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

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

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

N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/09/2006

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

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
45

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
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details

P.O. Box 22660
Amsterdam
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1100 DD

Sponsor type
Hospital/treatment centre

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, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

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