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Disorder-Specific Cognitive-Behavioral Therapy for Separation Anxiety Disorder in Young Children: A Randomized Waiting-List-Controlled Trial

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Key Words
Separation anxiety disorder · Young children · Disorder-specific cognitive-behavioral therapy · Family-based cognitive-behavioral therapy · Cognitive-behavioral therapy

Abstract
Background: Separation anxiety disorder (SAD) is one of the earliest and most common mental disorders in childhood, and a strong predictor of adult psychopathology. Despite significant progress in psychotherapy research on childhood anxiety disorders, no randomized controlled trial has been conducted with a disorder-specific treatment program for young children suffering from SAD. ***Methods:*** Forty-three children (ages 5–7) with SAD and their parents were assigned to either a 16-session disorder-specific SAD treatment program including parent training and classical cognitive-behavioral therapy (CBT) components, or to a 12-week waiting list group. Categorical and/or continuous data for anxiety, impairment/distress and quality of life were collected at baseline, after treatment/waiting list condition, and at a 4-week follow-up. ***Results:*** Intention-to-treat analyses indicate that 76.19% of children allocated to the treatment group definitively no longer fulfilled DSM-IV criteria for SAD at follow-up, compared to 13.64% in the waiting list group. Between 91 and 100% of children rated themselves or were rated by their father, mother or therapist as very much or much improved on the global success rating immediately after treatment. Results indicated large time by treatment condition interaction effect sizes (d = 0.98–1.41) across informants for reduction of distress/avoidance in separation situations after the test for the treatment condition. Further, parents reported significant improvements in impairment/distress in the child's major life domains and the child's quality of life. Treatment gains were maintained at the 4-week follow-up assessment. ***Conclusions:*** Results indicate the short-term efficacy of a disorder-specific treatment approach for SAD, and are among the first to indicate that CBT programs work with young children.

Trial registry name: Clinical Trials; registration identification number: NCT00255112; registry URL: http://www.clinicaltrials.gov.

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Introduction

Separation anxiety disorder (SAD) is the earliest and one of the most common anxiety disorders in childhood [1, 2], and is the only childhood anxiety disorder for which specific diagnostic criteria have been formulated in the DSM-IV [3]. SAD typically causes substantial impairment in kindergarten/school, family relationships, and social functioning [4]. Perhaps even more importantly, SAD is a significant risk factor for adult anxiety disorders, including panic disorder, depression and substance abuse disorders [5, 6]. Indeed, in one study, 73.5% of children and adolescents with an SAD diagnosis developed an episode of psychopathology in young adulthood [6]. Despite its early onset, high prevalence and unfavorable long-term prognosis, the treatment of SAD in young children remains significantly underresearched, although it is likely that effective early treatment could favorably alter the developmental course for children suffering from SAD, reducing not only current impairment, but the incidence of mental disorder in adolescence and adulthood as well.

Research on psychotherapy for childhood anxiety disorders has advanced considerably in recent years. Meta-analyses and reviews indicate that cognitive-behavioral therapy (CBT) can be considered an evidence-based psychotherapeutic technique for the treatment of anxiety disorders, with 68.9% of children completing CBT no longer meeting diagnostic criteria for their principal pretreatment anxiety disorder, on average, compared to only 12.9% of children assigned to a waiting list [7, 8]. Intention-to-treat analyses indicate an average remission rate for anxiety disorders of 56% after receiving CBT, versus 28.2–34.8% for controls [7, 9, 10]. Overall, across studies examining the effects of CBT on anxiety, results indicate medium to large effects [11], with a mean pre/post-treatment effect size of 0.86 for treatment completers and moderate effects of 0.58 in intention-to-treat analyses [7, 10]. The recently published pre/post-treatment results of the Child/Adolescent Anxiety Multimodal Study, the largest randomized controlled trial (RCT) to date to assess treatment outcomes in children with anxiety disorders, comparing 4 treatment conditions (CBT, SSRI medication, CBT + SSRI, and placebo), found short-term pre/post-treatment effect sizes of 0.31 for CBT, 0.45 for SSRI, and 0.86 for CBT + SSRI (effect size not reported for placebo) for children aged 7–17 using the intention-to-treat sample [12]. Finally, research indicates that CBT gains can be maintained up to several years after treatment [13].

In the treatment studies described above, however, treatment was administered to older children and adolescents, with a mean age of 10.9 years (range 6–18) in the meta-analysis by In-Albon and Schneider [7], and a range of 7–17 years in Walkup et al. [12]. In the review by James et al. [10], only 1 of the 13 studies reviewed included children younger than 7 years (range 6–16), with a mean age of 9.66 years, i.e. still far from examining treatment effectiveness for very young children. Further, SAD is typically grouped together with generalized anxiety disorder, social phobia, and occasionally with specific phobias, using a single 'global' CBT program, based on the symptom overlap and high comorbidity among anxiety disorders. Until now, the efficacy of a disorder-specific treatment, specifically tailored to the needs of young children with SAD, has remained untested. Research on adults indicates that disorder-specific treatments for anxiety disorders tend to produce higher effect sizes [14] than those indicated to date for treatment of childhood anxiety disorders [7] and by the Child/Adolescent Anxiety Multimodal Study results (panic disorder/agoraphobia: 1.48, social phobia: 1.06, generalized anxiety disorder: 1.01) [15]. While it is possible that psychotherapy simply works better for adults than for children, an alternative possibility is that the effect sizes are lower in children because child treatments have not been tailored to address specific anxiety disorders as they have for adults. Further, effect sizes for CBT with very young children are virtually unknown, given the dearth of studies for young children. Initial evidence in favor of disorder-specific approaches for children comes from a meta-analysis on treatment studies for social phobia, indicating large pre/post-treatment effect sizes of $d = 1.02$ for trait anxiety and $d = 1.06$ for social phobia symptoms [16].

In the area of SAD, evidence from two small pilot studies is convincing [17, 18]. Both treatments included parent training, targeting parent-child interactions and parenting behavior. While Choate et al. [17] trained parents exclusively in behavior management skills and in the improvement of parent-child relationships, Eisen et al. [18] included classical CBT ingredients such as psychoeducation, correction of dysfunctional cognitions in the child (mediated by the parent), exposure, and relapse prevention, in addition to parent training. Both studies demonstrated success. However, because of the pilot character of these studies (only 3–5 children, 4–10 years of age), these results await support from a larger sample using an RCT design.

The present study reports on findings from our treatment study, entitled 'Trennungsangstprogramm für

Familien' (TAFF; separation anxiety family therapy), which was specifically designed to address current gaps in psychotherapy and etiology research for children with SAD. The goals of the overarching study are twofold: (1) to evaluate the short-term efficacy of a disorder-specific CBT program for SAD in young children using an RCT design and a multi-informant approach, and (2) to evaluate the long-term efficacy of the treatment of SAD in childhood in reducing the incidence of mental disorder in adolescence and young adulthood. The present report provides an analysis of the short-term treatment effects in comparison to a waiting list condition, and on outcomes for both groups after treatment.

Method

Study Design

The present study was conducted at our university outpatient clinic from December 2004 to January 2009, and was reviewed and approved by the local ethics committee for medical research. As no other therapy for young children with SAD has been evaluated in an RCT to date, we tested the efficacy and safety of the new disorder-specific treatment against a waiting list group as a first step. The treatment condition included baseline assessment, 16 sessions of disorder-specific CBT across 12 weeks, post-treatment questionnaire assessment and follow-up assessments at 4 weeks, 12 months and 24 months. Data collection for the 1- and 2-year follow-up assessments is ongoing. Participants in the waiting list condition completed an initial baseline assessment, and were then placed on a 12-week waiting list before receiving treatment and participating in the 3 follow-ups. Diagnostic interviews were conducted at baseline and at each follow-up. Self-report measures were administered at baseline, at every fourth therapy session, after the waiting list condition (waiting list group only), after treatment, and at each follow-up. To gain a thorough understanding of the impact on diagnoses and mental health status, we used a multiple-informant approach, including reports from children, both parents, therapists, and blinded clinicians [19].

Participants

Participants were recruited from local child and adolescent psychiatrists, psychological therapists, pediatricians, and through newspaper advertisements and flyers. Inclusion criteria were a primary diagnosis of SAD according to the DSM-IV-TR [20], knowledge of the local language, age between 5 and 7 years, written parental informed consent and verbal child assent to randomized assignment to either the immediate treatment condition or the waiting list condition, and completion of psychological assessments. Children taking psychotropic medication were excluded. All participants received free diagnostic assessment and treatment.

Figure 1 provides a participation flowchart in accordance with the CONSORT guidelines and checklist (online supplementary checklist, www.karger.com/doi/10.1159/000323444) adhered to throughout the study [21, 22]. One hundred and twenty families contacted the department and underwent a telephone screening for participation in the present treatment study. Forty-three children meeting DSM-IV-TR criteria for SAD and their parents (9 boys and 13 girls in the waiting list condition, 9 boys and 12 girls in the treatment condition) met inclusion criteria for the present study and were randomly assigned to treatment or waiting list conditions. Randomization was conducted by a statistician using a computerized permuted block design, with assignments concealed until the time of group assignment. Two families in the treatment condition declined to begin treatment or to participate in assessment beyond baseline. One child in the treatment and 1 in the waiting list condition became inactive during treatment, and declined assessment beyond baseline. No known adverse events related to the treatment or study contributed to study withdrawal. Four children in the waiting list condition no longer needed treatment after the waiting period and thus did not receive treatment, but still participated in post-waiting list and follow-up assessment. Analyses include all available data on all children, and are considered intention-to-treat analyses, although post-treatment data were not available for 3 children in the treatment condition and for 1 child in the waiting list condition. Further, mothers were required to participate, but not all fathers participated in all assessments (varies by assessment).

Participant Demographics

The mean age of the children was 6.29 years (SD = 1.01) in the treatment group and 6.18 years (SD = 0.73) in the waiting list group with no between-group difference [$t(41) = 0.09$, $p > 0.05$]. The mean age of mothers was 38.26 years (SD = 4.00) in the treatment group and 36.66 years (SD = 4.43) in the waiting list group with no between-group difference [$t(36) = 1.23$, $p > 0.05$]. The mean age of fathers was 41.09 years (SD = 5.07) in the treatment group and 39.37 years (SD = 5.12) in the waiting list group with no between-group difference [$t(33) = 1.00$, $p > 0.05$]. Forty-two children (97.67%) were living with 1 or both biological parents, and 1 child from the waiting list group (2.33%) was adopted. Within the treatment group, 20 sets of parents were married or cohabiting, and 1 was divorced/single and within the waiting list group, 20 were married or cohabiting and 2 were divorced or single with no between-group difference [$\chi^2(1, n = 43) = 0.31$, $p > 0.05$]. Parents' education was indicated on a scale with the following values: 1 (did not finish school), 2 (obligatory school, equivalent to US 10th grade), 3 (vocational training), 4 ('Matur'; slightly higher than a high school diploma), 5 (professional training), 6 (university degree). Using this scale, mothers' mean education was 3.85 (SD = 1.18) in the treatment group and 3.19 (SD = 0.75) in the waiting list group [$t(39) = 2.14$, $p < 0.05$]. Mothers' education was not correlated with any outcomes at the Bonferroni-corrected 0.001 level, and thus was not considered to correlate more than would be expected by chance. Thus, mothers' education was not controlled for in further analyses. Fathers' mean education was 4.21 (SD = 1.03) in the treatment group and 4.50 (SD = 1.25) in the waiting list group with no between-group difference [$t(35) = -0.77$, $p > 0.05$]. Thirteen treatment group mothers and 10 waiting list mothers were working outside the home, and 7 treatment group mothers and 12 waiting list group mothers were not, with no between-group difference [$\chi^2(1, n = 42) = 1.62$, $p > 0.05$]. Sixteen treatment group fathers and 19 waiting list group fathers were working outside the home, while 2 treatment group fathers and 2 waiting list group fathers were not, with no between-group difference [$\chi^2(1, n = 39) = 0.03$, $p > 0.05$]. On a scale ranging from 1 (less than 2,000 CHF per month) to 6 (more than

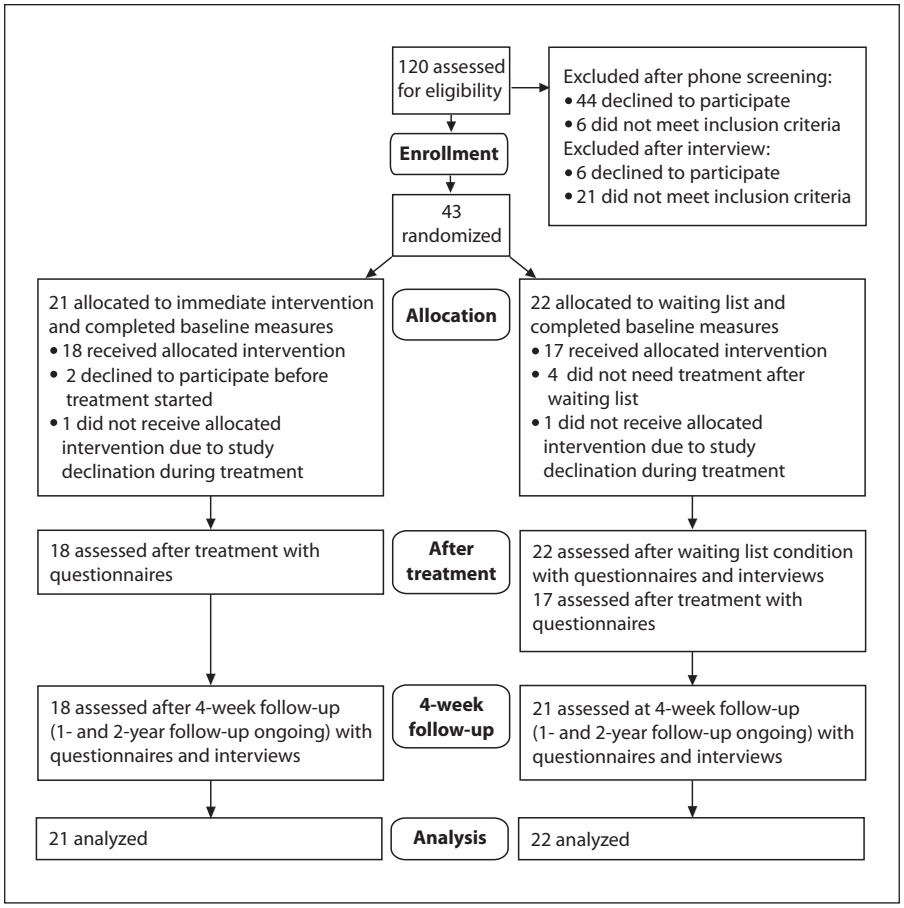

Fig. 1. Participation flowchart.

10,000 CHF per month), with 3 = 4,000–6,000 and 4 = 6,000–8,000 CHF per month, the mean income was 4.15 (SD = 1.42) in the treatment group, and 3.61 in the waiting list group, with no between-group difference [$t(36) = 1.03$, $p > 0.05$].

Clinical Severity Rating and Comorbidity

Mean clinician-rated severity on a scale ranging from 1 (no impairment) to 8 (very severe impairment), with a rating of ≥4 judged as clinically relevant for SAD, was 5.90 (SD = 0.91) in the treatment group, and 5.86 (SD = 1.32) in the waiting list group, with no significant between-group difference [$t(40) = 0.10$, $p > 0.05$]. Nine children (40.91%) in the waiting list condition, and 8 children (38.10%) in the treatment condition presented with clinically significant kindergarten/school reluctance [a score of 'often' or 'very often' on the school refusal item in the 'Diagnostisches Interview bei psychischen Störungen, im Kindes- und Jugendalter' (Kinder-DIPS; diagnostic interview for mental disorders in children and adolescents)], with no between-group difference [$\chi^2(1, n = 42) = 0.10$, $p > 0.05$]. Comorbid diagnoses were present in 44.18% of children in the whole sample. Eleven (52.38%) children in the treatment group presented with comorbid disorders [7 with another anxiety disorder, 2 with a sleeping disorder, 1 with a behavior disorder (oppositional defiant disorder), and 1 with a tic disorder], as did 8 (36.36%) children in the waiting list condition [6 with another anxiety disorder, 1 with an affective disorder, 1 with a sleeping disorder, 2 with a behavior disorder (1 attention deficit hyperactivity disorder, 1 oppositional defiant disorder), and 2 with an elimination disorder (some had multiple comorbidity)]. No significant difference was found for the presence of comorbidity between groups [$\chi^2(1, n = 43) = 1.12$, $p > 0.05$].

Treatment Protocol

The TAFF treatment manual was developed for the purpose of this study and is available upon request from the first author. Treatment was divided into individual and family sessions. The first 4 weeks of treatment consisted of SAD-specific psychoeducation in 4 weekly 50-min sessions with the child alone and 4 weekly 50-min sessions with the parents alone. Age-appropriate materials with pictorial illustrations were developed to educate the children. Children learned about normal and pathological anxiety, including the frequency of anxiety disorders in children, how to identify anxiety through body signs, and the interplay between thoughts, feelings, and actions. They learned to use an anxiety thermometer to rate their own anxiety, and learned about the habituation process using visual charts and graphs. They identified their own fears and, together with the therapist, created a fear hi-

erarchy and goals that they wanted to work on in therapy. Finally, children learned about the role of dysfunctional beliefs in maintaining anxiety, and learned how to change these beliefs via a 'reality check'. At the end of the 4 child sessions, the rationale for exposure was discussed, and tasks were created for the child to overcome during the exposure treatment. During the 4 parent sessions, parents received psychoeducation tailored to the child's SAD symptomatology, as well as on the etiology of SAD and separation as a developmental task. They, too, learned about the frequency of anxiety disorders, and about the interplay between emotions, thoughts, and behaviors. Parents were trained to identify and correct any of their own dysfunctional cognitions concerning separation anxiety [23], and learned to recognize and reframe dysfunctional beliefs about separation situations. They were also trained in appropriate parental behaviors during separation, and worked with the therapist to create goals for the exposure portion of the therapy. Finally, parents were given time to ask questions related to their own child's behavior, and were given brief training in general behavior management strategies. The second 8 weeks of treatment consisted of weekly 50-min family sessions, each split into two parts: one with parents and child together, and a second with the parents only. During the first part of the family sessions, exposure in vivo was planned and discussed, with the last session dedicated to relapse prevention. The first exposure was always carried out with the therapist present and leading the exposure, with the parents observing. The second exposure was conducted by the parents themselves, with one parent leading (the parents took turns), and the therapist coaching. When an exposure was planned for a session, it was carried out within a few minutes of the start of the meeting, and sufficient time was always allowed for habituation to take place. After the first two exposures, further exposures were typically carried out by the parents outside of the therapy session, although the therapist was present if necessary. The therapy session with both parents and child present was then used to process the last exposure and to plan the next. The parent-only portions of the family sessions involved intensive coaching, practicing of parental behavior prior to exposure, reframing irrational beliefs about separation and parental self-concept, parenting strategies, and introducing and practicing behavioral strategies to aid in developing children's autonomy and coping behavior. Ten qualified CBT psychotherapists with training in the disorder-specific CBT program for SAD conducted the therapy sessions. Therapists were trained and supervised weekly by the first author. Each session was videotaped, with consent, for the purpose of analyzing treatment integrity.

Measures

Clinical Diagnoses. The Kinder-DIPS [24] is a structured parent interview designed to assess mental disorders in children according to DSM-IV-TR criteria [20]. Clinician-based ratings of symptom frequency are assessed on a 4-point scale from 0 (never/seldom) to 3 (very often), with frequency ratings ≥ 2 judged as clinically relevant. Clinician-based ratings of the degree of distress and impairment (in home, school, friendship, and leisure domains) caused by the presenting symptoms for the child are provided on a 4-point scale from 0 (not at all) to 3 (very strong). Test-retest reliability ($\kappa = 0.85–0.94$; all DSM-IV diagnoses) and validity in past research are good, as are interrater reliability estimates for diagnoses of SAD ($\kappa = 0.85$), overall diagnosis of an anxiety disorder ($\kappa = 0.85$), and other axis I disorders ($\kappa = 0.85–0.94$) [25]. Interviews were conducted by trained clinical psychologists or advanced masters students, blinded to group status at all evaluations.

Global Success. Global success rating (child, parent, and therapist forms) [26] is a measure of clients' and therapists' subjective assessment of the overall success of treatment. Post-treatment global change was rated on a scale ranging from 1 (very much worse) to 7 (very much improved), with 4 indicating no change. This and all subsequent child measures were read aloud to the children.

Separation Anxiety. Parents and children completed the child and parent versions of the 12-item disorder-specific Separation Anxiety Inventory for Children (SAI) [27] to assess the degree of avoidance of separations in a variety of settings (e.g. 'I avoid going to sleep alone') using a 5-point scale ranging from 0 (never) to 4 (always). The original 12-item SAI showed good reliability (internal consistency = 0.85; test-retest reliability = 0.84) and construct validity [28]. In the present study, 1 item assessing experiences not typical for the present age group (e.g. sleep-away camp) was dropped. Reliability for the 11 items in the current clinical sample was $\alpha = 0.59$ (children), 0.55 (mothers), and 0.67 (fathers).

Distress and Impairment. Parents and children completed a German-adapted version of the 3-item Sheehan Disability Scale (SDS) [29, 30] to assess distress and functional impairment due to anxiety in school, family life, and social life by responding to 6 items on a scale ranging from 0 (mild) to 3 (extreme). Adult clinical research indicates high internal consistency ($\alpha = 0.89$) and good construct validity [31]. The present scale was adapted for use with children for this study, and a similar child adaptation has demonstrated good internal reliability and convergent and divergent validity using a 3-item scale ranging from 1 to 10 [32]. Reliability for the current sample was $\alpha = 0.60$ for children, 0.78 for mothers, and 0.57 for fathers.

Manifest Anxiety. Parents and children completed the German version of the Revised Children's Manifest Anxiety Scale (RCMAS [33, 34]; RCMAS-P [35, 36]) to assess general manifestations of the child's anxiety; α values for the total anxiety score summed across the 28 items = 0.83 (children), 0.88 (mothers), and 0.84 (fathers).

Quality of Life. Parents and children completed the 9-item child and parent versions of the Inventory for the Assessment of Quality of Life in Children and Adolescents (IQL) [37, 38] to assesses quality of life (e.g. 'How do you get along with your family?') on a scale ranging from 1 (very well) to 5 (very badly). Validity research indicates that the child and parent versions of the IQL discriminate between children receiving inpatient versus outpatient psychiatric care [38, 39]. Prior research in German-speaking school children yielded α values of 0.63 (for children aged 7 and above) and 0.76 (parents), and test-retest reliability r of 0.72 (children) and 0.80 (parents) [40]; internal consistency was 0.60 (children), 0.53 (mothers), and 0.48 (fathers).

Treatment Integrity. All therapy sessions were videotaped for later coding of the therapists' adherence to the treatment protocol. Videos from 10 randomly selected participants were each coded by 2 trained masters student assistants, using a standard coding checklist. Intraclass correlation coefficients (two-way random effects model with absolute agreement, average measure reliability) indicated that ratings were highly consistent for adherence to the treatment protocol (intraclass correlation for the average rating = 0.86, $p < 0.05$).

Table 1. Means and standard deviations by time and group, baseline group effects, and interaction effects

	Baseline					After waiting list/treatment				Time × condition effects	
	waiting list		treatment			waiting list		treatment			
	n	mean (SD)	n	mean (SD)	t (d.f.)	n	mean (SD)	n	mean (SD)	F (d.f.)	d
Primary outcomes											
Separation anxiety (SAI)											
Child	17	1.97 (0.91)	14	2.13 (0.99)	0.48 (29)	17	1.65 (1.00)	14	0.87 (0.90)	5.88 (30.98)*	0.98
Mother	22	2.62 (0.73)	18	2.59 (0.76)	−0.13 (38)	21	2.50 (0.74)	15	1.53 (0.69)	12.72 (37.34)**	1.31
Father	19	2.26 (0.76)	17	2.57 (0.83)	1.14 (34)	18	2.39 (0.75)	11	1.61 (0.69)	11.10 (31.45)**	1.41
Secondary outcomes											
Impairment/distress (SDS)											
Child	19	0.57 (0.41)	18	0.65 (0.59)	0.48 (35)	22	0.43 (0.64)	16	0.34 (0.41)	0.502 (37.49)	0.32
Mother	22	1.26 (0.60)	20	1.18 (0.51)	−0.43 (40)	21	1.23 (0.69)	16	0.42 (0.32)	13.83 (38.34)**	1.30
Father	20	1.03 (0.49)	20	1.03 (0.43)	0.00 (38)	18	1.18 (0.61)	12	0.51 (0.31)	10.36 (36.15)**	1.34
Manifest anxiety (RCMAS)											
Child	18	0.35 (0.22)	15	0.48 (0.19)	1.68 (31)	21	0.29 (0.22)	13	0.23 (0.20)	3.86 (33.16)	0.91
Mother	20	0.51 (0.20)	16	0.40 (0.25)	−1.36 (34)	19	0.46 (0.21)	14	0.23 (0.19)	2.61 (31.62)	0.65
Father	18	0.45 (0.23)	15	0.38 (0.20)	−0.94 (31)	17	0.40 (0.23)	10	0.22 (0.18)	7.59 (26.65)*	0.53
Quality of life (IQL)											
Child	19	2.04 (0.73)	18	2.00 (0.51)	−0.18 (35)	22	1.70 (0.61)	15	1.55 (0.57)	0.39 (36.09)	0.19
Mother	22	2.55 (0.47)	20	2.27 (0.30)	−2.34 (40)*	21	2.51 (0.73)	16	1.69 (0.37)	10.89 (38.63)**	0.66
Father	20	2.34 (0.40)	20	2.21 (0.35)	−1.03 (38)	18	2.26 (0.64)	11	1.73 (0.35)	7.52 (33.78)*	0.62

* $p < 0.05$; ** $p < 0.01$.

Statistical Analyses

The primary outcome measures included SAD diagnosis based on clinical interview, global success ratings (administered only after treatment), and SAI ratings. Impairment and distress, as assessed by the SDS, were used as a global outcome measure. Secondary outcome measures included the RCMAS and IQL.

Two separate models were calculated for each of the continuous outcome variables assessed before and after treatment (i.e., SAI, SDS, RCMAS, and IQL). In the first model, the efficacy of the treatment relative to the waiting list condition between baseline and end of treatment/end of waiting list was analyzed using linear mixed models to utilize all existing data [41], with time and treatment as fixed effects. In the second model, differences between post-treatment and 4-week follow-up scores were tested using the combined sample. Power analyses using G*Power 3 [42] indicated power (1 – β error probability) of 0.80 with $p < 0.05$ for meaningful medium and large effect sizes of 0.44 and greater.

Results

Treatment Integrity

Ratings of adherence to the treatment protocol (averaged across raters) indicated that across sessions, therapists implemented 78.43% (SD = 8.15%; range = 65–93%) of the critical elements required for each session.

Group Differences on Pretreatment Measures

Means and standard deviations for child self-report and parent report of child symptoms and quality of life are presented in table 1. Two-tailed independent t tests, also in table 1, indicated one group difference on the pretreatment variables: mothers in the waiting list condition reported higher scores on the IQL (indicating lower quality of life) than mothers in the treatment condition (effect size d = 0.71). As the linear mixed models accounted for baseline scores, no additional adjustments to the models were necessary based on this difference.

Treatment Efficacy: Primary Outcomes

SAD Diagnoses. Parent Kinder-DIPS interviews at the 4-week follow-up assessment confirmed that 3 (13.64%) of the 22 children allocated to the waiting list condition were definitively free from the SAD diagnosis after the waiting list period. In contrast, 16 (76.19%) of the 21 children allocated to the immediate treatment condition were definitively SAD free at the 4-week follow-up with a significant difference between the waiting list and treatment conditions when using the 39 children for whom these data were available [$\chi^2(1) = 21.59$, $p < 0.001$, effect size Somers' d = 0.74]. When assuming the 4 decliners retained SAD diagnoses at the 4-week follow-up (thus us-

Table 2. Global success ratings

	n	Range	Mean (SD)	Reporting much to very much improved, %
After treatment				
Child	35	2–7	6.46 (1.04)	91.43
Mother	33	6–7	6.61 (0.50)	100.00
Father	23	5–7	6.35 (0.57)	95.65
Therapist	35	5–7	6.43 (0.66)	91.43
4-week follow-up				
Child	35	5–7	6.43 (0.70)	88.57
Mother	35	3–7	6.17 (0.82)	88.57
Father	25	5–7	6.24 (0.52)	96.00
Therapist	34	5–7	6.21 (0.59)	91.18

Table 3. Paired differences between end of treatment and 4-week follow-up in the combined sample

	Mean difference (SD)	t (d.f.)
Primary outcomes		
Separation anxiety (SAI)		
Child	–0.05 (0.88)	–0.28 (27)
Mother	–0.10 (0.50)	–1.11 (27)
Father	0.03 (0.38)	0.36 (16)
Secondary outcomes		
Impairment/distress (SDS)		
Child	–0.01 (0.37)	–0.08 (30)
Mother	0.08 (0.41)	1.03 (28)
Father	0.08 (0.42)	0.81 (17)
General anxiety (RCMAS)		
Child	0.03 (0.13)	1.34 (25)
Mother	0.03 (0.16)	0.91 (25)
Father	–0.00 (0.14)	–0.06 (15)
Quality of life (IQL)		
Child	–0.11 (0.38)	–1.53 (29)
Mother	–0.11 (0.44)	–1.34 (28)
Father	–0.17 (0.29)	–2.40 (16)*

* 2-tailed $p < 0.05$.

ing the full n = 43 sample), $\chi^2(1) = 17.05$, $p < 0.001$, and effect size Somers' d = 0.63. After both groups had completed treatment, 33 children (76.74%) definitively no longer met criteria for SAD, 4 children continued to meet criteria (9.30%), and data were unavailable for 6 children (13.95%) at the 4-week follow-up.

Global Success Ratings. Mean global success ratings from children who engaged in therapy are displayed in table 2 for children, parents, and therapists at the end of treatment and at the 4-week follow-up. Mean ratings were between 6.19 and 6.69 across all raters and rating periods, with 88.57–100% of all raters indicating much to very much improvement both immediately after treatment and at the 4-week follow-up.

Treatment by Time Effects on the SAI. Table 1 displays the treatment (waiting list or immediate treatment) by time (before and after immediate treatment) interaction F tests and effect sizes. Linear mixed models indicated significant treatment by time interactions for child, mother and father reports of the level of child's avoidance in separation situations.

Maintenance of Effects on SAI at the 4-Week Follow-Up. A repeated-measures ANOVA comparing child, mother, and father reports on the SAI, RCMAS, SDS, and IQL indicated a nonsignificant omnibus within-subject effect comparing end-of-treatment ratings to 4-week follow-up ratings [$F(2, 12) = 0.47$, $p > 0.05$]. However, because the listwise deletion inherent in ANOVA reduced the sample size for all measures due to missing data, paired t tests were also conducted. Table 3 displays mean differences and t tests between the end of treatment and the 4-week follow-up. No significant differences were observed between end-of-treatment and 4-week follow-up scores on the SAI.

Treatment Efficacy: Secondary Outcomes

Treatment by Time Effects. Linear mixed model analyses (table 1) indicated significant treatment by time interactions for mother and father reports of distress/impairment (SDS), and of quality of life and for father reports of manifest anxiety (RCMAS). There were no significant treatment by time interaction effects for child-reported impairment and distress (SDS), child and mother reports of general manifest anxiety (RCMAS), or child-reported quality of life (IQL).

Maintenance of Effects at the 4-Week Follow-Up. Paired t tests (table 3) did indicate one significant difference between end-of-treatment and 4-week follow-up scores on secondary outcome measures. Fathers reported an increase in quality of life (IQL) at the 4-week follow-up (mean = 1.81, SD = 0.58) compared to the end of treatment [mean = 1.64, SD = 0.42, $t(16) = -2.40$, $p < 0.05$, $r = 0.52$].

Discussion

The present study is the first RCT of a disorder-specific CBT for SAD in young children, combining parent training, disorder-specific psychoeducation for children and parents, correction of disorder-specific dysfunctional cognition in both children and parents, and intensive exposure training in separation anxiety situations. Advantages of the present study are inclusion of more severe cases, such as those refusing to attend kindergarten or school, a group excluded in previous research [12], and the use of a multi-informant approach. As agreement between parents' and children's reports tends to be low [43], the generally consistent pattern of effects among raters in the present study is notable.

Results show significant improvements across all primary outcome measures. Intention-to-treat analyses indicate that at the 4-week follow-up, as compared to the post-waiting list time point, 76.19% of children allocated to the immediate treatment group (data not available for 3 decliners) definitively no longer fulfilled DSM-IV criteria for SAD according to parent interview, compared to 13.64% in the waiting list group (no post-data for 1 decliner). Eighty-eight to 100% of the child, father, mother and therapist global success ratings indicated much to very much improvement after treatment. Further, significant and large group by time interactions (d = 0.98–1.41) were observed in levels of mother-, father- and child-rated avoidance in separation situations (SAI) and mother- and father-rated impairment/distress (SDS) in important life domains. Significant medium effects (d = 0.62 and 0.66) were observed in parent-rated quality of life (IQL). Further, all improvements were maintained at the 4-week follow-up assessment. Notably, the present values indicate larger effects than those reported in prior meta-analyses and reviews on the effectiveness of CBT for children with anxiety disorders [7, 10].

Still, two results in particular warrant further discussion. First, while both mothers and fathers reported significant improvement in impairment/distress in major life domains, child ratings did not indicate significant improvement. An examination of child-reported baseline values indicates that children reported little to no impairment or suffering at baseline, leaving little to no room for improvement. Such ratings may have been influenced by the parent-referred, and not child-referred, nature of the present sample. Further, as parents may arrange everyday life around the child's separation anxiety, there may indeed be no distress or impairment for the child to perceive. Nonsignificant findings may also be related to the internal consistency of some measures, which was less than ideal. Second, the large effect size in separation anxiety ratings across all informants may not be directly comparable to the average effect sizes reported in existing meta-analyses, as these typically rely on trait anxiety measures rather than disorder-specific measurements, perhaps leading to larger effect sizes. Still, the effect size of 0.91 for child-reported trait anxiety in the present intention-to-treat analyses is higher than the average effect size of 0.58 for child reports [10], and thus supports the hypothesis that a disorder-specific approach may improve the effects of CBT in children with anxiety.

Limitations

Discerning the active ingredients responsible for treatment success in the present multicomponent approach was not possible, as treatment success was compared to the waiting list condition (used as no known comparison treatments have been validated for very young children, and considered a first step). In addition, as there are no representative data on sociodemographic and clinical characteristics of children with SAD in the population from which the sample was taken, we are not able to judge the representativeness of the present sample. Also, the present study does not address long-term maintenance, although further follow-ups are underway. Finally, it is unclear whether this new program would be effective with older children. A study directly comparing the present disorder-specific treatment program against a global treatment approach in older children is underway.

Conclusion

The present study indicates the short-term efficacy of a disorder-specific treatment approach for SAD, as compared to a waiting list, using parent training and classical CBT interventions specifically tailored to SAD. It is one of the first indicating that CBT programs can work with young children, and the first program specific to SAD. Follow-up assessments are expected to shed light on whether early successful treatment of SAD reduces not only immediate distress, but also the incidence of later mental disorders. Furthermore, our longitudinal data on the course of childhood SAD after treatment are expected to inform the field regarding the etiology of mental disorders in adulthood, as we follow up the children in the program and observe whether the incidence of adult disorder is reduced in comparison to existing studies on the outcomes of childhood anxiety disorders.

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