Day hospital Mentalization-Based treatment versus Intensive Outpatient Mentalization-Based Treatment for patients with severe borderline personality disorder: A multi-centre head-to-head randomized clinical trial

Published: 26-07-2012
Last updated: 26-04-2024

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

Summary

ID

NL-OMON37807

Source
ToetsingOnline

Brief title
MBT-DOS

Condition

- Personality disorders and disturbances in behaviour

Synonym
borderline personality disorder

Research involving

Human

Sponsors and support

Primary sponsor: Psychotherapeutisch Centrum De Viersprong (Halsteren)
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Borderline personality disorder, Mentalization-Based treatment, Multi-centre trial, Randomized controlled trial

Outcome measures

Primary outcome

Primary outcome variables are:

a) symptomatic distress (Brief Symptom Inventory; BSI)

b) parasuicidal behaviour (self-destructive acts and suicide attempts; SSHI).

Secondary outcome

Secondary outcome variables are:

a)depressive symptoms (Beck Depression Inventory; BDI)

b) DSM-IV axis I & II diagnoses (Structured Clinical Interview for DSM-IV Axis

I disorders; SCID-I, and The Structured Clinical Interview for DSM-IV Axis II

Personality disorders; SCID-II)

c)borderline symptoms (Personality Assessment Inventory-Boderline schaal;

PAI-BOR)

d)mentalization (Reflective Functioning Questionnaire; RFQ, Reading the Mind in

the Eyes Test; RMET, FaceMorph task)

e) personality pathology (Severity Indices of Personality Problems Short Form;

SIPP-SF, en Dimensional Assessment of Personality Pathology - Short Form;

DAPP-SF)

f)quality of life (EuroQol 5 dimensions; EQ-5D)

g)interpersonal functioning (Inventory of Interpersonal Problems; IIP-32)

h) intimate relationships (Experience in Close Relationships; ECR-R en ECR-2010

partner relationships)

i) mental health-related functional impairment (Sheehan Disability Scale; SDS)

j)treatment adherence (Compliance Rating Scale; CRS)

k)addiction and dependence of psychoactive substances (MATE)

l)economic evaluation (Trimbos/iMTA questionnaire for Costs associated with

Psychiatric Illness deel 1 en deel 2 ; TiC-P deel 1 en deel 2)

Study description

Background summary

Borderline personality disorder (BPD) generates a high burden to individual patients, society, health care, and economy, and this is especially true for patients with severe BPD. Until recently, these patients were often refused (curative) treatment, as clinicians were pessimistic about their change potential, and mental health care lacked specialized programs for this group. These patients typically display multiple problem behaviors that interfere with their own and others* treatments (e.g., violence, aggression, substance misuse, acting-out, non-adherence). Implementation of treatments for this group is thus important for not only the patients themselves, but also in order to reduce the burden on mental health care, and the inefficient use of resources. Studying the cost-effectiveness of various treatment options will also likely increase health benefits in the short term and a reduction in health care consumption and costs in the long run.

The Mentalization-Based Treatment (MBT) model assumes that enhancing the capacity for mentalization (i.e., the capacity to interpret the self and others in terms of internal mental states) improves functioning of severe BPD patients. Two RCTs demonstrated the effectiveness of Mentalization-Based

Treatment for patients with severe BPD in a Day Hospital setting (MBT-DH) as compared to usual care, and for MBT in an intensive outpatient setting (MBT-IOP) as compared to structured clinical management. Yet, in these trials, patients in MBT-DH and MBT-IOP differed substantially in terms of symptom severity at baseline, which makes it impossible to model an 'indirect comparison'. Moreover, substantial cost differences between both MBT-variants exist: MBT-DH consists out of 5 day a week treatment, while MBT-IOP is about 1.5 days. Such cost-differences warrant a *head to head* cost-effectiveness study. The aim of this trial is therefore to study the (cost-)effectiveness of MBT-DH as compared to MBT-IOP.

Study objective

The primary aim of this study is to investigate the efficacy of MBT-DH in comparison to MBT-IOP. A secondary aim is to explore the cost-effectiveness and matching potential of various baseline variables that might help treatment selection procedures and optimizing (cost-)effectiveness.

Study design

In order to assess the (cost-)effectiveness of MBT-DH and MBT-IOP, a randomized controlled trial will be performed in a clinical setting. Three mental health care institutes with four treatment locations are involved in this study: 1) The Viersprong, location Bergen op Zoom, 2) The Viersprong, location Amsterdam, 3) Arkin, location Amsterdam, and 4) Lentis, location Groningen. Two locations (1 and 3) will each realize two MBT-DH groups and two MBT-IOP groups exclusively consisting of randomized patients participating in the trial. The other two locations (2 and 4) will each conduct one MBT-DH group and one MBT-IOP group, with all treatment groups consisting of randomized patients participating in the trial.

All consecutive patients referred to the MBT-ward of these treatment centers are contacted by a psychotherapist. During a first individual meeting with this psychotherapist, patients are further screened for exclusion criteria, and receive information about the trial and treatments.
They have a week to consider their participation in the trial. After the individual meeting, the MBT-indication of every patient is discussed by the MBT-team. There are two options: 1). The MBT-indication is made definite 2). MBT-indication is not supported by the MBT-team and patient is sent back to the intake team. After this meeting, the patient is invited for a face-to-face meeting with the psychotherapist. The psychotherapist explains to the patient the decision of the MBT-team concerning MBT-indication and asks if the patient agrees with this. If the MBT-indication is made definite, and the patient is willing to participate in the trial, informed consent is signed. Then, the patient fills in the first set of questionnaires and afterwards the patients will be randomized to one of two groups: MBT-DH or MBT-IOP.

Both MBT-dosages have a treatment duration of max 18 months, followed by a maintenance phase (also 18 months max). Patients are assessed at day of definite indication for MBT, at the start of treatment and 6, 12, 18, 24, 30 and 36 months after the start of treatment. If patients refuse to participate in the study, they will be offered standard care in the same treatment centre.

Intervention

MBT-DH is provided 5 days/week and includes daily group psychotherapy, weekly individual psychotherapy, and art- and writing therapy. MBT-IOP includes group psychotherapy twice a week and weekly individual psychotherapy. Both MBT-dosages have a treatment duration of max 18 months, followed by mentalizing maintenance sessions (also 18 months max).

Study burden and risks

Participation involves minimal risk. MBT will be delivered by experienced professionals used to working with patients with BPD features. Participation in the trial involves a number of relatively time*consuming interviews and assessments which may be somewhat burdensome but do not carry specific risk. Studies have not shown iatrogenic effects of MBT. By contrast, studies have shown that MBT is associated with symptom and interpersonal improvement, decreases in self-harm, crisis interventions, and parasuicidality. Moreover, the safety board (see XX), will monitor any potential adverse events (e.g., suicide) that might be associated with the treatment, which may ultimately lead to stopping the trial or a treatment arm should this be warranted by the nature and/or frequency of the adverse events.

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

Inclusion criteria are: (a) diagnosis of borderline personality disorder (BPD), i.e., at least 5 BPD traits using the SCID-II (First et al., 1996), (b) 18 years or older, (c) sufficient knowledge of Dutch language.

Exclusion criteria

Exclusion criteria are: (a) responsibility for the care of children younger than 4 years, (b) having a stable job for longer than two years, (c) antisocial personality disorder and a history of severe physical violence, (d) travel time to the MBT-ward more than an hour, (e) chronic psychotic disorder or autism.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2012
Enrollment:	144
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-07-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL38571.078.12