Social anxiety and stress reactivity in Autism Spectrum Disorders

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

Summary

ID

NL-OMON43805

Source ToetsingOnline

Brief title StressAut

Condition

• Developmental disorders NEC

Synonym autism, autism spectrum disorders

Research involving Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven) Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autism, cortisol, social anxiety, stress reactivity

Outcome measures

Primary outcome

The levels of social anxiety, psychological and biological stress reactivity,

cortisollevels.

Secondary outcome

Comorbid subclinical psychotic reactivity in response to stress.

Study description

Background summary

Individuals with ASD are vulnerable for anxiety and stress (Baron et al. 2006). Although research in ASD is mainly focused on children and adolescents, there is some evidence for high levels of social anxiety in high functioning adults with ASD. It is not known which factors contribute to the development of anxiety in individuals with ASD (Kim et al. 2000). Besides high levels of social anxiety, individuals with ASD demonstrate poor stress management skills (White et al., 2009).

Clinically, they are often observed to react abnormally to environmental influences that are not stressful for individuals who are not diagnosed with ASD. Recent research among children with ASD demonstrated increased reactivity of the hypothalamic-pituitary-adrenal (HPA) axis to stressful stimuli, measured by levels of the stress-hormone cortisol (Spratt et al., 2012), however studies on adults with ASD are scarce.

Thus, there is a lack of understanding social anxiety and stress reactivity in the daily lives of adults with ASD. In addition the interaction between these variables, the association with physiological reactivity (cortisol) and the influence of contextual determinants has not been elucidated.

In order to examine the phenomenology of social anxiety, psychological and physiological reactivity in adults with ASD, daily life assessments will be done with the Experience Sampling Method (ESM). This is a structured diary technique, meaning that participants fill in short questionnaires via an app on their smartphone (PsyMate), several times per day after a random signal. At the same time points, they will be asked to collect a saliva sample in order to measure the stress hormone cortisol. The ESM method has been used before in a few (pilot) studies on ASD (Chen, Bundy, Cordier & Einfeld, 2014; Chen, Cordier & Brown, 2014; Hall, Dawson, van Os & Myin-Germeys, 2010).

Study objective

The main objective of this study is to compare levels of stress reactivity, social anxiety and cortisol in daily life between adults with ASD and healthy controls. Besides, fluctuations and interactions of these variables over time and their contextual determinants in real life will be examined. We expect that adults with ASD, with respect to controls, experience higher levels of social anxiety and higher levels of negative affect (NA) during stressful events, also known as stress reactivity. Moreover, we expect to find that higher cortisol reactivity in adults with ASD is associated with increased psychological stress reactivity. Lastly, based on phenomenological, neurobiological and genetic overlap between ASD and the psychosis spectrum (King & Lord, 2011). We expect not only expect to find increased NA in response to stress, but also increased subclinical psychosis in response to stress in patients with ASD.

Study design

The current study is an observational study. During 10 days, data will be collected through the PsyMate application (10 random signals per day), on which a short questionnaire (3 minutes) should be filled out. Hereby, daily life symptoms/experiences, contexts and activities are registered. At the same random beep moments, a saliva sample will be collected for cortisol measurements. In addition, a short electronic questionnaire (1 min) pops up daily after waking up and before sleeping. At the start and at the end of the PsyMate weeks participants are asked to fill in 3 regular (pen and paper) questionnaires. Furthermore they will be asked about their experiences with the PsyMate.

Study burden and risks

The total investment in time for participants in this study is about 10 hours. There is no risk associated with any of the tasks of this study (filling out questionnaires, participating in interviews and collecting saliva samples). In addition, previous studies using the same methods have shown that there are no health risks involved for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Age between 18 and 65 years.

- Presence of ASD diagnosis according to DSM-5 criteria, and as assessed with the ADOS-2 module 4 revised: Total score * 8 (section Social Affect and section Restricted and Repetitive Behavior; with section social affect * 6)

- Intelligence: Verbal Comprehension (VCI), Perceptual Reasoning (PRI) is * 70
- Minimal (max. 2 years) psychological and/ or psychiatric treatment history.;Control group:
- Age between 18 and 65 years
- Not diagnosed with ASD or any other lifetime psychiatric diagnosis
- No first-degree relative with ASD
- AQ < 26
- Intelligence: Verbal Comprehension (VCI), Perceptual Reasoning (PRI) is * 70

Exclusion criteria

- Specific somatic disorders: known genetic abnormality, metabolic disorder, epilepsy, traumatic brain injury

- Suicidal tendencies, acute psychosis, bipolar disorder

4 - Social anxiety and stress reactivity in Autism Spectrum Disorders 26-05-2025

- Clinical treatment (admission) history for any psychiatric disorder

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2016
Enrollment:	100
Туре:	Actual

Ethics review

Approved WMO	
Date:	30-03-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO

ID NL51997.068.15

Study results

Date completed:	01-01-2018
Actual enrolment:	101