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Cognitive-behaviour therapy for adolescents with body dysmorphic disorder

Submission date	Recruitment status	[ ] Prospectively registered
23/08/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/10/2015	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacinda Cadman

Contact details
Michael Rutter Centre for Children
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ
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Jacinda.Cadman@slam.nhs.uk

Additional identifiers

Protocol serial number
11503

Study information

Scientific Title
A pilot randomized controlled trial of cognitive-behaviour therapy for children and adolescents with body dysmorphic disorder

Study objectives
This is a pilot study to develop a specific CBT protocol for Body Dismorphic Disorder (BDD) in children and adolescents and to test the efficacy of this intervention via a pilot randomised controlled trial (RCT). Existing adult CBT protocol will be modified to suit young people with BDD and their families. The study will randomly allocate 30 young people with BDD to:

1. A BDDspecific CBT protocol involving 14 sessions over 4 months, or
2. A waitist control group comprising a psychoeducation package.

All patients will be followed up for 12 months after the end of the treatment. The results and study protocol/materials will be widely disseminated. The results will provide crucial efficacy data which will form the solid basis for future phase III/IV effectiveness trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11/LO/1605

Primary study design
Interventional

Study design
Randomised interventional trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Personality disorders

Interventions
CBT, Cognitive Behaviour therapy (CBT) designed for young people with BDD, and their families. The current trial involves 14 CBT sessions over 4 months and 4 follow up sessions over 12 months.
Follow Up Length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The Yale Brown Obsessive Compulsive Scale Modified for BDD Adolescent Version (BDD-YBOCS-A) 2. Admin to all participants at pre, mid, and post-intervention and at 2, 6, and 12 months follow-up.

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Age 12 to 18
2. DSM-IV diagnosis of BDD (they may have an additional diagnosis of Delusional Disorder when it refers to beliefs about being ugly or defective)
3. Score of 24 or higher on the 12-item BDDY-BOCS, indicating substantial symptom severity
4. Stable psychotropic medication for 12 weeks prior to randomisation (if relevant)
5. No plans to commence or increase the dose of psychotropic medication (if relevant)
6. Willingness to receive psychological treatment
7. Willingness to be randomised to a waitlist/psychoeducation control condition
8. Willingness/ability to travel to the clinic for CBT
9. Male and female participants
10. Aged between 12 - 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Current or past diagnosis of schizophrenia or bipolar affective disorder, current alcohol or substance dependence, severe disabling neurological disorder, global learning disability, pervasive developmental disorder, or an emerging borderline personality disorder that requires treatment in its own right
2. The patient has suicidal intent that requires hospitalisation
3. English too poor to engage in treatment; characteristics interfering with completion of treatment e.g. selective mutism, lack of motivation, unable to attend clinic.

Date of first enrolment
15/02/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Michael Rutter Centre for Children
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (UK) ref: PB-PG-0110-21231

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				

Results article	01/11/2015	Yes	No