Microbiome-Gut-Brain interaction in Anorexia Nervosa

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To study the differences in MI between short-term ill adolescents with AN (< illness duration 1 year) and patients who started their illness in adolescence and have been ill for at least 5 years consecutively and with healthy controls. A...

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

Summary

ID

NL-OMON54859

Source
ToetsingOnline

Brief title
Microbiome-Gut-Brain in Anorexia Nervosa

Condition

- Eating disorders and disturbances

Synonym
anorexia nervosa, eating disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ERANET (EU);250k Euros zijn toegekend voor het Nederlandse deel van het onderzoek door NWO.

Intervention

Keyword: anorexia nervosa, microbiome

Outcome measures

Primary outcome

Primary outcome: Differences in MI between short-term ill and long-term ill patients and HC, cross-sectional and longitudinally during weight restoration over 1 year.

Secondary outcome

Secondary outcomes: Changes in MI composition in relation to olanzapine use, locomotor activity, gastrointestinal complaints, eating disorder symptoms, anxiety, mood, neuropsychological inefficiencies, gut permeability, serum inflammation markers, IgG analysis.

Study description

Background summary

Anorexia nervosa (AN) is one of the most serious chronic disorders of youth. Up to now we only know moderately effective treatment strategies; less than 50% of affected patients fully recover. Recently, there has been an emerging evidence of an association between the bacteria living in the human gut (gut microbiome (MI)) and the brain; several studies demonstrated that the composition of the microbiome and its metabolism have an important influence on the development of mental disorders and on weight regulation disorders such as obesity. In AN, fasting (*starvation*) induces severe perturbations of the gut microbiome, which do not alleviate with weight gain. Animal models elucidate that the microbiome influences body weight, brain development and depression-like states. Thus, our aim is to improve the course of this disabling disorder by manipulating the patients* gut bacteria. We hypothesize that changes of the microbiome of chronically ill patients are more profound than those of patients with a short duration of AN, and differ from controls and that the composition of the microbiome is associated with neuropsychological functioning

Study objective

To study the differences in MI between short-term ill adolescents with AN (< illness duration 1 year) and patients who started their illness in adolescence and have been ill for at least 5 years consecutively and with healthy controls. A secondary objective is to relate the composition of the microbiome to physiological (hormone levels, hyperactivity) and psychological (cognitive flexibility) characteristics.

Study design

Our work plan comprises an observational longitudinal study by which we want to compare the microbiome of patients with a short duration of illness with the microbiome of those who are chronically ill and with healthy controls on three time points: at start treatment, after 6 months and after 1 year.

Study burden and risks

Patients will be assessed three times, controls twice. On each occasion participants fill in questionnaires and perform computer tasks, provide a stool and blood sample, and wear an Actiwatch for 2 days. The risk is considered low in this study considering the observational nature of the study.

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)

Inclusion criteria

Female patients between 13 and 20 years of age (first-time ill) for the first group, and between 18 and 35 years of age (start in adolescence) with AN and atypical AN according to DSM-5 for the second (chronic) patients.
Age-matched controls without eating disorder, BMI < 80th percentile and > 20th percentile.

Exclusion criteria

Organic brain disease, psychotic disorder, bipolar disorder, IQ < 80, insufficient knowledge of Dutch language, antibiotic use during the previous 6 weeks, substance abuse, pregnancy, diabetes, or gastrointestinal diseases.

Study design

Design

Study type:	Observational 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):	01-08-2020
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-12-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL70832.041.19
Other	NL8566