Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Citrus aurantium aroma on sleep quality in menopausal women

Protocol summary

Study aim
Determination of the effect of aromatherapy with essential oil of Citrus aurantium on the sexual function of postmenopausal women referring to health centers in Ahvaz city

Design
Randomized clinical trial, with control group, double-blind, with parallel group

Settings and conduct
This study will perform on menopause women referred to health center of 17 shahrivar in Ahvaz. The intervention group is inhaling the essential oil 2 times (10 and 22 hours) in day for 4 consecutive days in a week, for 4 weeks and every time 5 minutes. The control group also uses a placebo in the same way. In this study, information analyzer and researcher blindness will be used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent to participate in the study, good psychological and mental status according to the clinician's diagnosis,Having at least ability to read and write Exclusion criteria: Obtaining score of less than 5 in the sleep quality questionnaire

Intervention groups
Intervention group with Citrus aurantium (intervention group): The intervention group is inhaling the essential oil for 30 minutes at intervals of 5 minutes. Control group with almond: The control group is inhaling the almond oil for 30 minutes at intervals of 5 minutes.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160427027633N7**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **retrospective**

Last update: **2020-08-23, 1399/06/02**
Update count: **0**

Registration date
2020-08-23, 1399/06/02

Registrant information

Name
Foruzan Sharifipour

Name of organization / entity
Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-17, 1398/04/26

Expected recruitment end date
2019-09-17, 1398/06/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Citrus aurantium aroma on sleep quality in menopausal women

Public title
The effect of Citrus aurantium aroma on 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 Citrus aurantium 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

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocating subjects to the study groups (intervention and control) was done random block using six blocks. This was done with WinPepi11.0 software.This software generates random groups. In each block, 3 subjects were from the control group and 3 subjects were from the intervention group, which was arranged randomly.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-05-18, 1398/02/28

Ethics committee reference number

IR.AJUMS.REC.1398.162

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 of essential oil (headache)

Timepoint

During the intervention

Method of measurement

Questionnaire made by the resercher

2

Description

Complications of essential oil (nausea)

Timepoint

During the intervention

Method of measurement

Questionnaire made by the resercher

3

Description

Complications of essential oil (dizziness)

Timepoint

During the intervention

Method of measurement

Questionnaire made by the resercher

Intervention groups

1

Description
Intervention group(Intervention group with Citrus aurantium): 2 times (10 and 22 hours) in day and every time 2 drops of essential oil at a concentration of 5% (made by Wares pharmaceutical company) for 4 consecutive days in a week, for 4 weeks on the skin of the forearm, to inhalation to get 5 minutes at 30 centimeters.
Category
Rehabilitation

2

Description
Control group (control group with Almond): 2 times (10 and 22 hours) in day and every time 2 drops of essential oil for 4 consecutive days in a week, for 4 weeks on the skin of the forearm, to inhalation to get 5 minutes at 30 centimeters.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Health Center
Full name of responsible person
Foruzan Sharifipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Abbaspoor
Street address
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abbaspoor-z762@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Foruzan Sharifipour
Position
Ph.D. student of midwifery
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
Associate professor

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Person responsible for updating data

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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