Dialectical Behavior Therapy for patients with antisocial personality disorder: a pilot study in FPC Oldenkotte

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON30175

Source
ToetsingOnline

Brief title
DBT for antisocial patients

Condition

- Personality disorders and disturbances in behaviour

Synonym
antisocial personality disorder, character disorder

Research involving
Human

Sponsors and support

Primary sponsor: FPC Oldenkotte
Source(s) of monetary or material Support: Het Expertisecentrum Forensische Psychiatrie. Er wordt verder subsidie aangevraagd bij het Ministerie van Justitie.

Intervention

Keyword: antisocial personality disorder, dialectical behavior therapy

Outcome measures

Primary outcome

1. Impulsivity: operationalised as a impairment in response-inhibition, will be measured with a neuropsychological test, the Stop-task (Bekker et al. 2005) and with the BIS-part of the BIS-Bas self-report Scale (Montagne et al 2005); operationalised als level of selfcontrol impulsivity will be measured by assessing cortisol levels in sputum. (Loney et al. 2006).

2. Emotional sensitivity: heightened emotional sensitivity should improve achievement on a test for recognition of emotional facial expressions (Montagne et al. 2005, Blair 2004), especially recognition of fearful and sad expressions.

3. Hostile and dominant behavior will be measured in four ways:

1. Self report: BDHI-D, SCL-90, and the BAS-part of the BIS/BAS - scale. (Montagne et al. 2005).

2. (only for clinical patients:) Observation of hostile behavior by sociotherapists with the Atascadero Skills Profile (Vess 2001) and registration of violent incidents with the SOAS-r (Nijman, Muris & Merkelbach 2004).

3. Neuropsychologically with the Masked Emotional Stroop Test (Putman, Hermans en Van Honk 2004).

4. Level of testosteron in the sputum (Dabbs 1992)

Secondary outcome

Patient-therapist relationship will be measured with the WAV (Working Alliance

Inventory) client and therapist version, and the Feeling Word Checklist (De Ruiter & De Vogel 2003).

The adequacy of the procedure, drop-out of patients and the evaluation of the program by therapists and patients will be studied and the necessity of improvements in the program will be considered.

Study description

Background summary

This is a pilot study into the effects of a program of Dialectical Behavior Therapy (DBT) for antisocial patients. In forensic psychiatry en addiction care many patients with antisocial problems can be found. This kind of problems form a important risk factor for violent behavior. For antisocial patients there are no effective treatment programs available. DBT has been developed bij prof. M.Linehan in the US. The program has been proven affective for patients with a borderline personality disorder (BPD). It has been used now for two years in Oldenkotte.

Study objective

The objective of the study is to find out the possible effects of the DBT program for antisocial patients and the best instruments to measure these effects. It is a try-out of the program and it will be modified if necessary. The longer term aim is to make implementation possible in other tbs- and addiction clinics and to carry out a randomized clinical trial.

Study design

The design is a randomized repeated measurements design. The experimental group consists of two therapygroups of 6-8 patients. The controlgroup consists of the same number of patients getting treatment as usual.

Intervention

The intervention consist of 14 weeks of DBT.

Study burden and risks

The burden for the patients is not high, and there are no risks connected at participating in the study. We expect that they can benefit from the treatment. Assessments have a total duration of 2 x 2 hours, and besides that 2 - 3 hours for the outpatients. In session one they complete the self-report questionnaires, in session two the neuropsychological and the physiological tests. These tests consist of three, rapidly to carry out, computer-directed tasks and a non-evasive physiological test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with antisocial personality disorder or a personality disorder otherwise with antisocial features and impulsivity problems.

Exclusion criteria

Chronic psychotic symptoms, IQ <80, primary diagnosis of a borderline personality disorder.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	11-07-2006
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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
CCMO	NL11441.097.06