

# Cognitive behavioural treatment of children and adolescents with anxiety disorders: optimising treatment based on patient characteristics

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/04/2011	<b>Condition category</b> 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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

5484 (NFGV); NTR347

# Study information

## Scientific Title

## Study objectives

1. Group cognitive behavioural treatment is as effective as individual cognitive behavioural treatment
2. Treatment outcome is predicted by severity of the psychopathology, cognitive variables, social variables, biological variables and environmental variables
3. Children diagnosed with an anxiety disorder after the first phase of treatment will respond to prolongation of the treatment with active participation of parents

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from the local medical ethics committee

## Study design

Randomised, active controlled, parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Anxiety disorders

## Interventions

1. Individual cognitive behavioural treatment
2. Group cognitive behavioural treatment

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

1. Diagnostic status
2. Anxiety symptoms

**Secondary outcome measures**

1. Depressive symptoms
2. Other symptoms of psychopathology
3. Global level of functioning

**Overall study start date**

01/09/2002

**Completion date**

01/12/2006

## **Eligibility**

**Key inclusion criteria**

1. Children and adolescents between 8 and 16 years old
2. Primary diagnosed with at least one of following Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM IV) anxiety disorders: separation anxiety disorder, social phobia, generalised anxiety disorder or specific phobia

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

8 Years

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

180

**Key exclusion criteria**

1. Intelligence Quotient (IQ) less than 85
2. Children who are not proficient in the Dutch language
3. Somatic disease
4. Drug related disorder
5. Pervasive developmental disorder
6. Selective mutism

7. Psycho-somatic disease
8. Schizophrenia or other psychotic disorder
9. Obsessive compulsive disorder
10. Post-traumatic stress disorder
11. Acute stress disorder
12. Use of medication for anxiety
13. Concurrent psychotherapy

**Date of first enrolment**

01/09/2002

**Date of final enrolment**

01/12/2006

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Academisch Centrum Kinder - en Jeugdpsychiatrie Curium

Oegstgeest

Netherlands

2342 AK

## **Sponsor information**

**Organisation**

Leiden University Medical Centre (LUMC) (Netherlands)

**Sponsor details**

Albinusdreef 2

P.O. Box 9600

Leiden

Netherlands

2300 RC

**Sponsor type**

University/education

**Website**

<http://www.lumc.nl/>

**ROR**

<https://ror.org/027bh9e22>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands) - Revolving Fund

## Funder Name

National Fund for Public Mental Health (Nationaal Fonds Geestelijke Volksgezondheid [NFGV]) (The Netherlands)

## Funder Name

Sophia Foundation for Scientific Research (The 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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No