

The relationship between body fat and long-term clinical outcome in anorexia nervosa

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		<input type="checkbox"/> Protocol
Registration date 31/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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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
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)

Study design

Longitudinal study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found at: <http://www.villagarda.it/Libretto%20DA.pdf> (in Italian only)

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 measure

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 ≥ 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/m²

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/m²

2.3. Poor outcome: BMI < 18.5 kg/m²

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

Secondary outcome measures

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 ≥ 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/m²
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/m²
 - 2.3. Poor outcome: BMI < 18.5 kg/m²

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

Overall study start date

01/01/2012

Completion date

01/01/2015

Eligibility

Key inclusion criteria

1. Female patients aged 18-45 years
2. Diagnosis of anorexia nervosa
3. BMI ≤ 18.5 kg/m² at time zero
4. BMI ≥ 18.5 kg/m² at the end of the treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

55 female patients with a diagnosis of anorexia nervosa

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)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

http://www.villagarda.it/index_eng.html

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