

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 after 2 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 Babil 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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adavoodi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy 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 elderly

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 sadeghpour

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 sadeghpour

Position

Nursing student of MS/ Nurse

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing& Midwifery

Full name of responsible person

arefeh davoodi

Position

Master of nursing

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Master of nursing- Faculty member

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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