

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of pulmonary rehabilitation on Asthmatic pediatric quality of life

Protocol summary

Study aim

Determine the effect pulmonary rehabilitation on asthmatic pediatric quality of life

Design

Clinical trial with control group, with factorial groups, single blinded, randomized, on 60 children with asthma. The randomization website was used for randomization.

Settings and conduct

This study conducted in private clinic in Gorgan. The duration of this study is 8 sessions for each person. Each session consisted resistance movements related to increasing the strength of the scapular muscles and stretching the chest muscles, movements related to improving the strength of the Spine and mobility of this part. The main researcher does not know the allocation and participants do not know replaced in which group.

Participants/Inclusion and exclusion criteria

Entrance condition: Aged between 8- 12; Chronic Asthma
Non-entry conditions: Cardiovascular disease;
Musculoskeletal disorder; Physical disability

Intervention groups

For intervention pulmonary rehabilitation group, In addition to the usual interventions of the attending physician 8 training sessions for each patient between 20 to 40 minutes; Educational CD and follow-up phone calls at home were considered. The program of prescribed corrective and structural exercises in this program is designed on scientific findings, so that resistance movements related to increasing the strength of the scapular muscles and stretching the chest muscles, movements related to improving the strength of the Spine and mobility of this part is designed based on the training methods provided by Levenson. Control group received only the usual interventions of the attending physician.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041889N3**

Registration date: **2022-10-24, 1401/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-24, 1401/08/02**

Update count: **0**

Registration date

2022-10-24, 1401/08/02

Registrant information

Name

Hamid Hojjati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3222 5207

Email address

h_hojjati1362@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pulmonary rehabilitation on Asthmatic pediatric

quality of life

Public title
Effect of pulmonary rehabilitation on Asthmatic pediatric quality of life

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 8- 12 Chronic Asthma
Exclusion criteria:
No history of cardiovascular diseases Absence of musculoskeletal problems Physical disability

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method in this study is simple. The unit of randomization is person-to-person. Randomization will be done online in two test and control groups among 60 subjects. Concealment will be done through sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the main researcher does not know about the placement of the research units in the test and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Dezful Azad university
Street address
Azadegan Bulvar
City
Dezful
Province
Khouzestan
Postal code

646145169

Approval date
2022-03-13, 1400/12/22

Ethics committee reference number
IR.IAU.D.REC.1401.005

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
Quality of life
Timepoint
In the study "Effect of Pulmonary Rehabilitation on the Asthmatic pediatric Quality of Life", the measurement periods are at the beginning of the study and the eighth session after the start of the study.
Method of measurement
Pediatric Quality of Life Questionnaire (PedsQL)

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": In addition to receiving the usual interventions, 8 training sessions for each patient between 20 to 40 minutes, an educational CD and follow-up phone calls at home were considered. The program of prescribed corrective and structural exercises in this program is designed based on scientific findings, so that resistance movements related to increasing the strength of the scapular muscles and stretching the chest muscles, movements related to improving the strength of the open muscles Spine and mobility of this part is designed based on the training methods provided by Lebenson. No intervention was performed in control group
Category
Rehabilitation

2

Description
Control group: The control group conduct usual prescribed intervention by physician.
Category

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Nafiseh Hekmati Pour

Street address

Daneshgah Bulvare

City

Gorgan

Province

Golestan

Postal code

4579163931

Phone

+98 17 3423 7933

Email

n_hekmati68@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Salman Amirkhan

Street address

Daneshgah bulvare

City

Aliabad Katul

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Golestan

Postal code

4579163923

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Email

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nafiseh Hekmati Pour

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nafiseh Hekmati Pour

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after de-identifying people or, for example, only part of the data, such as information related to the main outcome or the like, can be shared.

When the data will become available and for how long

After 2023

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Academic institutions

From where data/document is obtainable

Academic institutions

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

Request information from aliabad azad university

Comments