Intestinal microbiota, executive functioning and micronutrient status in enduring anorexia nervosa: a pilot study

Published: 23-12-2016 Last updated: 15-04-2024

The current pilot study aims to investigate whether diversity and composition of the intestinal microbiota are different in patients with enduring anorexia nervosa compared to matched controls. Furthermore, this study aims to explore whether...

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

Summary

ID

NL-OMON53103

Source ToetsingOnline

Brief title Microbiota in enduring anorexia nervosa

Condition

• Eating disorders and disturbances

Synonym anorexia nervosa

Research involving Human

Sponsors and support

Primary sponsor: Stichting Rivierduinen **Source(s) of monetary or material Support:** Stichting GGZ Rivierduinen

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Intervention

Keyword: Anorexia nervosa, Executive functions, Microbiota, Micronutrients

Outcome measures

Primary outcome

Intestinal microbiota: Bacterial DNA will be extracted from stool samples. Neuropsychological Tasks (Executive functions): Wisconsin Card Sorting Test (WCST), Trail Making Test (TMT), Go/No Go task, Iowa Gambling Task (IGT). Questionnaires (Executive functions): Behavior Rating Inventory of Executive Function Adult Version (BRIEF-A-SR), Dickman Impulsivity Inventory (DII). Micronutrient status: Vitamin B1, vitamin B6, vitamin B12, vitamin D, folic acid, magnesium and zinc.

Secondary outcome

Eating disorder psychopathology: Eating Disorder Examination Questionnaire

(EDE-Q)

Depressive symptoms: Inventory of Depressive Symptomatology (IDS-SR)

IQ: Nederlandse Leestest voor Volwassenen

Food intake: dietary history with check/crosscheck (food diary during three

days)

Study description

Background summary

Anorexia nervosa is a severe psychiatric disorder marked by extreme dieting and low body weight. This extreme dieting may affect the diversity and composition of the intestinal microbiota (microorganisms that inhabit the human gut). Recent studies demonstrated the presence of a so called gut-brain axis;

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intestinal microbiota seem to affect emotional behavior and were associated with cognitive functioning. Anorexia nervosa itself is also associated with cognitive functioning, in particular deficits in executive functions are common. Executive functions are higher order control functions in the brain that play a role in self-control, self-regulation, decision making, and problem-solving. Moreover, the extreme dietary restrictions in anorexia nervosa may lead to insufficiencies of vitamins and minerals.

Study objective

The current pilot study aims to investigate whether diversity and composition of the intestinal microbiota are different in patients with enduring anorexia nervosa compared to matched controls. Furthermore, this study aims to explore whether diversity and composition of the intestinal microbiota is associated with executive functioning and/or micronutrient status (in patients with enduring anorexia nervosa).

Study design

Observational pilot study, with a cross-sectional case-control design in 20 participants with enduring (at least two year) anorexia nervosa) and 20 controls (partner/family member/room mate from same house). The study consists of three parts: 1. collecting a stool sample at home, with a special collecting kit, and bringing this sample to the appointment at GGZ Rivierduinen Ursula; 2. online completion of a number of questionnaires and a food diary during three days; 3. a visit to GGZ Rivierduinen Eetstoornissen Ursula for completing the neurospychological (computer)tasks, the dietary history and the blood extraction at the LUMC (for micronutrient assessment).

Study burden and risks

Risks for taking part in this study are minimal. Participants can collect a stool sample at home (a stool sample collection kit will be send by mail). Self-report questionnaires and food diary will be completed online (duration 60 minutes; BRIEF-A-SR, DII, EDE-Q and IDS-SR). A single visit to GGZ Rivierduinen Eetstoornissen Ursula to complete the neuropsychological tests (40 minutes; Nederlandse Leestest voor Volwassenen, WCST, TMT, Go/NoGo and IGT), and the dietary history (50 minutes) will be combined with the blood extraction at the LUMC (three 4 ml whole blood EDTA tubes and one 8.5 ml SST tube (serum)) for the micronutrient assessment. The participants will receive a financial reimbursement of x 10,00.

Contacts

Public GGZ Rivierduinen, Centrum Eetstoornissen Ursula

Sandifortdreef 19 Leiden 2333 ZZ NL **Scientific** GGZ Rivierduinen, Centrum Eetstoornissen Ursula

Sandifortdreef 19 Leiden 2333 ZZ NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

Inclusion criteria

-enduring anorexia nervosa (at least two year continuous presence) according to DSM-5 criteria -age between 18 and 60 years

Exclusion criteria

-renal failure
-liver disease
-chronic diarrhea
-current laxative use
-smoking > 5 cigarettes/day
-alcohol intake > 10.0 g/day (equals one standard glass alcohol)

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-current use of multivitamins -pregnancy -IQ below 85

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2018
Enrollment:	40
Туре:	Actual

Ethics review

Approved WMO	
Date:	23-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	29-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	05-03-2018
Application type:	Amendment
	Amenument
Review commission:	METC Leiden-Den Haag-Deift (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	17-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	19-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	14-12-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	12-05-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
ССМО	NL58583.058.16

Study results

Date completed:	27-11-2023
Actual enrolment:	16

Summary results

Trial ended prematurely