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Article · January 2017

DOI: 10.4172/2167-0870.1000330

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A Randomized Controlled Effectiveness Study Comparing Manualized Cognitive Behavioral Therapy (CBT) with Treatment-As-Usual for Clinically Anxious Children

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Received date: September 26, 2017; Accepted date: October 23, 2017; Published date: October 28, 2017

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Abstract

Objective: CBT is an empirically supported treatment for childhood anxiety disorders. However, it has been rarely tested in real-world clinical practice or compared to treatment-as-usual (TAU).

Method: The present study was a randomized controlled trial (RCT) comparing manualized CBT with TAU in Dutch mental health centers for clinically referred anxious children (N=88) aged 7-13 years. Treatment predictors included therapeutic alliance and parenting. Assessment took place at baseline, post-treatment, 6 and 12 months after treatment, and consisted of child-reports of anxiety, therapeutic alliance, and parenting; and mother-reports of children's anxiety, children's problem behavior, and parenting.

Results: Both groups benefitted significantly from treatment with medium to large effect sizes, for mother- and child-reported outcomes. CBT was not superior to TAU on primary or secondary outcomes. TAU was even superior to CBT in some instances. Treatment gains were maintained at follow-ups. Therapeutic alliance and parenting did not predict treatment outcome.

Conclusions: Manualized CBT did not produce better treatment outcomes than usual treatment within routine clinical practice. Findings suggest that CBT can be effective in a shorter and more flexible manner. More research is needed to identify which children profit best from which treatment.

Keywords: Randomized controlled trial (RCT); Cognitive behavioral therapy (CBT); Childhood anxiety disorders; Treatment predictors; Therapeutic alliance; Parenting

Introduction

CBT has consistently been identified as an effective and first-choice treatment for childhood anxiety disorders [1,2]. Over the last decades, many manualized CBT programs have been published (e.g., Coping Cat) [3] and evaluated by the criteria of The American Psychological Association Task Force on Promotion and Dissemination of Psychological Procedures. However, there are some concerns with these studies. First, they are typically employed using strict inclusion and exclusion criteria, controlled procedures, and delivered by a small number of trained therapists within specialized treatment settings or research clinics. In contrast, "real-world" effectiveness studies examine populations of children and families within community mental health centers, recruit agency-employed therapists, and conduct research in everyday clinical practice [4]. For generalizability to real-world clinical settings, it is critical to conduct RCTs outside of highly controlled clinical trials [1].

Second, there is a strong need to compare manualized CBT to usual treatment within routine clinical practice. Most community mental health centers have not incorporated manualized CBT programs; when they do, they usually apply the manual flexibly and use select parts [5]. RCTs often compare manualized CBT to waiting list conditions and

studies comparing CBT to active controls or TAU are scarce. The few studies that have compared CBT with active controls or TAU have shown no superior effect of CBT [2]. This is in line with evidence suggesting that CBT can be effective in a shorter and more flexible manner than prescribed by manualized CBT programs [6]. Third, therapists are usually not randomized to treatment conditions, resulting in uncontrolled therapist effects such as the preference or experience of the therapist with the specific treatment.

Furthermore, there has been a great deal of variability in treatment outcomes for individual children [7]. Investigating potential treatment predictors and moderators will specify for whom, and under what conditions, treatment works best. Predictors can be baseline characteristics that have a main effect on treatment outcome regardless of the treatment, while moderators have an interaction effect with the treatment [8]. This information can help clinicians personalize treatment for a specific child. Unfortunately, within the field of childhood anxiety, few studies are available that have conducted these types of detailed analyses, with the notable exception of the Child/Adolescent Anxiety Multimodal Study (CAMS). Numerous predictors and moderators in the CAMS trial were examined and only symptom severity and caregiver strain predicted treatment outcome [9]. Other family characteristics did not predict treatment outcome. This is somewhat surprising given the large body of developmental and epidemiological evidence that has shown links between family functioning and childhood anxiety [10]. It may be that general family characteristics do not predict treatment response, but more specific

parenting practices or dimensions do. Less maternal warmth and more control have been associated with less favorable treatment outcome in anxious children [11,12]. In the current study, was assessed whether specific anxiety-enhancing parenting (i.e., high warm and low rejecting and controlling behaviors) predicted treatment outcome.

Another predictor that has been examined in the CAMS trial is the relationship between the therapist and child [13]. A strong bond according to the child predicted better outcomes for children receiving CBT. However, there are studies that found no association for child-reports [14]. These inconsistencies might be explained by the timing of assessment, given that early assessment has been differentially associated with treatment progress compared to later assessment [15]. Symptom improvement can influence the therapeutic relationship over the course of treatment [7]. Especially for anxious children, it seems crucial to form a good relationship within the first treatment sessions [16]. In the current study, the therapeutic relationship was assessed after the first treatment session to indicate early in treatment whether therapeutic alliance predicted treatment outcome.

The primary aim of the present study was to evaluate the effectiveness of a manualized CBT program by comparing it to treatment-as-usual (TAU) in real-world clinical practice with randomized agency-employed therapists. The secondary aim was to examine whether therapeutic alliance and parenting predicted treatment effects. Assessment consisted of child-reports of anxiety, therapeutic alliance, and parenting; and mother-reports of children's anxiety, children's problem behavior, and parenting. The study was registered prior to beginning (Trial registration number: NTR2967) and hypotheses were published in a protocol paper [17]. First, we hypothesized that both treatments would be effective in reducing anxiety symptoms and problem behavior, but expected children receiving CBT to have significantly less anxiety symptoms and problem behavior after treatment compared to children receiving TAU. However, recent findings by James et al. [2] have called this optimistic hypothesis into question, showing no superior effect of CBT compared to TAU. Second, we expected that children of mothers with low anxiety-enhancing parenting (i.e., high warm and low rejecting and controlling behaviors) would have significantly better treatment outcomes compared to children of mothers with high anxiety-enhancing parenting (i.e., low warm and high rejecting and controlling behaviors). Furthermore, we predicted that children with a strong therapeutic relationship would have significantly better treatment outcome compared to children with a low therapeutic relationship.

Method

Participants

Participants were 88 children who were selected for this study by one of two procedures. In the first procedure, all children between seven and twelve years old, who were referred to one of three participating mental health care centers in the Netherlands between January 2012 and January 2014, and their mothers were asked to fill out the Screen for Child Anxiety Related Emotional Disorders (SCARED) [18] to assess the children's level of anxiety. If the child's or mother's total SCARED score or one of the following subscales: generalized anxiety, social anxiety, separation anxiety, or panic disorder fell in the 'high' or 'at risk' category, eligibility for participation was further examined by experienced agency clinicians. We wanted to interfere as little as possible with the regular diagnostic procedure that consisted of interview sessions in which DSM-IV diagnoses were

determined. If additional assessment was deemed necessary, further psychological assessment was conducted. Inclusion criteria were a DSM-IV anxiety disorder and exclusion criteria were a primary diagnosis of posttraumatic stress disorder, autism spectrum disorder, specific phobia, obsessive-compulsive disorder, an IQ below 80, and the need for immediate intervention to prevent the child or the family from harm (e.g., suicidal intentions). These exclusion criteria required a different approach and the manualized treatment that we used was not suitable for children meeting these exclusion criteria.

In the second procedure, primary schools were approached to participate in this study. All parents in participating schools with children in grade three to six had to give their active consent before children were allowed to fill out the SCARED. When children had a score in the category 'high' or 'at risk' on the SCARED total scale or one of the previously mentioned subscales, parents were called to ask if they recognized the anxiety of the child and if they had considered seeking help for these problems. Additionally, they were offered screening for eligibility in one of the participating mental health care centers and mothers were then asked to fill out the SCARED. Once families contacted the mental health care centers, the diagnostic assessment was the same as the first procedure.

Design and procedure

The study was approved by the Ethic Committee of Radboud University's faculty of Social Sciences. Families meeting inclusion criteria and agreeing participation, signed informed consent. All participants were randomly allocated to CBT or TAU with a block size 4 randomization scheme (Figure 1). Research assistants conducted the assessments at the children's homes at baseline, post-treatment, and six and twelve months after treatment. During the three months of treatment, research assistants had weekly telephone calls with children and mothers for assessment. Research assistants were all students with a bachelor's or master's degree in social sciences. All treatment sessions were audiotaped by the therapists.

Assessments

Screen for child anxiety related emotional disorders (scared): This child-report (C) and parent-report (P) assesses children's anxiety symptoms and generates a total score and scores on the subscales panic disorder, generalized anxiety disorder, separation anxiety disorder, social phobia, obsessive-compulsive disorder, post-traumatic stress disorder, and specific phobia. Each scale is categorized into a low, normal, high, or at risk score. For purposes of this study, we included the Total scale and the subscales Separation anxiety, Panic disorder, Social anxiety, and Generalized anxiety. The psychometric properties of the SCARED have been well established [19]. In the current study, reliability of the SCARED-C was excellent for the Total scale (Cronbach's $\alpha=0.91$); good for Panic disorder (Cronbach's $\alpha=0.83$) and Social anxiety (Cronbach's $\alpha=0.83$); and adequate for Generalized anxiety (Cronbach's $\alpha=0.74$) and Separation anxiety (Cronbach's $\alpha=0.71$). Reliability of the SCARED-P was good for the Total scale (Cronbach's $\alpha=0.88$), Social anxiety (Cronbach's $\alpha=0.86$), and Generalized anxiety (Cronbach's $\alpha=0.81$); and adequate for Panic disorder (Cronbach's $\alpha=0.74$) and Separation anxiety (Cronbach's $\alpha=0.72$).

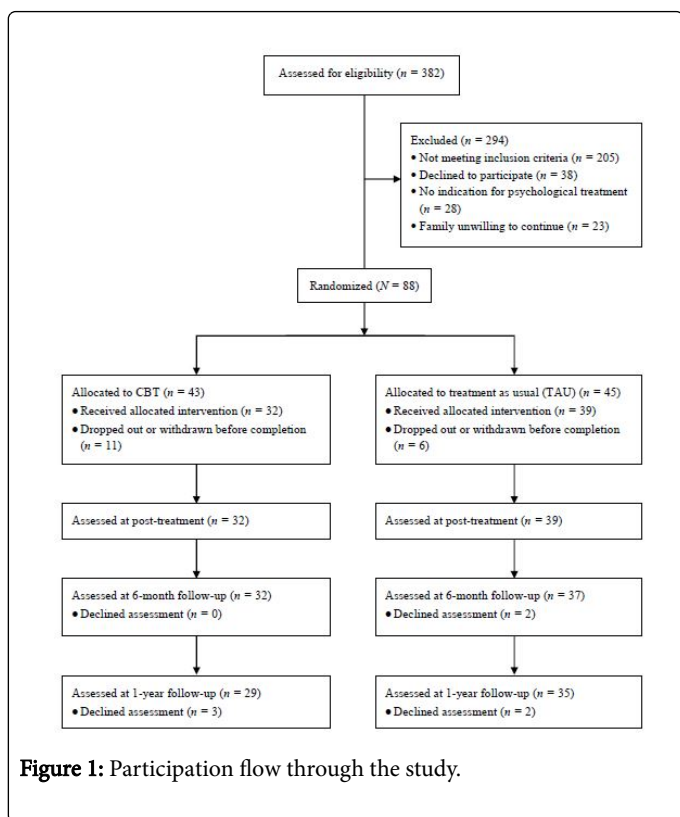


Figure 1: Participation flow through the study.

Child Behaviour Checklist

The CBCL is a widely-used parent-report that measures internalizing (anxious, depressed and withdrawn behavior) and externalizing problem behavior (aggressive and rule-breaking behavior). T-scores for the internalizing and externalizing subscale of 64 or higher represent the clinical range. The psychometric properties of the CBCL have been well established [20]. In the current study, reliability of the CBCL was good for externalizing problem behavior (Cronbach's $\alpha=0.84$) and adequate for internalizing problem behavior (Cronbach's $\alpha=0.79$).

Therapeutic alliance scale for children (TASC)

The TASC is a child-report that assesses the therapeutic alliance and generates three subscales: the bond, task, and negativity scale [21]. Previous research has demonstrated good reliability with Cronbach's $\alpha=0.88$ to 0.92 [22]. In the current study, the TASC had questionable reliability for the bond scale (Cronbach's $\alpha=0.66$) and poor reliability for the negativity (Cronbach's $\alpha=0.57$) and task scale (Cronbach's $\alpha=0.38$). We decided that Cronbach's α lower than 0.65 was unacceptable, resulting in pursuing analyses only with the bond scale.

Egna minnen betröffande uppfostran (EMBU-C/P)

The EMBU measures parenting with a child-report (C) and parent-report (P) [23]. The EMBU-C assessed three main parenting behaviors (warmth, rejection, and overprotection) as well as anxious rearing [24]. The EMBU-P measures the same three parenting behaviors as well as favoring subject [25]. Previous research has shown questionable to good reliability for both the EMBU-C with Cronbach's $\alpha=0.66$ to 0.81 [24] as for the EMBU-P with Cronbach's $\alpha=0.66$ to 0.84 [25]. In the

current study, we were primarily interested in the three anxiety-enhancing parenting behaviors: warmth, rejection, and overprotection. However, there were reliability issues with the overprotection scale of both reports. The EMBU-C had adequate reliability for the rejection scale (Cronbach's $\alpha=0.78$), and questionable reliability for the warmth scale (Cronbach's $\alpha=0.68$) and overprotection scale (Cronbach's $\alpha=0.60$). The EMBU-P had good reliability for the warmth scale (Cronbach's $\alpha=0.85$), adequate reliability for the rejection scale (Cronbach's $\alpha=0.71$), and poor reliability for the overprotection scale (Cronbach's $\alpha=0.58$). We decided that Cronbach's α lower than 0.65 was unacceptable, resulting in not pursuing analyses with the overprotection scale of both the EMBU-C and P.

Demographics	CBT (n=8)	TAU (n=11)
Age, M (SD)	51.63 (9.38)	31.45 (7.69)
Years of experience, M (SD)	19.75 (7.59)	8.09 (5.77)
Gender		
Female, n (%)	5 (62.5)	10 (90.9)
Registration		
Clinical psychologist, n (%)	0	1 (9.1)
Psychotherapist, n (%)	2 (25.0)	0
Health care psychologist, n (%)	4 (50.0)	5 (45.5)
Developmental psychologist, n (%)	0	4 (36.4)
Mental health worker, n (%)	2 (25.0)	1 (9.1)

Table 1: Therapeutic Demographics for CBT and TAU.

Therapists

Nineteen agency-employed therapists were randomly allocated to CBT or TAU. CBT therapists received a two-day training organized by the original author of the manualized CBT program 'Thinking +Doing=Daring' [26]. Therapists consulted other therapists when needed. After one year, a meeting took place with all the participating CBT therapists to discuss treatment coherence and related issues. During the course of the study, three TAU therapists changed jobs and were replaced by three new therapists. None of the treatments that were already started had to be taken over by a new therapist. Therapeutic demographics CBT and TAU are presented in Table 1. Despite the randomization, CBT therapists were significantly older, $t(17)=5.15$, $p=0.00$, and had more years of experience, $t(17)=3.81$, $p=0.001$, compared to TAU therapists.

Treatment

Manualized CBT: Children in CBT (n=43) received the Dutch manualized CBT program 'Thinking+Doing=Daring' [26] by a trained therapist. Evidence for its partial effectiveness has been tested with a RCT including individual CBT, family CBT, and waitlist [27]. Both CBT conditions showed medium to large effect sizes. Based on these results, the revised manualized CBT program was made out of individual CBT combined with elements of family CBT [26]. Manuals for therapists, children, and parents were published and widely used in the Netherlands. The manualized CBT program is comparable to other programs such as Coping Cat [3] and friends [28] but has a greater

emphasis on cognitive restructuring and behavioral experiments. The treatment contained 15 sessions in total. There were 12 weekly sessions with the child. During three of these 12 sessions, the parents participated in the session and there were three additional treatment sessions with the parents alone. Each session lasted 60 to 90 mins and the child and parents had to do homework assignments.

During the first session, psycho-education about anxiety was given and the rationale behind CBT was explained to child and parents. The second session focused on cognitive restructuring. The child learned to identify anxious cognitions and to generate alternative cognitions. During the third session, the child learned coping skills such as relaxation exercises. In the same week as the third session, a parent session took place to exercise with cognitive restructuring and the parents learned about the influence of their own anxiety on their children. The fourth session was with the child and the parents and focused on constructing the fear hierarchy and reward system. Exposure to anxiety-provoking situations started in session five and lasted until session ten. During these sessions, the therapist practiced facing fearful situations with the child and motivated the child to practice at home. In the same week as session six, the second parent session took place during which the parents were motivated to support their child during exposure tasks. Behavioral experiments were introduced in session seven and eight. The child learned to challenge anxious cognitions by conducting behavioral experiments. In the ninth session, there was a parent-child joint meeting that focused on communicating with each other about fears. With the parents, parenting styles were also discussed. A summary of the skills taught during therapy was given in session ten and dealing with anxiety in the future was discussed in session eleven. During the last session with the child and parents in week twelve, treatment was evaluated and relapse prevention was discussed. The child received a certificate at the end of treatment.

Treatment-as-usual

Children in TAU (n=45) received treatment considered by the therapist as most effective for that particular child. There were no restrictions to this condition. The therapist decided on the frequency and duration of the treatment. Children were tracked for a period of three months in treatment, since this was considered an average length of time for treatment and was equal to the manualized CBT program. After treatment, therapists were asked about the content of the provided treatment and the number of sessions with the child and/or parents. In most instances, the treatment was based on CBT principles (96%). CBT was combined with intensive parental involvement (47%; more sessions with the parents than with the child), minimal parental involvement (44%, less sessions with the parents than with the child), or without any parental involvement (4%). In just 4% of all therapies, treatment focused only on psychomotor therapy, a form of creative art therapy that focuses on body awareness exercises and physical activity as a therapeutic instrument to work on the relation between experiences and feelings [29].

Statistical analyses

Missing data on item level were imputed using the Missing Value Analysis (MVA) of SPSS. No more than 6% of the items were missing per questionnaire. In accordance with the intention-to-treat principle, all children randomized for treatment were included in the analyses to test the main hypotheses. All analyses were conducted for both intention-to-treat (ITT) and completers only (CO). For ITT, missing

values were imputed for all measurements using 20 imputation sets by multiple imputations in SPSS. Imputations were done separately for CBT and TAU, and variables that correlated significantly were used as auxiliary variables [30]. Baseline characteristics among the treatment groups were tested with independent t-tests and Chi square analyses. Primary outcomes were SCARED-C and P Total scale and the subscales Separation anxiety, Social anxiety, Panic disorder, and Generalized anxiety. Secondary outcomes were CBCL Internalizing and Externalizing problems.

Analyses of covariance (ANCOVA's) were conducted to compare the CBT with TAU. We controlled for experience of the therapists and gender of the children. No other demographic variables were related to treatment outcome or to the potential predictors. Effect sizes were computed using Cohen's d (using pooled SD), where values of 0.2, 0.5, and 0.8 correspond to small, medium, and large effect sizes, respectively [31]. Multiple linear regression analyses were conducted to test for predictor effects. This was done with the subscales of the TASC and EMBU-C at baseline as potential predictors for the SCARED-C Total scale; and the subscales of the EMBU-P at baseline as potential predictors for the SCARED-P Total scale and the CBCL Internalizing and Externalizing problems. All linear regression analyses were run separately for each potential predictor. Additionally, we tested moderation effects with the interaction of parenting x treatment condition and alliance x treatment condition.

Results

Baseline comparisons: Table 2 summarizes participants' baseline demographics and comparisons between CBT and TAU. No significant differences were observed. The baseline clinical characteristics are presented in Table 3.

No significant differences between CBT and TAU were observed for the SCARED-C (Total anxiety $t(86)=0.96$, $p=0.34$; Separation anxiety $t(86)=-0.97$, $p=0.34$; Social anxiety $t(86)=-0.85$, $p=0.40$; Panic disorder $t(86)=1.07$, $p=0.29$; Generalized anxiety $t(86)=1.23$, $p=0.22$), SCARED-P (Total anxiety $t(86)=-0.54$, $p=0.59$; Separation anxiety $t(86)=-1.62$, $p=0.11$; Social anxiety $t(86)=-0.83$, $p=0.41$; Panic disorder $t(86)=0.49$, $p=0.63$; Generalized anxiety $t(86)=-0.53$, $p=0.60$) and CBCL (Internalizing problems $t(86)=-0.26$, $p=0.79$; Externalizing problems $t(86)=0.07$, $p=0.95$).

Baseline Demographics	CBT (n=43)	TAU (n=45)	Comparisons
Child			
Age, M (SD)	9.86 (1.28)	10.11 (1.35)	$t(86)=-0.89$, $p=0.38$
Male, n (%)	12 (27.9)	19 (42.2)	$\chi^2(1, N=88)=1.98$, $p=0.16$
Caucasian, n (%)	37 (94.9)	42 (100.0)	$\chi^2(1, N=81)=2.21$, $p=0.14$
Mother			
Age, M (SD)	43.79 (4.71)	42.93 (4.82)	$t(86)=0.84$, $p=0.40$
Married, n (%)	29 (72.5)	30 (69.8)	$\chi^2(1, N=83)=0.08$, $p=0.78$

Education, college or higher, n (%)	13 (32.5)	18 (41.9)	χ^2 (1, N=83)=0.78, p=0.38
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Table 2: Baseline Demographics for CBT and TAU.

The percentage of children in CBT meeting the clinical range of the SCARED-C was 26% for Total anxiety, 16% for Separation anxiety, 47% for Social anxiety, 35% Panic disorder, and 35% for Generalized anxiety. For the CBCL this was 63% for Internalizing and 28% for

Externalizing problems. The clinical range in TAU for the SCARED-C was 22% for Total anxiety, 22% Separation anxiety, 42% for Social anxiety, 18% for Panic disorder, and 31% Generalized anxiety. For the CBCL this was 64% for Internalizing and 24% for Externalizing problems. There were no norm scores available for the SCARED-P. Furthermore, the number of families that dropped out was not significantly different between treatment conditions, χ^2 (1, N=88)=0.84, p=0.36.

	Baseline		Post-treatment				6-month follow-up				12-month follow-up			
	CBT	TAU	CBT		TAU		CBT		TAU		CBT		TAU	
Scale	M (SD)	M (SD)	M (SD)	d	M (SD)	d	M (SD)	d	M (SD)	d	M (SD)	d	M (SD)	d
SCARED TOT														
Child	0.80 (0.26)	0.74 (0.27)	0.51 (0.33)	0.96	0.55 (0.35)	0.63	0.41 (0.25)	1.53	0.43 (0.32)	1.06	0.40 (0.22)	1.65	0.41 (0.29)	1.2
Mother	0.62 (0.23)	0.64 (0.22)	0.52 (0.26)	0.42	0.47 (0.23)	0.78	0.48 (0.25)	0.6	0.40 (0.20)	1.17	0.37 (0.20)	1.18	0.38 (0.25)	1.12
SCARED SEP														
Child	0.67 (0.33)	0.74 (0.39)	0.38 (0.31)	0.91	0.44 (0.35)	0.79	0.29 (0.25)	1.32	0.37 (0.35)	1.01	0.29 (0.25)	1.29	0.25 (0.24)	1.51
Mother	0.63 (0.30)	0.74 (0.35)	0.49 (0.37)	0.42	0.44 (0.30)	0.92	0.39 (0.30)	0.81	0.41 (0.35)	0.94	0.33 (0.27)	1.07	0.31 (0.30)	1.32
SCARED SOC														
Child	1.25 (0.53)	1.16 (0.45)	0.88 (0.58)	0.66	1.00 (0.57)	0.31	0.67 (0.49)	1.12	0.70 (0.53)	0.94	0.71 (0.52)	1.01	0.79 (0.56)	0.73
Mother	1.06 (0.55)	1.15 (0.56)	1.03 (0.52)	0.06	0.88 (0.56)	0.48	0.98 (0.49)	0.14	0.75 (0.49)	0.76	0.73 (0.37)	0.69	0.77 (0.47)	0.73
SCARED PAN														
Child	0.62 (0.43)	0.53 (0.35)	0.41 (0.41)	0.5	0.44 (0.37)	0.24	0.27 (0.33)	0.93	0.35 (0.36)	0.52	0.31 (0.39)	0.76	0.34 (0.35)	0.55
Mother	0.36 (0.28)	0.34 (0.27)	0.28 (0.30)	0.27	0.27 (0.26)	0.24	0.28 (0.32)	0.27	0.18 (0.19)	0.66	0.20 (0.21)	0.67	0.22 (0.26)	0.45
SCARED GEN														
Child	0.93 (0.40)	0.82 (0.42)	0.59 (0.51)	0.73	0.59 (0.40)	0.46	0.43 (0.35)	1.33	0.47 (0.42)	0.85	0.44 (0.44)	1.17	0.48 (0.43)	0.8
Mother	0.90 (0.45)	0.95 (0.46)	0.75 (0.38)	0.37	0.69 (0.43)	0.59	0.71 (0.41)	0.44	0.62 (0.40)	0.77	0.60 (0.50)	0.63	0.59 (0.47)	0.77
CBCL INT	0.58 (0.37)	0.54 (0.33)	0.54 (0.39)	0.36	0.37 (0.33)	0.88	0.40 (0.36)	0.86	0.27 (0.26)	1.11	0.25 (0.21)	1.2	0.32 (0.32)	0.7
CBCL EXT	0.37 (0.33)	0.31 (0.27)	0.36 (0.37)	0.28	0.27 (0.30)	0.34	0.28 (0.31)	0.45	0.19 (0.20)	0.59	0.18 (0.19)	0.46	0.20 (0.25)	0.38

Note: ITT: Intention-to-Treat; SCARED: Screen for Child Anxiety Related Emotional Disorders; Child: Child-report; Mother: Mother-report; TOT: Total Scale; SEP: Separation anxiety; SOC: Social anxiety; PAN: Panic disorder; GEN: Generalized anxiety; CBCL: Child Behaviour Checklist; INT: Internalizing problems; EXT: Externalizing Problems.

Table 3: Primary and secondary outcomes for ITT analyses at post intervention and follow-ups.

Treatment efficacy

Primary and secondary outcomes for CBT and TAU are presented in Table 3. In line with expectations, both treatment conditions were effective in reducing anxiety symptoms and problem behavior. For CBT, a large effect size for SCARED-C Total anxiety and a small effect size for SCARED-P Total anxiety at post-treatment was found, while for TAU a medium effect size for SCARED-C and P Total anxiety was found. At subscale level of the SCARED and the CBCL, effect sizes for both conditions ranged from small to large directly after treatment.

At six-month follow-up, both treatment conditions demonstrated large effect sizes for SCARED-C total anxiety. For SCARED-P total anxiety, a medium effect size was observed for CBT and a large effect size for TAU. At subscale level of the SCARED and the CBCL, the effect sizes for CBT ranged from small to large and for TAU from medium to large six months after the treatment. At 12-month follow-up, effect sizes for both treatment conditions were large for SCARED-C and P Total anxiety. At subscale level of the SCARED and the CBCL, effect sizes for both conditions ranged from small to large 12 months after the treatment.

Scale	Baseline-Post		Baseline-6-month FU		Baseline-12-month FU	
	d	F1,83	d	F1,83	d	F1,83
SCARED Total						
child-report	-0.30	1.39	-0.27	2.15	-0.24	0.29
mother-report	0.32	0.79	0.46	2.78	0.05	1.73
SCARED Separation						
child-report	0.01	0.04	-0.06	1.23	0.37	0.20
mother-report	0.47	2.77	0.26	0.27	0.38	0.01
SCARED Social						
child-report	-0.40	0.51	-0.22	0.01	-0.32	2.91
mother-report	0.43	5.95*	0.64	5.81*	0.08	0.00
SCARED Panic						
child-report	-0.31	2.64	-0.46	0.53	-0.30	0.11
mother-report	-0.05	0.51	0.29	2.48	-0.18	0.00
SCARED Generalized						
child-report	-0.27	0.84	-0.36	1.04	-0.37	0.70
mother-report	0.25	0.58	0.34	3.71	0.14	3.08
CBCL Internalizing	0.58	6.28*	0.30	2.53	-0.20	0.29
CBCL Externalizing	0.07	0.00	0.10	2.01	-0.04	0.33

Note: *p<0.05; **p<0.01; ***p<0.001; Post: Post-treatment; FU: Follow-up; SCARED: Screen for Child Anxiety Related Emotional Disorders; CBCL: Child Behaviour Checklist.

Table 4: Effect Sizes and Treatment Outcome for CBT vs. TAU.

Manualized CBT vs. TAU

In contrast to our initial hypothesis and in line with recent findings, we did not find significant better treatment outcomes for CBT compared to TAU (Table 4). We observed significant differences in the opposite direction than expected. We found significant better treatment outcomes in TAU for SCARED-P Social anxiety at post-

treatment, $F(1,83)=5.95$, $p=0.017$, and at six-month follow-up, $F(1,83)=5.81$, $p=0.018$. The CBT versus TAU effect sizes for these significant differences were all in the medium range (Table 4). Furthermore, we observed significant better treatment outcomes in TAU for Internalizing problems at post-treatment, $F(1,83)=6.28$, $p=0.014$. The CBT vs. TAU effect size for baseline-post-treatment was medium.

Treatment predictors and moderators

Unexpectedly, we found no significant main effects of alliance and parenting on treatment outcomes. We additionally tested whether treatment differences by groups on outcomes showed specific moderation effects. Only one significant effect occurred between the bond and treatment conditions on outcome at post-treatment, $F(4,78)=4.32$, $p=0.037$, $R^2=0.18$. The therapeutic bond was differentially associated with treatment outcome (SCARED-C Total anxiety at post-treatment) for CBT versus TAU. Opposite to what we expected, we found that CBT children who rated the bond at baseline as low (<2.9) reported significantly lower anxiety symptoms at post-treatment, compared to children who rated the bond as high (>2.9). This result was not found for TAU.

Completers only analyses

In contrast to ITT analyses, results for treatment outcomes with CO analyses showed significant differences between CBT and TAU for SCARED-C only. At post-treatment, we observed significantly better treatment outcomes in TAU for generalized anxiety, $F(1,67)=5.24$, $p=0.025$ and panic disorder $F(1,67)=5.64$, $p=0.020$. However, we also found instances of significant better treatment outcome in CBT. At post-treatment, for total anxiety, $F(1,67)=7.50$, $p=0.008$, and social anxiety, $F(1,67)=12.98$, $p=0.001$. At six-month follow-up, for Social anxiety, $F(1,65)=4.35$, $p=0.041$, and for generalized anxiety, $F(1,65)=4.40$, $p=0.040$.

Similar to ITT analyses, we found no significant main effects of alliance on treatment outcomes and only one significant interaction effect between the bond and treatment conditions ($B=0.28$, $SE=0.09$, $p=0.004$) on SCARED-C Total anxiety at post-treatment, $F(4,67)=6.46$, $p<0.001$, $R^2=0.28$. In contrast to ITT analyses, we observed significant main effects of parenting on treatment outcomes. In line to what we expected, we found that mothers who rated their amount of rejection towards the child at baseline as low ($B=0.19$, $SE=0.08$, $p=0.016$ and $B=0.17$, $SE=0.05$, $p=0.003$), reported lower amounts of Internalizing, $F(3,68)=17.36$, $p=0.016$, $R^2=0.43$, and Externalizing problems at post-treatment, $F(3,68)=43.32$, $p=0.003$, $R^2=0.66$, compared to mothers who rated the amount of rejection as high. This relation was still present for rejection ($B=0.27$, $SE=0.10$, $p=0.010$ and $B=0.23$, $SE=0.09$, $p=0.016$) and internalizing problems at six-month follow-up, $F(4,65)=8.37$, $p<0.001$, $R^2=0.34$, and internalizing problems at 12-month follow-up, $F(4,58)=10.69$, $p<0.001$, $R^2=0.42$.

Furthermore, we found two significant interaction effect between parenting and treatment conditions on internalizing problems. First, we observed an interaction effect between rejection and treatment conditions ($B=-0.45$, $SE=0.16$, $p=0.005$) on internalizing problems at 12-month follow-up, $F(4,58)=10.69$, $p<0.001$, $R^2=0.43$. Second, we observed one interaction effect between warmth and treatment conditions ($B=0.28$, $SE=0.10$, $p=0.010$) on internalizing problems at six-month follow-up, $F(4,65)=8.60$, $p<0.001$, $R^2=0.35$.

Discussion

The main aim was to assess the efficacy of a manualized CBT program compared to treatment-as-usual (TAU) for clinically anxious children recruited from a sample of children treated in Dutch mental health treatment centers. In line with expectations, both CBT and TAU were significantly effective in reducing anxiety symptoms and internalizing and externalizing problem behavior. The effect sizes for CBT were comparable to those reported in Bodden et al. [27] and in

other studies that investigated CBT for anxious children [2]. Notably, the results demonstrated that treatment gains for children in both treatment conditions were sustained even after one year. Contrary to our original hypothesis, and in line with recent meta-analytic findings [2], CBT was not superior in reducing anxiety symptoms or problem behavior compared to TAU.

Perhaps the most probable explanation for the overall similar treatment effects is that the vast majority (96%) of TAU included elements of CBT. The general difference between CBT and TAU was that trained therapists administered the manualized CBT; hence, they conducted highly structured treatment sessions with exact instructions for the frequency and content of each session while in TAU, therapists were not trained and the frequency and content of treatment was entirely up to them. At the start of this study, we did not anticipate the extent to which CBT principles would be incorporated in regular treatment for children with anxiety disorders. Importantly, the rigid insistence on sticking to the content, structure, and sequence of the CBT manual did not seem to provide additional benefit with regards to treatment outcome. Within TAU, treatment was more flexible and perhaps more personalized and adjusted to the needs of the child and family. Moreover, the amount of treatment sessions within the 13 weeks of TAU were lower (on average 7.56 child sessions) compared to CBT (12 child sessions). This could indicate that the same treatment progress can be accomplished with fewer CBT sessions when treatment is custom fitted. Previous research also indicates that CBT can be effective in less session and more flexible than manualized CBT programs [6]. However, some caution is warranted, since we did not analyze the number of parent sessions for TAU and did not analyze the amount of treatment that the children might have received after the 13 weeks of TAU (nor for CBT).

Another difference between the treatment conditions was that parental involvement was minimal for CBT, while this was intensive in 47% of TAU cases. Perhaps relatedly, we found some minor differences in mother-reported treatment outcomes between the two conditions. Mothers in TAU noted less internalizing problems in their children directly after the treatment compared to mothers in CBT. This difference was no longer present at the follow-up assessments. A possible explanation could be that when mothers are intensely involved in the treatment, they perceive less depressive symptoms (since this effect was not present for anxiety symptoms) in their children directly after treatment. Perhaps children feel that their parents are concerned about them, and they receive more attention during this period from their parents, ultimately resulting in a temporarily expression of happiness and less depressive symptoms. However, this possibility should be interpreted with caution. We only had mothers' reports on children's internalizing problems and we did not have children's reports on their own depressive symptoms.

The second aim of the current study was to evaluate potential treatment predictors. In contrast to expectations, parenting and alliance did not predict treatment outcome. Perhaps the influence of parenting on childhood anxiety has been overrated. Support for this possibility was put forward in a meta-analysis by McLeod and colleagues [32] which demonstrated that parenting explains only 4% of variance in childhood anxiety, suggesting that it is more likely that genetic factors and non-shared environments contribute more to childhood anxiety. Finding from genetic research suggests that genetic factors influence the association between parenting behavior and anxiety symptoms [33]. Both parent and child interact with each other at a genetic and behavioral level, creating a shared dynamical

relationship. Children who do not improve following the treatment could be genetically predisposed, and they could have parents reacting in a more rejecting and controlling manner, while children who benefit from the treatment are either genetically predisposed or have parents reacting in a rejecting and controlling manner. Clinical trials that collect both genetic information and assess parenting behaviors would be important to conduct, to disentangle these hypotheses.

For alliance, one specific moderator effect occurred that was exclusive to children in the CBT condition. Children who experienced a low bond after the first session improved more on anxiety symptoms compared to children who experienced a high bond after the first session. This is in contrast to what we expected. Since this effect was specific to the children in CBT, perhaps a reason for this finding can be found within the content of treatment. The first session for children in CBT is a highly structured 90-minute treatment session with the therapist, child, and the parents in which the child learns a lot of new information about the therapist and the treatment. During this session, therapists need to strictly manage time and divide their attention among all family members. It can be quite overwhelming and anxiety provoking for children to learn what is expected from them within the subsequent couple of weeks, especially when the child feels rushed or relatively neglected during this session. This could result in the child reporting an initially low bond. The second session involves only the child and therapist. One might assume that further bonding with the therapist takes place which enhances the bond. Additionally, Chiu et al. [15] found that improvement in the child-therapist relationship over the course of the treatment, rather than one static measure of alliance at one point, predicted better treatment outcome. Perhaps for children, it is this repair or the trajectory of alliance over the course of the treatment that predicts outcomes best. It seems important for future research to examine alliance at multiple times in treatment, rather than at one point, to clarify these potentially complex and variable predictive relations.

Our conclusions about parenting and alliance should be interpreted with caution due to power and reliability issues. For parenting, we were not able to analyze whether maternal overprotection predicted treatment outcome, although we know that parental control has been more strongly associated with child anxiety compared to parental rejection and warmth [32]. Previous studies have also reported poor or questionable reliability of overprotection for both the EMBU-C and P [34]. Young et al. [35] found a strong correlation between overprotection and anxious rearing scales of the EMBU-C and suggested that these scales may not be adequately differentiated and even redundant. This seems plausible, considering that the EMBU-C and -P contain three overlapping parenting scales as well as additional non-overlapping scales. Furthermore, the EMBU was originally developed by Arrindell et al. [23] based on Baumrind's [36] model of parenting that considered warmth and control as two orthogonal dimensions of parenting. A meta-analysis by McLeod et al. [32] on parenting and childhood anxiety has identified two broad dimensions of parenting, rejection and control, each consisting of different sub-dimensions. Rejection is defined by withdrawal, aversiveness, and warmth, while control includes over-involvement and autonomy-granting. Further studies seem to be warranted to more reliably establish the definition and assessment of parenting constructs.

For alliance, analyses were only conducted with the bond scale, although its reliability was still questionable. Children in the current study were on average younger compared to other studies that achieved adequate reliability [37]. It may be that in terms of the

reliability issue, younger children have more trouble reflecting on the relationship with their therapist. Younger children are often considered less reliable as informants due to their limited cognitive and social-emotional development, such as their sensitivity to social desirability [38]. Additional assessment of child-therapist alliance is based on parental reports, therapist ratings, or treatment observations, though cross-informant agreement is generally low [22]. Because no gold standard for preferred informant exists, it may be useful for prospective studies with 8 to 12 years old children to combine alliance ratings from multiple informants. This will ultimately lead to a more comprehensive understanding of the dynamics between therapeutic alliance and treatment outcome for children, since recent findings suggest that the association is more complex compared to what has been previously assumed [14,37].

The current study has a number of notable strengths, including the use of treatment-as-usual as active control treatment, clinicians' treatment of children in mental health clinical practice, the use of mother- and child-reported outcomes, and long term follow-up assessments. Some limitations should also be considered when interpreting the findings. First, the diagnostic assessment of DSM-IV diagnoses was conducted by agency clinicians after an extensive diagnostic process that was usual in the agencies, but this was not done in a standardized manner such as with diagnostic interviews. Further research would benefit from assessment based on diagnostic interviews. Second, by actively screening children in primary schools, we probably included children who would not have sought or received treatment without recruitment in the current study. Thus, the sample was a mix of children with a clinical anxiety disorder referred for treatment and children who were in need for treatment but would otherwise not have received it. Although mean baseline anxiety scores reported by mother and child were comparable to those in other clinical trials [27], some caution is warranted to generalize the findings to clinical samples from routine child mental health services. Third, we were unable to include the number of children we anticipated [17]. Thus, the analyses were underpowered. More research with bigger sample sizes is needed. Last, we only asked mothers

Conclusions and Implications

Although this study has some limitations, it supports previous findings, which suggested that manualized CBT does not outperform usual treatment in routine clinical practice. Treatment-as-usual was even superior to CBT in some instances. Since treatment-as-usual in the participating Dutch agencies consisted of CBT components, the study adds to the growing literature that supports the efficacy of CBT for children with an anxiety disorder. Moreover, findings seem to suggest that CBT can be effective in a shorter and more flexible manner than prescribed by manualized CBT programs. However, treatment predictors and moderators still need to be assessed to determine which children benefit from which treatment.

Compliance with Ethical Standards

This study was financially supported by a grant from ZonMw, the Dutch organization for health research and development, grant number 80-82470-98-00-05. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

References

- Higa-McMillan CK, Francis SE, Rith-Najarian L, Chorpita BF (2016) Evidence base update: 50 years of research on treatment for child and adolescent anxiety. *J Clin Child Adolesc Psychol* 45: 91-113.
- James AC, James G, Cowdrey FA, Soler A, Choke A (2013) Cognitive behavioural therapy for anxiety disorders in children and adolescents. *Cochrane Database Syst Rev* 6: CD004690.
- Kendall PC, Hedtke KA (2006) Cognitive-behavioral treatment of anxious children: therapist manual. Ardmore, PA: Workbook Publishing.
- Weisz JR, Jensen-Doss A, Hawley KM (2006) Evidence-based youth psychotherapies versus usual clinical care: A meta-analysis of direct comparisons. *Am Psychol* 61: 671-689.
- Southam-Gerow MA, Weisz JR, Chu BC, McLeod BD, Gordis EB, et al. (2010) Does cognitive behavioral therapy for youth anxiety outperform usual care in community clinics? An initial effectiveness test. *J Am Acad Child Adolesc Psychiatry* 49: 1043-1052.
- Vande Voort JL, Svecova J, Brown Jacobsen A, Whiteside SP (2010) A retrospective examination of the similarity between clinical practice and manualized treatment of childhood anxiety disorders. *Cogn Behav Pract* 17: 322-328.
- Kazdin AE (2007) Mediators and mechanisms of change in psychotherapy research. *Annu Rev Clin Psychol* 3: 1-27.
- Kraemer HC, Wilson GT, Fairburn CG, Agras WS (2002) Mediators and moderators of treatment effects in randomized clinical trials. *Arch Gen Psychiatry* 59: 877-883.
- Compton SN, Peris TS, Almirall D, Birmaher B, Sherrill J, et al. (2014) Predictors and moderators of treatment response in childhood anxiety disorders: Results from the CAMS trial. *J Consult Clin Psychol* 82: 212-224.
- Creswell C, Murray L, Stacey J, Cooper P (2011) Parenting and child anxiety. In: Silverman, W. K. and Field, A. P. (eds.) *Anxiety disorders in children and adolescents*. 2nd edition, Cambridge: Cambridge University Press.
- Creswell C, Willetts L, Murray L, Singhal M, Cooper P (2008). Treatment of child anxiety: an exploratory study of the role of maternal anxiety and behaviours in treatment outcome. *Clin Psychol Psychother* 15: 38-44.
- Festen H, Hartman CA, Hogendoorn S, de Haan E, Prins PJ, et al. (2013) Temperament and parenting predicting anxiety change in cognitive behavioral therapy: The role of mothers, fathers, and children. *J Anxiety Disord* 27: 289-297.
- Cummings CM, Caporino NE, Settiani CA, Read KL, Compton SN, et al. (2013) The therapeutic relationship in cognitive-behavioral therapy and pharmacotherapy for anxious youth. *J Consult Clin Psychol* 81: 859-864.
- Marker CD, Comer JS, Abramova V, Kendall PC (2013) The reciprocal relationship between alliance and symptom improvement across the treatment of childhood anxiety. *J Clin Child Adolesc Psychol* 42: 22-33.
- Chiu AW, McLeod BD, Har K, Wood JJ (2009) Child-therapist alliance and clinical outcomes in cognitive behavioral therapy for child anxiety disorders. *J Child Psychol Psychiatry* 50: 751-758.
- Langer DA, McLeod BD, Weisz JR (2011) Do treatment manuals undermine youth-therapist alliance in community clinical practice? *J Consult Clin Psychol* 79: 427-432.
- Jansen M van Doorn MEM, Lichtwarck-Aschoff A, Kuijpers RCWM, Theunissen H, Korte M, et al. (2012) Effectiveness of a cognitive-behavioral therapy (CBT) manualized program for clinically anxious children: Study protocol of a randomized clinical trial. *BMC Psychiatry* 12: 16.
- Birmaher B, Brent DA, Chiappetta L, Bridge J, Monga S, et al. (1999) Psychometric properties of the Screen for Child Anxiety Related Emotional Disorders (SCARED): A replication study. *J Am Acad Child Adolesc Psychiatry* 38: 1230-1236.
- Muris P, Bodden D, Hale W, Birmaher B, Mayer B (2007) SCARED-NL: Vragenlijst over angst en bang-zijn bij kinderen en adolescenten. Handleiding bij de gereviseerde Nederlandse versie van de Screen for Child Anxiety Related Emotional Disorders. Amsterdam: Boom test uitgevers.
- Ivanova MY, Dobrea A, Dopfner M, Erol N, Fombonne E, et al. (2007) Testing the 8-syndrome structure of the child behavior checklist in 30 societies. *J Clin Child Adolesc Psychol* 36: 405-417.
- Shirk SR, Saiz CC (1992) Clinical, empirical, and developmental perspectives on the therapeutic relationship in child psychotherapy. *Dev Psychopathol* 4: 713-728.
- Creed TA, Kendall PC (2005) Therapist alliance-building behavior within a cognitive-behavioral treatment for anxiety in youth. *J Consult Clin Psychol* 73: 498-505.
- Arrindell WA, Emmelkamp PM, Brilman E, Monsma A (1983) Psychometric evaluation of an inventory for assessment of parental rearing practices: A Dutch form of the EMBU. *Acta Psychiatr Scand* 67: 163-177.
- Muris P, Meesters C, van Brakel A (2003) Assessment of anxious rearing behaviors with a modified version of "Egna Minnen Beträffande Uppfostran" questionnaire for children. *J Psychopathol Behav Assess* 25: 229-237.
- Castro J, de Pablo J, Gómez J, Arrindell WA, Toro J (1997) Assessing rearing behaviour from the perspective of the parents: a new form of the EMBU. *Soc Psychiatry Psychiatr Epidemiol* 32: 230-235.
- Bögels SM (2008) Behandeling van angststoornissen bij kinderen en adolescenten. Met het cognitief gedragstherapeutisch protocol Denken + Doen = Durven. Houten: Bohn Stafleu van Loghum.
- Bodden DH, Bögels SM, Nauta MH, De Haan E, Ringrose J (2008) Child versus family cognitive behavioral therapy in clinically anxious youth: An efficacy and partial effectiveness study. *J Am Acad Child Adolesc Psychiatry* 47: 1384-1394.
- Barrett PM, Lowry-Webster H, Turner C (2000) Friends program for children: Participants workbook. Brisbane: Australian Academic Press.
- Probst M, Knappen J, Poot G, Vancampfort D (2010) Psychomotor therapy and psychiatry: What's in a name? *Open Complement Med J* 2: 105-113.
- Graham JW (2009) Missing data analysis: Making it work in the real world. *Annu Rev Psychol* 60: 549-576.
- Cohen J (1988) *Statistical power analysis for the behavioral sciences*. 2nd ed. Hillsdale, NJ: Erlbaum.
- McLeod BD, Wood JJ, Weisz JR (2007) Examining the association between parenting and childhood anxiety: A meta-analysis. *Clin Psychol Rev* 27: 155-172.
- Eley TC, Napolitano M, Lau JY, Gregory AM (2010) Does childhood anxiety evoke maternal control? A genetically informed study. *J Child Psychol Psychiatry* 51: 772-779.
- Aluja A, del Barrio V, García LF (2006) Do parents and adolescents differ in their perceptions of rearing styles? Analysis of the EMBU versions for parents and adolescents. *Scand J Psychol* 47: 103-108.
- Young BJ, Wallace DP, Imig M, Borgerding L, Brown-Jacobsen AM, et al. (2013) Parenting behaviors and childhood anxiety: A psychometric investigation of the EMBU-C. *J Child Fam Stud* 22: 1138-1146.
- Baumrind D (1971) Current patterns of parental authority. *Dev Psychol Monograph* 4: 1-103.
- Fjermestad KW, Lerner MD, McLeod BD, Wergeland GJ, Heiervang ER, et al. (2016) Therapist-youth agreement on alliance change predicts long-term outcome in CBT for anxiety disorders. *J Child Psychol Psychiatry* 57: 625-632.
- Silverman WK, Ollendick TH (2005) Evidence-based assessment of anxiety and its disorders in children and adolescents. *J Clin Child Adolesc Psychol* 34: 380-411.