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Differences between breakfast eaters and breakfast skippers

Submission date
15/05/2014

Recruitment status
No longer recruiting

Registration date
22/05/2014

Overall study status
Completed

Last Edited
08/02/2016

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
There is an old saying that breakfast is the most important meal of the day, but we know that some people find it difficult to eat in the morning. Therefore we would like to investigate the reasons that some of us cant start the day without breakfast, while others cannot face it and how breakfast may or may not affect our health.

Who can participate?
Healthy individuals over the age of 18.

What does the study involve?
The study involves two parts, each lasting a week, with a break of at least one week in between. During one week we will ask you to eat breakfast and during the other week we will ask you to skip breakfast. Participants will need to come to the university early on four mornings. When you arrive at the laboratory, we will ask you to lie down on a small camp bed and we will measure your energy expenditure (metabolic rate). This is done with a bag that you breathe in to through what looks and feels like a snorkel. We will also like to take a finger prick sample of blood to measure for glucose. The measurements will be repeated every 30 minutes for 3 hours. For the measurements you will need to be lying down but in between measurements you can move around. Please feel free to bring something to read or do during this time. With your permission we would like to measure your weight, height and waist circumference. You will be asked to complete a health questionnaire. In between measurements in the lab we would like you to keep a food diary of everything you eat and record your activity levels using a pedometer.

What are the possible benefits and risks of participating?
By participating in this study you will helping research that is investigating if breakfast has any role in weight gain and or obesity. The risks are that you may feel like you lack energy on days you dont eat breakfast, but if you feel faint we recommend you eat something.

Where is the study run from?
The study will be run from the University of Roehampton (UK).

When is the study starting and how long is it expected to run for?
The study ran from April 2011 to April 2012.

Who is funding the study?
Kellogg Marketing and Sales Company (UK).

Who is the main contact?
Dr Sue Reeves

Contact information

Type(s)
Scientific

Contact name
Dr Sue Reeves

Contact details
University of Roehampton
Holybourne Ave
Roehampton
London
United Kingdom
SW15 4JD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LSC 11/ 010

Study information

Scientific Title
Uncovering the mechanisms explaining differences in body mass index between breakfast eaters and breakfast skippers

Study objectives
It is hypothesised that:
1. Breakfast will increase appetite and subsequent food intake.
2. Skipping breakfast will impact on energy balance and levels of physical activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Roehampton Ethics Committee, 06/04/2014, ref: LSC 11/ 010

Study design
Randomised crossover design consisting of two seven-day experimental periods plus a minimum of a one week wash-out in between

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Diet and obesity

Interventions
Participants will be randomly assigned to:
1. Breakfast eating condition (BE), where they consume breakfast within 1 hour of waking in the morning
2. No breakfast condition (NB), where they are asked to refrain from eating until midday.

Participants follow an assigned test condition for the first week of testing then, subsequent to the wash-out period, start the second week of testing where they follow the alternative test condition.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Energy expenditure measured as resting metabolic rate (RMR) and the thermic effect of food.
2. Blood glucose, insulin and leptin levels measured from finger prick blood samples.
3. Hunger assessed using visual analogue scales.
These outcomes will be measured on the first morning of each breakfast condition and the morning after the final day (day 8) of each breakfast condition

4. Energy intakes from food diaries and an indication of physical activity measured as steps per day using pedometers and accelerometers measured for 7 days in each breakfast condition

Secondary outcome measures
An indication of mechanisms that could possibly account for differences in energy balance and body weight maintenance between breakfast eaters and breakfast skippers. Measured after the study has been completed and all the data analysed.

Overall study start date
11/04/2011

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Participants may be male or female
2. Over the age of 18 years
3. Be healthy
4. Able to safely comply with the study
5. Be able to provide written informed consent (however participants are free to withdraw from the study at any time without having to give a reason)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Women who are pregnant, planning a pregnancy or lactating
2. Women taking hormone replacement therapy (HRT)
3. Anyone with a history of heart disease, diabetes, respiratory disorders, thyroid disease, kidney disease, or any bleeding disorder
4. Any musculoskeletal disorder that limits the participants ability to lie on a camp bed for prolonged periods or indication that skipping breakfast will cause a risk to the person, e.g. fainting
5. Anyone on medication for the above listed disorders, where the medication regime is affected by the exclusion of breakfast and medication that is known to affect metabolism or any of the measurements being made

Date of first enrolment

11/04/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Roehampton
London
United Kingdom
SW15 4JD

Sponsor information

Organisation
University of Roehampton

Sponsor details
c/o Professor Jorg Huber
Holybourne Ave
Roehampton
London
England
United Kingdom
SW15 4JD

Sponsor type
University/education

Website
http://www.roehampton.ac.uk/home/

ROR
https://ror.org/043071f54

Funder(s)

Funder type
Industry

Funder Name
Kellogg Marketing and Sales Company

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2015		Yes	No