

Comparison of varying dietary interventions in an obese population

Submission date
05/09/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
15/09/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
27/01/2011

Condition category
Nutritional, Metabolic, Endocrine

☐ 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
N/A

Study information

Scientific Title

Randomised clinical trial of standard dietary treatment versus protein-sparing modified fast or the LighterLife Programme in the management of obesity

Study objectives

To assess the effectiveness of a low carbohydrate/high protein, a commercial very low calorie diet (LighterLife) and a 600-kcal deficient diet in an obese population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the North of Scotland Research Ethics Service on the 3rd February 2005 (ref: 05/S0802/03).

Study design

Single centre randomised clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

Screening period:

600-kcal were subtracted from the subjects' estimated daily energy requirements. Portion sizes and food groups were explained to patients, who were also provided with written information. Patients were reviewed at 2, 4, 8 and 12 weeks.

Randomisation:

At the end of the screening period, patients who did not achieve a 5% weight loss were randomised to either protein-sparing modified fast (PSMF) or LighterLife (LL). PSMF patients were restricted to a maximum of 40 g of carbohydrate per day. Written information and examples of recipes were provided. The diet was supplemented with multivitamins and minerals. LighterLife is a commercial very-low calorie diet (VLCD) programme including group cognitive behaviour therapy (CBT). The programme consists of three stages: weight loss period of 100

days with VLCD provision and CBT; VLCD provision with continued counselling until target weight is achieved; 12-week weight management module with slow return to normal food and CBT. All participants were given additional lifestyle and dietary advice during 6 visits post randomisation.

These interventions were evaluated over 1 year, and patients were then followed up for 2 years.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Weight loss, measured in kilograms before screening, at screening and 3 and 9 months post-screening.

Secondary outcome measures

1. Changes in cardiovascular risk, measured by looking at total cholesterol, triacylglycerols, high density lipoprotein (HDL), low density lipoprotein (LDL), fasting glucose (all in mmol/L), fasting insulin (uU/ml), HbA1c (%) waist circumference (cm), blood pressure (mmHg)
2. Liver and kidney function; liver function assessed by measuring albumin (g/L), total bilirubin (umol/L), alkaline phosphatase, alanine aminotransferase and gamma-glutamyl transferase (U/L). For kidney function urea (mmol/L) and creatinine (umol/L) were measured and the estimated glomerular filtration was calculated.
3. Quality of life, measured using the following questionnaires: Physical activity (in house), the Dutch Eating Behaviour, the World Health Organization (WHO) quality of life, the Beck Depression Inventory, General Health, Lee fatigue scale and the Epworth Sleepiness Scale
4. Changes in adipokines

All measured before screening, at screening and 3 and 9 months post-screening.

Overall study start date

03/02/2005

Completion date

30/11/2009

Eligibility

Key inclusion criteria

1. Men and women older than 18 years of age
2. Body Mass Index (BMI) greater than or equal to 35 kg/m²

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

1. History of hepatic or renal disease
2. Cancer
3. Current pregnancy/lactating
4. On anti-depressants or anti-obesity medication
5. Eating disorders

Date of first enrolment

03/02/2005

Date of final enrolment

30/11/2009

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

The Robert Gordon University

Aberdeen

United Kingdom

AB25 1HG

Sponsor information**Organisation**

The Robert Gordon University (UK)

Sponsor details

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Sponsor type
University/education

Website
<http://www.rgu.ac.uk/>

ROR
<https://ror.org/04f0qj703>

Funder(s)

Funder type
Industry

Funder Name
LighterLife UK Limited (UK)

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	01/09/2009		Yes	No