Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effects of aerobic exercises compared to conventional chest physiotherapy on pulmonary function, functional capacity, sputum culture and quality of life in patients with cystic fibrosis: a randomized controlled trial

Protocol summary

Study aim

investigation of pulmonary function, functional capacity, sputum culture and quality of life, before and after 6 weeks of aerobic exercises and conventional chest physiotherapy in cystic fibrosis patients. Considering the important role of physiotherapy in airway clearance of these patients, if results of study show effectiveness of interventions, these exercises can be clinically recommended as a treatment priority.

Design

A randomized, double-blinded, sham controlled trial with a parallel 2-group design of 30 patients; block balanced randomization method

Settings and conduct

Study will be conducted in Tehran Children's Medical Center Hospital. First, patients perform active cycle of breathing technique at home for 1 week. Therapeutic interventions are performed for 6 weeks, 3 sessions per week. Evaluation of variables is done by examiner before first treatment session and after last session. Patients and examiner will be unaware of study grouping.

Participants/Inclusion and exclusion criteria

inclusion: cystic fibrosis patients, age 6 to 18 years exclusion: acute pulmonary symptoms, cardiac, neurological and orthopedic disorders, symptoms exacerbation in last 1 month, severe reflux or diabetes

Intervention groups

group A main treatment: 6 postural drainage positions, staying in each for 3-4 minutes with applying manual percussion and vibration, for 30 minutes placebo treatment: exercise using a motorized stationary bike, with speed control and preventing heart rate increase, for 30 minutes. group B main treatment: progressive exercises using treadmill and stationary bike, increasing speed and controlling heart rate based on calculated exercise intensity, for 30 minutes placebo treatment: use of supine and prone positions with percussion and vibration placebos, for 30 minutes.

Main outcome variables

forced expiratory volume in 1st-second, 6-minutes walk test

General information

Reason for update

The reason for updating this trial is the changes made in the primary variables to be evaluated. Due to the exclusion of the "exercise capacity" from the primary variables, this trial is being updated. Therefore, "exercise capacity" has been removed from the title of the study and "VO2max" and "cardiopulmonary exercise test" from the outcome measures. Due to the change in the outcome measures, the patient recruitment date has also been postponed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051181N5**
Registration date: **2023-02-19, 1401/11/30**
Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **1**

Registration date

2023-02-19, 1401/11/30

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-23, 1402/05/01
Expected recruitment end date
2024-01-20, 1402/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of aerobic exercises compared to conventional chest physiotherapy on pulmonary function, functional capacity, sputum culture and quality of life in patients with cystic fibrosis: a randomized controlled trial

Public title
Comparison of the effects of aerobic exercises and conventional chest physiotherapy in cystic fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of cystic fibrosis based on positive sweat test or genetics test by a specialist doctor Age 6 to 18 years
Exclusion criteria:
Active hemoptysis, pneumothorax, hemodynamic instability, severe hypoxia, acute airway infection and cognitive disorders Having cardiac disease such as heart failure or arrhythmia, neurologic and orthopedic disorders, or chest trauma History of fever, IV antibiotics or hospitalization in the last 1 month Having severe uncontrolled gastroesophageal reflux Severe lung disease (FEV1% < 30%) Lung transplantation or in the awaiting list Requirement of additional oxygen with exercise Having uncontrolled diabetics Improper patient cooperation during treatment sessions Absence in 3 or more consecutive sessions
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients in both groups are identical in terms of demographic characteristics and are randomly divided into one of the two treatment groups with a ratio of 1:1. Random allocation is done by the block balanced randomization method, which includes 4-letter blocks, made of letters A and B. The obtained treatment allocation is placed in numbered envelopes in the form of letters A and B. Four-letter blocks of letters A and B: 1- AABB 2- ABAB 3- BBAA 4-BABA 5-ABBA 6-BAAB. Considering that the blocks are four letters, in order that all 30 patients included in the study could be randomly divided in each of the two treatment groups, referring to the table of random numbers, 8 numbers from 1 to 6 (the number of blocks made above), was selected (4x8=32). The results obtained are as follows: 1(AABB) 3(BBAA) 3(BBAA) 6(BAAB) 2(ABAB) 3(BBAA) 6(BAAB) 6(BAAB) Group A includes the main treatment of conventional chest physiotherapy and placebo of aerobic exercise, and group B includes the main treatment of aerobic exercise and placebo of conventional chest physiotherapy. The randomization process was carried out by a statistician before the start of the study. Also, the effect of the confounding variable of doing sport activities was controlled by randomizing two groups. After the initial evaluations of the subjects by the examiner, the numbered envelopes, corresponding to the sequential number of each person entered into the study, are presented to him and the therapeutic intervention is adjusted based on the letters inside the envelope. The examiner and patients will be unaware of the letters inside the envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blinded study. The examiner of this study, who evaluates pulmonary function, functional capacity, sputum culture and quality of life of the patients, will be unaware of the randomization process and allocation of participants to each group, and this will be done by another person, therefore bias is avoided. Also, patients will not know about the grouping until the end of the study. It should be noted that the therapist is aware of the way of grouping and the patients included in each group.
Placebo
Used
Assignment
Parallel
Other design features
In this study, in both groups, two treatment methods including conventional chest physiotherapy and aerobic exercises will be performed, and in each group, one of the two methods is in the form of a placebo. Therefore, group A includes the main treatment of conventional chest physiotherapy and placebo of aerobic exercise, and group B includes the main treatment of aerobic exercise and placebo of conventional chest physiotherapy. In this way, patients will be unaware of the grouping method.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
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Province
Tehran
Postal code
1449614535
Approval date
2023-02-08, 1401/11/19
Ethics committee reference number
IR.IUMS.REC.1401.919

Health conditions studied

1

Description of health condition studied
cystic fibrosis with pulmonary symptoms
ICD-10 code
E84.0
ICD-10 code description
Cystic fibrosis with pulmonary manifestations

Primary outcomes

1

Description
forced expiratory volume in 1st second (FEV1)
Timepoint
Before starting physiotherapy interventions and after completing 18 treatment sessions for each group
Method of measurement
spirometer

2

Description
6 minutes walk test (6MWT)
Timepoint
Before starting physiotherapy interventions and after completing 18 treatment sessions for each group
Method of measurement
tape measure and field test

Secondary outcomes

1

Description
sputum culture
Timepoint
Before starting physiotherapy interventions and after completing 18 treatment sessions for each group
Method of measurement
Sterile container and laboratory culture kit

2

Description
forced vital capacity (FVC)
Timepoint
Before starting physiotherapy interventions and after completing 18 treatment sessions for each group
Method of measurement
spirometer

3

Description
quality of life
Timepoint
Before starting physiotherapy interventions and after completing 18 treatment sessions for each group
Method of measurement
cystic fibrosis questionnaire - revised (CFQ-R)

Intervention groups

1

Description
Group A (the main treatment of conventional chest physiotherapy and placebo of aerobic exercise): In this group, first the main treatment, i.e. conventional chest physiotherapy, and then the placebo, i.e. aerobic exercises, will be performed. The start of the treatment session will be at least 1 hour after the last meal. There is a 10-minute break between the two stages. The duration of the entire treatment session will be about 70 minutes. Conventional chest physiotherapy: In this technique, patients are placed in 6 standard postural drainage positions. Positioning of patients is done using a wedge with an angle of 45 degrees. Patients stay in each of the supine and prone positions, with upward and downward inclination, for 4 minutes, and in the right and left side lying positions, without inclination, for 3 minutes. (In supine positions, a pillow is put under the knees, in all positions, the hands are next to the body and the patient is placed in a comfortable position). During this period, manual percussion will be performed on draining segments. Percussion will be done in such a way that the hand is in the shape of a cup and strikes on the desired area, towards the hilum of the lung (anteriorly, parallel to the cartilage of the 3rd rib and the nipple, and posteriorly, parallel to the 6th thoracic vertebra), with medium intensity, so that the resonance sound caused by the impact is heard. In order not to irritate the patient's body, the percussion will be done on 1 layer of clothe with medium thickness. Then, at the

end of each position, by placing hands on the segments under drainage and coordinating with the patient's breathing rhythm, manual vibration, applying vibration with a little pressure during exhalation to empty more air, in the direction of the lung hilum, will be applied, for one minute. 1 minute rest is given at the end of supine and prone position. For example, in order to drain the anterior-upper segments on both sides, the patient is placed in a supine position with a 45-degree upwards incline and manual percussion will be performed on these 2 areas (area above the nipples) for 4 minutes. Then, maintaining the previous position, by placing hands on these areas, vibration is applied during exhalation for 1 minute. The order of the steps will be as follows: 1- Supine with 45 degrees upward incline, draining anterior-upper segments on both sides (above the nipples), duration 4 minutes with percussion, 1 minute vibration 2- Supine with 45 degrees downward incline, draining anterior-inferior and anterior-middle segments (lingula and right middle lobe) on 2 sides (below the nipples), duration 4 minutes with percussion, 1 minute vibration, 1 minute rest 3- Prone with 45 degrees upward incline, draining posterior-upper segments on both sides (above the 6th thoracic vertebra), duration 4 minutes with percussion, 1 minute vibration 4- Prone with 45 degrees downward incline, draining posterior-inferior segments on both sides (below the 6th thoracic vertebra), duration 4 minutes with percussion, 1 minute vibration, 1 minute rest 5- Right side lying without inclination, draining left lateral segments, duration 3 minutes with percussion, 1 minute vibration 6- Left side lying without inclination, draining right lateral segments, duration 3 minutes with percussion, 1 minute vibration. The total duration of the previous treatment steps will be 30 minutes. At the end, after completing previous steps, the patient is asked to sit down and cough for 1-2 minutes to expel the extracted secretions. If the patient needs to cough while performing the techniques, time is stopped, cough is performed in a sitting position, then he is returned to the drainage position and the rest of the treatment will be continued. Placebo of aerobic exercise : At this stage, aerobic exercises will be done using a motorized stationary bike in two 15-minute sections. Between the two parts, 1-2 minutes of time is taken to rest and drink water. The stationary bike will be adjusted according to the person's height so that the handles are easy to grip. Training will be done in a room with proper temperature and air conditioning, with proper sports clothes and shoes. Throughout the exercise, the heart rate and percentage of arterial oxygen saturation of the patient are monitored by a pulse oximeter. Patients are taught not to hold their breaths during the exercise and to breathe through their nose. In this group, in order to eliminate the aerobic effect of the exercises, based on the method of previous studies, increasing the respiratory demands and breathing ventilation is avoided until the end of the study. For this purpose, a stationary bicycle is used with an electric motor placed on its pedals. As a result, by putting feet on the pedal and turning on the engine, the bike training will be done completely passively. According to the available literature, increasing the intensity of aerobic exercise to 40% of the maximal possible heart rate for each person, in patients with cardio-respiratory diseases, is associated with the beginning of the aerobic effect of exercise. Therefore, to ensure that the aerobic effect of the exercises is minimized, the rotation speed of the pedals will be adjusted so that the heart rate of the subjects does not exceed 40% of HRmax during 30 minutes. How to calculate it for each person will be as follows; Calculation of the maximal possible heart rate for a person according to the formula HRmax = 220 - age, Calculation of the maximal heart rate allowed in training according to the formula target HR = 40% HRmax Heart rate will be controlled by pulse oximeter; therefore, if a person's heart rate is higher than the permissible limit, the speed of the engine is reduced so that his heart rate remains within the calculated range. The total time of the exercises is 30 minutes, and at the end, 1-2 minutes will be given for coughing, if needed. Considerations and trainings of patients between treatment sessions: The medical recommendations of individuals, such as drug treatments and airway clearance methods, which are prescribed under the supervision of a pediatric lung specialist and their omission may harm the patient, will not be changed and will not interfere with the designed treatment. Due to the risk of cross infection, 2 infected patients will not be in the same environment at the same time and will be treated separately, under observation. Before visiting the center, patients are asked to use their 7% sodium chloride nebulizer at home to prepare the airways (softening and moistening the secretions and reducing its viscosity). Patients are asked to visit for 6 weeks, 3 sessions per week, preferably 1 day in between and if the number of sessions is not completed in one week, compensatory sessions will be considered to complete 18 treatment sessions. In case of absence in 3 consecutive sessions or more, the patient will be excluded from the study. It is tried to carry out the treatment sessions at a specific and fixed time of the day, on all days. Patients are asked to refrain from sports activities from one week before the beginning to the end of the study. Instead, during the week before the start of the study, as well as the days between treatment sessions, the active cycle of breathing technique or ACBT, which can be learned from the age of 4, is substituted. This technique will be taught to the patients before the start of the study and they perform it 2 times a day, morning and evening, with at least 1 hour interval from the last meal. Also, in order to ensure that it is done correctly, a training sheet with explanations is given to the patients and one session in every week, ACBT is controlled by the therapist. The steps to implement the technique are as follows : 1- Breathing control: In this phase, the patient sits on a chair, leans back, the soles of the feet are placed on the floor, and keeps the chest and shoulders calm and relaxed. Then, for 20 to 30 seconds, he breathes slowly and fluently, at his desired depth and speed, in order to relax the respiratory system as well as the whole body and reduce the work of breathing. This phase is also used as a rest phase between the active phases of the technique. This form of breathing is done with the lower parts of the chest, and in case of severe

obstruction of airways, respiratory muscles are also used. 2- Chest expansion: in this phase, 3 or 4 deep breaths with a 3-second pause at the end of the breath, then a normal and slow exhalation is done. The purpose of this stage is to increase the lung volume beyond the tidal volume so that the resistance of the airways is reduced and the air is pushed behind the viscous secretions; As a result, it leads to their easier removal. 3- Forced expiration technique (FET): This phase consists of performing 2 huff techniques (high pressure active exhalation with open glottis) followed by breathing control, again, to prevent airway obstruction. In this technique, air is expelled with high pressure and high speed and leads to the production of shearing force; As a result, secretions are removed and pushed upwards. Patients are asked to repeat the cycle 5 times. This will take about 20 minutes. At the end, the secretions that have been removed and pushed up can be expelled by coughing. If needed, a 1-minute rest is allowed between cycle repetitions to prevent fatigue or other symptoms.

Category

Rehabilitation

2

Description

Group B (main treatment of aerobic exercises and placebo of conventional chest physiotherapy): In this group, first the main treatment, i.e. aerobic exercises, and then the placebo, i.e. conventional chest physiotherapy, will be performed. The beginning of the treatment session will be at least 1 hour after the last meal. There is a 10-minute break between the two stages. The duration of the entire treatment session will be about 70 minutes. Aerobic exercise: At this stage, aerobic exercises will be done in two parts, first 15 minutes on the treadmill and then 15 minutes on the stationary bike. Between the two parts of the exercise, 1-2 minutes are given to rest and drink water. First, a 3-minute warm-up with a gradual increase in speed, then 24 minutes of aerobic exercise with a determined intensity (12 minutes on treadmill and 12 minutes on stationary bike), and finally a 3-minute cool-down with a gradual decrease in speed, will be done. The treadmill and stationary bike will be adjusted according to the person's height so that the handles are easy to grip. Training will be done in a room with proper temperature and air conditioning, with proper sports clothes and shoes. Throughout the training, the heart rate and percentage of arterial oxygen saturation of patients are monitored by a pulse oximeter. If there is a sharp drop in oxygen percentage below 85%, the heart rate is disproportionate to the conditions, symptoms of severe shortness of breath or any other warning signs appear, the exercise is stopped. Patients are also taught not to hold their breath during the exercise and to breathe through their nose. During 24 minutes of aerobic exercises, with a treadmill and a stationary bike, the intensity of the exercise will be controlled through the heart rate of patients. Adjusting the intensity of exercises for each person is as follows: 1- Calculation of the maximal possible heart rate for a person according to the formula HRmax = 220 - age 2- Calculation of the range of 55-85% of HRmax, which will be considered as training intensity. This means that during 24 minutes of aerobic training, the patient should do the exercises so that his heart rate stays within the specified range. 3- For the first week, training starts with an intensity of 55-60% of HRmax. In the 3rd session of each week, if there are no signs of shortness of breath during the exercise with defined intensity (saying the number eleven in one section and continuously) and the difficulty of the exercise is in the green range according to the colored visual scale, for the next week, there will be a 5% increase in the intensity of the exercise. Otherwise, the training will be done with the previous intensity for 1 more week. Therefore, the weekly program of increasing the intensity of training will be as follows: First week: 55-60% HRmax, Second week: 60-65%, HRmax Third week: 65-70% HRmax, Fourth week: 70-75% HRmax, Fifth week: 75-80% HRmax, Sixth week: 80-85% HRmax. Increasing the difficulty of training on the treadmill and stationary bike will be by increasing the speed of doing it. The total time of the exercises is 30 minutes, and at the end, 1-2 minutes of time for coughing, if needed, are considered. Placebo of conventional chest physiotherapy: At this stage, to perform postural drainage, in order to remove the effect of gravity, only 2 positions of supine and prone without inclination will be used; the treated areas will be similar to the treated areas in group A. In order to eliminate the effect of manual percussion, these strikes will be done very slowly with a pressure just like touching the skin. In order to eliminate the effect of vibration and vibration’s pressure, hands are just placed on the desired areas and no vibration or pressure is applied during exhalation. The order of the steps is as follows: 1.supine, draining anterior-upper segments of both sides (above the nipples), duration 4 minutes with percussion placebo, 1 minute vibration placebo 2.supine, draining anterior-inferior and anterior-middle segments on both sides (below the nipples), duration 4 minutes with percussion placebo, 1 minute vibration placebo, 1 minute rest 3.prone, draining posterior-superior segments on both sides (above the 6th thoracic vertebra), duration 4 minutes with percussion placebo, 1 minute vibration placebo 4.prone, draining posterior-inferior segments on both sides (below the 6th thoracic vertebra), duration 4 minutes with percussion placebo, 1 minute vibration placebo, 1 minute rest 5.prone, draining left lateral segments, duration 3 minutes with percussion placebo, 1 minute vibration placebo 6.prone, draining right lateral segments, duration 3 minutes with percussion placebo, 1 minute vibration placebo. The duration of 6 steps will be about 30 minutes. At the end of the work, 1-2 minutes are taken for coughing, if needed. Considerations and trainings of patients between treatment sessions: The medical recommendations of individuals, such as drug treatments and airway clearance methods, which are prescribed under the supervision of a pediatric lung specialist and their omission may harm the patient, will not be changed and will not interfere with the designed treatment. Due to the risk of cross infection, 2 infected patients will not be in the same environment at the same time and will be treated separately, under observation.

Before visiting the center, patients are asked to use their 7% sodium chloride nebulizer at home to prepare the airways (softening and moistening the secretions and reducing its viscosity). Patients are asked to visit for 6 weeks, 3 sessions per week, preferably 1 day in between and if the number of sessions is not completed in one week, compensatory sessions will be considered to complete 18 treatment sessions. In case of absence in 3 consecutive sessions or more, the patient will be excluded from the study. It is tried to carry out the treatment sessions at a specific and fixed time of the day, on all days. Patients are asked to refrain from sports activities from one week before the beginning to the end of the study. Instead, during the week before the start of the study, as well as the days between treatment sessions, the active cycle of breathing technique or ACBT, which can be learned from the age of 4, is substituted. This technique will be taught to the patients before the start of the study and they perform it 2 times a day, morning and evening, with at least 1 hour interval from the last meal. Also, in order to ensure that it is done correctly, a training sheet with explanations is given to the patients and one session in every week, ACBT is controlled by the therapist. The steps to implement the technique are as follows : 1- Breathing control: In this phase, the patient sits on a chair, leans back, the soles of the feet are placed on the floor, and keeps the chest and shoulders calm and relaxed. Then, for 20 to 30 seconds, he breathes slowly and fluently, at his desired depth and speed, in order to relax the respiratory system as well as the whole body and reduce the work of breathing. This phase is also used as a rest phase between the active phases of the technique. This form of breathing is done with the lower parts of the chest, and in case of severe obstruction of airways, respiratory muscles are also used. 2- Chest expansion: in this phase, 3 or 4 deep breaths with a 3-second pause at the end of the breath, then a normal and slow exhalation is done. The purpose of this stage is to increase the lung volume beyond the tidal volume so that the resistance of the airways is reduced and the air is pushed behind the viscous secretions; As a result, it leads to their easier removal. 3- Forced expiration technique (FET): This phase consists of performing 2 huff techniques (high pressure active exhalation with open glottis) followed by breathing control, again, to prevent airway obstruction. In this technique, air is expelled with high pressure and high speed and leads to the production of shearing force; As a result, secretions are removed and pushed upwards. Patients are asked to repeat the cycle 5 times. This will take about 20 minutes. At the end, the secretions that have been removed and pushed up can be expelled by coughing. If needed, a 1-minute rest is allowed between cycle repetitions to prevent fatigue or other symptoms.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

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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
Iran 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

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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
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
Data can be shared after making participants unrecognizable.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
All researchers will be allowed to have access to the data, after the permission of the corresponding author.
Under which criteria data/document could be used
Any analysis of the data will be allowed only with the permission of the corresponding author.
From where data/document is obtainable
Email the researcher, Nadia Hamedi, nn00887@gmail.com
What processes are involved for a request to access data/document
6 months after the publication of the results, information

will be given to the applicant within a week by emailing the researcher.

Comments