

# Body composition, eating disorder psychopathology and psychological distress in anorexia nervosa

<b>Submission date</b> 08/12/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/05/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Anorexia nervosa (AN) is characterized by weight loss and reduction of body mass (lean and fat masses). Weight restoration is a key procedure in the treatment of these patients. However, for a normal resumption of physiological processes it is necessary to restore an adequate amount and distribution of body mass (lean and fat). Furthermore, no study has assessed the influence of body composition changes on eating disorder psychopathology and psychological distress in AN patients. The aim of this study is to assess body composition and fat mass distribution before and after body weight restoration and to investigate the relationship between body fat pattern changes and eating disorder and psychological distress in AN patients treated in a specialist inpatient unit.

### Who can participate?

We recruited 50 female patients with a diagnosis of anorexia nervosa, and 100 age and body mass index (BMI) matched healthy controls.

### What does the study involve?

All patients with AN received the same treatment: cognitive behavioural therapy (CBT-E) (psychological treatment) and weight restoration. Tests were done to measure body composition and assess eating disorder psychopathology and psychological distress in all patients.

### What are the possible benefits and risks of participating?

The benefits are the improvement of physical, psychological and social status of patients. There is no risk in participating in the study.

### Where is the study run from?

Villa Garda Hospital (Italy).

### When is the study starting and how long is it expected to run for?

The recruitment started in January 2011 and ended in January 2013.

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

Who is the main contact?  
Dr Marwan El Ghoch

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Marwan El Ghoch

**Contact details**  
Monte Baldo Street, 89  
Garda  
Italy  
37016

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
01

## Study information

**Scientific Title**  
Body composition, eating disorder psychopathology and psychological distress in anorexia nervosa: a longitudinal study

**Study objectives**  
Anorexia nervosa (AN) patients have different body composition with respect to healthy controls after immediate weight normalization. This difference in body composition may negatively influence treatment outcome and may have some psychological effects.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Institutional Review Board of Villa Garda Hospital, 15/12/2010

**Study design**

Longitudinal study

**Primary study design**

Observational

**Secondary study design**

Other

**Study setting(s)**

Hospital

**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**

Anorexia nervosa/body composition

**Interventions**

We recruited 50 female patients with a diagnosis of anorexia nervosa and 100 age and BMI matched healthy controls for an observational study. The interventions are weight restoration and cognitive behavioural therapy (psychological treatment). All patients received the same treatment.

Body composition was measured using dual-energy X-ray absorptiometry (DXA) in anorexia nervosa patients and in healthy controls. The Eating Disorder Examination interview (EDE) and the Brief Symptom Inventory (BSI) were used to assess eating disorder psychopathology and psychological distress, respectively.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. To assess the change in lean and fat masses and their distribution (using DXA) before and after complete weight restoration in AN patients.
2. To compare body composition and fat distribution (using DXA) of weight-restored AN patients with a healthy age- and post-treatment BMI-matched control group.

All outcomes were collected at baseline and at the end of the treatment (20 weeks of treatment).

**Secondary outcome measures**

To assess the relationship between body composition patterns (using DXA), eating disorder psychopathology (using EDE) and general distress (using BSI) in AN patients. All outcomes were collected at baseline and at the end of the treatment (20 weeks of treatment).

**Overall study start date**

01/01/2011

**Completion date**

07/01/2013

## Eligibility

**Key inclusion criteria**

1. Female patients aged 18-50 years
2. Diagnosis of anorexia nervosa
3. Body mass index (BMI)  $\leq 17.5$  kg/m<sup>2</sup> at time zero
4. BMI  $\geq 18.5$  kg/m<sup>2</sup> at the end of the treatment

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

50 female patients with a diagnosis of anorexia nervosa, and 100 age and BMI matched healthy controls

**Key exclusion criteria**

1. Participants that do not satisfy inclusion criteria
2. Participants with active substance abuse, schizophrenia and other psychotic disorders

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

07/01/2013

## Locations

**Countries of recruitment**

Italy

**Study participating centre**

**Monte Baldo Street, 89**

Garda

Italy

37016

## **Sponsor information**

### **Organisation**

Villa Garda Hospital (Italy)

### **Sponsor details**

Monte Baldo Street, 89

Garda

Italy

37016

### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/01mw6s018>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Villa Garda Hospital (Italy)

## **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?
<a href="#">Results article</a>	results	01/04/2014		Yes	No