Dosage-trial Mentalisation-Based Treatment (MBT): Intensive Outpatient MBT versus Day Hospital MBT.

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1. Intensive Outpatient Mentalisation-Based Treatment (IOP-MBT) and Day Hospital Mentalisation-Based Treatment (DH-MBT) will both result in clinical improvement for patients with severe Personality Disorders (PDs); 2. Matching-hypothesis: the...

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

Samenvatting

ID

NL-OMON22909

Bron
Nationaal Trial Register

Aandoening

Personality disorder (PD); Borderline personality disorder (BPD)
Persoonlijkheidsstoornissen; Borderline persoonlijkheidsstoornis

Ondersteuning

Primaire sponsor: Viersprong Institute for Studies on Personality Disorders (VISPD); MBT consortium (De Viersprong, Arkin, University of Amsterdam, Leuven University, Erasmus Medical Center)
Overige ondersteuning: Viersprong Institute for Studies on Personality Disorders (VISPD)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Frequency and severity of manifestations of (borderline) personality disorder (SCID-II, PAI-BOR);
2. Number of suicide acts (SSHI);
3. Number of self-mutilation acts (SSHI);
4. Subjective experience of symptoms (BSI);
5. Quality of life (EQ-5D);
6. Care consumption (TiC-P).

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

To compare the treatment outcome and costs of Intensive Outpatient Mentalisation-Based (IOP-MBT) and Day Hospital MBT (DH-MBT).

Design:

A randomised controlled trial comparing IOP-MBT with DH-MBT. After the baseline measurement, patients will be followed up every 6 months for a total of 36 months.

Study population and data analysis:

1. Referral to the MBT-program as implemented by De Viersprong;

2. At least one PD as diagnosed according to DSM-IV criteria.

Analysis will be performed according to the intention to treat principle. In both treatment arms (IOP-MBT and DH-MBT) at least 40 patients will be included.

Intervention:

The MBT-program offers 18-month psychotherapy designed specifically for treatment refractory patients with complex personality disorders, often complicated by multi-morbidity, who have typically had a history of unsuccessful treatments. DH-MBT consists of daily group psychotherapy, weekly individual psychotherapy, individual crisisplanning from a mentalizing perspective, art therapy twice a week, and writing therapy. IOP-MBT consists of group

psychotherapy twice a week, weekly individual psychotherapy, and individual crisisplanning from a mentalizing perspective.

Outcome measures:

The primary outcome measures refer to the frequency and severity of manifestions of (borderline) personality disorder, symptomatic functioning, quality of life, and care consumption. The secondary outcome measures include axis I diagnoses, interpersonal and personality functioning, mentalisation, and treatment adherence.

Doel van het onderzoek

1. Intensive Outpatient Mentalisation-Based Treatment (IOP-MBT) and Day Hospital Mentalisation-Based Treatment (DH-MBT) will both result in clinical improvement for patients with severe Personality Disorders (PDs);

2. Matching-hypothesis: the highest level of improvement is expected in DH-MBT, for patients with the highest level(s) of severity.

Onderzoeksopzet

Baseline measurements will be taken after randomisation and follow-up measurements will be conducted every 6 months after the baseline measurement (i.e. after 6, 12, 18, 24, 30, and 36 months).

Onderzoeksproduct en/of interventie

The MBT-program consists of a maximum of 18 months MBT, conducted conform the treatment manual (Bateman & Fonagy 2004, 2006), and continued by a maximum of 18 months of maintenance mentalizing (group) therapy. MBT aims to strenghten patients' capacity to understand their own and others' mental states in attachment contexts in order to address their difficulties with affect, impulse regulation, and interpersonal functioning, which act as triggers for acts of suicide and self-harm (Bateman & Fonagy, 2009).

MBT-DH: The day hospital program includes daily group psychotherapy, weekly individual psychotherapy, individual crisisplanning from a mentalizing perspective, art therapy twice a week, mentalizing cognitive therapy and writing therapy.

MBT-IOP: The outpatient MBT program consists of group psychotherapy twice a week, weekly individual psychotherapy, and individual crisisplanning from a mentalizing perspective.

Contactpersonen

Publiek

Viersprong Institute for Studies on Personality Disorders (VISPD)
P.O. Box 7
Helene Andrea
Halsteren 4660 AA
The Netherlands
+31 (0)164 632200

Wetenschappelijk

Viersprong Institute for Studies on Personality Disorders (VISPD)
P.O. Box 7
Helene Andrea
Halsteren 4660 AA
The Netherlands
+31 (0)164 632200

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Referral to the MBT-program as implemented by De Viersprong, i.e. 18-month psychotherapy designed specifically for treatment refractory patients with complex personality disorders, often complicated by multi-morbidity, who have typically had a history of unsuccessful treatments;

2. At least one PD as diagnosed according to DSM-IV criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients were only excluded if they met DSM-IV criteria for schizophrenia or intellectual impairment (IQ < 80). The WAIS was administered when intellectual impairment was suspected.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-02-2010
Aantal proefpersonen:	80
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	NL2168
NTR-old	NTR2292
Ander register	CE UvA afdeling Psychologie : 2010-KP-1258
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A