

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Study of the effect of education based on self-efficacy theory on self-efficacy , health literacy and the quality of life of health volunteers in Mashhad health centers

Protocol summary

Study aim

The aim of this study was to assess the effect of a health literacy training intervention on the self-efficacy and quality of life of menopausal women.

Design

A randomized controlled trial method was used to enroll 165 menopausal women from healthcare clinics in the Mashhad, Iran. All participants received a code, then, they were randomly divided into two control and intervention groups. The Short Test of Functional Health Literacy` Assessment (S-TOFHLA), and Menopause-Specific Quality Of Life (MENQOL) questionnaires, were answered by each subject before, immediately after and 3 months post-training. Multiple statistical analysis were used to assess whether the educational intervention improved women's health literacy, self-efficacy and quality of life after intervention.

Settings and conduct

The study population was women who referred to health centers in Mashhad, Iran. All participants were randomly divided into two control and training intervention groups. They filled all questionnaires before and 3 months after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: intention, age between 40-60 years , ability to read and write and living in Mashhad Exclusion criteria: Death, Unwillingness to participate in training sessions, Unable to give informed consent and they had suffered Refractory disease

Intervention groups

All participants were allocated into an educational intervention group and control group. In intervention group, the educational intervention was conducted based on the potential gaps with focus on Health Literacy in Practice (HLP) strategies. The control group did not receive any intervention education.

Main outcome variables

health literacy, self-efficacy, quality of life of menopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N26**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 915 502 6195

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical sciences

Expected recruitment start date

2016-08-28, 1395/06/07

Expected recruitment end date

2016-12-08, 1395/09/18

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of education based on self-efficacy theory on self-efficacy , health literacy and the quality of life of health volunteers in Mashhad health centers

Public title
Quality of Life, self efficacy and Health Literacy in menopause

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Person's intention to participate in the study Iranian health volunteer Age between 40-60 years Ability to read and write Residing in Mashhad Iranian nationality
Exclusion criteria:
 Death Unwillingness to participate in training sessions Refractory disease Unable to give informed consent They had suffered an acute-myocardial infarction and kidney disease had visual impairment, mental disturbance illiteracy, and upper limb disability

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: **165**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random sampling was used to select eligible women from the 2 health care center in Mashhad, Iran. Health secretaries provided different lists of women and all the women are assigned number. The researcher then used tables of random number to select each number of the women. in final, 60 menopausal women enrolled for the initial study were randomly assigned to intervention (n= 30) and control groups (n=30).

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 Health, Daneshgah18 Street, Danshgah Avenue, Mashhad

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Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2016-09-03, 1395/06/13

Ethics committee reference number

IR.MUMS.REC.1395.320

Health conditions studied

1

Description of health condition studied

menopause

ICD-10 code

N95.1

ICD-10 code description

N95 Symptomatic menopausal or female climacteric states

Primary outcomes

1

Description

improvement of self efficacy

Timepoint

Before The intervention, immediately and three months after interve

Method of measurement

general self-efficacy questionnaire (Sherer)

Secondary outcomes

1

Description

health literacy

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

The Short Test of Functional Health Literacy` Assessment (S-TOFHLA)

2

Description

improvement of quality of life

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

Menopause-Specific Quality Of Life (MENQOL) questionnaires

Intervention groups

1

Description

Intervention group: education training was conducted during 6 sessions (60 minutes) to address skills to health promotion based on Health Literacy in Practice (HLP) strategies and self efficacy theory among menopause women.

Category

Behavior

2

Description

Control group: this groups did not received any education training

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Mashhad University of Medical Sciences

Full name of responsible person

Nooshin Peyman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghod

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Mashhad University of Medical Sciences International Office, Administration Center (Qoreishi Building), Daneshgah St.

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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

Nooshin Peyman

Position

Department of Health Education and Health Promotion, between 16th and 18th Daneshgah, Daneshgah Stre

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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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

No - There is not 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 is sharable after distinguishing people

When the data will become available and for how long

Start the access period one month after the publication of result

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Data is sent through an official request and by email

From where data/document is obtainable

Dr Nooshin Peyman Peymann@mums.ac.ir

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

Data is sent through an official request and by email

Comments