

# Changes in lean and skeletal muscle body mass in adult females with anorexia nervosa (AN) before and after weight restoration

<b>Submission date</b> 12/04/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The eating disorder anorexia nervosa (AN) is a serious mental health condition in which people restrict the amount of food they eat to keep their body weight as low as possible. Weight loss in AN can result in an extreme reduction of body fat and lean body mass (LBM), such as muscle. A lot of research has investigated body fat and its distribution in AN patients, but LBM has not really been looked at in depth. Some studies show that AN patients lose more LBM in their arms and legs compared to the trunk of their body. This may be due to other conditions triggered by AN. Unfortunately, the results of these studies are not consistent; some studies found no change in LBM distribution in AN patients. Also, there is very little information on long-term changes in LBM distribution after they have regained a normal body weight. There are also very few studies which have looked at the total body skeletal muscle mass (SM) in patients with AN, and those that have looked at SM have used technology that is not usually available in regular clinics, such as magnetic resonance imaging (MRI) machines. Overall, research investigating LBM, LBM distribution and SM in women with AN before and after regaining a normal body weight are very few, inconsistent and often use methods that are poor or can't be replicated. The aim of this study is to assess changes in LBM, LBM distribution and SM before and after body weight restoration in a large sample of women with AN.

### Who can participate?

Women diagnosed with anorexia nervosa.

### What does the study involve?

Patients diagnosed with AN undergo treatment to regain a normal body weight using standard care and inpatient cognitive behavioural therapy (CBT). Following treatment to restore their weight, patients' post-treatment body composition (LBM, SM) is compared with healthy controls (women who are not AN) of the same age and equivalent body mass index (BMI). All participants have their body composition measured using dual-energy X-ray absorptiometry (DXA).

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

There are no risks or benefits to participants

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 2010 to February 2015

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

Who is the main contact?  
Dr M El Ghoch (scientific)  
marwan1979@hotmail.com

**Study website**  
www.villagarda.it (Italian)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
01\_2010

## Study information

**Scientific Title**

Changes in lean and skeletal muscle body mass in adult females with anorexia nervosa (AN) before and after weight restoration: a longitudinal study

### **Study objectives**

During AN, patients lose lean and skeletal muscle body mass especially from extremity regions, and complete weight restoration may overcome this situation.

### **Ethics approval required**

Old ethics approval format

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

Ethics Committee Institutional Review Board of Villa Garda Hospital, Verona, 15/12/2009, ref: 01\_2010

### **Study design**

Observational longitudinal study

### **Primary study design**

Observational

### **Secondary study design**

Longitudinal study

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

Hospital

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

Diagnostic

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

### **Health condition(s) or problem(s) studied**

Anorexia nervosa/body composition

### **Interventions**

1. Weight restoration
2. Inpatient cognitive behavioural therapy (CBT)

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Changes in lean body mass (LBM) and LBM distribution (extremity and trunk) measured by dual-energy X-ray absorptiometry (DXA) scan before and after weight restoration:

1. Total fat mass (FM): total fat mass in kilograms
2. Total FM percentage (%FM):  $\text{total FM} / \text{total body weight} \times 100$
3. LBM = total lean mass in kilograms
4. LBM percentage (%LBM) =  $\text{LBM} / \text{total body weight} \times 100$
5. Lean trunk mass percentage =  $\text{lean trunk mass} / \text{lean body mass} \times 100$

6. Lean extremity mass percentage = (lean arms mass + lean legs mass)/ lean body mass x 100  
7. Lean trunk to extremity ratio = lean trunk mass percentage/lean extremity mass percentage

### **Secondary outcome measures**

Changes in skeletal muscle (SM) with the use of a DXA-validated predictive model ( $SM = (1.19 \times ALM) - 1.01$ ) before and after weight restoration:

1. Appendicular (extremities) lean mass (ALM) in kilograms
2. Total body SM (kg)

### **Overall study start date**

01/01/2010

### **Completion date**

01/02/2015

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18–45
2. Diagnosis of AN
3. Body mass index (BMI)  $\leq 18.5$  kg/m<sup>2</sup> at baseline
4. BMI  $\geq 18.5$  kg/m<sup>2</sup> at end of the treatment

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

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

### **Target number of participants**

180

### **Key exclusion criteria**

1. Participants with active substance abuse
2. Participants with schizophrenia or other psychotic disorders

### **Date of first enrolment**

10/01/2010

### **Date of final enrolment**

01/10/2014

## **Locations**

## **Countries of recruitment**

Italy

## **Study participating centre**

**Villa Garda Hospital**

Monte Baldo Street, 89

Garda (VR)

Italy

37016

## **Sponsor information**

### **Organisation**

Villa Garda Hospital

### **Sponsor details**

Monte Baldo Street, 89

Garda (VR)

Italy

37016

### **Sponsor type**

Hospital/treatment centre

### **Website**

[www.villagarda.it](http://www.villagarda.it)

### **ROR**

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

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Villa Garda Hospital

## **Results and Publications**

## Publication and dissemination plan

We plan to publish several papers in international English peer review journals.

## Intention to publish date

01/07/2015

## 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	01/02/2017	22/01/2019	Yes	No