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Can exercise overcome the effects of overfeeding and under-activity?

Submission date
24/06/2011

Recruitment status
No longer recruiting

Registration date
04/08/2011

Overall study status
Completed

Last Edited
10/02/2016

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 accumulate excess body fat have an increased risk of diseases such as diabetes and cardiovascular disease. We do not really know why physical inactivity and/or eating more than you need increases risk of disease and we really need to find out more. We believe that chronic low-level inflammation and disturbed metabolism are critically important but it is very difficult to experimentally examine these pathways over a person's lifetime. Based on some recent research, we believe that we can simulate many of these changes through just a short-term intervention where we reduce a person's physical activity and give them more than they would usually eat. First of all, we need to see if the changes that we predict do actually take place and whether exercise can prevent these changes from taking place - and this is the purpose of the present study.

Who can participate?
We are looking for males, aged 18-40 years who are active (exercise more than 30 minutes per day, at least four times per week), who are non-smokers, not taking any drugs and whose weight has been stable for the last 6 months.

What does the study involve?
Participants will be asked to complete a range of preliminary tests (e.g., body mass, maximum oxygen uptake, body composition, habitual physical activity) after which they will complete a 1-week intervention.
Participants will be randomly allocated to one of two groups for the intervention. Both groups will be asked to reduce physical activity to <4000 pedometer steps per day for 7 days. During this period, one group will increase their energy intake by 50%. The other group will perform daily exercise at 70% maximum oxygen uptake for 45 min. This group will also increase energy intake by 50% above normal for 7 days but will also consume additional energy to offset exercise energy expenditure (and thus achieve the same energy surplus as the control group). Before and after the intervention, participants will come to the laboratory in the morning after an overnight fast. A cannula will be inserted for repeat blood sampling and an adipose tissue biopsy will be taken from abdomen. Participants will then consume a glucose-based solution and we will take blood samples over the following 2 hours.

What are the possible risks of participating?
1. Participants will be asked to complete a health questionnaire as well as a Physical Activity Readiness Questionnaire (PAR-Q) prior to participation in this study. The PAR-Q has been designed to identify the small number of adults for whom physical activity may be inappropriate or those who should have medical advice concerning the type of physical activity most suitable for them. In line with good practice, the laboratory is equipped with an automated defibrillator for use in the very unlikely event that resuscitation is required.
2. Participants will have to eat more food than normal. This might cause some inconvenience and discomfort.
3. Participants will have to temporarily interrupt normal exercise patterns and reduce other general physical activity in order to meet the 4000 step target. This might cause some inconvenience. Also, having to limit normal step count may affect some of the other activities that are normally performed (4000 steps would allow a typical office worker to go about their normal working life but not to undertake much additional walking or exercise).
4. A small fat sample will be taken at the beginning and end of the trial from around the waist. All fat samples will be taken by someone who has been specially trained to do so in order to minimise discomfort. There will be some bruising for a few days after taking this sample. There is a small chance of localised infection but good practice minimises this risk.
5. We will measure 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 (e.g. London to Paris) and is similar to the amount of background radiation that would be received in a normal day living around Bath (and a tiny fraction [1/30th] of the amount of radiation experienced during a typical chest x-ray). This technique is routinely used in hospitals and with elite athletes 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?
The research will take place at the University of Bath.

When is study starting and how long is it expected to run for?
Participants can choose when to take part (i.e., the intervention can take place at a time that is convenient to them).
The study is expected to take place between September 2008 and September 2011.

Who is funding the study?
The University of Bath

Who is the main contact?
Dr Dylan Thompson
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Can exercise overcome the effects of short term (one week) overfeeding and restricted physical activity on inflammatory markers and metabolic function?

Study objectives
To determine if exercise can overcome the effects of a week of overfeeding and restricted physical activity on inflammatory markers and metabolic function in young, healthy, lean and active males?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Bath Research Ethics Committee approved on 19th March 2008, amendment approved on 3rd September 2008 (ref 07/H0101/234)

Study design
Randomised parallel group study

Primary study design
Interventional

Study type(s)
Screening

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

Interventions

Control:
1. Reduce physical activity to < 4000 pedometer steps per day for 7 days
2. Increase energy intake by 50% above normal for 7 days

Intervention:
1. Reduce physical activity to < 4000 pedometer steps per day for 7 days
2. Exercise daily at 70% maximum oxygen uptake for 45 min
3. Increase energy intake by 50% above normal for 7 days plus consume additional energy to offset exercise energy expenditure (and thus achieve the same energy surplus as the control group).

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 7 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

Measured at baseline and at the end of the intervention (i.e., after 7 days).

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Male, aged 18 to 40
2. Physically active (more than 30 minutes per day 5 days per week)
3. Weight Stable (over the past 6 months)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Females
2. Smoker
3. Age outside range
4. Positive responses to Physical Activity Readiness Questionnaire
5. Taking medication
6. Doctor diagnosed condition that might interact with study measures (e.g. cardiovascular disease)

Date of first enrolment
03/09/2008

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department for Health
Bath
United Kingdom
BA2 7AY

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/12/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes