STUDY TITLE:

INTERACTIONS BETWEEN PHYSICAL TRAINING AND MEDICATION IN PATIENTS WITH METABOLIC SYNDROME

STUDY PROTOCOL 30 AUGUST, 2017

METHODS

PRE-POST research project with one ARM (group) and 2 evaluations in each of the times in a cross-over randomized fashion.

Recruitment strategy

Participants in this research will be recruited through advertisements in the local media (newspapers and radio), through which overweight volunteers will be requested according to body mass index (BMI <25). From this large pool of potential participants who respond to the advertisements, 40 sedentary men and women ages 25-65 who meet criteria for metabolic syndrome will be recruited.

Inclusion and exclusion criteria

The metabolic syndrome will be defined according to the presence of three of the criteria published by the International Diabetes Federation: waist circumference> 94 cm for men and> 80 for women of Caucasian ethnicity, high blood pressure figures (> 130 mmHg for systolic and> 85 for diastolic), high fasting blood glucose (> 100 mg / dl) or dyslipidemia: (triglycerides> 150 mg / dl, HDL <40 mg / dl) (1). Participants must be in treatment with ARA II hypotensive drugs. All subjects must be physically inactive, at least during the previous year according to the criteria of the American College of Sports Medicine-ACSM (less than 150 min / week of moderate physical activity or less than 75 min / week of vigorous physical activity).

In addition, participants must not have a diagnosis of any endocrine pathology other than carbohydrate intolerance and their hormonal levels (except insulin) must be within clinical normal ranges. Other exclusion criteria will be, recent surgery, cardiovascular disease (especially uncontrolled coronary disease, heart valve disease, heart failure, complex ventricular arrhythmias), diseases with kidney, liver, respiratory or neuromuscular involvement. Participants will be informed verbally and in writing of the risks and benefits regarding participation in the study and will provide their written consent. Participants will be supervised by their family doctors throughout the study.

Intervention with physical training

The training program will consist of 3 weekly sessions of interval aerobic exercise (EIA). EIA will consist of a cycle ergometer workout (or treadmill running) that includes a 10-minute warm-up period at 70% of the peak heart rate (HRpeak) followed by 5 intervals of vigorous exercise of 4 minutes at 90-95% of your HRpeak interspersed with periods of 3 minutes of active recovery at 70% of HRpeak, ending with a 10-minute cooldown, reaching a total of 55 min duration per workout. Considering the effects of the circadian rhythm on the heart rate, the workouts will be carried out at the same time of day and the load will be adjusted daily to provoke the indicated heart rate. Because of the adaptations produced by exercise, the training load must be adjusted to reach similar heart rates over time and thus comply with the principle of overload for physical training.

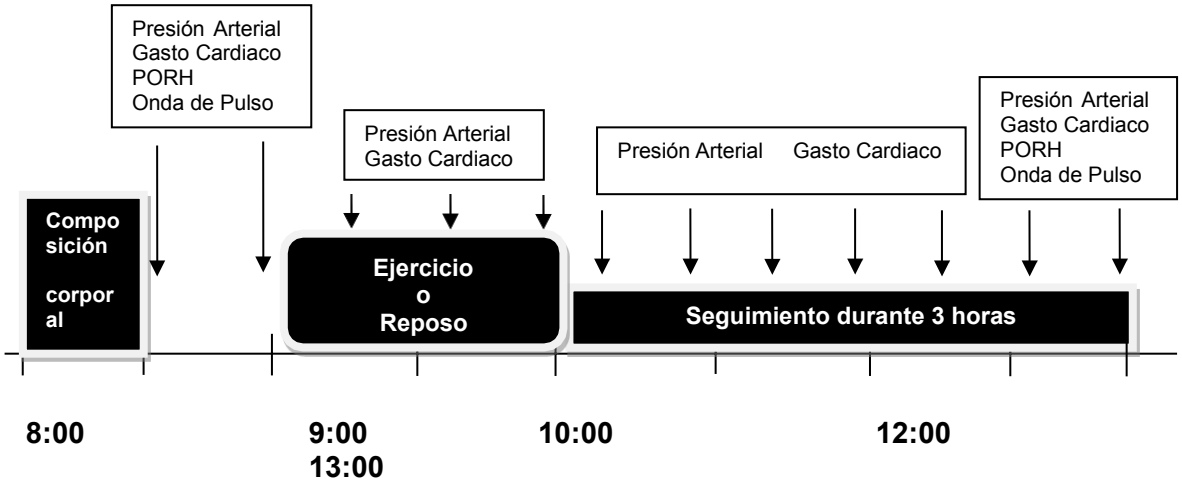
Nutritional control

During the week prior to the start of the interventions, all participants will keep a written record of their morning weight (completely naked) and of all food consumed with their respective weights. Total energy and macronutrient intake will be evaluated through the individual record of each participant using software adapted to the eating habits of Spaniards (CESNID Nutritional Calculation Program V 1.0 - Center d'Ensenyament Superior de Nutrició I Dietètica assigned to the a University of Barcelona). With these data, the usual caloric intake will be established that will be maintained during the 4 months of intervention to avoid biases due to weight loss resulting from a hypocaloric

diet that would confuse the effects of the training program.

Evaluation procedure
Participants will go to the laboratory in the morning after an overnight fast and with or without their medication depending on the test. In each one the following measurements will be made:

Figure 1. Diagram of the measurements of each of the test.



Description of the variables to be measured

Anthropometric measurements and blood pressure at rest
Weight and height will be evaluated using a standard scale and a stadiometer that allows measuring with a precision of 0.1 cm and kg respectively (Seca, Vogel & Halke Hamburg, Germany). The body mass index (BMI; in kg / m2) will be calculated using the subject's height and weight. The waist circumference (in the horizontal plane 2 centimeters below the rib edge (1)) will be measured using a plastic measuring tape with a precision of 0.1 cm.

To measure blood pressure, participants will be seated in a supine position for 15 min. The systolic (SBP) and diastolic (DBP) blood pressure will then be determined with the help of an ambulatory pressure monitor (SunTec Medical, Oscar, USA). The average of the last 2-3 measurements will be used as the value of the SBP and DBP.

Blood pressure during exercise
During the exercise we will use a specific pressure meter for this situation that not only has a very sensitive microphone in the pressure cuff but is also integrated with the ECG monitoring through three leads (SunTec Medical, Tango, USA). We will use cuffs adjusted to the size of the participant's arm.

Post-occlusive reactive hyperemia (PORH).
After 15 minutes of supine rest, participants will have a flush meter placed on the skin of the forearm (MoorLab, UK). This flowmeter is simply an adhesive probe that with laser technology measures the speed at which the red cells pass through the capillary circulation. Once the signal is good, a pressure cuff will be inflated on the arm 10 mmHg above the resting systolic pressure. The cuff will remain inflated for 3 minutes. After this period of circulatory arrest, the pressure cuff will be opened, and the flow rate will be measured for 2 minutes. This is a measure of the ability of the peripheral vasculature to dilate upon a short-lived ischemic stimulus.

Pulse wave
Pulse wave velocity will be measured as an indirect measure of arterial stiffness. For this, a tonometer () placed manually in the carotid and femoral arteries will be used after having measured the distance between them and with reference to the xyloid process. It will be measured sequentially, using the R wave of the electrocardiogram as a reference to synchronize the signals. The time interval is measured at the beginning of the same, since these points correspond to the beginning of the ejection where the possibility of reflections is considered null, the delay being due only to the propagation of the wave.

Blood chemistry analysis
After a 15-minute supine position and prior to performing the exercise, 10 ml of venous blood will be drawn for the analysis of metabolic syndrome factors in blood. Thus, plasma glucose, insulin, triglycerides, total cholesterol and HDL-cholesterol will be measured.