

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt  
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## Study Identification

Unique Protocol ID: Process HCRP: 1.387.040/2016

Brief Title: Mitochondrial Energy Metabolism in Obese Women

Official Title: Mitochondrial Energy Metabolism in Obese Women Undergoing Concurrent Physical Training

Secondary IDs:

## Study Status

Record Verification: April 2017

Overall Status: Completed

Study Start: April 1, 2016 [Actual]

Primary Completion: July 1, 2016 [Actual]

Study Completion: September 15, 2016 [Actual]

## Sponsor/Collaborators

Sponsor: University of Sao Paulo

Responsible Party: Principal Investigator  
Investigator: Julio Sergio Marchini [jmarchini]  
Official Title: Principal Investigator  
Affiliation: University of Sao Paulo

Collaborators:

## Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: 42445614.7.0000.5440

Board Name: Human Research Ethics Committee of Hospital das Clínicas de Ribeirão Preto

Board Affiliation: Faculty of Medicine of Ribeirão Preto, University of São Paulo

Phone: +55 (16)3602-2228

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Data Monitoring: Yes  
FDA Regulated Intervention: Yes  
Section 801 Clinical Trial: Yes

## Study Description

**Brief Summary:** Considering that the failure of the treatment of obesity is justified by the multifactorial pathophysiology of this morbidity, the present project has the following hypotheses:

1. The occurrence of obesity is due to the derangement of mitochondrial energy metabolism ;
2. The unbalance is therapeutically modified through physical training ;
3. Obesity courses with the break-down in energy metabolism mitochondrial disease associated with systemic inflammatory characteristics that can be corrected through a combined long-term physical training program.

This study have as objective : to analyse changes in mitochondrial function, inflammatory profile, oxidative stress and energy metabolism caused by concurrent physical training in obese women.

**Detailed Description:** Specific objectives:

Body composition by deuterium oxide; Metabolic rate of resting and oxidation of substrates by indirect calorimetry; Proinflammatory cytokines Anti-inflammatory cytokines Oxidative Stress: Malondialdehyde, Superoxide Dismutase, Glutathione-Peroxidase; Fatty acids: ceramide and palmitate; Mitochondrial respiration and citrate synthase enzyme; Quantify and qualify: mitochondrial number, endoplasmic reticulum structure, adipose cell size; Gene expression, quantify by microscopy and analyze the protein by western blot.

The study began with 20 women, however, there was withdrawal of 6, ending with 14 women.

## Conditions

Conditions: Metabolism Disorder  
Mitochondrial Alteration  
Physical Activity  
Obesity

Keywords:

## Study Design

Study Type: Interventional  
Primary Purpose: Treatment  
Study Phase: N/A  
Interventional Study Model: Single Group Assignment  
Number of Arms: 1  
Masking: None (Open Label)  
Allocation: N/A

## Arms and Interventions

Arms	Assigned Interventions
<p><b>Physical Training</b> There was concurrent physical training intervention: strength and aerobic exercises in the same session.</p> <p>Duration: 2 weeks of adaptation and learning to exercise, 8 weeks of physical training.</p> <p>Frequency: 3 times per week Duration: 55 minutes each session. Intensity: 75 to 90% of maximum heart rate.</p>	<p><b>Physical Training</b> Intervention with concurrent physical training: strength and aerobic exercises in the same session. Duration: 2 weeks of adaptation to physical exercise, 8 weeks of training. Frequency: 3 times a week. Time: 55 minutes each session. Intensity: 75 to 90% of maximum heart rate.</p>

## Outcome Measures

### Primary Outcome Measure:

1. Changes Body weight  
Body weight was measured by digital balance before and after the intervention  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
2. Changes Body composition  
The change in body composition through deuterium oxide was evaluated.  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
3. Changes White adipose tissue biopsy  
A subcutaneous tissue sample was collected for analysis of: mitochondrial respiration, citrate synthase enzyme, gene expression (UCP2 and UCP3).  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
4. Changes Indirect calorimetry  
With a gas analyzer (indirect calorimeter), we evaluated the metabolic rate and rest (REE) and oxidation of substrates (Lipids and carbohydrates).  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
5. Changes in fatty acids  
Collected in lithium heparin tubes, they were centrifuged.  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
6. Changes oxidative stress  
Collected in lithium heparin tubes, they were centrifuged.  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
7. Changes inflammatory cytokines  
Collected in lithium heparin tubes, they were centrifuged.  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
8. Changes in total cholesterol  
Collected in lithium heparin tubes, they were centrifuged.  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]
9. Changes Physical Performance  
Based on the Shuttle Walking Test adaptation.  
[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]

#### 10. Changes in Determination of Lactate

Blood samples were collected by manual puncture of the earlobe in previously calibrated and heparinized capillary tubes, stored in eppendorf with sodium fluoride. Analyzed by electrochemical lactate analyser.

[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]

#### 11. Changes Food intake

Food registry of 3 days, the quantification of the daily intake of nutrients will still be made using software.

[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]

#### 12. Changes Nitrogen Balance

Through the collection of urine of 24 hours the dosage of urinary nitrogen will be made by the chemiluminescence method for determination of protein nitrogen.

[Time Frame: Two times: (1) First day and (2) 10 weeks after adaptation and intervention]

## Eligibility

Minimum Age: 20 Years

Maximum Age: 40 Years

Sex: Female

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- This study included women with obesity (BMI of 30 to 40 kg / m<sup>2</sup>), sedentary, with no associated comorbidity, convenience sample

Exclusion Criteria:

- Women who have undergone bariatric surgery, menopause, cancer or any metabolic disease, smokers, alcoholics, who are in use of drugs that act directly on the metabolism and that have medical impediment to the practice of physical exercise.

## Contacts/Locations

Central Contact Person:

Central Contact Backup:

Study Officials:

Locations: Brazil

Camila Fernanda Cunha Brandão

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## IPDSharing

Plan to Share IPD: No

## References

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Links:

Available IPD/Information: