Effects of a Physical Exercise Program on the Responses Measured by HIF-1 Related to Ventilatory and Hematological Function in Patients With COPD Resident at 2600 m.s.n.m.

Informed consent

December 2020

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I _____ identified with CC No. _____ issued in the city of _____ declare through this document that I have been invited to participate in a research study called "Effects of a physical exercise program on transcriptional mechanisms of adaptation to hypoxia, in people with COPD residents 2600 meters above sea level. ", whose objective is to determine the effects of a physical exercise program on transcriptional mechanisms of adaptation to hypoxia, in people with COPD residents 2600 meters above sea level. The following is information that is intended to help you decide if you want to participate in this research. Please read it carefully. If you don't understand something, or if you have any questions, ask the researcher.

1. Study Steps:

The study will be developed in four phases: Phase 1. Identification of the behavior of the genetic transcription processes in COPD, Phase 2. Evaluation of the health condition and physical performance, Phase 3. Application of the exercise program, Phase 4. Reassessment of the behavior of the genetic transcription processes by means of a venous blood sample. The total participation in this research is two and a half months.

• Phase 1. Assessment of health condition and physical performance.

An initial medical and physiotherapeutic evaluation will be carried out to know the initial health condition. To know the severity or degree of COPD disease, a test will be performed to measure lung function through a spirometry test (this allows to look at FEV1, FVC and FEV1 / FVC).

Subsequently, the evaluation of global physical fitness will be carried out through the application of the Senior Fitnes Test, a test that has cross-cultural validation in Spanish and in the Colombian population. This test assesses physical fitness by: 1. Evaluation of upper limb strength by Arm curl Test, 2. Evaluation of lower limb strength by Chair Santd Test, 3. 6-minute walk test (6MWT) to evaluate cardiovascular endurance and lung, 4. Back scratch, to assess upper body flexibility, 5. Cahir Sit and Reach, to assess lower body flexibility, 6. Up and Go test, to assess agility and balance dynamic.

• Phase 2: Identification of the behavior of the gene transcription processes in COPD.

For the measurement of gene transcription processes in relation to the measurement of HIF-1, HADC 2,3,4,5,6,7,8, mRNAmEPO, mRNAVGEF; for which, a venous blood sample will be taken by venipuncture with a volume no greater than 45 ml. This process will be carried out by suitable and trained personnel for taking blood samples.

• Phase 3. Application of the physical exercise program.
The physical exercise program consists of 8 weeks of training; 3 sessions per week; each session with a duration of 90 min per session, distributed as follows: warm-up 10 min, core training aerobic capacity or muscle strengthening 45 min, stretching 10 min, cool down 5 min and health education 20 min. The program will be designed according to your basic physical conditions.

• Phase 4. Reassessment of the behavior of the genetic transcription processes.
At the end of the 8 weeks of physical training, the genetic transcription processes will be reevaluated, by means of a venous blood sample by venipuncture with a volume no greater than 45 ml. This process will be carried out by suitable and trained personnel for taking blood samples.

2. Assignment of their participation to research groups.
The assignment of their participation to a research group will be carried out taking into account the degree or commitment of their chronic obstructive pulmonary disease (COPD) and in accordance with the Global Initiative for Chronic Obstructive Pulmonary Disease "(GOLD report 2019) (1) ; for which, a pulmonary function test using spirometry will be performed in the physical examination. Before starting the intervention, you will be given 5 questionnaires, which we hope you will answer as honestly as possible. If you do not understand any questions, do not hesitate to ask the person on the research team that accompanies you. The completion of these questionnaires will be carried out in the physical evaluation session in a time of 20 to 30 minutes.

3. Benefits of participating in the study
You will receive a physical exercise program that will benefit your tolerance to fatigue, your functional independence and therefore your quality of life. This physical exercise program will be planned according to your basic physical conditions, which makes it a safe and efficient program to improve your physical performance. Additionally, this program has relevant educational aspects for your health care, which will allow you to understand your illness and the most important aspects for your own self-care. On the other hand, with your participation in this research you will support the development of new knowledge about Chronic Ostructive Pulmonary Disease (COPD) that promotes a better intervention to other people with this health condition. You will not be paid for your participation in this study, only travel expenses will be covered.

4. Risks of participating in this study
The activities to be developed in this research are routine processes in the intervention evaluation of COPD; Therefore, all activities have academic and scientific support, which guarantee the greatest security for their participation. The researcher has professional and postgraduate training that guarantees knowledge about each process to be carried out; Likewise, he has work experience in the development of physical exercise programs in COPD.

Risks presented during spirometry: Presented as possible momentary complications related to cough attacks, bronchospasm, chest pain, feeling of dizziness and urinary incontinence. (infrequent complications and outpatient management). Management

method: Initiation of oxygen therapy until SaO2 is ≥90%, feedback maneuvers of the respiratory cycle and respiratory pharmacological management with doses previously prescribed to the person.

Risks presented during venipuncture: Post-puncture pain, bruising, phlebitis and venous thrombosis. (Common complications compared to venipuncture. They are manageable on an outpatient basis). Management method: Removal of the tourniquet and extraction of the puncture needle, cold compresses and elevation of the puncture limb, application of topical NSAIDs.

Risks presented during the measurement of physical qualities or the execution of the physical exercise program:

• Exacerbation of COPD without respiratory failure with polypnea 20-30 / min, without use of accessory respiratory muscles, without altered mental status, without hypoxemia. Management method: Start nasal cannula oxygen therapy until a target level of SaO2 is ≥90%, feedback maneuvers of the respiratory cycle, constant monitoring.
• Exacerbation of COPD with non-life threatening respiratory failure, polypnea> 30 / min, use of accessory respiratory muscles, respiratory traces and moderate hypoxemia without altered mental status. Management method: Start of Venturi mask oxygen therapy until a target level of SaO2 is ≥90%, feedback maneuvers of the respiratory cycle, constant monitoring, respiratory pharmacological management with inhaled bronchodilators, anticholinergics and glucocorticoids according to medical formula.
• Moderate-severe exacerbation with life-threatening respiratory failure, polypnea> 30 / min, use of accessory respiratory muscles, expiratory draws, altered mental status, hypoxemia that does not improve with oxygen administration. Management method: Start of high flow oxygen therapy (Ambu - anesthesia mask) until reaching a target level of SaO2 is ≥90%. Start basic CPR if required, respiratory pharmacological management with inhaled bronchodilators, anticholinergics and glucocorticoids according to medical formula, referral to the nearest hospital.

5. Confidentiality and privacy of files and anonymity.
Only the research team can review the information provided as a result of this project. In order to maintain anonymity, each of the completed questionnaires will be coded and you will not have to enter your name. The results of this study will be published academically, but information that can personally identify you or your family member will never be included.

6. Voluntary Participation
The decision to participate in the research is completely voluntary; Therefore, you will not receive any financial benefit from participating, and refusal to participate will not lead to difficulties. Similarly, you must understand that you are free to withdraw at any time without negative consequences. During the time you participate in the research, you have the freedom to refuse to answer any question that causes you discomfort or, if you decide, you can withdraw from the study at any time, without affecting the medical care of your family member, or any activity of everyday life. When you do not

understand a question, you have the possibility to request clarification, receiving the necessary information.

Taking into account the above, you voluntarily agree to participate in this research:

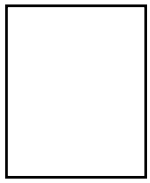
NAME _____

FIRM_____

IDENTIFICATION DOCUMENT _____

DATE: _____

FOOTPRINT:



Witness

NAME _____

FIRM_____

IDENTIFICATION DOCUMENT _____

DATE: _____

FOOTPRINT: