Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

The effect of group counseling based on Protection Motivation Theory on breast Self-examination on women referring to Health centers Mashhad.

Protocol summary

Study aim
Determining the effect of group counseling based on the theory of protection motivation in performing breast self-examination
Design
Clients of the health center based on even and odd days by simple random we choose
Settings and conduct
It will be done in the health center, first both groups will do the initial evaluation The control group then receives only routine care, but the groupThe intervention will be 4 sessions of counseling.
Participants/Inclusion and exclusion criteria
Iranian nationality, age between 20 to 60 years, no breast cancer in themselves or first-degree relatives such as: mother, sister, daughter, educability (no mental disorder), lack of education in medical and paramedical fields, not having No history of breast cancer education, no cancer in family and self, no mammogram within 6 months
Intervention groups
Counseling based on a model will be more effective in this study counseling basedThe theory of protection motivation includes: the structure of perceived sensitivity, intensity Perceived, reward, self-efficacy, response efficiency, response cost, fearEach structure is measured by a few questions
Main outcome variables
Creating fear to reinforce screening behavior (breast self-examination)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220103053610N1**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **prospective**
Last update: **2022-04-12, 1401/01/23**
Update count: **0**
Registration date
2022-04-12, 1401/01/23

Registrant information
Name
Monireh Zahabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3525 3427
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-09, 1401/01/20
Expected recruitment end date
2022-07-11, 1401/04/20
Actual recruitment start date
2022-09-11, 1401/06/20
Actual recruitment end date
2023-02-09, 1401/11/20
Trial completion date
2023-03-11, 1401/12/20

Scientific title
The effect of group counseling based on Protection Motivation Theory on breast Self-examination on women referring to Health centers Mashhad.

Public title
Evaluation of the effect of counseling on breast self-examination
Purpose
Screening
Inclusion/Exclusion criteria

Inclusion criteria:
Have you signed the written consent form? Are you Iranian and a resident of Mashhad? Are you between 18 and 69 years old? Have you ever had first-degree relatives like a mother, sister, daughter with a history of breast cancer? Do you have a history of medical illness? Do you have a history of mental illness? Are your studies in medical and paramedical majors? Have you ever been trained in breast cancer or breast disease? Have you had a mammogram in the last 9 months? Do you have a contact number (landline or mobile phone)?
Exclusion criteria:
Has the participant withdrawn from participating in the research? Has not attended more than one counseling session? Has a lump in the breast been detected during the study?

Age
From **18 years** old to **69 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Mashhad University of Medical Sciences

Street address
School of Nursing and Midwifery, Sina St, Crossroads Doctor, Street university, Mashhad Mashhad,

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2021-03-17, 1399/12/27

Ethics committee reference number
991314

Health conditions studied

1

Description of health condition studied
Breast Self Examination

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Group counseling based on Protection Motivation Theory

Timepoint
The beginning of the study and two months later

Method of measurement
Questionnaire on women's participation in preventive behaviors against breast cancer based on protection motivation theory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:There are groups that receive counseling based on the constructs of Rati's protection motivation theory in 4 sessions of 60 minutes. Participants included a questionnaire containing demographic characteristics (age, etc.), midwifery information (pregnancy history, etc.) and a questionnaire on participation in breast cancer prevention behaviors based on protection motivation theory.Includes: Perceived allergy questions such as: Because I eat canned and prepared foods, I am more likely to get breast cancer, Severely perceived questions such as: If my breast is surgically removed for cancerI lose my femininity, the reward structure of questions like: I do not seek to diagnose and treat breast cancer because I lose my beauty. The self-efficacy of questions like if I get breast cancer I can do nothing to control it and I have to wait for death.Efficiency structure of answering questions such as: If a lump in my breast is diagnosed as soon as possible with a doctor's examination or mammogram, I will be treated sooner. Structures of fear such asIf I get breast cancer, it 's hard for me to imagine not having a breast and what is the motivation to protect your decision to have a breast self - test?Breast anatomy Receives age-related changes in women and breasts, types of breast cancer, risks, types of diagnostic methods and how to perform them, best times To perform diagnostic tests, they receive the importance of self-examination, how to do it by lecturing method,

educational Motivational video, using group discussion mock-up.

Category
Behavior

2

Description
Control group:Receive routine care from the health center.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
No. 1 Health Center

Full name of responsible person
sherbafan

Street address
Boulevar vakil Abad

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Razavi Khorasan

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9179793945

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Talat khadivzadeh

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Unit 475, Fajr Complex 4, Shariati, Imam Ali Highway, Mashhad

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Monireh zahabi

Position
Student

Latest degree
Master

Other areas of specialty/work
Midwifery

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units 475, Fajr Complex 4, shariati, Imam Ali Highway, Mashhad

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available