Title: Strength Training in Hypoxia to Improve Bone and Cardiovascular Health of Elderly

NCT number: *not yet assigned*

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INFORMED CONSENT

The aim of this document is to give you information and invite you to be part of this research: "STRENGTH TRAINING IN HYPOXIA TO IMPROVE BONE AND CARDIOVASCULAR HEALTH OF ELDERLY". This investigation will be developed in the Faculty of Sport Science in Caceres (University of Extremadura) by the research personal of GAEDAF.

STUDY PROTOCOL AND DURATION

The objective of this investigation is to analyse the effects of of different methods of strength training combined with conditions of normobaric hypoxia on the bone and cardiovascular health of the elderly.

Volunteers will be subjects to a training programme of strength during 24 weeks, with a frequency of 3 days per week. Circuit training or whole-body vibration training will be developed in normoxic or hypoxic conditions (depending of assigned experimental group). Different testing will be development before and after training programme: body composition evaluation and bone densitometry; functional capacity evaluation (strength, flexibility and endurance), as well as the blood sample extraction to glucose, triglycerides, cholesterol (total, HDL and LDL) and bone remodelling, inflammatory and endothelial marks analyses. This sample will be used only with non-profit research purpose.

RISKS

Possibility of risks happening is very low and these could be associated risk to any physical activity, such as fatigue or others symptoms related to previous diseases.
On the other hand, regarding to blood sample extraction, sterile disposable material will be used and health personnel will control entire procedure. Any detected incompatibilities between volunteer and activity programme will be communicated and subsequent trials or activities will be suspended.

COST

Your participation in this research is entirely voluntary and you will not be given any economic incentives.

BENEFITS

If you wish, we will inform of your global results through a confidential results inform. Furthermore, we estimated that your participation of this programme could be had short- and long-term benefits on different parameters that may help you to prevent and/or treat some bone diseases, such as osteoporosis.

CONFIDENCIALITY

The information that we collect from only this research project will be kept confidential and aimed to research purpose to improve knowledge. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information according to Helsinki Declaration and the law 14/2007, of Biomedical Research.

Current legislation about personal data protection will be applied regarding to unexpected matter in this document (Law 41/2002, 14th November, BOE 274, 15th November 2002; Law 15/1999, BOE 298 14th December de 1999; Real Order 1720/2007, de 21st December that regulate Law 15/1999, de 13rd December, BOE 17, 19th January 2008), Law 14/2007, 3rd July Biomedical Research, BOE 159 de 4th July 2007) and any other applicable law.

If the sample were stored to subsequent analysis, as the Law 41/2007, 14th November (art. 9.3) says, the written consent of the patient (legal agent or heir if the patients had died) will be necessary to any action that will carry out.

Results of this investigation could be published in scientific journal or other general media. However, confidential information will not be shared.

CERTIFICATE OF CONSENT

Mr/Ms _____, with DNI number _____, have carefully read the characteristics, advantages and disadvantages of this investigation. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I am aware that my samples will be used only with non-profit research purpose; any physical activity may carry a risk (such as fatigue or discomfort related to previous illness). Furthermore, I understand that I am free to drop out the program at any time without justifying my withdrawal and requesting information on the results. Therefore, I CONSENT VOLUNTARILY TO PARTICIPATE AS A VOLUNTEER IN THIS RESEARCH.

Signature:

Name of Participant: _____DNI:_____

Cáceres, _____ _____ _____
Date (day/month/year)