

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of progressive muscle relaxation program on sleep quality in pre-university students

#### Protocol summary

##### Summary

The aim of this study was to determine the effects of progressive muscle relaxation on sleep quality pre-university students. In this clinical trial, 46 pre-university students from public schools Malayer city that inclusion criteria are randomized into two groups of progressive muscle relaxation (test) and take control. In the case group of progressive muscle relaxation training program will be asked to do this once a day for a month. The instruments are "Pittsburgh Sleep Quality Index", sheet relaxation and demographic questionnaire. The sleep quality of the samples using "Pittsburgh Sleep Quality Index", will be measured at the beginning and end of the intervention. Inclusion criteria include: Students who do not have any history of sleep disorders. Mourning history and history of hospitalization in the last 6 months have not, do not have any history of drug use and the completion of "Pittsburgh Sleep Quality Index", 5 and have more business and exclusion criteria were: non-completion questionnaire, failure to attend educational sessions, participate in any class consultation with psychiatrists, occurring situations disaster near death, parental divorce, accident, illness and possible hospitalization during treatment, do relaxation program forward less than 15 times intervention

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015080123450N1**

Registration date: **2015-09-06, 1394/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-06, 1394/06/15

#### Registrant information

##### Name

Tahereh Roozbahani

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
School of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 5366

##### Email address

t.roozbahani@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shahid Beheshti University of Medical Sciences, Faculty of Nursing and Midwifery Research Committee

#### Expected recruitment start date

2014-10-22, 1393/07/30

#### Expected recruitment end date

2015-01-20, 1393/10/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of progressive muscle relaxation program on sleep quality in pre-university students

#### Public title

effect of relaxation on sleep quality

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria of the study include: students do not have history of disease such as cancer, diabetes cardiovascular problems, hepatitis, epilepsy, muscular

paralysis, anemia, ulcers, asthma, kidney problems, migraine headaches and sleep disorders; do not have a history of mourning in the last 6 months; do not have history of hospitalization in the last 6 months; do not have a history of taking certain medications; have the necessary cooperation for the study; the completion of "quality index Pittsburgh Sleep ", 5 and have won more. Exclusion criteria included: failure to complete the questionnaire; absence of training sessions; not wanting to continue the cooperation in the study; participate in any class consultation with psychiatrists who study its possible impact on psychological variables; the occurrence of adverse situations such as the death of someone close; Her parents' divorce and an accident that reduces a person's motivation to continue the study; the risk of illness and hospitalization during treatment; perform progressive relaxation program more than 15 times during a month-long intervention

**Age**

From **16 years** old to **19 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences  
Faculty of Nursing and Midwifery

**Street address**

Shahid Beheshti Faculty of Nursing and Midwifery,  
Niyayesh Intersection, Valiasr Avenue

**City**

Tehran

**Postal code****Approval date**

2015-05-01, 1394/02/11

**Ethics committee reference number**

SBMU2.REC.1394.15

**Health conditions studied****1****Description of health condition studied**

sleep disorder

**ICD-10 code**

f51

**ICD-10 code description**

Nonorganic sleep disorders

**Primary outcomes****1****Description**

sleep quality

**Timepoint**

before and 30 days after relaxation

**Method of measurement**

Pittsburgh sleep quality index

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the experimental group, progressive muscle relaxation program that during the 5 sessions of educational CD, booklet and PowerPoint students will be trained and they will be asked to once a day for a month bedtime this program do

**Category**

Behavior

**2****Description**

In the control group not trained and there is no action

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Seyfiyeh High school

**Full name of responsible person**

Tahereh Roozbahani

**Street address**

Alley Emamy, Park Avenue

**City**

Malayer

## 2

### Recruitment center

**Name of recruitment center**

Fatemieh High school

**Full name of responsible person**

Tahereh ROOZBAHANI

**Street address**

Rajai Alley, Sadi Avenue

**City**

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### Recruitment center

**Name of recruitment center**

Motahary High school

**Full name of responsible person**

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Shahid Sadogi Alley, Barg Ball Avenue

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### Recruitment center

**Name of recruitment center**

Eshgi Fard High school

**Full name of responsible person**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

School of Nursing and Midwifery shahid Beheshti

**Full name of responsible person**

Amirhosayn Barbaz Esfahani

**Street address**

Shahid Beheshti Faculty of Nursing and Midwifery,  
Niyayesh Intersection, Valiasr Avenue

**City**

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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**

School of Nursing and Midwifery shahid Beheshti

**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

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Kiarash Saatchi

**Position**

Physical Therapist

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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Faculty of Nursing and Midwifery

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Manigeh Norian

**Position**

PhD Student in Nursing Education

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## Person responsible for updating data

### Contact

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**Web page address****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*