

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of Aromatherapy with lavender oil on sleep quality in menopause women

Protocol summary

Summary

This study aims to examine the effects of aromatherapy using lavender essential oil on the quality of sleep among the menopause women. This research is a clinical trial conducted on (76) menopause women. Participants were randomly categorized into two groups of intervention and control (n=38) group, Pittsburgh Sleep Quality Index (PSQI) was used for data gathering and was administered to both groups before and after aromatherapy. Inclusion criteria involved subjects passed 1 year of menopause, no background of asthma and allergy to flowers, no background of mental and physical disorders, no use of drug and alcohol. Exclusion criteria involved disease in research, allergy to Lavender aromatherapy, not aromatherapy for one week. Lavender essential oil used by in intervention group and distilled water was used as placebo in group control. The participants were asked to apply 2 drops of lavender essential oil or distilled water on a piece of cotton wool and place it beneath the exterior of their pillows for 3 nights in a week for 4 weeks. PSQI was completed by each subject of both groups after the intervention .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022321204N1**

Registration date: **2015-04-05, 1394/01/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-05, 1394/01/16

Registrant information

Name

Farzaneh Gholamalian

Name of organization / entity

Ahvaz University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Jundishapour University of Medical Sciences and Faculty Vice chancellor for research, Ahvaz of Arvand. Dr. Mostafa Fegghi. Golestan highway, Ahvaz, Khuzestan, Iran, Islamic Republic Of 61357-15794 00989134083774 00986113361544 mfegghi@ajums.ac.ir

Expected recruitment start date

2015-02-22, 1393/12/03

Expected recruitment end date

2015-04-23, 1394/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Aromatherapy with lavender oil on sleep quality in menopause women

Public title

Effect of Aromatherapy on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pass 1 year of menopause; having poor sleep quality; have not cure disease; have not deprivation; use not drug&alcohol and cigarette; not use

hormonotherapy, addiction to drugs, herbal remedies and alternative medicine for 6 months ago. Exclusion criteria: History of early-menopause (<40); allergies to aromatherapy and lavender; smell disorders, rhinitis and asthma, history of psychiatric disorders; bad happen and situation; don't aromatherapy for one week.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Ahvaz University of Medical Science

Street address

Golestan highway

City

Ahvaz

Postal code

iran

Approval date

2015-02-21, 1393/12/02

Ethics committee reference number

ajums.REC.1393.412

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

G47.9

ICD-10 code description

Sleep Disorder, Unspecified

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before intervention, After 4 weeks

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

No

Timepoint

No Act

Method of measurement

No

Intervention groups

1

Description

Intervention group: Treatment for 3 nights in the week continue for 4 weeks 2 drops of lavender essential oil product by "Barij Esans" of Kashan with quality certified ISO9001 and have standard IEC17/ISC, of stoch category flowers piece of cotton wool and place it beneath the exterior of their pillows on the participant's pillow at night.

Category

Treatment - Other

2

Description

control group: 2 drops of placebo (Distilled water) for 3 nights in the week continue for 4 weeks, piece of cotton wool and place it beneath the exterior of their pillows.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Num 2 East, Health Center

Full name of responsible person

Farzaneh Gholamalian

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"7 Tir" Park, Rastegar Street, Behbahani Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapour
University of Medical Sciences and Faculty of Arva

Full name of responsible person

Dr. Mostafa Fegghi

Street address

Golestan highway

City

Ahvaz

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, Ahvaz Jundishapour
University of Medical Sciences and Faculty of Arva

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

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Full name of responsible person

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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