

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of aerobic exercise and nutrition education on quality of life and early menopause symptoms: a randomized controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of aerobic exercise and nutrition education on quality of life and early menopause symptoms. **Design:** Four parallel arm Randomized Controlled Trial. **Setting and conduct:** This study will be conducted in Kaleibar city, located in East Azerbaijan- Iran. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. Eligible women will be randomly assigned into four groups of 27 subjects with block sizes of 4 and 8, stratified by menopausal status. **Participants:** 108 menopause or perimenopause married women aged 45 to 60 years old suffering from early menopause symptoms. **Interventions:** The three intervention groups will receive aerobic exercise, nutrition education or both, respectively. The control group will receive no intervention. Exercise program includes walking three times per week for 12 weeks with 60 to 70% of heart rate reserve, under direct supervision of a person from research team. Nutrition education includes three educational sessions; about 45 to 60 minutes lecture and group discussion; held for groups of 10 to 17 persons for three consecutive weeks. At the end of the first session, a booklet will be given to reinforce the education. **Main outcome measures:** Early menopause symptoms and quality of life will be assessed by the Green Scale questionnaire and menopause quality of life questionnaire (MENQOL), respectively at baseline, 8 and 12 weeks after starting the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111210324N6**

Registration date: **2013-01-15, 1391/10/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-01-15, 1391/10/26

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic exercise and nutrition education on quality of life and early menopause symptoms: a randomized controlled trial

Public title

The effect of aerobic exercise and nutrition education on quality of life and early menopause symptoms in perimenopause and monopause women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Perimenopause or menopause women aged 45 to 60 years old; suffering from hot flashes; being literate or having an educated one among family member Exclusion criteria: taking estrogens during the last three months; having exercise contraindications; doing regular exercise (more than 2 times per week for at least 30 minutes each time) during last three months; Having known thyroid, cardio-vascular, diabetes or mental diseases; following a specific diet; experiencing severe stressors such as the death of first-degree relatives in the last month.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction

number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, and East Azerbaijan

City

Tabriz

Postal code

Approval date

2012-12-04, 1391/09/14

Ethics committee reference number

91153

Health conditions studied

1

Description of health condition studied

Early menopause symptoms

ICD-10 code

N95.1, N95

ICD-10 code description

Menopausal and female climacteric states, Other specified menopausal and perimenopausal disorders

2

Description of health condition studied

Quality of life

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Total and subdomains scores of early menopause symptoms

Timepoint

Before intervention, 8 and 12 weeks after intervention

Method of measurement

Greene scale

2

Description

Total and subdomains scores of quality of life

Timepoint

Before interventions, 8 and 12 weeks after intervention

Method of measurement

Menopause specific quality of life (MENQOL) questionnaire

Secondary outcomes

1

Description

Frequency of hot flashes

Timepoint

Before interventions, 8 and 12 weeks after intervention

Method of measurement

Daily counts

Intervention groups

1

Description

The third group will receive both exercise intervention program and nutritional education.

Category

Lifestyle

2

Description

The control group will not receive the intervention.

Category

Lifestyle

3

Description

The first group will receive exercise intervention program. Exercise program includes walking sessions for 30 to 45 minutes, three times per week for 12 weeks with 60 to 70% of heart rate reserve, under direct supervision of a person from research team. Their heart rate will be measured using a Polar pulse meter.

Category

Lifestyle

4

Description

The second group will receive nutrition education. Nutrition education includes three educational sessions; about 45 to 60 minutes lecture and group discussion; held for groups of 10 to 17 persons for three consecutive weeks. At the end of the first session, a booklet will be given to reinforce the education.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fatemi health center

Full name of responsible person

Asghari Mehrnaz

Street address

Emam street, Kaleibar

City

Kaleibar

2

Recruitment center

Name of recruitment center

Shahid Pormorad health center

Full name of responsible person

Asghari Mehrnaz

Street address

Moallem street, kaleibar

City

kaleibar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Shakouri Seyyed Kazem

Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Asghari Mehrnaz

Position

Master in midwifery

Other areas of specialty/work

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Web page address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Other areas of specialty/work**Street address**

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Tabriz

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347-51745

Phone

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Fax**Email**

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Person responsible for updating data**Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty