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

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21667

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Anxiety
Personality disorders
co-morbidity

angst
persoonlijkheidsstoornis
comorbiditeit

Ondersteuning

Primaire sponsor: Leiden University
Pieter de la Court gebouw
Wassenaarseweg 52
2333 AK Leiden

tel: 071-5274003
Overige ondersteuning: ZonMw, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1468
NTR-old	NTR1537
Ander register	ZonMw Geestkracht (OOG) : 100002038
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A