

Treatment for Anxiety Disorders in Youth: An Effectiveness Study of Individual versus Group
Cognitive Behavioral Therapy.

Objective Examined the effectiveness of cognitive behavior therapy (CBT) for youth anxiety disorders, and the comparative effectiveness of an individual (ICBT) and group (GCBT) approach.

Methods A randomized controlled trial conducted in seven community clinics enrolling a volunteer outpatient sample of 182 patients ($M = 11.5$ years, $SD 2.1$, range 8-15 years, 53% girls, 90% Caucasian) with separation anxiety, social phobia, or generalized anxiety disorder. The intervention was the 10-session FRIENDS manual. Youth were randomly assigned to ICBT, GCBT or a waitlist control condition (WLC). Youth still meeting the inclusion criteria after WLC were randomized to ICBT and GCBT. Pre-, post- and one year follow-up assessments included the Anxiety Disorder Interview Schedule, the Spence Children's Anxiety Scale and the Short Mood and Feelings Questionnaire.

Results Significantly more youth lost all anxiety disorders after CBT compared to WLC ($z = -3.3$, $p = .001$), although the diagnostic recovery rate (22.9%) was lower than reported in previous trials. Among patients receiving ICBT the diagnostic recovery rate was 25.3%, compared to 20.5% in GCBT ($z = 0.6$, $p = .53$). There were no significant differences between the effectiveness of ICBT and GCBT at post treatment or at one year follow-up.

Conclusion Findings support the effectiveness of CBT compared to no treatment in youth with anxiety disorders, with no differences between individual and group approach. However, full recovery was only observed in a minority of youth and indicates a need to further understand factors contributing to non-response in community clinics.

Keywords: cognitive behavior therapy, children, anxiety, treatment, effectiveness

Treatment for Anxiety Disorders in Youth: An Effectiveness Study of Individual versus Group Cognitive Behavioral Therapy.

Cognitive behavioral therapy (CBT) is classified as a “probably efficacious” treatment for anxiety disorders in children and adolescents when delivered both as an individual and as a group approach (Silverman, Pina, & Viswesvaran, 2008). Treatment gains have been maintained up to 13 years post treatment (Saavedra, Silverman, Morgan-Lopez, & Kurtines, 2010). The evidence for CBT’s efficacy rests mainly on randomized controlled trials (RCTs) conducted in specialized research clinics. Such efficacy trials are designed for extensive control of trial factors to increase internal validity; more control than what is typically possible in community clinics (McEvoy, Nathan, Rapee, & Campbell, 2012). This includes factors relating to therapists (e.g., highly skilled therapists with relatively small case loads; Weisz, Weiss, & Donenberg, 1992); clients (e.g., relatively homogeneous self-referred client samples with carefully diagnosed disorders; Weisz et al., 1992) and treatment context (e.g., staff and facilities dedicated to research; Southam-Gerow, Weisz, & Kendall, 2003; Weisz et al., 1992).

The methodological rigor of efficacy trials to ensure high internal validity is offset to some extent with respect to their external validity (La Greca, Silverman, & Lochman, 2009; Silverman et al., 2008; Weisz & Jensen, 2001). Consequently, there is need for effectiveness trials with referred patients who are treated by therapists working in community clinics (Silverman et al., 2008; Weisz & Jensen, 2001). Effectiveness studies are also important because they address questions about the transportability of evidence based treatments to community clinic practice (Kendall, Settapani, & Cummings, 2012).

To date, six randomized controlled effectiveness trials examining CBT for a heterogeneous set of anxiety disorders in children and adolescents (hereafter youth unless referring to a specific age group) have been published (Barrington, Prior, Richardson, & Allen, 2005; Bodden et al., 2008; Lau, Chan, Li, & Au, 2010; Nauta, Scholing, Emmelkamp, & Minderaa, 2001; 2003; Southam-Gerow et al., 2010). These effectiveness trials have focused primarily on comparing individual CBT

with and without cognitive parent training (Nauta et al., 2001; 2003), or comparing ICBT to treatment as usual (Barrington et al., 2005; Southam-Gerow et al., 2010). With the exception of a 28% diagnostic recovery reported for the family arm in Bodden et al. (2008), the reported diagnostic recovery rates from these trials are overall in line with what is reported in efficacy trials (i.e., 56%, James, Soler, & Weatherall, 2005). However, no comparative effectiveness trial of individual CBT (ICBT) and group CBT (GCBT) has yet been published.

There are both conceptual and practical reasons why evaluating group versus individual therapy is important. Group treatment is likely to offer more opportunities for corrective experiences such as normalization, positive peer modeling, reinforcement, social support, and exposure to social situations (Manassis et al., 2002), and may be more cost-effective than ICBT (Flannery-Schroeder, Choudhury, & Kendall, 2005; Silverman et al., 1999). On the other hand, individual treatment is likely to offer more opportunities for tailored treatments to address the specific needs of each patient (de Groot, Cobham, Leong, & McDermott, 2007) and avoidant behavior may be more readily managed (Liber et al., 2008; Silverman et al., 1999).

Despite the absence of comparative ICBT and GCBT effectiveness trials, four comparative efficacy trials have been published (de Groot et al., 2007; Flannery-Schroeder & Kendall, 2000; Liber et al., 2008; Manassis et al., 2002). None of these trials have reported significant differences between the two approaches, but some important limitations to these studies need to be considered. Three of the trials had an insufficient sample size to detect other than large differences between the two treatment approaches (de Groot et al., 2007; Flannery-Schroeder & Kendall, 2000; Manassis et al., 2002). One study did not report diagnostic outcome (Manassis et al., 2002), and two studies included no follow-up data (Liber et al., 2008; Manassis et al., 2002). Also, none of the studies adjusted their analyses for dependency among subjects in the group approach (i.e., partially nested design). The lack of addressing such clustering may have lead to spurious effects (Bauer, Sterba, & Hallfors, 2008).

Compared to youth treated in efficacy trials, youth referred to community clinics tend to have more comorbid externalizing disorders, more often to come from single-parent and low-income families, and to report more strenuous life events (Southam-Gerow, Chorpita, Miller, & Gleacher, 2008; Southam-Gerow et al., 2003). One may therefore argue that youth in community clinics are in greater need of individually tailored treatment, and that ICBT therefore could be advantageous for these youth.

Another important issue regarding both ICBT and GCBT for youth with separation anxiety disorder (SAD), social phobia (SOP) and generalized anxiety disorder (GAD), is whether youth with these different primary anxiety diagnoses respond differentially to treatment. Since Kendall's pioneering CBT trial in children (Kendall, 1994), most study samples have included a mix of SAD, SOP and GAD, and the effect of CBT has been evaluated collectively for these disorders. The main reason for this is that these disorders are viewed as manifestations of a common underlying anxiety construct, and therefore are treated in similar ways although some adjustments to the characteristics of each disorder are made (Crawley, Beidas, Benjamin, Martin, & Kendall, 2008; Silverman & Kurtines, 1996). Only two studies have reported on disorder specific differences in outcome (Crawley et al., 2008; Manassis et al., 2002). One comparative ICBT versus GCBT study reported greater reduction in mother-rated anxiety symptoms for children with GAD compared to a group of children with either SAD, SOP or specific phobia (SP) across both treatment approaches (Manassis et al., 2002). In another study, Crawley et al. (2008) found better diagnostic outcome for youth with GAD and SAD than for youth with SOP. Taken together, this might indicate less effect of CBT for SOP than GAD, although this is not unequivocal due to combination of diagnoses in one of the studies (Manassis et al., 2002). In one of the studies, there was also an indication of an interaction effect between type of anxiety disorder and treatment approach (Manassis et al., 2002), since children with high levels of social anxiety showed treatment gains in favor of ICBT over GCBT. In contrast to this, Liber et al. (2008) reported greater treatment gains for children with SOP following

GCBT compared to ICBT, although this was only evident for father-rated internalizing symptoms on the Child Behavior Checklist (Achenbach & Rescorla, 2001).

The primary aim of the current study was to examine the effectiveness of CBT compared to a waitlist control condition (WLC) in youth with SAD, SOP or GAD referred to community mental health clinics, and to study the relative effectiveness of an ICBT versus a GCBT approach. Secondary aims included examinations of disorder specific outcomes or interaction effects between treatment approach and anxiety disorder.

We expected CBT (combined ICBT and GCBT) to be superior to WLC. Because ICBT allows for more individual treatment tailoring than GCBT, we hypothesized that ICBT would be the most effective approach in this sample. We also expected that treatment gains would be maintained at one year follow-up for both approaches. Based on findings reported by Manassis et al., (2002) and Crawley et al., (2008), we also hypothesized that youth with a primary diagnosis of SOP would have less favorable treatment outcome compared to youth with SAD or GAD. For the interaction between treatment approach (i.e., ICBT, GCBT) and type of anxiety disorder (SAD, SOP, GAD) we had no specific a priori hypothesis, due to inconsistent findings in previous efficacy trials and a lack of effectiveness studies investigating this issue.

Methods

Participants

The sample comprised 182 youths aged 8 to 15 years ($M = 11.5$ years, $SD 2.1$), recruited from referrals to seven public child and adolescent mental health outpatient clinics in Western Norway from 2008 to 2010. Parents of youth with anxiety symptoms were invited to enroll their children in the study and those youth meeting *DSM-IV* (American Psychiatric Association, 1994) criteria for a primary disorder of SAD, SOP or GAD were included. Exclusion criteria were pervasive developmental disorder, psychotic disorder, and/or mental retardation. Youths on psychotropic medication ($n = 11$, 6.0%) were included, if the dosage had been stable for at least

three months prior to study entry and kept constant during the treatment. Of 258 youths and parents invited for the initial evaluation, 221 accepted the invitation. Informed written consent from all the parents and assent from youths above age 12 was obtained. Following the initial evaluation, 182 youths met criteria for inclusion and were enrolled in the study. Most of the youths were Caucasian ($n = 165, 90.7\%$); three (1.6%) were Asian; while for 14 (7.7%) ethnicity was not reported. The majority of the youths lived in two-parent households ($n = 105, 57.7\%$); 36 (19.8%) lived with a single parent; 24 (13.2%) lived with one biological parent and a step parent; and three children (1.6%) lived in a foster family. Family composition was unknown for 14 participants (7.7%). Parents' occupational status were classified into five rank ordered social classes in accordance with the Registrar General Social Class coding scheme (Currie et al., 2008), with family social class defined by the highest ranking parent. The family social class was high for 30.7%, medium for 50.5% and low for 7.7% and unknown for the remaining families (11.1%). See [Figure 1](#) for the study Consort and [Table 1](#) for characteristics of the study sample.

Procedure

Assessments at pre treatment, post waitlist, post treatment and at one year follow-up were completed by the youth and their parents (one parent per child, 92.0% mothers). A block randomization was used where groups of 6 youths included at a clinic, either from the younger age group (8-12 years) or from the older age group (12 -15 years), were randomized to ICBT, GCBT and WLC. The mean duration of the waitlist period was equal to the treatment period (10 weeks). Of the 38 youths randomized to the WLC, one participant (2.6 %) no longer met the inclusion diagnostic criteria post waitlist, and two participants (5.3 %) did not want to be randomized to treatment. These three youths were included in the waitlist analyses only. The other 35 youths were randomized to ICBT or GCBT. Thus, the total number of youths randomized to treatment was 91 to ICBT and 88 to GCBT. Twenty-six youths (14.3%) did not complete the full treatment or post assessment. Eight additional youths were lost between post treatment and one year follow-up

assessment. Between these two assessments, seven youths in the ICBT condition and five in the GCBT condition received additional treatment for anxiety (7.7 % of the treatment completer sample, n=12). The study was approved by the Regional Committee for Medical and Health Research Ethics West, Norway.

Measures

The Anxiety Disorder Interview Schedule for DSM-IV, child and parent versions

(ADIS-C/P; American Psychiatric Association, 1994; Silverman & Albano, 1996); SAD, SOP and GAD sections was used to assess inclusion diagnoses. Youth and parents were interviewed separately, and diagnoses and clinician severity ratings (CSR) were assigned based on the combined parent and child report. Diagnoses were assigned when reported by at least one informant. When multiple inclusion diagnoses were present, the diagnosis causing highest interference was considered primary. A CSR of 4 or above (on a 0-8 scale) was required for inclusion. The ADIS has demonstrated excellent inter-rater reliability, retest reliability and concurrent validity (Lyneham, Abbott, & Rapee, 2007; Silverman, Saavedra, & Pina, 2001; Wood, Piacentini, Bergman, McCracken, & Barrios, 2002). All interviews were videotaped, and a random selection of 20% of the interviews at each time point covering each clinic were re-rated by expert raters blind to the clinic assessors' ratings. The overall inter rater agreement estimated by kappa (κ) for the presence of an inclusion anxiety diagnosis was 0.84 (ADIS-C) and 0.86 (ADIS-P). For the specific anxiety disorders in the combined child and parent report, kappas were: SAD = 0.86, SOP = 0.83 and GAD = 0.86. The intraclass correlations (ICCs) for the clinician severity score (CSR) for the total sample were 0.82 (ADIS-C) and 0.82 (ADIS-P), and for the specific anxiety disorders in the combined child and parent report 0.72 (SAD), 0.88 (SOP) and 0.89 (GAD).

The Development and Well-Being Assessment (DAWBA, Goodman, Ford, Richards, Gatward, & Meltzer, 2000) was part of the routine intake procedure at the participating clinics. We used parent and youth information from this web-based diagnostic interview to assess comorbid

disorders other than SAD, SOP and GAD, and for demographic information. The DAWBA has been found to discriminate well between community and clinic samples of youths (Goodman et al., 2000), and has shown good to excellent reliability (Ford, Goodman, & Meltzer, 2003). For rating of the DAWBA, the last author has documented inter-rater agreement with the developer (reference, authors own). In the current study, the first 50 interviews were rated jointly by the first and last author. Inter-rater reliability was based on independent ratings of the next 44 interviews. Agreement was excellent to satisfactory ($\kappa = 1.00$ for ODD, PDD and Tic disorders, 0.77 for Depression, 0.72 for SP, 0.66 for ADHD and 0.58 for other anxiety), thus the last 88 interviews were rated by the first author only.

Spence Children's Anxiety Scale (SCAS; Spence, 1998), child and parent versions, were administered to assess youth anxiety symptoms. The SCAS comprises 38 items, rated on a 4-point scale (0 = never; 1 = sometimes; 2 = often; 3 = always) yielding a maximum score of 114. Spence (1998) reported a six months test-retest reliability of .60 for the total SCAS score, and significant correlations of .71 to .75 have been found between SCAS total scores and the Revised Children's Manifest Anxiety Scale (Reynolds & Richmond, 1979; Spence, 1998; Spence, Barrett, & Turner, 2003). Internal consistency for SCAS in the current sample was good to excellent (parent $\alpha = .85$, child $\alpha = .91$).

Short Mood and Feelings Questionnaire (SMFQ; Angold, Costello, Messer, & Pickles, 1995), child and parent versions, were used to assess youth depressive symptoms. The SMFQ comprises 13 items rated on a 3-point scale (0 = not true, 1 = sometimes true and 2 = true), yielding a maximum total score of 26. A cutoff of ≥ 8 has proved the best balance between sensitivity and specificity to identify a depression diagnosis in a general population (Angold et al., 1995). Two-weeks test-retest reliability has been found to be .66 for child rating scale and .88 for parent (Kuo, Stoep, & Stewart, 2005). The SMFQ has been found to correlate with the Children's Depression Inventory scores (Kovacs, 1985), and discriminates well between psychiatric and non-psychiatric

patients (Angold et al., 1995; Kuo et al., 2005; Sharp, Goodyer, & Croudace, 2006). Internal consistency of the SMFQ in the current sample was good (parent $\alpha = .86$; child $\alpha = .88$).

Treatment

Children and adolescents were treated with the FRIENDS program (Barrett, 2004, 2008). FRIENDS is a 10-week manual-based CBT program addressing cognitive, physiological, and behavioral components that interact in the development and maintenance of anxiety. Previous efficacy studies have found FRIENDS to be effective for childhood anxiety disorders both when delivered individually and in groups (Liber et al., 2008; Shortt, Barrett, & Fox, 2001). FRIENDS is originally a group treatment with parental involvement, inspired by Philip Kendall's "Coping Cat" (Kendall, Kane, Howard, & Siqueland, 1990). The manual was translated into Norwegian by a team of researchers in co-operation with the manual author, and the translation and training in the use of the manual was available prior to study start. The same manual was used in individual and group treatment. The child version was used for children aged 8-12, and the adolescent version was used for ages 12-15. Among the 39 children 12 years old, 34 were included in the 8-12 years group, and five in the 12-15 years group. The program had 10 weekly sessions, lasting 60 minutes (ICBT) or 90 minutes (GCBT). Parents attended the last 15 minutes of each session in addition to two separate parent sessions (prior to session one and after session five). During the parent sessions, program content was explained in detail. Two booster sessions were conducted 1 and 3 months after session 10. Mean treatment period was 12.0 (SD 3.0) weeks, with group treatment lasting significantly shorter than individual therapy (GCBT: 10.7 (SD 1.1), ICBT: 13.5 (SD 3.7), $\beta = 2.8$, 95% CI [1.3, 4.2], $p = .001$).

Therapists and Assessors

Seventeen therapists (94% females) participated: ten clinical psychologists, six clinical pedagogues (i.e., masters of education with additional clinical training) and one social worker. All therapists had their ordinary employments at the participating clinics and volunteered for the study.

Therapists had on average 10.8 years of clinical experience (*SD* 6.3, range 3-27 years). Five therapists had completed a formal two-year post-graduation CBT training. All therapists attended a two-day workshop on CBT and childhood anxiety disorders, and a two-day FRIENDS workshop. During the training period, therapists received supervision at each clinic by one of two senior CBT therapists, who were licensed FRIENDS trainers. To be included, therapists had to treat two pilot cases approved by the supervisors. Throughout the study, clinicians participated in four additional two-day workshops, on anxiety disorders in youth. All therapists carried out both GCBT and ICBT. Supervision was offered every 2-4 weeks in the treatment period.

Assessors ($n=16$) were experienced clinicians also employed at the participating clinics. They attended workshops on CBT and anxiety disorders, and received training for the ADIS C/P in a two-day workshop with licensed ADIS C/P raters. The first and last author supervised and reviewed the interviews during the study, and met the assessors two to four times per year. The first author also had biweekly phone contacts with assessors throughout the study to discuss administration and scoring.

Treatment Integrity

All therapy sessions were videotaped, and 20% of sessions were randomly selected for adherence and competence ratings using an 11-item scale developed for the study (reference, authors own). The selection was stratified on early (2-5) and late (6-9) sessions, and all therapists were represented. The ratings were made by two experienced CBT and FRIENDS therapists and two graduate psychology students. Good to excellent inter-rater reliability was obtained according to criteria (Cicchetti, 1994), with ICC ranging from .70 to .93 for adherence and from .62 to .68 for competence. The mean score on the 0-6 scale was 4.60 (*SD* = 0.88; range 2.00 - 6.00) for adherence and 4.12 (*SD* = 0.96; range 1.67-6.00) for competence.

Data Analysis

Primary outcomes were the percentage of youth free of all anxiety diagnoses or free of primary anxiety diagnosis at post waitlist, post treatment and one year follow-up. Secondary outcomes were changes in youth- and parent-ratings of the youth's anxiety and depressive symptoms. Power calculations were conducted for comparisons of CBT (combined ICBT and GCBT) versus WLC and for ICBT versus GCBT. Sample size estimation was based on a two-tailed *t*-test for means with expected effect-sizes of .50 (medium) and .80 (large), an alpha of 0.05 and power of 80%. The needed sample size per cell was 26 to detect a large effect and 64 to detect a medium effect. In the final sample included, the power was 90% to detect a medium effect.

Missing data on the item level were predicted using the missing value analysis in SPSS 20 (IBM Statistics, Chicago, USA). The missing data were occurring randomly and did not exceed 11% for any questionnaire across all time points and informants, with the exception of four youth and one parent with higher levels of missing data ($M = 16.7\%$). Missing data were accommodated in structural equation modeling (SEM) by employing full information maximum likelihood (FIML) missing data methodology (Wothke, 2000), thus a missing data point did not result in deletion of the participant. Missing diagnostic data at post waitlist, post treatment and at one year follow-up were handled by using the pre treatment diagnosis in last-observation-carried-forward method.

For continuous variables, multivariate outliers were examined by leverage indices for each individual, defining an outlier as a leverage score four times greater than the sample mean leverage. Based on this analysis, six outliers were identified. Model based outliers were evaluated by examining variables that were regressed onto its relevant predictors and then standardized dfBetas were evaluated for each individual. Outliers were defined as individuals with an absolute standardized dfBeta greater than 1 for a given coefficient, giving a total of four outliers. Analyses were then run with and without outliers present. The inclusion of the outliers did not alter results, and were therefore included in the analyses. Examination of univariate indices of absolute skewness and kurtosis across all measures and time points revealed large variability, but no skewness greater

than 1.6 and no kurtosis greater than 4.7. Non-normality was evident in several of the variables. To account for the non-normality present in the data, SEM analyses were pursued in MPlus by using an estimator (MLR) robust to violations of normality based on the Huber-White algorithm (Muthén & Muthén, 2011).

Seven clinics participated in the study. The mean number of included participants at each clinic was 26 (range 19-32). The GCBT condition comprised 16 separate treatment groups while children in the ICBT condition were grouped as one cluster at each of the seven clinics, giving a total of 23 clusters. The design was therefore partially clustered and the model was adjusted for potential clustering effects (Baldwin, Bauer, Stice, & Rohde, 2011; Bauer et al., 2008). The equivalent of a logistic regression was conducted using SEM in MPlus to analyze diagnostic outcomes and to evaluate clinically significant change on symptom measures. SEM, as well as mixed models with random factors for subjects and fixed effects for condition and time and their two way interaction were used to measure child and parent reported symptoms and disorder severity.

Secondary analyses were conducted to examine the impact of the different primary anxiety disorders on outcome and if there was an interaction between anxiety disorder and treatment approach. When conducting multiple tests, the modified Bonferroni procedure described by Holm was applied to control the experiment-wise error rate at .05. Reliable Change Index (RCI) and Clinically Significant Change were used to assess clinically significant change on the SCAS and the SMFQ (Jacobson & Truax, 1991). These were computed from pre-, post-, and one year follow-up treatment scores. The RCI scores were grouped into three categories: reliable improved (RCI score >1.96), not reliably changed ($1.96 > \text{RCI} > -1.96$) and deteriorated (RCI-score <-1.96). Due to the small number of patients that deteriorated (SCAS-c/p $n=2$, SMFQ-c/p $n=6$), these patients were grouped with those with no reliably change into a no change category. When RCI-scores indicated reliable improvement and the score on the outcome measure was within the normal range at post

treatment, the child was considered to have a clinically significant (CS) change (recovered). The normal range for SCAS, was defined as a post score below the mean plus one standard deviation based on the norms specific for age and gender (Nauta et al., 2004; Spence, 1998), and for SMFQ below the clinical cutoff score of 8 (Angold et al., 1995). All analyses of outcome were conducted using the intent-to-treat principle (ITT), unless otherwise specified. For diagnostic outcome, completer analyses were included to examine the full-dose treatment effectiveness.

Results

Primary Analyses

Pretreatment comparisons. No pretreatment demographic or diagnostic characteristics differed significantly, neither between youth randomized to CBT (combined ICBT and GCBT) and WLC, nor between the two treatment approaches (Table 1). There were also no significant pretreatment differences for these comparisons on the anxiety or depression symptom measures, except for lower parent-reported anxiety (SCAS-p) for waitlist youth ($\beta = -6.4$, 95% CI [-12.1, -0.7], $p = .028$). This was however not significant after controlling for multiple testing (Table 2).

Attrition. Overall, 26 participants (14.3%) did not complete the full treatment program (16.5% for ICBT and 10.2% for GCBT, a non-significant difference). Post hoc comparisons of completers and non-completers showed no pretreatment differences for participant's age, gender, number and severity of anxiety disorders, other comorbid disorders, or symptom measures (SCAS-c/p, SMFQ-c/p).

Cognitive behavioral therapy versus waitlist. Thirty-three youth (22.9%) no longer met criteria for any of the included anxiety diagnoses after CBT, compared to one participant (2.6%) after WLC ($z = -3.3$, $p = .001$). Fifty-one youth (35.4%) had lost their primary anxiety diagnosis after CBT, compared to four after WLC (10.5%, $z = -2.8$, $p = .005$). Finally, 79 youth (54.9%) had lost at least one of the included anxiety diagnoses after CBT, compared to 12 youth (31.6%) after

WLC ($z = -4.3, p = .001$). Treatment completer analyses showed the same superiority for CBT treatment over WLC as did the ITT-analyses (data not shown).

SEM equivalence of a between-within subjects analysis of variance were conducted for symptom measures and severity ratings of primary and comorbid diagnoses, with CBT and WLC representing the between-subjects factor, and time (pre and post) as the within-subjects factor. These analyses showed significant main effects of time on all assessor-rated, self-report and parent-report measures, in favor of the CBT condition (see [Table 2](#)). There were no significant differences pre to post for the WLC on self-report measures, except for youth self-report anxiety symptoms ($\beta = -8.7, 95\% \text{ CI } [-12.9, -4.4], p < 0.0005$). Significant interaction effects were observed in favor of CBT on CSR for the primary and secondary anxiety diagnosis, SCAS-p, SMFQ-c, and SMFQ-p (Table 2).

Before pooling data from the WLC participants with data from those directly randomized to treatment, the treatment response of WLC youth was investigated by comparing pre-post therapy change scores for all the outcome variables. The only significant difference appeared for parent rated anxiety symptoms, indicating less improvement in those first randomized to WLC ($\beta = 4.5, 95\% \text{ CI } [0.6, 8.3], p = .023$). However, the WLC had a significantly lower average baseline level on this measure, which left less room for improvement. When adjusting for the pretreatment anxiety level, the difference in improvement on this measure disappeared ($\beta = 1.9, 95\% \text{ CI } [-1.9, 5.6], p = .32$). In other words, once the youth in the WLC received therapy, their improvement did not differ from the initially treated group. Data from these groups were therefore combined in all subsequent analyses.

Individual versus group treatment. At post treatment, logistic regression analyses showed no significant differences between ICBT and GCBT for a) loss of all anxiety diagnoses (25.3% vs. 20.5%, $z = 0.6, p = .524$), b) loss of primary anxiety diagnosis (35.2 % vs. 35.2%, $z = -.01, p = 0.99$) or c) loss of at least one included anxiety diagnosis (50.5% vs. 62.5%, $z = -1.63, p = 0.104$)

(Table 3). At one year follow-up, there was also no significant differences between the two treatment approaches for; a) loss of all anxiety diagnoses ($z = -1.10, p = .264$), b) loss of primary anxiety diagnosis ($z = -0.07, p = 0.946$), or c) loss of at least one inclusion diagnosis ($z = -1.10, p = 0.272$). Treatment completer analyses gave the same results, both at post treatment and at one year follow-up.

SEM equivalence of a between-within subjects analysis of variance were conducted for the symptom measures, with treatment approach (ICBT and GCBT) as the between-subjects factor, and time (pre and post) as the within-subjects factor. Significant main effects of time were observed for youth and parent reported anxiety and depressive symptoms, and for the clinical severity rating of primary and comorbid anxiety diagnoses (see Table 2). Main effects of treatment approach and interaction effects of time and approach were not statistically significant for any of these measures. At one year follow-up parents reported less depressive symptoms in youth receiving GCBT than ICBT ($z = 2.0, p = .045$), but this was no longer significant after controlling for multiple testing.

Clinically significant change. Proportions of youth in the clinical range before treatment was on SCAS-c 27.5% (ICBT) and 36.4% (GCBT), on SCAS-p 75.8% (ICBT) and 83.0% (GCBT), on SMFQ-c 50.5% (ICBT) and 47.7% (GCBT), and on SMFQ-p 26.4% vs. 29.5%. Only the children in the clinical range were included in analyses of clinically significant (CS) change, as CS change implies improvement on Reliable Change Index (RCI) and a post treatment score on the outcome measure that passes the cutoff from clinical range to normal range. For symptom measures, the proportion of youth categorized as “reliably changed and within normal range / reliably changed” or “not reliably changed” was compared between ICBT and GCBT at post treatment and at follow up (Table 4). These analyses revealed no differences between the two approaches on any of the symptom measures, neither at post treatment nor at one year follow-up.

Secondary Analyses

Age and gender effects. The younger age group had higher pretreatment parent-rated anxiety ($\beta = -3.3, 95\% \text{ CI } [-6.4, -0.3], p = .031$), while the older age group had higher self-rated

depression before treatment ($\beta = 2.6$, 95% CI [0.5, 4.7], $p = .017$). However, after adjusting for gender, treatment approach and pretreatment symptom levels, no age effects could be observed post treatment or at one year follow-up.

At pretreatment, girls reported higher anxiety ($\beta = 7.0$, 95% CI [4.6, 9.5], $p < .0005$) and also higher depressive symptoms ($\beta = 0.5$, 95% CI [1.2, 4.3], $p < .0005$) compared to boys. Adjusted for age group, treatment approach and pretreatment symptom levels, girls still reported higher anxiety post treatment ($\beta = 0.6$, 95% CI [0.1, 5.5], $p = .042$), but not at one year follow-up. The post treatment difference was, however, not significant after correction for multiple testing. In the treatment completer analyses, gender was unrelated to post treatment anxiety levels.

Effect of primary anxiety diagnosis. Differences in outcome for the three primary anxiety diagnoses were investigated using multiple logistic regressions for diagnostic outcomes, and growth curve for symptom measures. Both types of analyses controlled for gender, intervention and pretreatment youth reported anxiety level. The odds ratio for recovery at post treatment from the respective primary diagnosis were: SOP 0.5 (95% CI [0.3,1.0], $p < .05$), SAD 0.8 (95% CI [0.5,1.5], $p = .52$) and GAD 3.1 (95% CI [1.5,6.5], $p = .002$), with only GAD still remaining significant after Holm modified Bonferroni correction. Compared to GAD, the chance of recovery was lower both for SOP (OR 0.3; 95% CI [0.1,0.7], $p = .006$) and SAD (OR 0.4, 95% CI [0.2,0.8], $p = .010$). Youth with SOP, but not youth with SAD, had a smaller reduction in self-reported anxiety than youth with GAD ($\beta = 5.2$, 95% CI [0.3,10.1], $p = .039$). Differences in diagnostic recovery or symptom reduction between SOP and SAD were not significant. At one year follow-up, there were no significant differences in outcome between the three primary diagnostic groups.

Effects of treatment approach on primary diagnosis. For participants with a primary diagnosis of SOP there were no differences in outcome between ICBT and GCBT for diagnoses or anxiety symptoms, when controlling for age group and pretreatment youth rated anxiety and depressive symptoms. However, GCBT gave larger reduction for depressive symptoms than ICBT,

according to youth's ratings at post treatment ($\beta = 1.5$, 95% CI [0.0,2.9], $p = .048$), and according to parents' ratings at one year follow-up ($\beta = 3.3$, 95% CI [18.3,4.7], $p < .0005$). After correcting for multiple comparisons, only the effect on parent-rated depressive symptoms at one year follow-up remained significant. For participants with a primary diagnosis of GAD, there were no significant differences between ICBT and GCBT in diagnostic outcome or on youth reported depressive or anxiety symptoms. However, parents reported significant differences in favor of ICBT both for anxiety ($\beta = -10.82$, 95% CI [-17.1,-4.5], $p < .001$) and depressive symptoms ($\beta = -3.20$, 95% CI [-6.2,-0.2], $p = .037$) post treatment, and for anxiety symptoms at one year follow up ($\beta = -9.00$, 95% CI [-12.3,-5.6], $p < .0005$). For participants with a primary diagnosis of SAD, there were no differences between ICBT and GCBT, on any of the measures.

Discussion

As we expected, CBT (combined ICBT and GCBT) was superior to WLC, evident both from the loss of anxiety diagnoses and improvement on symptom measures. Our results are in line with prior effectiveness studies of CBT programs for child anxiety disorders (Bodden et al., 2008; Lau et al., 2010; Nauta et al., 2003), although our diagnostic recovery rate of 23% is in the lower end of what has been reported by others (28% to 60%). According to parent ratings, there was significant improvement in youth's anxiety (SCAS-p) and depressive (SMFQ-p) symptoms. Youth reported a significant effect of CBT compared to WLC for depressive symptoms, but not for anxiety symptoms (self-rated anxiety symptoms improved significantly both after CBT and after WLC). The non-significant difference between CBT and WLC in youth rated anxiety symptoms may be explained by the test-retest reliability for SCAS-c, which is found to be acceptable, but not high, in a normative sample (Spence, 1998), and may be poorer in a clinical sample with higher scores. Such a pattern for youth reports of anxiety has also been reported in another effectiveness study (Nauta et al., 2003).

Contrary to our expectation, there was no advantage for individual treatment (ICBT) over group treatment (GCBT). Both treatment approaches resulted in significant improvements evident from diagnostic outcome, severity ratings, symptom measures and clinically significant change indices. These findings are thus consistent with results obtained in previous comparative efficacy trials of ICBT versus GCBT (de Groot et al., 2007; Flannery-Schroeder & Kendall, 2000; Liber et al., 2008; Manassis et al., 2002). In light of the consistent pattern of no significant differences that have been observed across studies, these findings suggest that practitioners can have flexibility in choice of CBT approach (i.e., ICBT vs. GCBT) when working with anxious youth.

In the present study, recovery rates for youth with SOP was lower than for GAD, but not significantly lower than for youth with SAD, regardless of treatment approach. Poorer treatment gains for youth with SOP compared to both GAD and SAD were also evident for youth rated anxiety symptoms. One reason for lower treatment gains for youth with SOP or SAD may be insufficient exposure to social or separation situations in treatment programs for heterogeneous samples of anxiety disorders. Another possibility is that the participating therapists had less experience with exposure exercises. Although the FRIENDS manual advocates individual adjustment and exposure, many components of the program are more general tasks, i.e., relaxation techniques, coping skills, self-esteem issues, rewards and social support. This may benefit youth with GAD to a larger extent, as worrying and rumination may be more adequately addressed in such programs. Differences in treatment outcome by anxiety diagnosis as reported here, has also been suggested by some previous studies (Crawley et al., 2008; Manassis et al., 2002).

No significant interaction effect was observed between treatment approach and type of anxiety disorder regarding diagnostic outcome. For symptom measures however, significant interactions were observed for youth with a primary diagnosis of GAD and SOP. For GAD, ICBT was superior to GCBT on youth anxiety symptoms rated by parents both at post treatment and at follow-up, and for youth depressive symptoms rated by parents at post treatment. It is possible that

ICBT allows the therapists more opportunities to identify the specific worries and conduct more effective exposure exercises, which may often be a challenge for youth with GAD. Also, the extensive worries of many youth with GAD may have made the group approach overwhelming for these children and adolescents (Manassis et al., 2002). On the other hand, for youth with SOP, GCBT gave larger reduction than ICBT of parent rated depressive symptoms at one year follow-up. The FRIENDS efficacy study by Liber and colleagues (2008), also reported larger reductions in internalizing symptoms post treatment for GCBT compared to ICBT. One could speculate that the social aspect of the groups for youth with SOP may be important for the reduction of associated depressive symptoms, as these youth often have been found to be less socially competent. However, these interaction effects should be interpreted with caution, since they are not consistent across outcomes, informants and time points.

Despite the strengths of this effectiveness study, some limitations warrant consideration. First, clinicians assessing diagnostic status were not blinded for treatment allocation. However, we have no reason to believe that they had particular interests in favor of any of the outcomes assessed here. Second, demonstrating superiority of CBT over a WLC may be seen as a less strong argument for CBT than superiority over usual care. Two previous effectiveness trials of child anxiety disorders have in fact reported no significant differences of CBT over usual care for the main outcome measures (Barrington et al., 2005; Southam-Gerow et al., 2010). However, as these studies did not include a WLC, it is unknown as to what extent the observed improvement is due to spontaneous remission or treatment effect. Third, for ethical reasons we were not able to control for “natural course” between assessments at post treatment and at one year follow-up. Thus, part of the change from post to follow-up, may be explained by other factors than treatment. Fourth, the lack of Norwegian norms for the anxiety symptom measure (SCAS) was a problem when calculating clinically significant change. It is documented that parents (and teachers) from the Nordic countries on checklists report lower levels of emotional symptoms in children than in most other countries

(Heiervang, Goodman, & Goodman, 2008). The use of Dutch and Australian norms (Nauta et al., 2004; Spence, 1998) may therefore have biased the sample in a healthy way, reducing the validity and sensitivity of the Jacobsen change indices. Finally, as typical for most Norwegian community clinics the youth were mainly Caucasian, and the findings may therefore not necessarily apply to other ethnic groups.

To our knowledge, this is the first comparative trial of ICBT versus GCBT for youth referred to and treated in community mental health clinics. Also, it is the first effectiveness trial of CBT for a heterogeneous group of anxiety disorders in youth addressing dependence of data within groups. The recovery rate of 23% reported here is lower than the 55-57% rate reported in efficacy trials (In-Albon & Schneider, 2007; James et al., 2005), and of 28-60% reported in previous effectiveness trials (Bodden et al., 2008; Nauta et al., 2003). Some characteristics of the present study may have contributed to this lower improvement rate. First, we only included youth with primary diagnoses of SAD, SOP or GAD, whereas many previous studies also have included other primary diagnoses. In one study, 18% of the sample did not meet full criteria for any anxiety disorder at inclusion (Lau et al., 2010), and in another study primary diagnosis for 23% sample was specific phobia (Southam-Gerow et al., 2010), a condition often considered less pervasive and more amenable to treatment. Second, 46% of our sample had a primary diagnosis of SOP, compared to 17-39% in other effectiveness studies (Bodden et al., 2008; Nauta et al., 2003; Southam-Gerow et al., 2010). The large proportion of children with SOP, and indications from previous studies and our own findings here that SOP has a lower treatment response from general CBT programs, may have contributed to a low recovery rate. Third, the mean severity rating of the primary anxiety disorder reported here was high ($M\ CSR=7$). This is similar to one previous effectiveness study (Bodden et al., 2008), but higher than reported by other studies in this field. More severe disorders may be less responsive to treatment. Fourth, in most previous effectiveness trials therapists have been extensively trained in CBT before they participate in the study (Barrington et al., 2005; Lau et al.,

2010; Nauta et al., 2001; Nauta et al., 2003), more so than the majority of the therapists in our study. Note however that the competence and adherence ratings presented here indicate high (although variable) levels of treatment fidelity in this study. Fifth, the FRIENDS program consists of only 10 weekly sessions, compared to 12-16 sessions in most of the other programs (Bodden et al., 2008; Kendall, 1990; Nauta et al., 2003). Also, each individual sessions lasted for 60 minutes and group sessions 90 minutes, while other programs have had up to two hour sessions (Lau et al., 2010). It is conceivable that the total the treatment dosage was too low for many of the youth in this clinically referred sample.

In conclusion, this effectiveness trial of CBT, delivered individually or in groups, generally support its use for a heterogeneous group of anxiety disorders in youth. However, although the majority of the youth benefited from the treatment, the relatively low recovery rate indicates a need to understand factors contributing to non-response. There is a large room for improvement in the effect of CBT when delivered to youth referred to community clinics. This may involve both treatment and sample characteristics. The finding that program effectiveness varies by diagnosis (more effective for GAD) and some indications of treatment approach by diagnosis interaction, illustrates the need for further refinement of CBT interventions for these disorders.

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Figure 1. Study flow chart

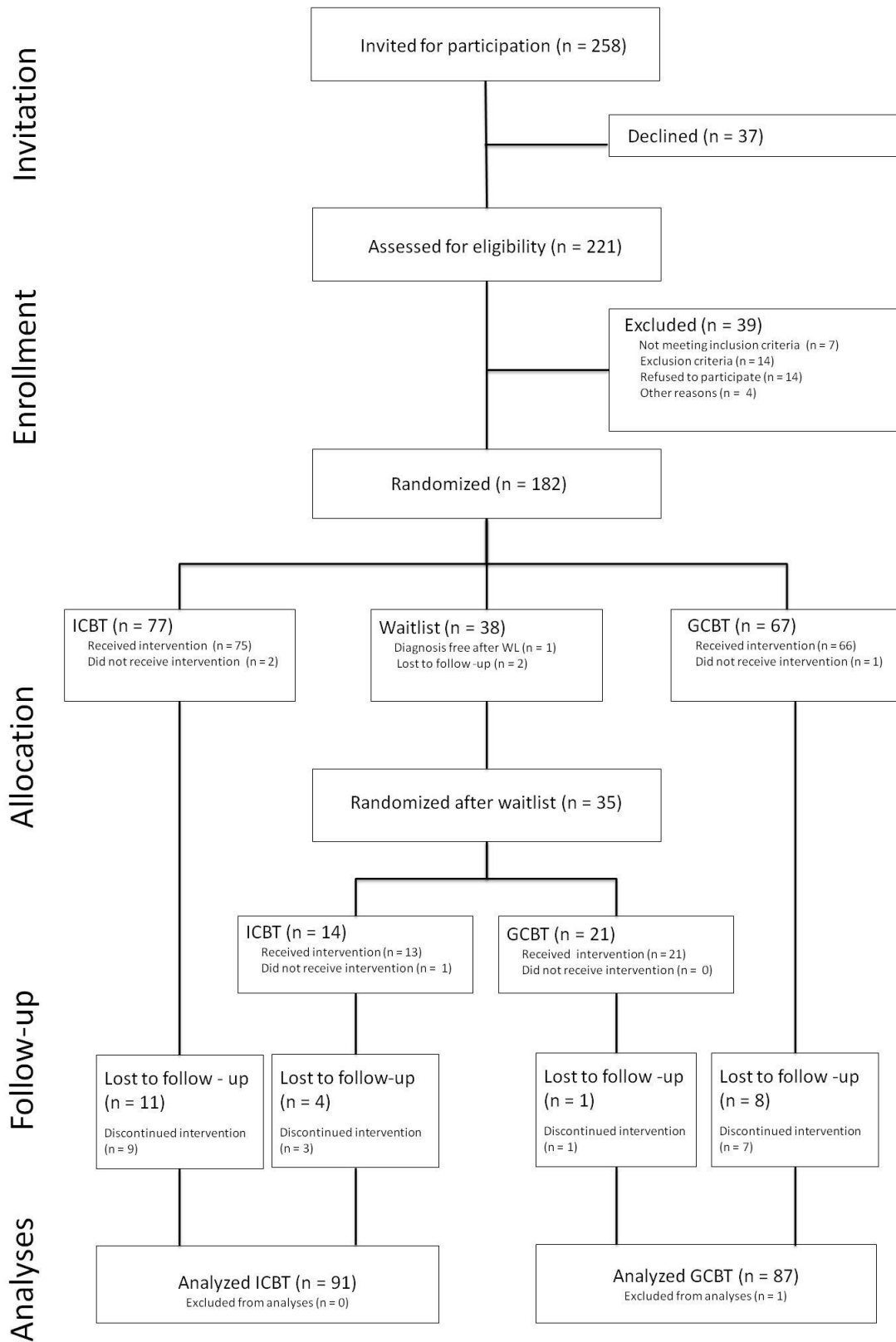


Table 1. Baseline characteristics in the CBT vs. WLC groups, and in the ICBT and GCBT after inclusion of the WLC patients.

	CBT vs. WLC					ICBT vs. GCBT - WLC Included													
	CBT (<i>n</i> = 144)		WLC (<i>n</i> = 38)			ICBT (<i>n</i> = 91)		GCBT (<i>n</i> = 88)											
	<i>M</i>	(<i>SD</i>)	<i>n</i>	%	<i>M</i>	(<i>SD</i>)	<i>n</i>	%	<i>p</i>	<i>M</i>	(<i>SD</i>)	<i>n</i>	%	<i>p</i>					
Age	11.6	(2.10)			11.4	(1.90)			.81	11.4	(2.10)				11.7	(2.10)			.62
Age group									.73										.31
8-12 yrs			93	64.6			27	71.1				67	73.6			51	58.0		
12-15 yrs			51	35.4			11	28.9				24	26.4			37	42.0		
Gender									.67										.66
Male			67	46.5			19	50.0				44	48.4			40	45.5		
Female			77	53.5			19	50.0				47	51.6			48	54.5		
Number of anxiety disorders	2.0	(0.80)			1.8	(0.80)			.26	2	(0.80)				2	(0.80)			.43
Comorbidity present			117	81.3			24	63.1	.02			71	78.0			69	78.4		.94
Primary diagnosis									.61										.89
SAD			47	32.6			12	31.6				29	31.9			29	33.0		
SOP			68	47.2			16	42.1				43	47.2			41	46.5		
GAD			29	20.1			10	26.3				19	20.9			18	20.5		
CSR for primary anxiety diagnosis	6.93	(1.13)			7.02	(1.22)			.60	7.01	(1.09)				6.92	(1.18)			.45
Other comorbidity									.11										.56
Specific Phobia			16	11.1			2	5.3				7	7.7			11	12.5		
Other specified anxiety disorders			7	4.9			2	5.3				5	5.5			4	4.5		
Depression			17	11.8			4	10.5				7	7.7			14	15.4		
ADHD			9	6.3			1	2.6				5	5.6			5	5.5		
ODD			7	4.9			3	7.9				8	8.8			2	2.3		
Tic disorder			10	6.7			2	5.3				6	6.6			6	6.8		
Anorexia			1	0.7			1	2.6				2	2.2			0			

Note. Other specified anxiety disorders: PTSD, OCD, Panic disorder

Table 2. Treatment outcome at post-treatment and follow-up. Main effects of groups and time, and interaction group*time.

	Original groups						With WLC included							
	CBT (<i>n</i> = 144)		WLC (<i>n</i> = 38)		<i>z</i>	<i>p</i>	ICBT (<i>n</i> = 91)		GCBT (<i>n</i> = 88)		Post treatment		1 year f-up	
	<i>Mean</i>	<i>(SD)</i>	<i>Mean</i>	<i>(SD)</i>			<i>Mean</i>	<i>(SD)</i>	<i>Mean</i>	<i>(SD)</i>	<i>z</i>	<i>p</i>	<i>z</i>	<i>p</i>
CSR primary anxiety diagnosis														
Pre treatment (<i>n</i> = 144, 38)	6.93	(1.13)	7.02	(1.22)	.53	.60 ^a	7.01	(1.09)	6.92	(1.18)	.72	.47 ^a	.72	.47 ^a
Post treatment	4.67	(2.45)	6.25	(1.81)	-10.62	<.001 ^b	4.76	(2.44)	4.65	(2.35)	-8.99	<.001 ^b	-14.98	<.001 ^b
Follow-up					3.92	<.001 ^c	3.72	(2.64)	3.70	(2.52)	.06	.95 ^c	-.30	.77 ^c
CSR secondary anxiety diagnosis														
Pre treatment (<i>n</i> = 104, 21)	6.30	(1.26)	6.48	(1.18)	.59	.56 ^a	6.34	(1.14)	6.34	(1.36)	.00	>.99 ^a	.00	>.99 ^a
Post treatment	4.02	(2.45)	5.76	(2.07)	-11.22	<.001 ^b	4.17	(2.58)	3.86	(2.40)	-9.51	<.001 ^b	-11.58	<.001 ^b
Follow-up					4.42	<.001 ^c	3.14	(2.25)	3.31	(2.30)	.71	.46 ^c	-.18	.86 ^c
CSR tertiary anxiety diagnosis														
Pre treatment (<i>n</i> = 42,11)	5.69	(1.24)	5.46	(2.10)	-.28	.78 ^a	5.52	(1.10)	5.75	(1.72)	-.49	.62 ^a	-.49	.62 ^a
Post treatment	3.83	(2.39)	5.09	(2.06)	-4.39	<.001 ^b	4.00	(2.24)	3.67	(2.46)	-3.97	<.001 ^b	-4.69	<.001 ^b
Follow-up					1.71	.09 ^c	4.22	(2.52)	2.93	(2.62)	.92	.36 ^c	1.92	.06 ^c
SCAS-c														
Pretreatment (<i>n</i> = 137, 32)	35.62	(15.94)	37.86	(19.49)	1.02	.31 ^a	36.03	(15.05)	36.61	(17.23)	-.50	.62 ^a	-.33	.74 ^a
Posttreatment	27.05	(14.71)	29.61	(16.23)	-6.41	<.001 ^b	27.26	(16.18)	27.68	(14.20)	-6.44	<.001 ^b	-7.01	<.001 ^b
Follow-up					-.03	.98 ^c	24.09	(15.88)	24.01	(19.00)	.32	.75 ^c	.31	.76 ^c
SCAS-p														
Pretreatment (<i>n</i> = 139, 33)	35.88	(13.24)	29.48	(8.76)	-1.87	.06 ^a	34.92	(13.96)	34.85	(11.01)	.08	.94 ^a	.09	.93 ^a
Posttreatment	27.28	(13.19)	30.53	(12.36)	-7.93	<.001 ^b	27.61	(15.02)	26.71	(11.65)	-5.85	<.001 ^b	-7.77	<.001 ^b
Follow-up					4.48	<.001 ^c	24.12	(12.78)	22.59	(14.00)	.34	.74 ^c	.59	.56 ^c
MFQ-c														
Pretreatment (<i>n</i> = 138, 29)	7.43	(5.53)	7.67	(5.74)	.32	.75 ^a	7.44	(5.54)	7.51	(5.59)	-.13	.90 ^a	-.08	.94 ^a
Posttreatment	5.55	(5.39)	7.36	(5.72)	-3.06	<.001 ^b	5.65	(5.11)	5.81	(5.43)	-3.87	<.001 ^b	-3.04	<.01 ^b
Follow-up					2.32	.02 ^c	5.61	(6.35)	5.16	(5.76)	-.05	.96 ^c	.56	.57 ^c
MFQ-p														
Pretreatment (<i>n</i> = 140, 34)	7.69	(5.14)	6.86	(4.51)	-1.26	.21 ^a	7.66	(4.77)	7.47	(5.30)	.16	.87 ^a	.26	.80 ^a
Posttreatment	5.33	(4.94)	7.01	(4.95)	-4.60	<0.001 ^b	5.87	(5.02)	5.10	(5.06)	-3.56	<.001 ^b	-4.68	<.001 ^b
Follow-up					2.30	.02 ^c	5.83	(5.10)	4.11	(4.10)	.62	.53 ^c	2.00	<.05 ^c

Table 3. Percentage anxiety disorder-free children after ICBT and GCBT, Intent-to-Treat analysis and completer analysis.

ADIS Compound Diagnosis	Post treatment				1 year follow-up			
	ICBT		GCBT		ICBT		GCBT	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Free of all anxiety disorders (intent to treat)	23	25.3	18	20.5	30	33.0	36	40.9
Free of all anxiety disorders (completer)	23	30.7	18	22.8	30	42.3	36	48.6
Primary anxiety disorder-free (intent-to-treat)	32	35.2	31	35.2	42	46.2	41	46.6
Primary anxiety disorder-free (completer)	32	42.7	31	39.2	42	59.2	41	54.7
Loss of at least one anxiety disorder (intent-to-treat)	46	50.5	55	62.5	50	54.9	56	63.6
Loss of at least one anxiety disorder (completer)	46	61.3	55	69.6	50	70.4	56	75.7

Table 4. Percentages of children with clinically significant change post treatment and at 1 year follow-up in ICBT and GCBT.

Scale		Post treatment				OR [95% CI], <i>p</i> **	1 year follow-up				OR [95% CI], <i>p</i> **
		ICBT (<i>n</i> = 91)		GCBT (<i>n</i> = 88)			ICBT (<i>n</i> = 91)		GCBT (<i>n</i> = 88)		
		<i>n</i> *	%	<i>n</i> *	%		<i>n</i> *	%	<i>n</i> *	%	
SCAS-child	Reliably changed and within normal range	14	56	15	47	0.66 [0.43, 1.00], > .05	14	56	21	66	0.84 [0.49, 1.45], .53
	Reliably changed	5	20	10	31		6	24	6	19	
	Not reliably changed	6	24	7	22		5	20	5	16	
SCAS-parent	Reliably changed and within normal range	11	16	18	25	0.90 [0.48, 1.66], .73	17	25	26	36	1.38 [0.83, 2.53], .30
	Reliably changed	22	32	15	21		20	29	19	26	
	Not reliably changed	36	52	40	54		32	46	28	39	
MFQ-child	Reliably changed and within normal range	13	28	15	36	0.60 [0.28, 1.26], .18	21	46	19	45	0.71 [0.35, 1.43], .34
	Reliably changed	15	33	11	26		10	22	9	21	
	Not reliably changed	18	39	16	38		15	32	14	33	
MFQ-parent	Reliably changed and within normal range	8	33	15	58	0.66 [0.33, 1.33], .25	7	29	18	69	1.26 [0.60, 2.65], .54
	Reliably changed	6	25	3	12		6	25	3	12	
	Not reliably changed	10	42	8	31		11	46	5	19	

* *n* is lower than 91 and 88, respectively, as only those patients who scored in the clinical range at pretreatment assessment are included. Only these can move from the clinical to the normal range. ** ORs are computed for the patients categorized as “not reliably changed” vs. the combined category of those “reliably changed” and “reliably changed and within normal range”.