# Mentalisation-Based Treatment for Dual Diagnoses

Submission date	Recruitment status  No longer recruiting	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>		
26/03/2009				
Registration date	Overall study status	Statistical analysis plan		
08/05/2009	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
01/09/2020	Mental and Behavioural Disorders			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Björn Philips

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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). Intentto-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 polysubstance 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?
	Results article	results	01/04/2018	01/09/2020	Yes	No
	Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
	Study website	Study website	11/11/2025	11/11/2025	No	Yes