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.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON46272

Source
ToetsingOnline

Brief title
BOOTS: Borderline Optimal Treatment Selection

Condition

- Personality disorders and disturbances in behaviour

Synonym
Borderline personality disorder, personality problems

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Achmea Gezondheidszorg en CZ Fonds

Intervention

Keyword: Borderline personality disorder, Mentalization-Based Treatment, RCT, Schema Therapy

Outcome measures

Primary outcome

The primary outcome measure is change in the severity and frequency of the DSM-5 BPD manifestations (BPDSI-IV, total score; Arntz et al., 2003; Giesen-Bloo, Wachters, Schouten, & Arntz, 2010). This outcome measure is frequently used in other studies of ST: Giesen-Bloo et al. (2006), Van Asselt et al. (2008), Nadort et al. (2009), and Wetzelaer et al. (2014).

Secondary outcome

As accumulating evidence suggests that symptoms and level of functioning are only loosely associated, attention will be paid to outcome in terms of both symptom change and functioning, including relational, occupational, and personal (wellbeing) functioning. Therefore, the secondary outcome measures will include:

* DSM-5 diagnostic status, assessed by the Structured Clinical Interviews for the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) Clinician Version (SCID-5-CV) and Personality Disorders (SCID-5-PD)*.

* 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).

* Psychopathology, personality characteristics, and behavioral proclivities, assessed by the Minnesota Multiphasic Personality Inventory-2 Restructured Form (MMPI-2-rf; Ben-Porath & Tellegen, 2008).

* 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).

* Quality of life, assessed using the EuroQol EQ-5D-5L (Rabin & Charro, 2001).

* 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, will be measured using a retrospective cost interview especially designed for BPD patients (Wetzelaer et al., 2014).

Both treatments include non-specific (attachment and alliance) and specific (mentalization in MBT and schema modes in ST) mechanisms of change. Measures of the mechanisms of change will include:

* Alliance, measured by the Working Alliance Inventory-Short Revised (WAI-S;

Horvarth & Greenberg, 1989; Vertommen & Vervaeke, 1990);

* Attachment, assessed by the Experiences in Close Relationships-Relationship Structures questionnaire (ECR-RS; Fraley, Heffernan, Vicary, & Brumbaugh, 2011) and the Adult Attachment Projective Picture System (AAP; George & West, 2001);

* Schema mode ratings, assessed by the Schema Mode Inventory (SMI; Young et al., 2007);

* Mentalizing ratings, measured by the Movie for the Assessment of Social Cognition (MASC; Dziobek et al., 2006), the Reflective Function Questionnaire (RFQ; Fonagy & Ghinai, 2008), two subscales, Difficulty in Identifying Feelings and Difficulty in Describing Feelings, of the Toronto Alexithymia Scale-20 (TAS-20; Bagby, Parker, & Taylor, 1994; Bagby, Taylor, & Parker, 1994; Kooiman, Spinhoven, & Trijsburg, 2002), and one subscale, Perspective Taking, of the Interpersonal Reactivity Index (Davis, 1980; De Corte et al., 2007).

Predictors of (differential) treatment response are selected based on the literature and expert clinicians* appraisals of BPD patient characteristics that predict (differential) treatment response across MBT and ST. In addition, patients* monthly ratings of symptoms, schemas and level of mentalization of the participants will be collected.

*As long as the Dutch versions of the SCID-5-CV and SCID-5-PD aren*t available, we will make use of the SCID-I for Axis I disorders of the DSM-IV and SCID-II for Axis II disorders (i.e., personality disorders) of the DSM-IV.

Study description

Background summary

Borderline personality disorder (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). The prevalence in general populations is estimated to be 1% to 3% (Trull, Jahng, Tomko, Wood, & Sher, 2010) and 10% to 25% among psychiatric outpatient and inpatient individuals (Leichsenring, Leibing, Kruse, New, & Leweke, 2011). BPD has traditionally been viewed as one of the most difficult psychiatric disorders to treat. However, during recent years, a number of promising treatments have been developed and evaluated. Among these are Mentalization Based Treatment (MBT; Bateman & Fonagy, 2004) and Schema Therapy (ST; Arntz & Van Genderen, 2009; Young et al., 2003).
Several studies have demonstrated the effectiveness and the efficacy of MBT (e.g., Bateman & Fonagy, 2008; Bales et al., 2012) and ST (for a review, see Jacob & Arntz, 2013). However, none of the studies investigated mechanisms of change (i.e., mediators of treatment effects). This is remarkable, given that information about mediational processes is very valuable for the development and improvement of effective interventions (Cheong, MacKinnon, & Khoo, 2003). In addition, research on moderators of treatment effectiveness is also lacking. In clinical practice it is not sufficient to know what treatment works in general; it is crucial to understand which treatment is optimal for the present patient. The selection of the optimal treatment for a particular patient (i.e., personalized medicine) is a daily task of the clinician and one of the major challenges in health care research, but very scant evidence is available to guide these decisions. This is problematic since BPD patients vary greatly in treatment outcome. Understanding and predicting variation in outcomes between BPD patients will yield great benefits for patients, including prevention of overtreatment and potential harm of treatments (e.g., demoralization). To conclude, research on mediators and moderators of treatment effects is needed.

Study objective

The aim of the present study is to optimize treatment selection by examining patient characteristics that predict (differential) treatment response across MBT and ST. These characteristics will be investigated and converted to actuarial formulas (see DeRubeis et al., 2014). In addition, mechanisms of change in MBT and ST will be investigated. Also therapeutic and organizational characteristics that may influence the effectiveness of MBT and ST will be investigated. Finally, the (cost-)effectiveness of MBT and ST among BPD patients will be examined.

Study design

The study design is a multisite randomized controlled trial (RCT) in which multiple mental health care centers will collaborate. Patients will be recruited from the mental health care centers. All patients with BPD or suspicion of BPD will be asked to participate in the screening process. In the screening process, patients will be assessed for eligibility to participate in this study based on the inclusion and exclusion criteria. Diagnostic criteria will be assessed by means of the SCID, executed by trained SCID interviewers. The other assessments will be conducted by the local research assistants. Furthermore, a motivational/availability interview will be part of the screening process. When a patient is eligible for participation, he or she will be randomized to MBT or ST by the research staff, using computerized random assignment. The first assessment will occur after inclusion and before randomization. The subsequent six assessments will occur at 7.5, 13.5, 19.5, 25.5, 31 and 36 months after the start of the treatment.

Intervention

1. Mentalization-Based Treatment (MBT)
2. Schema Therapy (ST)

There are two different intervention conditions, MBT or ST, which participants are randomly assigned to. Both treatments will consist of a combination of individual sessions and group sessions with nine patients. MBT has a maximum duration of 36 months. It starts with a pretreatment program of about six weeks consisting of an introductory course to MBT (MBT-I) and individual sessions with crisis planning as focus. The main treatment consists of a treatment phase and a maintenance phase. The treatment phase consists of weekly group (75 minutes) and individual (45 minutes) psychotherapy with a maximum duration of 18 months. The maintenance phase consists of intermittent individual sessions with a maximum of once a week and a maximum duration of 16.5 months. ST has a maximum duration of 25.5 months and starts with a pretreatment program of about six weeks consisting of several (approximately three) individual sessions. The main treatment consists of a treatment phase and a maintenance phase. The treatment phase has a maximum duration of 18 months and consists of weekly group (90 minutes) and individual (45 minutes) psychotherapy for a period of 12 months, continued by weekly group psychotherapy and biweekly individual psychotherapy for a period of six months. The maintenance phase consists of biweekly individual psychotherapy for a period of three months, continued by three months of one individual session each month.

Study burden and risks

There are in total seven measurements over three years. A measurement takes about three hours. The measurements are conducted by trained research

assistants. In addition, over a period of two years, the client completes every month a short online questionnaire (max. 10 minutes) about the experienced symptoms. The assessments will take a total of about 25 hours over three years. The results of the assessments can be partly used for routine outcome monitoring (ROM). ROM is required within institutions. The total time spent by a client in this study, without time spending on the ROM, is about two hours per measurement and in total about 18 hours over three years.

There are no direct risks involved for patients involved in this study. Patients will receive an evidence-based treatment. In addition, patients will receive a treatment they probably would receive even if they did not participate in the study. Participating in interviews and filling out questionnaires is often part of centers* regular practice and does not involve specific risks. Participants are told that Schema Therapy involves processing of adverse childhood experiences. Potential participants that don't want a treatment partially focusing on their childhood can therefore decide not to participate.

Finally, BPD is characterized by self-injury, suicidality, and crisis. For emergencies, the emergency procedure of each mental health care institute will be followed. An emergency hospitalization will take place in case this is necessary. Any additional treatment, whether individual sessions or hospitalization, will be monitored and included in the analyses. Patients will only be withdrawn for the study at their request.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Primary diagnosis of BPD
2. Age 18-65 years
3. Borderline Personality Disorder Severity Index, fourth edition (BPDSI-IV) score above 20
4. Dutch literacy
5. 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
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL61468.018.17