

Cognitive behaviour therapy for low self-esteem

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| Submission date 06/02/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 17/02/2012 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 02/10/2017 | 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

Background and study aims

Low self-esteem (LSE) has been shown to be both a consequence and a cause of psychiatric problems and is distressing and debilitating in its own right. As such, it is a frequent target for treatment in cognitive-behavioural interventions, yet it has rarely been the main focus of therapy. A cognitive-behavioural treatment (CBT) programme for LSE has been developed. CBT is a talking therapy that can help you manage your problems by changing the way you think and behave. While case studies suggest that this treatment approach may be an effective way to treat LSE, it has not yet been systematically evaluated. This study aimed to compare how well 10 sessions of individual CBT with workbooks for LSE works in patients with a full range of psychiatric diagnoses. The impact of CBT was measured using measures of self esteem, depression, anxiety and general functioning, as well as psychiatric diagnoses. The study also aimed to find out whether any treatment gains were maintained at a 10-week follow-up assessment.

Who can participate?

Patients aged 18 or older with LSE

What does the study involve?

Participants are randomly allocated to either begin treatment immediately or after a 10-week delay. All participants receive 10 sessions of CBT, taking place over 10 weeks. The appointments each last around 50 minutes and take place at the University of Reading Medical Practice. The first four sessions are twice weekly, the following four sessions are weekly and the final two sessions are fortnightly. Treatment involves trying to make sense of participants' LSE and identifying and modifying the beliefs and behaviours keeping it going. They work together with the therapist as a team and a crucial part of treatment is carrying out tasks between sessions, such as keeping a diary or experimenting with doing things differently. In order to monitor progress, they are asked to fill in some questionnaires at the beginning of each session. During the research they are asked not to change any medication that they are taking. Sessions are taped to ensure that the treatment was the best possible and participants get a copy to ensure that they get the most out of treatment.

What are the possible benefits and risks of participating?

The study involves treatment for LSE. While treatment sessions may involve discussing potentially upsetting situations, sessions are carried out with a qualified clinical psychologist. A

possible burden might be the time required to carry out the assessments and post-treatment and follow-up assessments. However, efforts are made to accommodate participants' schedules and set up appointments at times that are most convenient for them.

Where is the study run from?

University of Reading Medical Practice (UK)

When is study starting and how long is it expected to run for?

March 2008 to December 2008

Who is funding the study?

British Association for Behavioural and Cognitive Psychotherapies (UK)

Who is the main contact?

Dr Polly Waite

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Contact information

Type(s)

Scientific

Contact name

Dr Polly Waite

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

v2: 11.01.08

Study information

Scientific Title

Cognitive behaviour therapy for low self-esteem: a preliminary randomized controlled trial in a primary care setting

Study objectives

1. Compared to waitlist, cognitive behaviour therapy (CBT) for low self-esteem (LSE) will lead to greater improvements in self-esteem, anxiety, depression, and general functioning and a greater reduction in psychiatric diagnoses
2. Any treatment gains from CBT for LSE will be maintained at a follow-up assessment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Berkshire Research Ethics Committee, February 2008, ref: 07/H0505/196

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Low self-esteem

Interventions

1. Immediate treatment: 10 sessions of CBT delivered one-to-one, with accompanying workbooks
2. Ten week waitlist followed by above treatment

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The Robson Self-Concept Questionnaire (RSCQ; Robson, 1989)

Secondary outcome measures

1. The Structured Clinical Interview for DSM-IV Disorders (SCID-I-RV; First, Spitzer, Gibbon & Williams, 2002)
2. The Beck Depression Inventory-II (BDI-II; Beck, Steer & Brown, 1996)
3. The Beck Anxiety Inventory (BAI; Beck & Steer, 1990)
4. The Clinical Outcomes in Routine Evaluation "C Outcome Measure (CORE-OM; Evans, Connell, Barkham, Margison & McGrath, 2002)

Overall study start date

05/03/2008

Completion date

31/07/2009

Eligibility

Key inclusion criteria

1. Clinically significant low self-esteem as evidenced by:
 - 1.1. A score of more than one standard deviation below the mean on the Robson Self-Concept Questionnaire (RSCQ) (Robson, 1989)
 - 1.2. Psychological difficulties that interfered with functioning as evidenced by scoring outside the 'healthy' range on the Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM) (Evans, Connell, Barkham, Margison & McGrath, 2002)
2. If taking medication, this needs to be at a stable dosage for the preceding 6 weeks before being assessed for the trial

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Having been diagnosed with a psychotic illness
2. If severity of symptoms or suicidality meant that allocation to a delayed treatment condition would be unethical

Date of first enrolment

05/03/2008

Date of final enrolment

01/12/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Reading

Reading

United Kingdom

RG6 6AL

Sponsor information

Organisation

University of Reading (UK)

Sponsor details

c/o Dr Mike Proven

Research & Enterprise Services

Reading

England

United Kingdom

RG6 6AL

Sponsor type

University/education

Website

<http://www.reading.ac.uk/qar/index.htm>

ROR

<https://ror.org/05v62cm79>

Funder(s)

Funder type

Research organisation

Funder Name

British Association for Behavioural & Cognitive Psychotherapies [BABCP] (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 | 01/12/2012 | | Yes | No |