Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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

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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
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Sponsors / Funding sources

1

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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
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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