RESEARCH PROTOCOL

Autism Spectrum Disorder and Attachment

AN EXPLORATIVE STUDY OF ATTACHMENT STYLES IN ADULTS WITH AUTISM SPECTRUM DISORDER

(October 2023)

PROTOCOL TITLE An explorative study of attachment styles in adults with autism spectrum disorder

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PROTOCOL SIGNATURE SHEET

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
AR	**Adverse Reaction**
ASD	**Autism Spectrum Disorder**
ASQ	**Attachment Style Questionnaire**
ECR-R	**Experiences in Close Relationships Revised**
EU	**European Union**
EudraCT	**European drug regulatory affairs Clinical Trials**
HSL	**Hechtingsstijllijst**
METC	**Medical Research Ethics Committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
RDM	**Research Data Management**
RSQ	**Relationship Scales Questionnaire**
(S)AE	**(Serious) Adverse Event**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SRS-A	**Social Responsiveness Scale – Adult version**
SUSAR	**Suspected Unexpected Serious Adverse Reaction**
UMC	**University Medical Center**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Previous research on autism spectrum disorder (ASD) and attachment has improved understanding of the aetiology and development of the disorder. Research on adults with ASD, however is scarce. In the current study, we focus on attachment in adults with ASD.

Objective: The aim of the current study is to explore attachment styles of adults with ASD and examining the relationship between attachment and ASD.

Study design: Cross-sectional design: data will be analysed at a specific point in time.

Study population: Adults (>18 years) with ASD, and without intellectual disability. Participants will be recruited from SARR Autism Rotterdam and Antes, both part of Parnassia Group in the Netherlands. SARR Autism Rotterdam is specialized in psychodiagnostic assessments and interventions for children, adolescents, and adults with ASD. Antes and Parnassia Group are multisite mental health institutes specialized in psychodiagnostic assessments and interventions for adults with a broad range of psychiatric disorders, including ASD. The study requires 60 participants.

Intervention (if applicable): not applicable

Main study parameters/endpoints: Main study parameters are SRS-A score (ASD characteristics), ASQ (attachment style) and ECR-R (attachment anxiety and attachment avoidance).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants are asked to complete three online questionnaires, each taking no more than 15 minutes to complete. The questionnaires collect participants' information on their ASD characteristics and their experiences of interpersonal relationships. We do not expect this to be burdensome, as they are already familiar with diagnostic assessment. For individuals with ASD, the principal psychological benefit of knowing their attachment style may be that in those with insecure attachment this knowledge may function as a means of treatment.

1. INTRODUCTION AND RATIONALE

Autism spectrum disorder (ASD) is a neurodevelopmental disorder with early onset, and typical characteristics throughout one's lifetime. It is called a spectrum disorder because of variety in phenotypic presentation and severity of symptoms (Lai et al., 2013). Kanner (1943) described ASD as an inability to form effective contact with others. In the late 1970s, lack of attachment was mentioned as one of the characteristics of ASD (Rutter, 1978). DSM-III American Psychiatric Association, 1980) described ASD as a failure to develop normal attachment behaviour. However, recent research indicates that individuals with ADS are able to form secure attachment, albeit at lower rates and with more challenges (Chandler & Dissanayake, 2014; Giannotti & de Falco, 2021; Rutgers et al., 2004; Teague et al., 2017). In DSM-5-TR (American Psychiatric Association, 2022). Core features are persistent deficits in social communication, social interaction, and restricted, repetitive patterns of behaviour, interests, or activities. The social disability is multifaceted with deficits in social-emotional reciprocity, social non-verbal communication, and developing, understanding, and maintaining relationships. Both ASD and insecure attachment affect social functioning and relationships and little is known about attachment in adults with ASD and the relationship between ASD and attachment in adults.

For more than over 60 years, the concept of attachment is one of the most and well-known concepts in the field of clinical psychology. John Bowlby (1969; 1973; 1980), the first attachment theorist, formulated his attachment theory which has led to one of the major theories of affect regulation, interpersonal functioning, and psychopathology. Development of attachment begins in early infancy: children establish attachment bonds with their caregivers, serving as an evolutionary function keeping the child close to the caregiver in times of stress to increase chance of survival. During child development, attachment behaviours adapt. In infants, toddlers, and pre-schoolers, attachment behaviours are: crying, clinging to caregivers, wariness of strangers, preference for a specific caregiver, and using the caregiver as a safe-base to return when exploring the environment (Bowlby, 1969). In middle childhood (between 6 and 12 years of age), attachment behaviours become less dependent on the their physical proximity to caregivers. Instead, caregivers' unconditional availability and responsiveness, influence attachment behaviours (Kobak et al., 2005).

Ainsworth and colleagues (1978) extended Bowlby's attachment theory by delineating individual differences in attachment patterns through observation of behaviour of infants of 12 to 24 months approximately in response to separation from and reunion with the caregiver (i.e., the well-known Strange Situation procedure (Ainsworth et al., 1978). Three different patterns of interaction and behaviour shown by infants towards their caregiver were discovered: secure, anxious, and avoidant. Securely attached children were distressed

during separation, but recovered quickly, showing joy, affection, easily soothed upon reunion, and more openness and flexibility towards exploring the environment. Anxious attached children were highly distressed during separations, showing anger and resistance upon reunion, yearning for physical contact and comfort with contradictory and ambivalent responses towards the mother, highly sensitive to potential unavailability, maximizing their efforts to remain in close contact with the caregiver. Avoidant attached children showed little distress when separated, avoiding proximity upon return, suppressing their needs and feelings of distress and giving up their proximity-seeking efforts (Ainsworth & Bell, 1970). A fourth attachment style was added, which is called the disorganized attachment style (Main & Solomon, 1986). Children with this style show chaotic, contradictory behavior (indifferences upon mother's return after excessive distress during separation), misdirected (seeking proximity to a stranger instead of a parent after separation) or stereotypical behavior (pulling hair with dazed expression, even though the parent is available), stilling and freezing (unable to choose between proximity or avoiding the parent, stops moving as in trance, dissociated from regular thought processes) for a substantial amount of time, or they even fear the parent in stressful circumstances. Their behaviour is bizarre and incoherent, indicating stress and anxiety the child cannot resolve because the parent is source of fright as well as the only potential haven of safety (Main & Solomon, 1986; Van IJzendoorn et al., 1999).

Bowlby (1980) argued that attachment processes continue to influence close relationships across the life span. In adulthood, internal working models of attachment are generally conceptualized as sets of global beliefs about self and others, resulting in a combination of four attachment styles (secure, preoccupied, dismissing and fearful) (Bartholomew & Horowitz, 1991; Griffin & Bartholomew, 1994). Individuals with a *secure attachment style* have positive views of self and others, and are at ease in becoming emotionally close and depending to others. *Preoccupied attached* individuals have a positive view on others, but a negative view on self, desiring extreme intimacy with others who do not meet their attachment needs. *Avoidant – dismissing* individuals have a positive self-model and a negative other-model, feeling comfortable without close emotional relationships. Intimacy is avoided because independence, self-reliance and maintaining autonomy is very important for them. The *Avoidant – Fearful* individuals have a negative view on both self and others, avoiding intimacy for the fear to be hurt.

Until now, studies examining attachment in ASD mainly focused on children (Bauminger et al., 2010; Capps et al., 1994; Davidson et al., 2022; Davidson et al., 2015; Dissanayake & Sigman, 2001; McKenzie & Dallos, 2017; Minnis et al., 2020; Rutgers et al., 2004; Sivaratnam et al., 2018; Teague et al., 2017; Van IJzendoorn et al., 2007; Willemsen-

Swinkels et al., 2000). A review study on ASD and attachment showed 40%-63% children with ASD are securely attached to their caregiver, comparable to children without ASD.

Secure attachments appear to act as a protective factor in the social and cognitive development of children with ASD (Teague, 2017). When demonstrating secure attachment, children with ASD show more complex play behaviours (Naber et al., 2008), more joint attention (Naber et al., 2007), improved social skills and educational opportunities and outcomes (Bauminger et al., 2010. These findings are consistent with observations from the typically developing literature and with predictions from attachment theory (Teague, 2017). The severity of ASD and developmental delay are both associated with less secure attachments (Naber et al., 2006), but there is a lack of consensus on the extent to which attachment insecurity is a function of either developmental delay or the severity of autism symptoms. To the best of our knowledge, research on attachment in adults with ASD is scarce. To date, only one study on attachment in adults with high functioning ASD (*N*=20) found a minority (15%) to be securely attached comparable with a general clinical sample and lower than non-clinical samples, and attachment security was found not to be related to ASD characteristic and IQ (Taylor et al., 2008).

Very little research has investigated the relationship between attachment and behaviour and emotional problems in children with ASD (Teague et al., 2017). The aim of this study is to explore attachment styles in adults with ASD and examining the relationship between attachment and ASD. For individuals with ASD, the principal psychological benefit of knowing their attachment style may be that in those with insecure attachment this knowledge may function as a means of treatment.

2. OBJECTIVES

Primary Objective: Exploring the relationship between ASD and attachment by describing how attachment styles are distributed in an adult population with ASD. We calculate correlations between ASD characteristics based on the SRS-A and attachment styles, attachment anxiety and attachment avoidance, as well as between attachment and level of education and having a relationship.

3. STUDY DESIGN

A cross sectional design will be used (outcomes on SRS-A, ASQ, and ECR-R).

4. STUDY POPULATION

4.1 Population (base)

Adults (>18 years) with ASD, and without intellectual disability. Participants will be recruited from SARR Autism Rotterdam and Antes, both part of Parnassia Group in the Netherlands. SARR Autism Rotterdam is specialized in psychodiagnostic assessments and interventions for children, adolescents, and adults with ASD. Antes and Parnassia Group are multisite mental health institutes specialized in psychodiagnostic assessments and interventions for adults with a broad range of psychiatric disorders, including ASD. The study requires 60 participants.

4.2 Inclusion criteria

Inclusion criteria are: a DSM-5 ASD diagnosis, age 18-65 years and no intellectual disability (IQ >80).

4.3 Exclusion criteria

Exclusion criteria are: acute psychosis, acute suicidality, psychotic disorder, intellectual disability (IQ < 80)

4.4 Sample size calculation

A priori power analysis was conducted using G*Power version 3.1.9.7 (Faul et al., 2007) to determine the minimum sample size required to test the relationship between ASD (SRS-A score) and attachment (ASQ and ECR-R scores). To examine the relationship between SRS-A and attachment, Spearman correlation coefficients are computed. Sample size for Spearman correlation was determined using power analysis in G*Power version 3.1.9.7 (Faul et al., 2007), using an alpha of 0.05, a power of 0.80, and an effect size of .5 for a two-tailed test. Because Spearman's rank correlation coefficient is computationally identical, power analysis was conducted using software for estimating power of a Pearson's correlation. Based on the aforementioned assumptions, the required sample size was determined to be 56. To prevent the hypotheses from being underpowered, we included a total of 60 participants for each hypothesis.

5. TREATMENT OF SUBJECTS

This chapter is only applicable for intervention studies:

Not applicable

5.1 Investigational product/treatment

Not applicable

5.2 Use of co-intervention (if applicable)

Not applicable

5.3 Escape medication (if applicable)

Not applicable

6. INVESTIGATIONAL PRODUCT

Not applicable

6.1 Name and description of investigational product(s)

6.2 Summary of findings from non-clinical studies

6.3 Summary of findings from clinical studies

6.4 Summary of known and potential risks and benefits

6.5 Description and justification of route of administration and dosage

6.6 Dosages, dosage modifications and method of administration

6.7 Preparation and labelling of Investigational Medicinal Product

6.8 Drug accountability

7. NON-INVESTIGATIONAL PRODUCT

Not applicable

7.1 Name and description of non-investigational product(s)

7.2 Summary of findings from non-clinical studies

7.3 Summary of findings from clinical studies

7.4 Summary of known and potential risks and benefits

7.5 Description and justification of route of administration and dosage

7.6 Dosages, dosage modifications and method of administration

7.7 Preparation and labelling of Non Investigational Medicinal Product

7.8 Drug accountability

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

Main study parameters are the SRS-A score, the ASQ and ECR-R.

The *Social Responsiveness Scale – Adult version* (SRS-A) (Constantino, 2005; Dutch translation: Noens et al., 2012), a screening tool for identifying possible ASD characteristics in adults suspicious for ASD, is 64-item self-report questionnaire measuring various dimensions of interpersonal behavior, communication, and rigid, repetitive behaviour and interests, characteristic for adults with ASD. Each item is rated on a 1-4 point scale. The SRS-A showed average to good internal consistency and test-retest reliability, adequate content validity, and good congruent validity (Noens et al., 2012). The Cronbach's alpha for the SRS-A scales were for Social awareness .80, Social communication .82, Social motivation .81, and Restricted interests & repetitive behavior .81 (Bezemer et al., 2020).

The Attachment Styles Questionnaire (ASQ; Mosterman & Hofstra, 2015), translation of the Dutch Hechtingsstijllijst (HSL) (Oudenhoven et al., 2003), is a questionnaire consisting of 24 items based on four vignettes (Bartholomew & Horowitz, 1991) and the Relationship Scales Questionnaire (RSQ; Griffin & Bartholomew, 1994). The ASQ assesses four attachment styles (secure, preoccupied, fearful, and dismissing). The 5-point rating scale ranges from 1 (*strongly disagree*) to 5 (*strongly agree*). The internal consistencies (Cronbach's alpha) were 0.75 for the secure style, 0.80 for the preoccupied style, 0.79 for the fearful style, and 0.62 for the dismissing style (Mosterman & Hofstra, 2015).

The *Experiences in Close Relationships Questionnaire Revised* (ECR-R) (Fraley, Waller, & Brennan, 2000; Dutch translation by Conradi et al., 2006) measures adult attachment within romantic relationships in past and present in 36 items, consisting of two subscales of 18 items each (attachment anxiety and attachment avoidance). Each item is rated from 'strongly disagree' (1) to 'strongly agree' (7). The ECR-R is currently the most commonly used and recommended self-report measures with good psychometric properties (Conradi et al., 2006; Sibley et al., 2005; Sibley & Liu, 2004). Cronbach's alpha was 0.88 for attachment avoidance and 0.86 for attachment anxiety. In a validation study of the Dutch version, factor structure could be replicated, reliability was stable over time and there was good evidence for its construct validity

(Kooiman et al., 2013). Cronbach's alpha was 0.94 for attachment avoidance and 0.92 for attachment anxiety. Test–retest reliability of the avoidance subscale was .82, and .84 for the anxiety subscale ($p < 0.1$).

8.1.2 Secondary study parameters/endpoints (if applicable)

Not applicable

8.1.3 Other study parameters (if applicable)

Not applicable

8.2 Randomisation, blinding and treatment allocation

Not applicable

8.3 Study procedures

The procedure begins with a screening on inclusion- and exclusion criteria. Written informed consent is obtained. Participants are asked to complete three online questionnaires (SRS-A, ASQ and ECR-R), by computer each taking no more than 15 minutes to complete.

8.4 Withdrawal of individual subjects

Participants' requests for withdrawal will be granted without repercussions.

8.5 Replacement of individual subjects after withdrawal

Not applicable

8.6 Follow-up of subjects withdrawn from treatment

Not applicable

8.7 Premature termination of the study

The study will be prematurely terminated only when the principal investigator is no longer able to perform principal investigator's duties, and no replacement can be found.

9. SAFETY REPORTING

9.1 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

9.2 AEs, SAEs and SUSARs

9.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to [the investigational product / trial procedure/ the experimental intervention]. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

9.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

If an adverse event might occur, the sponsor will be notified. Due to the nature of our research (questionnaires, online at home) we do not expect these kind of SAE's.

The investigator will report all SAEs to the sponsor without undue delay after obtaining knowledge of the events, except for the following SAEs: none .

The sponsor will report the SAEs through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

9.2.3 Suspected unexpected serious adverse reactions (SUSARs)

Not applicable.

9.3 Annual safety report

Not applicable

9.4 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported till end of study within the Netherlands, as defined in the protocol

9.5 Safety Committee

Ethical approval will be obtained from an institutional review board (CWO Parnassia Psychiatric Institute Academy – Rotterdam – The Netherlands) and Medical Research Ethics Committee Amsterdam UMC.

10. STATISTICAL ANALYSIS

10.1 Primary study parameter(s)

Statistical analyses were performed using Statistical Package for the Social Sciences version 27 (SPSS Version 27, IBM, New York, NY, USA). First descriptive statistics were used to analyze participants' demographic data.

Spearman correlation coefficients were used to calculate the correlations between SRS-A scores and ASQ scores, and between SRS-A scores and ECR-R scores.
Multiple regression was used to test whether level of education and having a relationship influence a SRS-A score and attachment and whether this is a positive or a negative effect. For the analyses p-value of $< .05$ was considered statistically significant.

10.2 Secondary study parameter(s)

None

10.3 Other study parameters

None

10.4 Interim analysis (if applicable)

Not applicable

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

The *study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO).*

11.2 Recruitment and consent

Recruitment starts with contacting mental health therapists from Sarr Autism Rotterdam and Antes, both part of Parnassia Group in the Netherlands. They will be asked to inform their patients with ASD about the current study and to see if they are willing to participate. Additionally, adults with ASD included in earlier studies at Sarr Autism Rotterdam will also be recruited. Next, participants are screened for eligibility by a health care psychologist and clinical psychologists. When participants meet criteria, they will receive a letter of informed consent, which details the study (see attachment). They will have no deadline for consideration of participation. The SRS-A, ASQ and ECR-R will be administered by computer, online, at home. Participants can stop participating anytime, without explanation.

11.3 Objection by minors or incapacitated subjects (if applicable)

Not applicable

11.4 Benefits and risks assessment, group relatedness

Not applicable

11.5 Compensation for injury

The sponsor/investigator has a liability insurance which is in accordance with article 7 of the WMO. The sponsor (also) has an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO). This insurance provides cover for damage to research subjects through injury or death caused by the study.
The insurance applies to the damage that becomes apparent during the study or within 4 years after the end of the study.

11.6 Incentives (if applicable)

Not applicable

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Researchmanager Data Management (RDM) is used for data collection (scores on questionnaires) and coding and saving data.

12.2 Monitoring and Quality Assurance

Not applicable

12.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.
All substantial amendments will be notified to the METC and to the competent authority.
Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor.

12.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

12.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study,

to the accredited METC.

12.6 Public disclosure and publication policy

The data will be used for submitting a manuscript to a peer-reviewed international journal focusing on ASD.

13. STRUCTURED RISK ANALYSIS

Not applicable

13.1 Potential issues of concern

13.2 Synthesis

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