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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
06/04/2011

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

Contact name
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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?
Results article	results	01/01/2011		Yes	No