

# Mentalization Based Treatment vs care as usual in the treatment of severe Borderline Personality Disorder

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric and behavioural symptoms NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33534

### Source

ToetsingOnline

### Brief title

MBT for severe BPS

### Condition

- Psychiatric and behavioural symptoms NEC

### Synonym

'borderline', Borderline Disorder, Borderline Personality Disorder, Personality disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Arkin (Amsterdam)

**Source(s) of monetary or material Support:** ZONMW (aanvraag ingediend)

## Intervention

**Keyword:** Borderline Personality Disorder, MBT, Mentalization Based Treatment, Randomized Cotrolled Trial

## Outcome measures

### Primary outcome

The primary outcome variable is the frequency and severity of manifestations of Borderline Personality Disorder as measured with the Borderline Personality Disorder Severity Index (BPDSI), a semi structured interview.

### Secondary outcome

Suicide acts, self-mutilation: SSHI (Suicide and Self-Harm Inventory),

Depression: Beck Depression Inventory (BDI)

Subjective experiences of symptoms: Symptom Checklist (SCL-90)

Social and interpersonal functioning: Inventory of Interpersonal Problems (IIP)

Personality functioning: Severity Indices of Personality Problems (SIPP)

Quality of life: EQ5D

Adherence to treatment: Realised Dose Instrument (RD).

Attachement style (HSL)

Consumption of (mental) health care: Tic-P

Work characteristics: Tic-P

Work characteristics: Tic-P

Additional costutility: QALY\*s (Quality Adjusted Life Years

## Study description

### Background summary

Although there is a growing demand, evidence based treatments for patients with severe personality disorders (mostly borderline personality disorders) are not readily available. Recently, Mentalized Based Treatment (MBT) has been developed for patients with borderline personality disorder. One randomized controlled study demonstrated that a 5-day part-time MBT resulted in a clinical improvement up to 5 years after treatment compared to care as usual for patients with severe personality disorders (mostly borderline personality disorders). MBT also proved to be cost efficient. Given the fact that evidence for efficacy is based on only one RCT, it is essential new studies examine the effects of MBT.

### Study objective

A randomized multicentre trial is proposed. The aim of this study is to find answers to the following questions; 1) what is, compared to care as usual, the effect of MBT with respect to symptoms, level of functioning and well being, (mental) health care consumption, and 2) what is the long term cost efficiency of MBT. Based on the results we hope to be able to determine if further implementation of intensive part time MBT can be recommended.

### Study design

Patients with borderline personality disorder will be randomly assigned to one of two trial arms. In the experimental condition patients receive MBT, in the control condition patients receive care as usual. The intervention has a total duration of 36 months and. A base line measurement will be performed at the start of the intervention, and 6, 12, 18, 24, 30 and 36 months after. We expect a gradual improvement on clinical outcome variables during the first 18 months resulting in a 25% improvement at 18 months, compared with treatment as usual. After this, we expect this clinical improvement to remain stable during the next 18 months. At Arkin MBT can be offered to a total of 18 patients. Patients will be analysed according to the intention to treat principle. Based on one experiences and literature (including the study by Bateman and Fonagy), the proportion of patients who drop out within the first three months of treatment is approximately 20%. New patients will be recruited to fill up vacant MBT places and followed up according to protocol. Therefore we expect to have a total of 21 patients in the analysis per condition in the Arkin sample. With a sample of 21 patients per group, an effectsize of 0.9 on the BPDSI in an ANOVA

can be detected with a power of 81%.

With the participation of either Ingeest or DeViersprong we realize a randomization of 36 patients to MBT(four groups on two locations), and 36 patients to the care as usual. With a sample of 36 patients pergroup,an effects ize of 0.9 on the BPDSI in an ANOVA can be detected with a power of >90%.

## **Intervention**

Following MBT theory, mentalizing is the ability to understand oneself and others by inferring the mental states that lie behind overt behaviour. Failure to retain mentalizing, particularly in the midst of emotional interactions, is understood to be a core problem in (borderline) personality disorder, resulting in severe emotional fluctuations, impulsivity, and vulnerability to interpersonal and social interactions. The object of MBT is to increase mentalization capacity which should improve affect regulation and interpersonal relationships

Care as usual is provided by an outpatient team composed of psychiatrists, psychologists and mental health nurses. The team is experienced in the treatment of patients with personality disorders. Treatment is mainly ambulant. Day-treatment or hospitalization is only offered when necessary. The team aims at delivering optimal care by tailoring the intensity of the intervention and catering from a variety of interventions such as family interventions, VERS or Lineham training, social skills training, cognitive psychotherapy, psychodynamic psychotherapy, farmacotherapy, addiction treatment, inpatient treatment etcetera

## **Study burden and risks**

Burden: 6 moments of measurement (interview and selfrating scales) in 36 months

Risks: non

## **Contacts**

### **Public**

Arkin (Amsterdam)

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

A severe borderline personality disorder, based on standardized criteria for borderline personality disorder, assessed with the Dutch version of the Structured Clinical Interview for DSM-III-R (SCID-II) and the Borderline Personality Disorder Severity Index (BPDSI). Patients need to fulfill the criteria for borderline personality disorder as determined with the SCID-I, and need to have a total score on the BPDSI of  $> 25$  indicating a severe borderline personality disorder.

### Exclusion criteria

- Schizophrenia, as determined with the SCID-I,
- Bipolar disorder, as determined with the SCID-I,
- Substance dependency or misuse, as primary disorder as determined with the SCID-I
- Organic brain disorder,
- Mental impairment (IQ  $< 80$ )
- Inadequate mastery of the Dutch language
- Legal incapacity

## Study design

## Design

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	72
Type:	Actual

## Ethics review

Approved WMO	
Date:	10-04-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 23439  
Source: NTR  
Title:

## In other registers

Register	ID
CCMO	NL26308.097.09
OMON	NL-OMON23439