

**Effects of 12-week Aerobic Exercise on Arterial Stiffness, Inflammation, and  
Cardiorespiratory Fitness in Women with Systemic LUPUS Erythematosus:  
Non-Randomized Controlled Trial**

**NCT: NCT03107442**

**Document Date: 26/03/2024**

## **INFORMED CONSENT - PATIENT INFORMATION**

Before signing this informed consent form, please read the following information carefully and ask any questions you may have.

**Nature:** In the research project entitled "**EFFECTS OF A PHYSICAL EXERCISE PROGRAMME ON SUBCLINICAL ARTERIOSCLEROSIS AND INFLAMMATION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSIS**" subjects will undergo a physical exercise intervention (brisk walking) adapted to the patient's specific physical condition and characteristics.

**Objective:** Thanks to their participation in the project they will be able to help assess the effectiveness of a physical exercise programme based on brisk walking and will be able to know their general state of health, their level of physical fitness and the best way to minimise the long-term health problems associated with Systemic Lupus Erythematosus, specifically in relation to cardiovascular diseases.

### **Implications for the patient:**

- Participation is entirely voluntary.
- The patient may withdraw from the study at any time, without explanation, and without this having any repercussions on his or her medical care.
- All personal data obtained in this study are confidential and will be treated in accordance with the Organic Law on Personal Data Protection 15/99.
- The information obtained will be used exclusively for the specific purposes of this study.

**Risks of the research for the patient:** There are no risks to the patient.

*If you require additional information you can contact our staff at the "Hospital Universitario Virgen de las Nieves" by telephone at 958020494 or by e-mail: [joseantoniovh@hotmail.com](mailto:joseantoniovh@hotmail.com)*

## **INFORMED CONSENT - WRITTEN PATIENT CONSENT**

**Title: "EFFECTS OF A PHYSICAL EXERCISE PROGRAMME ON SUBCLINIC ARTERIOSCLEROSIS AND INFLAMMATION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSIS".**

I (Name) and  
Surname):.....

- I have read the information document accompanying this consent form (Patient Information).
- I have been able to ask questions about the study "EFFECTS OF A PHYSICAL EXERCISE PROGRAM ON SUBCLINICAL ARTERIOSCLEROSIS AND INFLAMMATION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSIS".
- I have received sufficient information about the study "EFFECTS OF A PHYSICAL EXERCISE PROGRAM ON SUBCLINIC ARTERIOSCLEROSIS AND INFLAMMATION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSIS".
- I have spoken to the reporting health professional: .....
- I understand that my participation is voluntary and I am free to participate in the study or not.
- I have been informed that all data obtained in this study will be confidential and will be treated in accordance with the Organic Law on Personal Data Protection 15/99.
- I have been informed that the information collected will only be used for the specific purposes of the research and that the biological sample obtained (blood) will be destroyed at the end of the study period.
- I wish to be informed of my genetic and other personal data obtained in the course of the research, including any unexpected discoveries that may occur, provided that this information is necessary to avoid serious harm to my health or that of my biological relatives (Yes, No).

I understand that I may withdraw from the study:

- Whenever I want.
- Without having to give explanations.
- Without affecting my medical care.

I freely agree to participate in the project entitled "**EFFECTS OF A PHYSICAL EXERCISE PROGRAM ON SUBCLINIC ARTERIOSCLEROSIS AND INFLAMMATION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSIS".**

*Signature of the patient*

*Signature of the professional informing health professional*

Name and surname: .....

Name and surname: .....

Date: .....

Date: .....