Mentalization-Based Treatment with and without Competitive Memory Training for patients with borderline personality disorder: randomnized controlled trial

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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-OMON39537

Source
ToetsingOnline

Brief title
nvt

Condition

- Personality disorders and disturbances in behaviour

Synonym
borderline

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Rivierduinen

Source(s) of monetary or material Support: Stichting Rivierduinen

Intervention

Keyword: Borderline, COMET, mentalization, self-esteem

Outcome measures

Primary outcome

The primary outcome measure is the frequency and severity of borderline personality symptomatology as assessed with the Borderline Personality Disorder Severity Index (BPDSI-IV), a semi-structured interview.

Secondary outcome

A secondary aim is to investigate whether this enhanced effectiveness is indeed mediated by changes in self-esteem and/or changes in a bias for negative emotional information.

Further it is tested whether a variation in the oxytocin receptor gene moderates the outcomes.

Study description

Background summary

Borderline personality disorder (BPD) is a serious psychiatric situation with a lifetime prevalence of about 3%.
This study focus on MBT as an evidence-based treatment for BPD and investigates whether the effectiveness of this procedure can be enhanced.
Understanding the mechanisms through which MBT works is necessary to further improve the treatment program.
In the search for alternative treatment components, in the present study a specific intervention for low self-esteem is added to the MBT treatment.

Study objective

The primary aim of the proposed study is to investigate whether adjunctive

treatment of negative self-image with a specific intervention module (i.e. COMET) has added value in the treatment of patients with BPD compared with MBT without such a specific addition.
A secondary aim is to investigate whether this enhanced effectiveness is indeed mediated by changes in self-esteem.

Study design

In this RCT, using music therapy as a credible placebo intervention, patients are randomized into two conditions: MBT + music therapy or to MBT + COMET. Both the music therapy and COMET are add-on modules, each with a duration of 8 weeks.
The first assessment is done at the onset of therapy (baseline); the second measurement is assessed after the music and COMET therapy (about 5 months post-baseline), the third measurement is done at the end of therapy (about 12 months post-baseline), and a final measurement is made at 24-months follow-up.

Intervention

Patients will receive either MBT + music therapy, or MBT + COMET.

Study burden and risks

All patients are treated with an evidence-based effective treatment (MBT), which is the first choice of treatment at the psychiatric institute Rivierduinen (location Duin en Bollenstreek) in the treatment of patients with BPD. In addition, 50% of the included patients are treated with a specific evidence-based treatment for low self-esteem (COMET) as an adjunct therapy. COMET has proven to be effective and beneficial in patients with personality disorders (Olij et al. 2006, Korrelboom et al. 2009; Korrelboom et al. 2011), as well as in other clinical populations (Korrelboom et al., 2009; Korrelboom et al., 2012). The remaining 50% of the patients are treated with music therapy as an add-on module besides the normal MBT treatment. Music therapy is a method often applied in clinical practice as a treatment for BPD (Christensen et al. 2007, Bollea and Guarino, 1991, Hannibal et al. 2012). However, there are no studies indicating symptom relief in patients with BPD. In the present study the main burden for the patient is the randomization, which implies that the patients cannot choose the treatment they prefer. Moreover, at three time points during treatment, and at follow-up, patients take part in assessment sessions consisting of interviews, questionnaires and two experimental tasks. However, the duration of these assessments does not exceed the duration of normal psychological investigation which all patients in the ambulatory care program *Personality Disorders* of Rivierduinen (location Duin en Bollenstreek) must complete.
Participants do not receive any financial (or other) compensation for participating in the study.

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

Patients are registered with the Rivierduinen care program Personality Disorders
Aged between 18 and 65 years
Confirmation of the primary diagnosis of borderline personality disorder using the international personality disorder examination(IPDE) for DSM-IV
BPDSI-IV score bigger than 20
informed consent

Exclusion criteria

Insufficient command of the Dutch language
Severe comorbid psychopathology such as: psychotic disorders(except short, reactive

psychotic episodes, that can be part of the clinical picture of BPD), bipolar disorder, dissociative identity disorder, antisocial personality disorder, attention deficit hyperactivity disorder, addiction of such severity that clinical detoxification is indicated (after which entering treatment is possible), psychiatric disorders secondary to medical conditions and mental retardation. Comorbid axis 1 and axis 2 disorders are allowed, as is medication use. Simultaneous participation in another specific psychiatric treatment, except medication.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-10-2013
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	18-01-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-05-2013

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL42115.058.12