Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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
Sleep quality of the elderly

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
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Langeroud School of Nursing and Midwifery, Martyr Yaghoub Sheikhi St. leyla kooh, Langeroud, Guilan, Iran
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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
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Other areas of specialty/work
Nursery
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Person responsible for updating data

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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