ISRCTN43414825 https://doi.org/10.1186/ISRCTN43414825

Effects of different intensities of exercise on health risk factors

Submission date	Recruitment status
09/02/2010	No longer recruiting
Registration date	**Overall study status**
11/02/2010	Completed
Last Edited	**Condition category**
28/03/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00955071

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
01/09/2009

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^2 (because a lifestyle-based intervention alone for obesity reduction is ideal for persons with a BMI less than 40 kg/m^2)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
320

Key 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
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Sponsor information

Organisation
Queen's University (Canada)

Sponsor details
Office of Research Services
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Sponsor type
University/education

Website
http://www.queensu.ca/ors/contact.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/01/2013		Yes	No
Results article	results	03/03/2015		Yes	No