Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Impact of family-centered empowerment model based on healthy lifestyle on quality of life and self-management behavior of post menopause women

Protocol summary

Study aim
Determining the effect of implementing a family-centered empowerment model based on a healthy lifestyle on the quality of life and self-management behaviors of postmenopausal women

Design
A randomized, parallel-group clinical trial conducted on 60 eligible menopausal women. Simple randomization is performed using a cluster sampling method.

Settings and conduct
One district out of the four districts in Jahrom County is randomly selected, and two girls' secondary schools are assigned to the two groups. Menopausal mothers of students who meet the study criteria are identified with the cooperation of the school principal and invited to an in-person session to introduce the study, explain its objectives, and obtain informed consent. Then, if they agree to participate in the continuation of the study, the intervention group receives 5 to 8 family-centered empowerment sessions. Outcome assessors and data analysts are blinded to group allocation; however, participant blinding is not possible.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Postmenopausal women over 45 years old, residing in Jahrom, willingness to participate in the study and signing the informed consent form, and having an empowerment score of 75 or lower. Exclusion criteria: Severe chronic illness or physical disability preventing participation in the intervention, use of specific medications or similar treatments that could affect the outcomes, inability to complete the questionnaires.

Intervention groups
Intervention Group: Includes eligible menopausal women who receive empowerment training based on a healthy lifestyle according to the family-centered empowerment model. Control Group: Includes eligible menopausal women who, after the completion of the intervention, receive all the training provided to the experimental group in a single session.

Main outcome variables
Mean empowerment score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250811066817N1**
Registration date: **2025-08-14, 1404/05/23**
Registration timing: **prospective**

Last update: **2025-08-14, 1404/05/23**
Update count: **0**

Registration date
2025-08-14, 1404/05/23

Registrant information

Name
seyedeh kimia torab jahromi

Name of organization / entity
Tarbiat modares university

Country
Iran (Islamic Republic of)

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+98 21 8288 3590

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torab.kimia@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-11-21, 1404/08/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Impact of family-centered empowerment model based on healthy lifestyle on quality of life and self-management behavior of post menopause women

Public title
The impact of implementing the empowerment model on the quality of life and self-management behaviors of postmenopausal women.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study No history of hysterectomy or oophorectomy Natural menopause No history of cancer No severe mental or physical illness At least 12 months have passed since the last menstrual bleeding Empowerment score of 75 or less No use of hormone therapy, selective serotonin reuptake inhibitors, or selective estrogen receptor modulators in the past 6 months If the participant is illiterate, an active family member must have at least a middle school education No use of psychiatric medications or visits to a behavioral specialist in the past 6 months
Exclusion criteria:
Lack of willingness to continue participation during the screening process Inability to complete the questionnaires Presence of an acute illness at the time of screening
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: First, one district will be randomly selected from the four districts (north, south, east, and west) of Jahrom city. After obtaining permission from Tarbiat Modares University and presenting an official introduction letter to the Department of Education in Jahrom, two schools will be selected (one school for the intervention group and one school for the control group). Upon presenting the introduction letter to the school principals, they will be asked to identify mothers aged over 45 years. With the cooperation of the school principals, written invitations will be sent to these mothers to attend a meeting at the school. In this meeting, after being informed about the study procedure, those who agree to participate will be asked to sign a written informed consent form. This process will be carried out in both the intervention and control groups. Sampling will be purposeful, based on the characteristics of the target population. Unit of randomization: Cluster (school) — one school will be assigned to the control group and one school to the intervention group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, outcome assessors and data analysts are blinded to group allocation to minimize bias in data collection and analysis. Participants are aware of their group assignments due to the educational nature of the intervention. Blinding of participants was not feasible because of the nature of the educational intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Tarbiat Modares University
Street address
Jalal Al-Ahmad Highway, Tarbiat Modares University, School of Medicine, Building 1, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
14115-111
Approval date
2025-07-28, 1404/05/06
Ethics committee reference number
IR.MODARES.REC.1404.079

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

Empowerment: Mean empowerment score of postmenopausal women

Timepoint

Empowerment level: before the intervention; 7 to 10 days after the end of the intervention

Method of measurement

Questionnaire of Empowerment for Postmenopausal Women (Researcher-made questionnaire); the tool was developed by the researcher; content validity was assessed by experts, and reliability was evaluated in a pilot sample.

Secondary outcomes

1

Description

Self management behavior: Mean self-management behavior score of postmenopausal women

Timepoint

The level of self-management behavior: Before the intervention; one and a half months after the end of the intervention

Method of measurement

The Self-Management Behavior Assessment Questionnaire for Menopausal Women (researcher-made questionnaire), which contains 88 questions, was developed by the researcher; its content validity was reviewed by experts, and its reliability was assessed in a pilot sample.

2

Description

Quality of Life of Postmenopausal Women: Mean quality of life score of postmenopausal women

Timepoint

Quality of Life Level: Before the intervention; one and a half months after the end of the intervention

Method of measurement

The Menopause-Specific Quality of Life Questionnaire, which contains 29 items

Intervention groups

1

Description

Intervention Phase: Based on the analysis of pre-test data, which leads to identifying resources, limitations, needs, strengths, and weaknesses of menopausal women regarding a healthy lifestyle and menopause, the content of the empowerment program will be revised and implemented for them according to the four steps of the family-centered empowerment model. Description of the implementation of the four steps of the family-centered empowerment model: Step One: Perceived Threat — This consists of two parts: perceived severity and perceived susceptibility.Perceived Susceptibility: The individual's recognition of the likelihood of developing the related disease or chronic condition; the person understands their situation and defines health correctly in relation to the disease, feels at risk, and considers the possibility of becoming affected. Perceived Severity: The individual's awareness and understanding of the problem, disease, or chronic condition; recognizing the dangers and complications involved, understanding its seriousness, and feeling threatened by it. Content of perceived susceptibility sessions: Introduction to the female reproductive system and personal hygiene. Explanation of menopause, physiological changes in middle-aged women, symptoms, and related complications. The importance of a healthy lifestyle, including understanding a healthy diet: discussing eating patterns and habits, calculating Body Mass Index (BMI), understanding the food pyramid and the value of each group, recognizing sources of Vitamin D, calcium, Vitamin E and its effect on sleep quality, and the importance of balanced intake. The importance of a healthy lifestyle, such as recognizing the importance of exercise and physical activity and the benefits of exercise; regular walking at a certain time of day improves glucose metabolism, reduces body fat, lowers blood pressure, and more. Relaxation during menopause; learning how to communicate with others, benefits of relaxation programs, and managing stress and anxiety during menopause. Enhancing spirituality; introducing spiritual customs and habits that promote the spiritual dimension. Content of perceived severity sessions: Observing hygiene of the female reproductive system during middle age, maintaining personal hygiene, and preventing vaginal dryness; wearing cotton and lightweight clothing during hot flashes and sweating. Maintaining and observing a healthy lifestyle, including following a healthy diet and the consequences of not doing so (reducing unhealthy eating habits like less consumption of bloating foods, eating according to the food pyramid, preventing visceral abdominal fat, etc.). Engaging in exercise and physical activity, and explaining the consequences of inactivity (e.g., regular exercise or walking for at least 30 minutes daily, pelvic floor muscle training (PFMT) to improve urinary incontinence (UI), increase pelvic floor muscle strength and endurance, and the positive effect of aerobic exercises on reducing anxiety, depression, and improving sleep quality). Educating about menopause’s effects on various body systems and providing solutions; menopause’s impact on increased risk of metabolic syndrome (feeling of swelling and puffiness), cardiovascular diseases, osteoporosis, etc. Maintaining calm during menopause; establishing healthy and intimate communication with others, avoiding isolation, using relaxation programs to manage stress and anxiety, and educating on sleep hygiene. Enhancing spirituality by observing spiritual customs and habits based on the study participants’ own habits and tendencies. Step Two: Self-Efficacy: To enhance self-efficacy and improve necessary skills, sessions are conducted using problem-solving group discussions. The educational content

includes 2 to 3 group discussion sessions with 5 to 7 menopausal women based on problem-solving stages. The session contents include: Problem Identification: Any symptoms and complications caused by menopause such as hot flashes, night sweats, mood changes, decreased marital satisfaction, sleep disorders, etc. Problem Analysis: Objectives are defined based on the causes and nature of the problem. For example, regarding hot flashes and night sweats, daily bathing and wearing cotton, loose clothing are suggested. Offering Solutions: Discussion, review, and finding the problem-solving process and the best solutions to improve menopausal women's skills, such as managing diet, sleep and rest, daily physical activity, stress control, spirituality, and boosting confidence through the feeling “I can play a role in improving my condition,” etc. Selecting the Best Solution: Menopausal women, under the researcher’s supervision, discuss examples of their situations and what actions they would take to improve similar problems with others. The final session summarizes the previous sessions and answers any questions. Step Three: Self-Belief (Self-Esteem): This step is carried out through participatory education. Self-belief or self-esteem refers to the degree of approval, acceptance, and value a person feels toward themselves. In this phase, feedback on educational content is evaluated.Participants are asked to teach the educational content, which is provided to them at the end of each session in the form of educational cards, to an active family member (sister, mother, aunt, etc.).An active family member is one approved by the patient, who has responsibility and significant influence in family decisions, is willing to cooperate, literate, and able to assist the patient in knowledge, attitude, motivation, and performance, as well as to transfer the learned materials to other family members. The menopausal women also feel comfortable with this person.This teaching responsibility enhances their self-esteem and helps consolidate the education received regarding menopause-related issues, benefiting both the menopausal women and the family member receiving the education. The family member may either be currently facing these issues or will face them in the near future, which empowers them and encourages them to help themselves.

Category

Behavior

2

Description

Control group: Since the control group is asked to complete the questionnaires at two stages—pre-test and post-test—during this period (while the intervention is being conducted for the experimental group), one of the personal hygiene topics, which is of interest to the majority, will be taught to them. Additionally, after the completion of the intervention and evaluation in the experimental group, the educational content will also be provided to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Public Girls' High School, Jahrom Alaviyeh Public Girls' High School, Jahrom

Full name of responsible person

Zahra Hanaei Jahromi, Masoumeh Vahidpour

Street address

Khalili Girls' High School: Azadi Street, next to Hatami School, Jahrom, Fars - Baharestan Crossroad, next to Jame Mosque, Jahrom, Fars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr. Gholamreza Mousavi – Deputy of Research, Faculty of Medical Sciences, Tarbiat Modares University

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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

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Fatemeh Alhani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Fatemeh Alhani

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Statistical data is considered and can be shared after code insertion.

When the data will become available and for how long

Starting to access data from 2026.

To whom data/document is available

Access to the data is open to all interested individuals.

Under which criteria data/document could be used

It is generalizable for training purposes to similar groups.

From where data/document is obtainable

(https://modares.ac.ir/res/managements/library)
Dr.Fatemeh Alhani(alhani_f@modares.ac.ir)

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

A formal request can be made via email to Dr. Fatemeh Alhani (alhani_f@modares.ac.ir) or by visiting the Tarbiat Modares University Library website at (https://modares.ac.ir/res/managements/library)

Comments

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