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

Contact name

Ms L H Wolters

Contact details

Academic Medical Center (AMC)
Department of Child and Adolescent Psychiatry
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 5662242
L.h.wolters@amc.uva.nl

Additional identifiers

Protocol serial number 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

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 Netherlands 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, AMC

Funding Body Type

Private sector 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