

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of education based on the theory of planned behavior and self-efficacy on the level of health literacy of postmenopausal women and their use of health services in comprehensive health centers of Mashhad,1396

Protocol summary

Study aim

This research aims to raise the level of women's health literacy for menopause by using an intervention method on the target group of 45-65 years, which eventually leads to improving the quality of life of this group

Design

This research is a semi-experimental study. The statistical population of this research is postmenopausal women who are 45 - 65 years old. The sample size is 400 people. In the intervention section, a random sampling method is used.

Settings and conduct

This study will be conducted in Mashhad

Participants/Inclusion and exclusion criteria

Entry criteria: Women's willingness to participate in study; no hormonal medications; no surgery; no menstruation for at least 12 months; resident of Mashhad. Exit criteria: unwillingness to continue cooperation; absence of an educational session; failure to answer more than 10% questions to the questionnaire; death before the completion of the study.

Intervention groups

The control group does not receive educational intervention. In the test group, education intervention is based on the study model to improve health literacy.

Main outcome variables

Measurement of the scores of mental health questionnaire, anxiety and self-regulation learning strategies before, immediately and three months after the intervention in the target group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N27**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **retrospective**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 502 6195

Email address

peymann@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2018-05-12, 1397/02/22

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on the theory of planned behavior and self-efficacy on the level of health literacy of postmenopausal women and their use of health services in comprehensive health centers of Mashhad,1396

Public title
The effect of education on health literacy and how to use health services in postmenopausal women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Entry criteria: 1. Women's willingness to participate in the study. 2. No hormonal medication use. 3. No hysterectomy. 4. Interruption of menstruation for at least 12 months. 6. Live in Mashhad
Exclusion criteria:
Exit criteria: 1. No desire to continue cooperation 2. Absence of more than one training session 3. No answer to more than 10% of questionnaire questions 4. Being fat

Age
From **45 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **400**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

University-University Street 18

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-05-12, 1397/02/22

Ethics committee reference number

IR.MUMS.REC.1397.030

Health conditions studied

1

Description of health condition studied

menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Health literacy

Timepoint

Before, immediately and three months after the intervention

Method of measurement

Tofla Short Health Literacy Questionnaire

Secondary outcomes

1

Description

How to use health services

Timepoint

Before, immediately and three months after the intervention

Method of measurement

Researcher made questionnaire

2

Description

Self-efficacy

Timepoint

Before, immediately and three months after the intervention

Method of measurement

Scherer self-efficacy questionnaire

Intervention groups

1

Description

Intervention group: Conducting educational classes according to the subject of discussion and based on the study model

Category

Behavior

2

Description

Control group: no intervention in this group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Services Centers

Full name of responsible person

Nooshin Peyman

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University Street between 16-18

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Mashhad University of Medical Sciences

Full name of responsible person

Research Deputy

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Mashhad University of Medical Sciences

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36468547

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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

Deputy of Research of 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

Nooshin Peyman

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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Nooshin Peyman

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Associate Professor

Latest degree

Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Potential data can be interchangeable after the differentiation of individuals

When the data will become available and for how long

The beginning of the access period is one month after the announcement of the result

To whom data/document is available

Researchers who work at the university

Under which criteria data/document could be used

The data is sent via an official request and by email

From where data/document is obtainable

Dr. nooshin peyman

What processes are involved for a request to access data/document

The data is sent via an official request and by email

Comments