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Regional fat distribution in adolescent girls and adults with anorexia nervosa

Submission date
16/05/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
30/09/2016

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 is an eating disorder in which people keep their body weight at low as possible by restricting the amount of food they eat, vomiting and excessive exercise. It leads to weight loss and a reduction of body mass. A severe loss in body weight can lead to a number of physical problems, such as extreme tiredness, headaches/abdominal pains, poor circulation and females can stop having their periods. These symptoms can only be treated by an adequate increase in weight and distribution of body mass. Available data suggest that during anorexia nervosa, adolescent females seem to lose more fat around their belly (central body fat), while adult females more peripheral fat (fat found elsewhere on the body). When these patients then regain their weight, adult females tend to deposit their newly acquired fat around their belly (central regions) while adolescents regain similar body fat distributions to non-sufferers with no increase in the proportion of belly fat. However, results reported in adolescent females are not consistent and need further investigation, and no comparison has made between adult and adolescent individuals that have undergone the same treatment. The aim of this study is to assess body fat mass and its distribution before and after regaining weight in adolescent and adult individuals with anorexia nervosa treated with same treatment (duration and weight gain rate).

Who can participate?
Female patients with a diagnosis of anorexia nervosa (adolescents 13-19 years, adults 20 years or over)

What does the study involve?
All patients with anorexia nervosa receive the same inpatient treatment based on gaining weight and enhanced cognitive behavioural therapy (CBT-E). Tests were done to measure body composition 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?
January 2012 to July 2014

Who is the 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
02

Study information

Scientific Title
Regional fat distribution in adolescent girls and adults with anorexia nervosa: a longitudinal study

Study objectives
Available data indicate that adults with anorexia nervosa, but not adolescents, seems to have different body fat distribution with respect to healthy controls before and after immediate weight normalization. However, to date no study compared the effect weight restoration on

body fat distribution in adults and adolescents with AN under the same circumstance (identical treatment). It is therefore possible that the differences observed in adults and adolescents with anorexia nervosa might be the results of different modality of nutritional rehabilitation and rate of weight regain. On the basis of this premise, we aimed to study adults and adolescents with anorexia nervosa with the same treatment to investigate if really exists a difference in body fat distribution after immediate weight restoration between the two populations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Villa Garda Hospital, 15/12/2011, ref. 02_2012

Study design
Longitudinal study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Anorexia nervosa/body composition

Interventions
We recruited 66 female patients with a diagnosis of anorexia nervosa and 66 controls of the same age (+ 2 years) with a BMI equivalent to the patients BMI after weight restoration 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 patients and in healthy controls.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Change in fat masses and their distribution (using DXA) before and after complete weight restoration in AN patients

Secondary outcome measures
Body composition and fat distribution (using DXA) of weight-restored AN patients

Overall study start date
01/01/2012

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Female patients aged 13 - 50 years (adolescents 13-19 years; adults ≥ 20 years)
2. Diagnosis of anorexia nervosa
3. BMI ≤18.5 kg/m² in adults or BMI percentiles ≤18.5 kg/m² in adolescents at time zero
4. BMI ≥ 18.5 kg/m² in adults or BMI percentiles correspondent to a BMI ≥ 18.5 kg/m² at the end of the treatment

Participant type(s)
Patient

Age group
Other

Sex
Female

Target number of participants
66 female patients with a diagnosis of anorexia nervosa, and 66 controls of the same age (+ 2 years) with a BMI equivalent to the patients BMI after weight restoration.

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
01/07/2014

Locations

Countries of recruitment
Italy

Study participating centre
Villa Garda Hospital
Garda
Italy
37016

Sponsor information

Organisation
Villa Garda Hospital (Italy)

Sponsor details
Via Monte Baldo, 89
Garda
Italy
37016

Sponsor type
Hospital/treatment centre

Website
http://www.villagarda.it/

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	01/12/2015		Yes	No