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Information processing, neuropsychological, and neurobiological processes in pediatric obsessive-compulsive disorder

Submission date 26/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/09/2006	**Overall study status** Completed	
Last Edited 10/03/2008	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

Information-processing:
1. Changes in measures of severity of Obsessive-Compulsive Disorder (OCD) are explained (partially) by changes in measures of meta-cognitions (explicit and/or implicit)
2. Changes in measures of meta-cognitions (explicit and implicit) precede changes in measures of severity of OCD

Neuropsychological processes:
1. Changes in measures of severity of OCD are explained (partially) by changes in measures of inhibition of attentional processes
2. Changes in measures of inhibition precede changes in measures of severity of OCD

Neurobiological processes:
1. Volumes of prefrontal cortex and striatum, activity of anterior cingulate, orbitofrontal region and striatum differ from healthy controls and change during treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive-Compulsive Disorder (OCD)

Interventions
1. 16 weekly sessions Cognitive Behavioral Therapy (CBT)
2. Waitlist (eight weeks) followed by 16 weekly sessions CBT

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Severity of OCD (CY-BOCS, measured at the start of the waitlist condition, directly before start of the CBT, session eight, 16 and follow up after 16 weeks)
2. Anxiety/Depression (Revised Child and Anxiety Depression Scale [RCADS]) measured at the start of the waitlist, directly before start of the CBT, at the end of the therapy (session 16) and follow up after 16 weeks)

Key secondary outcome(s)

1. Information-processing (explicit: Revised 44 item version of the Obsessive-Beliefs Questionnaire scale [OBQ-44 R], Meta-Cognitions Questionnaire for Adolescents [MCQ-A], Implicit: Implicit Association Procedure [IAP]) (measured at the start of the waitlist, directly before start of the CBT, session eight and 16 and follow up after 16 weeks)
2. Inhibition/selective attention (dot-probe, measured at the start of the waitlist, directly before start of the CBT, session eight and 16 and follow up after 16 weeks)
3. Neuroimaging data: volumes grey and white matter, activity on planning (tower of London), selective attention (Flanker) and inhibition (dot-probe) task in fMRI

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Children and adolescents eight to 18 years
2. Primary diagnosis: Obsessive Compulsive Disorder (OCD)
3. OCD symptoms for more than six months
4. Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) total score more than 16
5. IQ (Intelligence Quotient) more than 80
6. Informed consent of parents and child

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
Use of the following medication:
1. Selective Serotonin Reuptake Inhibitor (SSRI)
2. Tricyclic Antidepressant (TCA)
3. Anti-psychotic medication

For neurobiological measures (functional Magnetic Resonance Imaging [fMRI]):
1. Claustrophobia
2. Metal on body

Date of first enrolment
01/09/2006

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
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1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)
Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration