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BOrderline personality disorder Study of COgnitive Therapy trial

Submission date	Recruitment status
22/07/2005	No longer recruiting
Registration date	**Overall study status**
22/07/2005	Completed
Last Edited	**Condition category**
26/11/2012	Mental and Behavioural Disorders

[ ] Prospectively registered
[X] 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

ClinicalTrials.gov (NCT)
NCT00538135

Protocol serial number
064027; 01/27

Study information

Scientific Title
A randomised controlled trial of cognitive therapy plus treatment as usual versus treatment as usual in the treatment of borderline personality disorder

Acronym
BOSCOT

Study objectives
We anticipate that the addition of cognitive behavioural therapy to treatment as usual (CBT plus TAU) in participants with borderline personality disorder will decrease the number of participants with in-patient psychiatric hospitalisations or accident and emergency room contact or suicidal acts over twelve months treatment and twelve months follow-up, compared with treatment as usual (TAU). We also anticipate that CBT plus TAU will lead to superior improvement in quality of life, social, cognitive and mental health functioning compared to TAU alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of Greater Glasgow Primary Care NHS Trust gave approval on the 15th August 2001

Study design
Multicentre, randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Borderline personality disorder

Interventions
Those participants who met the inclusion criteria and who agreed to give written informed consent to take part in the study then completed baseline assessments and were randomly allocated to either one of two active treatment groups namely, TAU, or CBT plus TAU.

Interventions:
CBT is a structured, time limited, psycho-social intervention which has been developed to treat those with Cluster B personality disorder. Patients are encouraged to engage in treatment through a formulation of their problems within a cognitive framework.

Interventions focus on the patient's beliefs and behaviour that impair social and adaptive functioning. Up to 30 sessions (minimum 15) of treatment, each lasting up to one hour, are required to work on long-standing problems and develop new ways of thinking and behaving. Priority is given to behaviours that cause harm to self or others. In addition, participants received the usual treatment they would have received if the trial had not been in place.

Treatment as usual:
All participants received the standard treatment (TAU) they would have received if the trial had not been in place. It was thought that all participants would be in contact with mental health services and would have some contact with Accident and Emergency services for repeated self-harm episodes. TAU will be documented carefully after each patient exits the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Acts of deliberate self-harm in the twelve months prior to baseline, and the twelve months following baseline. Trial participants are being assessed on all measures at six monthly intervals.

Key secondary outcome(s))
1. Brief Symptom Inventory
2. Beck Depression Inventory-II
3. State-Trait Anxiety Inventory
4. Social Functioning Questionnaire
5. Inventory of Interpersonal Problems
6. Schema Questionnaire
7. The Euro-Qol quality of life questionnaire
8. Client Service Receipt Inventory (CSRI)

Trial participants are being assessed on all measures at six monthly intervals, except for the Schema Questionnaire and the Brief Symptom Inventory, where both are assessed at end of treatment and end of follow-up only.

Completion date
01/10/2004

Eligibility

Key inclusion criteria
1. Aged between 18 and 65, either sex
2. Met criteria for at least five items of the borderline personality disorder using the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV) Axis II Personality Disorders (SCID -II)
3. Had received either in-patient psychiatric services or an assessment at Accident and Emergency services or an episode of deliberate self-harm (either suicidal act or self-mutilation) in the previous 12 months
4. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Currently receiving in-patient treatment for a mental state disorder
2. Currently receiving a systematic psychological therapy or specialist service, particularly psychodynamic psychotherapy
3. Insufficient knowledge of English to enable them to be assessed adequately and to understand the treatment approach
4. Temporarily resident in the area
5. The existence of an organic illness, mental impairment, alcohol or drug dependence, schizophrenia or bipolar affective disorder, as assessed by SCID I, /P (W/Psychotic Screen) (version two)

Date of first enrolment
01/02/2002

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Glasgow Institute of Psychosocial Interventions
Glasgow
United Kingdom
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Sponsor information

Organisation
University of Glasgow (UK)

ROR

https://ror.org/00vtgdb53

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 064027)

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	cost-effectiveness results	01/10/2006		Yes	No
Results article	effectiveness results	01/10/2006		Yes	No
Results article	six year follow up results	01/12/2010		Yes	No
Protocol article	Protocol	01/10/2006		Yes	No