INFORMED CONSENT FORM

OFFICIAL TITLE: Effects of a Single Maximal Exercise Session on the Metabolic Function of Physically Inactive Young Adults

BRIEF TITLE: Single Maximal Exercise Session and the Metabolic Response of Physically Inactive Young Adults (EASY-Study)

NCT number: unavailable

November 4th, 2024

Universidad Austral de Chile
Conocimiento y Naturaleza

Faculty of Medicine
Institute of Musculoskeletal System and Rehabilitation

PARTICIPANT INFORMATION DOCUMENT AND INFORMED CONSENT FORM

This Informed Consent form is addressed to men and women who are kinesiology students at the Universidad Austral de Chile and who are invited to participate in the research entitled: "Influence of blood lactate on plasma concentrations of fibroblast factor 21 in physically inactive people."

Principal Investigator: Klgo. Dr. Sergio Martínez Huenchullán

Organization: Universidad Austral de Chile

- **This Informed Consent Document has two parts:**
- **• Information (provides information about the study)**
- **• Consent Form (to sign if you agree to participate)**

You will be given a copy of the complete Informed Consent Document.

PARTE I: Information

I am Sergio Martínez Huenchullán, I work for the Universidad Austral de Chile. We are doing research on the metabolic effects of exercise, particularly in a context of physical inactivity and obesity, conditions that are very common in this country. 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 you decide, you can talk to someone who feels comfortable about the research. There may be some words that you do not understand. Please stop me as I inform you to give me time to explain. If you have questions later, you can ask me, the doctor doing the research, or members of the team.

Purpose

Physical inactivity corresponds to a condition in which people do not meet the minimum criteria for spontaneous physical activity. This is defined as performing less than 150 minutes/week of moderate-intensity physical activity or 75 minutes/week of vigorous physical activity. Being physically inactive predisposes people to developing metabolic and cardiovascular diseases in the future, which is why physical exercise is recommended to prevent them. In this sense, it is known that exercise promotes the production of mediators that promote health, even in

physically inactive people. In this regard, although it is known that physical exercise is beneficial, the mechanisms by which these benefits are generated are not clear, so the objective of the study aims to have a better understanding of the effects of an exercise session in physically inactive people.

Type of Research Intervention

This research will involve 1 exercise session on a day and time to be agreed upon between you and the research team. Before starting the exercise session, clinical measurements (such as weight and height) will be taken, as well as a venous blood sample taken from your arm, a procedure that will be performed by someone trained to do so. The exercise session will be performed on a stationary bicycle, where you will start with very low loads and minute by minute the load will be increased according to your capacity. After completing the exercise session, blood will be taken again, in order to investigate what changes occurred with the exercise.

Participants selection

We are inviting all students from the Universidad Austral de Chile, who are between the ages of 18 and 30 and who are physically inactive.

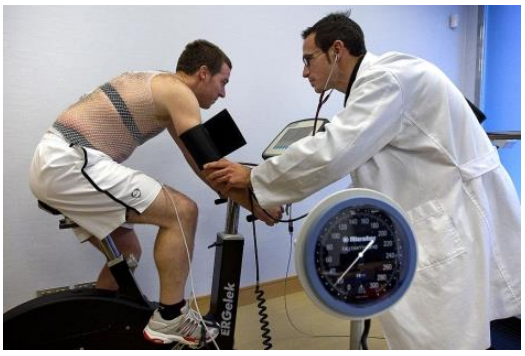
Voluntary participation

Your participation in this research is completely voluntary. You may choose to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed before.

Procedure and protocol

As part of this study, we will ask you to perform some physical tests, answer a questionnaire, and we will also need small samples of venous blood (5 ml).
The different tests are explained below:

1. **Cardiorespiratory fitness (exercise tolerance)**: Here we will ask you to pedal on a stationary bicycle (cycle ergometer) in a test that will gradually increase in difficulty. This test ends when you feel fatigued and unable to continue, so you will have control



over the test. Your vital signs (pulse and blood pressure) will be constantly measured to ensure that you are performing the test safely. In addition, the bicycle has safety handles, which you can hold on to at any time.

2. **Anthropometric measurements:** Your weight, height (stature), along with your waist and hip circumference (perimeter) will be measured to characterize your body shape.

3. **Body composition:** Here we will ask you to stand in an instrument called a bioimpedance meter, which can indirectly measure the amount of muscle and fat you have in your body. Here you will not feel anything at all while the instrument is working. The measurement takes 2 to 3 minutes.

4. **Spontaneous physical activity:** To measure the amount of spontaneous physical activity you do, we will ask you to answer a 7-question questionnaire, which will focus on asking you how much time, during the past week, you did vigorous, moderate, and light activities, as well as how much time you spent sitting.

5. **Venous blood sampling:** Before and after the exercise session, a venous blood sample will be taken from your arm. This will be used for laboratory tests to identify the effects of exercise on you. Here, two tubes of blood will be taken, one with anticoagulant (to obtain plasma) and one without anticoagulant (to obtain serum). The amount of blood to be obtained will be a maximum of 10 ml, or 2/3 of a tablespoon.

6. **Blood glucose and lactate measurement:** These will be assessed using portable devices that require only a drop of blood from one of your fingers through a sterile lancet.

Process description

1. During the investigation, you will make 1 visit to the Human Movement and Occupation Sciences Building, located at Rudloff 1650, to perform the tests that I have just explained to you.
2. 1. Upon arriving at the Building, and particularly at the Exercise Physiology Laboratory, you will sit down for 10 minutes, and then your vital signs will be taken at rest.
3. 2. Afterwards, venous blood will be taken in two tubes, one with EDTA and one without anticoagulant, for the laboratory tests. It should be noted that these tests will be performed by the Clinical Laboratory (LABOCLIN) of the Universidad Austral de Chile and by the principal investigator, Klgo. Dr. Sergio Martínez Huenchullán. In addition, blood glucose and lactate levels will be taken at rest or pre-exercise.
4. 3. Then, the stress test will be performed, in which your vital signs will be monitored minute by minute (pulse oximetry and heart rate), while blood pressure will be measured every 3 minutes.
5. 4. Once you reach a significant level of fatigue, the test will be stopped, and immediately afterward, blood samples and post-exercise blood sugar and lactate measurements will be taken again.
6. 5. Then, a recovery phase will begin in which your vital signs will continue to be monitored for 5 minutes, or until the levels observed before exercise have been reached.

Length

The research will last 1 hour in total. During this time, you will be required to come to the Human Movement and Occupation Sciences Building for one day only, for 1 hour. At the end of this time, your participation in the research will be terminated.

Secondary effects

These procedures may have some unwanted effects. They may make you feel tired and may cause physical or mental discomfort. It is possible that they may also cause problems that we are not aware of. However, we will monitor you and keep a record

of any unwanted effects or problems. If necessary, we will request medical evaluation if we encounter problems or unwanted effects.
If this is necessary, we will discuss it with you and you will always be consulted before proceeding to the next step.

Risks

By participating in this research, you may be exposed to a greater risk than if you did not participate. For example, there is a risk that you may experience muscle and/or joint pain associated with the tests or the physical exercise session. However, it is expected and normal for these discomforts to begin to subside after 48 hours of performing the physical effort. If this does not happen, we will request medical assistance to resolve your symptoms in the best possible way. In addition, it is possible that bruising may appear in the area from which the blood samples are taken. We will minimize this possibility by having professionals perform this procedure. However, if there are complications with this procedure, we will request the corresponding medical assistance.

Possible discomfort

When participating in this research, you may experience discomfort such as having your blood pressure taken several times or having your veins punctured, in addition to muscle and joint discomfort associated with the physical effort of the tests and exercise to be performed.

Benefits

If you participate in this research, you will have the following benefits: the laboratory tests that will be performed as part of the research (e.g.: lipid profile, transaminases, insulin, blood sugar and lactate) will be paid for by the study, so it will be free for you.

Incentives

This study does not contemplate monetary incentives for participants.

Confidenciality

With this research, something out of the ordinary is being done in your community. It is possible that if other members of the community know you are participating, they may ask you questions.
We will not share the identities of those who participate in the research. The information we collect for this research project will be kept confidential. Information about you that is collected during the research will be kept secret from anyone but

the researchers. Any information about you will have a number instead of your name. Only the researchers will know what your number is, and the information will be kept in a locked cabinet. It will not be shared or given to anyone.

Results sharing

The knowledge we gain from conducting this research will be shared with you before it is made available to the public. No confidential information will be shared. There will be small community meetups and these will be announced. After these meetups, the results will be published so that other interested people can learn from our research. However, your identity will never be disclosed.

Right to refuse or withdraw

You do not have to take part in this research if you do not want to. You can stop participating in the research at any time. It is your choice and all your rights will be respected.

Who to Contact

If you have any questions you can ask them now or later, even after the study has started. If you want to ask questions later, you can contact:

Sergio Martínez Huenchullán
Rudloff 1650, Valdivia
Phone: +56962859896
Email: sergio.martinez@uach.cl

This proposal has been reviewed and approved by the Scientific Ethics Committee of the Valdivia Health Service, which is a committee whose task is to ensure that research participants are protected from harm. If you wish to find out more about this committee, please contact the Committee President, Mr. Carlos Fernández Vega, at 63 228 1784.

PART II: Consent Form

I have been invited to participate in research into the effects of an exercise session on blood and clinical markers in physically inactive individuals.
I understand that I will be required to perform a physical exercise session for 1 day. I have been informed that the risks are minimal and may include only muscle and joint pain and bruising at the sites where blood samples are taken. I am aware that there may be no benefit to me and that I will not be compensated beyond the costs associated with laboratory tests. I have been provided with the name of a researcher who can be easily contacted using the name and address given to me of that person.

I have read the information provided or it has been read to me. I have had the opportunity to ask questions about it and have had my questions answered satisfactorily.
I voluntarily agree to participate in this research as a participant and understand that I have the right to withdraw from the research at any time without it affecting my medical care in any way.

Participant's name: _____

Signature: _____

Date: _____
Day/month/year

If you are illiterate

I have witnessed the accurate reading of the consent document to the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has freely given consent.

Witness' name: _____

Signature: _____

Date: _____
Day/month/year

I have accurately read or witnessed the accurate reading of the informed consent document for the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has freely given consent.

Researcher's name: _____

Signature: _____

Date: _____
Day/month/year

Name of the Director of the Establishment, delegate or Minister of Faith:

_____

Signature: _____

Date: _____
Day/month/year

A copy of this Informed Consent document has been provided to the participant _____ (investigator/assistant initials)