Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of education based on the pattern of change stages on the acceptance and understanding of mammography in women over 40 years

Protocol summary

Study aim

Determining the effectiveness of Education Based on Stages of Change Model on Mammography adoption and Perception in Women over 40 Years

Design

The present study will be performed using the intervention and control group.Sampling will initially be based on purpose and inclusion criteria and random allocation will be used for the intervention and control groups. the number of sample members in each statistical group will be 64 patients who are over 40 years old referring to comprehensive service centers. The health of Amol city will be in 1400.

Settings and conduct

A total of 128 women referring to comprehensive health centers in Amol city are included in the study based on the sample size formula and after completing the online form of informed consent and based on inclusion criteria and are divided into two groups of intervention and control based on random allocation. The study is as follows: 1) Before starting the educational intervention 2) Intervention stage 3) Follow-up stage

Participants/Inclusion and exclusion criteria

- Being 60 -40 years old - Iranian nationality - People's desire to participate in the study - Literacy -No history of breast cancer Exclusion criteria include the following: - Placing people in the Action and maintenance stage based on the Rakowski

Intervention groups

first questionnaires of demographic and stages of changing the behavior of mammography screening and the mammography decision balance are completed by the intervention and control group The intervention will include 4 online training sessions. Control group: does not receive any intervention After 4 weeks of training, the questionnaires for both intervention and control groups will be completed again.

Main outcome variables

acceptance and understanding of mammography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041911N3**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Seyede maryam Lotfipur rafsanjany

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

m.lotfi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on the pattern of change stages on the acceptance and understanding of mammography in women over 40 years

Public title
The Impact of Education Based on Stages of Change Model on Mammography adoption and Perception
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being 40-60 years old Being Iranian Willingness of people to participate in the study Literacy No history of breast cancer
Exclusion criteria:
Placement of individuals in the action and maintenance phase based on the stages of changing Rakowski mammography behavior
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is performed in this study by simple randomization. To assign individuals to each intervention and control groups, participants who have signed a consent form to participate in the study are asked to draw in one. Be divided into groups A and B.
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 rafsanjan university of medical sciences
Street address
Rafsanjan-Imam Ali Blvd. - Central Organization
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2021-02-03, 1399/11/15
Ethics committee reference number
IR.RUMS.REC.1399.255

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Percentage of mammography acceptance
Timepoint
before, immediately and one month after training
Method of measurement
Rakowski Mammography Behavior Change Stages Questionnaire

2

Description
the average score of perceived benefits of mammography
Timepoint
before, immediately and one month after training
Method of measurement
the mammography decision balance questionnaire

3

Description
the average score of perceived barriers to mammography
Timepoint
before, immediately and one month after training
Method of measurement
mammography decision balance questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training will be done based on the pattern of change stages of the intervention in the intervention group in 4 sessions of one hour. The sessions will be conducted theoretically and practically

using direct and group teaching methods such as lectures with questions and answers, slide shows and videos. The educational objectives of each session are as follows: Session 1: Transmitting information that increases the learner's understanding and corrects misconceptions and motivates them to read new material Session 2: Creating an exercise for thinking and encouraging participation in communication topics Or Participate in discussions, identify problems and contradictions, and improve new learning knowledge (increase benefits and reduce perceived disadvantages by expressing new and persuasive information. Session 3: Involve learners in decision-making, increase analytical skills , Increase emotional cognitive skills and increase skills and use the knowledge learned in life situations through group work in class, face-to-face class discussions Session 4: Support and encouragement to take advantage of opportunities Acquired skills, competencies, follow-up and support Immediately after the fourth training session, the Rakowski Mammography Screening Behavior Change Questionnaire and the Mammography Decision Balance Questionnaire will be completed for both intervention and control groups.

Category
Behavior

2

Description
Control group: No intervention is received

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
مرکز خدمات جامع سلامت شهر آمل

Full name of responsible person
-Hakimeh khosravi moghaddam

Street address
mahmud abad ave,Taleb amoli Blvd.

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Province
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+98 11 4426 1501

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Amo@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Ali Shamsi Zadeh

Street address
Motaahhari Blvd Faculty of Nursing,Midwifery,Rafsanjan

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7718796755

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Info@rums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
maryam ebrahimi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Haraz ave.Tabari blvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Seyyedeh MarymLotfipour rafsanjani

Position
Academic instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Position
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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
There is no more information

Study Protocol
No - There is not 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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available