ISRCTN11161411 https://doi.org/10.1186/ISRCTN11161411

Effects of music therapy as complement of chest physiotherapy in patients with cystic fibrosis

Submission date
12/06/2019

Recruitment status
No longer recruiting

Registration date
15/06/2019

Overall study status
Completed

Last Edited
04/11/2020

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
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. 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 be actively involved in their own techniques. This is why, even though they are very beneficial, they become a boring routine. We believe that converting chest physiotherapy into a more enjoyable activity for children and family members is very important for its correct management.

The aim of this study is to develop a music therapy strategy based on the use of specific composed, interpreted and compiled music as an adjunct to chest physiotherapy in cystic fibrosis children and to evaluate its effects.

Who can participate?
Cystic fibrosis children aged from 2 to 17 followed in the Unit of Paediatric Pulmonology at Malaga Regional Hospital

What does the study involve?
Participants will be randomly allocated to one or another study group. We propose that a group of cystic fibrosis children perform their chest physiotherapy routine listening to songs that a musician will compose especially to listen to during the development of this physiotherapy. The 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 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 without modifications on the treatment regimen. The specific composed music to use as an adjunct to chest physiotherapy will have 3 sections, the same sections as children chest

physiotherapy routine in the Unit: Nebulizer treatment, Chest physiotherapy work-bronchial clearance and Relaxation-nebulization. In this period of 12 weeks, regardless of the group to which participants will belong, they will do 3 interviews about their experience in general with chest physiotherapy: before starting, at 6 weeks and at the end of the study. In addition to the information obtained about the interviews, usual data included in clinic history will be collected, specifically data related to pulmonary symptomatology. Data will be included in a coded anonymous database, being no possible to identify participants. After these 3 months, this therapeutic music will be offered to those participants belonging to the groups that have not used it. If they wish, they will adjunct their chest physiotherapy routine with this music

What are the possible benefits and risks of participating?
This music therapy intervention could help to establish chest physiotherapy as a positive routine that could improve its management and its adherence and, therefore, the airway clearance. It could also benefit lung function and improve the children's and family member's quality of life. This study is a clinical trial without pharmacological intervention which is not associated with any specific risk due to the intervention consists of listening to music during chest physiotherapy. The intervention does not represent an increment in the number of clinic visit to the Unit, nor treatment modifications or usual follow-up.

Where is the study run from?
Malaga Regional Hospital, Unit of Pediatric Pulmonology (Spain)

When is the study starting and how long is it expected to run for?
July 2016 to September 2018

Who is funding the study?
Health Department, Andalusian Government (Spain)

Who is the main contact?
Dr. Elisa Martin-Montañez
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PIN-0342-2016

Study information

Scientific Title
Comparing use of specific Therapeutic Music as an adjunct to Chest PhysioTherapy versus commercial music or no music in Cystic Fibrosis children

Acronym
TM_CPT_CF

Study objectives
Significant differences are expected in chest physiotherapy enjoyment and perception, adherence to daily chest physiotherapy, pulmonary symptomatology and quality of life between participants that use specific composed music as an adjunct to chest physiotherapy routine (intervention group), commercial music as an adjunct to chest physiotherapy routine (control group with music), or no music (control group without music).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2016, Ethics in Human Research Committee of Malaga Regional Hospital (Comité de Ética de la Investigación Provincial de Málaga, Servicio Andaluz de Salud, Consejería de Salud, Junta de Andalucía. Hospital Regional Universitario de Málaga. Pabellón A. Hospital General, 7ª planta. 29010 – Malaga; Tel: + 34 951 29 14 47; Email: eticainvestiga.hch.sspa@juntadeandalucia.es), ref: 1016/PIA9

Primary study design
Interventional

Study design
Single centre randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Cystic fibrosis in children with chest physiotherapy prescription

Interventions
This is a randomised control parallel trial involving children with cystic fibrosis from 2 to 17 years old treated at the Paediatric Pulmonology Unit at Malaga Regional Hospital with chest physiotherapy prescription.

The intervention will consist of listening to instrumental music that will be specifically composed, interpreted and compiled to cystic fibrosis children as an adjunct to chest physiotherapy routine (intervention group), commercial music (placebo group) or no music (control group) without modifying the usual treatment regimens or follow-up.
Instrumental therapeutic music will be developed specifically to the cystic fibrosis children from the Paediatric Pulmonology Unit at Malaga Regional Hospital. A professional musician and music teacher of children will compose, interpret, record and edit the therapeutic music, being compiled in an audio-CD finally.
The music-CD will be divided into 3 sections, related to each part of the chest physiotherapy routine followed in this care unit. The chest physiotherapy treatment in the Unit is divided into 3 sections with a total length of about 40 minutes: During the first part, children should be relaxed while the nebulizer inhalation treatment is applied around 10-15 minutes. Next, airway clearance techniques are administered during 20-30 minutes to promote mucus expulsion. Finally, a new relaxation phase of about 5 minutes is proposed, where antibiotic nebulizer treatment is administered if necessary.

Eligible patients will meet all of the inclusion criteria and none of the exclusion criteria. A patient information sheet will be provided for those who fulfilled initial eligible criteria. Those who agreed to participate will be asked to provide written consent and will be recruited.

A baseline questionnaire will be completed after recruitment and 2 evaluation questionnaires after 6 and 12 weeks since the first interview. The questionnaires will be conducted about chest physiotherapy experiences to evaluate the evolution of routine characteristics such as enjoyment and perception or time or adherence to daily chest physiotherapy. The perception of pulmonary symptomatology and the impact on the quality of life will also be evaluated using a visual analogue scale (VAS) to assess the magnitude of dyspnoea in pulmonary diseases such as cystic fibrosis and the revised cystic fibrosis quality of life questionnaire.

A random allocation sequence will be carried out using the Epidat program. The participants will be randomly allocated into the intervention group, placebo group or control group.

The intervention group will use the Music-CD as an adjunct to each part of the chest physiotherapy routine. The audio-CD will be provided after the baseline questionnaire.

The placebo group will use commercial music that participants like as an adjunct to each part of the chest physiotherapy routine.

Control group will continue the chest physiotherapy without modifications.

At the end of the trial, music-CD will be offered to placebo and control participants.

Intervention Type
Other

Primary outcome(s)
1. Children's and family members' enjoyment to chest physiotherapy is evaluated via questionnaire with a Likert scale (-3 to +3): least enjoyment – neutral - most enjoyment. The outcome will be measured at baseline and after 12 weeks.
2. Perception of time taken to complete the routine will be evaluated via questionnaires. Perceived time values given on the questionnaire will be subtracted from actual time values given. These differences will be calculated, and then analysed. The outcome will be measured at baseline and after 12 weeks

Key secondary outcome(s)
1. Chest physiotherapy characteristics are determined using questionnaires at baseline and after 6 and 12 weeks.
1.1. Characteristics are defined as activities used to accompany the routine, such as toys, stories, music, radio and TV.
2. Chest physiotherapy adherence is evaluated via questionnaires at baseline and after 6 and 12 weeks.
2.1. Adherence is defined as routine frequency, the number of times per day, interruptions, length per session.
3. Music characteristics are evaluated via a questionnaire after 12 weeks.
3.1. Music characteristics are defined as the music use frequency, response to the use of music during routine, usefulness of music during the routine, to continue using this music as an adjunct to the routine in the future.
4. The impact on the quality of life is evaluated via questionnaires at baseline and after 12 weeks.
5. Perception of pulmonary symptomatology is evaluated using a dyspnoea visual analogue scale (being 1 no dyspnoea and 7 maximal dyspnoea) at baseline and after 12 weeks.
6. Demographic (age, gender) and clinical information (number of respiratory infection exacerbations that requiring hospitalization and days of hospitalization) are completed by paediatricians during the usual follow-up.

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Diagnosis of cystic fibrosis based on international criteria
2. Children between ages of 2-17
3. Undergoing periodic clinic visits in the cystic fibrosis Unit
4. Understanding the purpose of the study
5. To provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
17 Years

Sex
All

Key exclusion criteria
1. Children without chest physiotherapy prescription
2. Children with severe hearing loss
3. Children at radiologic or clinical risk of pneumothorax or pneumomediastinum
4. Children with barotrauma in the month prior to entry in the study
5. Children with past history of massive or life-threatening haemoptysis
6. Transplant recipients or children awaiting a lung transplant

Date of first enrolment
01/02/2018

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Spain

Study participating centre
Malaga Regional Hospital, Unit of Pediatric Pulmonology
Arroyo de los Ángeles Avenue
Malaga
Spain
29011

Sponsor information

Organisation
Fundación Pública Andaluza para la Investigación de Málaga en Biomedicina y Salud

ROR
https://ror.org/002nw1r81

Funder(s)

Funder type
Government

Funder Name
Health Department, Andalusian Government

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Elisa Martin-Montañez (email: emartinm@uma.es). All of the individual participant data collected during the trial, after being included in a coded anonymous database. Data confidentiality is assured according to the Spanish protection of personal data 15/1999 Law and the basic law 41/2002 that regulates patient autonomy and rights and obligations in terms of information and clinical documentation. Data is available immediately following publication (no end date) to researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals should be directed by email.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/10/2020	04/11/2020	Yes	No
Participant information sheet	version V1	14/06/2019	01/07/2019	No	Yes
Protocol file	version v1	14/06/2019	01/07/2019	No	No