Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Ocimum Basilicum leaf extract on the sleep quality in the female university students

Protocol summary

Study aim
Determining the effect of basil leaf extract on sleep quality in female students

Design
the randomized clinical controled trial, triple-blind, on 94 patients, and SPSS 22 statistical software will be used for data analysis.

Settings and conduct
Location: Dormitories in Khorramabad-Lorestan In the experimental group, basil capsules and in the control group, placebo will be consumed once a night, at 9-10 p.m., one to two hours before bedtime and with a glass of water, for a month. Neither the patient nor the person evaluating the patient will know what medication has been received. Also, the data analyst will be blind to the grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age between 18 and 35 years 2. Single 3. Iranian 4. Dormitory resident 5. Having sleep quality disorder according to the Pittsburgh questionnaire 6. Body mass index between 18.5 and 35 Exclusion criteria: 1. Alcohol and tobacco consumption 2. Consumption of more than 4 cups of coffee during the day 3. Any disease that affects sleep quality 5. Any significant acute or chronic disease 6. Previous or current use of psychotropic drugs 7. Consumption of any chemical and herbal medicine for sleep quality disorder 8. Consumption of hormonal pills 9. Having night shift jobs 10. Having stress, anxiety and depression according to the DOS21 scale 11. Sensitivity to basil extract during the study 12. Not taking basil extract capsules for two consecutive days

Intervention groups
in The intervention group, capsules containing basil extract will be consumed, and in the control group, capsules containing corn flour will be consumed once a night for a month.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250308064992N2**
Registration date: **2025-11-11, 1404/08/20**
Registration timing: **prospective**

Last update: **2025-11-11, 1404/08/20**
Update count: **0**

Registration date
2025-11-11, 1404/08/20

Registrant information

Name
Negin Rashti

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 4252 8986

Email address
neginrashti@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-02-20, 1404/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Ocimum Basilicum leaf extract on the sleep quality in the female university students

Public title
The effect of Ocimum Basilicum on the sleep quality
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18-35 years of age single Iranian residing in the dormitory Having sleep quality disorder according to the Pittsburgh questionnaire Body mass index between 18.5 and 35.
Exclusion criteria:
consuming alcohol, narcotics, or smoking Drinking more than 4 cups of coffee per day Any disease that affects sleep quality (narcolepsy, obstructive sleep apnea, restless leg syndrome, periodic limb movement syndrome, etc.) Previous (4 weeks prior to study) or current use of psychotropic medications (antiaxiants, sedatives, hypnotics, antipsychotics, antidepressants, centrally acting corticosteroids, and opioid analgesics) Use of any chemical or herbal medicine for sleep quality disorders during the study and 3 months prior to the study Taking hormonal pills Having jobs with night shifts being stressed, anxious or depressed as indicated by DASS21 test Participation in another study during the study and within one month before the intervention sensitivity to basil extract during the study not taking basil extract capsules for two consecutive days
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is accessible and based on the study entry criteria. In this way, after obtaining written consent from the samples, people are assigned to intervention and control groups using block random allocation method and blocks of 4. By using this method, it can be ensured that an equal number of participants enter the intervention and control groups in consecutive time intervals. Entry of people into each of the groups is done according to the number of selected blocks and the arrangement inside the block. For blocks of 4, six modes are considered as follows, and the said blocks will be used approximately 4 times so that the final sample size is allocated to two treatment and intervention groups: 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC All assessments and interventions will be conducted by the primary investigator, who is unaware of the group randomization.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The drug (basil) and the placebo are placed in the same packaging and envelopes coded by a trained midwife with 2 codes (code A for basil capsule and code B for placebo), which are similar in shape and size. Neither the patient nor the person evaluating the patient will know what medication has been received. Also, the data analyst will be blind to the grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences
Street address
Headquarters of Lorestan University of Medical Sciences, Anoushirvan Rezaei Square, Moalem St.
City
Khorramabad
Province
Lorestan
Postal code
8197978133
Approval date
2025-11-09, 1404/08/18
Ethics committee reference number
IR.LUMS.REC.1404.315

Health conditions studied

1

Description of health condition studied
Sleep quality disorder
ICD-10 code
F51
ICD-10 code description
Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Sleep quality
Timepoint

Before the study, one and two weeks after the start of the study

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The capsule containing basil extract will be taken once a night for one month.

Category

Treatment - Drugs

2

Description

Control group: The capsule containing corn flour (placebo) will be taken once a night for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University of Medical Sciences dormitories

Full name of responsible person

Negin Rashti

Street address

Department of midwifery, faculty of nursing and midwifery, Pardis Medical Campus, Kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6816979151

Phone

+98 66 3322 4547

Email

neginrashti@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Bahram Kamarei

Street address

Department of midwifery, faculty of nursing and midwifery, Pardis Medical Campus, Kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3330 0661

Email

publicrelation@lums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Negin Rashti

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Department of midwifery, faculty of nursing and midwifery, pardis medical campus, kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

381351698

Phone

+98 66 1322 9095

Email

neginrashti@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Negin Rashti

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Department of midwifery, faculty of nursing and midwifery, pardis medical campus, kamalvand, Khorramabad, Lorestan, Iran

City
Khorramabad

Province
Lorestan

Postal code
381351698

Phone
+98 66 1322 9095

Email
neginrashti@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Negin Rashti

Position
Master Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Department of midwifery, faculty of nursing and midwifery, pardis medical campus, kamalvand, Khorramabad, Lorestan, Iran

City
Khorramabad

Province
Lorestan

Postal code
381351698

Phone
+98 66 1322 9095

Email
neginrashti@gmail.com

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