

Continuous vs. intermittent energy restriction and weight loss

Submission date 09/10/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/10/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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?

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Contact information

Type(s)

Scientific

Contact name

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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

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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