

# Cognitive processes and the development of psychopathology in children at risk for anxiety disorders.

Published: 30-01-2008

Last updated: 07-05-2024

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<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31703

### Source

ToetsingOnline

### Brief title

Cognitive processes in children

### Condition

- Anxiety disorders and symptoms

### Synonym

anxiety disorders

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Katholieke Universiteit Nijmegen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cognitive bias, developmental psychopathology, high risk children, parental anxiety disorder

## Outcome measures

### Primary outcome

The main parameters are the level of the interpretation bias (as measured with the number of negative interpretations on ambiguous stories and the number of negative interpretations upon hearing ambiguous words), the attentional bias (as measured with speed of naming colors of threatening versus neutral words), the association between different stimuli (reaction times for valenced words and pictures), the level of anxiety (as measured with questionnaires), and the development of psychopathology (as measured with a diagnostic interview).

### Secondary outcome

We include as covariates constructs that are related to child anxiety: behavioural inhibition, perceived control, parenting style, attachment style, child depression, parental psychopathology and socio-economic status.

## Study description

### Background summary

This study addresses Children of Parents with an Anxiety Disorder (CPAD). They are at increased risk to develop an anxiety disorder somewhere in life. Little is known of the risk-factors that contribute to the vulnerability for anxiety disorders in these children.

Distortions in information processing seem to play a major role in the maintenance of anxiety disorders, but studies on causality are almost entirely lacking. By studying non anxious high risk children with a longitudinal design we can relate cognitive biases to later level of anxiety, adding evidence on the hypothesized causal role of cognitive biases. This knowledge is of greatest

importance scientifically as well as for possible prevention. The proposed study investigates associations between threat-related stimuli and biases in the perception of threat and selective attention to threat-stimuli in CPAD\*s. A follow-up of 2 years enables us to prospectively relate the cognitive bias to later level of anxiety.

This study will add to knowledge on risk factors for anxiety disorders, so that children at risk may be more precisely targeted and appropriate (preventive) interventions may be developed.

## **Study objective**

Goal of the study is to establish evidence on cognitive biases in a high risk population and on the longitudinal impact of such biases. We hypothesize that CPAD\*s show biases in their information processing when compared to control children. We expect that priming of fear relevant schema\*s lead to increased threat perception in children who do not have an anxiety disorder yet. We furthermore expect that especially the CPAD\*s who do show biases in their information processing are at higher risk to develop an anxiety disorder or symptoms of anxiety in the course of follow-up as compared to children without such a bias.

## **Study design**

Longitudinal observational study with matched controls to test for differences in performance on a number of computer tasks (indirect measures) that measure distortions in information processing (Ambiguous Story Task, Emotional Stroop Task, Auditory Interpretation Task, Affective Priming Task). Follow-up will be two years, with 1 assessment per year (the first year via questionnaires, the second again with the indirect measures), to investigate the relationship between cognitive distortions in information processing and future level of anxiety.

## **Intervention**

One of the computertasks, the Ambiguous Story Task, presents short stories that do not have an ending and include ambiguous information. Children are asked to finish the stories. During this task, a prime is added to activate a potential cognitive fear network in the children, through which their perceptions of the stories may be altered. The prime consists of three video fragments of a panic disordered, social phobic and a spider phobic woman. They describe their feelings, actions and thoughts when confronted with a fear provoking event. We expect that exposure to the prime in vulnerable children may activate their latent information processing biases, whereas we do not expect a priming effect (or a smaller priming effect) in the control children. The prime is considered to be an intervention because it may affect the children's behaviour, resulting in more negative interpretations of the stories in the Ambiguous Story Task.

The effect of the prime is neutralized by showing video fragments of a therapist that describes the treatment for social phobia, panic disorder and spider phobia.

## **Study burden and risks**

We consider the risk of serious adverse events due to our materials or design to be minimal, and we will register and report on any incidents that occur. Particularities of this study that may give rise to some concern about their impact are outlined in the following:

The first assessment consists of a diagnostic interview, questionnaires, and the computer tasks. This assessment will be spread over 2 appointments of 90 minutes to avoid weariness. The appointments will take place at the outpatient anxiety or can take place at their homes to minimize the travelling time for participants.

For a number of children, the diagnostic interview will result in a diagnosis of a psychiatric disorder. A psychologist will inform those children and their parents on the nature of the disorder and will advise them on the possibilities for treatment (in accordance with the multidisciplinary guidelines for treatment of anxiety disorders). The treatment advice will depend on the perceived burden of the disorder by the child and his parents.

During the Ambiguous Story Task, children will be exposed to three two-minute videos of three different women who describe their fear for spiders, fear for social situations or panic attacks. This priming is necessary to activate a potential latent fear network in children without symptoms of anxiety. After the children have completed the computer task, the priming will be neutralized by showing a video of a therapist describing the treatment of the disorders. Priming paradigms are often used in studies with adults, showing no harmful effects. In children, we know of only one study that used a prime (similar to the prime in the proposed study), no adverse effects were reported (Schneider et al., 2002).

The Emotional Stroop Task and the Affective Priming Task both measure reaction times on fearful versus non fearful stimuli, the use of these tests with normal, as well as clinically anxious children is common in experimental psychopathology research and no adverse effects are known. Usually, children tend to enjoy the computer tasks.

The proposed study is group related, as we can only investigate the structure of the information processing and its abnormalities in children at risk for anxiety disorder by examining this specific group.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Children of parents with an anxiety disorder are included when:

- at least one parent has a panic disorder or a social phobia as the primary disorder
- age 8 - 12
- attending primary school or high school

Control children are included when

- both parents do not have an anxiety disorder
- age 8 - 12
- attending primary school or high school

### Exclusion criteria

Children of parents with an anxiety disorder are excluded if:

- they attend a special school, relating to learning disabilities/handicaps; Control children are excluded if:
- they attend a special school, relating to learning disabilities/handicaps

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	223
Type:	Anticipated

## Ethics review

Not approved	
Date:	30-01-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

### Register

CCMO

### ID

NL21357.000.08