Social Spectrum Study: a multicenter study on Autism Spectrum Disorders in the South West of the Netherlands

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

Summary

ID

NL-OMON39197

Source
ToetsingOnline

Brief title
Social Spectrum Study

Condition

- Developmental disorders NEC

Synonym
Autism Spectrum Disorders (ASD); Pervasive Developmental Disorders (PDD)

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Financiering dmv Endowed Chair van de Sophia Stichting - SSWO

Intervention

Keyword: Aetiology, Autism Spectrum Disorders, Care utilisation, Screening

Outcome measures

Primary outcome

The main parameters of this study will be: (categorical) classification of ASD and co-morbid psychiatric disorders, (dimensional) developmental characteristics of children with ASD (e.g. social-communication, rigid/stereotype behaviour, adaptive functioning, motor skills, sensory sensitivities, IQ), quality of life of the child and parents/caregivers, and mental health care utilisation. Possible predictors for the developmental characteristics are demographic factors (e.g. ethnicity), child factors, multiplex vs simplex. Possible predictors for the quality of life and mental health care utilisation are several demographic factors, child characteristics, family functioning, and parental characteristics.

Secondary outcome

Not applicable

Study description

Background summary

Broadening of the concept from narrowly defined autism to a broader category of autism spectrum disorders (ASD) has increased variation among children with ASD on autistic core dimensions (social-communication and rigid behaviour/restricted interests) as well as on related developmental dimensions (e.g., co-occurring emotional and behavioural problems, and cognitive, adaptive, sensory, and motor functioning). There also exists variation in behaviours across contexts. Heterogeneity of ASD complicates diagnosis and research into the underlying genetic and neurobiological mechanisms. The Social

Spectrum Study will address this obstacle by carefully and comprehensively characterizing ASD and other developmental traits in a representative cohort of children and adolescents with ASD. This provides the opportunity to distinguish more homogenous ASD subgroups with similar developmental characteristics, and link these different subgroups to distinct patterns of genetic and environmental aetiology, familial and societal burden.

Study objective

The present study has the following objectives:
1) Investigating the clinical utility of screening instruments. As a part of this objective, we will examine how several demographics (e.g. ethnicity) affect the assessment of autistic and other developmental traits, and how the use of different informants can be complimentary.
2) Autistic phenotype characterization: Examining interrelationships between autistic and other developmental traits and differentiating subgroups within ASD with similar phenotypic profiles.
3) Link profiles of key autistic and other developmental traits to several aetiological factors such as familial loading.
4) The impact of ASD: investigating predictors of individual, familial, and societal burden.

Study design

Spectrum is a multi-centre study, in which six youth mental health care centres in the South West of the Netherlands will collaborate: Emergis (Zeeland), GGZ Westelijk Noord-Brabant (Bergen op Zoom), Lucertis (Rotterdam e.o.), Riagg Rijnmond (Rotterdam + Schiedam), Erasmus MC-Sophia (Rotterdam) en Yulius (Barendrecht + Dordrecht). The study will include all children aged 1,5 - 10 years old that are consecutively referred to one of the six participating youth mental health care centres during one year (~1 April 2011 - 1 August 2012). Before intake, all referrals will receive a registration form - that assesses demographics (including ethnicity and prior care use of the child) - and several screening questionnaires - that assess various developmental problems, including autistic social impairment. These questionnaires will be part of the standard clinical protocol. Children who are identified with possible ASD (screen positives; ca n = 400) and a randomly selected comparison group of children with a variety of other developmental problems (screen negatives; ca n =200) will be invited for participation in the present study. When children and parents/caregivers consent to participation, they will receive gold standard diagnostic procedures (including parent interview and sometimes an observational assessment of the child), and research into other developmental characteristics of the child, family characteristics and functioning will take place.

Study burden and risks

The risks of participating in the present study are negligible. Information will be collected using questionnaires, interviews, and direct behavioural assessment of the child. An advantage of participating is that the participants will go through a comprehensive assessment using golden standard diagnostic instruments that are not always used in local health services because of the time investment and training qualifications that are needed to use these instruments. If participants provide consent, the information from these assessments can be reported back to the clinicians, so this information can be used in the evaluation of the clinical diagnosis en in the forming of treatment plans. Since autism spectrum disorders are childhood neurodevelopmental disorders, it is important to study children with ASD from an early age on.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

-ASD high risk group: all screen positive children will be invited for further assessments. Children aged 2,5 -10 yrs are screen positive when total score of SRS parent >= 75.
- Control group: a random weighted (based on age and gender) selection of ca. 200 children from the screen negative children without an ASD diagnosis. A child is screen negative when they do not meet the cut-off that is explained above.

Exclusion criteria

Since the aim of the present study is to obtain a representative cohort of children with ASD, we do not want to set any exclusion criteria. However, we will comprehensively chart various behavioural and developmental aspects, in order to identify more homogeneous subgroups of children with similar developmental profiles. In different objectives of the study, we will attempt to link different (subgroups of) developmental profiles to various factors, therefore minimizing the disadvantages of not setting exclusion criteria en .
Assessments will be adapted to the developmental level of the child. We will assist parents who have below average IQ or who are not sufficiently skilled in the Dutch language with filling out the questionnaires. If needed, we will ask an interpreter to assist with conducting the interviews and/or filling out the questionnaires.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-03-2012

Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	10-05-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-09-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-05-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL35702.078.11