

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of *Salvia Officinalis* tea on the sleep quality of Students Living in Dormitories

Protocol summary

Study aim

Determining the effect of sage tea on sleep quality of medical students.

Design

This study is a clinical trial with a control group, with parallel groups, two-way blind, easily randomized, on 128 students living in dormitories of Iranshahr University of Medical Sciences. Excel software rand function was used for randomization.

Settings and conduct

First, the list of students living in the dormitories of Iranshahr University of Medical Sciences is extracted. A code room is provided for each student. In a simple random method based on the room (there is a possibility of using roommates from each other), using the software are divided into experimental and control groups. The intervention group was given bags containing sage The control group will be given bags containing brown sugar placebo. it is necessary to mention boxes and bags of tea will not differ in appearance, tea boxes are numbered by a third party who knows the contents at the bottom. The researcher then delivers boxes of the same number to the students in a room. In addition, researchers and participants will not have information about the main drink and placebo

Participants/Inclusion and exclusion criteria

No history of underlying disease, no history of mourning in the last 6 months, no history of hospitalization, no use of psychiatric drugs, no participation in counseling class Score 5 or more from the "Pittsburgh Sleep Quality Index", no history of allergies to herbs, unwillingness to continue cooperation, no use of sage for three nights, pregnancy, lactation

Intervention groups

The intervention group, who are medical students living in dormitories, were given bags containing *Salvia Officinalis* The control group, who are medical students living in dormitories, will be given bags containing brown sugar placebo

Main outcome variables

quality of students' sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141125020082N2**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Masooome Shahnnavazi

Name of organization / entity

Iranshahr University Of Medical Scinces

Country

Iran (Islamic Republic of)

Phone

+98 54 3721 0481

Email address

mshahnnavazi1392@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Salvia Officinalis tea on the sleep quality of Students Living in Dormitories

Public title
1- The effect of salvia officinalis tea on the sleep quality of Students Living in Dormitories of Iranshahr University of Medical Sciences, 2021.

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 No diseases such as diabetes, epilepsy, hypotension, kidney and liver problems No history of mourning in the last 6 months No hospitalization in the last 6 months Do not take certain medications such as anti-depressant, anti-anxiety and hypnotic Not participating in counseling classes with psychologists Score 5 or more on the "Pittsburgh Sleep Quality Index" Lack of sensitivity to medicinal plants
Exclusion criteria:
 Reluctance to continue cooperation Do not use Salvia Officinalis tea for three nights Unfortunate events (death of loved ones, divorce of parents and accident) Getting sick and hospitalized Pregnancy Breastfeeding

Age
From **18 years** old to **24 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the six student dormitories at Iranshahr University of Medical Sciences, students with sleep quality disorders are identified through a pre-test and then given a code to the rooms where students with sleep disorders meet the inclusion criteria and consent to participate in the study. To be. Using the random numbers software version CF-1.7.1, the rooms where students live are divided into two groups of test and control (it is possible to use roommates from each other).

Blinding (investigator's opinion)
Double blinded

Blinding description
Boxes and bags of tea will not differ in appearance, tea boxes are numbered by a third party who knows the contents at the bottom. The researcher then delivers boxes of the same number to the students in a room. In addition, researchers and participants will not have information about the main drink and placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Iranshahr University of Medical Sciences
Street address
 Balooch St.
City
 Iranshahr
Province
 Sistan-va-Balouchestan
Postal code
 9914786138
Approval date
 2019-12-21, 1398/09/30
Ethics committee reference number
 IR.IRSHUMS.REC.1400.012

Health conditions studied

1

Description of health condition studied
Sleep Disorder

ICD-10 code
F51

ICD-10 code description
Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
Salvia Officinalis may improve the quality of students' sleep

Timepoint
Students' quality score according to the "Pittsburgh Sleep Quality Index" should be below six

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group brews ten grams of sage and receives it every night, before going to bed for a month

Category

Other

2

Description

Control group: This group of placebo, which is brown sugar in the amount of ten grams, is inhaled and received every night before going to bed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranshahr, Baluch Blvd., Vice Chancellor for Education, Iranshahr University of Medical Sciences

Full name of responsible person

Masoom Shahnava

Street address

Iranshahr, Baluch Blvd., Vice Chancellor for Education, Iranshahr University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

دکتر فاطمه آذرکیش

Street address

Iranshahr, Baluch Blvd., Vice Chancellor for Education, Iranshahr University of Medical Sciences

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Irshums@irshums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranshahr 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

Iranshahr University of Medical Sciences

Full name of responsible person

Masoom Shahnava

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

maryam rigi

Position

Instructor of non-academic staff

Latest degree

Master

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some demographic information such as age, sex, marital status, household income, and information about students' sleep disorders will be published in the form of an article without identifying the participants.

When the data will become available and for how long

2022-2023

To whom data/document is available

Researchers in the field of medical sciences

Under which criteria data/document could be used

By referring to the archive of medical science journals

From where data/document is obtainable

By sending an email to the responsible author, Masooome Shahnavazi: mshanavazi1392@gmail.com

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

By sending an email to the responsible author, Masooome Shahnavazi: mshanavazi1392@gmail.com

Comments