

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Development and evaluation of the effectiveness of virtual education program for healthy sleep pattern on sleepiness reduction in 15 to 17 years old female students.

Protocol summary

Study aim

Determining and comparing the effectiveness of the educational intervention on the average score of the sleepiness of the intervention group compared to the control group before, after, and 3 months after the intervention in female students aged 15 to 17

Design

Before and after clinical trial, has a control group, randomized, not blinded on 103 participants

Settings and conduct

Girls' high schools in Abadan, Ilam province Is place of intervention, The intervention is done virtually using the SHAD program and Whats App Groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.High school female students 2.willing to participate in the study 3.Parents' consent to participate in the study exclusion criteria: 1. use of medication for sleep disorders

Intervention groups

Intervention group: Female high school students 15 to 17 years old: 53 students in the experimental group, do receive an educational intervention based on self-regulation theory aims to improve sleep health and reduce sleepiness in school students. Control group: Female high school students 15 to 17 years old: 53 students in the control group do not receive any educational intervention.

Main outcome variables

The sleep knowledge Positive attitude to sleep behavior Self-efficacy of sleep behavior The quantity and quality of sleep Self-regulatory sleep behavior The sleep hygiene Sleepiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201107049293N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

parvin ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3204

Email address

parvin_ghasemi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation of the effectiveness of virtual education program for healthy sleep pattern on

sleepiness reduction in 15 to 17 years old female students.

Public title
The effectiveness of healthy sleep pattern education in sleepiness reduction

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Female students studying in high school Parents' consent to participate in the study willing to participate in the study
Exclusion criteria:
The usage of medication which causes sleep disorders

Age
From **15 years** old to **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
A two-arm parallel-randomized controlled trial with sleep intervention and a control group, with 53 people sample size in each group. Using simple randomization method, two school will be randomly selected out of five schools. Out of two schools, one is randomly assigned to control group and one to the experimental group. Then, in every school each class is given a number and two numbers randomly will be selected and assigned to the experimental and control classes. In this study, to units of the statistical society (schools or classes) will be assigned a card number and then will be put all the cards in a box And every time after shaking the box, we will be Draw the card randomly from the box.

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib street, Isfahan University of Medical Sciences, Isfahan

City

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Province

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Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.460

Health conditions studied

1

Description of health condition studied

The students sleepiness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean sleep knowledge score

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Cognitive variables questionnaire

2

Description

Mean score of sleep health

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Adolescent Sleep Hygiene Scale

3

Description

Mean score quality of sleep

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

4

Description

Mean score of self-regulation sleep behavior

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Sleep Behavior Self-Regulation Questionnaire

5

Description

Mean score of sleepiness

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Cleveland Adolescent Sleepiness Questionnaire

6

Description

Attitude towards sleep

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Cognitive variables questionnaire

7

Description

Mean score of sleep behavior self-efficacy

Timepoint

Before, after and 3 months after the intervention

Method of measurement

Cognitive variables questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15-17-year-old female high school students. Self-regulation theory is the selection of intervention components and behavior change techniques and is the basis of all educational materials. Students in the sleep education program will receive 12 sessions (30 minutes each) online. The training program used in this study will include sleep knowledge, sleep hygiene and goal setting, self-control (including metacognitive and motivational strategies) and self-reflection. The content of the training will be presented to the intervention group in the form of PowerPoint, multimedia, short audio and text files. The intervention group will be invited to join a social network for example, WhatsApp or Instagram for 12 weeks to share their experiences with barriers and solutions to overcome healthy sleep barriers. A telephone consultation will be added to the program to maximize program participation and increase problem-solving and self-regulation skills. Educational intervention will be done in SHAD program and a link to educational sessions will be sent to students every week. Coordination and planning will be done with the school principal before the intervention.

Category

Lifestyle

2

Description

Control group: 17-15 year old female high school students. Students in the control group do not receive educational intervention But the content of the training will be provided to them after the end of the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Girls' high schools in Abdanan

Full name of responsible person

Parvin Ghasemi

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Sarab ave.Abdanan

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Ilam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Parvin Ghasemi

Position

Phd student

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data and results of the intervention and the intervention protocol potentially will be published as a scientific article

When the data will become available and for how long

Accessibility after printing results

To whom data/document is available

There is no limitation for statistical analysis

Under which criteria data/document could be used

Obtaining official permission from Isfahan University of Medical Sciences - Contact the research team-There is no

limitation for statistical analysis

From where data/document is obtainable

Isfahan University of Medical Sciences

What processes are involved for a request to access

data/document

Obtaining official permission from Isfahan University of
Medical Sciences - Contact the research team

Comments