Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 Aveniue

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
befor 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 Aveniue

City
Malayer

2

Recruitment center
Name of recruitment center
Fatemieh High school
Full name of responsible person
Tahereh ROOZBAHANI
Street address
Rajai Alley, Sadi Aveniue
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3

Recruitment center
Name of recruitment center
Motahary High school
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4

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
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Tehran
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
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Person responsible for scientific inquiries

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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