Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 35 3623 5079

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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

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Safaeiyeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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8915173160

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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

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Person responsible for scientific inquiries

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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