

# Emotion processing in anorexia nervosa: what happens in the brain?

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Eating disorders and disturbances
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON38444

### Source

ToetsingOnline

### Brief title

Emotion processing in anorexia nervosa

### Condition

- Eating disorders and disturbances

### Synonym

Anorexia Nervosa

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Altrecht GGZ (Den Dolder)

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Anorexia Nervosa, brain activity, cognitive functioning, Emotion-processing

## Outcome measures

### Primary outcome

Neural activation (BOLD signal change) in response to ambiguous affective stimuli.

### Secondary outcome

1) Emotion processing 2) (Negative) emotions

## Study description

### Background summary

In many psychiatric disorders difficulties/ abnormalities in appraising affective situations are linked to the maintenance of disorders and in relapse after treatment. This is also the case in anorexia nervosa (AN), where growing research shows poor emotion recognition and emotion regulation impairments in AN patients. Moreover, the majority of AN patients report high levels of negative emotions (e.g. anxiety), particularly in response to uncertain situations and events. There is research suggesting that these emotion processing difficulties may hinder treatment. Since treatment for AN is suboptimal, and relapse rates are high, there is an urgent need for a better understanding of the aetiology and pathophysiology of this illness. Neural responses to processing ambiguous emotional stimuli are understudied but can provide important information about the emotion problems found in AN patients.

### Study objective

The primary aims of this study are firstly to identify the brain regions involved in the appraisal of ambiguous affective stimuli in anorexia nervosa patients, and secondly to compare their responses with those of healthy control participants. The second aims of this study are to firstly assess emotion processing in AN patients, secondly, to assess the effects of ambiguous affective stimuli on levels of (negative) emotions in AN patients, and thirdly, to assess the association between measures of executive and cognitive function and emotional and neural responses to ambiguous affective stimuli in AN

patients.

## Study design

This is a case-control trial where AN patients and healthy control participants are asked to complete a number of questionnaires and computer tasks and one task in the scanner.

## Study burden and risks

On the study day participants will have a (30-minute) MRI session during which they will do two emotion processing tasks. This type of paradigm poses no risk. Functional MRI is a commonly used technique which is considered to be safe. Additionally, measurements will be done to assess relevant clinical characteristics along with a computer task to assess cognitive functioning. This task has been used in AN patients and is not considered to be a burden; it is even perceived as amusing to do. In summary, the risk associated with participation is assessed as low and the burden as minimal.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Anorexia Nervosa group: female anorexia nervosa patients, age 18-35 yr, BMI < 17.5 kg/m<sup>2</sup>

;Healthy Control group: healthy women, age 18-35, BMI 20-25 kg/m<sup>2</sup>

### Exclusion criteria

Anorexia Nervosa group: - Contra-indications to MRI scanning on the basis of the MRI screening form (e.g. claustrophobia, metal objects in the body incompatible with MRI scanning). - Having a history of medical or surgical events that may significantly affect the study outcome, such as brain surgery. - Excessive smoking (e.g. > 15 cigarettes a day).;Healthy Control group: - Contra-indications to MRI scanning on the basis of the MRI screening form (e.g. claustrophobia, metal objects in the body incompatible with MRI scanning). - Having a history of medical or surgical events that may significantly affect the study outcome, such as brain surgery. - Excessive smoking (e.g. > 15 cigarettes a day).;patients, age 18-35 yr, BMI < 17.5 kg/m<sup>2</sup> ;Healthy Control group: healthy women, age 18-35, BMI 20-25 kg/m<sup>2</sup>

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2014

Enrollment: 30  
Type: Actual

## Ethics review

Approved WMO  
Date: 06-12-2013  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 21380  
Source: Nationaal Trial Register  
Title:

### In other registers

Register	ID
CCMO	NL45093.041.13
OMON	NL-OMON21380