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Comparative effects of intermittent versus continuous energy restriction on metabolism following matched weight-loss

Submission date
29/11/2016

Recruitment status
No longer recruiting

Registration date
05/12/2016

Overall study status
Completed

Last Edited
24/01/2019

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
Intermittent (stop-start) energy (calorie) restriction, such as the 5:2 diet, has received considerable interest of late as a potential alternative to the conventional continuous energy restriction approach to weight-loss. Whilst there have been many studies demonstrating the efficacy of intermittent energy restriction as a viable means of weight-loss, little is known regarding its effects on blood sugar and fat breakdown after meals (postprandial glucose and fat metabolism). This is important because impairment to sugar and fat breakdown are important risk factors for type 2 diabetes and cardiovascular disease (e.g. heart disease, stroke). The aim of the study is therefore to compare the effects of intermittent and continuous energy restriction on postprandial glucose and fat metabolism. In addition, the study will compare changes in body composition (e.g. waist circumference and body fat), fuel utilisation (fat and glucose oxidation), resting calorie expenditure, eating behaviour and sleep quality with both diets.

Who can participate?
Healthy, weight-stable overweight/obese adults without significant medical conditions.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in intermittent energy restriction. This involves two days per week of very low energy intake (about 600 calories/day) through using commercially available meal replacement products (Lighterlife) and five days of healthy eating with no calorie restriction. Those in the second group take part in continuous energy restriction. This involves limiting daily intake to 600 calorie /day, following current best practice guidelines. At the start of the study and after participants have lost 5% of weight (as opposed to fixed duration of time), blood samples are taken 6 hours after drinking a test drink (chocolate milkshake) containing carbohydrate and fat to measure postprandial glucose and fat metabolism. In addition, resting calorie expenditure (the amount of calories expended maintaining essential body functions whilst at complete rest) is assessed using indirect calorimetry, which involves placing a plastic hood over the head which samples the amount of oxygen breathed in, is measured and participants undergo a Flanker task, which is a

computer based cognitive task designed to assess distraction to sweet/savoury foods. Finally, participants complete a range of questionnaires to assess changes in sleep quality, eating behaviour and mood. Weight of participants is tracked regularly during the study.

What are the possible benefits and risks of participating?
Participants benefit from intensive dietary support by registered dietitian and weight-loss guidance. In addition, if they lose weight then this is beneficial to their general health. The intermittent diet carries a risk of increased hunger, lethargy (sluggishness), insufficient fluid intake/dehydration due to the very low calorie nature of the intervention. Other risks include pain and bruising when blood samples are taken.

Where is the study run from?
Surrey Clinical Research Centre, Guildford (UK)

When is study starting and how long is it expected to run for?
May 2015 to August 2016

Who is funding the study?
LighterLife (UK)

Who is the main contact?
Dr Denise Robertson

Contact information

Type(s)
Scientific

Contact name
Dr Denise Robertson

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EC/2014/140/FHMS

Study information

Scientific Title
Comparative effects of intermittent versus continuous energy restriction on postprandial glucose and lipid metabolism following matched weight-loss

Study objectives
The relative reduction (improvement) in incremental triacylglycerol responses will be greater following weight-loss via intermittent energy restriction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Surrey Ethics Committee, 29/01/2015, ref: UEC/2014/140/FHMS

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Weight-loss

Interventions
Participants are randomised to one of two groups:

Intermittent energy restriction (IER): The study utilises a commercially available IER diet by LighterLife (Essex, UK). On two consecutive days of the week, participants consum four LighterLife Food Packs (2638kJ: 38%, 36% and 26% of total energy as carbohydrate, protein and fat respectively) which delivers approximately 25% of their estimated euenergetic needs. Meal replacement products are provided by study team. On the remaining five days of the week ("feed days"), participants self-select food intake but are asked to aim to consume an euenergetic diet compliant with healthy eating guidelines.

Continuous energy restriction (CER): Participants assigned to the CER diet consum a daily hypoenergetic diet of 2510kJ below their estimated energy requirements compliant with NICE obesity guidelines. Diets are not provided but are self-selected by participants.

In both groups, energy requirements are calculated using the Henry equations for BMR multiplied by an appropriate physical activity factor.

Metabolic and anthropometric assessments are conducted before and after participants attained a 5% weight-loss (as opposed to fixed duration of time). Weight tracked regularly over the course of the study.

Intervention Type
Behavioural

Primary outcome measure
1. 6-hour postprandial glucose (glucose, insulin, c-peptide) to a liquid mixed test meal is measured before and after attainment of 5% weight-loss
2. Lipid responses (triacylglycerol, non-esterified fatty acids) to a liquid mixed test meal is measured before and after attainment of 5% weight-loss

Secondary outcome measures
All outcomes are measured before and after 5% weight-loss:
1. Body composition is assessed via tape measure and bioimpedance
2. Rate of weight-loss
3. Fasting substrate utilisation is assessed via indirect calorimetry (respiratory quotient)
4. Postprandial substrate utilisation is assessed via serial blood sampling (3-hydroxybutyrate) for 6 hours after a liquid mixed test meal (400ml Fortisip, Nutricia, Trowbridge, UK: 2510kJ, 74g carbohydrate, 24g protein and 23g fat)
5. Fasting cardiometabolic risk markers (glucose, insulin, lipid profiles)
6. Resting energy expenditure (indirect calorimetry)
7. Sleep quality is measured using the Pittsburgh sleep quality index and Epworth sleep scale
8. Eating behaviour is measured using the Dutch eating behaviour questionnaire
9. Mood is measured using the positive affect negative affect scale
10. Self-efficacy is measured using a self-efficacy questionnaire
11. Hedonic food preference is measured using the Flanker psychometric task and power of food scale

Overall study start date
01/05/2015

Completion date
29/08/2016

Eligibility

Key inclusion criteria
1. Overweight and obese participants (BMI ≥25 kg/m2)
2. Aged 18 to 65 years
3. Weight-stable (±2 kg) over the preceding three months

4. No significant medical history
5. To control for the potential influence of the menstrual cycle between visits, female participants were either post-menopausal or taking oral contraceptives

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
27

Key exclusion criteria
Individuals not meeting the inclusion criteria.

Date of first enrolment
01/05/2015

Date of final enrolment
05/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surrey Clinical Research Centre
University of Surrey
Guildford
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Sponsor information

Organisation

Lighterlife UK Ltd

Sponsor details
Cavendish House
Parkway
Harlow Business Park
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Sponsor type
Industry

ROR
https://ror.org/00drp2z27

Funder(s)

Funder type
Industry

Funder Name
LighterLife

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

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

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018	24/01/2019	Yes	No