RCT of Cognitive therapy and Schematherapy for comorbid anxiety- and cluster C personality disorders.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21667

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Anxiety
Personality disorders
co-morbidity

angst
persoonlijkheidsstoornis
comorbiditeit

Sponsors and support

Primary sponsor: Leiden University
Pieter de la Court gebouw
Wassenaarseweg 52
2333 AK Leiden
tel: 071-5274003
Source(s) of monetary or material Support: ZonMw, The Netherlands Organization for
Health Research and Development

Intervention

Outcome measures

Primary outcome

As primary outcome measure significant changes in general anxiety as assessed with the Beck Anxiety Inventory (BAI) (Beck & Steer, 1990) will be used.

Secondary outcome

Secondary measures will assess:

- more specific forms of anxiety (PSWQ, ASI, FQ, LSAS, PI-R)

- general psychopathology (SCL-90R)

- interpersonal problems (IIP, WAV)

- personality pathology (ADP-IV, NEO-PI-R, NVM)

- cognitive schemas and schema modes (SV-1, PDBQ, YPI, YRAI, YCI, SMI-R)

- quality of life (WHOQOL-Bref, EQ-6D)

- direct and indirect costs (TIC-P)

- patient satisfaction (GGZ-thermometer).

Remission from anxiety and AXIS II disorder is measured with the MINI and the SCID-II at post treatment and at follow up. Also an implicit computer task will be used to measure the decrease of personality pathology. To evaluate the efficacy of the treatment modalities a cost analysis will be performed using data from a medical consumption diary kept by the patient.

Study description

Background summary

Background:
DSM-IV Cluster C personality disorders are the most prevalent personality disorders (Torgersen et al, 2001, Torgersen, 2005). This is also true for the Dutch general population (Sytema & Koopmans, 1998). The prevalence, according to the authors, ranges from 4.4 – 5.2 %. Research on the comorbidity of personality disorders and anxiety disorders suggests that

a common personality pattern, with predominantly Cluster C personality disorders, is characteristic for all anxiety disorders (Van Velzen & Emmelkamp, 1999). In existing Dutch guidelines of the Werkgroep angststoornissen (2003) and the Werkgroep Persoonlijkheidsstoornissen (2007) it is stated that there is no research available for the treatment of the co-occurrence of Axis I and Axis II disorders and the subsequent treatment options.

Objective of the study is to study the effects of combined treatment of Axis I and Axis II Anxiety disorders compared to the treatment of only Axis I or Axis II disorder on the short and long term.

Study Design:

Multi-center randomized controlled clinical trial with repeated measurements at baseline (M0), midtreatment (M5) posttreatment (M10) and follow-up M(6) and M(12) after posttreatment.

Study population:

The research study is aimed at adult patients with an anxiety disorder and a comorbid Cluster C personality disorder. The research sample will be recruited from the patients applying for treatment at the outpatient clinics of ADAPT (Dimence) in Deventer and Almelo, Angstpoli in Nijmegen (GGZ Nijmegen) and several of the outpatient branches of the HSK-Group in the Netherlands.

Study objective

The objective of this project is to gain knowledge about the how and when of cognitive behavioral treatment (CBT) of Axis I anxiety disorders when there is co-morbidity of an Axis II cluster C personality disorder.

It tries to answer the question whether a treatment of both Axis I and Axis II disorders is more effective than treatment of solely the Axis I or Axis II disorder.

Study design

Multi-center randomized controlled clinical trial with repeated measurements at baseline (M0), midtreatment (M5) posttreatment (M10) and follow-up M(6) and M(12) after posttreatment.

Intervention

In treating the Axis I anxiety disorder the recommendations of the Dutch guideline for Anxiety disorders will be followed. Treatment will consist of maximally 30 sessions of cognitive behavioral therapy. For the treatment of cluster c personality disorders a protocol of schema therapy will be used (maximally 30 sessions). Combined treatment will consist of treatment of anxiety disorders (15 sessions) followed by treatment of the cluster c personality disorder (15 sessions).

Contacts

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Eligibility criteria

Inclusion criteria

Patients with an Axis I anxiety disorder (of panic disorder with/without agoraphobia, agoraphobia without a history of panic disorder, obsessive-compulsive disorder, social phobia, generalized anxiety disorder) as primary diagnosis, according to DSM-IV-TR.

If there is an Axis I anxiety disorder present as primary diagnosis, patients will be screened for a co-occurring cluster C personality disorder (dependent personality disorder, avoidant personality disorder, obsessive-compulsive personality disorder), using a self-report

questionnaire, the ADP-4 as a screener (Scotte et al., 1998). When this screening list is positive for a Cluster C personality disorder, co-morbidity of an Axis II cluster C personality disorder will be formally established using the
corresponding part of the Structured Clinical Interview for DSM-IV Axis II Personality Disorders

Further inclusion criteria are as follows:

1. Patients have to be 18 years of age or older

2. Patients have to be fluent in the Dutch language

3. Treatment has to be voluntary

4. There has to be informed consent, both for the treatment itself and for participation in the research project.

Exclusion criteria

Exclusion criteria are as follows:

1. Evidence of a mental retardation with an IQ less then 70

2. Signs of acute danger to self or others and/or (need for) involuntary treatment

3. A history of psychotic disorders

4. Patients already in therapy and receiving a psychological treatment for their anxiety or Cluster C personality disorder

5. Patients who have a cluster A or cluster B personality disorder

6. Patients who have a major depressive disorder

7. Patients with a specific phobia (because of relative 'simplicity' and short duration of treatment) or post-traumatic stress disorder (because of relative 'complexity' and overall long duration of treatment(8) patients who are incapable of filling in the different questionnaires.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2009

Enrollment: 180

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

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	NL1468
NTR-old	NTR1537

Register	ID
Other	ZonMw Geestkracht (OOG) : 100002038
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A