Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 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
Masoomeh 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 ofarak 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 ofarak. 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 address
No.31, Ghorban Hoseinieh., Hatam Abadi Shahid Ave., Sedal Shohada Ave.
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M.Masnabadi95@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mrs Dr Nasrin Roozbahani
Street address
Pardis Educational Complex, Department Of Education And Research, Basij S.q
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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
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mrs Dr Nasrin Roozbahani
Position
Health Education
Latest degree
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Person responsible for updating data

Contact
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Masoomeh Masnabadi
Position
Master of science
Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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City

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Province

Markazi

Postal code

3817644913

Phone

+98 86 3405 0748

Email

M.Masnabadi95@arakmu.ac.ir

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