Mentalisation-Based Treatment versus care-as-usual in the treatment of severe borderline personality disorders.

No registrations found.

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

Summary

ID

NL-OMON23439

Source
Nationaal Trial Register

Health condition

Severe Borderline Personality Disorders

Sponsors and support

Primary sponsor: 1. Arkin Amsterdam, The Netherlands

Arkin
Afdeling Onderzoek Arkin Academy
Overschiestraat 65
1062 XD AMSTERDAM

2. GGZ inGeest, Amsterdam, The Netherlands
GGZ inGeest
Postbus 74077
1070 BB AMSTERDAM

3. De Viersprong, Halsteren, The Netherlands
PTC De Viersprong
Postbus 7

4660 AA HALSTEREN
Nederland

4. Vrije Universiteit, Faculteit der Aard- en Levenswetenschappen Ontwikkelingsgenetica, Amsterdam, The Netherlands

Vrije Universiteit Amsterdam
Faculteit der Aard- en Levenswetenschappen
Ontwikkelingsgenetica
Postbus 7161
1007 MC AMSTERDAM
Source(s) of monetary or material Support: ZonMw, Nederlands Organisatie voor gezondheidsonderzoek en zorginnovatie, , Den Haag, The Netherlands

Intervention

Outcome measures

Primary outcome

The frequency and severity of manifestations of BPD as measured with the BPDSI. The BPDSI is a semi structured interview, developed to assess short-term BPD pathology as defined by DSM-III-R/DSM-IV criteria (APA, 1987, 1994).

Secondary outcome

1. Number of suicide acts;

2. Self-mutilation;

3. Depression;

4. Subjective experiences of symptoms;

5. Social and interpersonal functioning;

6. Personality functioning;

7. Quality of life;

8. Treatment adherence.

Study description

Background summary

Objective

To examine the effectiveness/cost-effectiveness of Mentalisation-Based Treatment (MBT) for patients with severe Borderline Personality Disorders (BPD).

Design

A randomised controlled trial comparing standard psychiatric care with MBT. After a baseline measurement, patients will be followed up every 6 months for a total of 36 months.

Study populations/datasets

Patients with severe BPDs as determined with the SCID-II and a minimum score of 25 on the Borderline Personality Disorder Severity Index (BPDSI).

Intervention

The aim of MBT is to improve patients' ability to mentalise. The inability to mentalise, particularly in emotional interactions, is thought to be one of the main problems in severe borderline personality disorder. MBT is given in group sessions and individual sessions. The treatment is delivered by a multidisciplinary team in two phases of 18 months each. During the first treatment phase, patients receive intensive day treatment five days a week. In the second treatment phase, after-care treatment is provided: one individual session of psychotherapy and one group session of psychotherapy weekly.

Outcome measures

The primary clinical outcome measure is the frequency and severity of manifestations of Borderline Personality Disorder as measured with the BPDSI. Secondary outcome measures include a. number of suicide acts, b. self-mutilation, c. depression, d. subjective experiences of symptoms, e. social and interpersonal functioning, f. personality functioning, g. quality of life, h. treatment adherence.

Sample size calculation/data analysis

With two groups of 54 patients, an alpha of 0.05,an effect size of 0.9 can be detected with a

statistical power of >90%. Analysis will be performed according to the intention to treat principle.

Economic evaluation

The economic evaluation will be conducted from a societal perspective with a time horizon of 36 months. Resource use and occupation-related costs will be measured using the TiC-P and PRODISQ, and will be valued using Dutch standard prices. Bootstrapping will be used to estimate the uncertainty surrounding these ratios.

Study objective

Mentalisation-Based Treatment (MBT) for patients with severe Borderline Personality Disorders will result in a better clinical outcome compared with care as usual.

Study design

Baseline measurements will be taken after randomisation and follow-up measurements will be conducted 6, 12, 18, 24, 30 and 36 months after the baseline measurement.

Intervention

The concept of mentalising was developed in attachment research, psychoanalytical concepts, Theory
of Mind and neurobiological research. Mentalisation can be described as the ability to understand your
own and others' mental state on the basis of overt behaviour. The inability to mentalise, particularly in
emotional interactions, is considered to be one of the main problems in borderline personality disorder,
resulting in emotional instability, impulsive behaviour, and vulnerability in interpersonal and social
interactions. MBT was developed by Peter Fonagy and Anthony Bateman (6,7,15,16) with the aim of
improving patients' ability to mentalise, specifically in situations in which this is difficult for the patient.

MBT is given in group sessions and individual sessions. The treatment comprises two phases, each
taking 18 months. During the first treatment phase, patients receive intensive partial hospitalization
treatment, five days a week. In the second phase, after-care treatment is provided, consisting of one
session of individual psychotherapy and one session of group psychotherapy weekly. This

treatment is
relatively expensive and therefore it is justified to do a state of the art cost effectiveness study as
proposed in this application. In the study by Bateman and Fonagy such an extensive cost analysis was
not performed.

Contacts

Public
Arkin
Jack J.M. Dekker
Klaprozenweg 111
Amsterdam 1033NN
The Netherlands
Scientific
Arkin
Jack J.M. Dekker
Klaprozenweg 111
Amsterdam 1033NN
The Netherlands

Eligibility criteria

Inclusion criteria

A severe BPD on the basis of standardised criteria for borderline personality disorder and assessed with the Dutch version of the Structured Clinical Interview for DSM-III-R (SCID-II) (13), and the Borderline Personality Disorder Severity Index (BPDSI) (14). Patients must meet the criteria for borderline personality disorder as determined with the SCID-II and have a total score on the BPDSI of at least 24, indicating a severe BPD. Patients with co-morbid personality disorders will not be excluded.

Exclusion criteria

Patients will be excluded if they meet one of the following criteria:

1. Schizophrenia, as determined with the SCID-I;

2. Bipolar disorder, as determined with the SCID-I;

3. Substance addiction requiring specialist treatment;

4. Organic brain disorder;

5. Mental impairment (IQ < 80);

6. Inadequate mastery of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	108
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-01-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33534
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2058
NTR-old	NTR2175
CCMO	NL26308.097.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33534

Study results

Summary results
N/A