

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### 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

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

##### City

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

##### Street address

Mashhad University of Medical Sciences

##### City

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##### Province

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+98 51 3180 1337

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peymann@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghod

#### Street address

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

#### City

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#### Province

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#### Phone

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#### Email

tafaghodim@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

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

##### Street address

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##### Province

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Position**

PhD in Health Education

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

نوشین پیمان

**Position**

Professor Health Education and Health Promotion

**Latest degree**

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**Other areas of specialty/work**

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**Province**

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**Postal code**

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**Phone**

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**Email**

peymann@mums.ac.ir

**Web page address**

## 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**