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Prevention Of Parasuicide by Manual Assisted Cognitive-behavioural Therapy

Submission date	Recruitment status
23/10/2000	No longer recruiting
Registration date	**Overall study status**
23/10/2000	Completed
Last Edited	**Condition category**
12/09/2007	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9702283

Study information

Scientific Title

Acronym
POPMACT

Study objectives
To determine whether manual assisted cognitive behaviour therapy (MACT) is more effective than treatment as usual (TAU) in reducing the rate of episodes of deliberate self harm over a 12 month period

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)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Parasuicide

Interventions
1. Manual assisted cognitive behaviour therapy (MACT)
2. Treatment as usual (TAU)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Rate of episodes of deliberate self-harm (using the Parasuicidal Acts Scale of Linehan) over the 12 month period

Secondary outcome measures
1. Time to next episode of deliberate self-harm
2. Improvement in clinical symptoms (anxiety and depression) using the Hospital Anxiety and Depression Scale (HADS)
3. Change in social function (using the Social Functioning Questionnaire)
4. Cost of care

Overall study start date
01/12/1997

Completion date
01/10/2001

Eligibility

Key inclusion criteria
Patients presenting to the psychiatric services at any of five centres:
1. Southern General Hospital, Victoria Hospital and Stobhill Hospital in Glasgow
2. Royal Edinburgh Hospital, Edinburgh
3. Queen's Medical Centre, Nottingham
4. Chelsea and Westminster Hospital and St Mary's Hospital, West London
5. King's College Hospital, South London and Maidstone General Hospital, Kent

Patients will be included if they satisfy the following criteria:
1. Aged between 16 and 65
2. Have presented to an Accident & Emergency department after an episode of deliberate self-harm
3. They have had at least one other episode of deliberate self-harm previously
4. They give informed consent

Recruitment will take place over 20 months and randomisation of each patient will take place after all baseline assessments have been completed by the research assessor

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria

1. Patients who do not have sufficient knowledge of English to enable them to be assessed adequately and to understand the treatment manual
2. Patients who are only temporary residents in the area concerned (e.g. foreign visitors, tertiary referrals with a permanent address elsewhere) who are unlikely to be available for follow-up (This does not necessarily include many people who are homeless but who come from the geographical area concerned; this group is at high risk of repeated episodes and constitutes around one in six of all parasuicide episodes and many will be included if they have established links in the geographical area)
3. Those with a diagnosis within the organic (F00 to F09), alcohol/drug dependence (F10 to F19), schizophrenia group (F20 to F29) or bipolar affective disorder (F31) (using the International Classification of Diseases [ICD-10] coding)
4. People who require psychiatric hospitalisation after their self-harm episode. Recruitment will take place over 20 months and randomisation of each patient will take place after all base-line assessments have been completed by the research assessor

Date of first enrolment
01/12/1997

Date of final enrolment
01/10/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Department of Psychiatry
London
United Kingdom
W2 1PD

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom

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+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
UK Medical Research Council

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	01/02/2004		Yes	No