



## RESEARCH ON STRENGTH TRAINING IN PATIENTS WITH SEVERE MENTAL DISORDER

INFORMED CONSENT document for Mr. / Mrs. \_\_\_\_\_

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This Informed Consent Form is aimed at men and women who are cared for in one of the following centers: State Reference Center for Psychosocial Care (CREAP), Santos Andrés, Santiago y Miguel Foundation (SASM), ACOVA Association and Rey Ardid Foundation. These people are invited to participate in research on the impact of physical exercise on people with severe mental disorder.

**Main researchers: Sergio Lacamara Cano** (Responsible for Knowledge Management CREAP) and **Loreto Peyró Gregori** (Professor and researcher at the Faculty of Health Sciences of the CEU-Cardenal Herrera University).

The CEU - Cardenal Herrera University, in collaboration with the CREAP, SASM, ACOVA and Rey Ardid centers, are investigating the possible benefits of different forms of physical exercise in people with severe mental disorders. I am going to give you information and invite you to participate in this research. You do not have to decide today whether or not to participate in this research. Before deciding, you can discuss the research with someone you feel comfortable with and trust. There may be some words that you don't understand. Please do not hesitate to interrupt me to ask any questions or words you do not understand, and if you have questions later, you can ask me or the researchers conducting the study, whenever you want.

### PURPOSE OF THE STUDY

There are many studies that support the practice of physical exercise as an effective treatment to address different problems related to the disease you suffer, especially it has significant effects on the quality of life and the symptoms of these people. For this reason, an investigation will be carried out in order to assess the effectiveness of different types of training to improve the symptoms and quality of life of these people.

The investigation will last for about 3 months, during which you will participate in a training plan led by a professional at the facilities of the center to which you belong and within the schedule contemplated in your comprehensive rehabilitation plan, so that you participate in this study will not take longer than the usual time. In addition, three researchers from the CEU - Cardenal Herrera University (Alfara del Patriarca, Valencia) will visit their center to carry out a small assessment of each participant that will be repeated three times, before starting the physical exercise sessions, at the end and six months later for this intervention to end. This assessment



does not contain any invasive techniques, it is not annoying, nor does it pose any risk to your health and well-being. The three evaluations will be identical and carried out by the same people. In order to study the effects of the different forms of physical exercise, we will do four different groups, three of them with a different training, and the fourth will be the control group. The allocation to each group is random, that is, neither we nor you can choose which group to be in since the allocation is done randomly, as if we were tossing a coin.

### RISKS OR SIDE EFFECTS

None of the physical exercises carried out throughout the study will put the health and integrity of the person at risk. The exercises proposed for each type of training will be adapted to the physical condition of each participant to avoid any type of injury typical of physical exercise.

### BENEFITS

If you participate in this research, you will get the following benefits:

- It will improve your physical condition
- It will improve your cardiovascular and cardiorespiratory health
- It will improve your body composition
- You will have a fun time with the rest of the participants

### CONFIDENTIALITY

The information we collect during this research project will be kept confidential. Any information about you will have a number instead of your name, so only investigators will know what your number is, and the information will not be shared or released to anyone outside of the investigation team.

### TO REFUSE OR WITHDRAW

Your participation in this research is completely voluntary. You can choose to participate or not. Whether you choose to participate or decide not to, all the services you receive at your center will continue as normal. You can change your mind later and stop participating at any time even if you have previously stated that you do.

If you have any questions, you can ask them now or later, even after the study has started. If you have questions later, you can contact the following person: **Sergio Lacamara Cano** (963403520 / slacamara@reyardid.org) and **Loreto Peyró Gregori** (96 136 90 00 - 64311 / lpeyro@uchceu.es).

This proposal has been reviewed and approved by the CEU - Cardenal Herrera University Ethical Evaluation Committee, which is a Committee whose task is to ensure that research participants are protected from harm.



## INFORMED CONSENT SHEET

I have been invited to participate in **research on the effects of strength training in patients with severe mental disorders**. I have been informed about the purpose of the study, the risks, and the possible benefits.

I have read the information provided or it has been read to me. I have had the opportunity to ask about it and the questions I have asked have been answered satisfactorily. I voluntarily consent to participate in this research as a participant and understand that I have the right to withdraw from the research at any time without being affected in any way by the medical and psychosocial care I am receiving.

Participant Name: \_\_\_\_\_

Participant Signature: \_\_\_\_\_

Date (day / month): \_\_\_\_\_