

# Regional fat distribution in adolescent girls and adults with anorexia nervosa

<b>Submission date</b> 16/05/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/09/2016	<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 is an eating disorder in which people keep their body weight at low as possible by restricting the amount of food they eat, vomiting and excessive exercise. It leads to weight loss and a reduction of body mass. A severe loss in body weight can lead to a number of physical problems, such as extreme tiredness, headaches/abdominal pains, poor circulation and females can stop having their periods. These symptoms can only be treated by an adequate increase in weight and distribution of body mass. Available data suggest that during anorexia nervosa, adolescent females seem to lose more fat around their belly (central body fat), while adult females more peripheral fat (fat found elsewhere on the body). When these patients then regain their weight, adult females tend to deposit their newly acquired fat around their belly (central regions) while adolescents regain similar body fat distributions to non-sufferers with no increase in the proportion of belly fat. However, results reported in adolescent females are not consistent and need further investigation, and no comparison has made between adult and adolescent individuals that have undergone the same treatment. The aim of this study is to assess body fat mass and its distribution before and after regaining weight in adolescent and adult individuals with anorexia nervosa treated with same treatment (duration and weight gain rate).

### Who can participate?

Female patients with a diagnosis of anorexia nervosa (adolescents 13-19 years, adults 20 years or over)

### What does the study involve?

All patients with anorexia nervosa receive the same inpatient treatment based on gaining weight and enhanced cognitive behavioural therapy (CBT-E). Tests were done to measure body composition 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?  
January 2012 to July 2014

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

Who is the main contact?  
Dr Marwan El Ghoch  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
02

## Study information

**Scientific Title**  
Regional fat distribution in adolescent girls and adults with anorexia nervosa: a longitudinal study

**Study objectives**  
Available data indicate that adults with anorexia nervosa, but not adolescents, seems to have different body fat distribution with respect to healthy controls before and after immediate weight normalization. However, to date no study compared the effect weight restoration on

body fat distribution in adults and adolescents with AN under the same circumstance (identical treatment). It is therefore possible that the differences observed in adults and adolescents with anorexia nervosa might be the results of different modality of nutritional rehabilitation and rate of weight regain. On the basis of this premise, we aimed to study adults and adolescents with anorexia nervosa with the same treatment to investigate if really exists a difference in body fat distribution after immediate weight restoration between the two populations.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of Villa Garda Hospital, 15/12/2011, ref. 02\_2012

### **Study design**

Longitudinal study

### **Primary study design**

Observational

### **Secondary study design**

Case-control study

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **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**

Anorexia nervosa/body composition

### **Interventions**

We recruited 66 female patients with a diagnosis of anorexia nervosa and 66 controls of the same age (+ 2 years) with a BMI equivalent to the patients BMI after weight restoration for an observational study. The interventions are weight restoration and inpatient cognitive behavioural therapy. 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.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Change in fat masses and their distribution (using DXA) before and after complete weight restoration in AN patients

### **Secondary outcome measures**

Body composition and fat distribution (using DXA) of weight-restored AN patients

### **Overall study start date**

01/01/2012

### **Completion date**

01/07/2014

## **Eligibility**

### **Key inclusion criteria**

1. Female patients aged 13 - 50 years (adolescents 13-19 years; adults  $\geq 20$  years)
2. Diagnosis of anorexia nervosa
3. BMI  $\leq 18.5$  kg/m<sup>2</sup> in adults or BMI percentiles  $\leq 18.5$  kg/m<sup>2</sup> in adolescents at time zero
4. BMI  $\geq 18.5$  kg/m<sup>2</sup> in adults or BMI percentiles correspondent to a BMI  $\geq 18.5$  kg/m<sup>2</sup> at the end of the treatment

### **Participant type(s)**

Patient

### **Age group**

Other

### **Sex**

Female

### **Target number of participants**

66 female patients with a diagnosis of anorexia nervosa, and 66 controls of the same age (+ 2 years) with a BMI equivalent to the patients BMI after weight restoration.

### **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**

01/01/2012

### **Date of final enrolment**

01/07/2014

## **Locations**

### **Countries of recruitment**

Italy

**Study participating centre**  
**Villa Garda Hospital**  
Garda  
Italy  
37016

## **Sponsor information**

**Organisation**  
Villa Garda Hospital (Italy)

**Sponsor details**  
Via Monte Baldo, 89  
Garda  
Italy  
37016

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.villagarda.it/>

**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	01/12/2015		Yes	No