

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Studying the effect of pulmonary rehabilitation on quality of life in school age children with cystic fibrosis referred to Tehran children's medical center and their mother's caregiver burden in 1399

Protocol summary

Study aim

The purpose of this project is to assess and compare the quality of life in children at school age with cystic fibrosis before, immediate and eight weeks after performing pulmonary rehabilitation in control and intervention group, also in this project mothers caregiver burden in children at school age with cystic fibrosis before and immediately after performing pulmonary rehabilitation in intervention and control group will be assessed.

Design

The Clinical trial with control and intervention group. 35 child and mother in each group as an intervention and control group.

Settings and conduct

This project will be performed at Tehran Children Medical center. 12 sessions of pulmonary rehabilitation (6 session at the clinic and 6 sessions at home) will be done in 2 part: exercises (combination of balancing, flexibility and resistance movement) and educational (definition of cystic fibrosis condition and pulmonary rehabilitation, infection control, airway clearance, healthy life style). Sessions at home will be performed once a week.

Participants/Inclusion and exclusion criteria

Mother and child should have fluency in Persian language, be able to answer the questionnaire, live with each other, no history of having another child with chronic condition and caring of a person with chronic condition and access to smart phone and WhatsApp application, spirometry report.

Intervention groups

children who are in control group will have routine cares (taking medicine and having monthly visit at cystic fibrosis clinic). Children in intervention group will have 12 sessions for pulmonary rehabilitation (6 sessions at the clinic and 6 sessions at home) twice a week. In-person sessions consist of educational and exercise part.

Main outcome variables

Pulmonary rehabilitation
Quality of life
Caregiver burden
Children with cystic fibrosis
Mothers of children with Cystic fibrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161024030474N4**

Registration date: **2020-06-07, 1399/03/18**

Registration timing: **prospective**

Last update: **2020-06-07, 1399/03/18**

Update count: **0**

Registration date

2020-06-07, 1399/03/18

Registrant information

Name

Azam Shirinabadi Farahani

Name of organization / entity

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21886553668

Email address

farahani1381@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of pulmonary rehabilitation on quality of life in school age children with cystic fibrosis referred to Tehran children's medical center and their mother's caregiver burden in 1399

Public title

"Effect of pulmonary rehabilitation on quality of life in children with Cystic Fibrosis and their mother's caregiver burden"

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The Mother should have middle school degree at least, fluency in Persian language, be able to answer the questionnaires and read the educational content The Mother should not have another child with chronic condition Mother should not have a history of caring a person with chronic condition The Mother should live with her spouse and child The Mother should have access to smart phone and Whats App application Mother should have access to CD Player The child should live with both mother and father The child should have fluency in Persian language, be able to answer the questionnaire Having Spirometry report Cystic fibrosis disease should be confirmed by Pulmonary and Gastroenterology Pediatric specialist Physician The child should not have any other chronic or mental condition The child should have CD Player at home

Exclusion criteria:

The mother and child can not participate in rehabilitation sessions. The child does not have permission to participate in rehabilitation program that be confirmed by Pulmonary pediatric specialist.

AgeFrom **20 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti Medical University

Street address

No. 169, West Roudaki St., Derakhti Blvd., karaj

City

Karaj

Province

Alborz

Postal code

3139644898

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.074

Health conditions studied**1****Description of health condition studied**

Cystic fibrosis disease

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis

Primary outcomes**1****Description**

Quality of life scores in "cystic fibrosis revised questionnaire version of children 6-13 years and version of parents of children 6-13 years

Timepoint

Begging, immediately and 8 weeks after finishing the intervention

Method of measurement

"cystic fibrosis revised questionnaire"

2**Description**

Caregiver burden scores in "caring burden inventory"

Timepoint

Begging, immediately after finishing the intervention

Method of measurement

Zarit and et al "caring burden inventory"

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group for 6 weeks exercise sessions for 60-75 in and educational session for 60-90 min for children and mothers will be performed. exercise are combination of warm up, upper and lower extremities, abdominal, cool down. in educational part children and mothers will be informed in, definition of cystic fibrosis, pulmonary rehabilitation, airway clearance, medicine, oxygen therapy and healthy life style.

Category

Rehabilitation

2

Description

Control group: Routine cares such as taking medicine and having monthly visit with physician in cystic fibrosis clinic will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran children medical center

Full name of responsible person

Mohammadreza Modaresi

Street address

No. 62, Dr Mohammad Gharib St., Keshavarz Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afsin Zarghi

Street address

Depa No. 2, Shahid Beheshti medical university,
Aerabi St., Yaman Blvd., Tehran

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam Shirin abadi Farahani

Position

Associate Professor

Latest degree

Ph.D.

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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not 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

Pulmonary rehabilitation protocol and results could be shared.

When the data will become available and for how long

accessibility 6 month after publishing the result

To whom data/document is available

Researchers, students, clinical staff

Under which criteria data/document could be used

With mentioning the project name

From where data/document is obtainable

Nazanin Hadi: nazanin.hadi1375@gmail.com Dr Azam

Farahani: farahani1381@sbmu.ac.ir

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

Requests for data via Email Nazanin Hadi:

nazanin.hadi1375@gmail.com Dr Azam Farahani:

farahani1381@sbmu.ac.ir

Comments