Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of Salvia Officinalis aromatherapy on sleep quality in menopausal women

Protocol summary

Study aim
Determine the effects of aromatherapy with Salvia Officinalis on sleep quality in menopausal women

Design
This randomized double -blind clinical trial with parallel groups study will perform on 60 menopause women referred to health centers of Kermanshah with the aim of investigating the effects of aromatherapy with Salvia Officinalis on sleep quality in menopausal women. At the beginning of the study, each person is assigned a code of 1 or 2, and the individuals with code 1, the control group and the code-holders 2 form the intervention group. Each eligible person for inclusion in the study randomly takes one of these cards with the codes written on it. In this way, the random allocation of patients to each group is determined.

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 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. 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
Individuals should be allowed to enter the study who benefit most from the intervention . People who may be harmed by the intervention should not be included in the study.

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. 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: **IRCT20160427027633N4**
Registration date: **2018-08-12, 1397/05/21**
Registration timing: **prospective**

Last update: **2018-08-12, 1397/05/21**
Update count: **0**
Registration date
2018-08-12, 1397/05/21

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-23, 1397/07/01
Expected recruitment end date
2019-01-20, 1397/10/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Salvia Officinalis aromatherapy on sleep quality in menopausal women

Public title

Effect of Salvia Officinalis aroma on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

ages 45 to 65 years old through at least one year since the last menstruation not having a history of allergic rhinitis and known respiratory problems such as asthma the absence of physical and mental illness non-use of drugs, tobacco and alcohol Non-occurrence of stressful incidents in the past six months

Exclusion criteria:

the appearance of any physical and psychological illness during the study that causes sleep disorder the appearance of a significant change in sleep conditions unpredictably (divorce, death and travel) the sensation of Salvia aroma during the study Lack of the program performance for a maximum of one week during the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study, Simple randomization method is used for random allocation (hiding allocation). In this way, 60 cards matched in appearance are prepared and 30 of them have the number or code 1 that specifies the group "Intervention based on essence of Salvia Officinalis" and on 30 others of them the number or code 2 which specifies the control group(Distilled water) is written. Then, each eligible person for inclusion in the study randomly takes one of these cards with the codes written on it. In this way, the random allocation of patients to each group is determined without letting the participants to know the nature of the numbers 1 or 2 in the type of intervention that will be assigned.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to hide the allocation of aromas (essence of Salvia Officinalis) and placebo (Almond oil) Opaque envelopes sequentially numbered are used.Each envelope contains a glass of essence of Salvia Officinalis or placebo.Medications were placed on the envelope in the randomized allocation sequence by the person not involved in the study. Investigating individuals to study and delivering envelopes are done by the researcher himself from Nos. 1 to 60. 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

Province

Kermanshah

Postal code

6715847141

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.KUMS.REC.1397.234

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

Pittsburgh questionnaire

Secondary outcomes

1

Description
Complications
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
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
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Health Center
Full name of responsible person
foruzan sharifipour
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah 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
Kermanshah University of Medical Sciences
Proportion provided by this source
60
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
Lecturer
Latest degree
Master
Other areas of specialty/work
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Latest degree

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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