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A pilot study of D-cycloserine-augmented cognitive behavioural therapy (CBT) with exposure therapy in adolescents with obsessive-compulsive disorder (OCD)

Submission date
22/12/2008

Registration date
05/02/2009

Last Edited
25/11/2013

Recruitment status
No longer recruiting

Overall study status
Completed

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 and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RAA2008-014

Study information

Scientific Title
A randomised double-blind placebo-controlled pilot study of D-cycloserine-augmented exposure therapy in adolescents with obsessive-compulsive disorder

Study objectives
The principal research objective is to establish the clinical effectiveness of D-cycloserine- (DCS-) augmented cognitive behavioural therapy (CBT) for children and adolescents with obsessive-compulsive disorder (OCD). Our hypothesis is that the effectiveness of CBT for OCD, and speed of recovery, can be improved by the addition of a small dose of DCS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kings College Hospital Research Ethics Committee (REC) gave approval in December 2008 (ref: 08/H0808/203)

Study design
Single-centre double-blind randomised controlled 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
Obsessive-compulsive disorder

Interventions
The trial will consist of two arms. In the first arm, young people will receive cognitive behaviour therapy with a small dose of D-cycloserine (50 mg) given after sessions 3 to 12. In the second arm, young people will receive cognitive behaviour therapy with a placebo pill given after sessions 3 to 12.

Total duration of treatment in both arms is 14 weeks, and total duration of follow-up in both arms is 12 months, with follow-up evaluations planned to occur at 3 months, 6 months, and 12 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
D-cycloserine

Primary outcome measure
Children's Yale Brown Obsessive Compulsive Scale (CYBOCS), a well-validated clinician administered measure of OCD severity. For each arm, this measure will be administered at the beginning of each session, and again at 3 months, 6 months and 12 months post-treatment.

Secondary outcome measures
1. Diagnosis of OCD as determined with:
1.1. The Anxiety Disorders Interview Schedule for DSM-IV (ADIS), the Child Obsessive-Compulsive Inventory (ChOCI), child and parent versions
1.2. The Strengths and Difficulties Questionnaire (SDQ), child and parent versions
1.3. The Beck Depression Inventory for Youth (BDI-Y)
1.4. The Depression Anxiety and Stress Scale (DASS) for parents
1.5. The Family Accommodation Scale (FAS)
2. Additional process variables include measures of trait anxiety (RCMAS), threat perception (CARBQ-C/P), subjective anxiety (SUDS ratings), behavioural avoidance tasks (BATs), physiological arousal (heart rate variability) and the Patient Exposure Adherence Scale (PEAS)
3. Behavioural Avoidance Task (BAT). A single task, single-step BAT will be administered. The task will be described to the child using standardised instructions. The BAT is an individually tailored task in which the young person is asked to expose him/herself to a situation that usually causes him/her significant distress or results in compulsive rituals.
4. Subjective units of distress (SUDS). Young people will be asked to rate their subjective distress at various time points during the BAT task, based on an 8-point Likert scale thermometer (0 = none to 8 = extreme).
5. Heart Rate Variability (HRV). HRV is a measure of the beat-to-beat variations in heart rate. It is calculated by analysing a time series of beat-to-beat intervals from a heart rate monitor. HRV is an indicator of autonomic arousal, and there is a known relationship between HRV and emotional arousal. HRV has been shown to be sensitive to the emotion of fear in most people. Therefore HRV will be used as a measure of physiological arousal in relation to the BAT task. HRV will be measured using a Polar heart rate monitor (FT80). A heart rate monitor consists of two elements: a chest strap transmitter and a wrist receiver (a sports watch). The chest strap has electrodes in contact with the skin to monitor electrical voltages in the heart.
6. Cognitive and Avoidant Response Bias Questionnaire - Child and Parent Versions (CARBQ-C /P). Threat perception and coping expectations in response to both generic, non-salient situations as well as to personally salient situations (i.e. situations that the young person perceives to be anxiety provoking) will be measured using the Cognitive and Avoidant Response Bias Questionnaire (CARBQ). It is also of interest to examine parents (mothers) levels of threat perception and coping expectations for their child.

Secondary outcome measures will be completed at 3 months, 6 months and 12 months post-treatment.

Overall study start date
01/02/2009

Completion date
28/02/2010

Eligibility

Key inclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) diagnosis of OCD
2. Aged 12 to 18 years
3. Either sex
4. Any ethnicity, religious background or sexual orientation
5. Referred to the National and Specialist OCD Clinic at Maudsley Hospital
6. If on medication, this should be stable for 12 weeks and not be changed during the course of the trial
7. Provision of written informed consent (patient and carer)

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
24, with 12 in each arm of the trial

Key exclusion criteria
1. Current diagnosis of psychosis, current alcohol or substance abuse/dependence
2. English too poor to engage in treatment
3. Severe disabling neurological disorder
4. Medical contraindication to cycloserine, including epilepsy and porphyria
5. A diagnosed global learning disability or pervasive developmental disorder
6. Characteristics interfering with completion of treatment, e.g. life threatening or unstable medical illness
7. Pregnancy
8. Not suitable for CBT (selective mutism, lack of insight or motivation for change)

Date of first enrolment
01/02/2009

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
Institute of Psychiatry, Kings College London (UK)

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Sponsor type
Research organisation

Website
http://www.iop.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Biomedical Research Centre for Mental Health (ref: PAXKAYI)

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	01/01/2014		Yes	No
HRA research summary			28/06/2023	No	No