

Protocol

Impact of a Pluridisciplinary Protocol of Respiratory Physiotherapy and Active Music Therapy on Anxiety, Depression and Pain on Lung Post-Transplant Patients (PPRPAM)

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Abstract

Background: Lung transplantation improves survival and quality of life. However, the burden of the lived reality and the direct consequences of the intervention have considerable impacts related to psychopathological disorders. Meta-analyses of clinical trials have shown that music therapy, which is based on the use of the properties of music and sound properties for therapeutic purposes, have an impact on human beings, as it reduces anxiety, depression, and pain. Our hypothesis is that the combination of respiratory physiotherapy and active music therapy using the breathe (PPRPAM) will reduce on anxiety, depression, and pain in lung transplant patients. **Methods:** This study is a monocentre, prospective and non-randomized clinical trial. Within these two years-study, around 40 patients scheduled for mono or bi pulmonary transplant will be included to treatment group, beginning their therapy upon arrival at lung unity (3 sessions per week for 4 weeks). Neurophysiological impacts of active music therapy associated with singing technique and recorder (musical instrument) will support and strengthen the action of respiratory physiotherapy. Our main aim is to assess the benefit of PPRPAM in addition to standard physiotherapy treatment on anxiety, depression and pain under the Hospital Anxiety and Depression Scale (HAD test) and Visual Analog Scale (EVA). **Discussion:** The PPRPAM study will be the first trial aiming to assess the combination of respiratory physiotherapy and active music therapy to reduce anxiety, depression, and pain on lung post-transplant patients.

Key words: respiratory physiotherapy, active music therapy, transplantation, anxiety, depression and pain

Introduction

Transplantation is still the last resource to prolong a patient's life when reaching terminal respiratory failure stages.

Lung transplant improves survival and quality of life compared to medical treatment, at acceptable costs. However, the burden of the lived reality and the direct consequences of the intervention have considerable impacts. Transplanted patients face extraordinary physical and psychological challenges [1-3].

If the quality of life and the long-term prognosis are considerably improved, psychopathological disorders become frequent, mainly those related to anxiety.

High prevalence of psychopathological disorders is reported

by most retrospective and prospective studies. They basically consist on adaptation disorders (depressed mood and/or anxiety), added to the seriousness of the pre- and post-operative somatic reality [3,4].

Quality of life is a multidimensional concept that encompasses medical, social, cultural, psychological and economic factors. It is based on four dimensions: physical state, somatic sensations, psychological state and social status. Regarding the quality of the psychic evolution after transplantation, among the criteria that are usually analysed we find the adaptation to bodily changes and the management of anxiety [5,6].

Postoperative time course is painful due to the thoracic scar,

the spread ribs, the hyper-extensive position in the operating room, and the multiple thoracic drains [7]. Thoracotomies is one of the surgical procedures with the highest risk of causing severe postoperative pain due to nerve damage, chronic neuropathic pain, and immune and inflammatory responses [8].

Meta-analysis of clinical trials has shown that music therapy, which is based on the use of the properties of music and sound for therapeutic purposes, it has an impact on human beings, reducing anxiety, depression, and pain.

Two clinical trials have shown that pulmonary rehabilitation with active music therapy improves respiratory function and reduces dyspnea [9,10]. The concept of active music therapy, which favors sound production and improvisation, is a controlled technique of musical practice for therapeutic purposes. Playing a wind instrument, using vocal techniques and breathing rate modulation techniques would provide additional benefits for respiratory function.

The use of woodwind recorders as an oscillating device which provides resistance to expiration will allow to obtain conditions similar to the treatment carried out by a flutter (device for creating resistance to expiration which improves the evacuation of secretions) [11-13].

Our hypothesis is that the combination of respiratory physiotherapy and active music therapy using breath (PPRPAM) will reduce anxiety, depression, and pain in lung transplant patients.

Study purposes

Main purpose

To evaluate the benefits of a pluridisciplinary protocol in respiratory physiotherapy and active music therapy (PPRPAM) in addition to standard physiotherapy treatment in lung transplant patients on anxiety, depression and pain.

Secondary purposes

To evaluate the benefits of a pluridisciplinary protocol in respiratory physiotherapy and active music therapy (PPRPAM) on

- The evolution of dyspnea.
- The evolution of the quality of life of lung transplant patients.
- The evolution of the respiratory function.
- Exercise tolerance.

Materials and Methods

Study criteria

Main criteria

Evolution of HAD and pain EVA scores between the beginning and the end of treatment in the rehabilitation department.

Secondary criteria

- Difference in the dyspnea score according to the Borg scale before and after the 6-minute walk test (6MWT) between D0 and D28 and also between D0 and D90.
- Evolution of the quality of life score according to SF-12.
- Evolution of the vital capacity (CV) score, the maximal mid-expiratory flow rate (MMF) and the forced expiratory volume in seconds (FEV1).

- Exercise tolerance. Evolution of the difference in respiratory rate (number of breaths/15 seconds) before and after each 6MWT and the improvement percentage in the distance covered in meters and as a percentage of the norm during the 6MWT.

Design

National, pilot, phase II, monocentric, prospective and non-randomized study.

This study falls within the framework of Research Involving the Human Person.

Study population

This study will focus on adult patients under the age of 60 treated at the Louis Pradel Hospital for a recent lung transplant and whose therapeutic management has been optimized.

Screening and inclusion

Patients will be recruited during the pre-transplant assessment through an interview conducted by the physiotherapist, the pulmonologist and/or the transplant coordinator nurse. The patient will have the opportunity to share his response any time during his pre-transplantation stay. Based on recent statistics from the Louis Pradel Hospital pneumology department C, we can envisage recruiting 20 patients a year. The expected duration of inclusion is 24 months.

Inclusion criteria

- Patient between 18 and 60 y.o. (both included).
- Patients who have undergone lung transplant procedures 5 weeks before being transferred to the participating department, which will provide post-transplant follow up.
- Patient who carried out the pre-transplant assessment according to the practices of the reception service.
- Clinically stable patients according to the judgment of the investigator (pulmonologist).
- Patient who has been previously informed of the study and having given his or her consent to participate.

Exclusion criteria

- Alteration in the perception of music according to the judgment of the investigator: musico-genic epilepsies (i.e., convulsive seizures caused by hearing music), hyperacusis (i.e., an abnormally low noise tolerance threshold), dysmusia (music is perceived as an annoying noise), amusia (rhythm, melody, chords of music are not perceived).
- Physical impossibilities to perform the PPRPAM.
- Neurocognitive disorders that do not allow the performance of the PPRPAM, the questionnaires required by the protocol or the functional explorations.
- Dependence on oxygen therapy with a higher flow than 5L of O₂.
- Patients deprived of their liberty by a judicial or administrative decision.
- Patients subject to psychiatric care.
- Patients admitted to a health or social establishment for purposes other than research.

| | Inclusion visit | V0 - Chirurgie | V1 | V2 | V3 |
|-----------------------------------|---------------------------------|---|--|-------------------------|-------------------|
| | Pre-transplant assessment | Transplantation and Intensive Care Unit | Arrival in the post-transplant care department | Discharge from hospital | 3 month follow-up |
| | -6 months/-1 month ¹ | -1 month | D0 | D28 ±3 days | D90 ±10 days |
| Information / non opposition | X | | | | |
| Clinical examination ² | X | | | | |
| Medical history ³ | X | | | | |
| 6MWT ⁴ | X | | | X | X |
| Spirometry | X | | | X | X |
| SF-12 | | | X | X | X |
| HAD test | | | X | X | X |
| Pain score (EVA) | | | X | X | X |
| PPRPMA5 | | | | | |

¹The period between the collection of the non-objection and the transplantation depends on the availability of compatible organs. Similarly, the period between the transplant and the arrival in rehabilitation varies according to the postoperative state of the patient.

²Clinical examination: weight, heart rate, blood pressure, SPO2, respiratory rate (RR), index pathology requiring transplantation.

³Medical history: history of addictions, medical history.

⁴TM6 (6-minute walk test): Borg scale and heart rate (pre and post-TM6), oxygen supplementation, distance in meters and percentage of the norm

⁵PPRPMA: Pluridisciplinary Protocol in Respiratory Physiotherapy and Active Music Therapy: 3 weekly sessions lasting 45 minutes for 28 days.

X Specific to research.

- Patients subject to legal protection measures (guardianship, curatorship).

- Patients participating in other interventional researches including an exclusion period still in progress at pre-inclusion or which may interfere with the results of this research protocol.

Procedures (Table 1)

Experimental protocol

The Pluridisciplinary Protocol in Respiratory Physiotherapy and Active Music Therapy (PPRPAM) will be carried out over a period of 28 days with 3 weekly sessions of 45 minutes each.

Sessions include several stages (respiratory warm-up, active music therapy with a recorder, respiratory recovery, and review of the session) developed by respiratory physiotherapist and a clinical music therapist.

Expected benefits

This study will assess the benefits of respiratory physiotherapy and active music therapy based on breath.

Moreover, psycho-affective and psycho-physiological effects of music and vocal techniques associated with respiratory musculature rehabilitation techniques could reduce patient's levels of anxiety, depression, pain and other symptoms associated with transplantation.

Better adherence to the conventional protocols for long-term post-transplant follow-up should allow better efficacy of the treatment received. The expected public-healthcare benefits is enriching knowledge on the management of lung transplant patients. The evaluation of the effects of active music therapy in

respiratory physiotherapy could lead to its more widespread use in respiratory pathologies.

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Abbreviations

PPRPAM: Pluridisciplinary Protocol in Respiratory Physiotherapy and Active Music Therapy; HAD: Hospital Anxiety and Depressive score; EVA: Visual Analog Scale; 6MWT: six minutes walking test; CV: vital capacity score; MMF: maximal mid-expiratory flow rate; FEV1: Forced Expiratory Volume in first second.

Conflicts of Interest

The authors declare no conflict of interest.

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