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

Submission date
19/10/2014

Recruitment status
No longer recruiting

Registration date
31/10/2014

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Monte Baldo Street, 89
Garda
Italy
37016
+39 (0)456208611
marwan1979@hotmail.com

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 ≥ 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.

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 ≥ 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.

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Female patients aged 1845 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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes