# Family- versus child-alone CBT for children with anxiety disorders.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27870

**Source**
NTR

**Brief title**
N/A

**Health condition**

Anxiety disorders in children and adolescents.

### Sponsors and support

**Primary sponsor:** Academic Hospital Maastricht and University of Maastricht
**Source(s) of monetary or material Support:** This study was financially supported by a grant from ZonMw, the Netherlands organisation for health research and development, grant number 945-02-052.

### Intervention

### Outcome measures

**Primary outcome**

The treatment that cures most of the referred, anxiety disordered children, is considered as the most effective treatment. Therefore, the percentage of children free from anxiety disorders is the primary outcome variable. Anxiety disorders are assessed by means of the

(semi)Structured Anxiety Disorder Interview Schedule (ADIS; Silverman & Albano, 1996). Parents and child are interviewed separately concerning the possible mental disorders of the child, by research assistants with clinical experience, who are blind to the treatment condition of the child. Another operationalisation of cure of child anxiety disorders is by means of a child anxiety questionnaire, filled in by both the anxious child and its parents. The SCARED self- and parent report (Muris et al., 1999) and the STAIC (Spielberger, 1973) are used for this purpose. Finally, fear and avoidance ratings of the child's 5 target situations is used as an idiosyncratic, illness-specific measure.

**Secondary outcome**

The following secondary measures are used. The referred child's general psychopathology, general functioning, and quality of life, is assessed with the Child Behaviour Checklist (CBCL, Achenbach & Edelbrock, 1983) filled in by both parents separately. The degree to which the family benefits from the treatment, in terms of reduction of anxiety and psychopathology, is assessed as follows. By means of a (semi)Structured Anxiety disorder Interview for adulta (ADIS, DiNardo, Brown, & Barlow, 1994), each of the parents' own mental disorders are assessed, and by means of the ADIS the anxiety disorders of the siblings are measured. In addition, parents' self-reported anxiety are assessed using the State-Trait Anxiety Inventory (STAI, Spielberger et al., 1973) and the SCARED, and their general psychopathology by the SCL-90 (Arrindell & Ettema, 1983). Siblings also fill out the SCARED and STAIC.

Third, the following process measures are included. The functioning of the family is assessed with the Family Functioning Scale (Bloom, 1985), filled in by the referred child and the parents. Two aspects of parental attitudes toward child-rearing, that is, the degree to which parents overprotect their anxious child and discourage independent functioning, are measured by means of a new scale that consists of relevant items of four child rearing questionnaires (EMBU (Bogels et al., 2001), CRPBI (Shaefer & Shaefer), PBI () and MFP scale (Epstein, 1983)), filled in by the referred child and both parents. Such a new scale is made since the reliability of the now existing instruments is poor, probably as a result of too little items for each scale. The new scale is constructed on the basis of factor-analytic research that is currently conducted. In addition, overprotection and autonomy encouragement are measured by a discussion task (see Siqueland et al., 1996). Parents and child engage in a discussion about a) a general hot item, and b) an item related to the fear of the child. The discussion is videotaped and parental autonomy granting and overprotection is rated by independent observers.

Dysfunctional thinking of the referred child is assessed by means of CATS (Schniering & Rapee, 2002) and by the child's conviction rating of its 5 main idiosyncratic dysfunctional beliefs, related to its fear. Dysfunctional thinking of the parents with respect to their anxious child is assessed with a new questionnaire developed by Bögels and Siqueland on the basis of idiosyncratically reported dysfunctional beliefs of parents during treatment.

The existence of anxiety psychopathology (that is, one or more current axis I anxiety diagnoses) in the parents is the predictor variable, and is measured by means of a ADIS-interview with both parents before treatment.

# Study description

**Background summary**

Purpose of the study:

Cognitive Behavioural Therapy (CBT) is the only evidence-based treatment that is effective for children with anxiety disorders. Three Australian studies have shown that the effect of CBT improves substantially as a result of the parents being involved in the therapy ("family CBT"). This effect was found specifically when parents were anxious themselves. These studies were conducted using children with anxiety disorders, which were recruited by advertisements. However, the question arises whether these results can be generalised to a clinical population of children and adolescents. The purpose of this multi-center study is to investigate the effects of child and family CBT and the possible excess value of family CBT in a clinical population of children and adolescents with anxiety disorders.

Research questions:

Is family CBT more effective than child CBT in treating anxiety disorders in children? Is family CBT especially more effective than child CBT when the parents are anxious themselves? Does the age of the child influence the effect of both therapies differently? Is family CBT more cost-effective than child CBT?

Study design:

Families are randomly assigned to a three-month waiting list (to control for spontaneous recovery), child CBT, or family CBT. The effectiveness of both active treatments is being evaluated immediately after the three-month therapy (12 sessions), and also at follow-up measurements, three months and one year after the therapy.

Study population/data resources:

Children aged 8 to 18 years, who are applied to one of the participating mental health centres, meeting the criteria of one or more of the following anxiety disorders as main diagnosis: separation anxiety disorder, social phobia, generalised anxiety disorder, panic disorder, agoraphobia, anxiety disorder not otherwise specified, and simple phobia , can participate in this study. Children with attention deficit hyperactivity disorder, a disorder out of the autistic spectrum, a psychotic disorder, and addictions, are excluded. The parents and, if possible, the siblings have to be willing to participate.

Interventions:

In child CBT, children are taught to detect and challenge their fear-maintaining dysfunctional thoughts, and with exposure they learn to overcome their fear. In family CBT, both parents and children are taught the principles of CBT, together. The parents use CBT skills to guide their child, and, if necessary, to overcome their own fears. Furthermore, the parents are taught to challenge their own dysfunctional thoughts about the fear of their child and how to cope with that, and work on the communication between the family members.

Outcome measurements:

The percentage children free from anxiety disorders, as measured by a standardised interview, is the primary outcome measurement. Anxiety disorders in parents and siblings are being measured as well. Furthermore, questionnaires measuring anxiety, psychopathology, and dysfunctional thinking are being administered. Besides these disease specific measurements, general functioning and quality of life of all family members are measured. Finally, several questionnaires and observations measure family functioning and upbringing.
Power/data analysis. 60 patients will be treated in each active treatment condition. This number is determined with power analysis on the basis of the effect sizes from the Australian studies. The parametric data are being analysed by multivariate repeated measurement variance-analysis, in which the effect of waiting versus treatment, and the effect of the two treatments is being compared. The non-parametric data are being analysed using Chi-quadrate tests.

Economic evaluation:

Economic health experts will carry out a cost effectiveness analysis to compare the costs and effects of both treatment forms. Both direct costs within the health care and indirect costs caused by lost productivity will be analysed. The effects of both treatments will be expressed

in the diminishment of anxiety complaints and the improvement of quality of life.

Time schedule:

During the first quarter, the therapists will be trained and the pilot treatments will be carried out. The treatments will take place during 1 year and 9 months. The last year is preserved for follow-up measurements, data analysis, and compiling a report in the form of national and international publications.

**Study objective**

1. Is family CBT more effective than child CBT in treating childhood anxiety disorders in a clinical population?

2. Is family CBT especially more effective in case the parents suffer from anxiety disorders themselves?

3. Does age of the child influence the effects of both treatments differently?

4. Is family CBT more cost-effective than child CBT?

**Study design**

All measures are conducted at pre-treatment, posttreatment, 3-month follow-up and 1 year follow-up, except for the video-taped family discussion, that is organised solely at pre-test and post-test.

**Intervention**

General aspects of the two treatments. Both treatments consist of 1 pre-session with the therapist for assessment purposes, 12 treatment sessions, and 2 follow-up sessions, 1 at 3-month and 1 at 1-year follow-up. A treatment manual as been developed for both the child and the family CBT, that consists of 40 pages. Also, a detailed treatment manual for the therapist is made. Manuals are available from the primary researcher on request.

The child CBT is a modified version of Kendall’s (1997) coping cat program, the modifications concern a more elaborated series of cognitive interventions, based on new developments concerning information processing biases of anxious children and the recognition of (even young) children of their ability to apply cognitive techniques, and leaving out the relaxation part of the program. The treatment consists of the following elements: (I) registration of the child’s idiosyncratic fear maintaining dysfunctional beliefs and avoidance behavior, (II)

challenging dysfunctional beliefs using the Socratic dialogue and experiments; and (III) graded exposure-in-vivo by means of a fear hierarchy and reinforcement schedule.
Parents are involved in the individual CBT 4 times: at start of the treatment, to explain the principles of CBT, at session 6, to inform them about the progress, to get feedback about how the child is doing at home, and to explain the principles of exposure and parental reward for exposure exercises, at session 12, to evaluate the results with them and to talk about relapse prevention, and at the 3-month follow-up, to evaluate the treatment progress. Also, parents are invited at the 1-year follow-up session.

The family CBT consists of three components: (I) dyadic treatment of child and parental anxious symptomatology; (II) modification of parents' dysfunctional beliefs about parenting and their role as parents; and (III) treating problematic family interactions (Ginsburg et al., 1995; Siqueland & Diamond; 1998). The first component consists of simultaneously teaching both parents and child how to reduce anxiety symptoms using CBT skills (described under individual CBT, I,II, & III). Also, parents learn to model courageous behavior and guide and reward their child's exposure efforts. In the second component, parents' beliefs about parenting and the anxiety of their child that interfere with age-appropriate upbringing and emotional coaching, are identified and changed. Examples of such beliefs are: "It is bad to use authority or force", " The only safe place is home", "I should protect my child against strong emotions". The third component consist of encouraging parents to grant their child(ren)'s autonomy, and instructing families better problem-solving and communication skills, related to fear items. Moreover, high conflict and poor communication between parents about how to handle their anxious child, that prevents them from working as a "team" to achieve treatment goals, is addressed alone with the parents.

Of the 12 treatment sessions, 2 are with the child alone, 2 are with child and parents, 5 are with the parents alone, and 3 are with the whole family. Also, parents are included in the follow-up sessions.

## Contacts

**Public**
Universiteit Utrecht
P.O. Box 80140

Denise Bodden
Utrecht 3508 TC
The Netherlands
030-2534744
**Scientific**
Universiteit Utrecht

P.O. Box 80140

Denise Bodden
Utrecht 3508 TC
The Netherlands
030-2534744

# Eligibility criteria

## Inclusion criteria

1. Children aged 8-18

a. who are referred to one of the in the study participating centres,

b. and have one of the following anxiety disorders as their primary diagnosis: separation anxiety disorder, social phobia, generalised anxiety disorder, panic disorder with/without agoraphobia, anxiety disorder not otherwise specified, or simple phobia, form the selected population.

## Exclusion criteria

1. Excluded are children with disorders of the autistic spectrum, a psychotic disorder, attention deficit disorder, and addiction disorders.

2. Children using psychopharmacological medication for their anxiety disorders are guided to stop medication before starting treatment.

3. The parents and siblings need to be willing to participate.

4. In case one of the parents or siblings cannot be motivated to participate, treatment can still be offered, if at least one parent wants to participate.

# Study design

## Design

Study type: Interventional

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2002 |
| Enrollment: | 120 |
| Type: | Actual |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 06-03-2008 |
| Application type: | First submission |

## 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 | ID |
|---|---|
| NTR-new | NL1159 |
| NTR-old | NTR1203 |
| Other | ZonMw : 945-020052 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**

1. Bodden, D. H. M., Dirksen, C. D., Bögels, S. M., Nauta, M. H., de Haan, E., Ringrose, J. Appelboom, C., Brinkman, A. G., Appelboom-Geerts, C. M. M. J. (In press). Costs and cost effectiveness of Family CBT versus individual CBT in clinically anxious children. Clinical Child Psychology and Psychiatry. <br>
<br>
2. Bodden, D. H. M., Dirksen, C. D., & Bögels, S. M. (In press). Societal Burden of Clinically Anxious Youth Referred for Treatment: A Cost-of-illness Study. Journal of Abnormal Child Psychology. J Abnorm Child Psychol. 2008 = May;36(4):487-97. Epub 2008 Jan 23.<br>
<br>