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

Submission date
08/12/2013

Recruitment status
No longer recruiting

Registration date
16/12/2013

Overall study status
Completed

Last Edited
23/05/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

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Monte Baldo Street, 89
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37016

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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).

Secondary outcome measures
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).

Overall study start date
01/01/2011

Completion date
07/01/2013

Eligibility

Key inclusion criteria
1. Female patients aged 1850 years
2. Diagnosis of anorexia nervosa
3. Body mass index (BMI) ≤17.5 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
50 female patients with a diagnosis of anorexia nervosa, and 100 age and BMI matched healthy controls

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)

Sponsor details
Monte Baldo Street, 89
Garda
Italy
37016

Sponsor type
Hospital/treatment centre

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No