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Comparison of varying dietary interventions in an obese population

Submission date	Recruitment status	[_] Prospectively registered
05/09/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/09/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/01/2011	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 evaulated over 1 year, and patients were then followed up for 2 years.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

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

Key secondary outcome(s))
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.

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/m^2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

Study participating centre
The Robert Gordon University
Aberdeen
United Kingdom
AB25 1HG

Sponsor information

Organisation
The Robert Gordon University (UK)

ROR
https://ror.org/04f0qj703

Funder(s)

Funder type
Industry

Funder Name
LighterLife UK Limited (UK)

Results and Publications

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