

# Mentalisation-Based Treatment for Dual Diagnoses

<b>Submission date</b> 26/03/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/09/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

Mentalisation-Based Treatment for Dual Diagnoses: a randomised controlled trial

**Acronym**

MBTDD

**Study objectives**

Current hypothesis as of 10/12/2014:

The main hypothesis is that mentalisation-based treatment (MBT) as a complement to standard dependency care is a more efficacious treatment than standard dependency care alone in patients with borderline personality disorder and concomitant substance dependence.

Previous hypothesis:

The main hypothesis is that mentalisation-based treatment (MBT) as a complement to medication assisted treatment (MAT) for opiate dependence is a more efficacious treatment than current practice (MAT for opiate addiction alone) in patients with borderline personality disorder and concomitant opiate dependence.

On 10/12/2014 the overall trial end date was changed from 01/04/2012 to 30/06/2015.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Regional Ethical Review Board in Stockholm, 13/06/2007, ref: 2007/642-31/1

**Study design**

Randomised parallel-group rater-blinded clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Current condition as of 10/12/2014:

Borderline personality disorder with substance dependence (dependence on alcohol, amphetamines, cannabis, cocaine, hallucinogens, opioids, phencyclidine, sedatives/hypnotics /anxiolytics, or poly-substance – present or in remission)

Previous condition:

Borderline personality disorder with opiate dependence (present or in remission)

**Interventions**

Current interventions as of 10/12/2014:

Intervention group:

Mentalisation-based treatment (MBT) as a complement to standard dependency care. MBT in accordance to manual consists of mentalising focus work in an individual session and a group session once per week. The duration of treatment is 18 months. Therapists' adherence and competence will be examined based on video-taped therapy sessions.

Control group:  
Standard dependency care.

Previous interventions:

Intervention group:

Mentalisation-based treatment (MBT) as a complement to medication-assisted treatment (MAT) for opiate dependence. MBT in accordance to manual consists of mentalising focus work in an individual session and a group session once per week. The duration of treatment is 18 months. Therapists' adherence and competence will be examined based on video-taped therapy sessions.

Control group:

Medication assisted treatment (MAT) for opiate dependence alone.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The Borderline Personality Disorder Severity Index, 4th Edition (BPDSI-IV).

The main effect concerns change from baseline to termination of treatment (18 months). Intent-to-treat analysis by last observation carried forward will be used and the statistical analysis will be ANOVA with repeated measures.

## **Key secondary outcome(s)**

1. Timeline Follow Back and specimens of urine for use of opiates, alcohol and other drugs
2. Beck's Suicidal Intent Scale (SIS)
3. Deliberate Self-Harm Inventory (DSHI-9)
4. Global Assessment of Functioning (GAF)
5. Symptom Check List 90 (SCL-90)
6. Inventory of Interpersonal Problems (IIP), short version
7. Social Adjustment Scale - Self Report (SAS-SR)
8. Retention in treatment
9. Reflective Functioning Interview (for mediator analysis)

The measures are used at baseline and at 6-monthly intervals until the end of treatment. Follow up: 6 and 18-months after endpoint.

Long-term follow up from register data:

10. Health economy (health care utilisation and work/income)
11. Criminality
12. Survival

## **Completion date**

30/06/2015

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 10/12/2014:

Participant inclusion criteria

1. Aged 18 - 65 years, either sex
2. Provide written informed consent to participate in the study
3. Address and telephone number in Stockholm County where the patient can be reached
4. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) criteria for borderline personality disorder
5. Meet DSM-IV criteria for substance dependence (dependence on alcohol, amphetamines, cannabis, cocaine, hallucinogens, opioids, phencyclidine, sedatives/hypnotics/anxiolytics, or poly-substance – present or in remission)
6. Ongoing dependency care at a dependency care outpatient unit (for patients with opiate dependence, ongoing pharmacological treatment with buprenorphine or methadone for at least 3 months)

Previous inclusion criteria:

1. Aged 18 - 65 years, either sex
2. Provide written informed consent to participate in the study
3. Address and telephone number in Stockholm County where the patient can be reached
4. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) criteria for borderline personality disorder
5. Meet DSM-IV criteria for opiate dependence (present or in remission)
6. Ongoing pharmacological treatment with buprenorphine or methadone for at least 3 months

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

46

### **Key exclusion criteria**

1. Meet DSM-IV criteria for schizophrenia, schizoaffective disorder or bipolar I disorder, (other psychotic or mood disorders do not constitute exclusion criteria)
2. Mental retardation or borderline intellectual functioning (intelligence quotient [IQ] less than 85)
3. Autistic disorder or Aspergers disorder
4. Psychopathy according to Psychopathy Checklist: Screening Version (PCL-SV)
5. Psychotherapy outside the research project, which is ongoing or terminated less than three months ago

Added 10/12/2014:

6. Not able to communicate in Swedish without help from an interpreter

**Date of first enrolment**

13/05/2009

**Date of final enrolment**

20/12/2013

## Locations

**Countries of recruitment**

Sweden

**Study participating centre****Center for Dependency Disorders**

Stockholm County Council

Box 17914

Stockholm

Sweden

SE-11895

## Sponsor information

**Organisation**

Stockholm County Council (Sweden)

**ROR**

<https://ror.org/02zrae794>

## Funder(s)

**Funder type**

Government

**Funder Name**

Swedish Council for Working Life and Social Research (Sweden) (ref: 2007-0457)

**Alternative Name(s)**

Swedish Council for Working Life and Social Research, FAS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Sweden

**Funder Name**

Stockholms Läns Landsting

**Alternative Name(s)**

Stockholm County Council

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

**Funder Name**

Karolinska Institutet

**Alternative Name(s)**

Karolinska Institute, KI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2018	01/09/2020	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes