

Decision-making for differently valenced stimuli in anorexia nervosa

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We will use a conditioning paradigm to experimentally investigate how individuals with AN compared to healthy controls (HCs) avoid disorder-specific, as well as generally aversive and pleasant outcomes and to what extent avoidance behaviors return...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eating disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON55245

Source

ToetsingOnline

Brief title

DecisionStimAN

Condition

- Eating disorders and disturbances

Synonym

Anorexia nervosa, eating disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: NWO

Intervention

Keyword: Anorexia nervosa, Conditioning, Food avoidance, Mouse tracking

Outcome measures

Primary outcome

Characteristics of avoidance behaviors (i.e. frequency, velocity and directedness of avoidance decisions) and appetitive and aversive conditioned responses.

Secondary outcome

Valence ratings for the three outcomes (small portions of milkshake, aversive sounds, small monetary gain); symptoms of stress, depression and anxiety; sensitivity to reward and punishment.

Study description

Background summary

Anorexia nervosa (AN) is a severe and disabling mental disorder (Klump et al., 2009), that is accompanied by a range of mental and physical comorbidities (Mitchell & Crow, 2006) leading to one of the highest mortality rates in psychiatry (Papadopoulos et al., 2009). While there is an urgent need to improve current treatments, the mechanisms underlying AN are still poorly understood. One of the core symptoms of the disorder is the fear of (uncontrollable) weight gain and fear-induced avoidance of especially high-calorie food intake. Fear and avoidance have been related to long-term treatment outcomes and weight-recovery (Steinglass et al., 2010; Schebendach et al., 2008) and might play an important role in maintaining the eating disorder. In this project we focus on avoidance as a key mechanistic pathway underpinning the symptoms in anorexia nervosa and try to gain a better understanding of the dynamics of food avoidance behaviors in AN patients.

Study objective

We will use a conditioning paradigm to experimentally investigate how individuals with AN compared to healthy controls (HCs) avoid disorder-specific,

as well as generally aversive and pleasant outcomes and to what extent avoidance behaviors return after an extinction with response prevention phase. Furthermore, we will examine how appetitive and fear learning processes are related to food avoidance in AN patients.

Study design

Participants will take part in a conditioning task including three different outcomes: a small portion of a high-caloric milkshake, an aversive scream and a small monetary gain. The conditioning task consists of Pavlovian and Instrumental learning phases. This study will be a block-design experimental conditioning study. The order of the blocks is counter-balanced across participants.

Study burden and risks

The proposed study carries minimal risks and discomfort, but it is time-consuming for participants. However, the information they deliver significantly improves insights into the way individuals with AN make decisions about and eventually execute (food) avoidance behaviors. As an incentive and compensation for participation in the study, the participants will receive €15 in Amazon or bol.com vouchers and can earn additional €4 to €12 during the experiment depending on their performance in the computer task. We will also reimburse the extra costs of travel for those AN patients and HCs that come to the research facility from further away.

Contacts

Public

Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL

Scientific

Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Inclusion criteria

In order to be eligible for participation, subjects need to fulfill the following criteria:

Anorexia Nervosa

1. ≥ 16 years of age
2. Be able to give informed consent
3. Able to speak, read and understand Dutch
4. Fulfill the DSM-5 criteria for anorexia nervosa
5. Have a BMI between 14 and 18.5 (16 - 18 yr. old participants have a BMI, that falls below the 5th BMI-for-age percentile) and/or currently undergo treatment for their anorexia.

Healthy controls

1. ≥ 16 years of age
2. Be able to give informed consent
3. Able to speak, read and understand Dutch
4. Have a BMI between 20 and 25 (16 - 18 yr. old participants have a BMI that falls between the 40th and the 85th BMI-for-age percentile)
5. Fall within one standard deviation of the Eating Disorder Examination Questionnaire mean norm scores for the respective comparison group
6. Like the taste of milk shake

Exclusion criteria

Anorexia nervosa patients

1. A comorbid diagnosis of bipolar or psychotic disorder.

2. Use of psychotropic medication with a stable dosage for less than a month

Healthy control participants

1. A current or past diagnosis of an eating disorder or another psychiatric disorder

2. Use of psychotropic medication

For all participants

1. Visual problems if not corrected

2. Pregnancy

3. Chronic ear illnesses (e.g. tinnitus)

4. A known history of neurological disorders or injuries

5. Allergies or intolerances against the ingredients of the milkshakes

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO	
Date:	15-04-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	17-08-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL75115.068.20