

Cognitive-behaviour therapy for adolescents with body dysmorphic disorder

Submission date 23/08/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/10/2015	Condition category Mental and Behavioural Disorders	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Dysmorphic 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 waitlist 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

Study design

Randomised interventional 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 below to request a patient information sheet

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 measure

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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

15/02/2012

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

Age group

Child

Lower age limit

12 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 30

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**

England

United Kingdom

Study participating centre

Michael Rutter Centre for Children

London

United Kingdom

SE5 8AZ

Sponsor information**Organisation**

King's College London (UK)

Sponsor details

Institute of Psychiatry

Department of Psychology

Henry Wellcome Building

16 De Crespigny Park

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England
United Kingdom
SE5 8AF

Sponsor type
University/education

Website
<http://www.kcl.ac.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

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	01/11/2015		Yes	No