

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

Country

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

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Postal code

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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**Contact****Name of organization / entity**

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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