

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)

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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

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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

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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**

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Full name of responsible person

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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

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Person responsible for scientific inquiries

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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