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# Can different forms of daily exercise counteract the effects of short-term overfeeding and reduced physical activity?

**Submission date**
16/06/2015

**Recruitment status**
No longer recruiting

**Registration date**
24/06/2015

**Overall study status**
Completed

**Last Edited**
21/01/2019

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
The Western lifestyle is known for low levels of physical activity and excessive caloric intake, which can result in weight gain in the long term. This energy imbalance leads to obesity which is linked with increased risks of developing chronic diseases. Previous work conducted by our group have shown that a daily bout of vigorous-intensity running protects against the impact of positive energy balance (that is, when you are eating more calories than you are using) even whilst participants are gaining weight. Using this model, we successfully investigated some of the mechanisms by which exercise helps maintain health. Not many people will be able to engage in daily vigorous-intensity running. Wheelchair users are at increased risk of developing chronic diseases, probably linked to reduced physical activity levels. Arm crank ergometry is a form of upper body exercise which is achievable for this population. For many people, moderate-intensity exercise is a more achievable form of exercise than vigorous-intensity exercise. It is unknown whether physical activity breaks throughout the day are just as important as a single bout of exercise in maintaining health. The proposed study aims to assess whether a form of upper body exercise, a bout of walking or several small bouts of walking throughout the day all have the same capacity as running to maintain health in participants. This will show whether different forms of exercise which are relevant for many different people will generate similar benefits.

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

What does the study involve?
Participants are asked to complete a range of preliminary tests (e.g., body mass, maximum oxygen uptake, body composition, habitual physical activity and food diary) after which they complete a 1-week intervention. Participants are randomly allocated to one of four groups for the intervention:
1. <4000 steps a day and consuming 50% more calories than needed

2. 45 min of daily upper body exercise and ~70% more calories than needed
3. Daily moderate-intensity treadmill walking and ~60% more calories than needed
4. Several small bouts of daily walking and ~60% more calories than needed
All exercise groups 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 come to the laboratory in the morning after an overnight fast. A cannula is inserted for repeat blood sampling, an adipose tissue (fat) biopsy is taken from the abdomen (stomach) and a muscle biopsy is taken from the thigh (vastus lateralis). Participants then consume a glucose (sugar)-based solution and we take blood samples over the following 2 hours.

What are the possible benefits and risks of participating?
At the end of the study, participants are given a copy of their results and personalised feedback regarding body composition, fitness, diet, patterns of physical activity and various blood measurements (such as metabolic markers or lipid profiles) that would not normally be available to them. There is a small financial incentive for taking part in this study (£100), participants are also reimbursed for any travel expenses and the extra food required. Participants are 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. Participants have to eat more food than normal. This might cause some inconvenience and discomfort. Some participants 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). The use of an intravenous cannula to obtain blood samples can occasionally result in minor bruising. More serious complications are the very small risk of infection or embolism (i.e. a bubble or fragment of plastic that can become lodged in a blood vessel and potentially interfere with normal blood flow). However, the occurrence of such events is very rare and risks are further minimised by our strict adherence to best practice. A small fat sample is taken at the beginning and end of the trial from around the waist. 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. The technique used to acquire muscle biopsies has been in common use in exercise studies since the early 1960s and only minor complications are typically observed (e.g. bleeding from the skin wound, bruising and minor soreness over the days afterwards). Participants are provided with an extensive guide (included with the participant information sheet) to help manage these issues. This sheet also lists the possible complications which are more severe (e.g. intramuscular bleeding, denervation or infection) although these complications are fortunately very rare and risk are minimised by following best practice. The use of anaesthetic for fat and muscle biopsies may cause possible side effects including allergic reactions, heart arrhythmia and nausea. However, the initial health screen will be individually checked by a doctor who will sign a Patient Specific Direction (PSD) to prescribe the anaesthetic for the procedure. A patient information leaflet with further information regarding the anaesthetic will also be included in the participant information sheet. Body fat is measured 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). The estimation of VO2 max in the preliminary test will cause breathlessness and temporary fatigue. Full recovery should be achieved within 15 minutes. This is similar to running uphill. Participants will put some weight on during the study. Our previous work shows this to be temporary and volunteers go back to their previous weight quickly. The continuous glucose monitor will be fitted in the abdominal area. This can occasionally result in minor bruising. More serious complications are the very small risk of infection. However, the occurrence of such events is very rare and risks are further minimised by our strict adherence to best practice.

Where is the study run from?
The Exercise Physiology Laboratory within the Department for Health at the University of Bath (UK).

When is the study starting and how long is it expected to run for?
April 2015 to April 2017

Who is funding the study?
1. The University of Bath (UK)
2. Ministry of Education (Republic of China, Taiwan)

Who is the main contact?
Dr Jean-Philippe Walhin
j.walhin@bath.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Dr Jean-Philippe Walhin

### ORCID ID
https://orcid.org/0000-0002-8103-5541

### Contact details
Department for Health
Bath
United Kingdom
BA2 7AY
+44(0)1225386478
j.walhin@bath.ac.uk

# Additional identifiers

### Protocol serial number
N/A

# Study information

## Scientific Title
Can different forms of daily exercise counteract the effects of short-term overfeeding and reduced physical activity? A randomised parallel group study

## Study objectives
The hypothesis is that this protocol will induce changes in various biomarkers concentrations and that modifications in the expression of several key genes/proteins (within fat and skeletal muscle) will take place during this short intervention. This will allow the trialists to study what are the first changes to occur when people become inactive and are in positive energy balance which is what seems to happen to a large part of the population as they get older. The exercise trials will show whether upper body exercise or less intense exercise will prevent changes from taking place when we overfeed young, healthy, lean and active males. The proposed study will hopefully enable us to answer three research questions
1. Whether upper body exercise has the ability to maintain health which would inform our exercise guidelines for wheelchair users
2. Whether moderate-intensity exercise has the same impact on health as vigorous-intensity exercise
3. Whether the timing and duration of the exercise is also critical in maintaining health

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
NRES Committee South West of England – Cornwall & Plymouth, 16/02/2015, ref: 15/SW/0014.

## Study design
Randomised parallel group design

## Primary study design
Interventional

## Study type(s)
Quality of life

## 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:
1. Reduce physical activity to < 4000 pedometer steps per day for 7 days
2. Exercise daily at 70% maximum oxygen uptake for 45 min on arm crank ergometer
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#2:
1. Reduce physical activity to < 4000 pedometer steps per day for 7 days
2. Exercise daily at 50% maximum oxygen uptake for 45 min on treadmill
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#3:
1. Reduce physical activity to < 4000 pedometer steps per day for 7 days
2. Same exercise energy expenditure as intervention#2 group but achieved through walking at regular intervals throughout the day in order to break sitting time.
3. Increase energy intake by 50% above normal for 7 days plus consume additional energy to offset physical activity energy expenditure (and thus achieve the same energy surplus as the control group).

### Intervention Type
Other

### Primary outcome(s)
Insulin sensitivity (incremental area under the curve, HOMA-IR, Matsuda index), assessed following an oral glucose tolerance test (OGTT)

### Key secondary outcome(s))
1. The expression patterns of several key genes and proteins within adipose tissue
2. The expression patterns of several key genes and proteins within skeletal muscle
3. Various metabolic parameters assessed through blood analysis, including serum insulin, C-peptide and plasma glucose responses during an Oral Glucose Tolerance Test (OGTT). Lipid profiles including the measurement of Triglycerides, Non-esterified fatty acids (NEFA), Low-density lipoprotein cholesterol (LDLC) and High-densitylipoprotein cholesterol (HDLC)

### Completion date
31/08/2017

## Eligibility

### Key inclusion criteria
1. Males
2. Aged between 18-40 years
3. Active – exercise more than 30 minutes per day, at least three times per week
4. Stable weight in the last six months– changes in fat mass might influence some of the outcome measures

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
40 years

### Sex
Male

### Key exclusion criteria
1. Females
2. Smoker
3. Aged less than 18 years or greater than 40 years.
4. Positive responses to the Physical Activity Readiness Questionnaire (PAR–Q)
5. Taking any medication that might interfere with the study outcomes
6. Illness/condition that might interact with study measures (e.g. diabetes, heart disease)

### Date of first enrolment
01/05/2015

### Date of final enrolment
15/08/2017

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**University of Bath**
Claverton Down
Bath
United Kingdom
BA2 7AY

## Sponsor information

### Organisation
University of Bath (UK)

### ROR
https://ror.org/002h8g185

# Funder(s)

### Funder type
Government

### Funder Name
Ministry of Education of the People's Republic of China

### Alternative Name(s)
, Министерство образования Китайской Народной Республики, , Bildungsministerium der Volksrepublik China, Ministry of Education of China, Ministry of Education, The People's Republic of China, Ministry of Education of the Central People's Government, State Education Commission, MOE

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
China

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in the University of Bath's publically available repository

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 27/03/2018 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |