Schema therapy for adults with autism and personality disorder

No registrations found.

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

Summary

ID

NL-OMON28080

Source
Nationaal Trial Register

Health condition

schema therapy, adults, autism spectrum disorder, personality disorder, cognitive-behavioral, experiential

schematherapie, volwassenen, autismespectrumstoornis, persoonlijkheidsstoornis, cognitief gedragstherapeutisch, experientieel

Sponsors and support

Primary sponsor: Sarr expertise centre for autism
(part of Parnassia group)
Oudedijk 76
3062 AG Rotterdam
The Netherlands
Source(s) of monetary or material Support: Sarr expertise centre for autism
(part of Parnassia group)
Oudedijk 76
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The Netherlands

Intervention

Outcome measures

Primary outcome

Idiosyncratic belief strength: three to five idiosyncratic beliefs are formulated in collaboration with each participant, that are central to the participant's problems. Participants will rate the degree in which they believe in each statement on 100 mm visual analogue scales (VAS; Freyd, 1923) every week during treatment and monthly at follow-up. The average score constitutes the primary outcome. The VAS is a simple and frequently used scale measure and can be used for the assessment of variations in intensity of core beliefs. When responding to a VAS item, patients specify their level of agreement to a core belief by indicating a position along a continuous line between two end-points from 0 to 100. The core beliefs are formulated during the screening procedure before the baseline phase. All participants rate on the VAS core beliefs weekly during baseline, exploration phase, cognitive-behavioral intervention phase, experiential phase, and monthly during follow-up phase.

Secondary outcome

The secondary outcomes include maladaptive schema modes assessed with the Schema Mode Inventory (SMI; Young, Arntz, Atkinson, Lobbestael, Weishaar, van Vreeswijk, & Klokman, 2007), and personality disorder criteria assessed with the Structured Clinical Interview for Axis II Personality Disorders (SCID-II; First, Spitzer, Gibbon, Williams & Benjamin, 2000). The SMI contains 118 items that correspond to 14 schema modes, each rated on a 1-6 point scale for frequency. The Dutch version of the SMI will be used. All participants complete the SMI during screening procedure (i.e. before baseline), after baseline phase, after exploration phase, after cognitive-behavioral intervention phase, after experiential phase, during and after follow-up phase. The SCID-II is a structured clinical interview assessing the ten DSM-IV personality disorders (APA, 2000). Each SCID II criterion has a scoring range of 1 to 3. All participants are assessed by the SCID-II during screening (i.e. before baseline), at 5-month follow-up, and at 10-month follow-up.
Still another secondary outcome is severity of psychological symptoms on Symptom Check List (SCL-90; Arrindell & Ettema, 2003). The SCL-90 is a 90-item self-report questionnaire assessing psychological symptoms during the last week. Each item has five statements, rated on a 1-4 point scale for severity, resulting in a total score of 90 to 450. The Dutch version of the SCL-90 will be used. All participants complete the SCL-90 during screening procedure (i.e. before baseline), after baseline phase, after exploration phase, after cognitive-behavioral intervention phase, after experiential phase, at 5-month follow-up, and at 10-months follow-up.

The last secondary outcome will be an improvement of social responsiveness on the Social Responsiveness Scale – Adult version (SRS-A; Constantino, 2005; Noens, De la Marche & Scholte, 2012). The SRS-A is a 64-item self-report questionnaire for determining various dimensions of interpersonal behaviour, communication and rigid, repetitive behaviour and interests, characteristic for adults with ASD. The items correspond to 4 treatment scales i.e. Social consciousness, Social communication, Social motivation, and Rigidity and repetitiveness. Each item has four statements, rated on a 1-4 point scale. The Dutch version

of the SRS-A will be used. All participants complete the SRS-A during screening procedure (i.e. before baseline), after baseline phase, after exploration phase, after cognitive-behavioral intervention phase, after experiential phase, at 5-month follow-up, and at 10-month follow-up.

Study description

Background summary

Rationale: Research indicates significantly more personality pathology and personality disorders in adults with autism spectrum disorder (ASD) than in controls. To our knowledge treatment of personality disorder comorbidity in adults with ASD is understudied and is still in its infancy: we do not know if treatment of personality disorders may be applicable to adults with ASD. In particular, it is unknown whether patients with ASD benefit from experiential techniques that are part of schema therapy developed for the treatment of personality disorders,.

Objective: The aim of the study is to investigate the efficacy of a schema mode focused treatment with adult clients with ASD and comorbid personality pathology (i.e. at least one personality disorder). Specifically, we investigate if they can benefit from both cognitive-behavioral, and experiential interventions.

Study design: A multiple baseline case series study

Study population: Adult individuals (age > 21 years) with ASD and at least one personality disorder. Participants will be recruited from Sarr expertise center for autism in Rotterdam. The study requires 12 participants.

Intervention: The treatment protocol consists of 35 weekly offered sessions, followed by 10 monthly booster sessions. A multiple baseline design will be used with baseline varying from 5 to 10 weeks, with weekly supportive sessions. After baseline, a 5-week exploration phase follows with weekly sessions during which current and past functioning, psychological symptoms, schema modes are explored, and information about the treatment will be given. Then 15 weekly sessions with cognitive-behavioral interventions and 15 weekly sessions with experiential interventions will be given. Finally, there will be a 10-month follow-up phase with monthly booster sessions. Participants are randomly assigned to baseline length, and respond weekly during treatment and monthly at follow-up on Belief Strength of negative core beliefs (by VAS), and fill out SMI, SCL-90 and SRS-A 7 times during screening procedure (i.e. before baseline), after baseline, after exploration, after cognitive and behavioral interventions, after experiential interventions, and after 5- and 10- month follow-up. The

SCID-II will be administered during screening procedure (i.e. before baseline), at 5- and at 10-month follow-up.

Main study parameters: The primary study parameter is negative core beliefs. Secondary study parameters include: schema modes, personality disorder manifestations, psychological symptoms, and social interaction and communication.

Study objective

The aim of the study is to investigate if a schema mode treatment with cognitive-behavioral, and experiential interventions will be effective for adult patients with autism spectrum disorder (ASD) and at least one personality disorder (PD). The research question is 'Can patients with comorbid ASD-PD benefit from schema therapy, more specifically its cognitive-behavioral, and experiential interventions?
The first objective is to study in detail the effects of the major technique groups of schema therapy, that is cognitive-behavioral techniques and experiential techniques, on belief strength of negative core beliefs in comorbid ASD-PD patients. The research question is 'Will schema therapy lead to less belief strenght of negative core beliefs in comorbid ASD-PD patients?'. We hypothesize that schema therapy leads to less belief strenght of negative core beliefs.

A secondary objective is dysfunctional schema modes (i.e. personality pathology) being less frequently present. The research question is 'Will schema therapy lead to dysfunctional schema modes (i.e. personality pathology) being less frequently present and functional modes more often present in comorbid ASD-PD patients?'. We hypothesize that schema therapy leads to dysfunctional schema modes (i.e. personality pathology) being less frequently present, and functional modes more often present.

A third objective is remission of diagnostic criteria of a personality disorder. The research question is 'Will diagnostic criteria of the comorbid personality disorder in comorbid ASD-PD patients be in remission after schema therapy?' We hypothesize that schema therapy leads to personality traits being less frequently present.

A fourth objective is a change in severity of psychopathological symptoms, related to syndromal disorders like depression and anxiety disorders. The research question is 'Will psychopathological symptoms in comorbid ASD-PD patients diminish by schema therapy?' We hypothesize that psychopathological symptoms will be diminished by the given treatment.

Lastly, we hypothesize that schema therapy will lead to improvement in social interaction and communication. The research question is 'Will social interaction and communication in comorbid ASD-PD patients improve by schema therapy?' Our hypothesis is that more insight into one owns functioning by the given treatment will lead to improvement in social interaction and communication.

Study design

Participants will rate idiosyncratic negative core beliefs (Belief Strenght) every week.

Before baseline (in screening procedure) SMI, SCID-II, Belief Strength, SCL-90, SRS-A are assessed.

After baseline SMI, Belief Strength, SCL-90 and SRS-A are assessed.

After exploration SMI, Belief Strength, SCL-90 and SRS-A are assessed.

After cognitive-behavioral interventions: SMI, SCL-90, SRS-A are assessed.

After experiential interventions: SMI, SCL-90 and SRS-A are assessed.

During 10 monthly follow-up idiosyncratic negative core beliefs (Belief Strenght) are monthly assessed.

At 5-month follow-up SMI, SCID-II, Belief Strength, SCL-90, SRS-A are assessed.

At 10-month follow-up SMI, SCID-II, Belief Strength, SCL-90, SRS-A are assessed.

Intervention

The treatment protocol consists of 35 sessions, offered weekly, followed by 10 monthly booster sessions. A multiple baseline design will be used with baseline varying from 5 to 10 weeks, with weekly supportive sessions. After baseline, a 5-week exploration phase follows with weekly sessions during which current and past functioning, psychological symptoms, schema modes are explored, and information about the treatment will be given. Then 15 weekly sessions with cognitive-behavioral interventions and 15 weekly sessions with experiential interventions will be given. Finally, there will be a 10-month follow-up with monthly booster sessions. Participants are randomly assigned to baseline length, and 6 of them are first assigned to cognitive-behavioral interventions and then followed by experiential interventions, whereas the other 6 participants start with experiential interventions followed by cognitive-behavioral interventions.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria are a primary diagnosis of DSM-IV and/or DSM-5 autism spectrum disorder and personality disorder, age 18-65 years, with IQ at least normal intelligent (IQ > 80), at least a completed primary school and secondary education, having a reasonable degree of insight into their own personality and recognition of their (psychological) functioning, and a willingness to participate in the study for 2 years confirmed by a signed informed consent.

Exclusion criteria

Exclusion criteria are schizophrenia or other psychotic disorder, antisocial PD, eating disorder, psychiatric disorders secondary to medical conditions, mental retardation (IQ < 80), addiction (that needs clinical detox) and presence of current suicidal ideation. Participants are not allowed to follow another concurrent psychological treatment at the same time. Pharmacotherapy can be used as a co-intervention during the treatment when already started before the study intervention. This is no reason for exclusion from the study. When participants have to start with pharmacotherapy or another form of (support) therapy during the study intervention, for example in case of acute crisis, this will not lead to exclusion from

the study, only when this therapy and the results will be documented precisely.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2016
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-04-2016
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	NL5653
NTR-old	NTR5788
Other	ERB : 2015-CP-6374

Study results

Summary results

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