



Family-based exposure and response prevention therapy for preschool-aged children with obsessive-compulsive disorder: A pilot randomized controlled trial



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ABSTRACT

Aims: To examine the feasibility, acceptability and preliminary efficacy of family-based exposure/response prevention therapy (E/RP) versus treatment as usual (TAU) in a cohort of very young children with early onset obsessive-compulsive disorder (OCD).

Methods: Thirty-one children ages 3–8 years ($M = 5.8$ years) with a primary diagnosis of OCD were randomized to E/RP or TAU. The E/RP condition received 12 sessions of family-based E/RP twice weekly over 6 weeks. Families were assessed at baseline, post-treatment, 1-month and 3-month follow up. The Children's Yale Brown Obsessive Compulsive Scale and Clinical Global Impression served as primary outcome measures.

Results: A large group effect emerged in favor of the E/RP group ($d = 1.69$). Sixty-five percent of the E/RP group was considered treatment responders as compared to 7% in the TAU group. Symptom remission was achieved in 35.2% of the E/RP group and 0% of the TAU group. There was no attrition and satisfaction was high; gains were maintained at 3 months.

Conclusions: Even amongst children as young as 3 years, developmentally tailored E/RP is efficacious and well-tolerated in reducing OCD symptoms. Key adaptations for younger children include extensive parent involvement, targeting family accommodation, and frequent meetings while delivering a full course of E/RP.

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Pediatric obsessive compulsive disorder (OCD) is a chronic and disabling illness with a point-prevalence of 1–2% (Zohar, 1999). Age of symptom onset varies but generally occurs during key developmental periods such as pre-pubescence or adolescence/early adulthood, with up to 80% of adults reporting emergence of symptoms prior to the age of 18 years (AACAP, 2012). As pediatric OCD was previously believed to be rare amongst very young children, most

Abbreviations: E/RP, exposure and response prevention; TAU, treatment as usual; OCD, obsessive compulsive disorder.

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studies focus primarily on school-aged children above the age of 8 years. However, reports have noted OCD presentations amongst those as young as 2 years (Coskun & Zoroglu, 2009). While reports on early childhood OCD (i.e., onset of symptoms prior to age of 9 years e.g., Freeman et al., 2008) are scant, studies have noted that symptoms are associated with positive family history, increased distress, longer duration of illness, and higher rates of comorbid tics (Coskun & Zoroglu, 2009; Garcia et al., 2009; Nakatani et al., 2011). Those affected by early childhood OCD may be at particular risk as OCD symptoms may impede or hinder normal development during key milestone years (Flessner, Garcia, & Freeman, 2013; Valderhaug & Ivarsson, 2005). Consequently, early and aggressive intervention is paramount for younger children with OCD (Hirshfeld-Becker & Biederman, 2002; Lewin, Park, & Storch, 2013).

Early childhood OCD presents with a number of unique developmental factors, which should be addressed during the course of treatment. Children are generally enmeshed into the dynamics of the family and often do not have the ability to disengage with family related stressors such as marital dysfunction and parental mental health (Freeman et al., 2003). These factors may strongly influence the mental health of the child and affect treatment progress, as well as maintenance of gains (Kazdin, 1995; Kazdin & Weisz, 1998). Family accommodation, which refers to the involvement of family members in the child's OCD symptoms, is highly prevalent in children and adolescents with OCD (Storch, Geffken, Merlo, Jacob, et al., 2007). Family members may modify their family routine to allow children to avoid anxiety-provoking situations, or engage in rituals such as providing reassurance, assisting in mealtime, bedtime, or toileting rituals (Peris et al., 2008; Storch, Geffken, Merlo, Jacob, et al., 2007). Because of the involvement of family members in OCD symptoms, as well as the influence of family dynamics upon the course of the treatment, it is imperative that family members are involved in the treatment process.

There are two evidence-based treatments for pediatric OCD: serotonin reuptake inhibitors (SRIs) and exposure and response prevention (E/RP) (Lewin & Piacentini, 2009; POTS, 2004). Pooled effects suggest that E/RP has an advantage over SRI treatment alone (Abramowitz, Whiteside, & Deacon, 2005) leading to practice parameter recommendations that children receive E/RP alone in those with mild to moderate severity or with SRI therapy in more severe cases (AACAP, 2012). While efficacious, pharmacotherapy may have serious adverse events, somatic side effects (e.g., poor sleep, gastrointestinal complaints), and behavioral activation with increased risk at younger ages (Murphy, Segarra, Storch, & Goodman, 2008) even at small doses. For example, in an open trial of fluoxetine in six very young children with OCD, 50% developed significant medication-related side effects including two with behavioral disinhibition (Coskun & Zoroglu, 2009). Although a recent case series suggests fluoxetine produced clinical improvement in four treatment-refractory preschool aged youth with OCD (Ercan, Kandulu, & Akyol Ardic, 2012), medication is often undesirable to parents of young children, especially in cases of new onset/initial treatment.

Conversely, E/RP for pediatric OCD is a well-tolerated and acceptable option for parents (Patel & Simpson, 2010). Well-designed studies have had positive outcomes, particularly amongst children ages 7–17 years, with response rates ranging from 39% to 90% (Piacentini et al., 2011; POTS, 2004; Storch, Bussing, et al., 2013; Storch, Geffken, Merlo, Mann, et al., 2007). However, despite OCD being relatively common among very young children (Coskun, Zoroglu, & Ozturk, 2012; Flessner et al., 2013; Garcia et al., 2009) and practice parameters recommending E/RP as the first line intervention for pre-latency youth with OCD (AACAP, 2012; Gleason et al., 2007), strikingly few children below the age of 8 years have been included in the extant controlled research (Flessner et al., 2013). Indeed, Freeman et al. (2008) noted that within the Pediatric OCD Treatment Study I and Study II (POTS), which are considered the largest pediatric OCD treatment studies to date, only 10–16% were ages 7 or 8 years (POTS, 2004). Following the POTS trials, only one published trial to date has included youth under the age of 7 years (Freeman et al., 2008) although a larger trial for youth ages 5–8 years is underway (Freeman et al., 2012).

In Freeman et al. (2008), a 12-session family-based E/RP course was found efficacious for treating youth ages 5–8 years with OCD. Completer analysis showed a large group difference ($d = 0.85$) with greater obsessive-compulsive symptom reductions for youth receiving E/RP ($n = 16$) versus a 12-session relaxation training control ($n = 15$). Following the 12-session course, 69% of youth responded to E/RP compared to 20% of youth receiving relaxation

training. Notably, the authors implemented modifications to the E/RP protocol to address developmental, cognitive, and socio-emotional differences specific to children age 8 years and younger. Specific modifications included: (1) Inclusion of parents as coaches to foster motivation, increase adherence, and reduce accommodation; (2) Cognitive therapy components were simplified as concrete, child-specific examples and to foster allegiance in combating 'OCD' as a common adversary; (3) Addressing other demands associated with treating anxiety in a very young sample including child oppositionality/resistance, managing out-of-session E/RP homework, parental tolerance of their own distress during E/RP, and related logistical issues for parents. Despite this promising work, a clear need exists for replication and extension of these findings in youth age 8 years and under with OCD to help support E/RP as efficacious for this younger cohort.

Consequently, the present study is an investigation of feasibility, tolerability and preliminary efficacy of a family-based E/RP protocol designed for the youngest cohort of youth with OCD to date. Rather than an exact replication of Freeman et al. (2008), we introduced a novel protocol with several modifications given (1) the younger cohort (32% of our sample was below the range included in Freeman et al. (2008)), (2) to reduce attrition (26% in Freeman et al. (2008)) and (3) bolster responsiveness to this promising approach without (4) compromising acceptability. Briefly, key modifications included: (a) a primary focus on E/RP versus the inclusion of other treatment elements (e.g., 4–6 sessions in Freeman et al. (2008) without primary E/RP focus); (b) eliminating most cognitive procedures; (c) parent/child inclusion in all sessions; (d) twice-weekly format to expediate response; (e) tenacious targeting of family accommodation starting at session 1.

Contrasts with the promising Freeman et al. (2008, 2009) protocol were as follows. Treatment utilized in the present study was refined to emphasize the primacy of E/RP; rather than initiating E/RP at session 5 or 6, our revised protocol implemented E/RP no later than the second visit (but often during session 1). Moreover, after the first session, E/RP was the primary focus of each of the remaining sessions with even less emphasis on cognitive strategies/child focused psychoeducation (given the very young age of the targeted cohort, i.e., inclusion of 3–5 year olds). Several other modifications were implemented given the very young age range. First, both parents and youth were included in all sessions together (unlike Freeman et al. (2008) which excluded youth until session 3). While there is support for children as young as 4 years benefiting from verbally-presented information regarding exposure therapy (Scheeringa et al., 2011), emphasis was placed on parental understanding of E/RP concepts (Choate-Summers et al., 2008). Although parents desire their child to "understand" therapeutic concepts (Labouliere, Arnold, Storch & Lewin, 2014), there is little benefit in spending additional session time on child focused psychoeducation with a 3–5 year old (Choate-Summers et al., 2008), especially at the expense of reducing the time spent in E/RP. Thus, having the child present for parental psychoeducation could appease parents while preserving time dedicated for E/RP. Consequently, instead of utilizing two sessions for education, our revised protocol was more streamlined in order to maximize the dosage of E/RP. Another advantage of keeping the parent and child together in all sessions was the ability to provide singular focus on E/RP rather than separate parent and child goals in each session (Freeman & Garcia, 2009). Additionally, our study protocol addresses accommodation beginning week 1, as a mechanism for conducting exposure. Family accommodation is a hallmark of early childhood OCD (Garcia et al., 2009; Flessner et al., 2013; Freeman et al., 2003) and consequently E/RP was adapted to aggressively target accommodation. Parent engagement in child rituals and/or parent facilitation of OCD (e.g., allowing extra time, purchasing special products, making

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