ISRCTN97313434 https://doi.org/10.1186/ISRCTN97313434

Prevention Of Parasuicide by Manual Assisted Cognitive-behavioural Therapy

Submission date	Recruitment status	[ ] Prospectively registered
23/10/2000	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/09/2007	Mental and Behavioural Disorders	

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
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

Study type(s)
Not Specified

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
UK Medical Research Council

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	01/02/2004		Yes	No