

# Cognitive-behaviour therapy for adolescents with body dysmorphic disorder

<b>Submission date</b> 23/08/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/08/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2015	<b>Condition category</b> 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

**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 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 BDD-specific 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

## **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