# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**
Khouzestan
**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**
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**Postal code**
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**Phone**
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**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

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+98 916 311 9228

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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**
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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**
Fatemeh Razavinia

**Position**
Ph.D candidate

**Latest degree**
Master

**Other areas of specialty/work**
Midwifery

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## 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**