# Randomised controlled trial of cognitive behavioural treatment of obsessional compulsive disorder in children and adolescents.

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
08/01/2010	Mental and Behavioural Disorders			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Tim Williams

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

**SPGS 808** 

# Study information

#### Scientific Title

#### **Study objectives**

To evaluate the efficacy of cognitive behavioural treatment for children and adolescents with obsessive compulsive disorder. OCD is a severely handicapping chronic relapsing psychological disorder with affects 0.5% to 2% of the population. 50% of adults with OCD develop the condition in adolescence, and 50% of the children with OCD continue to be disabled by it in adulthood. Although cognitive behavioural treatment (CBT) is the first choice treatment in childhood according to recent consensus guidelines, there has only been one RCT in adolescents and children. That study suffers from difficulties of interpretation and used a less powerful form of CBT than the best currently used with adults. RCTs in adulthood have found that 70% of patients with OCD benefit from CBT, and remain well following the end of treatment. Research Objectives: To carry out a trial of a manulised cognitive behavioural treatment for obsessional compulsive disorder in children and adolescents, in order to ensure that it is effective in reducing the level of symptoms. To investigate the extent of the improvements in functioning resulting from the treatment method and compare them with the effects of time spent waiting for treatment.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Other

# Study type(s)

Treatment

#### Participant information sheet

# Health condition(s) or problem(s) studied

Obsessive compulsive disorder (OCD)

#### **Interventions**

- 1. Cognitive behavioural treatment
- 2. Waitlist control

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

The clinical status of the children and adolescents will be the main focus of the trial. The following tools will be used:

- 1. KIDDIE-SADS or equivalent semi-structured interview used to assess Mental state of the children
- 2. YBOCS (child version) used to measure obsessional compulsive symptoms by interview
- 3. Obsessive compulsive Inventory (OCI) self-report measure of OCD
- 4. Responsibility Interpretation Questionnaire (RIQ) self-report to measure cognitions specific to the treatment methods
- 5. Children's Depression Inventory (CDI)
- 6. Multidimensional Anxiety Scale for children (MASC) self report
- 7. National Institute of Mental Health (NIMH) global obsessive compulsive scale

Following the example of most other studies in this field the YBOCS total score is considered to be the main focus of analysis.

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/10/1999

#### Completion date

30/03/2002

# **Eligibility**

#### Key inclusion criteria

Children and adolescents aged between 8 years and 18 years of age in full time education with obsessional compulsive disorder defined by research diagnostic criteria and whose medication has remained stable for 12 weeks prior to entry to trial.

#### Participant type(s)

**Patient** 

#### Age group

Child

#### Lower age limit

8 Years

#### Upper age limit

18 Years

#### Sex

Both

#### Target number of participants

21 (added 08/01/10, see publication)

#### Key exclusion criteria

Children with severe learning disabilities or severe language difficulties - because the treatment requires the use of verbal reasoning skills at the eight year plus level

#### Date of first enrolment

01/10/1999

#### Date of final enrolment

30/03/2002

# Locations

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre

3 Craven Road

Reading United Kingdom RG1 5LF

# Sponsor information

## Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

#### Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

# Sponsor type

#### Government

#### Website

http://www.doh.gov.uk

# Funder(s)

# Funder type

Government

#### Funder Name

NHS Executive South East (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	01/05/2010		Yes	No