

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of educational intervention based on multi-theory model on improving the quality of life among postmenopausal women

#### Protocol summary

##### Study aim

Determining the effect of educational intervention based on multi-theoretical model on improving the quality of life of postmenopausal women

##### Design

Postmenopausal women referred to health care centers will be divided into intervention and control groups. The sampling method will be multi-stage random sampling. The Sample size at this stage will be determined after designing the questionnaire and conducting a pilot study on a small sample of the target group and determining the sample size using pilot results.

##### Settings and conduct

Health centers in Yazd The samples are divided into two groups of test and control randomly and for the test group based on the structures of the multi-theoretical model, intervention strategies are designed and implemented. Blinding will not be done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Passing one year from menopause lack of chronic disease or disability (sight and hearing impairment) Women are willing to participate in research and provide written and informed consent. Women have not participated in any courses about menopause since 6 month ago. Being between 45-55 years old. Exclusion criteria: -----

##### Intervention groups

For postmenopausal women in the test group, interventional strategies will be designed and implemented based on a multi-theoretical model and will not be intervened for the intervention group.

##### Main outcome variables

Matching behavior with menopause based on the structures of the multi-theoretical model- Quality of Life

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190206042640N1**

Registration date: **2019-04-21, 1398/02/01**

Registration timing: **prospective**

Last update: **2019-04-21, 1398/02/01**

Update count: **0**

#### Registration date

2019-04-21, 1398/02/01

#### Registrant information

##### Name

Nooshin Yoshany

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3623 5079

##### Email address

nooshin.yoshany@ssu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-10-12, 1398/07/20

#### Expected recruitment end date

2019-12-11, 1398/09/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of educational intervention based on multi-theory model on improving the quality of life among postmenopausal women

**Public title**

The effect of educational intervention on improving the quality of life among postmenopausal women

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

passing 1-5 years from menopause having natural menopause lack of disabling illness, physical disability (such as hearing & Sight impairment) and impaired consciousness being between 45-55 years old lack of addiction Women are willing to participate in the research and confirm the written and informed consent form. Women have not participated in any menopause training course since six months ago.

**Exclusion criteria:**

Menopause caused by hysterectomy and oophorectomy

**Age**

From **45 years** old to **55 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Health centers in Yazd will be selected using a multi-stage random sampling method. In the first stage, based on the socioeconomic status, the health centers of Yazd are divided into 3 categories (areas with weak, moderate and good socioeconomic status), then from each health centers in the area with good socioeconomic status (2) Center), medium (2 centers) and weak (2 centers) will be randomly selected. Then, three centers (from all three areas of good, moderate and weak) will be randomly assigned as intervention group and three centers (from all three areas) will be considered as the control group. Blocked randomization method with sizes 4 and 6 through statistical software will be used to determine the number of required sample sizes (which will subsequently be identified) to randomly assign the intervention to the two groups of subjects. Eligible Individual to study before a randomization is assigned a code. In order to hide the randomization, after the randomization by the researcher, the codes will be notified by telephone to the responsible training and implementation of the intervention.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic's committee of school of public health - Shahid Sadoughi university of medical sciences

**Street address**

Alem squer

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Approval date**

2019-02-02, 1397/11/13

**Ethics committee reference number**

IR.SSU.SPH.REC.1397.137

**Health conditions studied****1****Description of health condition studied**

menopause

**ICD-10 code**

N95

**ICD-10 code description**

Menopausal and other perimenopausal disorders

**Primary outcomes****1****Description**

quality of life

**Timepoint**

Before and two months after training

**Method of measurement**

MENQOL questionnaire

**Secondary outcomes****1****Description**

menopause coping

**Timepoint**

Before and two months after training

**Method of measurement**

Researcher made questionnaire

**Intervention groups**

## 1

### Description

The women in the intervention group will participate in 12 one-hour training sessions on the symptoms, nature, complications of menopause and ways to adapt to menopause, facial expressions, lectures, showing film, questions and answers, and will provide them with an educational booklet. . Based on the multi-theoretical model for the participatory dialogue structure, group discussion sessions to discuss the benefits and disadvantages of behavior change, for behavioral confidence construct, self-esteem skills training, for the structure of change in the physical environment Lobbying with organizations such as the Sports and Youth Department, the Municipality and etc, to allocate half-price tickets and sports equipment, for emotional transformation, it will be modified by the role playing by postmenopausal women for stimulating their emotions, about Practice for change Construct, a notebook for all the behaviors that they must follow will be prepare And for the change in social environment, the educational sessions will be held separately through showing film and lectures for spouses and children of postmenopausal women

### Category

Behavior

## 2

### Description

Control group: no intervention for women in the control group will be held. Only in order to observe ethical consideration, at the end of the study, the educational booklet will be give to women in control group

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Health center in yazd

#### Full name of responsible person

Nooshin Yoshany

#### Street address

Safaeiyeh

#### City

Yazd

#### Province

Yazd

#### Postal code

8915173160

#### Phone

+98 35 3623 5079

#### Fax

+98 35 3820 9119

#### Email

nooshin.yoshany@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Masoud Mirzaei

#### Street address

Safaeiyeh

#### City

Yazd

#### Province

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#### Postal code

8915173160

#### Phone

+98 35 3724 0171

#### Email

mirzaeim@mailfa.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Yazd 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

Yazd University of Medical Sciences

#### Full name of responsible person

Nooshin Yoshany

#### Position

student

#### Latest degree

Master

#### Other areas of specialty/work

Health Promotion

#### Street address

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#### Province

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Nooshin Yoshany

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Yazd University of Medical Sciences

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Nooshin Yoshany

**Position**

student

**Latest degree**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

The main consequence of the research is the effect of the educational program according to a multi-theoretical model on the quality of life of postmenopausal women.

**When the data will become available and for how long**

from 2020

**To whom data/document is available**

Researchers working in academic and scientific institutions, postmenopausal women

**Under which criteria data/document could be used**

In order to use the results in decisions, the use of postmenopausal women to improve quality of life

**From where data/document is obtainable**

Applicants for information can contact: nooshin.yoshany@yahoo.com or call: 09133511170.

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

Following the publication of the articles from the thesis, access to data is possible.

**Comments**