

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)

Phone

+98 51 3525 3427

Email address

zahabim961@mums.ac.ir

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 cancer I 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 as If 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
Boulevard vakil Abad
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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
Street address
Unit 475, Fajr Complex 4, Shariati, Imam Ali Highway, Mashhad
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Email
ZAHABIM961@MUMS.AC.IR
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
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Person responsible for updating data

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9137913199

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