

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

Name

Banafsheh Tavakoli Chaleshtori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3228

Email address

tavakoli.101@hlth.mui.ac.ir

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

City

Esfahan

Province

Isfahan

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

Banafsheh Tavakoli

Street address

Feiz Street

City

Esfahan

Province

Isfahan

Postal code

81649 69459

Phone

+98 31 3661 7062

Email

health-1@mui.ac.ir

2

Recruitment center

Name of recruitment center

Isfahan Health Center number two

Full name of responsible person

Banafsheh Tavakoli

Street address

Feiz Street

City

Esfahan

Province

Isfahan

Postal code

6945981649

Phone

+98 31 3661 7372

Fax

+98 31 3661 7328

Email

health-2@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash

Street address

Hezarjirib Street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3243

Email

h_shahnazi@yahoo.com

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

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education and Health Promotion, School of Health, Isfahan University of Medical Sciences, Hezar Jarib Street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3228

Email

tavakoli.bfsh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hosein Shahnazi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education and Health Promotion, School of Health, Isfahan University of Medical Sciences, Hezar Jarib Street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3243

Email

h_shahnazi@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Banafsheh Tavakoli

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education and Health Promotion, School of Health, Isfahan University of Medical Sciences, Hezar Jarib Street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3228

Email

tavakoli.bfsh@gmail.com

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 receive 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