Patient Information Sheet to participate in a research project

(This document will be signed in duplicate, keeping one copy for the researcher and another for the patient)

Study title	Effectiveness of a high-intensity interval training program in children and adolescents with post-infectious bronchiolitis obliterans: randomized controlled trial (PIBOHIIT)
CODE	PIBOHIIT
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CENTER	Hospital Universitario Vall D´Hebrón
SERVICE	Servicio de Unitat de Pneumología. Alergología Infantil i Fibrosi Quística
VERSION	Proyecto PIBOHIIT V3, Date 21/03/2023

Introduction

We are writing to you to report on a research study in which we invite you to participate. The study has been accepted by the Vall D'Hebrón University Hospital. Our intention is that you receive correct and sufficient information so that you can decide whether or not you agree to participate in this study. Before you agree to participate, you need to understand what it consists of. To do this, read this information sheet carefully and we will clarify any doubts that may arise or you can also consult with the people you consider.

Voluntary participation and right to revoke consent:

You should know that your participation in this study is voluntary and personal, that is, you can decide not to participate or change your decision whenever you want. This will not change your relationship with your doctor or change your treatments.

If you decide to participate, we will give you a sheet for you to sign accepting your participation.

If the main researcher or your Doctor believes that the study may be harmful to your health, they will invite you to abandon it, and will give you the necessary explanations.

Finally, once you have finished your participation, you must follow the instructions given by the Doctor to guarantee your safety.

Study Description

We are a team of people from the Respiratory Physiotherapy, Exercise Physiology and Biomedicine Units and a group of doctors from the pulmonology unit of the Vall D'Hebrón University Hospital. We study respiratory diseases well and have long known about the beneficial effect of exercise on health.

Our work consists of investigating physical exercise as a form of treatment for diseases. It has been observed that people suffering from respiratory diseases have low physical capacity or low tolerance to

physical exercise and therefore a decrease in their quality of life due to their respiratory distress. Therefore, one of the stimuli for proposing this project is to carry out a training program with short periods of high-intensity exercises (strong exercise) separated by short periods of low-intensity rest (light exercise). This type of exercise program has been practiced in healthy people and also with other chronic respiratory diseases and has seen an improvement in physical capacity, a greater tolerance to exercise and a better quality of life for the patient. In relation to this training, the short exercise times allow it to be better supported in people with respiratory diseases and at the same time entertained by the different exercises that in this case have. We hope that, should this type of training prove to be effective, these and other post-infectious bronchiolitis obliterans patients will be able to incorporate it into their daily routine in the future.

“There may be some words you don't understand or things you want me to explain better because you are interested or concerned about them. Please, you can ask me to stop at any time and I will take the time to explain it to you."

Objectives: Why are we doing this research?

We ask for your participation in this research project to measure the effects of a training program with short periods of high intensity exercise separated by short periods of low intensity rest in a "telematic" way (behind a computer screen) on the capacity Physical fitness and exercise tolerance, lung function, muscle strength, quality of life, and body composition in patients with post-infectious bronchiolitis obliterans.

Benefits:

It is possible that no direct benefit will be obtained. However, it has been seen that training with short periods of high and low intensity can improve cardiorespiratory fitness, muscle mass, level of physical fitness, and quality of life. In addition, the results may have other benefits for the evolution of the disease and could help other patients through a better understanding of the effects of a physical exercise program.

Study procedures: what will we do?

In this study we want to compare two forms of treatment, for this we must carry out the procedure in two groups: an Experimental Group (GE) and a Control Group (CG). The people who enter each of the groups will be chosen randomly. Your Doctor will not enter into this process. You will have a 50% chance of being in one group or the other.

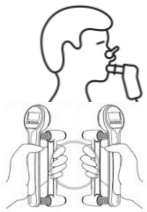
The Experimental Group (GE) will carry out exercises at home guided by a teacher who will show you and tell you what to do and how to do it through a video call on the computer via the Teams platform, official from the Vall d'Hebrón Hospital, the relationship between the person in charge and the person in charge of the treatment. The training consists of a circuit of exercises that you must perform short periods of high intensity (strong exercises) and short periods of rest at low intensity (light exercises).

You will be able to do exercises with your trainer for 16 weeks online 2 times a week (each class lasts between 30 and 40 minutes more or less). During the class there must be an adult present at home, accompanying you in the same space where you are exercising.
The Control Group will continue to carry out the recommendations of its treating Doctor.

Patients who decide to participate in the study must have time to do some initial tests (T1) in order to know their physical and health status, also if you are in the exercise group, teach you in person the exercises that you will do at home, that same day We will give you the materials so that you can carry out the exercises and you will not lack anything (T1: approximately 90-100 minutes). Then 16 weeks of treatment in either of the two groups. Finally, the final tests (T2) (T2: 60-80 minutes approximately). Both the initial and final tests are carried out in an individual appointment at the Vall D'Hebrón University Hospital. The online guided training will be with a maximum of 4 children at the same time who have a level of physical condition, age range and availability similar to yours.
To carry out the exercise classes we need to measure your heartbeat all the time, for this you must use a watch, which can be yours or loaned by us while you are participating in the study. The heartbeat will help us better control the intensity of the exercises to prevent you from feeling bad at any time.

The assessments will be made for both groups at two moments (T1 and T2) and will be as follows:

Incremental effort test to assess cardiorespiratory capacity during exercise on a treadmill using a mask that allows analysis of inspired and expired gases (oxygen and carbon dioxide).



Spirometry test to assess lung function through maximum inspirations and expirations.

Two strength tests to assess the muscular capacity of the lower and upper limbs: (i) for the lower body the test consists of sitting down and getting up from a chair for 30 seconds, (ii) for the upper body the test consists of performing a manual pressure to a dynamometer that measures the force exerted at that pressure.

Two self-reported questionnaires: (i) the first to find out the frequency and type of physical activity that you have done in the last 7 days, (ii) and the second to assess the quality of life through questions about the perception of your state of health with relation to respiratory capacity.

Taking anthropometric variables (height, weight and waist circumference) to assess body composition.

Information on the patient's medical history such as the date of diagnosis, severity of the disease, use of medications, etc.

Discomfort and possible risks derived from your participation in the study:

During the treadmill test, some short-lived symptoms may appear and usually resolve spontaneously such as an abnormal blood pressure response, fainting, and heart rhythm disturbances. The test design is designed to minimize these risks. The intensity of the exercise will be adapted to your age and condition. Therefore, the probability of complications is very low. It should be noted that during the stress test, a constant control of the exchange of gases that you breathe in inhalation and exhalation, oxygen saturation and heart rate is maintained, where the degree of your fatigue is visible.

If for any reason you decide to interrupt the test, your opinion will be respected. All of the possible risks and side effects are the same as those that occur with high-intensity exercise, such as running very fast. Otherwise, the test will be stopped when you are severely fatigued, there is a marked drop in oxygen saturation, or when a level of exertion sufficient for diagnosis is reached. Stress testing is also performed in clinical practice to assess these patients. A training program can carry risks of injury to any joint, although each session will be personalized for each one, it is important that you tell your trainer at all times about any discomfort you feel during or after the session or during the initial or final tests. Not exercising in these patients is at greater risk since a deficient muscle mass can cause more injuries in their own activities of daily living (example: running when taking a bus). We have an emergency team and trained personnel to help you in any emergency. The rest of the interventions, apart from the time spent, do not have any other associated risk or discomfort.

Personal data protection:

Your study physician-investigator will collect your personal information. This information, hereinafter called "data", will be recorded without your name in a data collection form. In all these data collection forms, your name will be replaced by a code. All data collected will be kept confidential. Authorized personnel will enter the data into a computerized database of the promoter. At no time will your identity, including your name, be shown in any work, study report or publication. Your study doctor will maintain a confidential list that matches your name to your code and only authorized people will have access to this list.

Both the sponsor and the center will ensure that the confidentiality of your personal data collected during the study is maintained, in compliance with both national data protection laws and European data protection laws.

We request your authorization for the reuse of the data obtained in this study for future research not related to these objectives. The researchers and the promoter guarantee that the use of your data will always be carried out anonymously.

Implications of the information obtained in the study:

You have the right to obtain a copy of the test reports we have performed on you. If any abnormality that could be important to your health is identified, you will be notified so that your doctor can assess the

decision to carry out an additional examination or treatment in the field of clinical care and outside of this investigation.

Signature of Participant Date: ____/____/____	Signature of Parent/Guardian Date: ____/____/____	Investigator Signature Date: ____/____/____