

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

No registrations found.

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

Summary

ID

NL-OMON22909

Source

Nationaal Trial Register

Health condition

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

Sponsors and support

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

Source(s) of monetary or material Support: Viersprong Institute for Studies on Personality Disorders (VISPD)

Intervention

Outcome measures

Primary outcome

1. Frequency and severity of manifestations of (borderline) personality disorder (SCID-II, PAI-BOR);

2. Number of suicide acts (SSH);
3. Number of self-mutilation acts (SSH);
4. Subjective experience of symptoms (BSI);
5. Quality of life (EQ-5D);
6. Care consumption (TiC-P).

Secondary outcome

1. Axis I diagnosis (SCID-I);
2. Depression (BDI);
3. Interpersonal functioning (IIP);
4. Personality functioning (DAPP-SF);
5. Mentalisation (ECR, RFQ);
6. Treatment adherence.

Study description

Background summary

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 manifestations 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.

Study objective

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.

Study design

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).

Intervention

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 strengthen 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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-02-2010
Enrollment:	80
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	NL2168
NTR-old	NTR2292
Other	CE UvA afdeling Psychologie : 2010-KP-1258
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A