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The effect of functional lipids on appetite in lean and obese participants

Submission date
01/09/2017

Recruitment status
No longer recruiting

Registration date
03/10/2017

Overall study status
Completed

Last Edited
03/06/2020

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 a convincing body of research showing how different fats elicit different effects on appetite, hunger and fullness, and as a result; energy intake. There are different types of fats called triglycerides that are used for energy. It has been shown that medium-chain triglycerides (triglycerides with a fatty acid chain length of 6-12 carbons, MCT) lead to reduced feelings of hunger and a suppression of food intake compared to long-chain triglycerides (triglycerides with a fatty acid chain length of over 12 carbons, LCT). Likewise, there have been studies suggesting that conjugated linoleic acid (CLA) (a healthy fatty acid that is found in meat and dairy products mostly) may also lead to greater satiation (feeling full) than the LCT found commonly in food. To date, only one study has been conducted to explain which fat has the most potential to be used to promote satiation and therefore decrease energy intake. Furthermore, most of the research currently conducted has been done so in lean individuals. As appetite regulation differs between lean and obese individuals the study of obese individuals can help provide insight into the satiating properties of various lipids, and their potential to be used in weight management strategies. The aim of this study is to compare the effects of two lipids (CLA and MCT) to each other and to a control on fullness in obese and lean controls and examine satiety hormones that influence food intake following the consumption of lipids in obese and lean controls.

Who can participate?
This study will recruit two groups: healthy-weight participants (BMI 18.5-24.9 kg/m2) and 16 obese (BMI 30-40 kg/m2) aged 18-60 who are not restricted eaters.

What does the study involve?
The study involves three non-consecutive test days in a randomised order. After a 24 hour standardisation period and overnight fast, participants come to the laboratory and consume a smoothie breakfast to which MCT, CLA or a control lipid is added (one per test day). Over the next three hours, subjective sensations of appetite, gastric emptying breath tests, and blood samples (via cannulation) are taken in order to elucidate the effects of these lipids on appetite, as well as the mechanisms behind any observed effects. After the data collection period, participants consume an ad libitum lunch to examine the satiety effect of the lipids, and participants are required to fill diet diaries for the remainder of the day and the following 24 hours. Participants are assessed for their fat-related appetite control and their energy intake.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Oxford Brookes Centre for Nutrition and Health (UK)

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

Who is funding the study?
1. Oxford Brookes University (UK)
2. TANITA Healthy Weight Community Trust (UK)

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
171082

Study information

Scientific Title
A comparison of the satiating properties of medium-chain triglycerides (MCT) and conjugated linoleic acid (CLA) in lean and obese participants

Study objectives
The study's two core aims are to:
1. Compare the effects of two functional lipids (CLA and MCT) to each other and to a control for perceived satiety and actual food intake in obese individuals and lean controls.
2. Examine satiety hormones that might be influencing food intake following the consumption of the functional lipids in obese individuals and lean controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Brooked University, 15/03/2017, ref: UREC 171082

Study design
Randomised cross-over design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Lean and obese individuals

Interventions
Following provision of informed consent and study screening, eligible participants are given weighing scales and a standardisation booklet in order to fulfil standardisation requirements. This requires abstaining from alcohol and strenuous physical activity, and to record all food and drink consumed throughout the 24 hours preceding each trial. This was to be repeated in the same period before the remaining trials.

Participants completed three trials in a random order: control, and the two functional lipids: MCT and CLA.

Upon arriving at the laboratory, participants are to be fitted with a cannula, give a baseline gastric emptying sample (GE), and fill baseline visual analogue scales (VAS) pertaining to appetite. After this, the smoothie breakfast containing the lipid is served, which participants have five minutes to consume. Participants remain in the lab for three hours whilst repeat

samples are taken until an ad libitum lunch is served. The ad libitum lunch is a single item buffet (pasta) which is served hot in multiple bowls. Bowls will be replaced once the participant has consumed ½ to ¾ of a bowl.

After the ad libitum lunch finishes, participants are free to leave the laboratory, with another diet diary, which is to be filled for the remainder of the day and following 24 hours.

Gastric emptying breath tests are taken every 15 minutes, visual analogue scales and blood samples every 30 minutes throughout the three hour period.

Intervention Type
Other

Primary outcome measure
1. Energy intake assessed by the ad libitum buffet lunch that participants consume at the end of each trial in isolated booths at 180-195 mins (until participants reach satiety)
2. Visual Analogue Scales will be used to measure subjective sensations of appetite: Hunger, Fullness, Desire to Eat, Prospective Food Consumption and Nausea at 0 mins, 30 mins, 60 mins, 90 mins 120 mins and 180 mins
3. Gastric emptying, measured through the 13C octanoic acid breath test at 0 mins, 15 mins, 30 mins, 45 mins, 60 mins, 75 mins, 90 mins, 105 mins, 120 mins, 135 mins, 150 mins, 165 mins and 180 mins
4. Blood parameters implicated in fat-related appetite control: cholecystokinin, acylated ghrelin, PYY and β-hydroxybutyrate. Blood samples taken at 0 mins, 30 mins, 60 mins, 90 mins 120 mins and 180 mins

Secondary outcome measures
1. 48 hour energy intake, through recorded diet diaries completed after the morning in the laboratory and the following day
2. Hedonic properties of the lipid (to outline palatability issues with the breakfasts which may confound the results) assessed by Qualitative Descriptive Analysis at 5 min

Overall study start date
01/05/2016

Completion date
30/03/2018

Eligibility

Key inclusion criteria
1. Aged 18-60 years
2. BMI of 18.5-25.0 kg/m2 or 30.0-40.0 kg/m2

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
Planned Sample Size: 32 total; 16 healthy weight and 16 obese

Total final enrolment
29

Key exclusion criteria
1. Allergic/intolerant to any of the foods provided in the study
2. Taking medication which could affect appetite
3. Smokers
4. A ‘restrained eater’, as defined by the TFEQ and DEBQ
5. Currently dieting to lose weight
6. Anaemic
7. Vegan

Date of first enrolment
12/07/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Brookes Centre for Nutrition and Health
Oxford Brookes University
Gipsy Lane
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Oxford
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OX3 0BP

Sponsor information

Organisation
Oxford Brookes University

Sponsor details
Gipsy Lane
Oxford
England
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OX3 0BP

Sponsor type
University/education

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
University/education

Funder Name
Oxford Brookes University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
TANITA Healthy Weight Community Trust

Results and Publications

Publication and dissemination plan

At the close of the trial, 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 scientific journals. Results will also be presented at relevant conferences.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Miriam Clegg, Oxford Brookes Centre for Nutrition and Health, Department of Sport Health Sciences and Social Work, Faculty of Health and Life Sciences, at mclegg@brookes.ac.uk (+44 1865 484365.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	03/06/2020	Yes	No