

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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 Science

##### 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**

Shahroud 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, unspecified Acute 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

Shahrood University of Medical Sciences

#### Full name of responsible person

Azam Hamidzadeh

#### Position

Master of Science in Midwifery

**Other areas of specialty/work**

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**Web page address**

**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*