

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

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

Contact name
Prof Peter Tyrer

Contact details
St Mary's Hospital Medical School
Patterson Centre
20 South Wharf Road
London
United Kingdom
W2 1PD
+44 (0)20 7886 1648
p.tyrer@ic.ac.uk

Additional identifiers

Protocol serial number
RDC00388

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

St Mary's Hospital Medical School

London

United Kingdom

W2 1PD

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

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?
Results article	Results	01/01/1999		Yes	No