Multi-Site RCT of Group Schema Therapy for Borderline Personality Disorder

Published: 13-01-2010
Last updated: 19-03-2025

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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-OMON43782

Source
ToetsingOnline

Brief title
'Group Schema Therapy for BPD'

Condition

- Personality disorders and disturbances in behaviour

Synonym
Borderline Personality Disorder, personality problems

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,Fonds Psychische Gezondheid

Intervention

Keyword: BPD, Group schema therapy, Multi-site, RCT

Outcome measures

Primary outcome

The primary outcome is reduction in BPD-severity assessed by the BPDSI interview (Arntz et al., 2003; Giesen-Bloo et al., 2006). Use of the BPDSI will allow direct comparisons with the other studies of ST: Giesen-Bloo et al. (2006), van Asselt et al. (2008), and Nadort et al. (2008, 2009).

Secondary outcome

Secondary outcomes include the dimensional subscales and total score of the BPDSI. Furthermore, the following self-report instruments will be used: the BPD-checklist (self report of burden of BPD manifestations); the SCL-90; the Young Schema Questionnaire; the Schema Mode Inventory (Lobbestael et al., 2008). Quality of Life will be assessed with the WHOQOL (short version; The WHOQOL Group, 1998), the EuroQol (Brooks 1996; Dolan, 1997), and the one-item happiness question, of which norms are available of 33 countries, including the US, Germany, the Netherlands and Norway,)(Veenhoven, 2008). General functioning will be assessed with the GAF (DSM-IV), and social and occupational functioning with the Social and Occupational Functioning Assessment Scale (SOFAS; DSM-IV; Goldman et al., 1992). Both are assessed by independent raters blind for condition, using a semi-structured interview (Bamelis et al., in progress). Social functioning will be also assessed with a self-report form, the Work and Social Adjustment Scale (WSAS) (Marks et al., 1973; Mataix-Cols et al., 2005) and the SAS-SR (Weissman & Bothwell, 1976) to allow comparability to

other studies conducted in the USA.

Study description

Background summary

A recent meta-analytic study did not think it possible to draw conclusions about the relative effectiveness of different psychotherapy approaches for BPD (McMain & Pos, 2007). The just released UK National Institute for Health and Clinical Excellence guidelines for BPD treatment and research (2009) suggest that many questions remain unanswered regarding descriptions of sub-populations of BPD, what comparator to use, and even which intervention is the most likely candidate for further research investment. Most reviews emphasize that the current RCTs of all models of BPD treatment are under-powered. Other problems noted include: a lack of rigorous comparator controls, inadequate length of follow-up periods to measure the maintenance of gains, confounding effects from concurrent active treatment. In addition, research for most approaches lacks adequate cost-effectiveness analysis, lacks replication or lacks feasibility of implementation in public health settings where the majority of BPD patients are treated.
Schema Therapy has demonstrated significant effects with all aspects of BPD in two RCTs of individual treatment (Giesen-Bloo et al., 2006; Nadort et al., 2008, 2009), one RCT of group treatment (Farrell et al., 2009), and one case-series (Nordahl & Nysaeter, 2005). Drop-out from ST is very low (0% over an eight month group and 20% over two years of individual therapy). Moreover, ST has demonstrated positive effects on quality of life (Giesen-Bloo et al., 2006; van Asselt et al., 2008; Nadort et al., 2008, 2009; Farrell, et al., 2009) and decreases in societal costs (van Asselt et al., 2008). Schema Therapy distinguishes itself by producing improvements in all nine criteria of BPD, as well as functioning and quality of life. It also demonstrates cost effectiveness, high retention of subjects, and high patient and therapist satisfaction with the treatment. The range of effectiveness of ST, the size of treatment effects demonstrated in RCTs, including the significant findings for ST in groups,make a strong case for further testing of ST in clinical trials.

Study objective

Our long-range goal is to develop a comprehensive, clinically and cost effective treatment for BPD that produces both symptom remission and functional recovery. We aim to determine the role that group ST can have in the comprehensive treatment of BPD, and whether it is a cost effective treatment, that can be made widely available in public and private healthcare settings.
Our central hypothesis is that eighteen months of group ST delivered with two varied amounts of individual sessions will significantly outperform a control

condition of treatment as usual (TAU). We base this hypothesis on the results of randomized controlled trials (RCTs) carried out and published by members of our research team that have demonstrated the broad and pronounced effectiveness of individual and group ST. The large effect sizes in an RCT of schema therapy in group, suggest that group interventions for people with BPD may have specific advantages and power that need to be further evaluated empirically. We chose TAU as a comparator because it has not been used before in trials of ST as a complete treatment, and it tests important questions regarding whether a treatment is feasible and can be cost effective.

We plan to test our central hypothesis and accomplish the overall objective of this application by pursuing the following specific aims:

1. Evaluate the effectiveness of group schema therapy as a core component of comprehensive treatment for BPD. The working hypothesis for this aim is that a combination of individual and group ST will be superior to TAU in ameliorating core BPD symptoms, enhancing social and occupational or academic functioning, and improving quality of life. Two combinations of individual and group sessions were developed for this trial based upon preliminary studies and the collective clinical experience of our research group. Comparison of the two ST conditions will allow us to begin to determine the minimal *dose* of more expensive individual therapy needed to support the effect of ST group treatment. Our paradigm is that the use of group therapy, with individual therapy as a limited adjunct, could fill a gap in public health care systems that struggle to provide individual specialized treatments for BPD with limited psychotherapy resources. In this process we will test a treatment manual for group ST that will be refined, published and provide the standard for future trials. We will also get an idea of the training and supervision needed for psychotherapists already trained in individual ST to reach an acceptable standard of fidelity in group ST. Our large sample, will allow us to begin to evaluate the hypothesized active ingredients of ST (reduction in maladaptive schemas and modes, establishment of secure attachment, and group cohesion).

2. Evaluate the cost-effectiveness of the group ST formats. The working hypothesis for this aim is that ST in both formats will be more cost-effective than TAU at all sites. A secondary hypothesis is that Format A will be more cost-effective that Format B.

3. Assess the opinions of the major stakeholders (BPD patients and their therapists) about the treatment using established qualitative methods. With in-depth interviews and focus-groups we will get information about what patients and therapists think about the treatment, to what degree it meets their needs, and what is missing in their opinion from the treatments. We will use this information as an additional source of information upon which to decide what ST-format should be used and to further adjust the preferred treatment to better meet the needs of patients and therapists, before its implementation in general practice is tested.

4. Identify predictors of treatment response from the assessment measures and repeated outcome measures employed. Our large sample size and psychometrically sound measures will allow us to test preliminary hypotheses about predictors of recovery and drop-out derived from the earlier RCT of individual ST. Moreover, we can conduct post hoc analyses of other potential predictors that can be tested a priori in a subsequent study.
Collectively, the empirical validation of our working hypotheses will add to the progress of BPD treatment research by further evaluating ST as a promising treatment with potential as a manualized, comprehensive, cost-effective, and replicable treatment for the devastating disorder of BPD.

5. Investigate changes in underlying brain processes and cognitive biases. Previous studies have found that BPD patients have increased amygdala and hippocampal responses and reduced ACC and medial prefrontal cortex responses to negative emotional stimuli, probably reflecting emotion regulation problems and easily triggered fight/flight responses. Similarly, BPD patients showed specific ACC response patterns associated with emotion-related impulsivity. Preliminary studies suggest that successful psychological treatment leads to normalization of these responses. The present study aims to investigate in more detail and with more power how brain responses in pertinent area change in association with the treatment. Other studies have documented cognitive biases towards threat, i.e. attentional and interpretational biases. Changes in these biases during treatment will be assessed and related to recovery of BPD and to changes in emotional brain responses. To interpret the baseline fMRI and threat-bias findings the BPD-group will be compared to clinical controls (Cluster-C PD patients) and nonpatients. This fundamental substudy will take place in 3 academic centres (Maastricht, Lübeck and Freiburg). In each center at least N=10 of each control group will be assessed.

Study design

To further evaluate the effectiveness of group ST with two schedules of individual ST we will conduct a multi-center RCT with adequate power to reach the following aims:
Specific Aim 1: Evaluate the comparative contributions of group and individual schema therapy to comprehensive treatment that leads to symptom remission and functional recovery from BPD, including meaningfully improved quality of life. This study will expand the Giesen-Bloo et al. (2008) study and the Farrell et al. (2009) study of group ST, by comparing two group formats to TAU, as well as comparing the two group formats with each other. We will compare the treatment and cost effectiveness of the two combinations of group and individual ST for two years (see table) versus TAU at two universities with multiple clinical sites each. The clinical sites are:
1) RIAGG Maastricht, Nederland
2) Mondriaan zorggroep, Heerlen, Nederland
3) GGZ Oost Brabant, vestiging Helmond, Nederland
4) GGZ Centraal, vestiging Hilversum, Nederland

5) De Viersprong, Amsterdam, Nederland
6) Vincent van Gogh Instituut Venray & Venlo, Nederland
7) Universitätsklinikum Freiburg, Freiburg, Duitsland
8) Institut für Verhaltenstherapie-Ausbildung, Hamburg, Duitsland
9) Klinik für Psychiatrie und Psychotherapie, Universität zu Lübeck, Duitsland
10) South Metropolitan Area Health Service, Mental Health Rockingham, Perth, Australia
11) South Metropolitan Area Health Service, Mental Health, Peel, Perth, Australia
12) Bradford District Care Trust, Bradford, UK.
13) South London and Maudsley NHS Foundation Trust, London, UK.
14) Department of Psychiatry, Eginition Hospital, Medical School, Athens University, Athens, Greece.

The range of clinical settings included * e.g., community mental health centers, university outpatient clinics, institutes, psychiatric hospital clinics - allows an initial evaluation of the generalizability of the treatment and lays the groundwork for future implementation studies. This is the first international multi-site trial of a BPD treatment and it makes good use of the combined resources and sites of the international researchers and experts in Schema therapy.

Diagnostic DSM-IV in/exclusion criteria will be assessed with SCID-I and SCID-II interviews executed by trained SCID interviewers. A complete medical history and, if indicated, a physical evaluation will be conducted at this time. (In addition, all subjects entering the study will have their saliva collected at Baseline 2 in order to create a *bank* for the subsequent analysis of DNA in this large sample. All collected saliva will be sent to Maastricht University for this process and will be part of a separate study.) The Borderline Personality Disorder Severity Index (BPDSI) will be administered at the first assessment session (baseline 1). All centers have a regular stream of BPD patients and it is expected that quotas at each site will be filled within one year. No formal or paid advertising is planned. All patients with BPD or suspicion of it will be asked to participate in the screening process. After an independent central research assistant has checked in/exclusion criteria, the informed consent procedure and the qualifying BPDSI have been completed, patients will wait for a 3 month qualification period, at the end of which the BPDSI will be administered again (baseline 2). The structured interviews and self-report questionnaires of our assessment battery will be scheduled on a weekly basis during the qualification period. These sessions will be with research assistants, conducted in a supportive and validating manner to engage the patient and to provide some support. Individual supportive sessions, utilizing TAU and not a specialized model of BPD treatment, will also be available to patients during this pre-randomization phase, delivered by psychotherapists who are not part of the study treatment team. The qualification period will filter out patients poorly motivated for the study, and control for early changes in the primary outcome measure (BPDSI). After the

second baseline BPDSI assessment, patients will be randomized over two conditions: group-ST or TAU. The central research assistant responsible for randomization (located at the main Netherlands site) will randomize blocks of 2 patients over the two conditions using a computerized randomization program. In other words, for each site this assistant waits until two new patients are included, then prompts the computer to randomize the patients over conditions, and communicates the condition assignment to the site coordinator. In this way condition assignment is unpredictable up to and including the very last patient of each site. The type of TAU patients will receive will be decided by regular clinical practice at each site, thus representing common clinical practice. The amount and kind of this naturalistic TAU provided will be tracked and described in the trial results. Half of the sites will first offer ST format A (twice a week group), and then ST format B (once a week group, once a week individual). The other sites will offer the formats in reverse order. Thus, order of group format type will be balanced over sites, controlling for therapist learning and any other time effects.

Intervention

1. Group Schema Therapy A (Group-focused): 124 group sessions plus 0-18 individual sessions

2. Group Schema Therapy B (Group and individual combined): 74 group sessions plus 62 individual sessions

3. Treatment-as-usual: session number varying, individual, group, day therapy, inpatient, pharmacotherapy

Study burden and risks

Assessments take a total of about 20 hrs. over 3 years, and will be executed by research assistants trained to relate to the participants in a supportive way.

For Maastricht, Heerlen, Freiburg & Lübeck participants an extra 3 hours fMRI assessment is planned, and an extra 3 hours of threat-bias assessment.

There are no direct risks involved in the interventions and in the assessments.

However, suicidality, self-injury and crisis are considered behavioral hallmarks of BPD. The emergency procedure of each clinical site will be followed for these emergencies. If needed, emergency hospitalization will take place. Individual crisis management sessions will be available before self-injury or suicide attempts occur. If contact is made with the individual or group therapists after these behaviors, contact will only be long enough to arrange any needed emergency treatment. The *bank* of individual sessions in the primarily group treatment condition allows for crisis management as well as

a patient*s request for an individual session. If a patient has used all the credit in their *bank*, in an emergency situation they can be seen by ER, the Crisis Intervention Unit of the clinic, or a therapist at the site, who is not part of the study. Any additional treatment, whether individual sessions or inpatient hospitalization will be monitored and examined as a possible predictor of adequacy of this treatment for a particular subgroup of patients. Patients will only be dropped from the study at their request.

Participants either receive treatment as usual, or ST that is known as one of the most effective treatments, and that does not have specific risks. Any treatment can be emotionally confonting for BPD patients. Patients receive information about the treatments, from which it becomes clear that they might get group-ST. Participants are also told that ST involves processing of adverse childhood experiences. Potential participants that don't want group treatment or don't want a treatment partially focusing on their childhood can therefore decide not to participate.

As to the additional threat-bias and fMRI study : there are no specific risks with the computer task to assess threat-bias, and with the fMRI assessment given the fact that we use the usual exclusion criteria for MRI assessments. Because of the extra time involved in the additional study, and the extra burden to travel to anaother building, a small financial compensation is offered.

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. Age 18-65 year
2. Primary DSM-IV diagnosis of BPD (assessed with the SCID-II interview)
3. BPD severity above 20 on the BPDSI interview
4. Willingness to participate in the study (informed consent procedure)
5. Ability to participate in (group) treatment and research for 2 years (e.g., no plans to move to other city)

Exclusion criteria

1. Lifetime psychotic disorder (short stress-related episodes are allowed, as described in DSM-IV BPD criterion 9)
2. IQ < 80 (in case of suspicion of low IQ, to be assessed with full intelligence test)
3. Unable to read, speak, or write the language used at the site (in case of suspicion an official language test is to be used)
4. ADHD (when suspected on basis of self-report for the KID-SCID is used to assess ADHD)
5. Bipolar disorder type 1 (SCID-1)
6. Dissociative Identity Disorder (confirmed by senior investigators)
7. Full or sub-threshold (defined as one less than the number of criteria to qualify for the diagnosis) narcissistic or antisocial personality disorder (SCID-2)
8. Substance dependence needing clinical detox (after detox and 2 months sobriety can be included).
9. Serious and/or unstable medical illness
10. Previous schema therapy of more than 3 months duration.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2010
Enrollment:	321
Type:	Actual

Ethics review

Approved WMO Date:	13-01-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-03-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-03-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-03-2010
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-08-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-07-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-08-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-09-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-12-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-04-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 25917
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL28016.068.09
OMON	NL-OMON25917