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# Assessment of neuroendocrine responses to hedonic eating in underweight and recently weight-restored patients with anorexia nervosa

**Submission date**
10/09/2014

**Recruitment status**
No longer recruiting

**Registration date**
29/09/2014

**Overall study status**
Completed

**Last Edited**
04/02/2015

**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
We eat food to maintain our energy levels and remain alive (homeostatic eating) and because we enjoy it (hedonic eating). Hedonic eating, therefore, may be a good way to assess the body's physiological response to seeing and smelling certain foods (food related rewards). The endocannabinoid system refers to a group of chemical compounds and receptors in the brain that are involved in controlling our appetite and our enjoyment in eating food. Anorexia nervosa (AN) is a serious mental health disorder in which sufferers have a distorted image of themselves, believing that they are fat when they are not. Symptoms include eating as little as possible, obsessively counting calories and making themselves vomit after meals. There is some evidence that suggests that AN sufferers have reduced endocannabinoid levels and fewer cannabinoid receptors than people that do not have the condition. Here, we want to look at the endocannabinoid system responses to hedonic eating in people who are either suffering from, or have recently recovered from, AN and compare them to those of healthy people.

Who can participate?
Adults who are, or have recovered from, the eating disorder AN and healthy adults who have not suffered from AN.

What does the study involve?
Each participant attends two test sessions. Initially they are all asked to state their favorite food. On the first test session, after a 12 hour fast, they are asked how hungry or satisfied they feel. They are then given breakfast and asked to report on their hunger and satisfaction levels again. An hour later, they are told that they will be given their favorite food. A blood sample is taken for analysis. For the next 5 minutes, they are able to see and smell the food, but are unable to eat it. They are then asked about how hungry or satisfied they feel, how much they want to eat the food and how much of the food they would want to eat. They are then given 10 minutes in which to eat as much of the food as they like. Three further blood samples are taken, one immediately after being exposed to the food for 5 minutes, one 15 minutes after eating the

food and, finally, one 2 hours afterwards. For the second test session, the process is repeated but participants are exposed to and asked to eat a non-favourite food. The blood samples are analysed for endocannabinoid-related compounds.

What are the possible benefits and risks of participating?
The are no immediate benefits for participants and no risks.

Where is the study run from?
1. Villa Garda Hospital, Verona (Italy)
2. The Department of Psychiatry, University of Naples SUN (Italy)

When is the study starting and how long is it expected to run for?
January 2011 to February 2014.

Who is funding the study?
The Department of Psychiatry of the University of Naples SUN (Italy)

Who is the main contact?
Professor Palmiero Monteleone
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Palmiero Monteleone

### Contact details
Via Allende
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# Additional identifiers

### Protocol serial number
012011

# Study information

### Scientific Title
Assessment of neuroendocrine responses to hedonic eating in underweight and recently weight-restored patients with anorexia nervosa: an observational case-control study

### Study objectives
Anhedonia, that is the reduced ability to experience reward, is a key symptom in the clinical presentation of anorexia nervosa (AN). Brain imaging studies in AN people have shown neuroanatomical abnormalities and dysfunctional activation of brain areas modulating reward.

Therefore, it is possible that an altered evaluation of reward stimuli in AN individuals, represented by reduced responsiveness toward food stimuli (especially foods with high caloric content and reward value) and enhanced reaction toward starvation-specific cues, might be involved in the pathophysiology of AN.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of the University of Naples SUN, 09/09/2010, ref: #3285

## Study design
Observational multicentre case-control study

## Primary study design
Observational

## Study type(s)
Diagnostic

## Health condition(s) or problem(s) studied
Anorexia nervosa

## Interventions
Before the first experimental session, each participant was asked to indicate his more favorite food by answering the following question: 'Which is your most favorite food that you would eat also when satiated, just for pleasure?'. On the first test session, after a 12-h fast, at 09:00 AM, participants were asked to rate their hunger and satiety on visual analogue scales (VAS); then they received a breakfast of 300 kcal. Immediately after breakfast, participants rated again their hunger and satiety by means of VAS. After 1 h, they were told that they would receive their previously chosen favorite food, and an iv catheter was inserted into an antecubital vein to collect a first blood sample (T = 0). Immediately afterwards, participants were exposed to the chosen favorite food for 5 min: during this time they could smell and see the food but could not eat it; at the end of the exposure, participants were asked to rate their hunger, satiety, urge to eat that food, pleasantness to experience a mouthful of that food and amount of food they would eat by means of VAS. Then they free to eat the palatable food ad libitum within 10 min. Further blood samples were drawn immediately after the exposure to the favorite food (T=5) and 15 (T=30) and 120 min (T=135) after eating it. At the end of the session, the amount of food eaten by each participant was calculated and the calories eaten were calculated. On the second test session, participants underwent the same experimental procedures of the first experimental session except for the fact that they were exposed to non-favorite food and had to eat an amount of it with the same nutrient composition and an equal quantity of calories as the favorite food they ate in the previous session within 10 min.

The blood samples were collected in tubes with EDTA as anticoagulant. Plasma was separated by centrifugation and stored at -20 °C. Plasma levels of the endocannabinoids anandamide (AEA) and 2-arachidonoylglycerol (2-AG), and the endocannabinoid-related compounds, oleoylethanolamide (OEA) and palmitoylethanolamide were determined by isotopic dilution-liquid chromatography-mass spectrometry.

## Intervention Type

Other

### Phase
Not Applicable

### Primary outcome(s)
Response patterns of endocannabinoids and endocannabinoid-related substances to hedonic and non-hedonic eating in patients with acute and weight-restored AN and in healthy subjects. Analyzed at time the blood sample is taken.

### Key secondary outcome(s))
Response patterns of other food-related reward biochemical mediators (ghrelin, cortisol) to hedonic and non-hedonic eating. Analyzed at time the blood sample is taken.

### Completion date
28/02/2014

## Eligibility

### Key inclusion criteria
1. Diagnosis of current or past anorexia nervosa (using the Structured Clinical Interview for DSM-IV Axis I disorders-patient edition)
2. Male and female patients aged 18-40 years
3. BMI ≤18.5 kg/m² in patients with current anorexia nervosa
4. BMI ≥ 18.5 kg/m² in patients with weight-restored anorexia nervosa
5. Male and female normal weight healthy subject aged 18-40 years

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
40 years

### Sex
All

### Key exclusion criteria
1. Participants who do not satisfy inclusion criteria
2. Participants currently treated with hormones or drugs, with a history of psychosis, diabetes mellitus, active substance use or head trauma, presence of severe physical disorders or comorbid psychiatric disorders

**Date of first enrolment**
01/01/2011

**Date of final enrolment**
28/02/2014

# Locations

**Countries of recruitment**
Italy

**Study participating centre**
**Via Allende**
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84081

# Sponsor information

**Organisation**
Department of Psychiatry, University of Naples SUN (Italy)

**ROR**
https://ror.org/02kqnpp86

# Funder(s)

**Funder type**
University/education

**Funder Name**
Department of Psychiatry, University of Naples SUN, Naples (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 | 01/02/2015 | | Yes | No |