Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of harmonica playing on pulmonary function in children with Cystic Fibrosis

Protocol summary

Study aim
Determining the effect of harmonica playing on pulmonary function in children with cystic fibrosis

Design
A clinical trial with a control group, with factorial groups, randomized, on 70 patients, for randomization of the same balls that are written inside each of the control or intervention groups and chosen by the child.

Settings and conduct
The study will be conducted at thePulmonary Clinic of the Children’s Medical Center .Demographic data and contact information will be collected for follow-up. Spirometry will measure the dependent variable before the intervention. Participants will be randomized using labeled balls ("intervention" or "control"). The intervention group will perform harmonica and breathing exercises (15 minutes, twice daily for 2 months) with routine airway clearance. The control group will only perform routine airway clearance. After 2 months, follow-up spirometry will be conducted.

Participants/Inclusion and exclusion criteria
The participant with a positive sweat test (chloride value ≥ 60 mmol/L) referred to the lung clinic of the Children's Medical Center Hospital. Children aged 8-18 years. The child should not have experience working with harmonica. Patients who referred for the first time are not included in the study

Intervention groups
In the intervention group, the airway cleaning routine recommended by the doctor along with breathing exercises with the harmonica In the control group, only the airway cleaning routine

Main outcome variables
Variables: first second forced expiratory volume and forced vital capacity Determining and comparing forced expiratory volume in the first second and forced vital capacity before and two months after the intervention in each of the intervention and control groups.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241208063992N1**
Registration date: **2024-12-23, 1403/10/03**
Registration timing: **prospective**

Last update: **2024-12-23, 1403/10/03**
Update count: **0**

Registration date
2024-12-23, 1403/10/03

Registrant information
Name
Hanieh Tavasoli
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-01-04, 1403/10/15
Expected recruitment end date
2025-03-15, 1403/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effect of harmonica playing on pulmonary function in children with Cystic Fibrosis

Public title
Effect of harmonica playing on pulmonary function in children with Cystic Fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The participant must have a positive sweat test (chloride value ≥ 60 mmol/L) (11). Patients with a positive sweat test should go to the lung clinic of the Children's Medical Center. Children should be between the ages of 8-18 years. The child should not have a history of working with an oral instrument. Patients who have been referred for the first time and have recently been diagnosed with a disease and do not have a history of performing airway cleaning routine, will not be included in the study.
Exclusion criteria:
Patients who have a history of playing wind instruments. Patients who present for the first time and have a newly diagnosed disease and do not perform routine airway clearance.
Age
From **8 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Two completely similar marbles, one of which is written for the intervention group and the other for the control group, the child chooses one marble. Based on that, it is determined which group it belongs to.
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
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
No. 66, Jangravi St., Khavaran St
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Approval date
2024-12-07, 1403/09/17
Ethics committee reference number
IR.TUMS.FNM.REC.1403.157

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
Forced exhalation reserve volume in the first second, scientific definition: the amount of air that is forced out of the lungs with pressure in the first second (27). Practical definition: it is a respiratory parameter that is measured in the spirometry test.
Timepoint
Before the start of the intervention, two months after the start of the intervention
Method of measurement
In this study, respiratory factors are measured with a spirometry device made in Austria, Schiller factory, GANSHORN SpiroScout model and a spirometry filter made by Lemon Medical Company. The device is periodically calibrated according to the protocol of the Children's Medical Center hospital.

Secondary outcomes

1

Description
Forced vital capacity, scientific definition. : The volume of air that comes out of the lungs with maximum power after a deep breath (27). Practical definition: It is a respiratory parameter that is measured in the spirometry test.
Timepoint
Before the start of the intervention, two months after the start of the intervention
Method of measurement
In this study, respiratory factors are measured with a spirometry device made in Austria, Schiller factory,

GANSHORN SpiroScout model and a spirometry filter made by Lemon Medical Company. The device is periodically calibrated according to the protocol of the Children's Medical Center hospital.

Intervention groups

1

Description

Intervention group:Before starting the intervention, the dependent variable is based on the routine of the lung clinic before the intervention, in the lung clinic with a model spirometry device.(Schiller, GANSHORN SpiroScout, Austria) will be measured. The spirometry device is periodically calibrated according to the hospital protocol of the Children's Medical Center. In this section, demographic information along with contact number will be collected for follow-up. The steps for conducting the exercises will be explained based on the type of group and provided to the participants in the form of a brochure. If the participant is in the intervention group, the simplest breathing exercise using the harmonica will be individually taught to the participant by the researcher, along with gifting a harmonica. Since children may forget the breathing exercises with the harmonica, an educational video on this subject will be prepared by the researcher and, after approval by a music instructor and the supervisor, will be provided to the intervention group.Learning diaphragmatic breathing is the prerequisite for harmonica training. Children will be taught to stand next to a wall or lie on their back, placing one hand on their chest and the other on their abdomen, ensuring that the chest moves minimally while the abdomen moves maximally. They will begin deep breathing slowly through the nose and exhale through the mouth. According to studies, the inhalation and exhalation in diaphragmatic breathing should take a total of approximately 6 seconds. Therefore, the child will be instructed to inhale for three counts and exhale for three counts. Additionally, the use of the harmonica and blowing and suction exercises will be taught to the child. Training will continue until appropriate feedback is achieved.Necessary instructions about the frequency and duration of harmonica exercises will be given to the child and their caregiver during the sampling session. (Breathing exercises and harmonica practice will be done twice a day, each session lasting 15 minutes, for two months). The duration and daily implementation of the intervention were designed based on two previous studies. Participants will be asked to adhere to home exercises by recording their practice on provided sheets. Furthermore, participants will be requested to send a one-minute audio recording of their harmonica practice to the researcher daily using accessible media.We will remind the child and his family that the oral intervention should be performed in addition to the airway cleaning routine prescribed by the doctor (including respiratory physiotherapy, fumigation therapy, breathing exercise (huffing)) and should not replace the airway cleaning routine.During the 2 months that the child performs the intervention, the researcher encourages the samples to perform the intervention by following up and sending a reminder message. Also, by creating a group and sending voice feedback in the group and creating a competitive atmosphere, the researcher will encourage children to do the intervention continuously. After 2 months, the client will be contacted to go to the clinic to get a spirometry test again and the test before and after the intervention will be compared.

Category

Treatment - Devices

2

Description

Control group: group:Before starting the intervention, the dependent variable is based on the routine of the lung clinic before the intervention, in the lung clinic with a model spirometry device.(Schiller, GANSHORN SpiroScout, Austria) will be measured. The spirometry device is periodically calibrated according to the hospital protocol of the Children's Medical Center. In this section, demographic information along with contact number will be collected for follow-up. The steps of doing the exercises are explained according to the type of group and are provided to the samples in the form of brochures. The airway cleaning routine prescribed by the doctor (including respiratory physiotherapy, fumigation therapy, breathing exercise (huffing)) according to the routine The treatment should be done every day. After 2 months, the client will be contacted to go to the clinic to get a spirometry test again.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Medical Center Hospital

Full name of responsible person
Hanieh Tavassoli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Dr Razieh Masoomi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The researcher herself

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Hanieh Tavassoli

Position
Master's student in pediatric nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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

A piece of data such as information about the main outcome

When the data will become available and for how long

The access period starts 6 months after the publication of the results

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Designing respiratory rehabilitation programs for children with cystic fibrosis. Educating and encouraging parents and nurses to use non-invasive techniques such as music therapy to improve lung function. Conducting further studies and developing similar interventions for other age groups or respiratory diseases.

From where data/document is obtainable

Please Email me :hanietavasoli2024@gmail.com

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

After viewing and reviewing the request as soon as possible

Comments