BOOTS: Borderline Optimal Treatment Selection

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21337

Source
NTR

Brief title
BOOTS

Health condition

The present study focuses on the treatment of patients with borderline personality disorder.

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), CZ Fonds, Stichting Achmea Gezondheidszorg

Intervention

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).

Secondary outcome

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);
- 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).

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);
- 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 and expert clinicians' appraisals of BPD patient characteristics that predict (differential) treatment response across DBT and ST. In addition, patients' 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;
- DBT skills use, assessed by the DBT-WCCL (Neacsiu, Rizvi, Vitaliano, Lynch, & Linehan, 2010).

Study description

Background summary

Rationale: Several studies have demonstrated the effectiveness and the efficacy of Dialectical Behavior Therapy (DBT) and Schema Therapy (ST) for borderline personality disorder (BPD). However, little research has examined the mechanisms of change (i.e., mediators of treatment effects). In addition, research on moderators of treatment effectiveness is also lacking. This is remarkable since BPD patients vary greatly in treatment outcome. Understanding and predicting variation in outcomes between BPD patients will yield great benefits for patients.

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. 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 randomized controlled intervention study.

Study population: The target group consists of adult patients (18-65) with BPD.

Intervention: 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 and both treatments will have a maximum duration of 25 months.

Main study parameters: The primary outcome measure is change in the severity and frequency of the Diagnostic and Statistical Manual of Mental Disorders BPD manifestations (Borderline Personality Disorder Severity Index, fifth edition, BPDSI-5).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Prior to randomization, patients will be assessed at baseline. After the baseline assessment, patients will complete at 6, 12, 18, 24, 30, and 36 months after the start of the treatment (group sessions) a battery of questionnaires and interviews. Each assessment will take approximately three hours to complete. In addition, over a period of two years, patients

will receive a short online questionnaire every month (max. 10 minutes to complete).
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.

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. 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 first assessment will occur after inclusion and before randomization. The subsequent five assessments will occur at 6, 12, 18, 24, 30 and 36 months after the start of the treatment (group sessions).

Intervention

There are two different intervention conditions, DBT or ST, which participants are randomly assigned to. DBT is a comprehensive cognitive behaviorally based treatment for BPD (Linehan, 1993a, 1993b). DBT is based on a biosocial model, incorporating both biological and social-environmental influences, whereby BPD is seen as the consequence of the dysfunction of the emotion regulation system. DBT aims to teach patients behavioral skills in areas like distress tolerance, emotion regulation, mindfulness, and interpersonal effectiveness. DBT integrates strategies from cognitive and behavioral treatments, Zen-based acceptance strategies, and dialectical strategies.
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.

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.

Contacts

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Eligibility criteria

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 (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 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
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-04-2019
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49443
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7699
CCMO	NL66731.018.18
OMON	NL-OMON49443

Study results