Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of educational program using Extended Parallel Process Model on improving breast cancer self-examination behavior in women

Protocol summary

Study aim
Determining the effect of educational program by using Extended Paralle Process Model on promoting breast self-examination behavior in women

Design
A randomized controlled clinical trial in which educational intervention was performed on 40 participants

Settings and conduct
After preparing a list of health centers in the city of Somehsara, select the two centers with the largest population and Sampling is done continuously from both centers and in an accessible manner on different days of the week

Participants/Inclusion and exclusion criteria
Conditions for entering are 20-60 years old, having literacy, and not having a breast self-examination incorrectly or not at all. Conditions of non-inclusion are, pregnancy and lactation, breast disease and other malignancies and a history of malignant breast tumors

Intervention groups
In the intervention and control group, questionnaires is completed before training, immediately after training and 2 months later.Also, the performance checklist of breast self-examination is completed with respect to the privacy of the participants by observing the performance by the researcher, before, immediately and two months after the last training session

Main outcome variables
Perceived threat score,Perceived susceptibility, Perceived severity, Perceived efficiency,Perceived self-efficacy, Perceived response efficacy and The critical point, which predicts behavioral intent.It indicates that the person is in the stage of risk control or fear control.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200525047565N1**
Registration date: **2020-08-20, 1399/05/30**
Registration timing: **retrospective**

Last update: **2020-08-20, 1399/05/30**
Update count: **0**

Registration date
2020-08-20, 1399/05/30

Registrant information

Name
Sharareh Jannesari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8820 2512

Email address
shararehjannesari@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-17, 1396/02/27

Expected recruitment end date
2017-06-21, 1396/03/31

Actual recruitment start date
2017-05-17, 1396/02/27

Actual recruitment end date
2017-06-21, 1396/03/31

Trial completion date
2017-07-21, 1396/04/30

Scientific title
The effect of educational program using Extended Parallel Process Model on improving breast cancer self-examination behavior in women

Public title

Investigating the effect of Extended parallel process model on breast self-examination behavior

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be between 20 and 60 years old Be literate Breast self-examination is done incorrectly or not at all.

Exclusion criteria:

to be during pregnancy and breastfeeding Have history of malignant breast tumors. Have breast diseases and other malignancies.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

This study is an educational intervention based on a Extended parallel process model aimed at promoting breast self-examination behavior in women.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee In Research , School of Farmecy , Nurssing ,Midwifery of Shahid Beheshti University

Street address

Valiasr Street, intersection of Niayesh Highway ,Schoole of Nursing and Midwifery,Tehran, Iran .

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.SBMU.PHNM.1395.577

Health conditions studied

1

Description of health condition studied

Educational intervention based on a Extended parallel process model to promote breast self-examination

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the average score of perceived threat of women

Timepoint

before the start of the intervention, Immediately and two months after educational intervention

Method of measurement

A researcher-made questionnaire based on Extended parallel process model

2

Description

the average score of women's perceived efficiency

Timepoint

before the start of the intervention, Immediately and two months after educational intervention

Method of measurement

A researcher-made questionnaire based on Extended parallel process model

3

Description

the mean score of women's perceived severity

Timepoint

before the start of the intervention, Immediately and two months after educational intervention

Method of measurement

A researcher-made questionnaire based on Extended parallel process model

4

Description

the mean score of women's perceived susceptibility

Timepoint

before the start of the intervention, Immediately and two months after educational intervention

Method of measurement

A researcher-made questionnaire based on Extended parallel process model

5

Description

the mean score of women's perceived response efficacy

Timepoint
before the start of the intervention, Immediately and two months after educational intervention
Method of measurement
A researcher-made questionnaire based on Extended parallel process model

6

Description
the average score of women's perceived self-efficacy
Timepoint
before the start of the intervention, Immediately and two months after educational intervention
Method of measurement
A researcher-made questionnaire based on Extended parallel process model

7

Description
the average score of women's performance in breast self-examination
Timepoint
before the start of the intervention, Immediately and two months after educational intervention
Method of measurement
A researcher-made questionnaire based on Extended parallel process model

Secondary outcomes

empty

Intervention groups

1

Description
The training package is developed using the opinions of health promotion specialists and reproductive health professionals based on EPPM and its presentation is based on the steps recommended in this model.Educational sessions in the intervention group are held in 4 sessions during 1 month and during 60-minute sessions.Thus, every week, on average, 4 ,1-hour sessions are held with the average participation of 7 to 10 people, overall 16 education sessions.Outlines of educational materials are:Breast anatomy, definition of breast cancer and its complications, its causes, introduction of prevention methods and early detection of breast cancer and practical training on the correct method of breast self-examination.In order to better convey and understand the content of educational aids such as anatomical mullage, showing videos using the experiences of people with breast cancer, slides and video projectors that convey the material through lectures and questions and answers are provided.
Category
Prevention

2

Description
At the end of the educational interventions, in order to comply with ethical standards and not deprive the control group of care in one session, a summary of training materials and important points for the control group will be given as a lecture within 20 minutes but without using multiple EPPM steps.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
No. 1 Health Center of Somehsara city
Full name of responsible person
Hamed ebrahimi
Street address
Imam Khomeini Ave, in front of Valiasr Mosque
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin zarghy
Street address
Shahid Arabi St, Yemen St, next to Ayatollah Taleghani Hospital,Shahid Chamran Highway،Tehran.
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Proportion provided by this source
1

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
sharareh jannesari
Position
Midwifery Instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
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Valiasr Street, Intersection of Niayesh Highway, Opposite to Rajaee Heart Hospital, Schoole of Nursing and Midwifery, Tehran, Iran .
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Person responsible for updating data

Contact

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Valiasr Street, Intersection of Niayesh Highway, Opposite to Rajaee Heart Hospital, Schoole of Nursing and Midwifery, Tehran, Iran .
City
Tehran
Province
Tehran
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1996835119
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+98 21 8820 2512
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sharareh jannesari@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 remain confidential to the researcher during the assurance given to them 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
This study is an intervention study based on an educational model conducted to promote breast self-examination in women.

When the data will become available and for how long
After the publication of the article, it is available in the relevant journal.

To whom data/document is available
Anyone interested in this research can read the final article.

Under which criteria data/document could be used
For health planners to increase self-care behavior in women in society

From where data/document is obtainable
Email the corresponding author

What processes are involved for a request to access data/document
Explain the reasons for requesting an article in the email.

Comments