

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A Study to Determine the Impact of a Sleep Hygiene Intervention on Sleep Habits in Children with Attention Deficit Hyperactivity Disorder (ADHD) and Comorbid Sleep Disorders

Protocol summary

Summary

Objectives: A Study to Determine the Impact of a Sleep Hygiene Intervention on Sleep Habits in Children with Attention Deficit Hyperactivity Disorder (ADHD) and Comorbid Sleep Disorders **Study Design:** Clinical trial, Interventional, Not blinded, Randomized. The study **Population:** Children aged 7 to 13 years who refer to Ali-Asghar Children's Hospital, and Tehran Institute of Psychiatry. **Inclusion criteria:** Age of 7 to 13 years; having ADHD diagnosis based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-VI-TR) criteria; having at least one sleep disorder formally confirmed by a child psychiatrist. **Exclusion criteria:** Suffering from an acute or chronic medical illness or mental disorder; and using medications for sleep disorders. **Target Sample Size:** 62 **Participants Study Intervention:** Sleep hygiene education In this study we will use Children's Sleep Habits Questionnaire (CSHQ) for data collection. At the baseline Questionnaires will be completed by children's mothers in the both experimental and control groups. Mothers of the children in experimental group will receive a sleep hygiene educational intervention which deliver through a training session and a booklet will follow by two follow up telephone calls were made at the third and fifth weeks after intervention and educational cell phone text messages based on the study purposes. Participants in the control group will receive usual clinical care. The post-test will perform two months after intervention, and then data will be analyzed; 1) To determine the effect of training in experimental group 2) To compare the experimental group with the control group **Primary outcome:** Improved sleep habits in experimental group 2 months after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100830212N1**

Registration date: **2016-11-29, 1395/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-29, 1395/09/09

Registrant information

Name

Hedieh Shahhatami

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Faculty of Medical Sciences, Tarbiat Modares University

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-11-20, 1394/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Study to Determine the Impact of a Sleep Hygiene Intervention on Sleep Habits in Children with Attention Deficit Hyperactivity Disorder (ADHD) and Comorbid Sleep Disorders

Public title

The Impact of Good Sleep Hygiene on Sleep Habits in Children with Attention Deficit Hyperactivity Disorder (ADHD)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age of 7 to 13 years; having ADHD diagnosis based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-VI-TR) criteria; having at least one sleep disorder formally confirmed by a child psychiatrist Exclusion criteria: Suffering from an acute or chronic medical illness or mental disorder; and using medications for sleep disorders

Age

From **7 years** old to **13 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **62**

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

1

Registry name

Secondary trial Id

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Medical Sciences,
Tarbiat Modares University

Street address

No 14115-111, Jalal Al Ahmad Highway, Tehran

City

Tehran

Postal code

Approval date

2015-05-27, 1394/03/06

Ethics committee reference number

IR.TMU.REC.1394.63

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

2

Description of health condition studied

Sleep Disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

Sleep habits

Timepoint

Before and two months after intervention

Method of measurement

Children Sleep Habits Questionair (CSHQ)

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Control group: Usual clinical care

Category

Behavior

2

Description

Intervention group: Sleep hygiene education and usual clinical care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Children's Hospital

Full name of responsible person

Hedieh Shahhatami

Street address

Vahid Dastgerdi St., Shariati Ave, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Tehran Psychiatric Institute

Full name of responsible person

Hedieh Shahhatami

Street address

ShahiedMansuri St., Niayesh St., Sattarkhan Ave.,
Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

said mousavian

Street address

No 14115-111, Jalal Al Ahmad Highway, Tehran

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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

Vice chancellor for research, Faculty of Medical Sciences,
Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Mansoureh Movahedin

Position

Ph.D. of Anatomy

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Person responsible for updating data

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Hedieh Shahhatami

Position

MSc student of Health education

Other areas of specialty/work

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Tehran

Postal code**Phone****Fax****Email****Web page address****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