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Early Childhood OCD: Preliminary Findings From a Family-Based Cognitive-Behavioral Approach

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Abstract

Objective—To examine the relative efficacy of family-based cognitive-behavioral therapy (CBT) versus family-based relaxation treatment (RT) for young children ages 5 to 8 years with obsessive-compulsive disorder (OCD).

Method—Forty-two young children with primary OCD were randomized to receive 12 sessions of family-based CBT or family-based RT. Assessments were conducted before and after treatment by independent raters blind to treatment assignment. Primary outcomes included scores on the Children's Yale-Brown Obsessive Compulsive Scale and Clinical Global Impressions-Improvement.

Results—For the intent-to-treat sample, CBT was associated with a moderate treatment effect ($d = 0.53$), although there was not a significant difference between the groups at conventional levels. For the completer sample, CBT had a large effect ($d = 0.85$), and there was a significant group difference favoring CBT. In the intent-to-treat sample, 50% of children in the CBT group achieved remission as compared to 20% in the RT group. In the completer sample, 69% of children in the CBT group achieved a clinical remission compared to 20% in the RT group.

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This article is dedicated to the memory of Henrietta L. Leonard, M.D.

This article is the subject of an editorial by Dr. John Piacentini in this issue.

Conclusions—Results indicate that children with early-onset OCD benefit from a treatment approach tailored to their developmental needs and family context. CBT was effective in reducing OCD symptoms and in helping a large number of children achieve a clinical remission.

Keywords

obsessive-compulsive disorder; cognitive-behavioral therapy; family-based treatment

Obsessive-compulsive disorder (OCD) has been observed in children as young as age 3 years.^{1,2} OCD with an onset before age 9 years, herein referred to as early childhood-onset OCD, is associated with significant functional impairment in a number of critical domains. Furthermore, this impairment may compound over time to derail the acquisition and mastery of other important developmental milestones.²⁻⁶ If left untreated or if inadequately treated, young children have an increased likelihood that OCD will severely disrupt normative development, impair functioning, and extend into adulthood. Despite the significant risk of compounding problems for this population of children over time, there are no empirically supported treatments for OCD in early childhood.

Exposure with response prevention (EX/RP) is the behavioral treatment of choice for OCD in both adults and children,⁷ but previous studies have not adequately addressed the efficacy of EX/RP for children with early childhood-onset OCD. Although children as young as age 7 have been included in previous randomized controlled trials of EX/RP, they were underrepresented in those samples relative to older children and adolescents. For example, in the Pediatric OCD Treatment Study I, 18 of 112 (16%) children were younger than age 9, 11 of 18 (10%) of children younger than age 9 received a CBT-containing condition, and the mean age of the sample was 11.8 years.⁸ This is important because young children with OCD may require specific adaptations to the traditional EX/RP treatment regimen.

These adaptations may be required for younger children due to their developmental needs and family context. Developmentally, younger children generally have less sophisticated emotion awareness and expression skills than older children. Such developmental differences are likely to affect the acquisition and application of skills that are integral to EX/RP, such as the development of fear hierarchies. Younger children are also less adept at comprehending abstract concepts such as the treatment rationale for EX/RP. All of these factors may limit a young child's ability and willingness to engage fully in exposure-based treatment.⁹

With regard to family context, younger children rely on parents for guidance and direction more so than do older children. Coupling this developmentally normal level of dependence with the fact that OCD tends to pull family members into rituals, parents may be more likely to inadvertently reinforce or even actively accommodate a young child's rituals.⁹⁻¹⁵

For the above-mentioned reasons, we believe that young children experiencing OCD require a treatment approach uniquely tailored to their developmental needs and family context.

Family-Based Cognitive-Behavioral Therapy (CBT)

Our family-based CBT for young children with OCD draws on extant approaches of CBT used with older children.^{10,11} The treatment program contains novel elements that have been specifically tailored to young children ages 5 to 8 with OCD that include attention to developmental stage and concomitant levels of cognitive and socioemotional skills and awareness of a child's involvement in and dependence on a family system. First, we addressed the cognitive and socioemotional levels of younger children through the use of specific, concrete, and child-friendly examples. These examples are used to provide the

rationale for EX/RP (e.g., making connections to other fears that the child has conquered or that it is kind of like taking a medicine that tastes “yucky” but makes you better), distinguish obsessional thoughts from other nonintrusive recurring cognitions or images (e.g., different than having a song stuck in your head or thinking about a scary movie you have seen), and identify the connection between obsessional thoughts and subsequent compulsions (e.g., obsession is like a “worry monster” that tells you to do things it wants you to do).

Throughout treatment, parents are included in structured, specific ways to address issues of family functioning and parenting. The inclusion of parents serves a threefold purpose. First, parents are trained as coaches for their children and play a key role in shaping treatment and ensuring adherence and motivation outside the session. Second, including parents directly addresses parents' tendency to accommodate their child's OCD behavior. Third, treatment has an “exposure” function for parents as well because they are asked to tolerate their own distress in the face of assisting their children with often upsetting exposure exercises and homework tasks.¹²

We also addressed the issue that this may be a family's first contact with the mental health system. Families are often unsure whether their child's symptoms are reflective of normative, if disturbing, developmental phases that they will outgrow, or whether they herald clinically serious issues. Moreover, entry into treatment is daunting for parents, who may be concerned that OCD symptoms at such a young age are perhaps insurmountable. Finally, given their child's developmental stage and the relatively greater demands that young children place on families, parents may have difficulty attending sessions, managing child oppositionality and treatment resistance, and consistently completing homework tasks. We conduct two 90-minute sessions at the outset of treatment for parents alone to address potential issues of the impact of treatment on the child and family, address logistical issues in scheduling of sessions and conducting homework tasks, and provide a clear rationale for how and why treatment may work.

The primary goal of this project was to develop, manualize, and empirically test our family-based CBT for young children with OCD in comparison to a family-based relaxation intervention. Here we report the preliminary acute treatment results (family-based CBT versus family-based relaxation treatment [RT]).

Method

Participants

The intent-to-treat (ITT) sample included 42 children living in and around a city in the New England region of the United States, ranging in age from 4 to 8 years (mean 7.11, SD 1.26) and their parents. Although the treatment and study were designed for children ages 5 to 8, we did enroll two children who were consented at age 4 but turned 5 during the course of treatment. Assessment and treatment took place in a child anxiety disorders specialty clinic within an academic medical center. To participate in the study, children met the following inclusion criteria at the time of evaluation: a *DSM-IV* diagnosis of OCD (primary) as determined by a semistructured interview (Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version [KSADS-PL]) administered jointly to parent and child, symptom duration of at least 3 months, ages 5 to 8, and at least one parent who was able to consistently attend treatment sessions. Parents gave written informed consent to participate in the study, which was approved by a hospital-based institutional review board.

Exclusion criteria included other primary psychiatric disorder or coprimary/secondary diagnosis that required initiation of other active treatment; pervasive developmental

disorder(s) including Asperger syndrome; documented mental retardation; thought disorder or psychotic symptoms; conduct disorder; acute suicidality; concurrent psychotherapy for OCD or behavioral parent training; treatment with psychiatric medication for depression or mood stabilization; treatment with psychiatric medication for OCD, attention-deficit/hyperactivity disorder (ADHD), and/or tic disorders, the dose of which was not stable (6 weeks at a stable dose before evaluation); previous failed trial of CBT for OCD (defined as 10 sessions of formalized EX/RP); and meeting research criteria for the pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS) subtype of OCD/tics or on antibiotic prophylaxis for PANDAS (due to concerns that apparent treatment gains could be a result of an episodic symptom course).

The sample was primarily white (80% white, 2% Hispanic, 2% Asian or Pacific Islander, 2% Native American, 2% multiracial, and 12% no response/unknown) and middle class (although 8% of the sample was below the poverty level) with roughly equal sex distribution (57% female). The race and ethnicity of the sample are consistent with other pediatric OCD treatment studies,⁸ but not fully representative of the community demographics based on the 2000 U.S. Census data (85% white, 4.5% African American, 2.3% Asian, 0.5% Native American/Alaskan, 5% other).¹³ The families were primarily married and living together (83.3%), but the majority of sessions were attended by only one parent.

With regard to comorbid diagnoses (as measured by the K-SADS), 54.8% had comorbid internalizing diagnoses, 35.7% had comorbid externalizing diagnoses, 9.5% had a tic disorder, and 19% had ADHD. In addition, 14.3% were taking a selective serotonin reuptake inhibitor for OCD and 4.8% were taking a psychostimulant for ADHD. As indexed by the baseline Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS; mean 22.36, SD 4.17, range 11–32) scores, the sample had moderately severe OCD symptoms. Checking and washing were the most common compulsions and contamination and aggressive obsessions were most the common obsessions, both of which are consistent with the broader literature on juvenile-onset OCD.¹⁴ The mean age at onset of the sample was 4.99 years (SD 1.27) and 16% ($n = 7$) of the children had previous treatment (either medication and/or psychotherapy).

Measures

Children's *DSM-IV* diagnoses were assessed by doctoral-level clinicians using the K-SADS-PL.^{15,16} The K-SADS-PL is a semistructured, clinician-rated interview administered to the caregiver(s) and the child that yields *DSM-IV* diagnoses across the major Axis I domains and possesses favorable psychometric properties. The K-SADS is routinely used to assess psychiatric diagnoses in children as young as 5 years old.^{17,18}

The CY-BOCS¹⁹ is a well-known 10-item, semistructured, clinician-rated interview merging data from clinical observation and parent and child report. It is adapted from the adult Y-BOCS^{20,21} and assesses both OCD symptoms and severity. Adequate reliability and validity have been demonstrated, as well as sensitivity to change after treatment in pharmacological and behavioral therapy studies. Scores range from 0 to 40, with higher scores indicating more severe illness.

The Clinical Global Impressions (CGI)-Improvement scale²² is used to assess overall clinical improvement based on symptoms observed and impairment reported (7-point scale ranging from 1 [very much improved] to 7 [very much worse]). The clinician-rated scale has been used successfully in patients with OCD.^{23,24}

National Institute of Mental Health (NIMH) Global Rating Scales²⁵ are clinician-rated indices of illness severity. Each scale is a single-item composite rating ranging from 1

(normal) to 15 (very severe) with good interrater reliability. The NIMH Global Impairment, Depression, Anxiety, and OCD Rating Scales have been used in multiple treatment studies.

Conners Parent Rating Scale-Revised (Long Version)²⁶ is an 80-item parent report of children's behavioral problems that is widely used both clinically and in research efforts and has strong, established psychometric properties. Higher scores on this measure indicate more severe symptoms. For the purpose of this study, we report on only the total score, which corresponds to *DSM-IV* symptoms of combined Inattentive and Hyperactive-Impulsive type ADHD.

The Beck Depression Inventory²⁷ is a well-known 21-item measure of adult depressive symptomatology that has established reliability and validity. Higher scores indicate more severe symptoms.

The Obsessive-Compulsive Inventory²⁸ is a 42-item self-report measure that assesses symptoms of OCD in adults. It has high test-retest reliability, good discriminant validity between individuals with OCD and those with other anxiety disorders, and satisfactory convergent validity.²⁸ Higher scores indicate more severe symptoms.

The Screen for Child Anxiety-Related Emotional Disorders²⁹ is a 38-item measure that assesses child anxiety symptoms. The measure has both parent and child reports; however, only the parent report was used in the present study. The measure has good test-retest reliability and internal consistency.^{29,30} The scale also has excellent discriminant validity, and subscales differentiate between children with various anxiety disorders.³⁰ Higher scores indicate more severe symptoms.

The Brief Symptom Inventory³¹ is a 53-item self-report measure of psychological symptoms for adults. The measure yields global severity scores indicating the total number of symptoms and severity of the distress, as well as nine primary symptom subscales. Only the total score was used in this study. The Brief Symptom Inventory has good internal consistency, test-retest reliability over 2 weeks, and convergent validity.³¹ Higher scores indicate more severe symptoms.

Evaluator Training and Supervision

Interviewers were trained on the K-SADS-PL via formalized training with the lead authors, observing and coding taped interviews, corating live interviews conducted by a trained evaluator, and then conducting a K-SADS interview while under the live supervision of a trained rater.

Trained independent evaluators (i.e., child clinical psychologists and child psychiatrists) who were blind to the family's treatment condition administered the CY-BOCS, the CGI-I, the NIMH Global Rating Scales, and Yale Tic Scale to rate OCD and global functioning at baseline and end of treatment (week 14). Training for independent evaluators involved formalized teaching, observation, and coding of taped gold-standard interviews until three or more reliability tapes were coded to a criterion of 80% or higher.

Procedures

Recruitment for the study included print advertisements in local parenting papers and public service talks. Children were referred by pediatricians, social workers, psychologists, school psychologists, and parents who suspected OCD or other anxiety disorders. Initial contact was made by telephone. Families reporting possible OCD symptoms were scheduled for an hour-long in-person screening. If during the screening the child and family reported probable OCD symptoms, then they were referred to the study for further evaluation. At the

evaluation, consent forms were signed and the diagnostic interview and baseline independent evaluator measures were administered. Children who met inclusion/exclusion criteria were randomized to either CBT or RT, blocking on age (young: 5- to 6-year-olds [9 to CBT and 8 to RT] and old: 7- to 8-year-olds [13 to CBT and 12 to RT]). Families learned of their assignment by their therapist at the first treatment session.

Intervention Programs

Both treatment protocols (CBT and RT) consisted of 12 sessions delivered during the course of 14 weeks. The first 10 sessions were delivered weekly, followed by two biweekly sessions. The first two sessions (90 minutes each) were conducted with parents only, and the remaining sessions (60 minutes each) were conducted jointly with parents and children. For more detail about the family-based CBT program, see also Choate-Summers et al.³²

Family-Based CBT—The overall focus of treatment is to provide both child and parents with a set of tools to help them understand, manage, and reduce OCD symptoms. The primary components of the treatment are as follows.

Psychoeducation—Ensuring that parents clearly understand the treatment program and rationale before children are introduced to treatment lays the groundwork because many young children will not fully understand the treatment rationale. Young children will vary in what they grasp, but can most often understand the concept of being the “boss” of OCD behaviors. To increase parent and child engagement and motivation, psychoeducation is presented as simply as possible via simple, engaging modalities, including the use of visual imagery, metaphors, and developmentally relevant examples.

Parent Tools—Parents are provided with a set of tools used throughout treatment to increase the child’s motivation for change and to more effectively manage their child’s OCD symptoms. The central parenting tools include differential attention, modeling, and scaffolding.

Child Tools—The goal of the EX/RP component for the child is to have parents and children actively work together to develop a hierarchy and implement EX/RP. This is accomplished by distilling the core concepts of treatment and making it fun (where possible). Home-based practice of EX/RP is facilitated by a reward program introduced early in treatment.

Family-Based RT—The primary components of the treatment were affective education (helping children identify both negative and positive feelings and recognize the connection between stress and anxiety), relaxation training including progressive muscle relaxation and verbally cued guided imagery to attain a relaxation response, and the use of a reward system to encourage relaxation practice between sessions.

Therapist Training and Supervision—All study therapists were clinical psychology interns, postdoctoral fellows, and clinical psychologists with expertise in the application of behavior therapy with anxiety disorders, parent behavior management training, and relaxation and family-based treatment. Doctoral-level clinical psychologists (J.B.F., A.M.G.) provided all of the training and supervision. Training included didactic instruction, familiarization with the treatment manuals, and role-playing of treatment procedures. All of the therapy sessions were videotaped and discussed in weekly group supervision.

Therapist adherence and competence in both treatment conditions were monitored through the use of therapy manuals, ongoing supervision, and regular monitoring and rating of

videotaped therapy sessions. Adherence and competence measures developed specifically for this study were rated by study clinicians who were not the provider for that case. Raters were trained until they reached at least 80% agreement. Fifteen percent of taped treatment sessions from each condition were selected to ensure equal representation of age and sex of patient, as well as session number. In the CBT condition, 92% ($n = 33$) of the sessions were perfectly adherent (all of the required elements present), 5% ($n = 2$) of the sessions missed one required component, and 3% ($n = 1$) of the sessions were rated as nonadherent. Notably, this last case was prematurely terminated from the study because another anxiety diagnosis became primary. In the RT condition, no tapes were rated as nonadherent. In both CBT and RT, no tapes were rated as including proscribed treatment elements.

Statistical and Analytical Approach

The effects of CBT and RT on OCD symptom severity were analyzed using symptom reduction and clinical remission as dependent variables. All of the comparisons were made using both ITT and completer models. Missing data for ITT noncompleters were imputed using the last observation carried forward method. Completer analyses were conducted on data from those subjects who completed both pretreatment and posttreatment assessments.

Symptom reduction was analyzed using independent-sample t tests to compare CY-BOCS change scores (i.e., baseline CY-BOCS total score – posttreatment CY-BOCS total score) for the two treatment groups. Effect sizes were estimated using Cohen d ($M_1 - M_2 / SD_{\text{pooled}}$).³³

Clinical remission was analyzed using both the CY-BOCS endpoint scores and endpoint CGI-I scores as outcome measures. Clinical remission on the CY-BOCS was defined as having a posttest CY-BOCS total score ≤ 12 (Foa et al., in preparation). On the CGI-I, clinical improvement was defined as an endpoint CGI-I score of 1 or 2 (very much improved or much improved, respectively). Chi-square tests, odds ratios (ORs), and numbers needed to treat (NNT) were used to analyze group differences in remission rates on both the CY-BOCS and CGI-I. The NNT represents the number of patients who would need to be treated with CBT to produce one additional responder (i.e., CY-BOCS score ≤ 12) beyond that obtainable with RT. Lower NNT scores are better, with most effective therapies for psychiatric disorders showing NNT indices of 3 to 6.³⁴

Results

Patient Disposition and Characteristics

A total of 109 patients and their parents were assessed at an in-person visit for all of the inclusion and exclusion criteria (Fig. 1). Of these, 42 patients were randomly assigned to one of the two treatment conditions: 22 (52%) were randomized to CBT and 20 (48%) were randomized to RT. The remaining 67 study candidates were deemed ineligible ($n = 57$; e.g., OCD was not the primary diagnosis) or were not interested in participating in the study ($n = 10$; e.g., did not want to participate in research, lived too far away, unable to attend appointments regularly).

Of the 42 randomized patients, 31 (74%) completed acute treatment (through week 14). Five patients (12%) were provided rescue treatments to address emergent clinical concerns that could not be managed within the treatment protocols. Of these, one patient's (in the RT condition) OCD symptoms worsened and required additional out-of-protocol treatment, and the remaining four patients had another diagnosis become primary (eating disorder, depressive disorder, separation anxiety disorder, tic disorder). Six (14%) patients dropped out of the study. Of these, one moved to another city, one was unhappy with outcome of randomization, two had family health problems (parent, grandparent) that interfered with

ability to attend sessions, and two completed all of the treatment sessions but not the last assessment. The attrition rate for this study ($n = 9$ or 26%) is consistent with that found in other pediatric anxiety treatment studies (22%–27%, 13%–38% CBT, 13%–30% control).^{35–38} The mean (median) numbers of completed CBT and RT sessions were 10.86 (12) for CBT and 11.1 (12) for RT.

There were no differences between completers ($n = 31$) and noncompleters ($n = 11$) in age, baseline CY-BOCS severity, race, sex, socioeconomic status, or comorbidity. There were also no differences between children randomized to CBT ($n = 22$) and those randomized to RT ($n = 20$) in these variables.

Baseline Characteristics

A series of independent-sample t tests show that the CBT and RT groups did not differ in any of the baseline child or parent psychopathology measures including parent-rated measures of child OCD, anxiety, and externalizing symptoms; global measures of child OCD, impairment, depression, and anxiety; parent self-rated psychiatric symptoms, depression, and OCD; or general family functioning (Table 1). These results show that the two treatment groups do not differ on any key characteristics and indicate the success of the randomization process.

Overall, the sample had clinically significant and impairing OCD (CY-BOCS, NIMH OCD), minimal depressive symptoms (NIMH Depression), and mild general anxiety symptoms (NIMH Anxiety). Parent-rated child anxiety symptoms (Screen for Child Anxiety-Related Emotional Disorders) were clinically elevated for mother report in the CBT group, but the treatment groups did not differ significantly. Parent-rated child externalizing symptoms (CPRS) were in the nonclinical range. None of the parent self-report measures of overall psychiatric symptoms, depression, or OCD showed clinical elevations.

Treatment Outcomes

The sample means for the pre- and posttreatment CY-BOCS, separated by group (CBT and RT) and type of analysis (ITT and completer), are provided in Tables 2 and 3 and are displayed graphically in Figure 2. An independent-samples t test comparing the two treatment groups on the CY-BOCS total score for the ITT sample failed to reveal a significant difference between CBT and RT at conventional levels ($t_{40} = 1.76$; $p = .09$); however, CBT was associated with moderate treatment effect ($d = 0.53$). The completer analysis did show a significant difference between the two groups favoring CBT ($t_{29} = 2.43$; $p = .02$). For the completer sample, the effect of CBT was large ($d = 0.85$).

Using the ITT sample, 11 of 22 (50%) participants randomized to CBT were classified as achieving clinical remission on the CY-BOCS (defined as a posttreatment CY-BOCS score ≤ 12) after 12 weeks of treatment compared with only four of 20 (20%) participants in the RT group. This difference in response rates was statistically and clinically significant ($\chi^2_1 = 4.11$, $p < .05$; OR 4.00, 95% CI 1.00–5.87; NNT 3). Using the completer sample, 11 of 16 (69%) participants randomized to CBT were classified on the CY-BOCS as achieving clinical remission compared with only three of 15 (20%) participants in the RT group. This difference (49%) was statistically and clinically significant ($\chi^2_1 = 7.43$, $p < .01$; OR 8.80, 95% CI 1.69–45.76; NNT 2). It is worth noting that the NNT was lower than what is found in most effective studies.³⁴

Using the CGI-I as a measure of clinical remission, 11 of 22 (50%) participants in the ITT sample who were randomized to CBT were classified as treatment responders (symptoms classified as very much improved or much improved) compared with eight of 20 (40%) participants in the RT group. This difference was not statistically or clinically significant

($\chi^2_1 = 0.42$, $p =$ not significant; OR 0.5, 95% CI 0.41–5.10; NNT 10). Using the completer sample, 11 of 16 (69%) participants randomized to CBT were classified as treatment responders on the CGI-I compared with six of 15 (40%) participants in the RT group. Although not statistically significant ($\chi^2_1 = 2.58$, $p =$ not significant; OR 3.3, 95% CI 0.75–4.47), the difference between groups is clinically meaningful, favoring CBT over RT (NNT 3).

Discussion

The results of this preliminary study are encouraging and indicate that children experiencing early childhood–onset OCD indeed benefit from a treatment approach that is uniquely tailored to their developmental needs and family context. The CBT program was effective in both decreasing OCD symptoms and, more important, helping a large number of children achieve a clinical remission as measured by the CY-BOCS.

These results are particularly promising given that as part of a pilot study we were able to demonstrate feasibility of recruiting, treating, and collecting data about young children with OCD. It is notable that the mean and median numbers of sessions attended were equivalent across treatment groups and that no families dropped out as a result of EX/RP treatment being aversive. We were able to show the tolerability and acceptability of the program to children and families³⁹ as well as the feasibility of combining family work and parent training skills alongside EX/RP for OCD.

The present results are consistent with those in the literature on CBT for childhood OCD that assert that treatment containing EX/RP is the behavioral treatment of choice for OCD. Our remission rates for the CBT group of 50% in the ITT sample and 69% in the completer sample are consistent with or better than rates of remission for individual CBT in the Pediatric OCD Treatment Study (53.6% for combined CBT + selective serotonin reuptake inhibitor, 39.3% for CBT alone) and somewhat lower than those of family-based treatment for older children in the study by Barrett and colleagues⁴⁰ (88% response rate in family-based CBT, 76% response rate for group CBT). Our method of determining remission was different from that of Barrett et al., which was not meeting full diagnostic criteria on a parent-only structured interview.⁷

The success of the family-based CBT program in this study expands on earlier work that supports the importance of the role of parents in the treatment of childhood OCD.^{11,41} However, this is the first study to focus exclusively on a sample of children experiencing early childhood–onset OCD and their parents. These findings also suggest that children in this age range can actively participate in and benefit from CBT that is appropriately tailored to their cognitive developmental level.

A notable strength of the study was the use of an active treatment (RT) as a control condition and not a waitlist control, as is common in preliminary treatment development studies. Relaxation was selected as a comparison condition due to ethical and methodological concerns with both waitlist and minimal attention control groups. The benefits of using RT as a comparison condition include the ability to control for key variables such as therapist contact, intensity of treatment experience, treatment expectancy, acceptability, and credibility for families. This allowed for a much more stringent test of our treatment.

The finding that children in the RT group improved (albeit not to the degree of children in CBT) was not entirely unexpected given that other studies have also demonstrated that active control conditions may be beneficial.^{36,42} The RT program was meant not only to

control for nonspecific therapy effects but also to provide some general anxiety management skills to children and their families.

As we explained to families who were randomized to RT, because OCD is a stress-sensitive illness, we expected that decreasing the overall stress level in the child and family may indirectly lead to an improvement in OCD symptoms. However, because this treatment contained minimal psychoeducation about OCD and did not contain any EX/RP (either in-session or assigned as homework), we did not expect it to be efficacious in terms of OCD symptom ratings.

We have considered many possible explanations as to why the children in the RT group improved. Possible reasons for this finding may include the nonspecific effects of the therapeutic relationship, the RT treatment was fun (i.e., many games, active relaxation exercises), and it encouraged families to work together (e.g., practicing relaxation as a family). There is also some evidence that families in the RT condition “feel better” after treatment even when their CY-BOCS scores are still in the clinical range.

The study has limitations that warrant mention. The sample was not diverse with respect to race and ethnicity. Although this is common in pediatric OCD treatment trials, this is an area of priority for future study. Due to the relatively small sample size, we had low statistical power, yet were able to find a significant effect. In addition, the study would have benefited from the inclusion of additional outcome measures such as measures of parent psychopathology and measures of family functioning. In addition, the lack of longer term follow-up limits conclusions about maintenance of treatment effects.

Given these limitations, future studies using larger samples should compare the efficacy of CBT and RT in an adequately powered trial, include measures of functional impairment and quality of life, evaluate potential moderators and mediators of response to treatment, explore differences in the time course of response and dropout rates, and measure longer term maintenance of treatment gains.

This study underscores the importance of a family-based treatment model for children experiencing early childhood-onset OCD. Based on these results and our experiences during this study, we offer the following clinical considerations and recommendations. Treatment of children experiencing early childhood-onset OCD will be most effective if parents are involved in all phases of treatment. Clinicians should consider the child's unique developmental characteristics and tailor psychoeducation, exposures, and homework accordingly. Clinicians should take time to understand the family context and, in particular, the parents' response to their child's anxieties. Parents of young children are particularly likely to accommodate OCD—to minimize both their own and their child's distress and to streamline family functioning. From a clinical standpoint, we believe that a key element of our treatment program is teaching parents to tolerate their own anxiety about their child's level of distress. Finally, we also encourage clinicians to use humor generously. Overall, we believe that this family-based CBT for early childhood-onset OCD offers a promising intervention that may help to decrease the chronicity and morbidity of this debilitating illness.

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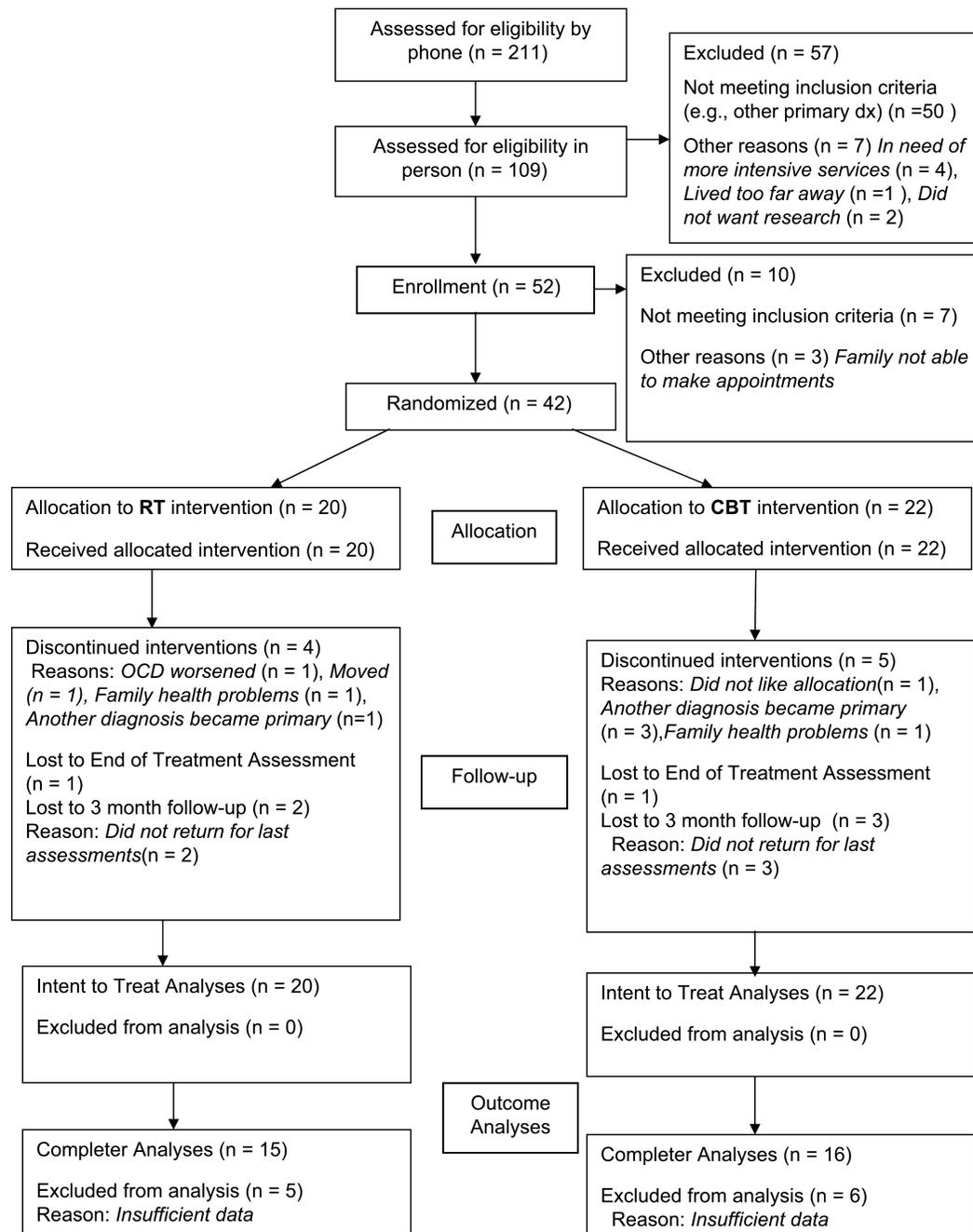


Fig. 1. Consort statement flowchart. dx = diagnosis; RT = relaxation treatment; CBT = cognitive-behavioral therapy; OCD = obsessive-compulsive disorder.

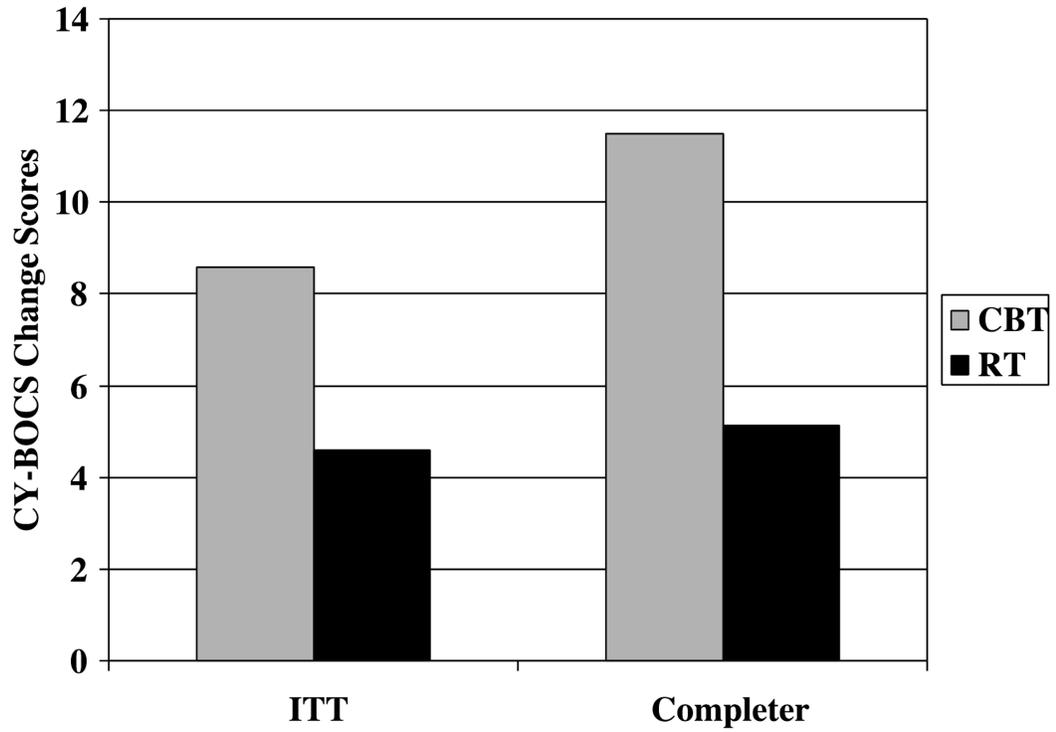


Fig. 2. Mean levels of Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) change scores for subjects in cognitive-behavioral therapy (CBT) versus relaxation treatment (RT). Higher scores indicate greater pre- to postchange. ITT = intent-to-treat.

Table 1

Child and Parent Baseline Characteristics

Measures	CBT	RT	<i>t</i> Tests
Child measurements			
CY-BOCS	22.95 ^a	21.70 ^a	$t_{1,40} = 0.97; p = .34$
NIMH OCD	7.52 ^a	7.83 ^a	$t_{1,37} = -0.52; p = .60$
NIMH CGI	6.76	6.28	$t_{1,37} = 0.88; p = .39$
NIMH Depression	3.05	2.41	$t_{1,35} = 1.05; p = .30$
NIMH Anxiety	5.65	6.00	$t_{1,35} = -0.54; p = .59$
Mother CPRS (<i>T</i> score)	59.81	54.59	$t_{1,35} = 1.45; p = .15$
Father CPRS (<i>T</i> score)	56.35	55.06	$t_{1,30} = 0.34; p = .74$
Mother SCARED total score	25.56 ^a	22.28	$t_{1,34} = 0.59; p = .56$
Father SCARED total score	15.82	15.00	$t_{1,31} = 0.20; p = .84$
Parent measurements			
Mother BDI	8.94	8.28	$t_{1,34} = 0.25; p = .80$
Father BDI	8.35	6.21	$t_{1,29} = 0.75; p = .46$
Mother BSI (<i>t</i> score)	51.71	49.25	$t_{1,31} = -0.68; p = .50$
Father BSI (<i>t</i> score)	53.82	48.71	$t_{1,29} = 1.19; p = .24$
Mother OCI	23.58	13.17	$t_{1,24} = 1.50; p = .15$
Father OCI	22.28	16.20	$t_{1,30} = 0.89; p = .38$

Note: CBT = cognitive-behavioral therapy; RT = relaxation treatment; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; NIMH OCD = National Institute of Mental Health Obsessive-Compulsive Disorder Rating Scale; NIMH CGI = National Institute of Mental Health Clinical Global Impairment Rating Scale; NIMH Anx = National Institute of Mental Health Anxiety Rating Scale, CPRS = Conners Parent Rating Scale; SCARED = Screen for Child Anxiety-Related Emotional Disorders; BDI = Beck Depression Inventory; BSI = Brief Symptom Inventory; OCI = Obsessive Compulsive Inventory.

^aClinically elevated.

Table 2

Pretreatment and Posttreatment Outcome Data for the ITT Sample

	Week 0		Week 14	
	CBT	RT	CBT	RT
CY-BOCS				
Mean	22.95	21.70	14.45	17.10
SD	3.84	4.52	8.16	7.57
CY-BOCS Δ				
Mean	—	—	-8.59	-4.60
SD	—	—	7.84	6.73
CGI-Severity				
Mean	4.14	3.77	—	—
SD	0.66	1.24	—	—
CGI-Improvement				
Mean	—	—	2.37	2.76
SD	—	—	1.17	1.09

Note: ITT = intent-to-treat; CBT = cognitive-behavioral therapy; RT = relaxation treatment; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; CGI = Clinical Global Impressions.

Table 3

Pretreatment and Posttreatment Outcome Data for Completer Sample

	Week 0		Week 14	
	CBT	RT	CBT	RT
CY-BOCS				
Mean	22.88	22.00	11.50	16.87
SD	4.30	5.13	7.68	8.22
CY-BOCS Δ				
Mean	—	—	-11.50	-5.13
SD	—	—	7.16	7.44
CGI-Severity				
Mean	4.18	3.70	—	—
SD	0.75	1.42	—	—
CGI-Improvement				
Mean	—	—	1.93	2.79
SD	—	—	1.00	1.12

Note: CBT = cognitive-behavioral therapy; RT = relaxation treatment; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; CGI = Clinical Global Impressions.