A randomized controlled study of the efficacy of an intensified, partial inpatient adaptation of Dialectical Behavior Therapy (DBT) for a population of Borderline patients (young adults/adults:18 - 40), compared with standard outpatient DBT

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Main objectives: to compare the effect of a short term intensive DBT treatment program (3 months) with the effect of outpatient DBT, (1) in terms of reduction of suicidal and/or self-destructive behaviour and (2) with regard to reduction of severity...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational non invasive

Summary

ID

NL-OMON35751

Source
ToetsingOnline

Brief title
Inpatient intensified adaptation of DBT vs standard outpatient DBT

Condition

- Personality disorders and disturbances in behaviour

Synonym
severe emotional disturbance, severe personality disorder, suicidal/ selfdestructive behavior

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Rivierduinen
Source(s) of monetary or material Support: GGZ Rivierdinen

Intervention

Keyword: Borderline Personality Disorder, DBT, Partial inpatient treatment

Outcome measures

Primary outcome

Main study parameter is the number of suicide attempts/self-destructive acts (measured by the Life Time Parasuicide Count and The Borderline Personality Severity Index). We expect that after 12 weeks 20% of the patients of the intervention group still show suicidal and/or self-destructive behaviour compared to 60% of the patients in the control condition, and that this difference sustains at 24 weeks and will gradually be reduced between 24 and 52 weeks.

Secondary outcome

Second study parameter is the severity of borderline symptomatology (as measured by the BPDSI), reduced BPDSI scores. The results on the SF-36 (Quality of life), on the BSI (psychopathological symptoms) and on the IDS-SR (depression), part of the Routine Outcome Monitoring of Rivierduinen, will be taken into account also. We expect a stronger decline in LPC scores and in BPDSI general symptomatology scores in the first 4 months, and that these differences sustain at 24 weeks and will gradually be reduced between 24 and 52

weeks.

Study description

Background summary

The efficacy of Dialectical Behavior Therapy (DBT) in reducing suicidal and self-destructive behaviour with chronically suicidal borderline patients, within six to twelve months, has been firmly established in more than seven RCT*s. The reduction of this life threatening behaviour (i.e. learn to regulate emotions and control impulses), enhances the quality of life of the patients and opens the opportunity to solve the problems that have resulted in the problem behaviour in the first place. Therefore, the faster the reduction takes place, the better. DBT is an outpatient program. It is hypothesized that intensification of the program, by giving the patients partial inpatient treatment for 4 months, will accelerate the reduction of the suicidal and self-destructive behaviour.

Study objective

Main objectives: to compare the effect of a short term intensive DBT treatment program (3 months) with the effect of outpatient DBT, (1) in terms of reduction of suicidal and/or self-destructive behaviour and (2) with regard to reduction of severity of general BPD symptomatology.

Study design

A randomized controlled trial with four measurement occasions; baseline (before randomization), and 12, 24 and 52 weeks after the start of the treatment.

Study burden and risks

The program has been carried out since October 2009 as a pilot. Even though it was expected that the burden associated with participation would be higher for participants, mainly because they have to live together in a group, results show that patient drop out equals the drop out found in standard DBT, nor has there been any suicide. Therefore the burden or risk does not seem to be higher than in standard DBT (or other evidence based programs for BPD like Mentalisation Based Treatment).

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

(young) adult borderline patients with severe suicidal and selfdestructive behavior with al least 6 out of 9 diagnostic criteria of the DSM-IV TR of the bordeline personality disorder, with a Borderline Personality Disorder Severity Index total score of at least 24.

Exclusion criteria

IQ < 80, a chronic psychotic condition, bipolar disorder, hard drug abuse and a forced treatment framework.

Study design

Design

Study type:	Observational non invasive
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):	20-02-2012
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL35714.058.11