

Informed Consent

Dear Participant:

The Catholic University of Maule is conducting a research project entitled "Physical Exercise and Nutrition Program for Improving Health Determinants in a Population Working Under Intermittent Hypobaric Hypoxia," developed by Researcher Jorge Torres Mejías as part of his Doctoral Thesis project, funded by the ALMA Observatory and the Andean Research Center for Geographic Altitude (CIAAG). This document aims to inform you about the details of the study and request your informed consent to participate.

1. Research Objective

To evaluate the effect of a physical exercise and nutrition protocol on the determinants of aerobic capacity, body composition, glycolytic metabolism, gut microbiota, sleep quality, and quality of life of workers exposed to intermittent hypobaric hypoxia, after two weeks of intervention.

2. Brief Project Description

High-altitude areas generally have low humidity, significant temperature fluctuations between day and night, and lower partial pressure of oxygen, which is the main factor in causing altitude sickness.

Due to the harsh geographical conditions where this radio telescope is located and the constantly changing environment in which the workers operate, understanding the level of physiological stress is crucial to improving the health and quality of life of workers exposed to intermittent hypobaric hypoxia. The initial days of general malaise, which can be felt at the start of a work shift—headaches, fatigue, and stomach upset—are of particular interest. These are some of the questions that our research team has been exploring with ALMA staff since 2018, and which we intend to continue investigating to develop strategies for mitigating the challenges of adapting to high altitude and low oxygen pressure. This research aims to improve the quality of life for those who live, visit, or work in hypoxic conditions. Intermittent hypobaric exposure.

3. Methodology

A battery of tests will be performed on each individual who agrees to participate in this research and signs the informed consent form. The tests will be conducted in the following order:

Stage 1: Initial Assessment

A complete nutritional assessment will be performed, consisting of determining weight, height, and body composition (for the latter, you must fast for at least 4 hours).

At this same time, members of the research team will administer two surveys to determine your quality of life and sleep quality.

To complete this first stage, you will be given two new containers for fecal samples. You will be asked to collect a small 50-gram sample of your own stool on the first day of exposure to altitude and a second sample on the last day of your work shift.

Physical Examinations: After settling into your respective rooms and having eaten at the observatory, you will be asked to go to one of the facility's gyms wearing comfortable athletic clothing. There, you will undergo two short physical tests and have three pieces of scientific equipment fitted, which you will need to keep on for two

weeks. First, a chest heart rate monitor will be fitted using an elastic band around your chest. This will connect via Bluetooth to your cell phone using the Polar Beat app (a free app that we will ask you to download to your phone).

Second, an accelerometry device will be fitted using an elastic band around your hip. This device should be worn under your clothing and adjusted to the iliac crest.

Finally, a patch will be applied to the triceps of your non-dominant arm. This patch will remain in place for 15 days and will be removed when you return to work. Along with this, you will be asked to install a free mobile application (Freestyle Libre), which will record your glucose readings. (Estimated equipment installation time: 15 minutes)

After the equipment is installed, you will perform a step test (modified Queens box), where you will step up and down a 20cm high step for 6 minutes. (Estimated test duration: 15 minutes)

Following the installation of the reading equipment, a step test (modified Queens box) will be performed, where you will have to step up and down a 20cm high step for 6 minutes. (Estimated test duration: 15 minutes). Once this test is completed, a record of the maximum weight your body can lift (1RM calculation) will be made for exercises targeting pectoral muscles (bench press), quadriceps (leg press), biceps (biceps curl), and gastrocnemius muscles (calf raises). (Estimated time for this set of exercises: 30 minutes).

Stage 2: (Second Evaluation)

In this second stage, which will take place on the last day of your work shift, the nutritional and physical exercise evaluations will be repeated, and a second stool sample will be requested.

Stage 3: (Final Evaluation)

Upon returning to a new work shift, you will be asked to complete the nutritional assessments, 24-hour recall survey, and provide a new stool sample from that day.

4. Your Participation in the Study

Your participation in this study is free and voluntary. You may request to be excluded from this research and that your contributions not be considered in this study without prior justification or detriment to you.

If you participate in this research, you do so with your express informed consent, which you sign and authorize.

5. Confidentiality

The confidentiality of your identity will be protected by the following measures:

1. Information and data collection forms will be anonymous, and only the principal investigator will have access to the data provided.
2. Interviews will be assigned a code for each participant, which will only be known to the principal investigator of this study. Interviews will be conducted in a conducive environment that encourages communication and anonymity, chosen by the participant.

In the overall data analysis, a coding structure will be used to identify the information obtained, its relevance to the instrument, and the time it was collected. Given the nature of the study, the data will only be used in academic research and for the dissemination of research findings.

In the presentation of results, coded names will be used, and any possible identifying information, such as locations, institutions, security personnel, etc., will be withheld.

Furthermore, the Principal Investigator assumes a commitment to confidentiality to protect the identity of all those involved in this study.

6. Benefits

This study does not offer you any direct benefits. Therefore, your participation does not generate any financial or other type of incentive. It is also important to note that your participation in this study is free of charge, as the Principal Investigator will come to your preferred location to collect the data.

In this sense, we believe that the research produces more indirect benefits for its participants, as it will allow them to reflect on and perhaps holistically understand important aspects of intercultural communication in work environments. Along with this, a generalized report of the research results will be provided to the administration of your workplace, taking care not to mention any of the study participants or provide any data that could identify them.

7. Risks or discomforts associated with participation

If any controversy, discomfort, or question arises as a result of any physical test, intervention, or reflection during your participation in the data collection, the Principal Investigator will endeavor to provide emotional support and the necessary assistance to the participant.

8. Storage and safeguarding of information

All information collected for this research will always be safeguarded and under the care of the Principal Investigator, who will designate a locked locker in their office where all documents related to this research will be stored.

Interviews, surveys, and data collection, as well as associated transcripts, will be conducted solely by the Principal Investigator. All electronic materials will be properly stored and backed up on the investigator's password-protected computers.

Both this consent form and any printed documents generated and required for use will be stored for five years from the end of the study. After this period, they will be confidentially disposed of.

9. Access to Research Results

Participants may access the information they have generated at any time during the project by requesting it from the Principal Investigator, who agrees to cooperate and propose methods for such access.

Asimismo, el Investigador Responsable se compromete con cada participante a enviar el informe de investigación que se genere al final del estudio a los correos electrónicos respectivos, así también copia de los artículos científicos que pudieran resultar del estudio.

10. Commitment

By accepting this agreement, participants commit to:

1. Providing truthful information whenever requested and responding according to their understanding, knowledge, and experience, as well as using their natural language when writing, responding, or reflecting.

11. Contact

If you have questions about your rights as a participant in this study, complaints, or concerns about this research, please contact the Principal Investigator, Jorge Torres Mejías, by phone at +56954043713 or by email at Jorge.torres.mejias2@gmail.com, or the Chair of the Scientific Ethics Committee of the Catholic University of Maule, Dr. Ivana Leao Riveiro, by email at ileao@ucm.cl.



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I declare that I am aware of the terms of this informed consent, the objectives of the research, the forms of participation, the costs and risks involved, and the procedures for accessing and safeguarding information produced during the study. I acknowledge that the information I provide during this research is strictly confidential and anonymous. Furthermore, it will be used solely for scientific dissemination purposes.

I have been informed that I can ask questions about the project at any time and that I can withdraw from it whenever I choose, without having to give explanations or suffer any consequences for such a decision.

Participant's Full Name:.....

Email:

Participant's Signature

Principal Research
Jorge Torres Mejías
Universidad Católica del Maule

It is hereby noted that this document (informed consent) will be signed in duplicate, with one copy remaining with the principal investigator and the other with the participant.