Anxiety treatment for Anorexia nervosa

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It will be investigated whether a new form of exposure therapy, aiming at the reduction of anxiety by the disconfirmation of expectancies and learning of new inhibitory associations will lead to less AN symptoms, better acceptance of weight gain and...

Ethical review	Approved WMO
Status	Completed
Health condition type	Eating disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON55027

Source
ToetsingOnline

Brief title
Anxiety Treatment for Anorexia Nervosa

Condition

- Eating disorders and disturbances

Synonym
anorexia nervosa, eating disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Stichting Vogelgezang Foundation (http://vogelgezangfoundation.com)

Intervention

Keyword: Anorexia nervosa, Anxiety, Eating disorders, Exposure therapy

Outcome measures

Primary outcome

• Eating disorder symptoms (Eating Disorder Examination Questionnaire; EDEQ;

Global Score en Subscale Scores)

• Body weight and length (BMI)

• Anxiety in different situations or tasks (State Anxiety; Visual Analog Scale;

VAS)

• Probability and credibility of the frightening thoughts different situations

or tasks

• Acceptance of body weight (scale test and VR)

• Food intake (lab breakfast)

• Body image (VR)

• Body image (lichaamswaarderingslijst)

Secondary outcome

• General anxiety (Trait Anxiety)

• Intolerance of uncertainty

• Depression

• Personality disorders

• Expectance of the therapy

• Number of exposure sessions

• Content of exposure sessions

• Therapist per exposure session

• Number of sessions and duration of regular treatment

Study description

Background summary

Anorexia nervosa is an eating disorder that often takes a chronic course and potentially becomes life threatening: the mortality rate amongst all psychiatric disorders is highest in AN. Up until now, treatment is mostly unsuccessful. Therefore, it is important to develop better treatment for AN; especially personalized treatment, targeting factors that maintain the disorder is necessary. Anxiety plays a central role in AN and it is suggested that specifically anxiety and associated avoidance behaviors maintain the disorder. In common praxis, however, anxieties that patients with AN face are not targeted, which may reduce treatment success and heighten the relapse rate. We expect that targeting and reducing AN specific anxieties will improve treatment outcomes in AN.

Study objective

It will be investigated whether a new form of exposure therapy, aiming at the reduction of anxiety by the disconfirmation of expectancies and learning of new inhibitory associations will lead to less AN symptoms, better acceptance of weight gain and higher body weight. The intervention will be offered to parts of the AN patients at the MUMC+ and Youz Maastricht in addition to their regular treatment. Also, patients who are not currently in treatment are asked to participate.

Study design

Because the current intervention is *personalized treatment* we will predominantly study effects in a within subjects clinical case series design. To assess the additional value of our intervention we will compare outcomes with a group of AN patients who will not receive our intervention but only their regular treatment/ no treatment.

Intervention

Some participants will receive regular treatment that is offered at the section for eating disorders. Also, patients who are not currently in treatment are asked to participate. We will randomly assign 30 participants to the condition where the additional exposure intervention is offered. They will receive a minimum of 30 and a maximum of 40 individual exposure sessions. In this group the exposure will thus be offered in addition to the regular treatment/ no treatment.

Study burden and risks

Risks: participation can be burdensome in a sense that it requires time and energy to conduct the measurements and exposure sessions. Moreover, participation can cause a temporary rise of anxiety. Other than this no risks are known.
Benefits: the participants receive a reward for participating at the measurements. Patients who receive our new exposure intervention will more likely experience a stronger reduction in eating disorder symptomatology than patients who will not receive the intervention. Further, our additional intervention is gratis.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ET
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ET
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1)Primary diagnosis: Anorexia Nervosa according to DSM5 (307.1)

2) participant is or will be in treatment for Anorexia Nervosa at the MUMC+ or Youz Maastricht or is not currently in treatment
3) age: 16 years and older
4)Body Mass Index between 13 and 18,5
5)Patient is able to give Informed Consent

Exclusion criteria

Patients with a primary diagnosis of Anorexia nervosa (DSM5: 307.1) who fulfill one or more of the following criteria will be excluded from participation:
1) Body Mass Index below 13
2) Regular treatment is not predominately focusing on AN but a on secondary diagnosis
3) Acute danger of suicide
4) Serious medical or psychological condition that makes participation impossible or dangerous
5) Patient is not able to give Informed Consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-04-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	16-11-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2021
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
Other	Het onderzoek wordt bij www.asPredicted.org geregistreerd zodra het door de METC goedgekeurd is
CCMO	NL72174.068.20

Study results

Date completed: 01-01-2024

Summary results
Trial ended prematurely