



**Informed Consent Form**

**EFFECTIVENESS OF COMBINED  
AEROBIC AND STRENGTH  
TRAINING IN ACUTE AND  
CHRONIC ADAPTATIONS IN  
PATIENTS WITH HEART FAILURE**

Date: 19/10/2017

## **CONSENT INFORMED FREE AND ENLIGHTENED FOR INVESTIGATION SCIENTIFIC WITH HUMAN BEINGS**

### **Project Title:**

Effectiveness of combined aerobic and strength training in acute and chronic adaptations in patients with heart failure

**Person Responsible for Project:** Professor Helena Santa Clara

**Host institution:** Faculty of Human Kinetics - University of Lisbon

This document, called **Consent, Informed, Free and Clear**, contains important information about the study for which was addressed / a and what to expect if you decide to participate in it. Please read carefully all the information contained herein. You should feel entirely free to ask any question, as well as to discuss with third parties (friends, relatives) the decision of your participation in this study.

### **General information**

The guidelines both European and American, recommend that people with chronic heart failure should join a cardiac rehabilitation program in order to reduce their risk factors as well as to reduce the risk of sudden death, control the cardiovascular symptoms, stabilize or reverse the disease process and improve the psychological state and vocational.

The Center for Cardiovascular Rehabilitation of Lisbon (CRECUL) aims to provide the Portuguese population, especially in the center of Lisbon, with the possibility of integration into a structured program of Community Cardiac Rehabilitation. The objectives of this study will allow to analyze the efficiency of different protocols combined exercise (aerobic exercise and muscle force) in central and peripheral variables such as heart function; arterial stiffness; cardiorespiratory fitness; the maximum force; body composition; functional physical fitness; physical activity and quality of life.

### **How long will my participation last?**

The period provided for participation will be 3 months.

It will be assessed / a in two different times during the three months, distributed on different days of the week: M0) before starting the program CRECUL and M1) 3 months after the start of the program. All assessments will be made in these two moments.

The planned duration of every moment of action is 4 visits: 1 visit to the Hospital Pulido Valente (echocardiogram and maximum effort), 1 visit to the Faculty of Human Kinetics (body composition and physical activity) and 2 visits CRECUL, built during the days of the exercise sessions (arterial stiffness, maximum strength, functional fitness and quality of life).

The exercise sessions will be held 3 times a week (2nd, 4th and 6th days) with an expected duration of each 60 - minute training session.

### **What study procedures will I take part in?**

I will participate for 3 months in a structured exercise program which will include a set of specific evaluations in three different locations: Hospital Pulido de Valente, School of Human Kinetics and Gym of the University Stadium of Lisbon. These assessments are considered to be non - invasive and will be carried out by specialized technicians in each of the parameters to be evaluated. Two of the exams will be subject to the payment of a moderating rate hospital (tests: echocardiography and cardiopulmonary stress test).

*Site of the structured exercise program: CRECUL - Fitness Academy of the University Stadium of Lisbon*

- **Exercise:** will be implemented one of two types of protocols that are being studied in this research project. for 3 months, three times a week (2nd, 4th and 6th) in defined period (morning, afternoon or night) with a duration of 60 minutes each session will be accompanied / a by exercise physiologists that will make the prescription form of exercise progressive and individualized. Before each workout blood pressure and heart rate will be monitored as well as a number of issues related to medication (if it was taken and / or changed) and their physical condition and time of health (signs or symptoms of injuries and malaise) will be performed. They will be placed in the room trunk area electrodes bonded adhesives telemetry ECG monitoring (telemetry NORAV) that will measure heart rate throughout the session as well as the cardiac rhythm through ECG waveform as a way to control and safety of exercise. Each exercise session consists of a warm-up, one component muscular strength which will have number 1 or 3 dependedo force training type to 40-80% of its maximum, an aerobic component comprises a high intensity workout interval of 5 to 10, depending on the type of training, with heights of 2 minutes at high intensity (85- 90% of its maximum) and 1 minutes stopped between levels, and a return to calm. At the end of each session will be monitored again the same blood pressure measurements and heart rate. You will be billed monthly (30 in 30 days) a fee of 20 €, which will have access to physical exercise sessions, changing rooms and parking within the respective EUL.

*Place of evaluation: Hospital Pulido Valente*

- **Cardiac Function:**
  - **Echocardiogram:** An echocardiogram will be performed which is a complementary diagnostic test that is based on the use of ultrasound for static or m and moving images of your heart, heart valves and blood vessels that are close to him. The echocardiogram is used to study morphological and functional cardiac changes. The duration of this test is approximately 20 minutes there is associated a hospital rate moderator € 10.

*Place of assessment: Faculty of Human Motricity*

- **Fitness cardiopulmonary:**
  - **Maximum stress test:** will be avaliad using a proof stress maximum cardiorespiratory responses simultaneous study of the respiratory and cardiovascular systems to a certain effort. For the ECG recording will be placed on the adhesive chest electrodes connected to an ECG recorder 12 leads. The blood pressure measurements will be performed by a clamp connected to the evaluation unit. For cardiorespiratory recording will be used a mask that does not interfere with breathing and can cause discomfort. During the examination, will ride a stationary bike being done periodically and progressively increasing intensity. In this way, it will be increased the effort required to perform the test until at ingir maximum fatigue or other symptoms diagnosed to end the stress test. The total duration of the cycling effort test differs from person to person, however the test itself should last between 8-12 minutes.
- **Body Composition:** the radiological densitometry dual energy absorptiometry (DXA) is a full - body examination, using X-ray (low radiation and short exposure time) with a duration of seven minutes that allows to know the fat mass and content the participant's bone mineral. This technique uses Rx with a low dose of radiation (1-3 $\mu$ Sv / test), much lower than the usual exposure to our natural involvement (5-8 $\mu$ Sv / day) or a chest X R (50-150 $\mu$ Sv / test).

*Place of evaluation: CRECUL - Fitness Academy of the University Stadium of Lisbon*

- **Arterial Stiffness:** measured will be the speed of the pulse wave between a carotid artery and femoral, radial and distal artery. Al lazing V / a supine position, in order to stabilize their blood pressure and heart rate. The technician will find by palpation surface carotid artery, femoral, radial and distal to be removed so the central

pulse wave velocity and peripheral through sensors placed at points located by the evaluator. It will be evaluated also the arterial stiffness of the carotid artery of a trough ultrasound assessment under the same conditions of pulse wave but here with a gel placed on their arteries in the neck area using a transducer and to obtain the image. This s s examination will last for approximately 30 minutes.

- **Functional Physical fitness:** to evaluate the physical and functional autonomy will be applied to battery of tests - Functional fitness test Rikli and Jones (1999). This set of tests was developed to evaluate the main physical parameters associated with functional mobility (strength, endurance, flexibility, agility and balance). The Functional Fitness Test consists of five tests: 1) get up and sit in the chair; 2) sit and reach; 3) sit up and come back to sit down; 4) reach behind the back; 5) 6 - minute walking. All these evaluations will have a duration of 20 minutes.
- **Maximum Strength:** to evaluate the strength will be used to test one repetition maximum (1 RM) to 6 exercises Specific machines for strength training (leg press, leg curl, leg extension, lat pull down, low row and chest press) that are in the University Stadium exercise room Lisbon. After a warm-up will be made the evaluation of 1RM. Performing 1RM will be considered when you can not perform the movement properly more than once. The handgrip will be evaluated by a dynamometer JAMAR digital plus (Sammons Preston, Bolingbrook, IL). It will be assessed on both limbs alternately following the protocol of the American Society of Hand Therapists. According to the protocol, will be sitting with the elbow next to the trunk and flexed at 90° and the wrist and hand in neutral position. There will be 3 attempts in each hand with 90 seconds of rest between repetitions and the results will be taken in kg. After the three attempts in both hands, the highest value will be counted.
- **Quality in Life:** O quiz The to be implemented go to be O Mos Short's Form Health Survey 36 Item v2 (SF-36) with the objective of measuring and evaluating the health status of the participant. The duration of its completion will be approximately 10 minutes.

### **Is my participation voluntary?**

Your participation is voluntary and you may refuse to participate. If you decide to participate in this study, it is important to know that you can quit at any time, without any consequences to you. In case of deciding leave the study, their relationship between professionals of both colleges, School of Human Kinetics and the Faculty of Medicina de Lisboa, will not be affected.

### **What are the possible benefits of my participation?**

By joining this Cardiac Rehabilitation program you will be practicing physical activity on a regular and safe basis. Thus, its associated benefits are many including in reducing the risk of sudden death, control of cardiovascular symptoms, stabilize or even reverse the disease process and improve the psychological and vocational status. Still, they will be delivered individual reports on the examinations previously referred to that already there is also a comparison before and after the proposed exercise protocol. In these reports are presented the values of each of the components with the normative values for their age and gender.

### **What are the possible risks of my participation?**

Behavioral changes during the cardiac rehabilitation process may have some risks. Despite being in a controlled environment, very rarely, physical activity during cardiac rehabilitation can cause associated problems and risks. These problems can be muscle and / or skeletal injuries or even heart rhythm problems. In case of emergency, in this team will always be a doctor and the entire technical team is certified with the training of basic life support with automated external defibrillator and an action plan in case of emergency. The location of the Heart Rehabilitation Center itself is very close to the Hospital de Santa Maria, making intervention in an emergency quick and efficient.

### **Who takes responsibility in the event of a negative event?**

In case of a negative event at the Fitness Academy, participants are assured by an insurance company. Regarding the examinations performed at the Hospital Pulido Valente, before the cardiorespiratory effort test, all participants will have access to a specific informed consent from the Hospital that will cover it at home with a negative event. The assessments to be carried out at the School of Human Kinetics are not associated with possible injuries to practice activity physical.

**Is there coverage by an insurance company?**

Partially, by making registration for CRECUL, participants pay an amount of € 3 insurance sports being covered by insurance the Exercise sessions.

**Who should be contacted in case of emergency?**

In the first session an emergency contact is requested with the following details: name of the contact person, degree of relationship to the study participant and telephone contact.

**How is data confidentiality ensured?**

The results of this study may be published, and your identity will not be revealed. In order to maintain the confidentiality of its records, the project investigator will use codes, which will be protected by individualized access to the resulting database.

**What will happen to the data when the investigation is over?**

The data will be properly processed by the research team of the Exercise and Health Laboratory. Data storage will be the responsibility of this Laboratory.

**How will the results of the study be disseminated and for what purposes?**

The results of the study will be disseminated through the publication of articles in national and / or international journals, without the participants ever being identified. Another means of dissemination of the results will also be through oral and poster presentations in national and international scientific conferences. The main purpose will be to share and add to the scientific community the results of this innovative study so that it can be replicated in several cardiac rehabilitation centers Community policies.

**In case of doubt, who should I contact?**

For any questions related to your participation in this study, please contact the study 's principal investigator: Helena Santa Clara or doctoral study: Vanessa Santos.

Contacts:

**Institution:** Faculty of Human Motricity - University of Lisbon

**Lab:** Exercise and Health

**Web:** <http://www.fmh.ulisboa.pt/>

**Home address:** Faculty of Human Motricity, Estrada da Costa, 1495 - 688 Cruz Broken

## Signature of Informed Consent, Free and Informed

I read (or someone read to me) the present paper and I am well aware of what to expect regarding my participation in the study "The Effect of a Long Term Periodic Exercise Program on People with Cardiovascular Disease: Central and Peripheral Adaptations." I had the opportunity to put all the questions and the answers clarified all my doubts. Therefore, I voluntarily accept to participate in this study. A copy of this form will be provided to me.

\_\_\_\_\_ Date: \_\_\_\_\_  
Name of the participant      Signature of the participant

I certify that I explained to the above participant the nature and purpose of participating in the study, having answered all the questions put to me and witnessing the signature.

I have provided a copy of this form to the participant in this study.

### Subscriptions:

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