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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
22/02/2008

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
United Kingdom
W2 1PD

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

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?
Results article	Results	01/01/1999		Yes	No