

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of Behavioral intervention on sleep problem in school age children

Protocol summary

Summary

The aim of this study is determination of effect of Behavioral intervention on Sleep disorder in school age children. The project was approved by the Iran University of Medical Sciences and all participants will complete informed consents prior to participation. Cluster random sampling will be done within 22 regions of Tehran. All participants will complete a demographic questionnaire and screening BRARS pretest measures at the beginning of the intervention. The intervention included a sleep hygiene education session with principal investigator. Participants will complete posttest measures at four and 12 weeks after the completion of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412031788N9**

Registration date: **2015-08-02, 1394/05/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-08-02, 1394/05/11

Registrant information

Name

Leili Borimnejad

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Centre for Nursing Care Research Iran University of Medical Sciences

Expected recruitment start date

2015-09-20, 1394/06/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Behavioral intervention on sleep problem in school age children

Public title

behavioral intervention on sleep problems

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: 6-12 years old; sleep disorder based on BEARS Questionnaire Exclusion Criteria: Receiving specialised help for their sleep from a psychologist or a specialised sleep clinic

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Hemmat
City
Tehran
Postal code
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
IR.IUMS.REC.1394.25011

Health conditions studied

1

Description of health condition studied
sleep disorder
ICD-10 code
G47.9
ICD-10 code description
Sleep disorder, unspecified

Primary outcomes

1

Description
sleep disorder
Timepoint
before,after 4 week , after 12 week
Method of measurement
Bears Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: NO Intervention
Category
N/A

2

Description
All parents will received the sleep hygiene education programme delivered, in a session to the participant by the principal investigator. During the intervention session approximately 45-60 minutes, A handout containing all the information covered will be given to the parent(s). Families will offer one follow-up telephone call four weeks later
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Primary School in Tehran
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Center for Nursing Care Research Iran University of Medical Sciences
Full name of responsible person
Sedighe Khanjari
Street address
Yasemi Street
City
Tehran
Grant name
Grant code / Reference number
25011
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Center for Nursing Care Research Iran University of Medical Sciences
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

Iran University of Medical Sciences

Full name of responsible person

Leili Borimnejad

Position

Ph.D Educational Affair

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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