

# A multi-site randomized controlled trial comparing Schema Therapy and Mentalization-Based Treatment for borderline personality disorder: A framework for the study of (differential) change processes and the empirical search for treatment selection criteria.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21791

### Source

NTR

### Health condition

The present study focuses on the treatment of patients with borderline personality disorder (BPD). BPD is a complex and severe mental disorder, characterized by a pervasive pattern of instability in emotion regulation, self-image, interpersonal relationships, and impulse control (APA, 1994; Skodol et al., 2002).

Keywords: borderline personality disorder, BPD, borderline persoonlijkheidsstoornis, BPS.

## Sponsors and support

**Primary sponsor:** University of Amsterdam, Department of Clinical Psychology

**Source(s) of monetary or material Support:** University of Amsterdam, Department of Clinical Psychology

## Intervention

### Outcome measures

#### Primary outcome

The primary outcome measure is change in the severity and frequency of the DSM-IV BPD manifestations (BPDSI-IV, total score; Arntz et al., 2003; Giesen-Bloo, Wouters, Schouten, & Arntz, 2010).

#### Secondary outcome

- DSM-IV diagnostic status, assessed by the Structured Clinical Interviews for the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) Axis I disorders (SCID I; Van Groenestijn, Akkerhuis, Kupka, Schneider, & Nolen, 1998) and Axis II disorders (SCID II; Weertman, Arntz, & Kerkhofs, 2000);
- BPDSI-IV (Arntz et al., 2003; Giesen-Bloo et al., 2010) reliable change and recovery (i.e., score below 15);
- Dimensional scores for each of the DSM-5 BPD-criteria as assessed with the BPDSI-IV (Arntz et al., 2003; Giesen-Bloo et al., 2006);
- Quality of life, assessed using the EuroQol EQ-5D-3L (Rabin & Charro, 2001);
- General functioning, including work/study and societal participation, assessed by the WHO Disability Assessment Schedule (WHODAS 2.0; Üstün, Kostanjsek, Chatterji, & Rehm, 2010);
- General psychopathology as measured with the Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983);
- Happiness, measured with a single question on general happiness (Veenhoven, 2008);
- Sleep, measured using the Insomnia Sleep Index (Bastien, Vallières, & Morin, 2001) and two items measuring nightmare frequency;
- Costs, including healthcare, patient and family costs and costs outside the health care sector, measured using a retrospective cost interview especially designed for BPD patients (Wetzelaer et al., 2014).

## Study description

#### Background summary

! This study has not started !

## **Study objective**

The primary aim of the study is to investigate patient characteristics that predict (differential) treatment response across MBT and ST. In addition, mechanisms of change in MBT and ST will be examined. Furthermore, the (cost-)effectiveness of MBT and ST will be investigated. Finally, therapeutic and organizational characteristics that may influence the effectiveness of MBT and ST will be examined.

## **Study design**

The first assessment will occur after inclusion and before randomization. The subsequent five assessments will occur at 7.5, 13.5, 19.5, 25.5, 31 and 36 months after the start of the treatment.

## **Intervention**

Mentalization-Based Treatment (MBT):

MBT is a psychodynamic-oriented treatment that focuses on increasing mentalization in borderline patients. Mentalization refers to the process of implicitly and explicitly interpreting behaviors of oneself and others in term of mental states (e.g., feelings, desires, needs, beliefs, and intentions; Bateman & Fonagy, 2010). Bateman and Fonagy (2010) defined the unstable capacity for mentalization as the core feature of BPD. The mentalizing capacity of patients with BPD typically fails in the context of intimate relationships and high arousal. Consequently, patients with BPD are unable to make sense of actions and internal experiences of oneself and others, which results in impulsive behavior, emotional instability, and difficulties in interpersonal functioning.

Schema Therapy (ST):

ST is based on an integrative cognitive therapy, combining cognitive behavior therapy with attachment theory, psychodynamic concepts, and experiential therapies (Jacob & Arntz, 2013). Central concepts are early maladaptive schemas and schema modes. Early maladaptive schemas can be defined as broad, pervasive patterns of thoughts, emotions, memories, and cognitions regarding oneself and relationships with others, developed during childhood (Young et al., 2003). A schema mode refers to an activated set of schemas and the associated coping response (i.e., overcompensation, avoidance, and surrender), and describes the momentary emotional, cognitive, and behavioral state of the patient. ST aims to replace the maladaptive schemas of patients with BPD by more healthy schemas.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

1. Primary diagnosis of BPD
2. Borderline Personality Disorder Severity Index, fourth edition (BPDSI-IV) score above 20
3. Dutch literacy
4. The willingness and ability to participate in (group) treatment for at least 24 months

### **Exclusion criteria**

1. Psychotic disorder (except short reactive psychotic episodes, see BPD criterion 9 of the DSM 5)
2. Severe addiction requiring clinical detoxification (after which entering is possible)
3. Bipolar I disorder (except when in full remission)

4. IQ < 80

5. Travel time to the MBT or ST setting longer than 45 minutes (except when the participant lives in the same city)

6. No fixed home address

7. Have received ST or MBT in the previous year

8. Antisocial personality disorder with a history of physical interpersonal violence (in the last two years)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	200
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	22-02-2016
Application type:	First submission

## 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 NL5641

NTR-old NTR5756

Other Ethics Review Board of the Faculty of Social and Behavioural Sciences, University of Amsterdam : 2015-CP-4738

## Study results