Official title:

PACE - Physical Activity in COPD Using E-Health: Effectiveness of a Personalised eHealth Platform Integrated into Pulmonary Rehabilitation to Increase Physical Activity in Patients with COPD - a Randomized Controlled Trial

Date:

04/12/2024

INFORMED CONSENT FORM

Title of the study: PACE - Effectiveness of Physical Activity Coaching using E-Health in patients with COPD: a randomized controlled trial

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This study is part of PhD project of researcher X, funding by Foundation for Science and Technology (Ref.: X), developed at X, in collaboration with X. The primary goal is to assess whether integrating a mobile application promoting physical activity during and after pulmonary rehabilitation programs can improve the medium-term physical activity levels of individuals with COPD.

The study requires 5 data collection sessions, which will take place at the hospital where you are attending the pulmonary rehabilitation program: before, midway through, and at the end of the program, as well as 3- and 6-months post-program. We will ask you to complete questionnaires covering the following: sociodemographic data, clinical information, technological habits, symptoms, and quality of life. Additionally, you will perform a spirometry and a walking test. Spirometry is a simple test that evaluates the speed and volume of air entering and leaving the lungs by exhaling through a tube connected to a spirometer. The walking test involves walking for six minutes on a flat surface to assess your exercise tolerance. Both tests are straightforward and will be conducted by qualified healthcare professionals to ensure your safety and comfort.

At the end of the session, you will be given an accelerometer to wear discreetly around your waist for 7 days. After this period, the equipment will be collected, and the accelerometer will record your movements to assess your physical activity levels. Data collection sessions will always be scheduled according to your availability.

Participants will be randomly assigned to two groups: one group will participate in a pulmonary rehabilitation program (Group 1); the other group (Group 2) will also participate in a pulmonary rehabilitation program but will receive additional instructions midway through the program to improve physical activity levels using a smartphone application and a smartband (both devices will monitor daily step counts). You will be guided on how to use the equipment. The data collected by these devices will be sent to a healthcare professional who will monitor your physical activity and set individualized goals. You will also receive periodic phone calls from the project researcher to ensure the application is functioning correctly and to address any

questions. Each data collection session will take approximately one hour, and your total participation in the study will last 8 months (2 months for the pulmonary rehabilitation program and 6 months of follow-up).

The study intervention does not interfere with the usual care provided to patients. Assessment moments are incorporated into the regular evaluations conducted for patients participating in pulmonary rehabilitation programs. This study has received ethical approval and authorization from the relevant institutional authorities. Your participation is entirely voluntary, and all information obtained during this interview will remain anonymous and confidential, used solely for research purposes. Your privacy is always assured. You may withdraw from the study at any time without any repercussions.

For further clarification, please do not hesitate to contact:

Researcher's name, E-mail: X, Telephone contact: X

Data Protection Officer: X

Thank you for your collaboration.

Researcher's signature: _____

I hereby declare that I have read and understood this document, as well as the verbal information provided by the individual who has signed above. I have been assured that I may decline participation at any time without any consequences, and data collection will cease from that moment. Therefore, I consent to participate in this study and authorize the use of my data, trusting that it will only be used for this research under the guarantees of confidentiality and anonymity provided by the researchers.

***Yes**, I agree to participate in the study* □ ***No,** I decline to participate in the study* □

If you agree, please fill out the following details:

To be signed and dated by the participant

Participants' name: _____

Signature:_____

Date: _____/_____/_____