

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Examining the effect of aromatherapy with Rosa damascene essential oil on the sleep quality of the elderly in nursing homes

Protocol summary

Sleep quality of the elderly

Study aim

The effect of aromatherapy with Rosa damascene essential oil on the sleep quality of the elderly

Design

A quasi-experimental before and after study will be performed on 35 elderly people with using convenient sampling-based in Rasht nursing home

Settings and conduct

The instruments used in the study are demographic information questionnaire and PSQI. After completing the questionnaire, the essential oil of Rosa damascene is used. Thus, every night one hour before the normal bedtime, for 10 nights, 5 drops of 10% Rosa damascene essential oil is dropped with a dropper on a pre-prepared cotton ball 3-5 cm away through the nose and is inhaled for 20 minutes. Then the same cotton ball is attached to the elderly collar after being put inside a piece of cloth with a pin and is thrown away after waking up. At the end of the tenth day, the sleep quality of the elderly will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 60 years and older; willingness to participate in the study and to give informed consent to perform it; residing in the nursing home; the ability to answer the questionnaire questions; any history of allergy to Rosa damascene or its compounds; using the herbal tea or extract of Rosa damascene; asthma and sensitivity to essential oils according to the patient report and health record at the center. Exclusion criteria: any disease during the study period; which leads to prohibition of using of Rosa damascene extract; including allergic rhinitis, eczema; known respiratory problems; excluding the participant from the study in case of forgetting the intervention more than three times; showing any allergic reaction to Rosa damascene during the study.

Intervention groups

Rosa damascene, 10%, 5 drops, 10 nights

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190805044438N1**

Registration date: **2019-11-13, 1398/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-13, 1398/08/22**

Update count: **0**

Registration date

2019-11-13, 1398/08/22

Registrant information

Name

Roya Mansour-ghanaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4256 5058

Email address

r_ghanaei@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-21, 1398/06/30

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the effect of aromatherapy with Rosa damascene essential oil on the sleep quality of the elderly in nursing homes

Public title

The effect of aromatherapy with Rosa damascene essential oil on the sleep quality of the elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly 60 years and older Willingness to participate in the study and to give informed consent to perform it Residing in the nursing home The ability to answer the questionnaire questions

Exclusion criteria:

Any history of allergy to Rosa damascene or its compounds Using the herbal tea or extract of Rosa damascene Asthma and sensitivity to essential oils according to the patient report and health record at the center

Age

From 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 35

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Langeroud School of Nursing and Midwifery, Martyr Yaghoub Sheikhi St. leyla kooh, Langeroud, Guilan

City

Langeroud

Province

Guilan

Postal code

4477163485

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.GUMS.REC.1398.383

Health conditions studied

1

Description of health condition studied

Sleep disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

sleep quality (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, daytime dysfunction)

Timepoint

Before intervention - 10 days after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rosa damascene, 10%, 5 drops, for 10 nights, Rosa damascene essential oil is dropped with a dropper on a pre-prepared cotton ball 3-5 cm away through the nose and is inhaled for 20 minutes. Then the same cotton ball is attached to the elderly collar after being put inside a piece of cloth with a pin and is thrown away after waking up.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Old people's home in Rasht

Full name of responsible person

Roya Mansour-ghanaei

Street address

Langeroud School of Nursing and Midwifery, Martyr
Yaghoub Sheikhi St. leyla kooh, Langeroud, Guilan,
Iran

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Email

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Shademan Nemati

Street address

Deputy of university Research and Technology of the
University, Old Bldg (building) School of Health, in
front of 17 Shahrivar Hospital, Shahid Siadati Ave,
Namjoo St, Rasht

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Roya Mansour Ghanaei

Position

instructor, faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available