

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

**A comparative study of the effectiveness of adding melatonin and sleep hygiene education to the usual treatment (pharmacological and non-pharmacological treatment) in reducing the symptoms of attention deficit hyperactivity disorder in adolescents with attention deficit hyperactivity disorder and sleep phase delay syndrome.**

### Protocol summary

#### Study aim

A comparative study of the effectiveness of adding melatonin and sleep hygiene education to the usual treatment (pharmacological and non-pharmacological treatment) in reducing the symptoms of attention deficit hyperactivity disorder in adolescents with attention deficit hyperactivity disorder and sleep phase delay syndrome.

#### Design

A clinical trial with a randomized control group of 75 patients

#### Settings and conduct

The study is conducted in psychiatric clinics and on teenagers aged 12 to 18 with attention deficit hyperactivity disorder. Children in two groups will be given medicine and sleep hygiene education. Questionnaires will be filled out before, during, and after the study.

#### Participants/Inclusion and exclusion criteria

1. Definitive diagnosis of ADHD with DSPS 2. Age range: between 12 and 18 years 3. Informed consent to participate in the research project 4. Having minimum education (reading and writing literacy) parents for sleep training for teenagers 1. Suffering from a chronic disease physical, including diabetes, liver problems, immune system defects, and autoimmune diseases 2. Presence of major psychiatric disorders such as bipolar disorder 3. Taking medicine with side effects of sleep problems such as insomnia or hypersomnia

#### Intervention groups

Group 1: For each patient, 3 mg of melatonin is added to his routine treatment. This group is treated with melatonin for 5 weeks. Group 2: This educational program as a psychoeducational program includes 5

sessions of 50 minutes.

#### Main outcome variables

Reducing symptoms of attention deficit hyperactivity disorder

### General information

#### Reason for update

#### Acronym

ADHD

#### IRCT registration information

IRCT registration number: **IRCT20211004052670N5**

Registration date: **2023-11-13, 1402/08/22**

Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**

Update count: **0**

#### Registration date

2023-11-13, 1402/08/22

#### Registrant information

#### Name

afsaneh karbasi amel

#### Name of organization / entity

#### Country

Iran (Islamic Republic of)

#### Phone

+98 31 3641 1255

#### Email address

afsaneh\_karbasi@med.mui.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-11-22, 1402/09/01  
**Expected recruitment end date**  
2024-06-21, 1403/04/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### Scientific title

A comparative study of the effectiveness of adding melatonin and sleep hygiene education to the usual treatment (pharmacological and non-pharmacological treatment) in reducing the symptoms of attention deficit hyperactivity disorder in adolescents with attention deficit hyperactivity disorder and sleep phase delay syndrome.

#### Public title

Effectiveness of adding melatonin and sleep hygiene education to the usual treatment of attention deficit hyperactivity disorder with sleep phase delay syndrome.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Definitive diagnosis of ADHD with DSPTS between 12 and 18 years Informed consent to participate in the research project Having minimum education (reading and writing literacy) of parents for sleep training for teenagers

##### Exclusion criteria:

Suffering from chronic physical diseases including diabetes, liver problems, immune system defects and autoimmune diseases Taking medicine with side effects of sleep problems such as insomnia or hypersomnia

#### Age

From **12 years** old to **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **75**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The sample in this research consists of 75 adolescents with ADHD and sleep phase delay syndrome with the opinion of a specialist in pediatric psychiatry based on the fifth edition of the Diagnostic and Statistical Manual of Psychiatric Disorders, who are selected by available sampling. Then on 25 leaves letter A, 25 leaves letter B, and 25 leaves letter C are written and each is placed in an envelope. Then each patient is asked to choose one envelope from among the envelopes. According to the selected envelope, the patient will be allocated to one of the three groups. The size of each group is 25 people and the waiting list is also 25 people.

#### 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

Ethical Committee of Isfahan University of Medical Sciences

##### Street address

Ibn Sina Street, Amin Hospital

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8148653141

#### Approval date

2023-07-12, 1402/04/21

#### Ethics committee reference number

IR.MUI.MED.REC.1402.166

## Health conditions studied

### 1

#### Description of health condition studied

Attention Deficit-Hyperactivity Disorder

#### ICD-10 code

F90.2

#### ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

## Primary outcomes

### 1

#### Description

Determining the mean scores of Conners Hyperactivity Questionnaire

#### Timepoint

The questionnaire is administered at the baseline visit (before the intervention), after participating in sleep health education sessions and taking melatonin medicine, and then three months after the intervention is completed for follow-up.

#### Method of measurement

Conners Hyperactivity Questionnaire

## Secondary outcomes

### 1

#### Description

Sleep quality score

#### Timepoint

The questionnaire is administered at the baseline visit (before the intervention), after the training sessions on sleep hygiene and the use of melatonin medication, and three months after the end of the intervention for follow-up.

#### Method of measurement

Petersburg Sleep Quality Questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: For each patient, 3 mg of melatonin is added to his routine treatment. The chemical structure of this drug is similar to serotonin. It has a fast and complete oral absorption and reaches the plasma peak within an hour, so it is used for people with sleep delay problems. In this group, patients are first given a checklist of drug side effects, and the checklist is checked during three visits. This group is treated with melatonin for 5 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: This educational program as a psychoeducational program includes 5 50-minute sessions that are conducted by a psychologist for parents of teenagers in a group and during 5 consecutive days. The first session: In this session, how teenagers are deprived of enough sleep to Parents are explained. The second session: why teenagers are so affected by lack of sleep. In other words, the causes and factors of sleep deprivation are taught to parents in this section. The third session: The consequences of sleep deprivation in teenagers are taught to parents. The fourth and fifth sessions: How can you help teenagers get enough sleep. In these two sessions, parents are taught various effective methods to help teenagers improve their sleep quality and quantity.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amin Hospital

##### Full name of responsible person

Karbasi Amel Afsaneh

#### Street address

Ibn Sina Street, Amin Hospital

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

غلامرضا عسگری

##### Street address

Hezarjaribi St. Isfahan University of Medical Sciences

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askari@mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Afsaneh Karbasi Amel

##### Position

Assistant Professor of Child and Adolescent Psychiatry

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Afsaneh Karbasi amel

**Position**

Assistant Professor of Child and Adolescent Psychiatry

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Afsaneh Karbasi Amel

**Position**

Assistant Professor of Child and Adolescent Psychiatry

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available