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Changes in lean and skeletal muscle body mass in adult females with anorexia nervosa (AN) before and after weight restoration

Submission date
12/04/2015

Registration date
06/05/2015

Last Edited
22/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

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
The eating disorder anorexia nervosa (AN) is a serious mental health condition in which people restrict the amount of food they eat to keep their body weight as low as possible. Weight loss in AN can result in an extreme reduction of body fat and lean body mass (LBM), such as muscle. A lot of research has investigated body fat and its distribution in AN patients, but LBM has not really been looked at in depth. Some studies show that AN patients lose more LBM in their arms and legs compared to the trunk of their body. This may be due to other conditions triggered by AN. Unfortunately, the results of these studies are not consistent; some studies found no change in LBM distribution in AN patients. Also, there is very little information on long-term changes in LBM distribution after they have regained a normal body weight. There are also very few studies which have looked at the total body skeletal muscle mass (SM) in patients with AN, and those that have looked at SM have used technology that is not usually available in regular clinics, such as magnetic resonance imaging (MRI) machines. Overall, research investigating LBM, LBM distribution and SM in women with AN before and after regaining a normal body weight are very few, inconsistent and often use methods that are poor or can't be replicated. The aim of this study is to assess changes in LBM, LBM distribution and SM before and after body weight restoration in a large sample of women with AN.

Who can participate?
Women diagnosed with anorexia nervosa.

What does the study involve?
Patients diagnosed with AN undergo treatment to regain a normal body weight using standard care and inpatient cognitive behavioural therapy (CBT). Following treatment to restore their weight, patients' post-treatment body composition (LBM, SM) is compared with healthy controls (women who are not AN) of the same age and equivalent body mass index (BMI). All participants have their body composition measured using dual-energy X-ray absorptiometry (DXA).

What are the possible benefits and risks of participating?
There are no risks or benefits to participants

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 2010 to February 2015

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01_2010

Study information

Scientific Title
Changes in lean and skeletal muscle body mass in adult females with anorexia nervosa (AN) before and after weight restoration: a longitudinal study

Study objectives
During AN, patients lose lean and skeletal muscle body mass especially from extremity regions, and complete weight restoration may overcome this situation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Institutional Review Board of Villa Garda Hospital, Verona, 15/12/2009, ref: 01_2010

Study design
Obeservational longitudinal study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
1. Weight restoration
2. Inpatient cognitive behavioural therapy (CBT)

Intervention Type
Behavioural

Primary outcome(s)
Changes in lean body mass (LBM) and LBM distribution (extremity and trunk) measured by dual-energy X-ray absorptiometry (DXA) scan before and after weight restoration:
1. Total fat mass (FM): total fat mass in kilograms
2. Total FM percentage (%FM): total FM/total body weight x 100
3. LBM = total lean mass in kilograms
4. LBM percentage (%LBM) = LBM/total body weight x 100
5. Lean trunk mass percentage = lean trunk mass/lean body mass x 100
6. Lean extremity mass percentage = (lean arms mass + lean legs mass)/ lean body mass x 100
7. Lean trunk to extremity ratio = lean trunk mass percentage/lean extremity mass percentage

Key secondary outcome(s))
Changes in skeletal muscle (SM) with the use of a DXA-validated predictive model (SM = (1.19 x ALM) − 1.01) before and after weight restoration:
1. Appendicular (extremities) lean mass (ALM) in kilograms
2. Total body SM (kg)

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Aged 18–45
2. Diagnosis of AN
3. Body mass index (BMI) ≤18.5 kg/m² at baseline
4. BMI ≥18.5 kg/m² at 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 with active substance abuse
2. Participants with schizophrenia or other psychotic disorders

Date of first enrolment

10/01/2010

Date of final enrolment

01/10/2014

Locations

Countries of recruitment

Italy

Study participating centre
Villa Garda Hospital
Monte Baldo Street, 89
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37016

Sponsor information

Organisation

Villa Garda Hospital

ROR

https://ror.org/01mw6s018

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Villa Garda Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
[Results article](#)	results	01/02/2017	22/01/2019	Yes	No
[Participant information sheet](#)	Participant information sheet	11/11/2025	11/11/2025	No	Yes
[Study website](#)	Study website	11/11/2025	11/11/2025	No	Yes