Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effects of aromatherapy with Lavender oil and Caria Chamomilla on self-esteem, stress, anxiety and depression, sleep quality and quality of life of the elderly in Shahroud–A clinical trial.

Protocol summary

Summary

Objective: Comparing the effects of aromatherapy with Lavender oil and Caria Chamomilla on self-esteem, stress, anxiety and depression, sleep quality and quality of life of the elderly in Shahroud. Study design: Randomized control trial, duoble blind, two groups (experimental) and one group (control) before and after. Population: Elderly live at home in Shahroud. Inclusion criteria: Minimum age 65 years, the lack of psychiatric disease, no history of anti-anxiety drugs, stress and depression, the ability to communicate verbally, no known respiratory problems such as asthma, independence or any addiction to drugs, tranquilizers. Exclusion criteria: history of asthma and allergies to flowers and plants, smell disorders, history of psychiatric disorders, a history of tensions event in the last 3 months, herbal remedies and alternative medicine use in a week. Sample Size: 183. Interventions: Perfuse 3 drops of lavender essential oil, essential oil chamomile and distilled water on a piece of cotton wool and place it beneath the exterior of their pillows for 30 nights. Main outcome measures (variables): self-esteem, sleep quality, stress, anxiety and depression, quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606144281N2**
Registration date: **2016-08-20, 1395/05/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-20, 1395/05/30

Registrant information

Name

Azam Hamidzadeh

Name of organization / entity

Shahroud University of Medical Sceince

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

azhamidzadeh@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahroud University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of aromatherapy with Lavender oil and Caria Chamomilla on self-esteem, stress, anxiety and depression, sleep quality and quality of life of the elderly in Shahroud–A clinical trial.

Public title

Effects of aromatherapy on self-esteem, stress, anxiety and depression, sleep quality and quality of life of the elderly.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Minimum age 65 years; The lack of psychiatric disease; No history of anti-anxiety drugs, stress and depression; The ability to communicate verbally; No known respiratory problems such as asthma; Independence or any addiction to drugs; tranquilizers. Exclusion criteria: History of asthma and allergies to flowers and plants; Smell disorders; History of psychiatric disorders; A history of tensions event in the last 3 months; Herbal remedies and alternative medicine use in a week.

Age

From **65 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **183**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In the present study according to exclusion criteria, participants that distinguish the smell of Lavender oil and Caria Chamomilla will be excluded. So participants will be blind to the type of intervention. Also, due to the time of data collection (before, the first day and one month after the intervention),when there is no smell of Lavender oil and Caria Chamomilla at home, so data collector who is someone other than the principal investigator, will be unaware to the type of intervention. Data analyst will be unaware of groups (experimental and control group) too, therefore, this is a triple-blind study.

Secondary Ids

1

Registry name

ندارد

Secondary trial Id

ندارد

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

Shahrood University of Medical Sciences, Hafte-Tir square

City

Shahroud

Postal code

3613773955

Approval date

2016-04-12, 1395/01/24

Ethics committee reference number

SHMU.REC.1395.14

Health conditions studied

1

Description of health condition studied

Self-esteem ,Sleep quality, stress, anxiety, depression , quality of life

ICD-10 code

F88-G47.9-

ICD-10 code description

Other disorders of psychological development-Sleep disorder, unspecifiedAcute stress reaction-Anxiety disorder, unspecified-Mild depressive episode-Person encountering health services in unspecified circumstances

Primary outcomes

1

Description

Self steam

Timepoint

Before and after intervention (The first day and one month after the intervention)

Method of measurement

Questionnaire measured self-esteem scale of Rosenberg

2

Description

Quality of sleep

Timepoint

Before and after intervention (The first day and one month after the intervention)

Method of measurement

Pittsburgh Sleep Quality Iquestionare (PSQI)

Secondary outcomes

1

Description

Stress

Timepoint
Before and after intervention (The first day and one month after the intervention)
Method of measurement
Questionnaire of Stress, Anxiety and Depression-DASS-21

2

Description
Anxitey
Timepoint
Before and after intervention (The first day and one month after the intervention)
Method of measurement
Questionnaire of Stress, Anxiety and Depression-DASS-21

3

Description
Depression
Timepoint
Before and after intervention (The first day and one month after the intervention)
Method of measurement
Questionnaire of Stress, Anxiety and Depression-DASS-21

4

Description
Quality of life
Timepoint
Before and after intervention (The first day and one month after the intervention)
Method of measurement
Quality of life Questionnaire SF12

Intervention groups

1

Description
Intervention group 1: 3 drop of lavender essential oil on the participant’s pillow at night, repeated for 30 day
Category
Other

2

Description
Intervention group 2: 3 drop of Chamomile essential oil on the participant’s pillow at night, repeated for 30 day.
Category
Other

3

Description
control group: 3 drop of Distilled water on the participant’s pillow at night, repeated for 30 day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Elderly's homes
Full name of responsible person
Azam Hamidzadeh
Street address
Shahrood University of Medical Sciences, Hafte-Tir square
City
Shahroud

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, shahroud University of Medical Sciences
Full name of responsible person
Dr Mohammad Hasam Emamiam
Street address
Shahrood University of Medical Sciences, Hafte-Tir square
City
Shahroud
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Azam Hamidzadeh
Position

Master of Science in Midwifery
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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