Brain functioning and attentional processing in adolescent anorexia nervosa: predictors of its differential course?

Published: 09-12-2016
Last updated: 17-04-2024

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

Summary

ID

NL-OMON55400

Source
ToetsingOnline

Brief title
BRAVE

Condition

- Eating disorders and disturbances

Synonym
anorexia nervosa

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Sophia Stichting Wetenschappelijk Onderzoek

Intervention

Keyword: anorexia nervosa, eye tracking, imaging, neurocognitive functioning

Outcome measures

Primary outcome

The main study parameters are brain measures (fMRI, eye tracking, attentional processes) within and between contrasts of the patient and control group at T1 and T2.

Secondary outcome

Secondary outcome parameters are neurocognitive measures.

Study description

Background summary

Anorexia nervosa (AN) is a debilitating psychiatric disorder, of which the etiology is thought to be heterogeneous, involving multiple (neuro)biological and psychosocial factors. The heterogeneity is perplexing, as a subset of girls have a relatively short-lived illness and recover quite quickly, whereas others have a prolonged illness with multiple hospitalizations and long-term impairment. Two potential determinants of differential treatment response are brain functioning and attentional bias. We postulate that adolescents with AN show altered brain function, measured by fMRI and neurocognitive tasks, and an attentional bias, measured by the probe dot task and eye tracking, towards disorder related words and images of body shapes at time of diagnosis. Furthermore we think that these parameters may predict treatment response after a year of treatment.

Study objective

The first aim of this research is to identify predictors of one-year treatment response after initial clinical diagnosis in a large sample of adolescent girls with AN. The results of this study could allow us to assess different treatment strategies in an attempt to curb what appears to be a deeply rooted biological

process. Second, we will investigate the association between clinically significant changes and neurobiological, neurocognitive and attentional changes during one-year treatment.

Study design

We will use a longitudinal case-control repeated measures design. The study is a collaboration with mental health organizations, specialized in diagnostics and treatment of patients with AN. After signed informed consent, assessment will take place at inclusion (T1) and after one year (T2). Between T1 and T2, patients with AN will receive treatment as usual; this proposal has no planned intervention for the controls.

Study burden and risks

To our knowledge and with proper screening, there are no medical risks associated with fMRI-scanning and eye-tracking. There are no known risks in the administration of neuropsychological tasks and filling in questionnaires. During the fMRI-scanning procedure, the investigator will constantly assess whether the investigation should be stopped. The study will immediately be ceased if the participant, the parents or the investigator desires

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patient group:
- Girls,12 to 22 years old
- Diagnostic and Statistical Manual of Mental Disorders 5th edition: criteria for anorexia nervosa are met
- Diagnosis made within the past 12 months., control group:
- Girls 12 to 22 years old
- No history of a current DSM-5 diagnosis
- Normal weight (BMI SDS > -1.3 SD and BMI SDS < +1.3 SD)

Exclusion criteria

-Significant motor or sensory disorder (for example deaf or blind adolescents, which would likely create differences in brain development and formation)
-Substance related disorders
-Organic psychosyndrome
-Schizophrenia or other psychotic disorders
-Claustrophobia
- Poor command of the Dutch language
- IQ<70 as measured by an intelligence test in the past, while having a healthy weight and a normal eating pattern.
- An inability to fill in questionnaires independently

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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2018
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-10-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL55175.078.16