

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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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

Dr Saeid Bashirian

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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

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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