Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 physician8 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 Lebenson. 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)

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+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

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
private clinic
Full name of responsible person
Nafiseh Hekmati Pour
Street address
Daneshgah Bulvare
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4579163931
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n_hekmati68@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Salman Amirkhan
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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
Academic

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
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Person responsible for updating data

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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