

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of incidence of sleep disorder and effect of oral almond on sleep quality in medical science students in tehran university of medical sciences

Protocol summary

Summary

The main goal of the current study is to investigate the impact of sweet almond on quality of sleep. For this purpose, a before-after design will be employed. Study population includes the students residing in Tehran University of Medical Science's dormitories during the study period. Inclusion criteria: age range of 18 -30 years and informed consent. Exclusion criteria: Being medical intern or resident , having history of psychological disorders. With regard to the previous studies the sample size is 400. Since some of the questionnaires won't be returned, 450 questionnaires will be distributed to the participants. In the first part of the study, using the Insomnia Severity Index questionnaire, quality of sleep will be determined. It is worth noting that its validity and reliability is previously confirmed by Insomnia Research Institute affiliated to TUMS. Then, each participant will receive 10 almonds each night for a period of 14 days . In the current study each participant will be his/her own control and case. In addition, no placebo will be used in the study. In the second part, the participants will again fill in the questionnaires. The data gathered will be analyzed using SPSS version 23 by Wilcoxon Signed Rank test to investigate the impact of almond on quality of sleep.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121131341N1**

Registration date: **2017-07-07, 1396/04/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-07, 1396/04/16

Registrant information

Name

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Iran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of incidence of sleep disorder and effect of oral almond on sleep quality in medical science students in tehran university of medical sciences

Public title

Investigating the impact of sweet almond on sleep quality.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: students of Tehran University of Medical Science and written consent. Exclusion criteria: medical interns , residents and students with a history of physiological disorder.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of the Iran University of Medical Sciences

Street address

School of Traditional Medicine,Hafez Street,Tehran,Iran.1143995711

City

Tehan

Postal code

11439957181

Approval date

2016-12-13, 1395/09/23

Ethics committee reference number

ir.iums.rec.1395.9321309005

2

Ethics committee

Name of ethics committee

Ethical Committee of the Iran University of Medical Sciences, School of Traditional Medicine

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Hafez Street , Behesht avenue's corner

City

Tehran

Postal code

1439957181

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

ir.iums.rec.1395.9321309005

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

-G47.0

ICD-10 code description

-Disorders of initiating and maintaining sleep

Primary outcomes

1

Description

Insomnia

Timepoint

Onset of study, 2 weeks later

Method of measurement

ISI questionnaire score

Secondary outcomes

1

Description

Improvement of sleep quality

Timepoint

Two weeks after the intervention

Method of measurement

Questionnaire score

Intervention groups

1

Description

Initially the quality of sleep will be assessed; then by using a before-after design, the cases will serve as their own controls.Each sample member will take 10 sweet almonds for two weeks; then the quality of sleep will be assessed again by a standard questionnaire.This is a before-after study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences
Full name of responsible person
Dr Ghafarzadeh Jafar. Head of dormitory Affairs
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Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy for Research, Iran University of Medical Sciences
Full name of responsible person
Morteza Naserbakht
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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
Deputy for Research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty