Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of lavender and Salvia Officinalis aroma on the sleep quality of postmenopausal women

Protocol summary

Study aim
Comparison of the effect of lavender and Salvia Officinalis aroma on the sleep quality of postmenopausal women

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, on 159 patients.

Settings and conduct
This study will perform on menopause women referred to health centers. The intervention group for 3 nights in a week, for one month, 2 drops of essential oil that is in a dropper, on a cotton ball in the form of a neck pendant, and before Sleep is inhaled and removed from the neck after awakening. The control group also uses a placebo in the same way. in this study, researcher and data analyzer blindness will be used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: willingness to participate in the study and through at least one year since the last menstruation. Non-entry criteria: sensitivity to lavender, salvia officinalis and almond oil history of allergic rhinitis and known respiratory problems such as asthma.

Intervention groups
Intervention group with Salvia Officinalis (intervention group): for 3 nights in a week, for one month, 2 drops of essential oil of salvia that is in a dropper, on a cotton ball in the form of a neck pendant, and before Sleep is inhaled and removed from the neck after awakening. Intervention group with Lavender (intervention group):this group uses lavender essential oil in the same way. Control group with Almond (control group):The control group also uses a placebo containing Almond oil in the same way.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160427027633N11**
Registration date: **2024-06-14, 1403/03/25**
Registration timing: **prospective**

Last update: **2024-06-14, 1403/03/25**
Update count: **0**

Registration date
2024-06-14, 1403/03/25

Registrant information

Name
Foruzan Sharifipour

Name of organization / entity
Kermanshah 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
2024-06-20, 1403/03/31

Expected recruitment end date
2024-10-21, 1403/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of lavender and Salvia Officinalis aroma on the sleep quality of postmenopausal

women

Public title
Comparison of the effect of lavender and Salvia Officinalis aroma on the sleep quality
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Acquiring the sleep quality questionnaire score ≥ 5 Through at least one year since the last menstruation Having enough literacy to fill out a questionnaire Age of at least 45 years
Exclusion criteria:
Occurrence of stressful incidents in the past six months Use of drugs, tobacco and alcohol Physical and mental illness Sensitivity to lavender, Salvia Officinalis and almond oil History of allergic rhinitis and known respiratory problems such as asthma
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **159**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of subjects to study groups (two intervention groups and one control group) will be done by block randomization method and using blocks of 6. This will be done with WinPepi11.0 software. This software generates random groups. In each block, 2 subjects will belong to the control group, 2 subjects will belong to the intervention group with salvia and 2 subjects will belong to the intervention group with lavender, and their order will be random. We will have 26 blocks of 6 and one block of 3 with ratio of 1:1:1.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blindness is not possible for the participant. Therefore, in this study, researcher and data analyzer blindness (lack of knowledge of the subject code) will be used, so the study will be double-blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Shahid Beheshti
City
Kermanshah
Postal code
6715847141
Approval date
2024-05-27, 1403/03/07
Ethics committee reference number
IR.KUMS.REC.1403.101

Health conditions studied

1

Description of health condition studied
Sleep quality
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep quality
Timepoint
Before and after the end of the intervention period
Method of measurement
Sleep quality questionnaire of Pittsburgh

Secondary outcomes

1

Description
Complications(dyspnea, headache, dizziness, nausea and vomiting)
Timepoint
During the intervention
Method of measurement
Questionnaire made by the researcher

Intervention groups

1

Description
Intervention group: The aromatherapy with essence of Salvia Officinalis with a concentration of 10% is made by the Vares Pharmaceutical Research Company. For 3 nights in a week, for one month, 2 drops of essence of Salvia Officinalis of that is in a dropper, on a cotton ball

in the form of a neck pendant, and before Sleep is inhaled and removed from the neck after awakening.

Category

Rehabilitation

2

Description

Intervention group: The aromatherapy with essence of Lavender with a concentration of 10% is made by the Vares Pharmaceutical Research Company. For 3 nights in a week, for one month, 2 drops of essence of Salvia Officinalis of that is in a dropper, on a cotton ball in the form of a neck pendant, and before Sleep is inhaled and removed from the neck after awakening.

Category

Rehabilitation

3

Description

Control group: The aromatherapy with almond oil with a concentration of 10% is made by the Vares Pharmaceutical Research Company. For 3 nights in a week, for one month, 2 drops of almond oil of that is in a dropper, on a cotton ball in the form of a neck pendant, and before Sleep is inhaled and removed from the neck after awakening.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kermanshah City Health Center

Full name of responsible person
Foruzan Sharifipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Foruzan Sharifipour

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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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