

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Feb 2026

The effect of vitamin E supplementation on the sleep quality of postmenopausal women

Protocol summary

Study aim

Determining the effect of vitamin E supplementation on sleep quality of postmenopausal women

Design

A randomized controlled clinical trial with parallel groups, triple-blind (researcher, participant, and data and safety monitoring board), phase 3, involving 66 postmenopausal women. Block randomization will be used for randomization, employing the website www.sealedenvelope.com.

Settings and conduct

This study will be conducted on 66 postmenopausal women referring to health centers in East and West Ahvaz. Postmenopausal women will be screened based on inclusion and exclusion criteria, and if they meet the criteria and are willing to participate in the study, written informed consent will be obtained and initial assessments will be performed. Participants will receive vitamin E supplements and placebo in a permutation randomization block method with a 1:1 allocation sequence in two groups.

Participants/Inclusion and exclusion criteria

Women with physiological menopause who have been at least 10 years post-menopausal, who are free of physical or mental illnesses, and who have scored more than 5 on the Pittsburgh Sleep Quality Questionnaire will be included in the study. People who have taken sleep medications, vitamin E, or other supplements within the three months prior to the study will not be included in the study.

Intervention groups

Intervention group: will consume 400 units of vitamin E supplements daily for 4 weeks. Control group: will consume a similar placebo daily for 4 weeks

Main outcome variables

Sleep quality in postmenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240928063192N1**

Registration date: **2024-12-16, 1403/09/26**

Registration timing: **prospective**

Last update: **2024-12-16, 1403/09/26**

Update count: **0**

Registration date

2024-12-16, 1403/09/26

Registrant information

Name

Masomeh Nikbakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5227 1409

Email address

nikbakht.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin E supplementation on the sleep quality of postmenopausal women

Public title

The effect of vitamin E supplementation on the sleep quality of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the study
Age 45 to 65 years
Physiological menopause
A maximum of ten years have passed since the onset of menopause
Obtaining a score of more than 5 in the Pittsburgh Sleep Quality Questionnaire
Absence of depression according to the Beck depression questionnaire
No smoking or alcohol consumption

Exclusion criteria:

Simultaneous participation in other clinical trials
Not taking vitamin E supplements or other supplements in the last three months
Chronic diseases such as heart diseases, diabetes, gastrointestinal diseases, etc

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two intervention and control groups using a permuted block randomization method with block sizes of two and six using the randomization website www.sealedenvelope.com. Sealed opaque envelopes will be used to conceal randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo will be made in exactly the same shape, size, and color, and the researcher, participants, and statistician will be blinded to group assignment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Ahvaz University of Medical Sciences

Street address

Esfand Street, Golestan Blvd, Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2024-11-02, 1403/08/12

Ethics committee reference number

IR.AJUMS.REC.1403.419

Health conditions studied

1

Description of health condition studied

Sleep quality of postmenopausal women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality of postmenopausal women

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

The variables are measured by demographic information questionnaire, Pittsburgh sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group who meet the inclusion criteria will complete the demographic information form and the PSQI questionnaire after receiving a detailed explanation of the thesis project and providing informed consent before the intervention begins. The intervention will involve the daily consumption of 400 IU of vitamin E (one capsule per day) for a duration of 4 weeks. The 400 IU vitamin E capsules will be prepared in the Pharmaceutics Laboratory of the Faculty of Pharmacy, where vitamin E

powder will be manually filled into plant-based capsules using precise tools and stored under dry and cool conditions to maintain quality. Additionally, all study participants will complete the questionnaires again in the 4th and 8th weeks after the start of the intervention.

Category

Treatment - Other

2**Description**

In the control group, the intervention is administered by placebo. The placebo also contains dry bread powder, which is filled by the same device in capsules of the same size and color, which are completely similar in appearance to vitamin E supplements, and is given once daily for 4 weeks. 4 and 8 weeks after the start of the intervention, the questionnaires will be completed again by all study subjects.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

East and west Ahvaz Health Center

Full name of responsible person

Masoumeh Nikbakht

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Golestan Blvd. Ahvaz, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Research Affairs, Jundishapur University of Medical Sciences, Golestan Blvd, Opposite Central Building, Iran

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Masoumeh Nikbakht

Position

Midwifery master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

Ahvaz University of Medical Sciences

Full name of responsible person

Somaye Makvandi

Position

Associate professor

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The results of the clinical study will be published in the form of an article

When the data will become available and for how long

Immediately after the publication of the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific use with reference to the article

From where data/document is obtainable

nikbakhtalphamobile97@gmail.com

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

Up to one week after correspondence by email

Comments