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Continuous vs. intermittent energy restriction and weight loss

Submission date	Recruitment status	[X] Prospectively registered
09/10/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/01/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/10/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
An intermittent energy restriction (IER) approach to weight loss is easier for some people to follow as it involves short spells of severe energy restriction alternated with days of usual energy intake. However, there is currently not enough evidence regarding the potential effectiveness and benefits of IER compared with other food-based weight loss methods. We aim to compare the effectiveness of IER with continuous energy restriction (CER) on weight loss, blood glucose levels and markers of CVD risk in a selected group of NHS Rotherham Institute of Obesity (RIO) weight loss patients.

Who can participate?
Obese male and female patients, aged 18-65, attending a weight loss programme at the Rotherham Institute of Obesity are eligible to participate in this study.

What does the study involve?
The study will involve participating in a six-month weight loss programme. Participants will be randomly allocated to either the IER or the CER programme. The IER programme will be given in the form of the LighterLife Fast plan, which advocates 5 days unrestricted healthy eating and 2 days fasting, which consists of 4 fast LighterLife Foodpacks providing about 600 kcal each day. This will be compared with the CER programme, whereby patients will be instructed to consume a healthy diet with a daily deficit of about 500 kcal. Weight loss, changes in waist circumference as well as changes in blood glucose, fasting glucose and insulin, full lipids and inflammatory markers will be assessed. We will also assess changes in blood flow and blood pressure as well as dietary adherence using food diaries.

What are the possible benefits and risks of participating?
Patients will lose weight and may see improvements in other diseases associated with being obese. The study will contribute to a greater understanding and depth of knowledge about how well the different weight loss methods work and may provide the patient with a more acceptable way to lose and manage their weight. There are no foreseen disadvantages or risks of taking part.

Where is the study run from?
Rotherham Institute of Obesity, Rotherham, UK.

When is the study starting and how long is it expected to run for?
The study is expected to start in early February 2014 and will run for 6 months.

Who is funding the study?
Lighterlife UK Ltd, UK.

Who is the main contact?
Dr Kelly Johnston
01279 636998
Kelly.Johnston@lighterlife.com

Contact information

Type(s)
Scientific

Contact name
Dr Matthew Capehorn

Contact details
Rotherham Institute for Obesity (RIO)
Clifton Medical Centre
The Health Village
Doncaster Gate
Rotherham
United Kingdom
S65 1DA
+44 (0)844 477 3622
mcapehorn@yahoo.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Rotherham Institute for Obesity (RIO)/Lighterlife Fast

Study information

Scientific Title
The comparative effects of continuous versus intermittent energy restriction (CER and IER respectively) on changes in weight, anthropometry and other cardio-metabolic disease risk markers in a selected cohort of RIO weight loss patients

Study objectives
The aim of this study is to compare the feasibility and efficacy of IER with CER on a range of outcomes measures including weight loss & anthropometry, measures of glycaemic control and appetite, and other biochemical markers of CVD risk..

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire NHS Ethics Committee, ref: 14-YH-0018

Study design
Randomised non-blinded single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Weight loss in obese individuals

Interventions
Randomised comparison using 200 overweight or obese, male and female participants (100 randomised to each group).

The IER leg of this study will be delivered in the form of the Lighterlife Fast 5:2 diet, which advocates 5 days healthy eating (consuming energy levels commensurate with weight maintenance) and 2 days fasting, which advises consumption of 4 fast Lighterlife Fast foodpacks providing 600 kcal on those two days. This will be compared with the CER leg of the study, whereby patients will be instructed to consume a healthy diet with a daily deficit of approximately 500 kcal.

The total duration of the intervention is 26 weeks. Participants on this trial remain patients of RIO and as such will be followed up regularly thereafter, but data will not be collected for this study.

Updated 16/04/2014:
Participants return at 12 months for the following measurements:

1. Weight
2. Height
3. BMI
4. Waist circumference
5. Hip circumference
6. Chest circumference
7. Blood pressure
8. Bio-impedance
9. Report on co-morbidities
10. Current medication

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Weight
2. Waist circumference

Secondary outcome measures
1. Fasting glucose, lipids and insulin
2. Liver function tests (LFTs), thyroid function tests (TFTs), Hba1c, adiponectin, leptin, C-reactive protein and IGF-1
3. Bio-impedance and blood pressure as well as dietary adherence using validated food diaries

Overall study start date
01/02/2014

Completion date
31/08/2014

Eligibility

Key inclusion criteria
1. Healthy males and females, aged 18-65
2. Body mass index (BMI) > 30

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
200

Total final enrolment
197

Key exclusion criteria
Those who are pregnant or breastfeeding

Date of first enrolment
01/02/2014

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rotherham Institute for Obesity (RIO)
Rotherham,
United Kingdom
S65 1DA

Sponsor information

Organisation
Lighterlife UK Ltd (UK)

Sponsor details
Cavendish House
Parkway
Harlow Business Park
Harlow
United Kingdom
CM19 5QF
+44 (0)127 963 6955
kelly.johnston@lighterlife.com

Sponsor type
Industry

ROR
https://ror.org/00drp2z27

Funder(s)

Funder type
Industry

Funder Name
Lighterlife (UK)

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
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	14/10/2019	Yes	No