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The pediatric obsessive compulsive disorder treatment study for young children (POTS Jr): Developmental considerations in the rationale, design, and methods

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ABSTRACT

This paper presents the rationale, design, and methods of the pediatric obsessive compulsive disorder treatment study for young children (POTS Jr). The study is a multi-site randomized controlled trial (RCT) of family-based cognitive behavioral treatment (CBT) vs. family-based relaxation therapy for young children (ages 5–8) with obsessive compulsive disorder (OCD), which examines the effect of treatment on symptom reduction, functional impairment, and quality of life. Secondary aims evaluate: potential moderators and mediators of treatment response, differences in time course of response, retention rates, and maintenance of treatment gains over one year post-treatment. The sample included 127 children (53% female) and their parents. With regard to ethnicity, 89% of the sample described themselves as non-Hispanic, 5% Hispanic/Latino, and 6% did not endorse a category. In terms of race, the sample was predominantly (91%) white. Because the rationale and methods of the multi-site RCT have been well established, we emphasize here the methodological aspects of the study that were tailored to meet the developmental needs of young children with OCD. Aspects that are highlighted include: choice of control group, inclusion/exclusion criteria, assessment/measurement issues, treatment adaptations, training, and recruitment.

1. Introduction

Obsessive compulsive disorder (OCD) is a neurobiological disorder with a lifetime prevalence of 2% to 4% in children and adolescents (Zohar, 1999). Point prevalence estimates have shown that between 0.5 and 1% of the pediatric population suffers from OCD at any given moment (Flament et al., 1988). These figures likely underestimate the true prevalence of the condition in children younger than 8 years, because children of this age may lack the ability to articulate their symptoms and distress to others. Although OCD in older children and adolescents has been recognized as a serious mental illness requiring specialized treatment, less attention has been paid to OCD that begins before age 8. A recent paper, however, documented that children under the age of 8 with OCD suffer from the same symptoms and level of impairment as older children with OCD (Garcia et al., 2009). Research suggests that OCD in older children and adolescents can be especially pernicious in its impact, disrupting social, family, and academic functioning early in life and compounding its negative impact over time as it disrupts normal developmental milestones of early childhood (Piacentini, Bergman, Keller, & McCracken, 2003; Valderhaug & Ivarsson, 2005). Given that early onset OCD coincides with the beginning of formal schooling, OCD-related difficulties during this critical period may have particularly devastating impact as they disrupt normal developmental milestones of early childhood (Leonard, Lenane, & Swedo, 1993; Nakatani, Krebs, Micali, Turner, & Heyman, 2011). Because of the impact of OCD across many areas of functioning, it is imperative to treat children early in the course of their illness. However, a number of developmental adaptations to existing treatments for OCD are needed.

The POTS Jr. study grew out of a collaborative relationship among investigators at Brown University (Drs. Henrietta Leonard, Jennifer Freeman, & Abbe Garcia), the University of Pennsylvania (Drs. Martin Franklin & Edna Foa) and Duke University (Dr. John March) and their respective research teams that began with the

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pediatric obsessive compulsive disorder treatment study (POTS I). The POTS I project was the first randomized trial in pediatric OCD to compare the efficacy of cognitive behavioral treatment (CBT) to sertraline and their combination to a placebo control condition in treatment of 7–17 year olds with clinically significant OCD (POTS Study Team, 2004). Intent-to-treat analyses indicated a statistically significant advantage for CBT alone, sertraline alone, and combined treatment compared with placebo. Combined treatment also proved superior to CBT alone and to sertraline alone, which did not differ from each other. Site differences emerged for CBT and sertraline but not for combined treatment, suggesting that combined treatment is less susceptible to setting-specific variations. In the POTS II study (Franklin et al., 2011), the same three sites randomized 124 pediatric outpatients (ages 7 to 17) with primary OCD to 1 of 3 treatment strategies: Medication management alone, Medication management+instructions in CBT, or Medication management+CBT. The medication management plus CBT strategy was superior to the other 2 strategies on all outcome measures and there was no site by treatment interaction.

Although the CBT protocol used in POTS I and POTS II proved efficacious for children and adolescents ages 7–17, it was not tested specifically for use with younger children. Only about 10% of both the POTS I and POTS II samples who received CBT were children ages 7–8. Although there was no evidence that age (treated as a continuous variable) moderated treatment outcome in either study, this result does not address the performance of the children in the 7–8 age range specifically, nor are further subanalyses appropriate given the very small number of children in that age range. Notably, although the manual used in the previous POTS studies does allow for parent involvement, it does not require or provide explicit and systematic instructions for how to structure this parental participation. Similarly, it does not provide specific strategies for explaining core concepts to patients with less advanced cognitive abilities. The only other existing family-based CBT treatments for pediatric OCD also targeted older age groups (Barrett, Healy-Farrell, & March, 2004). Thus, there are no empirically validated psychosocial treatments for OCD in children aged 5–8.

In pilot work for this project, our research group at Rhode Island Hospital/Brown Medical School developed, manualized, and completed preliminary empirical testing for a family-based CBT for OCD in young children (aged 5–8; R21MH60669). Our initial study demonstrated the feasibility of family-based CBT for young children and pilot-tested its efficacy compared to a family-based relaxation treatment (RT). Results of this preliminary study were very encouraging, indicating that the family-based CBT was associated with a moderate ITT treatment effect (ES=0.53), even when compared to a rather stringent psychosocial control condition (Freeman et al., 2008).

As the logical next step in this treatment development program, funded under the R01 mechanism by the National Institute of Mental Health, the POTS Jr study is a multi-site RCT of family-based CBT vs. family-based RT for young children (ages 5–8) with OCD, which examines the effect of treatment on symptom reduction, functional impairment, and quality of life. Secondary aims evaluate: potential moderators and mediators of treatment response, differences in time course of response, retention rates, and maintenance of treatment gains over one year post-treatment.

This report presents the rationale for the study, describes the design choices made, and outlines the methods used to carry out the trial. Because the rationale and methods of the multi-site RCT approach have been well established, we emphasize here the methodological aspects of the study that were tailored to meet the developmental needs of young children with OCD. The purpose of this paper is to provide an in depth discussion of the modifications to the assessment process, details of the treatment interventions, and the challenges faced by the study team. This level of detail goes well beyond the information that could be presented in a standard methods section of a more comprehensive report on the study and provides important information for those who treat OCD or design treatment trials with young children. Aspects that will be highlighted include: choice of control group, inclusion/exclusion criteria, assessment/measurement issues, treatment adaptations, training, and recruitment.

2. Methods

2.1. Study design

The overall goal of this study was to compare the relative efficacy of two active manualized treatment programs, family-based CBT versus family-based RT, in young children (aged 5–8) who experience early-onset OCD. A total of 127 children were treated, with children randomly assigned to each of the treatment conditions. The sample was 53% female. With regard to ethnicity, 89% of the sample described themselves as non-Hispanic, 5% Hispanic/Latino, and 6% did not endorse a category. In terms of race, the sample was 90.6% White, 3.1% Asian, 3.1% African American/Black, 0.8% American Indian/Alaska Native, and 0.8% Native Hawaiian/Pacific Islander and 1.6% not endorsed/missing. Follow-up assessments at 3-, 6- and 12- months post treatment have been conducted and are still ongoing for some participants.

We selected RT as the comparison condition due to ethical and methodological concerns with both waitlist and minimal attention control, particularly in young children. RT has components of both a control and an active treatment (e.g., demand characteristics and expectancies). From a methodological standpoint, the downside of using an active comparator was the risk of attenuated effect sizes and decreased statistical power. Despite this concern, our design choice was driven by the following factors: (1) RT controlled for the key variables of therapist contact, intensity of treatment experience, treatment acceptability and expectancy as well as the passage of time; (2) it allowed us to replicate the design of the pilot R21 with a larger sample; (3) it provided families with a more acceptable treatment for this age range than medication; (4) relaxation is a common intervention for anxiety in community settings; and (5) it had been used as a comparison condition in another large scale family based OCD treatment trial with older children (Piacentini et al., 2011), as well as for adult OCD (e.g., Fals-Stewart, Marks, & Schafer, 1993).

Somewhat unexpectedly, we found the choice of RT as a control treatment to have added benefit and importance in this sample of young children and their families. The family based RT intervention was not only tolerable to most children and families, but often the more desired of the two treatment arms. This is likely due to the fact that RT as an intervention, particularly for young anxious children, had a great deal of face validity. The following rationale was presented at study consent: "Most young children with OCD have other anxiety as well. The family based CBT intervention focuses directly on OCD symptoms and we expect that as OCD symptoms decrease, other anxiety will decrease indirectly as well. In the family based RT intervention, we focus more broadly on all anxiety and because OCD is a stress sensitive illness, we expect OCD symptoms to benefit indirectly as well." In addition to its face validity, it also seemed that the RT intervention was especially tolerable for the many children and families for whom this was their first contact with the mental health system.

2.2. Subject recruitment

All patients were evaluated and treated through pediatric anxiety/OCD specialty clinics at each participating site. The clinics at each of the three sites had an already steady flow of treatment seeking youth with OCD calling for services when this study ensued. However, the recruitment of young children posed some new challenges. Recruitment for the pilot R21 at the Brown site had initially been challenging as well, and much work was done at the time to build a referral base with community mental health and pediatric practitioners.

Given the age of the participants, many of these youth were experiencing their first onset of illness and first contact with the mental health system; therefore more traditional methods of recruitment (print or internet advertising) were less fruitful. Overall, our single best recruitment source was community pediatricians to whom families were most often presenting with their concerns about early onset OCD. The bulk of our recruitment efforts involved face-to-face meetings with local community pediatricians as well as outreach to local elementary schools.

2.3. Entry and inclusion/exclusion criteria

We employed a three-gate assessment procedure to screen patients for eligibility and interest in participating in the study. This procedure was used successfully in POTS I (POTS Study Team, 2004) and POTS II to reduce patient burden and promote efficiency (Franklin et al., 2011). Gate A consisted of screening interviews (telephone and/or in-person) to assess preliminary eligibility. Eligible patients proceeded to Gate B, including (1) a systematic diagnostic assessment with the parent(s) and child and (2) a team meeting to review all available data and to establish caseness and suitability for study entry. Patients determined to be eligible were invited back for Gate C, a baseline visit to complete the week 0 independent evaluator (IE) assessment.

Inclusion and exclusion criteria (Table 1) were designed to balance generalizability of findings to real-world settings (external validity) with sufficient experimental control to test study hypotheses (internal validity). Although we required a primary diagnosis of OCD, we included patients with most co-morbid diagnoses in order to increase the generalizability of our findings. There is evidence that children with OCD have increased rates of co-morbidity (e.g., anxiety, tics, attention deficit hyperactivity disorder (ADHD)), and given that psychiatric diagnoses in young children are particularly difficult to disentangle, we erred on the side of inclusivity. However, we excluded psychiatric conditions and symptoms likely to interfere with treatment (e.g., major depression, suicidality, and pervasive developmental disorder (PDD)) in order to test the CBT manual effectively and ensure that patients received best possible care.

2.4. Allowable concurrent psychotropic treatment

To increase generalizablity of the sample with regard to comorbidity and illness severity, concurrent medications were allowed as needed for treatment of common comorbid conditions (e.g., tics, anxiety, ADHD) as well as for OCD. Although we did not originally intend to include children on medication for OCD, results from our prior pilot research showed that a small but not insignificant number of children were already taking a stable selective serotonin reuptake inhibitor (SSRI) (14%; (Garcia et al., 2009)) and therefore changed our protocol prior to the start of the study. Children on SSRI medications for OCD were included when they had been taking that medication for >12 weeks, were at the same dose for >8 weeks and continued to meet severity criteria consistent with the inclusion criteria of the study (Table 1). Children entering the study on an SSRI for OCD were followed by a study pharmacotherapist (clinic psychiatrists not otherwise involved in this trial) with brief (15 min) medication checks at each IE visit in order to monitor medication use or any changes in medication. With the exception of downward adjustment due to side effects, study pharmacotherapists and families were instructed to keep medications stable throughout acute treatment.

2.5. Pediatric autoimmune disorders associated with strep (PANDAS)

PANDAS is a syndrome in which OCD symptoms begin soon after streptococcal infection. Hallmarks of PANDAS include prepubertal onset, acute onset of symptoms, a "sawtooth" or remitting-relapsing course, and significant neuropsychiatric comorbidity (e.g., separation anxiety, ADHD-like symptoms, motor tics, acute onset enuresis) (Leonard et al., 1999; Swedo et al., 1998). Given that PANDAS is by definition a prepubertal phenomenon and that children with streptococcal precipitated OCD appear to have a more episodic symptom course, we considered carefully the implications of this diagnosis for the current study of early onset OCD. Our decisions were guided by the state of the PANDAS literature in 2006 when the study was designed and funded. To protect against confounding by PANDAS, participants who met the published research diagnostic criteria for PANDAS (Swedo, Leonard, & Rapoport, 2004) and/or were taking ongoing antibiotics for treatment/prophylaxis of OCD, tic symptoms, or rheumatic fever were excluded from the study. Following randomization, children with group A ß-hemolytic streptococcal (GABHS) infections received care through their primary care physician as deemed appropriate. It should be noted that the PANDAS literature has continued to grow since the time this study was conceived and the diagnosis of PANDAS or the more recent PANS (Pediatric Acute-onset Neuropsychiatric Syndrome) (Swedo, Leckman, & Rose, 2012) remains a controversial one, with researchers and clinicians falling on either side of the coin regarding the disorder's validity. A full discussion of PANDAS/PANS and its diagnostic set of procedures are beyond the scope of this article (for an in depth review of PANDAS, see Kurlan & Kaplan, 2004).

2.6. Assessment

Independent evaluators (IEs) at all sites were doctoral level psychologists not actively involved in the research program and blind to treatment condition. IEs were trained to a reliable standard on the CY-BOCS, YGTSS, and CGI through joint interviews, videotape reviews, and formalized training and completed monthly, blinded cross-site calls led by the IE coordinator. All study IEs were trained to meet an initial reliability criteria of.80 (Cohen's K). Reliability was checked bi-weekly with randomly selected tapes. IEs were retrained to criterion if they fell below 80% agreement. IE training was tailored in consideration of the young age of participants and the expectation that assessments were likely to represent first contact with the mental health system (e.g., explaining terminology; special considerations for making children and families feel comfortable such as fun activities/snacks for children).

Acute treatment IE evaluations were completed at weeks 0, 5, 9 and 14. Naturalistic follow-up IE evaluations were completed at 3, 6, and 12 months. All self-, parent-, and therapist-report measures were completed on scheduled visit days or at treatment sessions as described in Table 2. Consistent with an intent-to-treat approach, all patients were assessed at all time points.

Due to the young age of participants, we considered several factors in the selection and administration of measures. First, few measures are validated for use with children as young as 5. Therefore, we chose measures validated for use in this age range whenever available (e.g., using the K-SADS rather than the ADIS for diagnoses). Second, the majority of measures were administered to or completed by parents rather than by children. In addition to lack of available measures, many children at this developmental level are unable to complete self-report forms or to understand interview questions and articulate answers. Thus, we relied more on

Table 1
Inclusion/exclusion criteria and rationale.

Inclusion criteria	Rationale
Age 5–8	Target population
Primary diagnosis of OCD	Target disorder
CY-BOCS score >16	Indicates clinically important OCD
Symptoms stable >3 months	Indicates clinically important OCD; decreases chance of spontaneous remission
Outpatient	Inpatient care confounds study treatment
Parent available to participate in treatment	Treatment requires parent presence
Exclusion criteria	**Rationale**
Other primary diagnosis	May require additional/different treatment
Pervasive developmental disorder	May require additional/different treatment
Mental retardation	May not benefit from specified treatments
Thought disorder/psychosis	May require additional/different treatment
Acute suicidality	May require additional/different treatment
Conduct disorder	May require additional/different treatment
Concurrent psychotherapy	Confounds internal validity
Medication for depression/mood	Confounds internal validity
Medication for ADHD, OCD, or tics not stable >8 weeks	Confounds internal validity
Prior failed trial of CBT for OCD	Confounds internal validity
Meets research criteria for PANDAS	Confounds internal validity

Table 2
Measures by aim, domain, rater, and timing of administration.

Aim	Domain	Measure	Rater	Timing of administration				
				Gates	Baseline	Each session	Acute treatment	Naturalistic follow-up
	Inclusion/exclusion	Phone Screen	SC					
1: Symptoms	OCD symptoms/severity	CYBOCS	IE	X	X		X	X
		CGI- improvement	IE		X		X	X
2: Impairment and QOL	Functioning	COIS	P		X		X	X
	Quality of Life	CGAS	IE		X		X	X
		PQ-LES-Q	P		X		X	X
3: Moderators	Demographics	CMDQ	P	X				
	Comorbidity	KSADS	IE	X				
		YGTSS	IE	X				
		CARS	IE	X				
		CBCL	P	X				
	Parent psychopathology	DASS	P	X				
		OCI-R	P	X				
	Family functioning	FAM	P	X				
	Medication status	Medication History	PT	X				
3: Mediators	Homework compliance	HW form	T, P			X		
	Treatment attendance	T note	T			X		
	Family accommodation	FAS	P		X		X	X
4: Treatment Course and Acceptability	Time course of response	CYBOCS, CGI	IE		X		X	X
	ASAP sessions	ASAP form	SC			X[a]		
	Drop-out rates, PMT status	Change in study status form	SC			X[a]		
5: Long term follow-up	Functioning	(see Aim 2 above)	IE, P		X		X	X
	Relapse	(see Aim 1 above)	IE					X
	Utilization of other treatment	CTTS	SC					X
Adverse Events	Suicidal, homicidal ideation	HARM	T			X		
	Adverse events on meds	PAERS	P, PT			X[b]		

SC = study coordinator, IE = independent evaluator, P = parent, T = therapist, PT = pharmacotherapist, ASAP= Adjunctive Services and Attrition Prevention.

[a] As needed.

[b] Each PT session.

parent-report and clinician observation (see "Measures" for information specific to relevant measures).

As noted above, diagnostic clarity and symptom presentation is also different in these young children when compared to older counterparts (Garcia et al., 2009). Young children may be more likely to present without stated obsessions (compulsions only) although it is not clear whether this is due to limited cognitive/verbal abilities. They also are more likely to have some OCD symptoms that overlap with other disorders. For example, young children with "not just right" or sensory symptoms may best fit a diagnosis of OCD, Tic Disorder, or PDD. To address these issues, we tailored IE training to emphasize understanding of these symptoms in the context of 5- to 8-year-old development. For example, IEs were advised to consider the larger contexts in which the symptoms were occurring (e.g., did the larger diagnostic picture include other symptoms of anxiety versus PDD?), the function of the symptoms (e.g., to reduce anxiety versus to increase pleasure), and the course of the symptoms. In cases where diagnosis remained confusing, we employed significant behavioral observation (particularly to observe social functioning) as well as other parent report data (tic and PDD ratings scales). To improve diagnostic clarity, we required cross-site diagnostic consensus (discussed via phone conference) before randomization. New cases were briefly discussed in the weekly conference call, which constitued a Caseness Panel. Following procedures used successfully in the POTS II, questionable cases were reviewed in greater detail by all of the investigators in order to establish a set of precedents for resolving ambiguity in implementing inclusion/exclusion criteria. Decisions for inclusion/exclusion were decided based on full consensus by the lead PIs at each site.

2.6.1. Assessment adaptations

We altered our assessment approach from the prior POTS I and POTS II studies so that we could ensure the most accurate data collection in this younger group of children. First, interview questions were tailored to the cognitive/developmental abilities of this age group. In general, the younger children are, the more difficulty they have understanding questions that relate to their thoughts (Grave & Blissett, 2004). They also have more difficulty understanding concepts such as estimating, averaging, and time. Assessors were trained to use concrete examples to obtain self-report information about young children's symptoms and behavior. Parents were often helpful in generating recent examples where children may have demonstrated the symptom(s) in question, as well as in rephrasing ("translating") questions so that their child understood what an evaluator was asking.

Second, psychoeducation was infused into the assessment process. While orienting the child and parent to the assessment process it was important to gauge their understanding of the terms "obsessions" and "compulsions" and to differentiate these symptoms from other symptoms that were similar or even dissimilar. We found that some parents, especially those with young children who may have not had any previous mental health contacts, over-incorporated OCD to account for their child's behavior. It was important that assessors not make this same error and instead help the parent to better differentiate what is and what is not an OCD symptom.

Third, care was taken to gauge the accuracy of child responding. While introducing these concepts and their descriptive and operational boundaries, it was also necessary for assessors to gauge how helpful the child's report would be to their ratings. Some children were able to report quite reliably on their symptoms with parent help, some children were able to contribute to the discussion with parents providing most of the information, and some children because of immaturity, resistance, or both were not able to participate in the assessment, other than perhaps confirming or denying parents' impressions of symptoms.

Assessors were trained to begin the CY-BOCS administration by describing obsessions and compulsions, as described above, but to gather information about compulsions first. Compulsions were easier for the parents to observe and report upon and in general young children were more aware of compulsions in comparison to thoughts/obsessions. Information about compulsions often helped anchor the child later when asking about obsessions (e.g., "You said that you wash your hands 3 × per hour, but you're not sure how often you worry about germs. Do you usually wash your hands when you're worrying about germs? Are there times that you worry about germs but don't wash your hands?").

A particularly tricky assessment issue involved situations in which the child did not report obsessions. Our convention for this trial was that obsessions could be inferred from parent report, but only when the clinician was confident that the parent reliably described anxiety as driving the child's behavior and there was not an assumption that obsessions were there if they were not endorsed or reliably described.

Finally, the IEs were advised to use their time wisely to capitalize on younger children's shorter attention spans. It was important for the clinician to balance inquiry with maintaining the child's attention. Assessors were trained to be judicious in their management of inquiry into a particular topic, balancing the need to obtain better information from the child and parent with the need to cover the information from the entire interview.

2.7. Measures

OCD Symptoms and Severity were measured using the Child Yale-Brown Obsessive Compulsive Scale (CY-BOCS; (Scahill et al., 1997)) and the Clinical Global Improvement scale (CGI; (Guy, 1976)). The CY-BOCS is a "gold standard" clinician interview yielding a combined obsessions and compulsions total score (0–40) and demonstrating adequate reliability and validity (Scahill et al., 1997). Developmentally sensitive anchors and probes were developed. The literature supports the use of the measure in children as young as 6 years (March & Leonard, 1998) and it was used successfully in our prior studies with 5 year olds (Freeman et al., 2008). The CGI is a 7-point scale measuring clinician-rated improvement in treatment and shows adequate reliability and validity (Garvey et al., 1999; Perlmutter et al., 1999).

Functioning was measured using the Children's OCD Impact Scale (COIS; (Piacentini et al., 2003)) and Children's Global Assessment Scale (CGAS; (Green, Shirk, Hanze, & Wanstrath, 1994; Schaffer et al., 1983)). The COIS provides a standardized format for assessing the impact of OCD on social, school, and home functioning and shows excellent internal consistency and adequate concurrent validity (Piacentini et al., 2003). The CGAS measures global functioning, with scores over 70 indicating normal adjustment. It has been shown to have adequate reliability, validity, and internal consistency (Schaffer et al., 1983).

Quality of Life was measured using the pediatric quality of life enjoyment and satisfaction questionnaire (PQ-LES-Q). The PQ-LES-Q is a 15-item scale measuring QOL in a variety of domains. The scale has solid psychometric properties with excellent internal consistency and adequate concurrent validity (Endicott, Nee, Yang, & Wohlberg, 2006). We used a parent report of this measure, based on the finding that close relatives are able to give accurate proxy ratings on QOL measures (Sneeuw et al., 1998).

Demographics were measured using the Conners March Developmental Questionnaire (CMDQ; (Conners & March, 1996), including age, grade level, gender, race, and socioeconomic status, and was completed by parents.

Comorbidity was assessed using several measures. The Kiddie Schedule for affective disorders and Schizophrenia for School Age Children-Present and Lifetime Version (K-SADS-P/L; (Chambers et al., 1985; Kaufmanet al., 1997)) is a semi-structured, clinician rated interview that yields DSM-IV diagnoses and has favorable psychometric properties. Interviews were administered to the parent(s) (or primary caretakers) regarding the child, and to children (although 5–6 year old children varied in their ability to participate actively in the interview). The K-SADS is routinely used to assess psychiatric diagnoses in children as young as 5 years (Hirshfeld-Becker & Biederman, 2002; Youngstrom, Gracious, Danielson, Findling, & Calabrese, 2003).

The Yale Global Tic Severity Scale (YGTSS; (Leckman et al., 1989)) is a clinician-rated scale used to assess tic severity and impairment. The YGTSS has demonstrated excellent psychometric properties with solid internal consistency, excellent inter-rater reliability, and excellent convergent and divergent validity (Leckman et al., 1989).

The Child Behavior Checklist—Parent Report Form (CBCL; (Achenbach & Rescorla, 2001)) is a parent-rated scale that assesses an array of behavioral problems in children ages 6–18 years and has well established psychometric properties. For children age 5 years, the CBCL 1.5-5-Parent Report form (Achenbach & Rescorla, 2000), an adaptation of the CBCL for preschool age children, was used.

Features of PDD were screened using the Social Communication Questionnaire (SCQ) and the Social Responsiveness Questionnaire (SRS). The SCQ is a 40-item parent report that measures behaviors characteristic of autism spectrum disorders including communication skills and social functioning. The measures has demonstrated good internal consistency and concurrent validity (Rutter, Bailey, & Lord, 2003). The SRS is a 65-item parent report that assesses abilities and deficits in social reciprocity in children ages 4–18 years. It has good internal consistency, temporal stability, and concurrent and discriminant validity (Constantino & Gruber, 2005).

Parent psychopathology was assessed using the Depression Anxiety Stress Scales (DASS-21; (Lovibond & Lovibond, 1995), a measure yielding scores for depression (DASS-D), Anxiety (DASS-A), and Stress (DASS-S). The DASS has been shown to have excellent psychometric properties in clinical (Antony, Bieling, Cox, Enns, & Swinson, 1998) (Brown, Chorpita, Korotitsch, & Barlow, 1997) and non-clinical samples (Clara, Cox, & Enns, 2001). Parents also completed the obsessive-compulsive inventory-revised (OCI-R; (Edna B. Foa et al., 2002), a brief (18 items) instrument measuring obsessive-compulsive symptoms in six domains. It has excellent discriminant validity, good convergent validity, and good test-retest reliability (E. B. Foa et al., 2002).

Family Functioning was assessed using the Family Assessment Measure-III Short Form (Brief FAM III; (Skinner, Steinhauer, & Santa-Barbara, 1995)), which was independently administered to each parent and provides a global index of family dysfunction. The Brief FAM-III was derived from the original FAM-III which possesses good psychometric performance in terms of both internal consistency and construct validity. Family accommodation was measured using items from the family accommodation scale (FAS; (Calvocoressi et al., 1999)), completed by parents. The FAS has adequate reliability and validity.

Other study measures included a medication history form (record of current and past medications, including history of dose, length of time, response, and reason for discontinuation), homework compliance form (parent/therapist versions detailing the amount and quality of homework completed), ASAP Form (documents ASAP session length, type, reason, and outcome, any serious or adverse events and action taken), and the concomitant treatment tracking form (CTTS; categorizes all psychosocial, medical, and other treatments initiated by the family in the time interval). These measures have all been used successfully in POTS I and II (Franklin et al., 2011; POTS Study Team, 2004).

Adverse Events were monitored using the HARM form (suicidal or homicidal ideation/intent) and the pediatric adverse event rating scale (PAERS; suicidal ideation and behavior related to medication including any potential SSRI related activation symptoms). These forms have been used successfully for this purpose in the POTS II study (Franklin et al., 2011).

2.8. Treatment program

2.8.1. Treatment delivery schedule

Twelve sessions were delivered over the course of 14 weeks in both treatment conditions (Table 1). The first two sessions (90 min) were conducted with parents only, while the remaining sessions (60 min) were conducted jointly with parents and children.

2.8.2. Therapist training and supervision

All therapists were clinical psychology interns, postdoctoral fellows, and clinical psychologists, many of whom were already familiar with CBT for OCD in older youth. All therapists participated in weekly group conference calls for supervision and review of clinical issues to prevent protocol violations and increase consistency of treatment application. The current POTS Jr study has employed the same training and supervision strategies as POTS II including in-person training at study inception as well as extensive site-level supervision and weekly cross-site supervision for patients in both treatment arms. Preliminary examination of the data demonstrates no site effect in the current study.

2.8.3. Family-based CBT: Outline of treatment components

Family-based CBT focused on providing child and parent "tools" to understand, manage, and reduce OCD symptoms. Primary components included: (1) psychoeducation, (2) behavior management skills training (parent tools), (3) externalizing OCD and Exposure with Response Prevention (EX/RP) (child tools), and (4) family process components. Psychoeducation topics included the neurobiology of OCD, correction of OCD misattributions, differentiation of OCD and non-OCD behaviors, and the treatment rationale. Parenting tools focused on effective management of the child's OCD symptoms and included differential attention (including a reward program), modeling, and scaffolding (parent guides child's emotional regulation in response to event or situation and child ultimately internalizes response as self-regulation). In the case of children who resisted EX/RP practice due to oppositional behavior, contingency management techniques were also presented. All parenting tools were rehearsed in session and practiced at home as part of weekly homework assignments.

EX/RP involved active collaboration between parents and children to develop a hierarchy and implement EX/RP. The basic goal of EX/RP is to gradually expose the child to the situations that are most uncomfortable for them until fear decreases without the performance of rituals (habituation). EX/RP began with developmentally appropriate tools to promote exposure implementation, including learning how to externalize ("boss back") OCD and use a fear thermometer to rate anxiety and create a hierarchy. Parents were actively involved during in-session exposures to increase the likelihood that home-based practice of EX/RP would be done effectively. Home-based practice of EX/RP was also facilitated by the reward program introduced early in treatment.

Finally, family process components were not required elements (i.e., therapist adherence) but were highlighted in the manual to enhance the treatment process when needed (i.e., therapist competence). Goals of the family process components were to: (1) reduce family accommodation of child OCD symptoms, (2) reduce criticism and hostility related to child OCD symptoms, (3) promote positive family problem solving related to child OCD, and (4) help parents to understand the role of their own modeling of anxious interpretations and behaviors. Coupled with the more traditional parent training (parenting tools) elements of treatment, the family process components allowed the therapist to address such common issues as family accommodation, criticism, and blame as they arise during the course of treatment. These family process elements were not assigned as specific required elements, but rather meant to encourage therapists to flexibly meet the needs of specific families. Examples of topics that were covered included: helping to identify and correct negative and distorted/incorrect attributions or assumptions about OCD, addressing accommodation in a process-oriented rather than didactic manner, and exploring areas of secondary gain (for child and for family) that may act as a barrier to success in treatment.

2.8.4. Family-based RT: Outline of treatment components

Family-based RT focused on teaching the child and parent relaxation strategies aimed at lowering the child's overall anxiety level. RT components included: (1) psychoeducation, (2) affective education, and (3) relaxation training. Psychoeducation content included the relationship between stress management and anxiety, a rationale for RT to treat OCD, and the use of a reward system to encourage relaxation skill practice. During affective education, the child was taught to identify negative and positive feelings, including thoughts and physical sensations associated with each. Emphasis was placed on recognizing anxiety. Relaxation training consisted of systematic instruction in progressive muscle relaxation and verbally-cued guided imagery. Developmental adaptations included the frequent use of active, child-focused engagement strategies such as drawing, relaxation games (e.g., variants of the card games "Go Fish" and "Concentration" with relaxation themed cards and built in practice), and practicing the portability of relaxation techniques by moving around the office, the building, and even going outside. Children were initially asked to practice skills daily and later to generalize skills to situations in which they feel worried/anxious.

2.8.5. Specific CBT treatment adaptations

Several key adaptations were made to CBT to better fit this young age group, including modified psychoeducation, increased focus on parent-based skills, and simplification of CBT skills. The key components of psychoeducation were introduced to parents alone in two initial (1.5 h) sessions—a departure from individual treatment models which would include parents and children together or the child alone. Ensuring that parents clearly understood the program and rationale before children were introduced to treatment was extremely important because many young children did not fully understand the treatment rationale and learned a great deal from watching their parents understand and apply CBT principles.

As part of the psychoeducation process, it was also important to differentiate "normal" developmental rituals (sleep, eating, clothing, etc…) from OCD symptoms that cause true interference. We worked with parents to differentiate OCD from other problematic behaviors or diagnoses, as well as from rigid temperament. Meeting alone with the therapist gave parents a place to discuss the emotional experience of having a child with OCD without the child present. Given that this was often a family's first contact with the mental health system, this was particularly crucial before treatment could proceed.

The primary aim of the child psychoeducation component was to help children, with their parents, externalize OCD as separate from the child. Externalizing OCD is a standard part of CBT for OCD in youth, but comprehension of this concept varied among the young children in this study. Most often, they understood (at very least) the concept of being the "boss" of these OCD behaviors. A child's developmental level played a key role in determining how much of the treatment rationale they could truly understand. In many cases, we saw it as most important that the parent grasp the concepts so that they could model and teach these approach behaviors to their children.

The basic goals of externalizing and EX/RP were accomplished by distilling the key concepts, tailored to the child's age and verbal ability, as well as making the process as hands-on, active, and engaging as possible. Therapists were trained to present materials via simple, engaging modalities (drawing on big paper, building things), visual imagery, metaphors, and developmentally relevant examples (i.e., a "worry monster" that causes thoughts to pop into your head; image of a printer that won't stop spitting out paper; or compulsion as "re-do's"). Therapists worked with parents to explain the rationale for facing one's fears rather than avoidance, often using examples from the child's life of other fears they had overcome (e.g., the dark, dogs). Therapists also used young child friendly ways to engage children in the idea that OCD was actually getting in their way (Choate-Summers et al., 2008).

Again, cognitive developmental differences played a large part in children's abilities to understand and engage in exposure tasks and affected their ability to create and use therapy tools (such as fear thermometers and fear hierarchies). With many patients, we simplified rating scales (e.g., pictorial scales with three faces- happy, neutral, scared; coloring on a blank feelings thermometer to indicate level of anxiety). For some patients, we moved away from traditional ratings scales all together and used stacking cups of varying sizes (or other physical objects) to indicate differing levels of fear/anxiety. Even with such adaptations, some children were not able to use a rating scale. In these cases, therapists used behavioral cues to estimate anxiety reactions. Many young children with OCD have an "all or none" approach to anxiety ratings and seem to go from a 0 to a 10 with little warning during an exposure task. Part of the treatment involved anticipating this situation and training the parents to be able to identify more subtle cues and to break situations down for their child. In time this helped children to learn to be more accurate in their ratings.

With regard to actual exposure tasks, we found it most helpful for therapists to model a broad, approach oriented behavioral repertoire in the presence of a feared stimulus. The goal was to teach children that avoidance is but one option when you encounter a scary thought or situation. Therapists worked to make exposure into a game where possible (i.e., having fun, playing games, doing silly things in the presence of a feared stimulus). Of course, some content simply did not lend itself to being as active or silly (e.g., aggressive and sexual obsessions). Another common difficulty was when the child has not articulated a clear obsession. Given the hypothesized functional relationship between obsessions and compulsions, a well-designed EX/RP task should trigger the appropriate obsession. For example, an appropriate EX/RP task for a child who avoids "poisons" might focus on touching those items himself (when the obsession is related to harm to self) or on giving those items to others (when the obsession is related to harm to others). In situations where the obsession is less clear, we have found that doing EX/RP tasks with particular attention to the function of children's rituals and avoidance behaviors can sometimes increase our ability to understand a young child's obsession. In other words, obsessional content is sometimes revealed verbally or behaviorally during an EX/RP task. Many children may only describe feeling "weird" or "gross." In all exposure work that is done, teaching children and parents to avoid family accommodation and distraction was key.

In sum, the following adaptations to standard individual OCD treatment models were most crucial: (1) Treatment will be most effective if parents are involved in all phases of treatment; (2) Clinicians should consider the child's unique developmental characteristics and tailor psychoeducation, exposures, and homework accordingly; and (3) clinicians should take time to understand the family context (e.g., lack of familiarity with the mental health system, patterns of family accommodation, parental psychopathology) and in particular, the parent's response to their child's anxieties. From a clinical standpoint, we feel that a key element in this treatment program is the "exposure" function it serves for parents as they learn to tolerate their own anxiety and distress in the face of assisting their children with difficult and often upsetting in-session and homework tasks.

3. Conclusion

Early onset OCD is a significant public health problem with numerous consequences for later functioning. The impact of these consequences can be attenuated by timely intervention. To date, there are no other large scale controlled studies that evaluate the efficacy of a family based intervention for young children with OCD. Given concerns about the developmental impact of early onset OCD and the potential for compounding its negative effects over time, such interventions are sorely needed (Garcia et al., 2009).

This trial adheres to the methodological rigor of a large scale, multi site clinical trial (Franklin et al., 2011; POTS Study Team, 2004; TADS Study Team, 2004; Walkup et al., 2008) while making significant developmental adaptations to meet the needs of this population of youth with early onset OCD. These include having parents as active participants in treatment, addressing OCD-maintaining aspects of the larger family system, recognizing unique correlates of early onset OCD, and considering the importance of a family's first contact the with mental health system (Freeman et al., 2007). These adaptations also include cognitive developmental changes to the assessment and treatments themselves (Freeman & Garcia, 2008).

The methods of this study and specifically the adaptations for young children were thoughtfully developed and executed over the course of many years of this project. As a result, we can place more confidence in the overall results of this trial and ultimately provide a better test of whether this newly adapted treatment is effective. Examination of efficacy, tolerability/acceptability, and long term maintenance of treatment gains are the primary goals of the project. Results of this trial will provide important information about the comparability of this treatment program with existing CBT models for older children and adolescents with OCD. Ultimately, it may also provide a model for intervening in early onset anxiety disorders more broadly and engaging young children and their families in exposure-based treatments before significant impact on development occurs.

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