

Psychological treatment of Personality Disorders: A multi-centered randomised controlled trial on the (cost-)effectiveness of Schema-Focused Therapy.

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To assess the (cost-)effectiveness of Schema-Focused Therapy (SFT) compared to Treatment as Usual (TAU) and Client Centered Therapy according to Sachse (CCT) as treatment for 6 Personality Disorders (PDs).

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25278

Bron

NTR

Verkorte titel

N/A

Aandoening

Schema-Focused Therapy (SFT) and Treatment as Usual (TAU)

Ondersteuning

Overige ondersteuning: ZonMW Doelmatigheid 3353

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Presence vs. absence of Personality Disorder(s) (assessed with SCID-2 and ADP-IV (intermediate)).

Toelichting onderzoek

Achtergrond van het onderzoek

With a Multi-Centered Randomized Controlled Trial with pre-post assessments the (cost-)effectiveness of Schema-Focused Therapy (SFT) compared to Treatment as Usual (TAU) and Client Centered Therapy according to Sachse (CCT) will be assessed as treatment for 6 Personality Disorders (PDs). 250 outpatients of mental health institutes in the Netherlands with a cluster-C, narcissistic, histrionic or paranoid PD as defined by DSM-IV criteria as first diagnosis will be recruited. The primary outcome measure is recovery of PDs as assessed with the SCID-2 interview. Secondary outcome measures include Quality of Life, general psychopathology complaints, axis-1 diagnoses, personality measures, social functioning, global functioning (GAF score DSM-IV). Power/data analysis: N = 100 per condition suffices to demonstrate with power = 90% (2-tailed test) a difference between TAU and SFT in % recovered patients of 23.8% vs. 45.5 % (odds ratio = 2.667) which is expected on the basis of experiences with open trials and the BPD trial. (N = 250 includes a 18% study drop-out). Data-analyses will be done by survival analysis and logistic regression (primary outcome) and MANOVA (secondary outcome measures). Both an intention-to-treat and a completers analysis will be done. For the economic evaluation a combined cost-effectiveness/cost-utility analysis will be performed from a societal perspective.

Doel van het onderzoek

To assess the (cost-)effectiveness of Schema-Focused Therapy (SFT) compared to Treatment as Usual (TAU) and Client Centered Therapy according to Sachse (CCT) as treatment for 6 Personality Disorders (PDs).

Onderzoeksproduct en/of interventie

Schema-Focused Therapy (SFT) versus Treatment as Usual (TAU) and Client Centered Therapy according to Sachse (CCT).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

250 outpatients of mental health institutes in the Netherlands with a cluster-C PD, a narcissistic, histrionic or paranoid PD as defined by DSM-IV criteria as first diagnosis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. IQ less than 80;
2. Problems with Dutch language (talking, reading, writing);
3. Borderline, antisocial, schizoid, schizotypal personality disorder;
4. Psychotic or bipolar disorder on axis-I, DSM-IV;
5. Substance dependence needing clinical detoxification (after detoxification this is no longer an exclusion criterion);
6. Immediate suicide risk.

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2006
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	17-01-2006
Soort:	Eerste indiening

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	NL522
NTR-old	NTR566

Register

Ander register
ISRCTN

ID

: 3353 (ZonMW DO)
ISRCTN17752014

Resultaten

Samenvatting resultaten

N/A