

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

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

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

### **Study type(s)**

Treatment

### **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(s)**

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.

**Key secondary outcome(s))**

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.

**Completion date**

31/07/2012

## **Eligibility**

**Key inclusion criteria**

1. Diagnosis of BPD2
2. Suicide attempt or episode of severe self-harm within last six months
3. Aged 18 - 65 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**St Ann's Hospital**

London

United Kingdom

N15 3TH

## Sponsor information

**Organisation**

Barnet, Enfield and Haringey Mental Health Trust (UK)

**ROR**

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

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Borderline Personality Disorder Research Foundation (USA)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/12/2009		Yes	No
<a href="#">Results article</a>	results	01/09/2013		Yes	No
<a href="#">Results article</a>	results	30/08/2016		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes