

Body composition, eating disorder psychopathology and psychological distress in anorexia nervosa

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
08/12/2013	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
16/12/2013	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
23/05/2014	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Anorexia nervosa (AN) is characterized by weight loss and reduction of body mass (lean and fat masses). Weight restoration is a key procedure in the treatment of these patients. However, for a normal resumption of physiological processes it is necessary to restore an adequate amount and distribution of body mass (lean and fat). Furthermore, no study has assessed the influence of body composition changes on eating disorder psychopathology and psychological distress in AN patients. The aim of this study is to assess body composition and fat mass distribution before and after body weight restoration and to investigate the relationship between body fat pattern changes and eating disorder and psychological distress in AN patients treated in a specialist inpatient unit.

Who can participate?

We recruited 50 female patients with a diagnosis of anorexia nervosa, and 100 age and body mass index (BMI) matched healthy controls.

What does the study involve?

All patients with AN received the same treatment: cognitive behavioural therapy (CBT-E) (psychological treatment) and weight restoration. Tests were done to measure body composition and assess eating disorder psychopathology and psychological distress 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?

The recruitment started in January 2011 and ended in January 2013.

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

Who is the main contact?
Dr Marwan El Ghoch

Contact information

Type(s)

Scientific

Contact name

Dr Marwan El Ghoch

Contact details

Monte Baldo Street, 89
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37016

Additional identifiers

Protocol serial number

01

Study information

Scientific Title

Body composition, eating disorder psychopathology and psychological distress in anorexia nervosa: a longitudinal study

Study objectives

Anorexia nervosa (AN) patients have different body composition with respect to healthy controls after immediate weight normalization. This difference in body composition may negatively influence treatment outcome and may have some psychological effects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Villa Garda Hospital, 15/12/2010

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 50 female patients with a diagnosis of anorexia nervosa and 100 age and BMI matched healthy controls for an observational study. The interventions are weight restoration and cognitive behavioural therapy (psychological treatment). 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. The Eating Disorder Examination interview (EDE) and the Brief Symptom Inventory (BSI) were used to assess eating disorder psychopathology and psychological distress, respectively.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. To assess the change in lean and fat masses and their distribution (using DXA) before and after complete weight restoration in AN patients.
2. To compare body composition and fat distribution (using DXA) of weight-restored AN patients with a healthy age- and post-treatment BMI-matched control group.

All outcomes were collected at baseline and at the end of the treatment (20 weeks of treatment).

Key secondary outcome(s)

To assess the relationship between body composition patterns (using DXA), eating disorder psychopathology (using EDE) and general distress (using BSI) in AN patients. All outcomes were collected at baseline and at the end of the treatment (20 weeks of treatment).

Completion date

07/01/2013

Eligibility

Key inclusion criteria

1. Female patients aged 18-50 years
2. Diagnosis of anorexia nervosa
3. Body mass index (BMI) $\leq 17.5 \text{ kg/m}^2$ at time zero
4. BMI $\geq 18.5 \text{ kg/m}^2$ 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

01/01/2011

Date of final enrolment

07/01/2013

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?
Results article	results	01/04/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes