

# 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

+98 21 7711 9728

##### 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

**City**

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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.,  
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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

**City**

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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**Position**

MSc student of Health education

**Other areas of specialty/work**

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**City**

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**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*