

# Pilot study of the efficacy of a psychosocial intervention for frequent parasuicide attempters with personality disturbance

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/02/2008	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

### Study objectives

A pilot study will test the efficacy of a new psychological treatment for patients seen after an episode of deliberate self-harm (parasuicide or attempted suicide). The treatment is based on a self-treatment manual (suicide behaviour prevention manual) developed by us from previous work by Linehan and Davidson on the cognitive treatment of patients with borderline and anti-social personality disorder. Although the previous treatment has been shown to be successful in reducing episodes of deliberate self-harm it is very intensive and not suitable for general use. Our treatment comprises one session of explanation of the manual followed by a maximum of five further sessions of treatment using a psychoeducational and problem solving approach to suicide behaviour.

60 patients aged between 16 and 40 living in Paddington, Marylebone, Chelsea and Kensington will be seen after an episode of deliberate self-harm who have at least one previous suicide attempt in the past year and qualify for personality disturbance (either difficulty or disorder) in one of the flamboyant categories (histrionic, borderline, impulsive, anti-social). They will be randomised to treatment as usual or to the experimental group and treated for up to three months. Assessment of health service costs, suicide intent and acts, mood disturbance and social functioning will be made before randomisation and after six months by an independent research psychologist.

If the treatment is found to be successful an application will be made to the MRC for a larger study in a population with less restrictive entrance criteria.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration.

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

## **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Mental and behavioural disorders: Other mental disorder

### **Interventions**

1. Psychological treatment using a psychoeducational and problem solving approach to suicide behaviour: manual-assisted cognitive-behaviour therapy (MACT)
2. Standard care

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

The main outcome measures will be the time of the next parasuicide act (using Linehan's definition of this, which is more minor than an actual suicide attempt). Our expectation is that our experimental treatment will extend this from a mean of three weeks to a mean of three months and this will require a sample size of 30 in each treatment group.

### **Secondary outcome measures**

1. Time to first suicidal act
2. Rate of suicidal acts
3. Change in anxiety and depressive symptoms

### **Overall study start date**

01/01/1996

### **Completion date**

31/12/1998

## **Eligibility**

### **Key inclusion criteria**

Efficacy of a new brief manualised form of cognitive behaviour therapy in those with personality disturbance within the flamboyant (cluster B) group. Thirty four patients were enrolled and 32 (18 MACT; 14 TAU) were seen at follow-up.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

**Target number of participants**

34

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/01/1996

**Date of final enrolment**

31/12/1998

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St Mary's Hospital Medical School**

London

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## **Sponsor information**

**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

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**Sponsor type**

Government

**Website**

http://www.doh.gov.uk

## Funder(s)

**Funder type**

Government

**Funder Name**

NHS Executive London (UK)

## 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?
<a href="#">Results article</a>	Results	01/01/1999		Yes	No