

Drivers of eating behaviour during chronic overconsumption

Submission date 14/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/03/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BB/G530141/1

Study information

Scientific Title

Drivers of eating behaviour during chronic overconsumption: role of food hedonics (liking and wanting) and peptide biomarkers on satiation and satiety

Study objectives

The aim of this study follows on from the findings of our previous BBSRC grant (BBS/B/05079: The impact of physical activity on appetite control). Participants are involved in two concurrent sub-studies. Study 1, looks at changes at energy balance over the duration of the intervention. Study 2 looks at the kinetics of gut peptides after consumption of breakfast. During the exercise intervention in study 1, a proportion of participants are expected to show compensatory increases in energy intake which will offset the energy deficit. This relative overconsumption is safe because it does not result in significant weight gain, but does confer other health benefits such as increased fitness, lowered blood pressure, resting heart rate and reduced waist circumference (a marker of visceral fat).

The principal objective of the study is to characterise and compare those participants who lose the amount of weight predicted by their exercise expenditure (based on measured changes in their fat and lean mass) with those participants who do not lose the amount of weight predicted.

The outcomes of the study will yield important information about the processes that underpin eating behaviour during a prolonged elevation in food intake (relative overconsumption) in response to an increase in energy expenditure from exercise.

Ethics approval required

Old ethics approval format

Ethics approval(s)

UK National Health Service Research Ethics Committee Leeds (West) approved on the 20th January 2009 (ref: 09/H1307/7)

Study design

Single centre medium term (12-week) experimental controlled study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Overweight, obesity

Interventions

Supervised exercise to expend 500 kcal 5 times/week for 12 weeks. Assessments at week 0, week 6 and week 12. No exercise overweight/obese and lean comparators.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Study 1:

Change in energy balance from week 0 to week 12 measured by the product of the energy cost of a unit change in fat mass by the observed change in fat mass and summing it with the product of the energy cost of a unit change in lean mass by the observed change in lean mass.

Study 2:

Rise and fall in concentration of gut peptides assayed from the participants blood samples in the four hour period following consumption of breakfast.

Secondary outcome measures

Study 1:

- 1.1. Cardiovascular fitness at week 12 will be measured by VO2 maximal test of aerobic capacity
- 1.2. Resting heart rate and Blood pressure at week 12 will be measured by an integrated digital blood pressure and heart rate monitor with inflatable cuff
- 1.3. Resting metabolic rate at week 12 will be measured by Gas Exchange Measurement
- 1.4. Substrate oxidation at week 12 will be measured by indirect calorimetry
- 1.5. Eating behaviour at week 12 will be measured by intake of test meals designed to vary in macronutrient composition (20:65:15 and 35:50:15, % carbohydrate:fat:protein) and quantitative ratings of hunger and satiety by questionnaire

Study 2:

Quantitative ratings of hunger and satiety by questionnaire.

Overall study start date

28/01/2008

Completion date

29/10/2015

Eligibility

Key inclusion criteria

1. 18 - 55 years old
2. Sedentary lifestyle (no leisure-time physical activity in previous 6 months)
3. Body Mass Index (BMI) between 27 - 38 kg/m² or 18 - 23 kg/m² (lean control)
4. Signed consent given
5. No objection from participant's GP

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

78

Key exclusion criteria

1. Inability to fully comply with intervention or study procedures
2. Insufficient English language skills to complete all questionnaires
3. Pre-existing injuries or conditions that could be aggravated by regular physical activity
4. Medication that could influence accumulation or expenditure of energy
5. Cardiac problems (arrhythmia, Congestive heart disease)
6. Uncontrolled hypertension
7. Genetic syndromes associated with obesity
8. Presence of untreated hypothyroidism
9. Recent body weight change (± 2 kg in previous 3 months)
10. Currently following weight loss regime
11. Food allergies or aversions

Date of first enrolment

28/01/2008

Date of final enrolment

29/10/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Institute of Psychological Sciences

Leeds

United Kingdom

LS2 9JT

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

c/o Rachel De Souza
Leeds
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Sponsor type

University/education

Website

<http://www.leeds.ac.uk/>

ROR

<https://ror.org/024mrxd33>

Funder(s)**Funder type**

Research council

Funder Name

Biotechnology and Biological Sciences Research Council (BBSRC) (UK) - (ref: BB/G530141/1)

Alternative Name(s)

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	08/06/2011		Yes	No
Results article	results	01/02/2012		Yes	No
Results article	results	01/01/2013		Yes	No