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

Submission date	Recruitment status	Prospectively registered		
20/12/2005	No longer recruiting	☐ Protocol		
Registration date 20/12/2005	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
06/04/2011	Mental and Behavioural Disorders			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Adelinde J.M. van der Leeden

Contact details

Academisch Centrum Kinder - en Jeugdpsychiatrie Curium Endegeesterstraatweg 27 Oegstgeest Netherlands 2342 AK +31 (0)71 515 9600 A.J.M.van.der.Leeden@umail.leidenuniv.nl

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 1. Diagnostic status
- 2. Anxiety symptoms

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

16 years

Sex

Αll

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

Study participating centre
Academisch Centrum Kinder - en Jeugdpsychiatrie Curium
Oegstgeest
Netherlands
2342 AK

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011		Yes	No