Mentalization Based Treatment vs care as ususal in the treatment of severe Borderline Personality Disorder

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON33534

Source
ToetsingOnline

Brief title
MBT for severe BPS

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
'borderline', Borderline Disorder, Borderline Personality Disorder, Personality disorder

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: ZONMW (aanvraag ingediend)

Intervention

Keyword: Borderline Personality Disorder, MBT, Mentalization Based Treatment, Randomized Cotrolled Trial

Outcome measures

Primary outcome

The primary outcome variable is the frequency and severity of manifestations of

Borderline Personality Disorder as measured with the Borderline Personality

Disorder Severity Index (BPDSI), a semi structured interview.

Secondary outcome

Suicide acts, self-mutilation: SSHI (Suïcide and Self-Harm Inventory),

Depression: Beck Depression Inventory (BDI)

Subjective experiences of symptoms: Symptom Checklist (SCL-90)

Social and interpersonal functioning: Inventory of Interpersonal Problems (IIP)

Personality functioning: Severity Indices of Personality Problems (SIPP)

Quality of life: EQ5D

Adherence to treatment: Realised Dose Instrument (RD).

Attachement style (HSL)

Consumption of (mental) health care: Tic-P

Work characteristics: Tic-P

Work characteristics: Tic-P

Additional costutility: QALY*s (Quality Adjusted Life Years

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Study description

Background summary

Although there is a growing demand, evidence based treatments for patients with severe personality disorders (mostly borderline personality disorders) are not readily available. Recently, Mentalized Based Treatment (MBT) has been developed for patients with borderline personality disorder. One randomized controlled study demonstrated that a 5-day part-time MBT resulted in a clinical improvement up to 5 years after treatment compared to care as usual for patients with severe personality disorders (mostly borderline personality disorders). MBT also proved to be cost efficient. Given the fact that evidence for efficacy is based on only one RCT, it is essential new studies examine the effects of MBT.

Study objective

A randomized multicentre trial is proposed. The aim of this study is to find answers to the following questions; 1) what is, compared to care as usual, the effect of MBT with respect to symptoms, level of functioning and well being, (mental) health care consumption, and 2) what is the long term cost efficiency of MBT. Based on the results we hope to be able to determine if further implementation of intensive part time MBT can be recommended.

Study design

Patients with borderline personality disorder will be randomly assigned to one of two trial arms. In the experimental condition patients receive MBT, in the control condition patients receive care as usual. The intervention has a total duration of 36 months and. A base line measurement will be performed at the start of the intervention, and 6, 12, 18, 24, 30 and 36 months after. We expect a gradual improvement on clinical outcome variables during the first 18 months resulting in a 25% improvement at 18 months, compared with treatment as usual. After this, we expect this clinical improvement to remain stable during the next 18 months. At Arkin MBT can be offered to a total of 18 patients. Patients will be analysed according to the intention to treat principle. Based one experiences and literature (including the study by Bateman and Fonagy), the proportion of patients who drop out within thefirst three month s of treatment is approximately 20%. New patients will be recruited to fillup vacant MBT places and followed up according to protocol. Therefore we expect to have a total of 21patients in the analysis per condition in the Arkin sample. With a sample of 21 patients per group, an effectsize of 0.9 on the BPDSI in an ANOVA

can be detected with a power of 81%.
With the participation of either Ingeest or DeViersprong we realize a randomization of 36 patients to MBT(four groups on two locations), and 36 patients to the care as usual. With a sample of 36 patients pergroup,an effects ize of 0.9 on the BPDSI in an ANOVA can be detected with a power of >90%.

Intervention

Following MBT theory, mentalizing is the ability to understand oneself and others by inferring the mental states that lie behind overt behaviour. Failure to retain mentalizing, particularly in the midst of emotional interactions, is understood to be a core problem in (borderline) personality disorder, resulting in severe emotional fluctuations, impulsivity, and vulnerability to interpersonal and social interactions. The object of MBT is to increase mentalization capacity which should improve affect regulation and interpersonal relationships
Care as usual is provided by an outpatient team composed of psychiatrists, psychologists and mental health nurses. The team is experienced in the treatment of patients with personality disorders. Treatment is mainly ambulant. Day-treatment or hospitalization is only offered when necessary. The team aims at delivering optimal care by tailoring the intensity of the intervention and catering from a variety of interventions such as family interventions, VERS or Lineham training, social skills training, cognitive psychotherapy, psychodynamic psychotherapy, farmacotherapy, addiction treatment, inpatient treatment etcetera

Study burden and risks

Burden: 6 moments of measurement (interview and selfrating scales) in 36 months
Risks: non

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

A severe borderline personality disorder, based on standardized criteria for borderline personality disorder, assessed with the Dutch version of the Structured Clinical Interview for DSM-III-R (SCID-II) and the Borderline Personality Disorder Severity Index (BPDSI). Patients need to fullfill the criteria for borderline personality disorder as determined with the SCID-I, and need to have a total score on the BPDSI of > 25 indicating a severe borderline personality disorder.

Exclusion criteria

•Schizophrenia, as determined with the SCID-I,
•Bipolar disorder, as determined with the SCID-I,
•Substance dependency or misuse, as primary disorder as determined with the SCID-I
•Organic brain disorder,
•Mental impairment (IQ < 80)
•Inadequate mastery of the Dutch language
•Legal incapacity

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:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2009
Application type:	First submission
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: 23439
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL26308.097.09
OMON	NL-OMON23439