Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Designing and evaluating the impact of the empowerment program on the health and quality of life of postmenopausal women: The application of the PRECEDE-PROCEED model and the Longwe empowerment framework

Protocol summary

Study aim
Evaluation of the impact of an empowerment program on the quality of life and health of postmenopausal women using the model.

Design
The health centers in Shiraz will be categorized into three groups based on the socio-economic status of the region. Using PASS software, two centers will be randomly selected from each region. These selected centers will then be assigned to either the intervention or control group using the block randomization method. Within these centers, women will be chosen using the consecutive sampling method. The estimated sample size for this study is 150 women, as determined by the PASS software.

Settings and conduct
The empowerment program will be designed and implemented based on the Longwe framework for Menopausal women in Shiraz health centers. According to the PPM, an assessment (pre-test) and evaluation (post-test) of the program will be conducted before, two weeks after, and four months after the intervention, respectively.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Menopausal women aged 45 to 65 with a history of at least one year of menopause, possessing literacy skills, and willing to sign an informed consent form. Exclusion criteria: suffering from mental illnesses, chronic diseases, or cancer; history of hormone therapy, hysterectomy, or oophorectomy; abnormal vaginal bleeding.

Intervention groups
Intervention Group: A problem-based and participation-oriented educational program will be implemented in a face-to-face setting, comprising of 8 sessions lasting 90 minutes each. The participants will be given educational booklets on menopause and self-care, adhering to the guidelines established by the Ministry of Health, Iran. Control Group: The control group will receive standard care and will be provided with a training booklet after the final post-test.

Main outcome variables
Quality of life; Health status; Self-care.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230716058792N1**
Registration date: **2023-08-14, 1402/05/23**
Registration timing: **prospective**

Last update: **2023-08-14, 1402/05/23**
Update count: **0**

Registration date
2023-08-14, 1402/05/23

Registrant information

Name
Khadijeh Khademi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3725 1001

Email address
khadijehkhademi@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-28, 1402/08/06
Expected recruitment end date
2023-12-21, 1402/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing and evaluating the impact of the empowerment program on the health and quality of life of postmenopausal women: The application of the PRECEDE-PROCEED model and the Longwe empowerment framework

Public title
The impact of the empowerment program on the health and quality of life of postmenopausal women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Be between the ages of 45 and 65. According to the scientific definition, they are considered menopause. At least one year has passed since their menopause. Have reading and writing literacy at least the end of the third grade or equivalent or higher. To participate in the study, declare your agreement and sign the informed consent form.
Exclusion criteria:
under the care of a psychiatrist due to suffering from mental illnesses. Suffering from chronic diseases (including diabetes, hypertension, heart failure, kidney failure) and cancer. Use of hormone therapy during the last 6 months. History of hysterectomy and oophorectomy. Suffering from abnormal vaginal bleeding.
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
With the formation of the elite panel and based on their opinions, 43 health centers in Shiraz are considered and divided into three groups of health centers in prosperous (rich), medium urban (relatively rich) and undeveloped (less rich) areas. In this study, the health centers of Shiraz city were selected as clusters, which were randomly selected using NCSS-PASS version 15 (2020) software from each of the 2 cluster areas, and were selected as control and intervention groups using randomization allocation method with equal blocks of each of these 2 clusters. Then, by referring to the selected health centers and reviewing the records of postmenopausal women covered by the center, postmenopausal women eligible to participate in the study will be invited by telephone to participate in the research project with consecutive sampling until the desired sample size is reached in each cluster.
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 Shiraz University of Medical Sciences
Street address
Health school., Razi Blvd.
City
Shiraz
Province
Fars
Postal code
7153675541
Approval date
2023-06-25, 1402/04/04
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1402.049

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
Quality of life score in World Health Organization Questionnaire
Timepoint
Before, 2 weeks and 4 months after the educational

intervention.

Method of measurement

World Health Organization Quality of Life Questionnaire

2

Description

Health score in Women's Health Questionnaire

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

Women's Health Questionnaire

Secondary outcomes

1

Description

Self-care score in Menopause Self-care Questionnaire

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

Menopause Self-care Questionnaire

2

Description

The score of knowledge and attitude towards menopause in the knowledge and attitude towards menopause questionnaire

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

knowledge and attitude towards menopause questionnaire

3

Description

Self-care knowledge and attitude score in self-care knowledge and attitude questionnaire

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

Self-care knowledge and attitude questionnaire

4

Description

Self-efficacy score in the General Self-Efficacy beliefs Scale

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

General Self-Efficacy beliefs Scale

5

Description

Perceived health control score in MHLC- C for postmenopausal women

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

MHLC- C for postmenopausal women

6

Description

Social support score in MSPSS

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

MSPSS

7

Description

The score of enabling factors in the women's perceived health enablers questionnaire

Timepoint

Before, 2 weeks and 4 months after the educational intervention.

Method of measurement

women's perceived health enablers questionnaire

Intervention groups

1

Description

Intervention group: The educational program for the intervention group is designed to cater to their specific needs and literacy levels. It is conducted through face-to-face meetings, lasting 90 minutes each, once a week. The timing of these meetings is agreed upon by the participants. The sessions are conducted in a collaborative manner, with group discussions focusing on problem-solving and feedback provision.The participants are provided with a booklet that contains information on various aspects related to menopause. This includes education on menopause symptoms, healthy nutrition, physical activity, menopause health, seeking healthcare, and social support. The content of the booklet is based on the guidelines provided by the Office of Education and Health Promotion as well as the Office of Population, Family Health, and Madrasa under the deputy health department of Iran's Ministry of Health, Treatment, and Medical Education.

Category

Behavior

2

Description

Control group: No intervention is performed and they only receive routine care. However, after the last post-

test, they will be provided with an educational booklet aimed at increasing their knowledge about menopause and self-care practices during this period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

The health centers covered by the Health and Treatment Networks of Englab and Wal-Fajr

Full name of responsible person

Khadijeh Khademi

Street address

Shiraz

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7153675541

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Kaveh

Street address

Health school., Razi Blvd.

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Kaveh@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Khademi

Position

PhD candidate of health education and promotion

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Email

khademikhadijeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Kaveh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Khadijeh Khademi

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Health Promotion

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khademikhadijeh@gmail.com

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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Confirmation of Professor Mohammad Hossein Kaveh.

From where data/document is obtainable
Kaveh@sums.ac.ir

What processes are involved for a request to access data/document
Through the corresponding author of the articles within a period of 1 week to 1 month.

Comments