

# 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

##### Street address

Tarbiat Street, Kaleibar

##### City

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##### Postal code

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##### Phone

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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**

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**Position**

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**Phone**

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**Web page address**

<http://nursing.tbzmed.ac.ir>

**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*