

# “Peter Hess sound massage versus Music Care relaxation session for coronary bypass patient’s anxiety and pain’s care in thoracic and cardiovascular surgery: a comparative controlled and randomised study”

**Cardiac surgery patients** often undergo **anxiousness** and **pain**. Before surgery, anxiety is often caused by the idea of sternotomy, extracorporeal circulation, fear of post-operative pain, and even death. After operation, anxiety and pain can be the consequences of operative and peri-operative procedures. **We believe that reducing stress and pain by a relaxation therapy would lead to better stay in hospital and a better recovery after surgery.**

The **Peter Hess sound massage** in a **holistic relaxation technic** (body and mind) that uses **sound vibrations** generated by therapeutic singing bowls. Its **efficiency** (quiet immediate relaxation) and **adaptability** (each sound massage is adapted to the beneficiary’s need) make it a complementary method that can be pertinent for many hospital departments, both for patients and caregivers.

## Protocol summary:

Music Care relaxation technic has already proven with several clinical studies its efficiency for reducing pain and anxiety in hospital. It consists



into listening to an audio relaxing soundtrack of your choice (from 20 to 30min). As both part of music therapy, we will compare these technics. And because the Peter Hess sound massage is not only acting on the brain (like Music Care) but also on the body, we believe that we can have better results. Depending on which group the patient will be, he will receive either a musical relaxation session, or a sound massage. In order to avoid bias, we tried as much as possible to homogenise technics (same timing 30’, single blind design...).

Concerning the sound massages, it will be given into the patient’s bedroom. A **first sound massage** will be given **the night of their arrival**, on a dedicated massage table. On the **second and fourth morning after surgery**, experimental group’s patients will receive a specific sound massage directly on their hospital’s bed. As the method stipulate (one of the base’s principal is to act far from the pain), **no bowls will be placed around the thoracic region**, the method is

## Scientific Team:

### **Pr. Pascal Leprince**

Scientific Director

### **Raphaël Cornet**

Coordinating investigator

### **Dr. Jacques Ropers**

Methodologist and biostatistician

### **Stéphane Guétin** Music

Care creator

### **Mireille Toy-Miou**

Project manager

## Fundings:

**Fond Patrick de Brou de Laurière**

**Fond Apicil**

**Peter Hess Institut**

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focusing on the beneficiary resources, by acting on the mental and by strengthening the healthy part of the body. **Questionnaires** will be filled by patients with clinical research associates' help, in order to **evaluate both method's impact on anxiety and pain**. Data will be then analysed by the biostatistician. We'll finally conclude the study by writing an article that we will publish into specialised press in the medical, therapeutic and maybe wider public field. Due to its focus of interests, the study has already been mentioned by Pr. Gilbert Deray in his book "Choisissez votre destin génétique" ("Choose your genetic destiny") and in september in the tv show called "Télématin", on a national french channel.

- **Design of the study:** Controlled randomized single blind clinical trial / Interventional research protocol implying human being that doesn't involve any health product

- **Hypothesis:** Peter Hess sound massage will lead to a better result than Music Care for reducing anxiety, pain and increase recovery



- **Treatments, strategies and procedures:** Two randomised patient's group
  - 1) Peter Hess sound massage, a relaxation technic using singing bowls' sound vibrations
  - 2) Music Care, a receptive music therapy technic using audio relaxation music diffused in dedicated headphone.

- **Main Objective:** Prove a better efficiency of the Peter Hess sound massage for reducing anxiety and pain compared to Music Care

- **Main criteria:** difference between the two groups on anxiety scores' variation (measured by STAI) between pré-op. visit (J-1) et post op. visit (J+7)

- **Secondary Objectives:**

-> Demonstrate a benefit of the sound massage on:

- 1) Reduction of the level of anxiety measured by the anxiolytics and sleeping drugs administration (prescription, dosage, length)
- 2) Reduction of the level of pain measured by Analog Visual Scale
- 3) Reduction of the level of pain measured by medication (analgesics, anti-inflammatory), and requirement of physiotherapist analgesic care

-> Safety of sound massage measured by blood pressure and cardiac rhythm

-> No difference in routine cares between the two groups, measured by length of hospitalization and adverse events

- **Secondary criterias:**

- State Trait Anxiety Inventory (STAI) variations before and after interventions
- Anxiolytic's consumption measures

- Visual analogic scale for pain
  - Analgesic and anti-inflammatory consumption measures, physiotherapist's need
  - Blood pressure and cardiac frequency delta before and after sound massage
  - length of hospitalisation
  - Case report form about the undesirable effects of the sound massage
- **Population:** 80 patients, divided into 2 groupes, 40 Music Care and 40 Peter Hess sound massage
  - **Calendar:** more or less 12 months from first inclusion
  - **Inclusion criterias:**
    - 1) Patients between 40 and 70 years old
    - 2) Hospitalised for a coronary bypass
    - 3) That has given his written consent
  - **Exclusion criterias:**
    - 1) Urgent surgery
    - 2) impaired ventricular fonction (ejection fraction < 45%)
    - 3) combined surgery
    - 4) patient with chronic dialysis
    - 5) diagnosed with strong chronic depression
    - 6) patient unable to give his consent
    - 7) patient under guardianship or tutelage
    - 8) pregnant women or nursing



Photo taken during the meeting between Peter Hess, Pr. Gandjbakhch (Adicare's president, ex head of the thoracic surgery department) and Pr. Leprince (head of the cardiology center in La Pitié Salpêtrière hospital in Paris)

