Group schematherapy versus group cognitive behavioral therapy for social anxiety disorder with comorbid avoidant personality disorder.

No registrations found.

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

Summary

ID

NL-OMON29460

Source
Nationaal Trial Register

Health condition

Social Anxiety Disorder (Sociale Angststoornis), Avoidant Personality Disorder (Ontwijkende Persoonlijkheidsstoornis)

Sponsors and support

Primary sponsor: PsyQ en de Universiteit Leiden, afdeling klinische-, gezondheid- en neuropsychologie
Source(s) of monetary or material Support: PsyQ

Intervention

Outcome measures

Primary outcome

1. Mini-International Neuropsychiatric Interview (MINI) will be used to obtain DSM-IV diagnoses for inclusion;

2. Structured Clinical Interview for DSM Axis II Disorders (SCID II) will be used to assess the presence versus absence of avoidant personality disorder and comorbid Axis II diagnoses;

3. The clinician-administered version of the Liebowitz Social Anxiety Scale (LSAS-CA) will be used to assess the range of anxiety in social interaction and performance in situations which patients with social anxiety disorder may fear.

Secondary outcome

1. Schema Mode Inventory II (SMI-2);

2. The social anxiety disorder section of the Mini International Neuropsychiatric Interview (MINI).

3. The avoidant personality disorder section of the Structured Clinical Interview for DSM Axis II Disorders (SCIDII)

4. Inventory of depressive symptomatology self-report (IDS-SR);

5. World Health Organization Quality of Life – Bref(WHOQOL-Bref);
6. Difficulties in Emotion Regulation Scale (DERS);
7. The Rosenberg Self-Esteem Scale (RSES);

8. Acceptance and Action Questionnaire (AAQ-II)

Study description

Background summary

Social phobia with comorbid avoidant personality disorder has a high prevalence and is associated with serious psychosocial problems and high societal costs. The current multidisciplinary guidelines advice to offer prolonged CBT in case of social anxiety disorder with avoidant personality disorder. There is increasing evidence for the effectiveness of group schema therapy (GST) for personality disorders. GST focuses on changing the underlying dysfunctional schemas and coping strategies. Until now, it is unknown whether GST for social phobia and comorbid avoidant personality disorder is more effective than CBT.

Study objective

Patients included in this trial will be diagnosed with both

social anxiety disorder and avoidant personality disorder.

Improvements can thus be realized on 2 different domains,

namely with respect to severity of social anxiety disorder and

with respect to avoidant personality disorder. Since no

previous studies have been conducted with this specific

patient group, there are no a priori hypotheses about

differences in treatment effectiveness.

Study design

1. M 1 - 3: Preparations;

2. M 3 - 24: Screening (M0) and treatment;

3. M 9 – 29: Midtests (M1);

4. M 14 – 34: Posttests (M2);

5. M 20 - 40: 6- month follow-up 6 (M3);

6. M 26 - 46: 12- month follow-up (M4);

7. M 26 – 60: Analyses and publications.

Changed 28-jun-2016: Measurements will be done at start (T0), halfway (T1) and at the end (T2) of the treatment period and during follow up at 3 (T3), 6 (T4) and 12 months after study treatment (T5).

Intervention

1. The self-report version of the Liebowitz Social Anxiety Scale (LSAS-SR) will be used as primary outcome for social anxiety disorder. The LSAS-SR assesses the range of anxiety in social interaction and performance in situations which patients with social anxiety disorder may fear.

2. The primary outcome measure for severity of avoidant personality disorder is the clinician-administered Avoidant Personality Disorder Severity Index (AVPDSI). The AVPDSI is a semi-structured interview developed specifically for this study to assess the frequency and severity of manifestations of avoidant personality disorder, as defined in the DSM-IV/5, during the last month. Both therapies will be given in 30 sessions of 90 minutes.

Contacts

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Eligibility criteria

Inclusion criteria

Patients aged between 18 and 65 with primary diagnoses of social anxiety disorder on axis I and comorbid avoidant personality disorder on axis-II (i.e. the principal focus of attention of treatment, according to both patient and clinical staff) will be included in the study. Other inclusion criteria are willingness, motivation and practical ability to attend 30 sessions of group therapy and to refrain from treatment or counseling outside the context of the present trial. The use of antidepressant medication or benzodiazepine will be permitted, under the condition that the medication dose has been stable for at least 3 months before inclusion and patients are willing not to change the dosage or change medication during the active phase of the trial. Furthermore, patients have to be willing to complete daily homework assignments between sessions and have to sign written informed consent to participate in the study.

Exclusion criteria

Changed 28-jun-2016: Exclusion criteria will be a Axis-I diagnosis of substance abuse or dependence which needs, according to the clinical staff, detoxification (after successful detoxification patients can participate), suicidality, and the presence of psychotic or bipolar symptoms because these conditions could interfere with the measurement and treatment procedures and suggest an immediate need for alternative interventions. Other exclusion criteria are: a primary Axis II diagnosis of a Borderline, antisocial, schizoid, schizotypal personality disorder (because they need highly specialized treatment), and IQ less than 80 (in

case of suspicion an intelligence test is taken), suspicion of an autism spectrum disorder (based on the sum score on the Autisme-Spectrum Quotient (AQ) higher than 32)and problems with Dutch language (talking, reading, writing).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2013
Enrollment:	128
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-03-2013
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	NL3757
NTR-old	NTR3921
Other	METC : 41303
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A