

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of scheduled exercises on sleep habits of children with asthma

#### Protocol summary

##### Study aim

Determining the effect of scheduled exercises on sleep habits of children with asthma

##### Design

Clinical trial with control group, with 2 parallel groups, without blinding, randomized, with 60 patients.

##### Settings and conduct

In the intervention group, the scheduled exercises in the physiotherapy ward of Akbar Children's Hospital will be taught to the children by the researcher. Then they will do exercises at home for eight weeks and 6 sessions per week (3 sessions of breathing exercises and 3 sessions of physical exercises periodically).

##### Participants/Inclusion and exclusion criteria

The desire of the child and her/his parents to participate in the research The age of the child is from 6 years to 15 years Registration of mild to moderate persistent asthma according to the doctor (at least 3 months ago) the child's asthma is well controlled Permission from the treating physician to participate in the research Attendance of the child in physiotherapy, occupational therapy and rehabilitation programs Have a history of regular exercise in the last 6 months Having a specific mental illness Having epilepsy Have a history of heart and thyroid disease Existence of movement problems or joint disorders Use of sleeping pills and tobacco Having known congenital disorders

##### Intervention groups

For the intervention group, the scheduled exercises will be performed for eight weeks and six sessions per week (3 sessions of breathing exercises and 3 sessions of physical exercises) in a safe space at home. During this period, the control group, while receiving the routine process, will continue their normal daily activities and will receive an educational pamphlet on routine care of a child with asthma.

##### Main outcome variables

improved Resistance to going to bed, Delayed sleep onset time, Duration of sleep, Sleep anxiety, Night awakenings, Parasomnia, Respiratory problems in sleep,

Daily drowsiness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210830052343N1**

Registration date: **2021-10-10, 1400/07/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-10, 1400/07/18**

Update count: **0**

##### Registration date

2021-10-10, 1400/07/18

##### Registrant information

##### Name

Saeed Parnian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5345 3019

##### Email address

parnians992@mums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-10-09, 1400/07/17

##### Expected recruitment end date

2021-12-08, 1400/09/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of scheduled exercises on sleep habits of children with asthma

## Public title

The effect of exercise on sleep habits of children with asthma

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The desire of the child and her/his parents to participate in the research  
The age of the child is from 6 years to 15 years  
Registration of mild to moderate persistent asthma according to the doctor (at least 3 months ago)  
According to the doctor's diagnosis, the child's asthma is well controlled  
Permission from the treating physician to participate in the research

### Exclusion criteria:

Attendance of the child in physiotherapy, occupational therapy and rehabilitation programs  
Have a history of regular exercise in the last 6 months  
Having a specific mental illness  
Having epilepsy  
Have a history of heart and thyroid disease  
Existence of movement problems or joint disorders  
Use of sleeping pills and tobacco  
Having known congenital disorders

## Age

From **6 years** old to **15 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, based on the inclusion criteria, available sampling will be done and then the list of sample people will be given to SPSS software and using random block sequence generation software, half of the sample will be allocated to the intervention group and the other half to the control group. Concealment of random allocation will be done by the method of opaque sealed envelopes.

## 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

Ethics Committee of Mashhad University of Medical Sciences

#### Street address

the central building of Mashhad University of Medical Sciences, University Street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Approval date

2021-09-14, 1400/06/23

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1400.053

## Health conditions studied

## 1

### Description of health condition studied

Asthma

### ICD-10 code

X (J45)

### ICD-10 code description

Diseases of the respiratory system (Asthma)

## Primary outcomes

## 1

### Description

Sleep Habits Score in Children's Sleep Habits Questionnaire

### Timepoint

Sleep habits will be measured in 3 times. 1. Before the intervention 2. During the intervention (4 weeks after the start of the intervention) 3. After the intervention

### Method of measurement

Children's Sleep Habits Questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In this group, the scheduled exercises will be taught to children and parents by the researcher in the physiotherapy department of Akbar Children's Hospital. After the training session, these children will perform the exercises in three sleeping, sitting and standing positions in a safe space at home for eight weeks and six sessions per week (3 sessions of physical exercises and 3 sessions of breathing exercises-

periodically). One physical training session will include 3 parts of warm-up movements (10-15 minutes), selected core exercises (30-35 minutes) and cooling exercises (about 10 minutes). Breathing exercises will include normal breathing, bud lip breathing, and diaphragmatic breathing. Each session will gradually increase the number and timing of physical exercises and breathing exercises.

**Category**

Lifestyle

**2****Description**

Control group: Children in the control group will receive routine care during this period and will engage in normal and daily physical activities. They will also receive an educational pamphlet on routine care for a child with asthma.

**Category**

N/A

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

Akbar Children's Hospital

**Full name of responsible person**

Dr. Seyyed Ali Jafari

**Street address**

Akbar Children's Hospital, in front of Shahid Kaveh 24, Shahid Kaveh Boulevard

**City**

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**Province**

Razavi Khorasan

**Postal code**

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**Email**

ak.pr@mums.ac.ir

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**2****Recruitment center****Name of recruitment center**

Dr. Seyyed Javad Seyyedi's office

**Full name of responsible person**

Dr. Seyyed Javad Seyyedi

**Street address**

Haami Doctors Building, No. 162, between Naser Khosrow St. and Abuzar Ghaffari Intersection, Besat Blvd.

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi Piyade Gheybi

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the central building of Mashhad University of Medical Sciences, University Street

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vcresraech@mums.ac.ir

**Web page address**

<https://v-research.mums.ac.ir/>

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeed Parnian

**Position**

Masters student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Golestan Dormitory, Dormitory Affairs Office,  
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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Monir Ramezani Farmad

**Position**

Assistant Professor

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Ph.D.

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Nursery

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## Person responsible for updating data

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**Position**

Masters student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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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