Eating Disorders Genetics Initiative Netherlands

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

Summary

ID

NL-OMON52241

Source
ToetsingOnline

Brief title
EDGI-NL

Condition

- Eating disorders and disturbances

Synonym
binge-eating disorder, bulimia nervosa, eating disorders: anorexia nervosa

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Eating disorders, Genetics

Outcome measures

Primary outcome

Online self-report questionnaires to assess: lifetime eating disorder diagnosis, eating disorder psychopathology. DNA of participants will be isolated from a saliva sample.

Secondary outcome

Online self-report questionnaires to asses: treatment and impact of eating disorder, quality of life, obsessive compulsive disorder, mood and anxiety symptoms, substance use, life events, excessive exercise and perfectionism

Study description

Background summary

Eating disorders (anorexia nervosa [AN], bulimia nervosa [BN] and binge eating disorder [BED]) are severe psychiatric disorders. Little is known about the aetiology of eating disorders, but there seems to be a substantial heritable component. To advance genetic discovery of biologically, clinically, and therapeutically meaningful insights large samples of cases with eating disorders and controls are required to perform Genome Wide Association (GWA) Studies. The Eating Disorders Genetics Initiative (EDGI) is an international collaboration designed to recruit 4,500 individuals with AN, 5,950 individuals with BN, 4,050 individuals with BED and 1,500 ancestrally matched controls. The current EDGI-NL project will recruit Dutch cases with eating disorders and controls to contribute to EDGI and the Eating Disorders workgroup of the Psychiatric Genomics Consortium (PGC-ED).

Study objective

EDGI aims to enhance the understanding of the underlying biology and genetic architecture of the different eating disorders. Therefore GWA analyses (both within and cross disorder analyses) will be performed in the EDGI samples

combined with the PGC-ED samples (total 35,000 cases, 100,000 controls). The EDGI-NL project will ascertain Dutch eating disorder cases and controls and contribute to the EDGI project and goals by delivering DNA and questionnaire data of at least 200 cases with AN, 200 cases with BN, 100 cases with BED and 150 controls.

Study design

Observational study, using a cross-sectional case-control design at least 200 cases with AN, 200 cases with BN, 100 cases with BED and 150 controls will be ascertained. Participation in the study consists of three steps (1. Online screening questionnaire; 2. Additional online questionnaires; 3. Collection saliva sample at home and returned by mail) and will take approximately three hours. The consent procedure exists of two parts. First the participant has to give consent for the first part of the study (the screening questionnaire). If the participant is eligible to take part in the rest of the study, the research team will contact the participant by telephone for a check (information on the study, are there any questions concerning the research, does the participant understand what he/she will give consent for). Then they will receive a second information letter by Email. At the end of this information a link to a secure online consent form is given. After the participant completed the consent form, the participant will continue with part two and three of the study.

Study burden and risks

Participation in the study consists of three steps (1. Online screening questionnaire; 2. Additional online questionnaires; 3. Collection saliva sample) and will take approximately three hours. The saliva sample can be collected at home and returned by mail. Phenotypic information will be ascertained online, questionnaires do not have to be completed at once, but can be completed in parts.If participants are eligible to take part in the study, based on the screening questionniare, and they complete the additional online questionnaires and collect the spit sample, they will receive a ¤20 Bol.com gift card.

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

Patients:
-fulfil criteria for a lifetime history for AN, BN or BED according to the DSM-5
-between 18 and 65 years old
-be able to understand and complete the questionnaires of the EDGI-NL study

Controls:
-lifetime adult minimum BMI>18.5 kg/m2
-no history of an eating disorder or disordered eating behaviours
-between 18 and 65 years old
-be able to understand and complete the questionnaires of the EDGI-NL study

Exclusion criteria

none

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:	Pending
Start date (anticipated):	15-01-2022
Enrollment:	650
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-01-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-07-2022
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
CCMO	NL77279.058.21