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Effects of caloric restriction combined with moderate or vigorous intensity exercise on metabolic control and inflammation

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
19/11/2013

Overall study status
Completed

Last Edited
17/01/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
People who do not do much physical activity or who have excess body fat have an increased risk of diseases such as type 2 diabetes and cardiovascular disease. Physical activity alone or in combination with caloric restriction (a calorie restricted diet) offer huge benefits in terms of weight loss and metabolic control. The purpose of the study is to investigate whether vigorous-intensity exercise offers additional health benefits compared to energy-matched moderate-intensity exercise in combination with caloric restriction.

Who can participate?
Males and postmenopausal women, aged 45-64 years who are overweight/obese and inactive (no participation in regular structured exercise and less than 30 minutes of moderate-intensity exercise on most days of the week), non-smokers, not taking any drugs that may interfere with the study and whose weight has been stable for the last 6 months.

What does the study involve?
Participants were asked to complete a range of preliminary tests (e.g., body mass, maximum oxygen uptake, body composition, habitual physical activity) after which they completed a 3-week intervention.
Participants were randomly allocated to either a moderate (MOD) or a vigorous (VIG) physical exercise group. Both groups experienced a fixed energy loss induced by caloric restriction and increased physical activity via either moderate (MOD) or vigorous (VIG) physical exercise.
Before and after the intervention, participants came to the laboratory in the morning after an overnight fast. A cannula (tube) was inserted for repeat blood sampling and a biopsy was taken from the abdominal (stomach) area. Participants then consumed a glucose-based solution and blood samples were taken over the following 2 hours.

What are the possible benefits and risks of participating?
Participants who took part in this study were given a copy of their personalised results and the normal range for these measures: Cardio-respiratory fitness (e.g., how fit you are), diet (e.g., the good and bad aspects of your diet), blood measurements (e.g., cholesterol), blood pressure,

percentage body fat, muscle mass, etc.
Participants were on a low energy diet, they therefore might have become hungry on several occasions throughout the study. However, the intervention was designed to result in a safe level of weight loss.
Participants temporarily increased their normal exercise patterns. This might have caused some inconvenience. A small fat sample was taken at the beginning and end of the trial from around the waist. All fat samples were taken by someone who has been specially trained to do so in order to minimise discomfort. Bruising might have occurred for a few days after taking this sample. There is a small chance of localised infection but good practice minimises this risk.
We measured body fat using a very sophisticated and precise technique (dual energy x-ray absorptiometry or DEXA). DEXA is a non-invasive technique that uses a very low exposure to radiation. The radiation dose is often compared to the small exposure experienced during a short flight. This technique is routinely used in hospitals but at the same time this does represent some exposure to a small amount of radiation. The risks associated with this amount of radiation are described as 'trivial' (less than 1 in ten million per whole body scan).

Where is the study run from?
University of Bath (UK)

When is the study starting and how long is it expected to run for?
The study started in January 2009 and completed in June 2011.

Who is funding the study?
University of Bath (UK).

Who is the main contact?
1. Professor Dylan Thompson (scientific)
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Contact information

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Study information

Scientific Title
Effects of caloric restriction combined with moderate or vigorous intensity short-term (three weeks) exercise training on metabolic control and inflammation in middle-aged, overweight and inactive men and postmenopausal women

Study objectives
Can vigorous-intensity exercise alongside caloric restriction further improve metabolic control and chronic inflammation in inactive and overweight/obese men and postmenopausal women over the course of a three-week intervention relative to moderate-intensity exercise?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Bath Research Ethics Committee, 05/11/2008, ref: 08/H0101/194

Primary study design
Interventional

Study design
Randomised parallel group study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Obesity, type 2 diabetes, cardiovascular disease

Interventions
Participants were asked to complete a range of preliminary tests (e.g., body mass, maximum oxygen uptake, body composition, habitual physical activity) after which they completed a 3-week intervention.

Participants were randomly allocated to one of two groups for the intervention. Both groups experienced a fixed energy deficit of 29330 kJ.week-1, induced by caloric restriction and increased physical activity via either moderate (MOD) or vigorous (VIG) physical exercise. Volunteers in both groups were asked to reduce their caloric intake by under-consuming their habitual diet in order to create a caloric deficit of 20950 kJ.week-1. In addition, participants in the MOD group increased their physical activity by walking on a treadmill five times per week at 50% of their maximum oxygen uptake while participants in the VIG group increased their physical activity by walking on a treadmill five times per week at 70% of their maximum oxygen uptake. Importantly, both groups expended 8380 kJ.week-1 (1676 kJ per session for both groups) above rest through increased physical activity. Both groups achieved the same energy deficit over the course of the intervention.

Before and after the intervention, participants came to the laboratory in the morning after an overnight fast. A cannula was inserted for repeat blood sampling and an adipose tissue biopsy was taken from the abdominal area. Participants then consumed a glucose-based solution and blood samples were taken over the following 2 hours.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Changes in insulin sensitivity and glycaemic control. Measured at baseline and at the end of the intervention (i.e., after 21 days).

Key secondary outcome(s)
1. Other blood measures related to metabolic function and inflammation (e.g., cholesterol, non-esterified fatty acids [NEFA], triacylglycerol, alanine aminotransferase [ALT], interleukin (IL)-6, leptin, adiponectin)
2. Changes in adipose tissue gene expression related to metabolic function and inflammation were measured using real-time quantitative polymerase chain reaction (qPCR).

Measured at baseline and at the end of the intervention (i.e., after 21 days).

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. Male and postmenopausal women, aged 45 to 64
2. Overweight/obese (body mass index [BMI] >25 kg.m-2)
3. Physically inactive (no participation in regular structured exercise and they did not do >30

minutes of moderate-intensity exercise on most days of the week)
4. Weight stable (over the past 6 months)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Smoker
2. Age outside range (<45 and >64 years)
3. Positive responses to Physical Activity Readiness Questionnaire
4. Taking medication that may interfere with study
5. Doctor diagnosed condition that might interact with study measures (e.g. cardiovascular disease)

Date of first enrolment
01/01/2009

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bath
Claverton Down
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Sponsor information

Organisation
University of Bath (UK)

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
University/education

Funder Name
University of Bath (UK)

Alternative Name(s)
UniofBath

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study are stored in the University of Bath's publically available repository via https://doi.org/10.15125/BATH-00313

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016	17/01/2019	Yes	No