

BOrderline personality disorder Study of COgnitive Therapy trial

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 26/11/2012	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

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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

Primary study design

Interventional

Study design

Multicentre, randomised controlled trial

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

G12 0XH

Sponsor information**Organisation**

University of Glasgow (UK)

ROR

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