Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 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 woment'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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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
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Other areas of specialty/work
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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