

Dialectical Behavior Therapy for men with borderline personality disorder and antisocial behavior

Submission date 02/06/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 11/09/2014	Overall study status Completed	
Last Edited 25/06/2020	Condition category Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Dialectical behavior therapy (DBT) is a psychological treatment that is known to work well for women with borderline personality disorder (BPD). It has been developed from cognitive behavior therapy (CBT) but modified to meet the needs of people with BPD. CBT focuses on helping people change unhelpful ways of thinking and behaving. DBT does this too, but it also encourages people to accept who they are and includes elements of mindfulness, a mind-body approach developed to help people change how they think about experiences and how to reduce feelings of stress and anxiety. However, to date, there has been a lack of DBT-treatment studies looking at how it may help men with BPD being treated in outpatient clinics. Here, we will look at how well DBT performs when treating men with BPD with a history of anti-social behavior. We want to know to what extent 12 months of DBT might reduce suicidal, impulsive and antisocial behaviors, how much it improves psychological well-being and whether it is considered useful by the participants involved. We also want to investigate variables that might influence the effect of the treatment.

Who can participate?

Men with a diagnosis of borderline personality disorder and antisocial behaviors within Stockholm Psychiatry

What does the study involve?

After the diagnosis of BPD has been made, participants are asked to self-record their antisocial and impulsive behaviors for 4 weeks before the treatment starts. They also attend an interview where they recall their antisocial behavior. They then start a 12 month course of DBT therapy, where they learn how to manage their emotional reactions and destructive behaviors. Participants are asked to self-record their antisocial/impulsive behaviors and attend further interviews 6 months after the treatment starts and at the end of treatment.

What are the possible benefits and risks of participating?

All participants receive intensive DBT treatment, which is known to be helpful for women with BPD. Based on earlier studies, we expect the treatment to help most participants reduce their self-harming, impulsive and anti-social behaviors.

Where is the study run from?

The treatment will be conducted at two psychiatric outpatient clinics in Stockholm.

When is the study starting and how long is it expected to run?

December 2013 to December 2016

Who is funding the study?

Swedish Prison and Probation Service (Sweden)

Who is the main contact?

Pia Enebrink, Ph.D.

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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171 65

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effectiveness trial of Dialectical Behavior Therapy for men with borderline personality disorder and antisocial behavior

Study objectives

1. What effect does Dialectical Behavior Therapy (DBT) have on self-injurious behavior, depression, anxiety, as well as antisocial, criminal behaviors for men with borderline personality disorder?
2. How do participants experience the treatment, and are there any components of the treatment they find particularly helpful?
3. What is the potential cost-effectiveness of the intervention?
4. Which variables predict (moderators), or explain (mediators) the outcome of DBT?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The regional ethical committee in Stockholm, 06/03/2012, ref. 2012/91-31/4

Study design

Intervention study with within-subjects design

Primary study design

Interventional

Secondary study design

Other

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Borderline personality disorder

Interventions

Dialectical Behavior Therapy. DBT is based on cognitive behavior therapy (CBT) with the addition of acceptance and mindfulness practices. In treatment, participants learn skills to manage their intensive emotional reactions and destructive behaviors. The treatment is characterized by a combination of individual sessions and skills treatment in group and telephone support for the client, and supervision for the therapists. The treatment lasts for 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Structured interviews collecting data on earlier antisocial behaviors using the Timeline Follow Back Method
2. Daily registration of antisocial behaviors: participants will register antisocial and impulsive behaviors during a 4-week baseline period before treatment starts, as well as throughout the treatment period
3. Swedish National Centre for Crime Prevention, reported offenses

Secondary outcome measures

Self-ratings:

1. Beck Depression Inventory II (BDI)
2. Beck Anxiety Inventory (BAI)
3. Alcohol use disorders identification test (AUDIT)
4. Drug use disorders identification test (DUDIT)
5. Karolinska affective and borderline symptom scale- self rating (KABOSS-S)
6. ASEBA-ASR (Adult Behavior Checklist)
7. DBT-skills rating scale
8. Health and occupation survey

Questionnaire for relatives:

1. ASEBA-ABCL (Adult Behavior Checklist)

Therapist ratings:

1. Attendance of therapy sessions
2. Homework completion

Overall study start date

09/12/2013

Completion date

31/12/2016

Eligibility

Key inclusion criteria

Men with borderline personality disorder and antisocial behavior

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

32

Total final enrolment

Key exclusion criteria

1. Psychotic disorder
2. Severe substance abuse
3. Autistic disorders

Date of first enrolment

09/12/2013

Date of final enrolment

31/12/2016

Locations**Countries of recruitment**

Sweden

Study participating centre**Division of Psychology**

Solna

Sweden

171 65

Sponsor information**Organisation**

Swedish Prison and Probation Service (Sweden)

Sponsor details

Kriminalvården

601 80 Norrköping

Norrköping

Sweden

601 80

Sponsor type

Government

ROR

<https://ror.org/04030gz13>

Funder(s)

Funder type
Government

Funder Name
Swedish Prison and Probation Service (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	25/06/2020	Yes	No