

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of self-care education on quality of life and lung function in children with Cystic Fibrosis

Protocol summary

Study aim

By implementing self-care education programs for children if it is effective in promoting children's learning, frequent lung infections and subsequent hospitalization are less common and financial costs are reduced.

Design

Performance 6 face to face training sessions

Settings and conduct

Holding training classes during 6 sessions in Akbar Cystic Fibrosis Clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: child and their parents' willingness to participate in the study, aged 6 to 13 years old; diagnosis of cystic fibrosis disease according to expert physician; lack of mental and physical illness; child and family tendency to participate in self-care education program-outcome criteria: child and parent's desire to leave the study; more than one absence of attendance at school; incident or specific illness affecting quality of life.

Intervention groups

Self-care education in the field of CF

Main outcome variables

Quality of life and lung function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180829040905N1**

Registration date: **2018-10-05, 1397/07/13**

Registration timing: **prospective**

Last update: **2018-10-05, 1397/07/13**

Update count: **0**

Registration date

2018-10-05, 1397/07/13

Registrant information

Name

sara Kakadinparvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3761 2098

Email address

kakadinps1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of self-care education on quality of life and lung function in children with Cystic Fibrosis

Public title

Effect of self care in children with Cystic Fibrosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Desire of the child and their parents to participate in the study Aged 6 to 13 years old Diagnosis of fibroscopic disease, according to the expert physician Lack of specific mental and physical illnesses Child and family tendency to participate in self-care education program

Exclusion criteria:

Child and parents' unwillingness to cooperate The development of specific illnesses affecting the quality of life and the occurrence of illness and mental disorders

Age

From **6 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

All children with CF who have the characteristics of the research unit are selected and the random allocation block (n=4) method is used to allocate the individuals to the control and intervention groups.

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Jorjani Faculty, Mashhad University of Medical Sciences, Doctora cross road

City

Mashad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-08-12, 1397/05/21

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.025

Health conditions studied

1

Description of health condition studied

Cystic Fibrosis

ICD-10 code

E84.8

ICD-10 code description

Cystic fibrosis with other manifestations

Primary outcomes

1

Description

Evaluation of children's quality of life after educational interventions

Timepoint

Evaluation of the quality of life and lung function before and after intervention and 2 months after the study

Method of measurement

Specific Quality of Life Questionnaire for Cystic Fibrosis Children and Spirometric Data Analysis

Secondary outcomes

1

Description

Analysis of spirometric data

Timepoint

Before the study - two weeks after the training and two months later

Method of measurement

Spirometric data analysis

Intervention groups

1

Description

Intervention group: self-care education for children with Cystic Fibrosis 6 to 13 years - The intervention is self-care education during 6 sessions, each session is 45 minutes. Training items include breathing exercises - Benulisser training - Correct nutrition education - Handwashing and exercise training tailored to the child's age

Category

Rehabilitation

2

Description

Control group: there is no intervention. Under the usual care of the CF Center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar hospital

Full name of responsible person

Soheila Karbandi

Street address

Daneshgah St,Ibn-e Sina St, School of Nursing and Midwifery

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Postal code

91859-43548

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Email

kakadinps1@mums.ac.ir

Full name of responsible person

Soheila Karbandi

Position

Faculty member of School of Nursing and Midwifery Mashhad

Latest degree

Master

Other areas of specialty/work

Nursing Education; Pediatric Nursing

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Deputy of Research and Technology University, Building Qureshi, Daneshgah St, Mashhad

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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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Soheila Karbandi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursing Education; Pediatric Nursing

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Sara Kakadinparvar

Position

MSc pediatric nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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