Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effect of peer education on menopausal symptoms in menopausal women

Protocol summary

Study aim
Determine the effect of peer education on menopausal symptoms

Design
Clinical trial with intervention and control groups, with parallel groups,Not blind, randomized

Settings and conduct
This study will be conducted on 120 menopausal women, who will be referred to health centers in Tehran. The researchers assistant will do sampling in different Centers, In case of menopausal women who will meet the inclusion criteria, during the telephone call with researcher 1, with respect to the computerized tables, they will be placed in one of the intervention groups (peer education group) and control group (routine service receiving group). Hunter's Women's Health Questionnaire will be completed before random assignment to the two groups, immediately after the intervention and one month after the intervention. Because the participants are going to be trained, they cannot be blinded. After completion the intervention and during the follow-up, the researcher's assistant will not be aware of the allocation of individuals to the groups. The person who will analyze the data, will also not be aware of the group of people.

Participants/Inclusion and exclusion criteria
Inclusion conditions: At least one year and maximum 5 years after menopause Non-arrival conditions: use of hormone drugs to reduce menopausal symptoms.

Intervention groups
In the first stage of the intervention, selected peers will be educated in 4 sessions by the researcher. At the second stage, the women in the intervention group will be trained,by a peer group of 4 sessions. The educational content will be about the methods of coping with menopausal symptoms. The control group will receive only routine services and training is going to be provided at health centers. .

Main outcome variables
Vasomotor symptoms, Physical symptoms, Sexual problems, Anxiety and fear, Memory and concentration, Depressed mood, Sleep problems, and Attractiveness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170705034914N1**
Registration date: **2019-09-30, 1398/07/08**
Registration timing: **prospective**

Last update: **2019-09-30, 1398/07/08**
Update count: **0**

Registration date
2019-09-30, 1398/07/08

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7738 0715

Email address
m.ahmadi@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-07, 1398/07/15

Expected recruitment end date
2019-12-06, 1398/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of peer education on menopausal symptoms in menopausal women

Public title
The effect of peer education on menopausal symptoms

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having a health record at a health care center Having at least the elementary school literacy Being married and having sex Having symptoms of menopause At least one year and up to 5 years after menopause Menopause occurs naturally Having Iranian nationality Having mental and physical health Voluntary participation and written consent

Exclusion criteria:
Treated with hormonal drugs to relieve menopausal symptoms Being addicted to cigarette. drugs and alcohol Having mental, neurological and cancer diseases

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: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the randomization unit will be individual. Block randomization is going to be used for randomization. 120 samples will randomly be divided into control and intervention groups in 30 blocks of 4(Including 2 participants in intervention group and 2 participants in control group), based on the random numbers that will be produced using website https://www.sealedenvelope.com/simple -randomizer. (60 participants in intervention group and 60 participants in control group). Using the central method, the allocation sequence will be concealed. The allocation sequence will be performed with the help of researcher assistance 1. At each center, researcher's assistance (2, 3, and 4) will register eligible individuals, and by contacting with the researcher assistance 1, Individuals, as they will be enrolled in the study, will also enter to a central list and assign to target groups.

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 Shahroud University of Medical Sciences

Street address
HaftTir Sq., Central building of Shahroud University of Medical Sciences and Health Services

City
Shahroud

Province
Semnan

Postal code
3614773947

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
IR.SHMU.REC.1396.66

Health conditions studied

1

Description of health condition studied
Menopause

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Vasomotor symptoms

Timepoint
Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement
Women's Health Questionnaire (WHQ)

2

Description
Somatic symptoms

Timepoint
Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement
Women's Health Questionnaire (WHQ)

3

Description

Sexual problems

Timepoint

Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement

Women's Health Questionnaire (WHQ)

4

Description

Anxiety/fear

Timepoint

Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement

Women's Health Questionnaire (WHQ)

5

Description

Memory / concentration

Timepoint

Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement

Women's Health Questionnaire (WHQ)

6

Description

Sleep problems

Timepoint

Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement

Women's Health Questionnaire (WHQ)

7

Description

Depressed mood

Timepoint

Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement

Women's Health Questionnaire (WHQ)

8

Description

Attractiveness

Timepoint

Before the intervention , immediately after the intervention and one month after the intervention

Method of measurement

Women's Health Questionnaire (WHQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, intervention is going to be performed at two stages. The first stage will be selecting the peer group and educating them and the second stage, performing the intervention. At the stage of selecting the peers, six menopausal women (2 peers from each center), who will have some characteristics such as ability to run educational sessions, willingness to cooperate with the researcher, have appropriate social communications, having at least high school degree and interest in leading the group will be selected by the researcher as the trainers of the peer group. During 4 sessions (2 hours twice a week for duration of 2 week), selected peers who will be educated by the researcher about the importance and advantages of peer education, menopause, menopausal symptom and the methods of confronting and coping with it.Education will be performed using speech, question and answer with the help of learn assist tools (slides, images, etc.). After each educational session is going to be completed, the participants will exercise the trained items in the presence of the researcher using role play method. at the second stage, 60 participants for the peer education group will be divided into six groups of 10 and each of the selected peers will be allocated to educate one of the divisions; educating the peers is going to be performed during 4 educational sessions (2 hours once a week for duration of 4 week). The intervention group, In addition to services that will be provided in health centers, will receive peer education.

Category

Other

2

Description

Control group: Sixty menopausal women who will be referred to health centers in the control group will receive no intervention. They will receive only routine services and train is going to be provided at health centers

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Meysam Comprehensive Health Center

Full name of responsible person

Maryam Sobhani

Street address

Obeidzakani Ave., Dorahei Ghapan , Qazvin St.

City

Tehran

Province

Tehran
Postal code
1359674153
Phone
+98 21 5573 2820
Email
hashemi.mozhgan@yahoo.com

2

Recruitment center
Name of recruitment center
Kadus Comprehensive Health Center
Full name of responsible person
Marzeayeah Kasaeeyan
Street address
No.16 , Sojdeei North St., Jashnvareh St., Tehranpars 2nd Sq.
City
Tehran
Province
Tehran
Postal code
0000000000
Phone
+98 21 7729 7383
Email
katayoon_faraji@yahoo.com

3

Recruitment center
Name of recruitment center
Nemat Abad Comprehensive Health Service Center
Full name of responsible person
Mahrokh Alaei
Street address
Shahid foladi St., Sadeghiyeh Town , Ayatollah Saeedi Highway
City
Tehran
Province
Tehran
Postal code
0000000000
Phone
+98 21 5582 3055
Email
elmira.rezvani90@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohamadhassan Emamyyn
Street address
Haft Tir Sq.,Central building of Shahroud University of Medical Sciences and Health Service
City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 6714
Email
info@shmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Leila Mollaahmadi
Position
PhD Student in Reproductive Health
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
1st floor, unit 2, No.122, 206 Eastern Ave., Tehran pars 3rd Sq.
City
Tehran
Province
Tehran
Postal code
1655716866
Phone
+98 21 7738 0715
Email
ahmadileila49@yahoo.co.uk

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Leila Mollaahmadi
Position
PhD Student in Reproductive Health
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
1st floor, unit 2, No.122, 206 Eastern Ave., Tehran pars 3rd Sq.
City
Tehran
Province
Tehran
Postal code
1655716866
Phone
+98 21 7738 0715
Email
ahmadileila49@yahoo.co.uk

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Leila Mollaahmadi
Position
PhD Student in Reproductive Health
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
1st floor, unit 2, No.122, 206 Eastern Ave., Tehran pars 3rd Sq.
City
Tehran
Province
Tehran
Postal code
1655716866
Phone
+98 21 7738 0715
Email
ahmadileila49@yahoo.co.uk

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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable