Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 menopaused; 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

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Iran (Islamic Republic of)

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+98 915 502 6195

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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 menopaused 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
Street address
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
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Other areas of specialty/work
Health Promotion
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Person responsible for updating data

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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