

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of aromatherapy with essential oils of lavender on sleep quality in the elderly

Protocol summary

Study aim

the effect of lavender essential oil on the sleep quality of the elderly

Design

The elderly are randomly assigned to the control and intervention groups based on a random number table.

Settings and conduct

Elderly Examination Group take 2 drops of lavender in the test group every night for 4 weeks. Then 4 weeks after the intervention, the assessment of sleep quality is measured by the assessor. The place of study was Ghaemshahr city.

Participants/Inclusion and exclusion criteria

Criteria for entering the study, over 60 years of age, having a healthy sense of smell, having no history of allergic rhinitis and known respiratory problems. Exit criteria include: physical and mental illnesses, drug use, tobacco and alcohol.

Intervention groups

Both groups (intervention and control) were performed. For the intervention group, lavender and paraffin were used for the control group.

Main outcome variables

sleep quality of the elderly

General information

Reason for update

Acronym

اثر اسطوخودوس بر خواب سالمندان

IRCT registration information

IRCT registration number: **IRCT20110906007494N28**

Registration date: **2018-10-11, 1397/07/19**

Registration timing: **retrospective**

Last update: **2018-10-11, 1397/07/19**

Update count: **0**

Registration date

2018-10-11, 1397/07/19

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Student Research Committee of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with essential oils of lavender on sleep quality in the elderly

Public title

The effect of aromatherapy with essential oils of lavender on sleep quality in the elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

over 60 years of age having a healthy sense of smell
having no history of allergic rhinitis and known
respiratory problems such as asthma

Exclusion criteria:

physical or mental illness drug use, tobacco and alcohol
cognitive impairment and speech impairment

Age

From **60 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method was based on a random
number table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

"Ethics committee "of Mazandaran University of
Medical Sciences

Street address

sari-Juibar tree way

City

sari

Province

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Postal code

481578-33971

Approval date

2016-06-20, 1395/03/31

Ethics committee reference number

95-356

Health conditions studied

1

Description of health condition studied

sleep disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lavender effect on elderly sleep quality

Timepoint

4 weeks after the intervention

Method of measurement

Pittsburgh Quality Index

2

Description

sleep disorder

Timepoint

4 weeks after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Elderly take 2 drops of lavender in the test group every
night for 4 weeks

Category

Lifestyle

2

Description

In the control group, placebo (paraffin solution) is used.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Daily aging care centers

Full name of responsible person

Leila Meskini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
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College Student Research Committee
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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
Mazandaran 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
Mazandaran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available