

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison with of inhalation Aromatherapy lavender, chamomile and sour orange flower on sleep quality in elderly city of Zabol

Protocol summary

Summary

The aim of this study was to compare aromatherapy inhaler Tuesday lavender, chamomile and sour orange flower on sleep quality in elderly Bashd.myarhay enter at least 60 years of age, the desire to participate in the study, having poor sleep quality, having the proper recognition, non-use of herbal medicines two weeks ago, no history of allergy or sensitivity test was conducted on herbs and sour orange, avoid caffeinated beverages and alcohol three hours before intervention is no history of mental disorders. Participants who are ill or show signs of sensitivity are excluded. 4 is a clinical trial study on 100 elderly people in nursing homes is done in Zabol city. Participants were randomly divided into four groups: the experimental group 1 (lavender) and test 2 (sour orange essential oil) and test 3 (essential oil of chamomile) and control group (n = 25) are divided. The data gathered, Pittsburgh Sleep Quality Index by four groups before and after treatment is completed. In the intervention group and the control group was given essence of distilled water is used. After treatment in every 4 th night, sleep quality questionnaire is completed.

General information

Acronym

Non

IRCT registration information

IRCT registration number: **IRCT2016022126680N1**

Registration date: **2016-05-31, 1395/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-31, 1395/03/11

Registrant information

Name

Leila Fahimzade

Name of organization / entity

School of Nursing and Midwifery, Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-03-12, 1394/12/22

Expected recruitment end date

2016-04-10, 1395/01/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison with of inhalation Aromatherapy lavender, chamomile and sour orange flower on sleep quality in elderly city of Zabol

Public title

The effects of aromatherapy on sleep

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being willing to cooperate in the study and signed an informed consent form; no history of allergy to drugs, herbal ingredients, the smell of flowers or sour orange test sensitivity; poor sleep quality by

Pittsburgh Sleep Quality Index; do not use drugs plant in the past two weeks ; at least 60 years of age; Appropriate Cognitive status (ie: lack of disease dementia, Alzheimer's disease and Huntington's disease and delirium); avoid caffeinated beverages or alcohol containing at least 3 hours before the intervention; no history of disease psychiatric neuroscience is leading to hospitalization or medication. Exclusion criteria: patient's unwillingness to continue to cooperate in the study; the incidence of allergy symptoms ; duration of study participants who become ill or died.

Age

From **60 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Moallem street, South Khorasan

City

Birjand

Postal code

53577 - 97178

Approval date

2016-02-08, 1394/11/19

Ethics committee reference number

ir.bums.1394.314

Health conditions studied

1

Description of health condition studied

sleep quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

sleep quality

Timepoint

1. Before the intervention, 2. The seventh night after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: In this group every night from 10 pm to 6 am for seven nights, before you go to bed elderly person, a researcher two drops of lavender oil on a cotton ball through a dropper that squeezed inside patch which has already been prepared and are attached to dress elderly and elderly sniffed it out at bedtime.

Category

Other

2

Description

The second intervention group: In this group every night from 10 pm to 6 am for seven nights, before you go to bed elderly person, a researcher at the drop of sour orange essential oil on a cotton ball through a dropper that squeezed inside patch which has already been prepared and are attached to dress elderly and elderly sniffed it out at bedtime.

Category

Other

3

Description

The third intervention group: In this group every night from 10 pm to 6 am for seven nights, before you go to bed elderly person, a researcher two drops of chamomile essential oil on a cotton ball with a dropper that squeezed inside patch which has already been prepared and are attached to dress elderly and elderly sniffed it out at bedtime.

Category

Other

4

Description

control group: already been prepared and are attached to dress elderly and elderly at bedtime it does not breathe.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Elderly care centers

Full name of responsible person

Leila fahimzade - Master of Nursing

Street address

Martyr Khedri Home for the Aged, Zabol

City

Zabol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Doctor Ahmad Nasiri forg

Street address

Vice President of Research, School of Nursing and Midwifery, Birjand University of Medical Sciences

City

Birjand

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

leila fahimzade

Position

Master of Nursing

Other areas of specialty/work

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Doctor Ahmad Nasiri forg

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty