

# 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](http://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

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##### 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 |                                                                                                                                                                                                                                                                                                                                               | <b>Ethics committees</b>                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Public title</b>                                                                  | The effect of vitamin E supplementation on the sleep quality of postmenopausal women                                                                                                                                                                                                                                                          | <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Purpose</b>                                                                       | Treatment                                                                                                                                                                                                                                                                                                                                     | <b>Ethics committee</b>                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Inclusion/Exclusion criteria</b>                                                  |                                                                                                                                                                                                                                                                                                                                               | <b>Name of ethics committee</b>                | Medical Ethics Committee of Ahvaz University of Medical Sciences                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Inclusion criteria:</b>                                                           | 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 | <b>Street address</b>                          | Esfand Street, Golestan Blvd, Ahvaz, Iran                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Exclusion criteria:</b>                                                           | 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                                                                                                                          | <b>City</b>                                    | Ahvaz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Age</b>                                                                           | From <b>45 years</b> old to <b>65 years</b> old                                                                                                                                                                                                                                                                                               | <b>Province</b>                                | Khouzestan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Gender</b>                                                                        | Female                                                                                                                                                                                                                                                                                                                                        | <b>Postal code</b>                             | 61357-15794                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Phase</b>                                                                         | 3                                                                                                                                                                                                                                                                                                                                             | <b>Approval date</b>                           | 2024-11-02, 1403/08/12                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Groups that have been masked</b>                                                  | <ul style="list-style-type: none"> <li>Participant</li> <li>Investigator</li> <li>Data and Safety Monitoring Board</li> </ul>                                                                                                                                                                                                                 | <b>Ethics committee reference number</b>       | IR.AJUMS.REC.1403.419                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Sample size</b>                                                                   | Target sample size: <b>66</b>                                                                                                                                                                                                                                                                                                                 | <b>Health conditions studied</b>               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization (investigator's opinion)</b>                                        | Randomized                                                                                                                                                                                                                                                                                                                                    | <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization description</b>                                                     | 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 <a href="http://www.sealedenvelope.com">www.sealedenvelope.com</a> . Sealed opaque envelopes will be used to conceal randomization.                 | <b>Description of health condition studied</b> | Sleep quality of postmenopausal women                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Blinding (investigator's opinion)</b>                                             | Triple blinded                                                                                                                                                                                                                                                                                                                                | <b>ICD-10 code</b>                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Blinding description</b>                                                          | 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.                                                                                                                                                                         | <b>ICD-10 code description</b>                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Placebo</b>                                                                       | Used                                                                                                                                                                                                                                                                                                                                          | <b>Primary outcomes</b>                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Assignment</b>                                                                    | Parallel                                                                                                                                                                                                                                                                                                                                      | <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Other design features</b>                                                         |                                                                                                                                                                                                                                                                                                                                               | <b>Description</b>                             | Sleep quality of postmenopausal women                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Secondary Ids</b>                                                                 | empty                                                                                                                                                                                                                                                                                                                                         | <b>Timepoint</b>                               | Before the intervention, 4 and 8 weeks after the intervention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                               | <b>Method of measurement</b>                   | The variables are measured by demographic information questionnaire, Pittsburgh sleep quality questionnaire                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                               | <b>Secondary outcomes</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                               | empty                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                               | <b>Intervention groups</b>                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                               | <b><u>1</u></b>                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                               | <b>Description</b>                             | 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 Pharmaceuticals 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

**Street address**

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**

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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**

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**Full name of responsible person**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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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**