and fully justify people about holding upcoming sessions,Week 2: Implementation of the intervention to reduce the level of concerns in middle-aged women about breast cancer screening behaviors, consists of holding a training session by a mental health expert, showing a video, discussion with clarification, using muscle relaxation

techniques, commitment of participants to decrease their worries about performing breast cancer screening behaviors. Week 3: Implementing an intervention aimed at improving the level of stress management among middle-aged women regarding breast cancer screening behaviors, including holding training session by a mental health expert, recording stress on a daily basis by participants, practicing problem-solving skills, introducing free counseling centers in the city, recording stress reduction goals, introducing active support groups and sports centers, as well as teaching yoga and meditation to participants. Week 4: Implementing an intervention aimed at improving the motivation of middle-aged women to perform breast cancer screening behaviors, including holding a training session by a mental health expert and midwife, playing a role, introducing participants who have successful experiences in screening behaviors, giving verbal encouragement , inviting and interviewing women who have developed breast cancer due to lack of screening behavior as well as Providing participants an incentives to engage in screening behaviors.Week 5: Implementing an intervention aimed at empowering middle-aged women to perform breast cancer self-care, including holding a training session in which a lecture and discussion were included by a midwife or doctor, sending training files on self-care in virtual channels, introducing and interviewing women who were able to discover the mass due to screening, practicing for setting goals, self-monitoring their presence, and considering personal punishment and encouragement for participants' failure or achievement of goals.Week 6: Implementation of the intervention with the aim of improving the level of information search to perform breast cancer screening behaviors, including holding a training session in which lectures and questions and answers by midwives and health education and health promotion experts were included, introducing valid sources, sites and databases for receiving information about breast cancer and ways to prevent it and the positive experience of participants in the field of information search.Week 7: Intervention with the aim of strengthening the support system of the intervention group to perform breast cancer screening behaviors, including holding a training session for women and their husbands to enhance emotional and non-emotional support and a separate training session for midwives of selected health centers to enhance information support as well as providing successful experiences by spouses and staff, forming self-help and support groups,Week 8: Answering questions, repeating topics as needed and updating trainings and sending additional files, getting feedback from participants

Category

Early detection

2

Description

Control group: For this group, the following will be done: 1- describing the objectives of the study to the participants and obtaining their consent 2- Creating a communication channel (Whats app) to send questionnaires 3- Provide routine care and advice in comprehensive health centers in the field of prevention and performance of breast cancer screening behaviors 4- Providing educational content to all members of the control group after completing the study

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Health Center number one

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Banafsheh Tavakoli
Position
Ph.D student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Participants' data will remain confidential to the researcher due to the given assurance at the beginning of the study.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Some of the information about the main consequences can be shared
When the data will become available and for how long
One year after the results are published
To whom data/document is available
Isfahan University of Medical Sciences Vice Chancellor of Research
Under which criteria data/document could be used
obtain a license from Isfahan University of Medical Sciences
From where data/document is obtainable
Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
The applicant who desires to receives the documents can submit her/his request for obtaining the documents one year after the publication of the results through the Vice Chancellor of Research in Isfahan University of Medical Sciences
Comments