Validatie-onderzoek van het Nederlands Interview ten behoeve van Diagnostiek Autismespectrumstoornis bij volwassenen (NIDA)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27396

Source
Nationaal Trial Register

Health condition

autismespectrumstoornis, autism spectrum disorder, persoonlijkheidsstoornis, personality disorder

Sponsors and support

Primary sponsor: Sarr Expertisecentrum Autisme
Oudedijk 76
3062 AG Rotterdam
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Source(s) of monetary or material Support: Sarr Expertisecentrum Autisme
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Intervention

Outcome measures

Primary outcome

In order to answer the main research question ‘Is the NIDA a methodologically sound instrument for diagnosing ASD in adults?’, the following instruments will be used: NIDA, ADOS, SCID-5-PD interview and SCID-5-SPQ
In order to answer the first research question ‘Does the NIDA have a good interrater reliability?, we study the correlation of the outcomes on the eight questions of the NIDA between the interviewer and the observer, independently judging the item scores for current functioning on this instrument.

Secondary outcome

In order to answer the second research question ‘Does the NIDA have a good convergent validity?’, we study the outcomes (yes ASD, no ASD) on the ASD assessment. With respect to the NIDA we will first use the sum score of 3 for questions 1-3 and sum score of ≥2 for questions 4-7 for current functioning. The combination of these sum scores will lead to yes or no current ASD. We compare this combination (yes or no current ASD) with ADOS total score of ≥8 or ≥10 (yes current ASD). Second, we will compare the combination of the sum scores of the eight questions for current functioning of NIDA (yes or no current ASD) to the clinically diagnosed ASD (yes for current ASD).

In order to answer the third research question ‘Does the NIDA have a good discriminant validity?’, we use the NIDA, SCID-5-PD interview and the SCID-5-SPQ screening tool. We use the total sum scores for current functioning on the NIDA to allocate the participants into one of the three groups (ASD, PD without ASD, and COM), expecting higher total sum scores for participants with ASD than for participants with PD without ASD, and COM. The SCID-5-PD interview and SCID-5-SPQ will be used to diagnose PDs.

Study description

Background summary

Rationale: Autism spectrum disorder (ASD) in adults is an important clinical entity, for which there are several diagnostic instruments available. Guidelines on diagnosis of adults on ASD cannot give a best available suggestion for diagnostic assessment of an adult with possible autism, because of insufficient evidence for any specific formal assessment tool for ASD in adults.

Objective: The aim of the study is the psychometric evaluation of one of the diagnostic instruments for ASD in Dutch, which is the NIDA (Nederlands Interview ten behoeve van

Autismespectrumstoornis bij volwassenen - Netherlands Interview for Diagnostic assessment of Autism spectrum disorder in adults). We will assess the reliability and validity of the NIDA by measuring its interrater reliability, convergent and discriminant validity (sensitivity, specificity) in a Dutch-speaking sample in the Netherlands.

Study design: A cross-sectional validation study design, with multiple groups: ASD, Personality Disorders (PD), and non-clinical comparison group (COM).

Study population: Male adult individuals (age ≥ 18 years) with ASD who were clinically diagnosed by a multidisciplinary team of psychologists and a psychiatrist in the (recent) past, and male adult individuals (age ≥ 18 years) with a PD who were assessed with the Structural Clinical Interview for DSM-IV (SCID-II) or DSM-5 Personality Disorders (SCID-5-PD), and male non-ASD and non-PD adult individuals (age ≥ 18 years; COM). Participants with ASD will be recruited from an expertise centre for autism. Participants with PD will be recruited from an outpatient psychiatric clinic in Rotterdam. COM participants will be recruited by advertisements and flyers. The study requires 90 participants (30 with ASD, 30 with PD and 30 COM). None of the participants will have an intellectual disability.

Procedure: Administering NIDA, ADOS, SCID-5-PD, and SCID-5-CV.

Main study parameters: The main study parameters are the sum and item scores of the 8 questions for current functioning on the NIDA.

Study objective

We hypothesize that the NIDA is a reliable instrument and that individuals with a clinically diagnosed autistic disorder (AD; DSM-IV) or Asperger's Disorder (AS; DSM-IV) and/or ASD (DSM-5) report more ASD features (according to the DSM-5) with the NIDA compared to those with a personality disorder (PD) and without AD/AS/ASD (no DSM-IV AD or AS classification and/or no DSM-5 ASD classification) and to those without PD and without AD/AS/ASD.

Study design

one moment per participant

Intervention

To decide if a person can or can not participate in one of the three groups, a questionnaire

for general information about primary diagnosis, age, education, marital status etc. and the SCID-5-SPQ (First et al. 2016a), the self-report screening tool for PDs will be assessed. When eligible for one of the three groups according this assessment, each participant will be once interviewed by a psychologist and once interviewed and observed by two other psychologists, all three qualified for diagnostic assessments. The NIDA, ADOS, SCID-5-PD interview and Structured Clinical Interview for DSM-5® Disorders-Clinician Version (SCID-5-CV; First et al. 2016b) will be administered to all participants (n = 90). All interviewers and observers are well trained and educated in at least ASD in adults, and in the NIDA by the study author, in the ADOS by ADOS-specialized trainers, and/or in the SCID by a SCID-specialized trainer. The interviewers and observers will be blind for diagnostic group and will not be permitted to obtain other sources of information to ensure that the final DSM-classification ASD for current functioning will be based only on the result of the NIDA.

To establish the interrater reliability of the NIDA, two psychologists jointly will assess 90 participants (30 with ASD, and 30 with PD without ASD, and 30 COM). One will perform the interview, the second will observe, and both will independently evaluate the participant according to this interview.

To establish convergent validity (sensitivity and specificity) scores on the NIDA and the ADOS will be compared for three groups of participants (ASD > PD without ASD > COM), and scores on the NIDA will be compared to the clinically assessed DSM-IV or DSM 5 ASD diagnosis. The order of NIDA and ADOS will be counterbalanced across participants, and will be administered by the same psychologists: one performs and the second observes. Both psychologists judge separately the social interaction style of the participant by indicating the most prominent style of making contact (i.e., aloof, passive, active-but-odd, over-formal).

To establish discriminant validity we compare the scores on the NIDA between three groups of participants (ASD > PD without ASD > COM). A third psychologist assesses PDs with the SCID-5-PD interview, and DSM-5 disorders with the SCID-5-CV in all three groups.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for the ASD group are a primary diagnosis of DSM-IV Autistic Disorder or Asperger's Disorder, and/or DSM-5 ASD, with or without a comorbid DSM-IV/5 personality disorder (PD), male gender, age ≥ 18 years, and no intellectual disability), at least a completed primary school and secondary education, and being able to state and/or recognize own (psychological and problematic) functioning. We will solely include males as males are diagnosed with ASD 3 to 4 times more than females. The diagnosis ASD (including AD and AS) will be verified by studying the diagnostic report including the diagnosis ASD based on clinical evaluation of autism-specific behaviors by direct observation of the patient and report of developmental and behavioral history and current functioning obtained by partner, parent or mentor. The ASD must be diagnosed in a multidisciplinair team consisting of at least a registered psychologist or psychiatrist. A possible comorbid PD must be assessed with the Dutch version of the Structured Clinical Interview for DSM-IV Axis II or DSM-5® Personality Disorders (SCID-II; First et al. 1997; SCID-5-PD; First et al. 2016a).

Inclusion criteria for the PD group are a primary diagnosis of DSM-IV and/or DSM-5 PD, assessed with the Dutch version of the SCID-II (First et al. 1997) or SCID-5-PD (First et al. 2016a), no past or current suspicion by health care professionals of and no diagnosis of DSM-IV/DSM-5 ASD, male gender, age ≥ 18 years, no intellectual disability, at least a completed primary school and secondary education, and being able to state and/or recognize own (psychological and problematic) functioning.

Inclusion criteria for the non-ASD/non-PD group are no ASD and no PD diagnosis, male gender, age ≥ 18 years, no intellectual disability, at least a completed primary school and secondary education, having a reasonable degree of insight into and recognition of their (psychological) functioning.

Exclusion criteria

Exclusion criteria for all participants are intellectual disability (IQ < 80), female gender, and presence of current suicidal ideation, and those who have been diagnosed ASD with the NIDA in the past.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2017
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-05-2017
Application type:	First submission

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
NTR-new	NL6219
NTR-old	NTR6391
Other	Commissie Ethiek Universiteit van Amsterdam : 2017-CP-7839

Study results