Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of lavender aromatherapy on sleep quality and satisfaction with life of elderies

Protocol summary

Summary

This study is a single-blind clinical randomized controlled trial to determine the effect of aromatherapy on sleep quality and life satisfaction in elders by using the Pittsburgh Sleep Quality and Satisfaction with Life Questionnaire. Inclusion criteria: Elderly men 60 years and older, elderly men referred to Monempour Health Center of Tabriz, The relative independence in daily activities due to the high score of 20 by Barthel Scale, Good health of smell, having mental health. Exclusion criteria: Having allergic rhinitis, eczema, Respiratory problems such as asthma known, removing participants from the study intervention, if they forget do intervention more than three times. The sample size n = 40 for each group have been calculated. The intervention group will receive aromatherapy as 2 drop of pure lavender essence on a prepared cotton ball and inhale from 3-5 cm distance from nose for 20 minutes during 2 weeks, an hour before routine bedtime and then the cotton ball will be connected to the collar and after waking up will be separated and discarded. The control group will not receive any intervention. Participants will follow up by phone. Questionnaire for all two groups, will be completed by the research assistant after2 weeks. The research assistant will be blind and unaware of the study groups and purpose. The most important outcome of this study is to promote the quality of sleep and life satisfaction in elders.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020119919N2**
Registration date: **2016-02-03, 1394/11/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-03, 1394/11/14

Registrant information

Name

Arefeh Davoodi Bavil Oliaii

Name of organization / entity

Nursing and Midwifery of Faculty, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0648

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Recruitment status

Recruitment complete

Funding source

Depurty for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-01-15, 1394/10/25

Expected recruitment end date

2016-04-14, 1395/01/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lavender aromatherapy on sleep quality and satisfaction with life of elderies

Public title

Sleep quality and satisfaction of life in eldery

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Elderly men 60 years and older, Elderly men referred to Monempour Health Center of Tabriz, The relative independence in daily activities due to the high score of 20 by Barthel Scale, Good health of smell, Having mental health. Exclusion criteria: Having allergic rhinitis, eczema, Respiratory problems such as asthma known, Removing participants from the study intervention, If they forget do intervention more than three times.

Age
From **60 years** old to **75 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
central Is Not Registered in Any

Secondary trial Id
No Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
South Shariety St; Faculty of Nursing and Midwifery-Tabriz, East Azarbayjan Iran, Islamic Republic Of

City
Tabriz

Postal code

Approval date
2016-01-09, 1394/10/19

Ethics committee reference number
11602/4/5

Health conditions studied

1

Description of health condition studied
sleep quality and life satisfacton

ICD-10 code
G47.9

ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
sleep quality

Timepoint
End of 14 nights

Method of measurement
pittsburg scale

Secondary outcomes

1

Description
life satisfaction

Timepoint
End of 14 nights

Method of measurement
Diener satisfaction of life scale

Intervention groups

1

Description
Intervention Group 2 weeks (14 nights) and how it works is that every night one hour before bedtime routine, pure lavender essential oils with dropper 2 drops on a cotton ball prepared, and dropped from 3 -5 cm through the nose for 20 minutes, and then the cotton ball with pin 14 nights inhalation elderly elderly and attached to the collar after waking up from the collar is removed and discarded. In control group, do their routine life and do not receive any intervention.

Category
Other

2

Description
In control group was not intervention performed.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences
Full name of responsible person
sevda sadeghpoor
Street address
Shariety South St ; Faculty of Nursing & Midwifery
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research, Tabriz University of Medical Sciences
Full name of responsible person
Dr.Rashidi
Street address
Deputy of Medical Sciences University of Tabriz,Tabriz, Est Azarbayjan
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research, Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
sevda sadeghpoor
Position
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Person responsible for scientific inquiries

Contact
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arefeh davoodi
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Person responsible for updating data

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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