# Effects of different intensities of exercise on health risk factors

| Submission date   | Recruitment status  No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------|--|--|--|--|
| 09/02/2010        |  | [X] Protocol                               |  |  |
| Registration date | Overall study status                     | Statistical analysis plan                  |  |  |
| 11/02/2010        | Completed                                | [X] Results                                |  |  |
| Last Edited       | Condition category                       | [] Individual participant data             |  |  |
| 28/03/2019        | Nutritional, Metabolic, Endocrine        |  |  |  |

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Prof Robert Ross

#### Contact details

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### Additional identifiers

ClinicalTrials.gov (NCT)

NCT00955071

Protocol serial number

MCT-190617

# Study information

#### Scientific Title

Dose-response effects of exercise on abdominal obesity and risk factors for cardiovascular disease (CVD) in women and men

#### Acronym

**SERENA** 

#### **Study objectives**

The driving hypothesis is that the attenuation of health risk with exercise is largely explained by associated reductions in abdominal obesity, in particular visceral fat. Specifically, we will test the following hypotheses:

- 1. That by comparison to controls, all treatments will be associated with reduction in abdominal subcutaneous, visceral fat, liver fat and insulin resistance
- 2. That reduction in abdominal subcutaneous, visceral and liver fat and insulin resistance in high volume low intensity exercise (HVLI) and low volume high intensity exercise (LVHI) will be greater than low volume low intensity exercise (LVLI)
- 3. That hypotheses 1 and 2 are true independent of gender

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Queens University, Faculty of Health Sciences Research Ethics Board (REB) approved on the 22nd July 2009 (ref: PHE-093-09)

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Cardiometabolic risk

#### **Interventions**

The intervention (duration of treatment) will be six months and the negative energy balance will be induced by the increase in exercise alone (e.g., no caloric restriction).

- 1. No exercise, wait list control group
- 2. Low volume (180 kcal), low intensity (50%) exercise group
- 3. High volume (360 kcal), low intensity (50%) exercise group
- 4. Low volume (180 kcal), high intensity (75%) exercise group

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Waist circumference and 2-hour glucose, measured at baseline, 16, 24 and 48 weeks

#### Key secondary outcome(s))

Measured at baseline, 16, 24 and 48 weeks:

- 1. Visceral fat
- 2. Metabolic syndrome variables (glucose, systolic and diastolic blood pressure, triglycerides and high density lipoprotein [HDL]-cholesterol)

#### Completion date

31/08/2013

## Eligibility

#### Key inclusion criteria

- 1. Men and women between 40 and 60 years of age. The lower age range for men and women is selected to help ensure recruitment of a sample with metabolic syndrome as prevalence of metabolic syndrome is significantly related to age. The selection of 60 years for the upper age range reflects concerns we have randomising older adults to the high intensity exercise group wherein exercise at 75 80% of maximum may be difficult to achieve, and likely to be associated with increased orthopaedic injury and thus, poor compliance. We also considered lowering the lower age range from 40 to 35 years, but decided against doing so to increase the cost-effectiveness of recruitment (e.g., ensure a higher yield of those with metabolic syndrome)

  2. Abdominally obese (waist circumference greater than 88 and 102 cm for women and men respectively) and National Cholesterol Education Program, Adult Treatment Panel III (NCEP-ATPIII) defined metabolic syndrome. Abdominal obesity for non-Caucasians will be determined using values suggested by the International Diabetes Federation.
- 3. Sedentary lifestyle (planned physical activity for the purpose of health one day per week or less)
- 4. Weight stable (± 2 kg) for 6 months prior to the beginning of the study
- 5. Body mass index (BMI) less than 40 kg/m<sup>2</sup> (because a lifestyle-based intervention alone for obesity reduction is ideal for persons with a BMI less than 40 kg/m<sup>2</sup>)

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Kev exclusion criteria

1. Physical impairment which would make the intervention very difficult, or unsafe according to the patient's physician including history of myocardial infarction, stroke, coronary bypass surgery or angioplasty in the last 6 months; peripheral artery disease, unstable angina or

#### ischaemia

- 2. Diabetes
- 3. Current smokers
- 4. Alcohol consumption greater than 21 drinks per week
- 5. Plans to move from the area
- 6. Participating in another research study
- 7. Clinically judged to be unsuitable for participation or adherence as determined by the participants physician
- 8. Inability or unwillingness to provide informed consent
- 9. For women, planned pregnancy in the next year

#### Date of first enrolment

01/09/2009

#### Date of final enrolment

31/08/2013

#### Locations

#### Countries of recruitment

Canada

# Study participating centre Queen's University

Kingston Canada K7L 3N6

# Sponsor information

#### Organisation

Queen's University (Canada)

#### **ROR**

https://ror.org/02y72wh86

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-190617)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

| Output type                   | Details                       | Date created Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|-------------------------|----------------|-----------------|
| Results article               | results                       | 03/03/2015              | Yes            | No              |
| <u>Protocol article</u>       | protocol                      | 01/01/2013              | Yes            | No              |
| Participant information sheet | Participant information sheet | 11/11/2025 11/11/2025   | No             | Yes             |