# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jul 2026

## Effect of cognitive-behavioral group counseling with lavender scent versus placebo on the sleep quality of postmenopausal women with sleep disorder: a single-blind randomized clinical trial

## Protocol summary

**Study aim**
To assess the effect of cognitive-behavioral group counseling with lavender scent versus placebo on the sleep quality of postmenopausal women with sleep disorder

**Design**
This is a single-blind randomized clinical trial with control group, phase III, in which 136 patients will be randomly assigned through the block randomization to the intervention and control groups

**Settings and conduct**
This study will be performed in the Comprehensive Health Centers on 136 eligible postmenopausal women with sleep disorder. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 50 to 75 years; Being menopausal; Sleep disorder; Being literate Exclusion criteria: Olfactory disorder; Mental disorder; Drug use or smoking

**Intervention groups**
Intervention group: Cognitive-behavioral group counseling for 60 to 90 minutes weekly for 8 weeks (including sleep mechanism training and its stages, sleep and wake cycles and the underlying factors, relaxation training, sleep hygiene training, prevention of daily naps, problem solving skills, cycle of thought and feeling and behavior) in addition to dripping 3 drops of lavender essential oil on a cotton ball and placing it under the pillow every night for a month Control group: Cognitive-behavioral group counseling for 60 to 90 minutes weekly for 8 weeks (including sleep mechanism training and its stages, sleep and wake cycles and the underlying factors, relaxation training, sleep hygiene training, prevention of daily naps, problem solving skills, cycle of thought and feeling and behavior) in addition to dripping 3 drops of placebo on a cotton ball and placing it under the pillow every night for a month

**Main outcome variables**
Primary outcome: Sleep quality

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120215009014N446**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**
Update count: **0**

**Registration date**
2022-11-21, 1401/08/30

**Registrant information**

**Name**
Jalal Poorolajal
**Name of organization / entity**
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-12-22, 1401/10/01

**Expected recruitment end date**
2023-12-22, 1402/10/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of cognitive-behavioral group counseling with lavender scent versus placebo on the sleep quality of postmenopausal women with sleep disorder: a single-blind randomized clinical trial

**Public title**
Effect of cognitive-behavioral group counseling with lavender scent versus placebo on the sleep quality of postmenopausal women with sleep disorder
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 50 to 75 years Being menopausal Sleep disorder Being literate
**Exclusion criteria:**
Olfactory disorder Mental disorder Drug use or smoking
**Age**
From **50 years** old to **75 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **136**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. Thus, the trial will be run as single-blind.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Hamadan University of Medical Sciences
**Street address**
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
**City**
Hamadan
**Province**
Hamadan
**Postal code**
6517838695
**Approval date**
2022-08-12, 1401/05/21
**Ethics committee reference number**
IR.UMSHA.REC.1401.591

## Health conditions studied

### 1

**Description of health condition studied**
Sleep disorders
**ICD-10 code**
F51.8
**ICD-10 code description**
Other sleep disorders not due to a substance or known physiological condition

## Primary outcomes

### 1

**Description**
Sleep quality
**Timepoint**
Before the intervention and one month after the intervention
**Method of measurement**
Using the Pittsburgh Sleep Quality Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Cognitive-behavioral group counseling for 60 to 90 minutes weekly for 8 weeks

(including sleep mechanism training and its stages, sleep and wake cycles and the underlying factors, relaxation training, sleep hygiene training, prevention of daily naps, problem solving skills, cycle of thought and feeling and behavior) in addition to dripping 3 drops of lavender essential oil on a cotton ball and placing it under the pillow every night for a month

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Cognitive-behavioral group counseling for 60 to 90 minutes weekly for 8 weeks (including sleep mechanism training and its stages, sleep and wake cycles and the underlying factors, relaxation training, sleep hygiene training, prevention of daily naps, problem solving skills, cycle of thought and feeling and behavior) in addition to dripping 3 drops of placebo on a cotton ball and placing it under the pillow every night for a month

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Comprehensive Health Centers

**Full name of responsible person**
Arezoo Shayan

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Hamedan University of Medical Sciences

**Full name of responsible person**
Dr. Reza Shokoohi

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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**
Hamedan 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**
Hamedan University of Medical Sciences

**Full name of responsible person**
Arezoo Shayan

**Position**
Master of Midwifery

**Latest degree**
Master

**Other areas of specialty/work**
Midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Professor of Epidemiology

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## Sharing plan

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

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

**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**

Undecided - It is not yet known if there will be 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