

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 the Pulmonary 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  $\geq 60$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3373 3994

##### Email address

hanietavasoli2024@gmail.com

##### 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  $\geq 60$  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

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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: 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

##### Street address

No. 66, Jangravi St., Khavaran St

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Tehran

##### Province

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##### Phone

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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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## Person responsible for scientific inquiries

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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**Position**

Master's student in pediatric nursing

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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**