

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Developing a «sleep guide for child with autism spectrum disorder for parents with emphasis on self-regulation strategies in occupational therapy » and investigating its efficacy on sleep and Severity of symptoms in children with autism spectrum disorder aged 6 to 12 years old: Randomized Clinical Trial

#### Protocol summary

##### Study aim

Investigating the effect of "child's sleep guide" on sleep and severity of symptoms in 6-12 year old children with autism spectrum disorder.

##### Design

In this study, 30 participants will be randomly assigned to the intervention (15 people) and control (15 people) group. In order to randomize the allocation of samples to intervention and control groups, a random list of 30 people was produced in groups A and B, and by lottery (tossing a coin), the letter A or B will be considered for the samples of the intervention group and the control group. In two intervention and control groups, matching is done in terms of autism level.

##### Settings and conduct

The present study will be conducted on children with ASD aged 6 to 12 years, in schools or autism centers in Tehran or in the clinic of the rehabilitation faculty of Iran University of Medical Sciences without blinding.

##### Participants/Inclusion and exclusion criteria

having reading and writing literacy and complaining about sleep problems in children with ASD in parents; Having a diagnosis of ASD at Level 1 or 2 and the child scoring above 41 on the CSHQ; Having at least 5 years of clinical and research work experience related to children with ASD in specialists.

##### Intervention groups

Intervention group: Pretests and SSP-2 and CASES will be administered. Then, the content of the manual will be implemented by the child's main caregiver at home for 8 weeks. The Sleep Diary will be completed daily. Then the post-tests will be implemented. Follow-up assessments will be conducted 8 weeks after the end of the intervention. Control group: Pretests will be

administered. The Sleep Diary will be completed daily. Children will receive common occupational therapy interventions. Then the post-tests will be implemented. Follow-up assessments will be conducted 8 weeks after the end of the intervention.

##### Main outcome variables

Sleep; Severity of symptoms

#### General information

##### Reason for update

Because we were unable to obtain accurate scores for one of the questionnaires, we changed the questionnaire and the age range of the participants changed according to the new questionnaire.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240105060616N1**

Registration date: **2024-02-12, 1402/11/23**

Registration timing: **prospective**

Last update: **2025-03-21, 1404/01/01**

Update count: **1**

##### Registration date

2024-02-12, 1402/11/23

##### Registrant information

##### Name

Simin Asadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5547 6212

##### Email address

asadi.si@iums.ac.ir

**Recruitment status**  
Recruitment complete  
**Funding source**

**Expected recruitment start date**  
2024-05-21, 1403/03/01

**Expected recruitment end date**  
2024-06-20, 1403/03/31

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

#### **Scientific title**

Developing a «sleep guide for child with autism spectrum disorder for parents with emphasis on self-regulation strategies in occupational therapy » and investigating its efficacy on sleep and Severity of symptoms in children with autism spectrum disorder aged 6 to 12 years old:  
Randomized Clinical Trial

#### **Public title**

Developing a sleep guide for child with autism spectrum disorder and investigating its efficacy on sleep and Severity of symptoms in children with autism spectrum disorder

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Inclusion criteria for parents: being able to read and write; Having complaint about sleep problems in child with ASD; Willingness and declaration of readiness to cooperate with the researcher to implement the intervention at home; Availability of at least one parent who can continuously participate in educational and research activities. Children's inclusion criteria: having an ASD diagnosis by a child psychiatrist; The severity of autism according to the GARS test be at level 1 or 2; Obtaining a score higher than 41 in CSHQ; The child is in the age range of 6 to 12 years. Having at least 5 years of clinical and research experience in working with children with ASD; Having expertise related to children with ASD such as pediatric psychiatrist, pediatric occupational therapist, pediatric psychologist.

##### **Exclusion criteria:**

Having a psychiatric disorder in the active phase, in the primary caregiver according to the SCID. Taking drugs that have the potential to induce sleep during the intervention and after 6 pm by the child (such as melatonin, benzodiazepines, antipsychotics such as haloperidol, olanzapine, risperidone, quetiapine, perphenazine, chlorpromazine, antidepressants such as imipramine, amitriptyline and clomipramine) The presence of severe medical problems in the child based on the medical record or as reported by the parents

#### **Age**

From **6 years** old to **12 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Outcome assessor

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

In this study, we use the randomization list of the investigated samples in the intervention and control groups and by lottery (tossing a coin), the letter A or B will be considered for the samples of the intervention group and the control group. It is worth mentioning that in the two intervention and control groups, matching is done in terms of the level of autism.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

The person who scores the outcome assessments and then enters them into the SPSS software is blind.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

###### **Street address**

Unit 2, No. 8, Hoveyda Alley, Shahid Mahloji Qomi St, Molvi St.

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1196683311

##### **Approval date**

2023-12-27, 1402/10/06

##### **Ethics committee reference number**

IR.IUMS.REC.1402.805

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

Autism Spectrum Disorder

##### **ICD-10 code**

F84.0

## ICD-10 code description

Autistic disorder

## Primary outcomes

### 1

#### Description

sleep

#### Timepoint

Before the intervention, After the intervention, At the follow-up time two months after the intervention.

#### Method of measurement

Children's Sleep Habits Questionnaire (CSHQ)

### 2

#### Description

Severity of symptoms

#### Timepoint

Before the intervention, After the intervention, At the follow-up time two months after the intervention.

#### Method of measurement

Autism Treatment Evaluation Checklist (ATEC)

### 3

#### Description

Severity of symptoms

#### Timepoint

Before the intervention, After the intervention, At the follow-up time two months after the intervention.

#### Method of measurement

Sensory Processing Measure 2- child's School form (SPM-2)

## Secondary outcomes

### 1

#### Description

parent stress

#### Timepoint

Before the intervention, After the intervention, At the follow-up time two months after the intervention

#### Method of measurement

Parent Stress Index-Short form (PSI-SF)

### 2

#### Description

Executive Function

#### Timepoint

Before the intervention, After the intervention, At the follow-up time two months after the intervention

#### Method of measurement

Behaviour Rating Inventory of Executive Function-Parent version (BRIEF)

## Intervention groups

### 1

#### Description

Intervention group: After designing and developing the manual with emphasis on self-regulation strategies for children with ASD aged 6 to 12 years based on the texts and compliance with OTPF and the "child-environment-sleep occupation" model, the research objectives are explained for the main caregivers of children with ASD. Then the demographic form will be completed. In the demographic form, the common occupational therapy treatment plan will be reported, and actions that directly or indirectly overlap or interfere with sleep interventions will be identified and controlled. Then the pre-tests (ATEC, SPM-2, CSHQ, PSI-SF, BRIEF) will be conducted in schools or autism centers or in the clinic of the rehabilitation faculty of Iran University of Medical Sciences, in the middle of the Season (so that the change of season does not affect the child's sleep). In the intervention group, SSP-2 will also be completed in order to determine the sensory needs of children with ASD in order to determine which part of the draft protocol to be taught to the family. Also, in the intervention group, a video or photo of the child's sleeping environment will be prepared by the family and matched with the "Child and Adolescent Sleeping Environment Scale" (CASES) so that environmental modifications in each child's sleeping environment can be considered if needed. Then, the content of the booklet will be taught to the main caregivers of the children in special sessions for implementation at home. In these sessions, according to the child's age, the child's sleeping environment, his sensory needs, and other conditions related to the child's home and family, some items in the booklet will be explained to the main caregiver. Then the intervention at home will be implemented by the main caregiver based on similar studies for 8 weeks. During this period, by using the Log Book, the family's loyalty to the implementation of the items taught in the meetings and the manual at home will be recorded by the main caregiver, and parents' feedback will be received and examined by weekly phone calls. At this stage, the MPOC-20 form will be completed monthly by the main caregiver of the child in order to check the views of the parents regarding the services provided by the researchers, and in this way, we will check the opinion of the main caregivers regarding the interventions. Also, in order to monitor children's sleep more accurately, the Sleep Diary will be completed daily by the main caregiver. Conducting secondary evaluations: CSHQ, ATEC, SPM-2, PSI-SF and BRIEF evaluations will be done again in autism centers or in the clinic of the rehabilitation faculty of Iran University of Medical Sciences in the middle of the year. Conducting follow-up evaluations: CSHQ, ATEC, SPM-2, PSI-SF and BRIEF evaluations will be done again 8 weeks after the end of the intervention.

#### Category

Rehabilitation

### 2

#### Description

Control group: After explaining the objectives of the research for the main caregivers of children with ASD, the demographic form will be completed. In the demographic form, the common occupational therapy treatment plan will be reported, and actions that directly or indirectly overlap or interfere with sleep interventions will be identified and controlled. Then the pre-tests (ATEC, SPM-2, CSHQ, PSI-SF, BRIEF) will be performed in the control group in schools or autism centers or in the clinic of the Rehabilitation Faculty of Iran University of Medical Sciences, in the middle of the Season (so that the change of season does not affect the child's sleep). Also, in order to monitor children's sleep more accurately, Sleep Diary will be completed daily by the main caregiver. Participants in the control group will receive common occupational therapy interventions provided in centers or schools, including cognitive or educational interventions, or social interventions, etc. Performing secondary evaluations: CSHQ, ATEC, SPM-2, PSI-SF and BRIEF evaluations will be done again in autism centers or in the clinic of the rehabilitation faculty of Iran University of Medical Sciences in the middle of the season. Conducting follow-up evaluations: CSHQ, ATEC, SPM-2, PSI-SF and BRIEF evaluations will be done again 8 weeks later.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Schools or Autism Centers in Tehran or in the clinic of the rehabilitation faculty of Iran University

**Full name of responsible person**

Simin Asadi

**Street address**

Madadkaran Street; Shah Nazari Street; Mother Square; Mirdamad

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۸۷ ۱۵۴۵۹

**Phone**

+98 21 2222 2059

**Email**

siminasadi.ot@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Falak

**Street address**

5th floor of the central headquarters; Iran University of Medical Sciences; next to Milad Tower; Hemat Highway; Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 8670 2504

**Email**

research-m@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Simin Asadi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

No. 8; Hoveyda Alley; Shahid Mahloji Qomi St; Molvi St

**City**

Tehran

**Province**

Tehran

**Postal code**

1196683311

**Phone**

+98 21 5547 6212

**Email**

siminasadi.ot@gmail.com

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samauneh Karamali Esmaeili

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Faculty of Rehabilitation Sciences; Iran University of Medical Sciences; Shah Nazari St.; Madadkaran St.; Mader Square; Mirdamad; Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+98 21 2222 2059

**Email**

samauneh.esmaeili@gmail.com

1196683311

**Phone**

+98 21 5547 6212

**Email**

siminasadi.ot@gmail.com

## **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**

Yes - There is 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

**Title and more details about the data/document**

I have not consulted with the research team about this yet.

**When the data will become available and for how long**

I have not consulted with the research team about this yet.

**To whom data/document is available**

I have not consulted with the research team about this yet.

**Under which criteria data/document could be used**

I have not consulted with the research team about this yet.

**From where data/document is obtainable**

I have not consulted with the research team about this yet.

**What processes are involved for a request to access data/document**

I have not consulted with the research team about this yet.

**Comments**

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

SiminAsadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Unit 2; No. 8; Hoveyda Alley; Shahid Mahloji Qomi St.; Molvi St.

**City**

Tehran

**Province**

Tehran

**Postal code**