Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 envelops 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

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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 perimonopause 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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Person responsible for scientific inquiries

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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