

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/03/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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**  
Dr Riccardo Dalle Grave

**Contact details**  
Monte Baldo Street, 89  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **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 measure**

Percent weight loss at study end (1 year)

### **Secondary outcome measures**

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

### **Overall study start date**

19/06/2007

### **Completion date**

01/01/2011

## **Eligibility**

### **Key inclusion criteria**

1. Age range 18-65 years
2. Body mass index (BMI)  $\geq 40.0$  kg/m<sup>2</sup> 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

### **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

88 patients with obesity, 44 for each type of diet

**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)

**Sponsor details**

Aldo Moro Street 21

Bologna

Italy  
40127

**Sponsor type**  
Government

**ROR**  
<https://ror.org/02edavb98>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Villa Garda Hospital (Italy)

## Results and Publications

**Publication and dissemination plan**  
To be confirmed at a later date

**Intention to publish date**

**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?
<a href="#">Results article</a>	results	01/01/2017		Yes	No