Implementation of a Trimodal Prehabilitation Program as a Preoperative Optimization Strategy in Cardiac Surgery and Heart Transplant

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INFORMATION FOR PATIENTS AND INFORMED CONSENT FORM SUB-PROJECT#2, CONTROL.

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INFORMATION FOR PATIENTS AND INFORMED CONSENT FORM.

Research Project: Implementation of a trimodal prehabilitation program as a perioperative strategy in cardiac surgery and heart transplantation

Sub-Project #2: Patients with coronary and/or valvular heart disease undergoing cardiac surgery.

Principal investigators: Dr Graciela Martínez Pallí, Dr María José Arguis,
Center: Hospital Clínic

PATIENT STUDY NUMBER: _____
GENERAL DESCRIPTION OF THE STUDY:

We are inviting you to participate in this study because you are waiting for cardiac surgery. This study aims to investigate if your physical status and level of physical activity are related to postoperative complications and recovery after surgery.

Before you decide whether or not to participate in this study, you must understand the requirements, as well as potential risks and benefits from your participation. In this document you can find information about the study. We ask you to read it carefully. You may not understand some words or phrases on it, please do not hesitate to ask any member of the investigation team for clarifications. If you decide to enrol into this study, we will ask you to sign this document and you will have a copy of it.

Cardiac surgery is a highly complex and stressful procedure for the body. Previous research coming from other types of surgeries suggests that the function of the lungs and heart, as long the level of physical activity before surgery are especially important as they could predict the occurrence of complications after surgery. This is especially important in patients who may have high surgical risk like you.

PURPOSE OF THE STUDY:
This study aims to prove there is a relationship between your cardiorespiratory reserve, your physical activity level and the presence of complications as well as your capacity to recover after surgery.
STUDY PROCEDURES

1. **Purpose of the study:**

The study we are inviting you to participate aim to prove there is a relationship between your cardiorespiratory reserve, your physical activity level and the presence of complications as well as your capacity to recover after surgery.

2. ***What does it mean for me to participate in the study?***

If you agree to participate in this study, your functional status, quality of life, level of physical activity, nutritional and cognitive status will be evaluated by our team at the Hospital Clinic in Barcelona.

Compared to standard clinical practice, your participation in the study involves:

1) The completion of a comprehensive evaluation that aims to measure the capability of your heart and lungs to face surgery. These tests will be conducted at the beginning of the study and will be repeated just the week before surgery:

   a.The walking tests consists of taking a 6-minuts walk that will allow us to evaluate your functional capacity. This test is related to your ability to perform daily activities. The sit-to-stand test is a 30-second test to assess your lower body strength and you will simply need to repeatedly get up and sit down from your chair.

   b. During the cardiopulmonary stress test you will use a device like a stationary bicycle. This is a **non-invasive** test that aims to assess both your cardiovascular and respiratory function at rest and during exercise. During the test you will be pedaling for 8 to 10 minutes on the stationary bicycle. We will monitor and record your heart and respiratory rates as long as other parameters. A doctor will be monitoring you and making sure you perform the test under utmost safety conditions. You will be performing this test twice with different resistance on the bicycle each time. Complications related to this test are minimal and the mortality risk is similar to that reported with other exercise tests. The test will last one hour approximately and does not require hospital admission.

2) We will ask you to complete a health **survey**, as long as questionnaires regarding your psychological state and physical activity level (20 minutes).

3) Nutritional assessment: you will complete a questionnaire regarding your eating habits. This questionnaire will provide us with information about what you eat and how many how many calories, and protein you take from your regular diet. The results will be evaluated by a nutrition specialist.

4) Assessment of your cognitive status: We will assess your cognitive performance (memory, language, reasoning, planning, temporal and spatial location) through **non-invasive** neuropsychological tests (30-45 minutes in total). These tests involve simple questions and tasks (such as remembering some words and numbers). This cognitive assessment is risk-free and does not require hospital admission.

Three months after surgery, we will meet you again to see how you are doing and repeat the assessments you did before surgery to see how you have recovered physically and mentally.

3. ¿ What are the disadvantages and risks of participating in the study?

Your participation in the study will NOT interfere with the waiting time for surgery, which will be similar to the waiting time for other patients undergoing the same procedure as you.

The risk that your experience any heart problems during the walking and the cardiopulmonary stress tests is minimal. A doctor will be monitoring your heart at all times during these tests to ensure that the intensity of the exercise is safe for you.

By agreeing to participate in this project, you are not waiving any of your legal rights or exempting the researchers or the institution from their civil and professional responsibility.

4. What happens if I decide not to participate

Nothing. Your participation is voluntary and free. You may withdraw from the study at any time without affecting your relationship with your doctor.

CONFIDENTIALITY

The processing, communication and transfer of personal data of all participating patients in this study will comply with the provisions of Organic Law 15/1999, of December 13, on the protection of personal data.

The data will be collected in a center research file and will be processed solely and exclusively within the framework of your participation in this study.

If you have a smartphone, it is possible to monitor your physical activity during the period of the program through a device called Nuubo care device nECG. This device, which is place on the chest surface, records heart rate and electrocardiogram during exercise and sends the information to an application on your smartphone via Bluetooth. The data is stored encrypted on a server and only the research team will be able to access this information.

In accordance with what is established by data protection legislation, you can exercise your rights of access, modification, opposition and cancellation of data, for which you must contact your study doctor.
The data collected for the study will be identified by a code and only your study doctor/collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be revealed to anyone except for cases of medical emergency or legal requirement.

Access to your personal information will be restricted to the study doctor/collaborators, health authorities (Spanish Agency for Medicines and Health Products), the Clinical Research Ethics Committee and personnel authorized by the promoter, when they need it to verify the data and procedures of the study, but always maintaining their confidentiality in accordance with current legislation.
Only the data collected for the study will be transmitted to third parties and other countries, which in no case will contain information that can directly identify you, such as name and surname, initials, address, social security number, etc. If this transfer occurs, it will be for the same purposes of the study described and guaranteeing confidentiality.

Patient consent form

Tittle of the study: **Implementation of a trimodal prehabilitation program as a perioperative strategy in cardiac surgery and heart transplantation**

Sub-Project #2: Patients with coronary and/or valvular heart disease undergoing cardiac surgery.

Code: HCB_preHAB_CCV

I, *(participant name and surname)…….....*

- I have read the information sheet that has been given to me about the study.
- I have been able to ask questions about the study.
- I have received enough information about the study.
- I have spoken with: (researcher name) .....
- I understand that my participation is voluntary.
- I understand that I can withdraw from the study:
- Whenever I want.
- Without having to give explanations.
- Without this affecting my medical care.

- In accordance with the provisions of Organic Law 15/1999, of December 13, on the Protection of Personal Data (article 3, point 6 of Royal Decree 223/2004), I declare that I have been informed of the existence of a file or processing of personal data, the purpose of its collection and the recipients of the information.
- I freely give my consent to participate in the study.

Participant signature	Researcher signature
Date: ____/____/____	Date: ____/____/____

I would like you to communicate to me the information derived from the research that may be relevant to my health: □ SI □ NO

Participant signature Date: ____/____/____	Researcher signature Date: ____/____/____