Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 alcoho 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

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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

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Sponsors / Funding sources

1

Sponsor
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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

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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