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

Submission date 23/01/2004	**Recruitment status** No longer recruiting
Registration date 23/01/2004	**Overall study status** Completed
Last Edited 08/01/2010	**Condition category** Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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
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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