

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of rose oil on insomnia and sleep quality of students living in the girls' dormitory

Protocol summary

Study aim

Determining the effect of rose oil on insomnia and sleep quality of students living in the girls' dormitory of Ahvaz Jundi Shapur University of Medical Sciences.

Design

After obtaining written consent and random allocation, people are divided into two groups A and B using a random table. Then the prepared demographic checklists are completed. The absence of anxiety and depression of students is checked with the Beck Depression and Anxiety Questionnaire before the intervention. Then, the amount and presence of insomnia will be determined with the Pittsburgh Questionnaire. Rose oil and placebo oil will be made by the pharmacist and both rose oil and placebo will be coded (A, B). Necessary information will be given to students through face-to-face training by the researcher, as well as information sheets. Students in both groups are asked to massage the bottle containing 3 to 5 drops of oil on their forehead for a week and once a day before going to sleep. Finally, in order to measure the level of insomnia of the students after the intervention, at the end of the restudy, the Petzberg questionnaire will be completed by the researcher of the unit.

Settings and conduct

Rose oil and placebo oil will be made by the pharmacist and both rose oil and placebo will be coded (A, B). Necessary information will be given to students through face-to-face training by the researcher, as well as information sheets. Students in both groups are asked to massage the bottle containing 3 to 5 drops of oil on their forehead for a week and once a day before going to sleep.

Participants/Inclusion and exclusion criteria

1. A female student living in the dormitory

Intervention groups

40 recipients of rose oil

Main outcome variables

insomnia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056938N3**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

Registration date

2023-08-10, 1402/05/19

Registrant information

Name

Fatemeh Razavinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 210 3403

Email address

fatemehrazavinia15@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of rose oil on insomnia and sleep quality of students living in the girls' dormitory

Public title

Investigating the effect of rose oil on insomnia and sleep quality of students

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A female student living in the dormitory Iranian Having a sleep disorder and insomnia with the Pittsburgh Questionnaire Willingness to participate in the study

Exclusion criteria:

Having a specific disease including depression, anxiety and migraine headaches Taking drugs affecting sleep in the last two weeks, such as sleeping pills Allergy to rose A person's refusal to continue participating in the study

Age

From **18 years** old to **36 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation, people are divided into two groups A and B using a random table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Rose oil and placebo oil will be made by the pharmacist and both rose oil and placebo will be coded (A, B). For the preparation of medicines, 40 bottles with rose oil from the company and another 40 bottles will be prepared by the placebo substance and will be filled with the same color and shape as rose oil. Roses prepared from Attari are put in olive oil at a ratio of 4 times olive oil to roses for 48 hours in a greenhouse, then strained and this is done 3 times. Also, the placebo is paraffin oil, we grease the wall of the paraffin oil can with 5ppm of rose essential oil. Study at the patient level, the outcome evaluator and the statistical analyst of the results will be blinded. Before being filled, the drug and placebo bottles are divided into two equal groups of 40 numbers based on the random number table in the blocky method, and then based on the results obtained, the bottles are filled with drug essence or placebo. Only the researcher can decipher the contents of each bottle based on the initial form of the randomization results. The research unit and the researcher will not be aware of the type of medicine in the Kedar bottles. Finally, the researcher will deliver

the coded drugs to the students and give them the necessary training on how to use them.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Committee of Jundishapur University of Medical Sciences, Ahvaz

Street address

Ahvaz, academic city, next to the central organization of Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz, Vice-Chancellor of Research and Technology Development

City

Ahvaz

Province

Khuzestan

Postal code

15794 - 61357

Approval date

2023-04-10, 1402/01/21

Ethics committee reference number

IR.AJUMS.REC.1402.249

Health conditions studied**1****Description of health condition studied**

insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes**1****Description**

Insomnia or lack of sleep is a symptom that a person does not fall asleep continuously. In other words, difficulty in falling asleep, waking up repeatedly during the night with inability or difficulty in falling asleep again, waking up very early in the morning and sleep that does not rejuvenate are called insomnia.

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving rose oil .. Rose oil and placebo oil will be made by the pharmacist and both rose oil and placebo will be coded (A, B). For the preparation of medicines, 40 bottles will be filled with rose oil. Roses prepared from Attari in olive oil at a ratio of 4 times olive oil to roses are placed in a greenhouse for 48 hours, then strained and this is done 3 times. Massage 5 drops on your forehead once a day before going to bed for a week.

Category

Treatment - Drugs

2

Description

Control group: another 40 bottles will be prepared by the placebo substance and will be filled with the same color and shape with rose oil. The placebo is paraffin oil, we grease the wall of the paraffin oil can with 5ppm of rose essential oil. Massage the bottle containing 3 to 5 drops of oil on your forehead once a day before going to bed for a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Girls' dormitory of Jundishapur University of Medical Sciences, Ahvaz

Full name of responsible person

Fatemeh Razavinia

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 911 210 3403

Email

fatemehrazavinia15@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Naghmeh Yazdi

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 916 311 9228

Email

naghmehyazdi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

60

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

Ahvaz University of Medical Sciences

Full name of responsible person

Naghmeh Yazdi

Position

asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

karegar

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 916 311 9228

Email

naghmehyazdi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Naghmeh Yazdi

Position

Asistant profesor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 916 311 9228

Email

naghmehyazdi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Razavinia

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 911 210 3403

Email

fatemehrazavinia15@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It is published as an article.

When the data will become available and for how long

After completing the study

To whom data/document is available

all people

Under which criteria data/document could be used

article

From where data/document is obtainable

Correspond

What processes are involved for a request to access data/document

email

Comments