Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Self-care education on health promoting lifestyle in postmenopausal women in Qazvin in 1997

Protocol summary

Study aim
Determine the effect of self-care education on health promoting lifestyle in postmenopausal women

Design
In this study, 84 samples of postmenopausal women referring to Qazvin comprehensive health centers are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct
In this study, among postmenopausal women referring to these centers, if they had the inclusion criteria by random allocation method, they were divided into intervention and control groups, and after obtaining written informed consent, a questionnaire for demographic information, a light measurement questionnaire Health promotion life is completed in two groups. In the intervention group, filling the health promotion lifestyle questionnaire in one and two months after the end of the intervention, and in the control group only filling in the questionnaire in one and two months later.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: Natural menopause, passing one year from the last menstruation, non-participation in other similar studies, having a contact number for follow up, ability to speak in Persian, The desire to participate in the study Exit criteria: the use of any alternative hormone drugs in the past 3 months or during the study, receiving any training on menopause, by other means , The need for surgical interventions, mental illness, according to the person in the last 6 months, the use of alcohol or tobacco (cigarettes, hookahs, etc.), the use of a particular diet (water therapy, vegetarianism, crustaceans and so on). ..)

Intervention groups
The intervention group, 4 sessions, 60 to 90 minutes, will have a group of 5 to 12 people. A booklet is presented in accordance with the educational materials.

Main outcome variables
Health promoting lifestyle

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180408039234N1**
Registration date: **2018-10-01, 1397/07/09**
Registration timing: **retrospective**

Last update: **2018-10-01, 1397/07/09**
Update count: **0**

Registration date
2018-10-01, 1397/07/09

Registrant information

Name
Reihane Sadat mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2244 3980

Email address
reihane.mmw@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-06-22, 1397/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

The effect of Self-care education on health promoting lifestyle in postmenopausal women in Qazvin in 1997

Public title

The effect of self-care on improving the health of postmenopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal natural Pass one year of the last menstruation Not participating in other similar studies Calling number to track Ability to speak Persian At least 45 years old

Exclusion criteria:

Taking any alternative hormone drugs in the last 3 months or during the study Get any training on menopause, in other ways Need for surgical intervention Mental illness, according to a person in the last 6 months The appearance of any spotting in the last year Use of alcohol or tobacco (cigarettes, hookahs, etc.) Use a special diet (water therapy, vegetarianism, raw food, etc.)

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will use a multi-stage sampling method. First, the city of Qazvin, according to its urban areas, is divided into 3 urban areas and one of the centers of urban health in each region is randomly selected cluster center and from among postmenopausal women referring to these centers The available form will be sampled and women will be included in the study if they meet the criteria for entering the study after completing the written consent. They are then randomly allocated into two groups of intervention and control, in which 84 pieces of paper are written on half of that control word and the other half of the intervention written by the person after signing the consent from one of the envelopes of the paper. has it

Blinding (investigator's opinion)

Single blinded

Blinding description

Blind technique is used to reduce possible bias in the results. Blindness should be done correctly, ie groups that have the potential to cause bias in the study, our study priority is to be blinded one by one and the information analyst is not aware of the control or interference of the samples. Samples in both groups are aware of which groups are in the study. The researcher also has the knowledge to provide the training in the intervention group.The information analyzer receives information in the form of numerical codes in two groups, because their control or intervention is unknown.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Unit 21، Sepid Tower، Arash Alley، Farhangian Alley،Noobhar Street، Azhgol، Tehran

City

Qazvin

Province

Qazvin

Postal code

1696815479

Approval date

2018-01-04, 1396/10/14

Ethics committee reference number

IR.QUMS.REC.1396.362

Health conditions studied

1

Description of health condition studied

Lifestyle Improvement Health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lifestyle Improvement Health

Timepoint

At the beginning of the study (before the intervention), one month and a half and three months later

Method of measurement

Health Promotion Lifestyle Assessment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" Education sessions for postmenopausal women will be based on the sub-scales of the health promotion lifestyle questionnaire. These scales include nutrition, physical activity, stress management, health responsibility, interpersonal relationships, and spiritual growth. The training sessions will take place in four sessions in four weeks, and the duration of the sessions is 60 to 90 minutes. The sessions will be held in groups of 12 to 5, and at the end of each meeting, questions will be answered as needed. To increase the impact of education and help to get a better understanding of the booklet in this area related to the topics discussed. In this curriculum, the self-care education content of the Ministry of Health and Medical Education, which is provided by the Vice-Chancellor, and the Clinical Guide and Executive Program of the Health Team for the provision of menopause services to women aged 45-60, will be used as a teacher's guide. Also, in order to better understand the concepts, part of the training was a question and answer. At the end of each session, a brief educational pamphlet will be provided to the participants on the content presented at the meeting. This training will be carried out in Qazvin comprehensive health centers. In the intervention group, filling in the health promotion lifestyle questionnaire will be done one and two and three months after the end of the intervention.

Category

Lifestyle

2

Description

Control group: Control group: In this group, receiving routine care provided by comprehensive health centers. At the beginning of the study, filling in the health promotion lifestyle questionnaire, and repeating this questionnaire in one and two and three months later.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin City Health Centers

Full name of responsible person

Reyhana Sadat Mousavi

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Shahid Bahonar Blvd، Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Nasim Bahrami

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Reyhana Sadat Mousavi

Position

Senior Counseling Midwifery Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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