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Mentalisation-Based Treatment for Dual Diagnoses

Submission date	Recruitment status
26/03/2009	No longer recruiting
Registration date	**Overall study status**
08/05/2009	Completed
Last Edited	**Condition category**
01/09/2020	Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.beroendecentrum.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (in Swedish)

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2 x 40 patients

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)

Sponsor details
c/o Johan Franck
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SE-11895

Sponsor type
Government

Website
http://www.beroendecentrum.se

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

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

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