EGAL: Environmental and Genetic Effects on Autism Longitudinal

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The aim of this project is to examine the association and interaction between environmental and genetic factors and development over time in adults with ASD. We examine if and how genetic and environmental factors might contribute to the course of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Developmental disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON51612

Source
ToetsingOnline

Brief title
EGAL: Environmental and Genetic Effects on Autism Longitudinal

Condition

- Developmental disorders NEC

Synonym
Autism, Autism Spectrum Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Autism, Environment, Genes

Outcome measures

Primary outcome

-ASD case/control status

-Autistic traits: Autistic traits are measured using validated questionnaires

(e.g. Autism Quotient Short (AQ-short))

-Self-reported comorbidities: Assessed comorbities include additional

diagnoses, mood problems and insomnia. Comorbities are measured using validated

questionnaires (e.g. Strengths and Difficulties Questionnaire (SDQ), Hospital

Anxiety and Depression Rating Scale (HADS)) and self-report.

-Self-reported quality of life. Quality of life is measured using the Cantril

Self-Anchoring Scale: the Ladder and with validated, more in-depth quality of

life questionnaires. In addition, quality of life is measured with questions on

occupation history, and educational attainment.

Secondary outcome

n/a

Study description

Background summary

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder with approximately 2% prevalence. It is characterized by atypical social communicative- and repetitive and restrictive behaviour. However, it is a highly heterogenous disorder as well. Although a biological basis of ASD has been suspected for a long time, only recently were genetic variants identified that contribute to ASD, mood disorders, and sleeping problems. Considering the

highly heritable nature of ASD, including genetic factors in prediction models might be crucial to gain a deep understanding of ASD aetiology. Environmental factors are additionally promising in predicting the course of ASD. Yet the current literature is limited, and focused on the causes of ASD, instead of the effect of environmental and genetic factors on the course of ASD and quality of life.

Study objective

The aim of this project is to examine the association and interaction between environmental and genetic factors and development over time in adults with ASD. We examine if and how genetic and environmental factors might contribute to the course of core and comorbid ASD symptoms, and to quality of life in ASD.

Study design

Observational case-control and cohort study. Participants of the Dutch Autism Register are invited to collect saliva, from which DNA will be isolated. Genetic scores are calculated from genetic data. In addition, objective environmental variables are requested from a publicly available database based on the four digits of participants' zip code.

Study burden and risks

We will ask the 1000 NAR participants to provide a saliva sample to isolate DNA from. We will invite participants by email. If participants agree, we will send the saliva kit, including instruction, informed consent form, and return envelope. The saliva sample, and informed consent can be returned with the return envelope. Collecting saliva is risk free and takes approximately 5 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

ASD diagnosis
>= 16 years old
Able to provide consent for themselves

To ensure most of the data can be used in our analyses, the following additional inclusion criteria apply:
Consent to use four digits of postal code
European ethnicity

Exclusion criteria

No ASD diagnosis
<16 years old
Non-European ancestry
No consent to use four digits of postal code
Not able to provide consent for themselves

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):	01-02-2022
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-03-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL79422.029.21