

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of a sleepHygiene Intervention on sleep Habits among of elementary students

Protocol summary

Study aim

Determine The effect of a sleep hygiene Intervention on sleep habits among of elementary students

Design

randomized controlled trial

Settings and conduct

In the beginning of the study, randomly from four school from districts 1 and 2 arak were selected. The number of each groups were 50 people.

Participants/Inclusion and exclusion criteria

(Inclusion criteria: Informed consent was signed by parents, Students study at elementary state schools, No Behavioral Disorders in Student, Life with Father and Mother) (Exclusion criteria: The absence of parents and students at training sessions, Unwilling to participate in the study, The student can not be reached at the time of completing the questionnaire and transfer to another school.)

Intervention groups

Intervention group Four educational sessions of 90 minutes hold about Sleep Hygiene, by present education, the book and education pamphlet which this study was hold by helping school administrators. In the end, after three months, questionnaires in this respect shall be filled by mothers of the participating students and the control group is also given the training packages which.

Main outcome variables

(Determine and compare educational intervention, sleep habits, bedtime resistance, sleep onset latency, sleep duration, sleep anxiety, sleep waking, sleep disturbance, sleep breathing , daytime sleepiness, student age,gender student, mother of education, occupation of Mother on the sleep habits of elementary students.)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039849N1**

Registration date: **2018-07-07, 1397/04/16**

Registration timing: **retrospective**

Last update: **2018-07-07, 1397/04/16**

Update count: **0**

Registration date

2018-07-07, 1397/04/16

Registrant information

Name

Masoomah Masnabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3405 0748

Email address

m.masnabadi95@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-05, 1396/09/14

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a sleepHygiene Intervention on sleep Habits among of elementary students

Public title

The Effect of a sleep Hygiene Intervention on sleep

Habits among of elementary students

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent was signed by parents Students study at elementary state schools No Behavioral Disorders in Students Life with Father and Mother

Exclusion criteria:

The absence of parents and students at training sessions Unwilling to participate in the study The student can not be reached at the time of completing the questionnaire and transfer to another school

Age

From **7 years** old to **12 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Multi-stage cluster randomization

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 arak university of Medical Sciences

Street address

Pardis Educational Complex, Department Of Education And Research, Basij S.q

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2017-12-03, 1396/09/12

Ethics committee reference number

IR.ARAKMU.REC.1396.200

Health conditions studied

1

Description of health condition studied

Sleep Hygiene

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

(Determine and compare educational intervention, sleep habits, bedtime resistance, sleep onset latency, sleep duration, sleep anxiety, sleep waking, sleep disturbance, sleep breathing disorder, daytime sleepiness, student age, school gender, mother of education, occupation of Mother on the sleep habits of elementary students)

Timepoint

Before the intervention and three months after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The Intervention group of this study consisted of 50 Elementary school girls of arak city which four educational sessions of 90 minutes hold about Sleep hygiene, by present education, the book and education pamphlet which this process was hold by helping school administrators.

Category

Other

2

Description

The control group of this study consisted of 50 Elementary school girls of arak. Simultaneously with the intervention group, after three months, questionnaires in this respect shall be filled by Mothers of the participating students the control group is also given the training packages which intervention group has given about Sleep hygiene.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Elementary School Girls

Full name of responsible person

Masoomeh Masnabadi

Street addressNo.31, Ghorban Hoseinieh., Hatam Abadi Shahid Ave.,
Sedal Shohada Ave.**City**

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3817644913

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M.Masnabadi95@arakmu.ac.ir

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mrs Dr Nasrin Roozbahani

Position

Health Education

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street addressPardis Educational Complex, Department Of
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak 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

Arak 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mrs Dr Nasrinn Roozbahani

Position

Health Education

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Masoomeh Masnabadi

Position

Master of science

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available