# Sex differences in Social Cognition in Autism Spectrum Disorders (ASD)

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The main objective of this study is to identify similarities and/or differences in social cognition between males and females with ASD at the behavioral, neuropsychological, and neurophysiological level during adolescence.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON49826

**Source**
ToetsingOnline

**Brief title**
Social Cognition in Autism Spectrum Disorder (SCASS)

### Condition

- Other condition
- Developmental disorders NEC

**Synonym**
Autism, Autism Spectrum Disorders

**Health condition**

Autisme Spectrum Stoornissen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Accare
**Source(s) of monetary or material Support:** Accare

## Intervention

**Keyword:** Autism Spectrum Disorders (ASD), Electroencephalography (EEG), Sex differences, Social Cognition

## Outcome measures

### Primary outcome

The study parameters include questionnaires, neuropsychological tests, neurophysiological measurements during rest and neuropsychological computer tasks that evoke social cognition (assessed with electroencephalography [EEG]), and a clinical diagnostic assessment. The main study parameter is the difference in neurocognitive performance and neurophysiology between males and females with and without ASD.

### Secondary outcome

Niet van toepassing

# Study description

### Background summary

Impairments in social cognition are one of the key symptoms of Autism Spectrum Disorder (ASD). The mechanisms underlying the impairments in social cognition remain largely unknown. Adolescence is an important developmental stage in which social cognition is being shaped due to significant psychological challenges in terms of identity, self-consciousness, and relationships with others. Previous efforts that addressed the etiology of social impairments in ASD have been hampered by the highly heterogeneous nature of ASD. One of the most striking sources of heterogeneity in ASD is biological sex, as demonstrated by the 4:1 male:female ratio. Even though sex differences in the general population in the social domain have been well established, sex

differences in the ASD population remain understudied. Previous research has suggested a female presentation of ASD that is associated with attenuated ASD core symptoms and a distinctive psychopathology including better social cognition resulting in more enhanced socio-communicative behavior compared to males with the condition. Due to this distinct female phenotype in ASD, females with ASD are often diagnosed after a significant delay, are misdiagnosed, or may not be diagnosed altogether, resulting in a lack of support and treatment. It is of great importance to better understand the phenotype of females with ASD and its underlying mechanisms, particularly with respect to their similarities and differences compared to affected males. Seeing the lack of studies addressing this issue, it is important to investigate sex differences in ASD in a comprehensive range of aspects of social cognition, ranging from basic processes like facial emotion recognition to more complex processes like empathy and theory of mind.

**Study objective**

The main objective of this study is to identify similarities and/or differences in social cognition between males and females with ASD at the behavioral, neuropsychological, and neurophysiological level during adolescence.

**Study design**

This study has a cross-sectional, 2x2 full factorial design with sex and presence or absence of ASD as factors.

**Study burden and risks**

The risks, possible discomforts and burden of this study are estimated as low. Questionnaires will be filled out at home, while the other assessments will be performed during a single clinic visit. The total duration of the study is approximately 6 hours for participants with ASD and approximately 5 hours for typically developing control participants, including filling out questionnaires at home (40 min), an diagnostic assessment of ASD traits (60 min; ASD participants only), an EEG assessment (120 min including breaks), a neuropsychological assessment including an IQ screener (65 min including breaks) and breaks. Possible discomforts include wearing an EEG cap, washing hair subsequent to the EEG assessment, and the concentration required during the neuropsychological assessments. A better understanding of the female phenotype in ASD and the underlying mechanisms of impairments in social cognition in the disorder is essential for future improvement of treatments as well as better recognition of females with ASD. It is crucial that sex differences in social cognition in ASD are assessed in adolescents, since adolescence is the most important stage of life for both the development of social cognition and the development of sex specific behaviors.

# Contacts

**Public**
Accare

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)

## Inclusion criteria

- Aged 12-17 at inclusion
- Ability to understand and speak Dutch
- Deemed reliable and compliant with the study protocol
- Be right-handed

Only for ASD participants:
- At least 14 days on stable medication
- Score of >60 on the SRS

### Exclusion criteria

• Intellectual disability (IQ < 70) based on available IQ measure or the clinical opinion of the investigator (taking into account relevant psychosocial information, e.g. educational level)
• History of or current head injury
• Genetic disorders associated with ASD (e.g. fragile X)
• Subject has known epilepsy
• Known lifetime history of a psychotic disorder or bipolar disorder, or current severe mental state (e.g. depression)

Additional exclusion criteria for controls:
• A parent- or (where appropriate) self-reported diagnosis of a psychiatric disorder.
• A score of > 60 on the parent-reported Social Responsiveness Scales (SRS)

## Study design

### Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-01-2022 |
| Enrollment: | 142 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 28-01-2021 |
| Application type: | First submission |

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| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 19-05-2021 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 02-12-2024 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL75060.042.20 |