

# 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

Jafar Ghafarzadeh

###### Name of organization / entity

School of Traditional Medicine, Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8800 5291

###### Email address

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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**

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Hafez Street , Behesht avenue's corner

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**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  
**Street address**  
Hemat High way Iran University of Medical Siences  
**City**  
Tehran  
**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

### Contact

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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*