# The relationship between body fat and longterm clinical outcome in anorexia nervosa

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/10/2014	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
31/10/2014	Completed	☐ Results
Last Edited	ted Condition category	Individual participant data
29/05/2020	Mental and Behavioural Disorders	Record updated in last year

### Plain English summary of protocol

Background and study aims

Anorexia nervosa is an eating disorder in which people try to lose as much weight as possible, usually by a combination of restricting the amount of food that they eat, doing an excessive amount of exercise and by taking laxatives. Treatment for the condition typically involves psychological therapy and supervised weight gain. However, the amount of fat in the body (percentage body fat) after the anorexic has been restored to a healthy weight influences whether they are likely to relapse (become anorexic again). Females that have recently gained weight after being treated for anorexia nervosa tend to have body fat build up around the stomach and abdomen (central adiposity phenotype). This results in a pot belly appearance (abdominal protrusion) that may affect how the patient feels about her body shape and weight. This, in turn, could cause a relapse. However, there have been no studies to date that looks at how the central adiposity phenotype may affect the long-term clinical outcome for people with anorexia nervosa. Here, we want to see if there is a relationship between the total amount of body fat after treatment, and where that fat builds up in the body, with long-term prognosis for anorexia nervosa sufferers.

Who can participate?

Females aged between 18-45 and diagnosed with anorexia nervosa.

What does the study involve?

All participants receive inpatient cognitive behavioural therapy and undergo supervised weight gain. They all receive the same treatment.

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 study ran from January 2012 to January 2015.

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

Who is the main contact? Dr Marwan El Ghoch marwan1979@hotmail.com

# Contact information

### Type(s)

Scientific

#### Contact name

Dr Marwan El Ghoch

### Contact details

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# Additional identifiers

## Protocol serial number

03

# Study information

### Scientific Title

The relationship between body fat and long-term clinical outcome in anorexia nervosa: a longitudinal study

### Study objectives

The body composition assessed after immediate weight restoration achieved in inpatient treatment may influence clinical long-outcome in adult females with anorexia nervosa, namely lower percent total body fat and higher percent trunk fat, may predict long-term relapse.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Institutional Review Board of Villa Garda Hospital, 15/12/2011, ref. 03\_2012

# Study design

Longitudinal study

# Primary study design

### Observational

### Study type(s)

**Treatment** 

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

Anorexia nervosa/body composition

#### Interventions

We recruited 55 female patients with a diagnosis of anorexia nervosa 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. The treatment last 20 weeks and comprises 13 weeks of inpatient therapy followed by 7 weeks of partial hospitalization. More over there was a 1 year follow-up after treatment.

### Intervention Type

Other

#### Phase

Not Applicable

### Primary outcome(s)

Assessing whether lower percent total body fat predict long-term relapse.

Clinical outcome was determined using:

- 1. Morgan-Russell criteria:
- 1.1. Full outcome: No DSM criteria for anorexia nervosa for a minimum of eight weeks
- 1.2. Good outcome: BMI  $\geq$  18.5 kg/m<sup>2</sup>, normal menses, may have some binge eating or purging behavior or psychological symptoms of anorexia nervosa
- 1.3. Fair outcome: BMI ≥ 18.5 kg/m²; amenorrhea
- 1.4. Poor outcome: BMI < 18.5 kg/m<sup>2</sup>
- 2. Eating Disorder Examination Interview:
- 2.1. Full outcome: BMI ≥18.5 kg/m<sup>2</sup> and EDE total score < 1.74
- 2.2. Good outcome: BMI ≥ 18.5 kg/m<sup>2</sup>
- 2.3. Poor outcome: BMI <  $18.5 \text{ kg/m}^2$
- \*Outcome was dichotomized into 'full, good or fair' and 'poor'.

Evaluated at the end of one year follow-up.

### Key secondary outcome(s))

Assessing whether higher percent trunk fat may predict long-term relapse.

Clinical outcome was determined using:

- 1. Morgan-Russell criteria:
- 1.1. Full outcome: No DSM criteria for anorexia nervosa for a minimum of eight weeks
- 1.2. Good outcome: BMI  $\geq$  18.5 kg/m², normal menses, may have some binge eating or purging behavior or psychological symptoms of anorexia nervosa
- 1.3. Fair outcome: BMI ≥ 18.5 kg/m²; amenorrhea
- 1.4. Poor outcome: BMI < 18.5 kg/m<sup>2</sup>
- 2. Eating Disorder Examination Interview:

2.1. Full outcome: BMI ≥18.5 kg/m² and EDE total score < 1.74

2.2. Good outcome: BMI ≥ 18.5 kg/m<sup>2</sup> 2.3. Poor outcome: BMI < 18.5 kg/m<sup>2</sup>

\*Outcome was dichotomized into 'full, good or fair' and 'poor'. Evaluated at the end of one year follow-up.

### Completion date

01/01/2015

# **Eligibility**

## Key inclusion criteria

- 1. Female patients aged 1845 years
- 2. Diagnosis of anorexia nervosa
- 3. BMI  $\leq$ 18.5 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** 

## Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

#### Sex

Female

### 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

01/01/2015

# Locations

### Countries of recruitment

Italy

Study participating centre Monte Baldo Street, 89 Garda Italy 37016

# Sponsor information

### Organisation

Villa Garda Hospital (Italy)

### **ROR**

https://ror.org/01mw6s018

# 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

Not provided at time of registration

### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Yes

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No