STUDY TITLE

INTERACTIONS BETWEEN PHYSICAL TRAINING AND MEDICATION IN PATIENTS WITH METABOLIC SYNDROME

STATISTICAL ANALYSIS PLAN (30 AUGUST, 2017)

Experimental design and calculation of the sample size.

The experimental scheme that we propose for this research project does not use a parallel control, but the control situation is the PRE training test when the participants are oblivious to the exercise adaptations. Therefore, it is an experimental longitudinal scheme with repeated measures in the same participants. This greatly reduces biological variability since each participant will be compared with himself before and after the intervention, which in this case is training.

In each of the 2 visits where data will be collected for the experiment, four evaluations will be carried out following the scheme of isolating or combining our two factors to study: a) medication and b) exercise.

Thus, we will have the following situations:

a) CONTROL (NO MED, NO TRAIN). Participants have not started training and their habitual antihypertensive medication has been withdrawn for 72 h.

b) MEDICATION. Participants have not started training and they are taking their habitual dose of antihypertensive medication.

b) TRAINED. Participants have completed the 4 months of aerobic exercise training and their habitual antihypertensive medication has been withdrawn for 72 h.

d) EXERCISE + MEDICATION. Participants have completed the 4 months of aerobic exercise training and there are taking their habitual antihypertensive medication.

The group will be composed of 40 participants taking into account that the power analysis of a study in which similar exercise programs (3 months of duration) were used in similar subjects indicates that to observe significant effects on the components of the metabolic syndrome, 27 participants were necessary, so we propose to recruit 30 to have a 10% lack of adherence to the exercise or diet program.

Statistical analysis

To evaluate the differences between the PRE-training and POST-training situation, repeated measures analysis of variance (ANOVA) will be used, in which the factors associated with both medicine withdrawal (MEDIC vs NO-MEDIC) and training (TRAINED vs NO-TRAINED) will be analyzed. Values of $P < 0.05$ will be considered significant. Results will be presented as means ± SD. All statistical analysis will be performed using SPSS software (version 19.0