ISRCTN12558934 https://doi.org/10.1186/ISRCTN12558934

Differences between energy-restricted high-protein versus high-carbohydrate, low-fat diet in weight loss and maintenance

Submission date
13/05/2016

Recruitment status
No longer recruiting

Registration date
16/05/2016

Overall study status
Completed

Last Edited
16/03/2017

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
A low-calorie, low-fat, high-carbohydrate diet is the recommended diet for the treatment of obesity because it helps with weight loss. This recommendation has been recently challenged by studies showing that low-carbohydrate diets might result in greater weight loss at 6 months. However, in the longer term (1-2 years) weight loss is modest with both approaches, and the advantages of low-carbohydrate diets on weight loss are not universally demonstrated. For this reason we aim to evaluate the effects of long-term (1 year) reduced calorie intake associated with different type of diets (high-protein and high-carbohydrate diets with a similar amount of energy from fats and saturated fats).

Who can participate?
Patients aged 18-65 with severe obesity

What does the study involve?
Participants are randomly allocated to consume either a high-protein diet or a high-carbohydrate diet. All participants receive Cognitive Behaviour Therapy (CBT), education about diet and exercise, and attend exercise sessions.

What are the possible benefits and risks of participating?
We expect that both groups should lose weight and decrease their risk of heart disease. Possible risks are not known.

Where is the study run from?
Villa Garda Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2007 to January 2011

Who is funding the study?
Villa Garda Hospital (Italy)

Who is the main contact?
Dr Riccardo Dalle Grave

Contact information

Type(s)
Scientific

Contact name
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Protocol serial number
USL22#01/07-CEP31

Study information

Scientific Title
A randomized trial of energy-restricted high-protein versus high-carbohydrate, low-fat diet in morbid obesity

Study objectives
No difference will be found between the two types of diet in patients with severe obesity assessed at inpatient admission, and after 27 weeks and 1 year

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethical committee of the Local Health Unit 22-Bussolengo, 19/06/2007, ref: USL22#01/07-CEP31

Study design
Randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Class II and III obesity

Interventions

The treatment was divided into two stages: Stage One (inpatient treatment; 3 weeks); Stage Two (outpatient treatment; 48 weeks).

Participants started the assigned diet on the second inpatient day, and continued it during the whole Stage Two. They were admitted in consecutive blocks of 8, all following the same diet, to avoid exchanges between participants allocated to different diets. Both diets were energy-restricted (1,200 kcal/day for women and 1,500 kcal/day for men), with 20% energy from fats (<10% from saturated fats) and daily multivitamin supplements. The high-protein diet (HPD) derived 34% energy from proteins and 46% from carbohydrates, whereas the high-carbohydrate diet (HCD) had 17% energy from proteins and 63% from carbohydrates.

Cognitive Behaviour Therapy (CBT) intervention
All participants received a comprehensive manual-based CBT to enhance the adherence to lifestyle modification integrating education with cognitive behavioural procedures and strategies. Stage One included 15 CBT groups (five a week), chaired by physicians, dieticians and psychologists, 18 sessions of aerobic exercises (e.g., 30 min of tapis roulant or cyclette) and six sessions callisthenic, chaired by physical trainers. Education addressed the following main topics:
1. Energy balance
2. The food pyramid, size of portions and regular eating
3. Calorie counting
4. Shopping and food labels
5. Physical activity, when and how much.

The cognitive behavioural procedures and strategies included:
1. Self-monitoring of food intake, energy and body weight
2. Stimulus control strategies (in particular how to reduce food stimuli at home)
3. Problem solving
4. Cognitive restructuring of dysfunctional thoughts that hinder weight loss and weight loss maintenance
5. Relapse prevention.

Stage Two included 12 sessions of 45 min each over 48 weeks with a CBT-trained dietician. The first 4 sessions were carried out every 2 weeks, followed by 4 sessions every 4 weeks and then by 4 sessions every 6 weeks in the last 24 weeks. Every session had the following content:
1. Weighing the patient and recording on a graph
2. Checking home weight control
3. Reviewing the self-monitoring record of food and drink intake and of number of daily steps assessed by a pedometer
4. Setting the agenda collaboratively
5. Working through agenda topics
6. Agreeing on new homework assignments
7. Summarizing the session.

The first 24 weeks of stage two (27 weeks from treatment start) were dedicated to address barriers to weight loss, the remaining sessions to weight maintenance. In this last phase the calorie content was gradually increased to maintain the weight, without changes in macronutrient composition.

Intervention Type

Behavioural

Primary outcome(s)
Percent weight loss at study end (1 year)

Key secondary outcome(s))
The secondary outcomes were assessed at baseline, after 3 weeks, after 27 weeks and after 1 year.
1. Attrition rates
2. Cardiovascular risk factors and psychological profile, measured using:
2.1. The Body Uneasiness Test-A
2.2. The Binge Eating test
2.3. Beck Depression Inventory
2.4. Beck Anxiety Inventory

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Age range 18-65 years
2. Body mass index (BMI) ≥ 40.0 kg/m2 or between 35 and 39.9 with at least one weight loss-responsive comorbidity (e.g., type 2 diabetes, cardiovascular diseases, sleep apnea, severe joint disease, two or more risk factors defined by the Adult Treatment Panel III)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Pregnancy or lactating
2. Took medications affecting body weight
3. Medical comorbidities associated with weight loss or had severe psychiatric disorders (e.g., acute psychotic states, bipolar disorder, bulimia nervosa)

Date of first enrolment
01/09/2007

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Italy

Study participating centre
Villa Garda Hospital
Department of Eating Disorder and Obesity
Italy
37016

Sponsor information

Organisation
Regional Agency for Health and Social Care, Regione Emilia-Romagna (Italy)

ROR
https://ror.org/02edavb98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Villa Garda Hospital (Italy)

Results and Publications

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	01/01/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes