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Two different versions of cognitive behaviour therapy for body dysmorphic disorder

Submission date	Recruitment status	[ ] Prospectively registered
31/03/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/03/2016	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

ClinicalTrials.gov (NCT)
NCT00871143

Study information

Scientific Title
A randomised controlled trial of two different versions of cognitive behaviour therapy for body dysmorphic disorder

Study objectives
The hypotheses to be tested are that:
1. Specific cognitive behavioural therapy (CBT) for body dysmorphic disorder (BDD) will be more effective than non-specific CBT at 12 weeks
2. Treatment effects from specific CBT will be maintained at 1 month, 3 months and 1 year follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint South London and Maudsley and the Institute of Psychiatry Research Ethics Committee (REC), 23/03/2009, ref: 09/H0807/9

Primary study design
Interventional

Study design
Single-centre single-blinded parallel-group randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Body dysmorphic disorder

Interventions
CBT specific for BDD:
A pilot study 12 years ago has demonstrated a significant benefit of CBT over a waiting list. The mean reduction was about 50% on the primary outcome measure (YBOCS for BDD). This consisted of a reduction of 12 points and a standard deviation of 7 on the YBOCS for BDD and the treatment is now thought to be better than in 1996.

CBT not specific for BDD:
Stress management and cognitive restructuring, which has been shown to be a credible alternative psychological treatment to CBT in health anxiety. However, in two pilot cases of BDD, the benefits were minimal with a reduction of between zero and 10% on the YBOCS for BDD. At the most this equates to a maximum of 3 points reduction.

The treatments are provided over 12 weeks (twice a week for the first 4 weeks and once a week for 8 weeks). For CBT specific to BDD there will be three follow-up sessions at 1 and 3 months and at 1 year, making a maximum total of 19 sessions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Yale Brown Obsessive Compulsive Scale (modified for BDD) (BDD-YBOCS), which will be done by a blind assessor at 12 weeks.

Key secondary outcome(s)
Two observer-rated scales:
1. Brown Assessment of Beliefs to measure the strength of conviction in beliefs about being ugly
2. Montgomery Asberg Depression rating scale

Five brief self-rated scales:
1. The Body Image Quality Of Life (BIQL) inventory, which is a disorder-specific quality of life measure and used in BDD
2. Depression (nine-item Patient Health Questionnaire [PHQ9])
3. Anxiety (Generalised Anxiety Disorder Assessment [GAD7])
4. Appearance Anxiety Inventory (AAI)
5. EQ5-D, a measure of health-related quality of life

Patients will be reassessed on all measures at 6 and 12 weeks. Patients in the CBT specific for BDD group will be assessed at 1 month, 3 months and 1 year following treatment. In addition, the PHQ9, GAD7 and AAI are measured weekly for case tracking during treatment. The primary end-point is at 12 weeks. Patient preference as to treatment group and their expectations and beliefs about treatment (pre- and post-) will also be recorded.

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. BDD is the main psychological problem. We will use Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria as BDD does not exist as a separate diagnosis in the International Classification of Disease, version 10 (ICD-10). They may have an additional diagnosis of delusional disorder when it refers to beliefs about being ugly or defective.
2. They must have a total of 24 or more on the twelve-item Yale-Brown Obsessive Compulsive Scale (YBOCS) modified for BDD
3. They may be of either gender but must be 17 years or above
4. They are willing to travel to the treatment centre for weekly sessions
5. They are willing to complete regular questionnaires and be audiotaped for supervision and for listening to enhance their learning
6. They may be taking psychotropic medication so long as it is stabilised and there are no plans to increase the dose

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. They have a current or past diagnosis of schizophrenia, bipolar affective disorder
2. They have current suicidal intent or severe self-neglect that requires hospitalisation
3. They have a current alcohol or substance dependence or anorexia nervosa or borderline personality disorder that requires treatment in its own right
4. They are currently receiving any other form of psychotherapy
5. They have received CBT for BDD in the past 6 months, which is judged as competently delivered and did not respond
6. They cannot speak sufficient English for CBT (assistance will be provided for those who speak English but are unable to read questionnaires)

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Anxiety Disorders and Trauma
London
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Sponsor information

Organisation
Institute of Psychiatry, Kings College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
Institute of Psychiatry, Kings College London (UK) - Biomedical Research Centre for Mental Health (ref: PAXKAYR)

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	01/02/2014		Yes	No
Basic results				No	No