# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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**
**Name**
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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

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**Province**

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**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**
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## Sponsors / Funding sources

### 1

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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

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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