

Mediators and moderators of cognitive behavioral therapy for childhood anxiety disorders: information processing, emotion regulation and stress reactivity

Submission date 26/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Mediators and moderators of cognitive behavioral therapy for childhood anxiety disorders: information processing, emotion regulation and stress reactivity

Study objectives

1. Changes in outcome measures of anxiety can be partly explained by changes in:
 - a. self-reported thoughts
 - b. selective attention and by changes in fear relevant cognitive schema's
2. Changes in outcome measures of anxiety can be partly explained by changes in:
 - a. self-reported emotion regulation strategies
 - b. processes of attention regulation and by changes in underlying schema's of 'perceived control'
3. Effortful control will moderate the treatment effect
4. Executive functions will moderate the relation between mediators and the treatment effect. The treatment effect will be larger when executive functions are more developed
5. Stress-reactivity will moderate the treatment effect
6. Stress-reactivity is a vulnerability factor for developing an anxiety disorder and is an effect of an anxiety disorder
7. Part of the variance in treatment effect can be explained by family characteristics (parents psychopathology and parenting style) and characteristics of the therapist

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

Anxiety disorders

Interventions

Group one: 12 sessions of Cognitive Behavioural Therapy (CBT) according to the Coping Cat manual.

Four measure points: before therapy, after eight sessions, after therapy and after 12 week follow-up period.

Group two: Eight week Waiting List (WL) group. Children will receive the same therapy as group one after the waiting period.

Five measure points: before waiting list, before therapy, after eight sessions of therapy, after therapy and after 12 week follow-up period

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Effect of treatment (diagnosis of anxiety disorder and scores on anxiety questionnaires)
2. Mediating effect of information processing
3. Mediating effect of emotion regulation
4. Moderating effect of effortful control, executive functions and stress-reactivity

Secondary outcome measures

1. Correlation between explicit and implicit measures
2. Development of implicit measures

Overall study start date

01/09/2006

Completion date

01/09/2008

Eligibility

Key inclusion criteria

1. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) anxiety disorder as primary diagnosis
2. Age between seven and 18 years
3. Intelligence Quotient (IQ) more than or equal to 80
4. Informed consent from parents and child

Participant type(s)

Patient

Age group

Child

Lower age limit

7 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

120

Total final enrolment

145

Key exclusion criteria

1. Psychosis
2. Obsessive compulsive disorder as primary disorder
3. Post-traumatic stress disorder as primary disorder
4. Acute stress disorder
5. Drug and/or alcohol problems
6. Selective mutism
7. Current treatment with Selective Serotonin Reuptake Inhibitor (SSRI) or treatment with SSRI within half a year before inclusion
8. Psychotherapeutic treatment within the last half year

Date of first enrolment

01/09/2006

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 AL

Sponsor information

Organisation

Academic Medical Center

Sponsor details

PO Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type

University/education

Website

<https://www.amc.nl/web/Zorg.htm>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

University/education

Funder Name

Universiteit van Amsterdam

Alternative Name(s)

University of Amsterdam, UvA

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Funder Name

Accare (The Netherlands)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013	06/01/2021	Yes	No