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Energy expenditure in obese and overweight individuals after a low energy followed by a high energy intervention

Submission date
08/05/2017

Recruitment status
No longer recruiting

Registration date
18/05/2017

Overall study status
Completed

Last Edited
17/05/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
A large number of obese and overweight individuals often experience diets focused on weight loss, or on maintaining their weight. It is difficult to know how much energy they use each day and therefore whether they are eating more than they need. This is particularly important when people are trying to lose body weight as they have no idea if they are using their own body-fat stores as their main energy source or simply using some/all of the energy in the food they have eaten that day. Currently, people trying to lose weight are given advice on how many calories to consume daily based on either the estimated average requirement for their gender or predictive equations based on their weight, age, gender and activity levels. Some studies conducted after low energy diets suggest an improvement in exogenous glucose oxidation (energy usage), but no studies have been carried out to investigate what could precisely happen to exogenous glucose oxidation whenever individuals fail in lifestyle changes and go back to a high energy diet. The aim of this study is to accurately measure individual's energy usage, the type of fuel they use (carbohydrate or fat) and the glucose metabolism (the process the turns energy from food into fuel) in order to know how many calories the body needs to function each day.

Who can participate?
Adults aged 18 to 60 years old who have a BMI greater than 25 kg/m2

What does the study involve?
Participants attend a pretest where they complete questionnaires about their health, eating and exercise habits. They are measured for their height, weight, BMI, blood pressure, insulin and glucose (blood sugar) levels. They are asked to keep a food diary for four days. The main study takes place over seven days. Participants are asked to fast overnight prior to attending the first study session. They are told to rest for 20 minutes on their backs and are measured for their resting metabolic rate. After this, participants drink a glucose drink and their breath samples are collected every 15 minutes for the next four hours. They are also measured every 30 minutes for the amount of energy they use. Participants also provide fingerprick blood samples prior to drinking the glucose drink and repeat this every 15 minutes for the first 60 minutes and then every 30 minutes until four hours has been reached. Participants are provided with a low calorie

diet for them to follow for the next three days. After this, they return for a second test day where they repeat the tests. They are then given a high calorie diet to follow for the next three days. Finally, on day seven they attend a third study sessions where they are retested.

What are the possible benefits and risks of participating?
There are no notable benefits with participating. There are no notable risks however participants may experience discomfort and sensitivity from the fingerprick tests. There are no major risks to the participants.

Where is the study run from?
Oxford Brookes University (UK)

When is the study starting and how long is it expected to run for?
February 2016 to June 2018

Who is funding the study?
Capes Brazil Ministry of Education (Brazil)

Who is the main contact?
Dr Miriam Clegg

Contact information

Type(s)
Scientific

Contact name
Dr Miriam Clegg

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
n/a

Study information

Scientific Title
Glucose oxidation and resting energy expenditure in obese and overweight individuals after a low energy followed by a high energy intervention

Study objectives
1. There are changes on energy expenditure and glucose oxidation after a low energy diet followed by a high diet energy
2. There is a reduced exogenous glucose oxidation before insulin resistance is clinically detected

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Brookes University Research Ethics Committee, 09/06/2016, ref: 161009

Study design
Single centered non randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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
Obese and overweight individuals

Interventions
Participants are provided with the information sheet at least 48 hours prior to commencing the study so that they have time to consider their participation.

Pretest
Following giving informed consent participants are asked to attend the study centre fasted in order to complete questionnaires (pertaining to health, eating and exercise habits and menstrual cycle in females) in the Functional Food Centre. They are also measured for height and weight (BMI), body composition, abdominal and hip circumference, blood pressure, fasting

blood glucose, insulin and glucagon (this will involve taking a finger-prick blood sample after participant has being fasted overnight). Participants are asked to keep a food diary to be recorded for four days prior to test day one. This session will take no more than 20 minutes.

Intervention
The intervention takes place over seven sequential days. The first day consists of a test day. In the 24 hours prior to testing participants are asked not to participate in any strenuous exercise and not to consume alcohol, maze, pineapple or sugar cane. They are requested to attend the laboratory after an overnight (~12 hours) fast having only consumed water. They are asked to travel to the laboratory using sedentary methods (bus or car). On arrival in the laboratory they have their height, body composition and weight, waist and hip circumference measured. Participants are then asked to rest for 20 minutes on supine (lying on their back) position. Following the 20 minutes rest they have their resting metabolic rate measurements taken using the GEM indirect calorimeter under standardised conditions (early in the morning, with participants at complete rest in a thermoneutral environment (24-26 degress celsius)). This involves lying under a see through hood for 30 minutes. Participants are asked to lie completely still during the measurement. Following this first test the participant drinks a stable isotope carbon 13 glucose solution containing 75g of carbon 13 labelled-glucose and breath samples are collected every 15 minutes for the next four hours. Energy expenditure measurements using the indirect calorimeter are taken every 30 minutes.

Fingerprick blood samples are taken at baseline and every 15 minutes for the first 60 minutes after the drink and then every 30 minutes until four hours. Samples are required for measurement of blood glucose (5 µL) insulin (300 µL) and glucagon (300µL). Finger pricks are made using the Unistik 3 single-use lancing device and blood is collected into chilled microvette® capillary blood collection tubes treated with di Potassium EDTA (CB 300 K2E; Sarstedt Ltd). The microvette® tubes are centrifuged to obtain 200 µL of the supernatant plasma. The plasma samples will be frozen at or below -20C within 4 hours of collection.

This visit should take no more than 5 hours. Participants are offered a balanced lunch after the test. Following this, participants are provided with a diet to follow for the next three days and all the food which they need to eat. This is a low calorie intervention which will consist of 650Kcal /day for males and 565Kcal/day for females. They then come back to the lab for a second test day (repeating the first test day). Again they will be given all of there food for the next three days. This will be a high calorie intervention where the participants will receive a 50% higher calorie intake than the information provided on their dietary diary. They will then be tested for the final time on day seven. After completing the test participants will again be offered lunch.

Intervention Type
Other

Primary outcome measure
1. Glucose oxidation is measured using the 13C labelled glucose breath test at baseline, and then every 15 minutes for the next four hours
2. Metabolic rate is measured using indirect calorimetry at baseline (resting metabolic rate) at baseline and every 30 minutes for four hours.
3. Substrate oxidation is measured using indirect calorimetry (resting metabolic rate) at baseline and every 30 minutes for four hours.

Secondary outcome measures

1. Plasma glucagon levels is measured from finger prick blood samples taken at baseline and every 15 minutes for the first 60 minutes after the drink and then every 30 minutes for four hours
2. Blood glucose blood levels is measured from finger prick blood samples taken at baseline and every 15 minutes for the first 60 minutes after the drink and then every 30 minutes for four hours
3. Insulin levels are measured from finger prick blood samples taken at baseline and every 15 minutes for the first 60 minutes after the drink and then every 30 minutes for four hours

Overall study start date
09/02/2016

Completion date
09/06/2018

Eligibility

Key inclusion criteria
1. BMI greater than 25kg/m2
2. Fat percentage higher than 22 at the body composition check
3. Aged from 18 to 60 years
4. Will not be diabetic or on a weight loss diet. At the beginning of the study, participants will complete a health-screening questionnaire and their anthropometric measurements will be taken. The health questionnaire will include questions regarding medical conditions and medication. If a participant presents a risk for disease or takes medication known to interfere with glucose metabolism, insulin signalling or energy metabolism they will be excluded from the study.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
1. Diabetic individuals
2. History of hypoglycemia
3. Individuals on a weight loss diet

4. High blood pressure (Hypertension)
5. Low blood pressure (Hypotension)
6. Individuals who does not fulfil the inclusion criteria

Date of first enrolment
09/06/2016

Date of final enrolment
09/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Brookes University
Gipsy Lane
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Sponsor information

Organisation
Oxford Brookes University

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Sponsor type
University/education

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Government

Funder Name
Capes Brazil Ministry of Education

Results and Publications

Publication and dissemination plan
Participants who have expressed interest in knowing the results of the study will be contacted. The results will be analysed, and written up for publication to relevant medical scientific journals. Results will also be presented at relevant conferences.

Intention to publish date
09/01/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Miriam Clegg, mclegg@brookes.ac.uk

IPD sharing plan summary
Available on request