

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of couple training based on self-efficacy theory on quality of life, self-efficacy and health literacy in postmenopausal women

Protocol summary

Study aim

Determining the effect of educational intervention of couples in menopausal age based on self-efficacy theory on quality of life, health literacy and self-efficacy in postmenopausal women in Mashhad

Design

This research was a semi-experimental study. First of all, in the descriptive stage, participants were determined in 5 health center of Mashhad according to the number of samples. They were married women with lived husbands in the age range of 45_60 years old. Then in the next level, one center was chosen randomly from the five centers in Mashhad, and four comprehensive centers were randomly selected from that center. Two centers were assigned as experimental group and two centers were assigned as control group.

Settings and conduct

Menopause women aged 45-60 years old referring to Mashhad comprehensive health centers in Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women at the age of 45-60 years; living with husband; physiologically menopausal; Passed 1-10 years from menstruation pause; Willingness to participate in this study. Non-compliance criterion: history of hormone therapy over the past 6 months; History of hysterectomy; Not being Iranian; Severe physical or mental illness.

Intervention groups

In this study, married menopausal women referring to comprehensive health centers of Mashhad city will be randomly assigned into two groups of test and control groups. In the test group, educational intervention will be based on the theory of self-efficacy. The control group will not receive any training.

Main outcome variables

Self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N28**

Registration date: **2018-06-24, 1397/04/03**

Registration timing: **retrospective**

Last update: **2018-06-24, 1397/04/03**

Update count: **0**

Registration date

2018-06-24, 1397/04/03

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

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of couple training based on self-efficacy theory on quality of life, self-efficacy and health literacy in postmenopausal women

Public title

The effect of couples training on quality of life, health literacy and self-efficacy of postmenopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women at the age of 45-60 years living with husband physiologically menopausal Passed 1-10 years from menstruation pause Willingness to participate in this study

Exclusion criteria:

history of hormone therapy over the past 6 months History of hysterectomy Not Iranian Severe physical and mental illness

Age

From **45 years** old to **60 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

This research was a semi-experimental study. First of all, in the descriptive stage, participants were determined in 5 health center of Mashhad according to the number of samples. They were married women with lived husbands in the age range of 45_60 years old. Then in the next level, one center was chosen randomly from the five centers in Mashhad, and four comprehensive centers were randomly selected from that center. Two centers were assigned as experimental group and two centers were assigned as control group. Experimental and control groups were homogenized and had acceptable distance from each other.

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

Between Daneshgah16 and Daneshgah18, Danshgah street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.MUMS.REC.1397.011

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

Self efficacy

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Health literacy

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

Questionnaire

2

Description

Quality of life

Timepoint

Before The intervention, immediately and three months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Health educational intervention is based on self-efficacy theory in the intervention group. The number and content of sessions and the duration of the course will be determined through need assessment in the descriptive phase of the study.

Category

Behavior

2

Description

Control group: The control group will not receive any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Comprehensive Health Centers

Full name of responsible person

Nooshin Peyman

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School of Health, Daneshgah18 Avenue, Danshgah Street, Mashhad

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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

Mohsen Tafaghodi

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Daneshgah18, Danshgah Avenue

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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

Assistant Professor of Health Education and Health Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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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 is sharable after distinguishing people

When the data will become available and for how long

the access period will be start one month after the result is published

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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nooshin Peyman

Position

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Latest degree

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Other areas of specialty/work

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