Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Bitter orange and chamomile inhalation aromatherapy versus placebo on the sleep quality of admitted patients: a single-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of Bitter orange and chamomile inhalation aromatherapy versus placebo on the sleep quality of admitted patients

Design
This is a single-blind randomized clinical trial, phase II, in which 132 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients who will refer to Farshchian Heart Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded so that the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 35 to 65 years, Sleep disorder Exclusion criteria: Mental and psychiatric disease, History of sensitivity to Bitter orange and chamomile, Olfactory sense disorder, History of respiratory allergy or asthma

Intervention groups
Intervention group 1: Inhalation aromatherapy with Bitter orange 2.5% every night 2 hours before sleep for 3 nights Intervention group 2: Inhalation aromatherapy with chamomile 2.5% every night 2 hours before sleep for 3 nights Control group: Inhalation aromatherapy with distilled water every night 2 hours before sleep for 3 nights

Main outcome variables
Primary outcome: Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N298**
Registration date: **2019-09-22, 1398/06/31**
Registration timing: **prospective**

Last update: **2019-09-22, 1398/06/31**
Update count: **0**

Registration date
2019-09-22, 1398/06/31

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan 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
2019-10-07, 1398/07/15

Expected recruitment end date
2020-05-04, 1399/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Bitter orange and chamomile inhalation

aromatherapy versus placebo on the sleep quality of admitted patients: a single-blind randomized clinical trial

Public title
Effect of Bitter orange and chamomile inhalation aromatherapy versus placebo on the sleep quality of admitted patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 35 to 65 years, Sleep disorder
Exclusion criteria:
Mental and psychiatric disease, History of sensitivity to Bitter orange and chamomile, Olfactory sense disorder, History of respiratory allergy or asthma
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Single blinded
Blinding description
The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-09-14, 1398/06/23
Ethics committee reference number
IR.UMSHA.REC.1398.466

Health conditions studied

1

Description of health condition studied
Sleep disorder
ICD-10 code
F51.8
ICD-10 code description
Other sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Sleep quality
Timepoint
Before the intervention and 3 days later
Method of measurement
Using St. Mary's Hospital Sleep Questionnaire (SMHSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Inhalation aromatherapy with Bitter orange 2.5% every night 2 hours before sleep for 3 nights
Category
Other

2

Description

Intervention group 2: Inhalation aromatherapy with chamomile 2.5% every night 2 hours before sleep for 3 nights

Category

Other

3

Description

Control group: Inhalation aromatherapy with distilled water every night 2 hours before sleep for 3 nights

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital in Hamadan City

Full name of responsible person

Nazanin Gholami

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan 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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nazanin Gholami

Position

Student of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Professor of Epidemiology

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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