

INFORMED CONSENT – INFORMATION SHEET

Effects of music therapy as an adjunct to chest physiotherapy in patients with cystic fibrosis.

Before signing this informed consent form, please read carefully the information provided below and ask the questions you consider appropriate.

Background:

Airway clearance techniques used one or twice daily in people with cystic fibrosis are treatments that help these people stay healthy and breathe easier. These chest physiotherapy techniques loosen the thick and sticky mucus, that it is removed coughing or blowing. The airway clearance reduces lung infections and improves lung function.

These techniques require a significant commitment of time and energy for patients and family members, in the case of young children who can not to be actively involved in their own techniques. This is why, even though they are very beneficial, they become a boring routine.

Importance:

We believe that converting chest physiotherapy into a more enjoyable activity for children and family members is very important for its correct management.

This study is a clinical trial without pharmacological intervention where the patients are assigned to one or another study arm at random. We propose that a group of cystic fibrosis children perform their chest physiotherapy routine listening to songs that a musician has composed especially to listen to during the development of this physiotherapy. A second group of children with cystic fibrosis will be proposed to adjunct their chest physiotherapy routine with commercial music chosen by the patient. And in a third study group cystic fibrosis children will continue to perform their chest physiotherapy as usual.

The specific composed music to use as an adjunct to chest physiotherapy has 3 sections, the same sections as your chest physiotherapy routine:

1. Nebulizer treatment
2. Chest physiotherapy work-bronchial clearance
3. Relaxation-nebulization

The two groups that will perform chest physiotherapy listening to music should adapt their usual physiotherapy to music and not the other way around. We just want the music to complement the activity.

In this period, regardless of the group to which you will belong, we will do 3 interviews about your experience in general with chest physiotherapy: before starting, at 6 weeks and at the end of the study. The study will last 3 months.

In addition to the information obtained about the interviews, usual data included in your clinic history will be collected, specifically data related to your pulmonary symptomatology.

Data obtained will be included in a coded anonymous database, being no possible to identify patients. In the reports study your name will not appear, and your identity cannot be known except legal requirement. The study results may be communicated to the health authorities and, eventually, to the scientific community through congresses and / or publications.

During the study, you should continue with your cystic fibrosis usual treatment regimen without modifications. You should know, that participation in this study, will not involve the realization of additional monitoring techniques or any measure that may harm or bother you, or the extraction of extra biological samples, or alterations in treatment and follow-up.

After these 3 months, this therapeutic music will be offered to those patients belonging to the groups that have not used it. If they wish, they will adjunct their chest physiotherapy routine with this music.

Patient implications:

- Participation is entirely voluntary.
- Patients may choose to leave the trial at any time, without explanations and without affecting their medical care.
- Personal data obtained in this study are confidential and will be treated according to the Protection of Personal Data 15/99 Law.
- Information obtained will be used for the specific purposes of this study exclusively.

Patient risks:

This study does not presents risks for patients due to the intervention consists of use the music as an adjunct to usual chest physiotherapy. The intervention not represents an increment in the number of clinic visit to the Unit, nor treatment modifications or usual follow-up.

If you have any questions or require additional information, please contact our staff of the Cystic Fibrosis Unit by telephone: 951292187 or by email: emartinm@uma.es

INFORMED CONSENT – WRITTEN CONSENT FORM**Effects of music therapy as an adjunct to chest physiotherapy in patients with cystic fibrosis.**

I (full name):.....

- I have read the foregoing information (Information sheet)
- I have had the opportunity to ask questions about the study *Effects of music therapy as an adjunct to chest physiotherapy in patients with cystic fibrosis*.
- I have received enough information about the study *Effects of music therapy as an adjunct to chest physiotherapy in patients with cystic fibrosis*. I have spoken with the healthcare professional informant: Dr. Javier Pérez Frías.
- I understand that my participation is voluntary and I am free to participate or not in the study.
- I have been informed that data obtained in this study will be confidential and will be treated according to the Protection of Personal Data 15/99 Law.
- I have been informed that information obtained will be used for the specific purposes of this study exclusively.
- **I would like to be informed about** my genetic and other personal data obtained during this investigation, including any unexpected discoveries that may occur, provided that this information is necessary to avoid serious damage to my health or my biological relatives health.

Yes

No

I understand that I can choose to leave the trial:

- At any time
- Without explanations
- Without affecting my medical care

I am freely accepting my agreement to participate in the project entitled *Effects of music therapy as an adjunct to chest physiotherapy in patients with cystic fibrosis*.

Signature of patient
(over the age of 12)

Signature of parents
(or legal guardian)

Signature of healthcare
professional informant

Full name:
.....

Full name:
.....

Full name:
.....

Date:

Date:

Date:

INFORMED ASSENT FORM FOR CHILDREN/MINORS – INFORMATION SHEET

Effects of music therapy as an adjunct to chest physiotherapy in patients with cystic fibrosis.

Before signing this informed consent form, please read carefully the information provided below and ask the questions you consider appropriate.

Background:

The Doctor Javier Pérez Frías has informed me that in cystic fibrosis children the airway clearance techniques, such as the techniques that I have to be use once or twice daily, help me to breath better and to feel healthier. These chest physiotherapy techniques loosen the thick and sticky mucus, so I can remove it by coughing or blowing. The airway clearance makes I have less lung infections and improve my lung function.

These techniques tend to tire the patient and they consume a lot of time every day, so even though they help you to breathe better they can be boring. We think that turning these techniques into a funnier activity can help you to use them correctly, for example, if you listen to music during the session.

Methodology used in the study:

- How will the study be done?

It will be done with children who like me have cystic fibrosis and do airway clearance techniques every day. Some children will do chest physiotherapy listening to some songs that a musician has composed especially for us. Others children will do chest physiotherapy listening to the music they like and others children will do chest physiotherapy as usual. Children in each group will be chosen "by lots". So, children belonging to group 1 will do the chest physiotherapy listening to the songs that the musician has composed, children belonging to the group 2 will do it listening to the music that he likes and children belonging to group 3 will do it as usual. Children treatments and cares will not been changed.

- What will the interventions consist of?

Children who participate in the study, during their aerosol administration and when they try to expulse the mucus every day for 3 months, will listen to the music that the musician has composed especially for them (if they belong to the group 1), they will listen to the music they like (if they belong to the group 2), and in the case of group 3, children will not listen to music.

The two groups that will perform chest physiotherapy listening to music should adapt their usual physiotherapy to music and not the other way around. We just want the music to complement the activity.

During the study, children should continue with their cystic fibrosis usual treatment regimen without modifications. You should know, that participation in this study, will not involve the realization of additional monitoring techniques or any measure that may harm or bother you, or the extraction of extra biological samples, or alterations in treatment and follow-up. There is nothing new except music.

Patients will answer 3 interviews about how they do chest physiotherapy and how they feel during the routine. The first interview will be before starting, the second at 6 weeks and the third at the end of the study (after 3 months).

When the study finished, the music specifically composed will be offered to those patients belonging to the groups that have not used it. If they wish, they will do their chest physiotherapy routine with this music.

-What data will be collected?

In addition to the information obtained about the interviews, usual data included in your clinic history will be collected, specifically data related to your pulmonary symptomatology.

-Will it pose any risk to the child?

This study does not present risks for you, due to the intervention consists of listening to music during chest physiotherapy. The intervention not represents an increment in the number of clinic visit to the Unit, nor treatment modifications or usual follow-up.

-How will the anonymity of patients be guaranteed?

Data obtained will be included in a coded anonymous database, being your identification no possible. In the reports study your name will not appear, and your identity cannot be known except legal requirement. The study results may be communicated to the health authorities and, eventually, to the scientific community through congresses and / or publications but without your name or personal data.

Patient implications:

- Participation is entirely voluntary.
- You can choose to leave the trial at any time, without explanations and without affecting your medical care.
- Personal data obtained in this study are confidential and will be treated according to the Protection of Personal Data 15/99 Law.
- Information obtained will be used for the specific purposes of this study exclusively.

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(or legal guardian)

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Date:

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