

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

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<b>Registration date</b> 18/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
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		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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/m<sup>2</sup>

### 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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<https://orcid.org/0000-0002-8871-0116>

**Contact details**

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## Additional identifiers

**Protocol serial number**

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

## **Study type(s)**

Other

## **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, maize, 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 degrees 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(s)**

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.

### **Key secondary outcome(s)**

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

### **Completion date**

09/06/2018

## **Eligibility**

### **Key inclusion criteria**

1. BMI greater than 25kg/m<sup>2</sup>
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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Oxford Brookes University**

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## Sponsor information

### Organisation

Oxford Brookes University

### ROR

<https://ror.org/04v2twj65>

## Funder(s)

### Funder type

Government

### Funder Name

Capes Brazil Ministry of Education

## Results and Publications

### 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](mailto:mclegg@brookes.ac.uk)

### IPD sharing plan summary

Available on request