ISRCTN46352117 https://doi.org/10.1186/ISRCTN46352117

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

Registration date
26/09/2006

Overall study status
Completed

Last Edited
06/01/2021

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

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
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
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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