A multi-site randomized controlled trial comparing Schema Therapy and Dialectical Behavior Therapy 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	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON49443

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, Dialectical Behavior Therapy, 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-5, 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-5 (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-5 (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) and the Mental Health Quality of Life seven-dimensional Questionnaire (MHQoL-7D; van Krugten et al., 2019).

- 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).

- A subgroup of patients (N=30) will receive two additional questionnaires, including the Young Schema Questionnaire-3 short form (YSQ-3SF; Rijkeboer, 2012) and the PTSD Checklist for DSM-5 (PCL-5; Weathers et al., 2013), in order

to get more insight in the effect of timing of trauma treatment in ST by using Imagery Rescripting (ImRs).

Both treatments include non-specific (e.g., alliance) and specific (e.g., 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);
- ST: schema mode ratings, assessed by the Schema Mode Inventory (SMI; Young et al., 2007);
- DBT: DBT skills use, assessed by the Dialectical Behavior Therapy-Ways of Coping Checklist (DBT-WCCL; Neacsiu, Rizvi, Vitaliano, Lynch, & Linehan, 2010), emotion regulation, assessed by the Difficulties in Emotion Regulation Scale Short Form (DERS-SF; Kaufman et al., 2016) excluding the Awareness subscale, based on recommendations of among others Hallion, Steinman, Tolin, and Diefenbach (2018) and Bardeen, Fergus, and Orcutt (2012), and awareness, assessed by the Difficulties in Emotion Regulation Scale 18 (DERS-18; Victor & Klonsky, 2016).

Predictors of (differential) treatment response have been selected based on the literature, suggestions of an expert by experience, and expert clinicians*

appraisals of BPD patient characteristics that predict (differential) treatment response across DBT and ST. A subgroup of patients (N=30) will also receive the Childhood Trauma Questionnaire-Short Form (CTQ-SF; Bernstein et al., 2003).
In addition, patients* three-monthly ratings of their symptoms and the proposed mechanisms of change will be collected, including:
- BPS symptoms, assessed by a selection of items of the BPD Checklist (Ultrashort BPD Checklist; Bloo, Arntz, & Schouten, 2018);
- Functioning, assessed by a modified version of the Outcome Rating Scale (ORS; Miller, Duncan, Brown, Sparks, & Claud, 2003);
- Happiness, measured with a single question on general happiness (Veenhoven, 2008);
- Core beliefs, measured by using a semi-structured interview following the procedure of among others Videler et al. (2017);
- VAS items measuring proposed mechanisms of change of Schema Therapy;
- A selection of schema modes, measured by the SMI, consisting of five maladaptive schema modes central to BPD (i.e., vulnerable child, angry child, impulsive child, detached protector, and punitive parent) and one functional schema mode (i.e., healthy adult);
- DBT skills use, assessed by the DBT-WCCL (Neacsiu, Rizvi, Vitaliano, Lynch, & Linehan, 2010).

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 Dialectical Behavior Therapy (DBT; Linehan, 1993a, 1993b) and Schema Therapy (ST; Arntz & Van Genderen, 2009; Young et al., 2003).
Several studies have demonstrated the effectiveness and the efficacy of DBT (for a review, see for example Kliem, Kröger, & Kosfelder, 2010; Panos, Jackson, Hasan, & Panos, 2014) and ST (for a review, see Jacob & Arntz, 2013). However, mechanisms of change (i.e., mediators of treatment effects) have rarely been studied. 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 DBT and ST. These characteristics will be investigated and converted to actuarial formulas (see DeRubeis et al., 2014). In addition, mechanisms of change in DBT and ST will be investigated. Also therapeutic and organizational characteristics that may influence the effectiveness of DBT and ST will be investigated. Finally, the (cost-)effectiveness of DBT 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 DBT or ST by the research staff, using computerized covariate adaptive randomization, taking into account gender, severity of BPD (BPDSI-5 score <= 24; BPDSI-5 score > 24), and treatment capacity. Patients recruited in PsyQ Rotterdam that have been randomized to ST will be randomized again to condition A, in which patients receive ImRs during months two, three, and four, or condition B, in which patients receive ImRs after the first four months.
The first assessment will occur after inclusion and before randomization. The subsequent six assessments will occur at 7, 13, 19, 25, 31 and 36 months after the start of the treatment.

Intervention

1. Dialectical Behavior Therapy (DBT)
2. Schema Therapy (ST)

There are two different intervention conditions, DBT or ST, which participants are randomly assigned to. Both treatments will consist of a combination of individual sessions and group sessions with nine patients. DBT has a maximum duration of 25 months. It starts with a pretreatment program of four weeks consisting of several (approximately five) individual sessions. The main treatment consists of a treatment phase and a maintenance phase. The treatment phase consists of weekly individual psychotherapy sessions (50 minutes), weekly skills training groups (150 minutes), and phone consultation, with a maximum duration of 12 months. The maintenance phase has a maximum duration of 12 months and consists of an eHealth intervention, monthly individual psychotherapy sessions, and three-monthly group sessions.
ST has a maximum duration of 25 months and starts with a pretreatment program of four 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.

The treatments will be delivered face-to-face. If face-to-face treatment is not possible due to restrictions of visits to mental health care centers taken by the government during the COVID-19 pandemic, the treatment will be delivered

via videoconferencing.

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 three-month a short online questionnaire (max. 20 minutes) about the experienced symptoms. A subgroup of patients (N=30) will receive an extended version of the first three-monthly assessment. The assessments will take a total of about 25-28 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 18-20 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, fifth edition (BPDSI-5) score above 20
4. Dutch literacy
5. The willingness and ability to participate in (group) treatment for a maximum of 24 months and to complete the assessments over a period of three years

Exclusion criteria

1. Psychotic disorder in the past year (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 with at least one manic episode in the past year
4. IQ< 80
5. Travel time to the DBT 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 DBT 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:	Recruiting
Start date (anticipated):	17-02-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-11-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	08-10-2020
Application type:	Amendment
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: 21337
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66731.018.18