Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effect of the physical activity plan on the life quality of children aged 12-8 years with cystic fibrosis

Protocol summary

Study aim

Determining the effect of the physical activity plan on the life quality of children aged 12-8 years with cystic fibrosis

Design

Single blind randomized clinical trial with intervention and control groups (children aged 8-12 who have had cystic fibrosis for 6 months)

Settings and conduct

Prior to the intervention, life quality questionnaire is divided between the control and intervention groups. In the intervention phase, the intervention group do physical activity. The control group does no activities.In the post-intervention phase, an evaluation will be performed from both intervention and control groups.

Participants/Inclusion and exclusion criteria

All children aged 8 to 12 years old with cystic fibrosis .Entry conditions 1) conscious willingness to participate in research 2) the recipient training has the ability to understand Persian language 3) the lack of children with acute and chronic mental and physical diseases other than 4کیستیک fibrosis) is the severity of the disease with the diagnosis of the physician at the moderate level and the ability to exercise 5) duration of minimum disease Six months and the conditions of non-entry to study age below 8 and above 12 and patients in the acute phase of disease and the ability to perform physical activity BASHDV the lack of concurrent disease with cystic fibrosis

Intervention groups

The subjects in the intervention group will receive, regularly according to their interest, aerobic physical exercises, like cycling, swimming, walking, dancing, playing with ball, rope skipping, jumping, as well as stretching guidelines for upper limbs, body and lower limbs (gymnastics) throughout four sessions of physical activity. However, the control group will not receive any training

Main outcome variables

Effective and principled training to reduce the complications of this disease and to enhance the life quality of the children with cystic fibrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190407043190N1**
Registration date: **2019-12-04, 1398/09/13**
Registration timing: **retrospective**

Last update: **2019-12-04, 1398/09/13**
Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Kosar Tabatabaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3323 3813

Email address

skttmy70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-02, 1396/09/11

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

2017-12-02, 1396/09/11

Actual recruitment end date

2018-01-10, 1396/10/20

Trial completion date

2018-01-10, 1396/10/20

Scientific title

Determining the effect of the physical activity plan on the life quality of children aged 12-8 years with cystic fibrosis

Public title

effect of the physical activity plan on the quality of life in children with cystic fibrosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The informed willingness to participate in the study the learner should be able to understand Persian the child's non-suffering from acute and chronic psychological and physical illnesses except cystic fibrosis the severity of the disease should be moderate medically diagnosed by the physician and should have the ability to exercise duration of disease should be at least 6 months

Exclusion criteria:

Under 8 years and over 12 years The patient is not in an acute condition and is able to perform physical activity Absence of concomitant disease with cystic fibrosis

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is simple with the launch of a coin, which is 70 people in the study and how to allocate a und, which is divided into twelve groups of six in the intervention and control group.

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Khouzestan, iran

City

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Province

Khouzestan

Postal code

6135715794

Approval date

2018-11-26, 1397/09/05

Ethics committee reference number

IR.AJUMS.REC.1397.632

Health conditions studied

1

Description of health condition studied

Cystic Fibrosis

ICD-10 code

E84.0

ICD-10 code description

Cystic fibrosis with pulmonary manifestations

Primary outcomes

1

Description

The effect of physical activity on the quality of life of children with cystic fibrosis based on quality of life questionnaire

Timepoint

Four weeks after the intervention

Method of measurement

Pediatric Quality Of Life Inventory TM

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group received eight to twelve years old children with cystic fibrosis. The intervention group is based on regular interest in aerobic exercise guidelines such as cycling, swimming, hiking, dancing, playing with balls, drawstring, jumbo as well as stretch limbs instructions Upper body, trunk and lower limbs (gymnastics) were trained for four sessions of physical activity during four weeks. People were told that they would be able to replicate the exercise exercises that

they prefer during the week for 20 minutes. During the intervention, Pjohshgrbeh to strengthen aerobic exercises Farad the intervention group and their possible questions regarding these activities are contacted by phone calls or social networks and will receive a report of their activities.

Category

Rehabilitation

2

Description

In the control group, children with cystic fibrosis are eight to twelve years old and the control group will not be given any training and in order to appreciate them at the end of the manual intervention with a compact disc containing the animation of the training.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Ashraf al-sadat Hakim

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ashraf al-sadat Hakim

Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Changes in life quality due to physical activity will be released after making the individuals unidentifiable
When the data will become available and for how long
The beginning of the data access period is one year after the publication of the results.
To whom data/document is available
Data and other documentation are only available for use by researchers working in academic institutes
Under which criteria data/document could be used
The results of the study can be used to complete the studies of academic researchers on patients with cystic fibrosis
From where data/document is obtainable
One can contact Ms. Ashraf-Alsadat Hakim (cited in the Iranian Center for Clinical Trials) through various communication methods to access the results of the studies.
What processes are involved for a request to access data/document
Six months after the publication of the results, the applicants can request to use the data and documentation by communication channels specified in Iranian Registry of Clinical Trials, and at least three months after the date of the request, the request will be responded to appropriately.
Comments