

Mentalisation-Based Treatment for Dual Diagnoses

Submission date 26/03/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 08/05/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/09/2020	Condition category Mental and Behavioural Disorders	☐ 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

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

Primary study design

Interventional

Study design

Randomised parallel-group rater-blinded clinical trial

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?
Results article	results	01/04/2018	01/09/2020	Yes	No

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes