

Randomised controlled trial of manualised outpatient individual and group therapy for borderline personality disorder

Submission date 12/10/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/09/2016	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effectiveness of intensive out-patient psychotherapy for treatment of borderline personality disorder: a pragmatic randomised single blind controlled study

Study objectives

Mentalisation based treatment (MBT) when delivered in an out-patient NHS clinical service by mental health professionals who receive limited training is a more effective treatment for suicidal and self-harming patients with borderline personality disorder (BPD) than current best practice. Structured and coherent practice is considered to be a component of effective practice when treating patients with BPD. To control for the non-specific effects of a structured treatment the comparison group will receive a protocol-driven manualised treatment with structured clinical management representing best current clinical practice with equivalent supervision.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Barnet, Enfield and Haringey Local Research Ethics Committee, formerly Enfield and Haringey Health Authority Local Research Ethics Committee, June 1999/January 2007, ref: 658. Ethics approval for 5-year follow-up applied for to Barnet, Enfield and Haringey Local Research Ethics Committee.

Study design

Pragmatic randomised single-blind controlled study, single centre

Primary study design

Interventional

Secondary study design

Randomised controlled 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

Health condition(s) or problem(s) studied

Borderline personality disorder

Interventions

Mentalisation based therapy (MBT) compared with structured clinical management (SCM):

1. MBT consists of mentalising focus work in an individual session and a group session once per week
2. SCM consists of advocacy work, problem solving in an individual session and a group session once per week

The duration of treatment is 18 months and the follow-up is over a 5-year period.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The presence or absence or frequency in a 6-month period of severe parasuicidal behaviour as indicated by:

1. Suicide attempt
2. Life-threatening self-harm
3. Hospital admission. Hospital is included because in general mental health services patients with BPD are primarily offered in-patient care in anticipation of suicide attempts and during episodes of severe self-harm.

Secondary outcome measures

1. Psychiatric symptoms
2. Social and interpersonal function

Measured at baseline and at 6-monthly intervals to the end of treatment and then yearly over the follow-up period.

Overall study start date

03/03/2003

Completion date

31/07/2012

Eligibility

Key inclusion criteria

1. Diagnosis of BPD
2. Suicide attempt or episode of severe self-harm within last six months
3. Aged 18 - 65 years, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Currently in a long term psychotherapeutic treatment
2. Meet Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for psychotic disorder or bipolar I disorder
3. Have opiate dependence with physiological dependence requiring specialist treatment
4. Have mental impairment or evidence of organic brain disorder

Date of first enrolment

03/03/2003

Date of final enrolment

31/07/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Ann's Hospital

London

United Kingdom

N15 3TH

Sponsor information

Organisation

Barnet, Enfield and Haringey Mental Health Trust (UK)

Sponsor details

c/o Dr Gerry Leavey/Dr Eric Sabine

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Sponsor type

Hospital/treatment centre

Website

<http://www.beh-mht.nhs.uk/>

ROR

<https://ror.org/00d2v4e22>

Funder(s)

Funder type

Research organisation

Funder Name

Borderline Personality Disorder Research Foundation (USA)

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	01/12/2009		Yes	No
Results article	results	01/09/2013		Yes	No
Results article	results	30/08/2016		Yes	No