



# Trajectory of Change in Parental Accommodation and Its Relation to Symptom Severity and Impairment in Pediatric OCD

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## Abstract

Family accommodation (FA) has been shown to relate to poorer treatment outcomes in pediatric obsessive compulsive disorder (OCD), yet few studies have examined the trajectory of change in FA throughout treatment and its relation to treatment outcomes. This study examined change in FA in relation to change in symptom severity and impairment in 63 youth receiving a family-based intervention for early-onset OCD. FA, symptom severity and functional impairment were assessed at baseline, week 5, week 9, and post-treatment (week 14). Results suggested that changes in FA in the beginning stages of treatment preceded global symptom improvement (but not OCD specific improvement) whereas changes in functional impairment preceded changes in FA. In the latter half of treatment, changes in FA preceded improvement in global and OCD specific symptom severity as well as functional impairment. These findings highlight the importance of reducing FA, especially in the later stages of treatment, in order to optimize treatment outcomes in early-onset OCD.

**Keywords** Accommodation · OCD · Pediatric · Treatment

## Introduction

Obsessive compulsive disorder (OCD) is a chronic and debilitating disorder affecting both children and adolescents [1–3]. OCD can disrupt functioning across a number of domains, including familial, social and academic and when left untreated, is associated with delayed developmental milestones and adult disability [4–6]. Strong evidence supports cognitive-behavioral therapy (CBT) with exposure with response prevention (ERP) as a front-line intervention for children and adolescents [1, 7, 8]. Recent advancements have targeted early-onset OCD due to the need for developmentally sensitive interventions which take into account the crucial role of the family in treatment and provide an

opportunity to address symptoms before they become even more tightly ingrained in family functioning [9–11].

Family-based cognitive-behavioral therapy methods have proven efficacious for young children with OCD [9–13]. Due to young children's reliance on family members for instruction, guidance and skill acquisition, family members play a crucial role in treatment [14]. Programs designed for young children promote heavy parental involvement due to the ways in which parents commonly inadvertently reinforce child symptoms. Family accommodation (FA), referring to the ways in which caregivers facilitate child avoidance of anxiety-provoking stimuli or in alleviating distress caused by anxiety, is a well-studied construct in pediatric OCD [15–19]. FA often includes caregiver participation in symptom-related behavior or modifications to family routines [18]. FA has been found to relate to symptom severity, such that youth with more severe symptom presentations have caregivers who engage in greater FA [19–22]. Greater FA is also associated with higher levels of youth impairment, even when controlling for OC symptom severity [23], with one study finding that FA mediated the relationship between OC symptom severity and functional impairment [13].

A number of studies have identified FA as an important treatment target for pediatric OCD [11–13], given that FA

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runs counter to exposure with response prevention (ERP), a key component in current evidence-based treatments for pediatric OCD. ERP encourages youth to approach a feared stimulus without engaging in compensatory behavior to decrease distress, thus allowing for natural extinction of the fear/distress [24–26]. In contrast, FA negatively reinforces child symptoms by reducing the child's distress in the moment and reinforcing the child's perception that the feared situation or stimulus warranted the distress response, thereby interfering with the extinction process [27]. Indeed, research has demonstrated that FA interferes with treatment effectiveness, showing that higher levels of FA at the beginning of treatment correspond with poorer treatment outcomes [20, 28] and the degree to which FA decreases over the course of treatment is associated with more positive treatment outcomes, even when controlling for symptom severity [21]. More recently, a study examining an adjunctive treatment (positive family interaction therapy) designed to target family dynamics that interfere with exposure-based treatment in complex pediatric OCD cases found that change in FA mediated treatment response [13].

Although the relationship between FA and treatment outcomes are well-established, with a number of treatment programs demonstrating effectiveness at reducing FA [9–11, 13], few studies have examined changes in FA at various points throughout treatment. Understanding the relationship between FA and outcomes throughout treatment is key to better understanding FA as a treatment mechanism. For instance, it may be that reductions in FA earlier in treatment allow for parents to create more opportunity for exposure practices, thus leading to symptom improvement. Or conversely, perhaps early improvement in youth symptoms leads to reductions in FA because parents feel more confident in their ability to change their own behavior after seeing improvement in their child's behavior and functioning.

Only one published study has examined changes in FA throughout treatment and its relation to symptom severity and impairment [29]. This study found that improvements in FA precede OCD symptom improvement and functional impairment in both individual and family-based treatment [29]. These findings highlight the importance of FA as a potential treatment mechanism and suggest that reducing FA earlier in treatment may bolster treatment response. However, given that these analyses were conducted across treatment groups, it is unclear whether these findings were specific to the treatment specifically targeting FA. Moreover, no study to date has examined the timing of change in FA throughout treatment and its relation to symptom severity and impairment in a sample of youth with early-onset OCD, a sample in which FA is particularly relevant given the reliance on parents to help young children generalize treatment skills [30, 31]. Targeting FA at critical points in treatment may be an important treatment optimization strategy in this

age group, especially given that a number of youth remain symptomatic following exposure-based treatments [32, 33].

The current study evaluates FA, symptom severity and OCD-related functional impairment over the course of a family-based intervention for early-onset OCD. Specifically, these constructs were examined at multiple time points across treatment in order to examine effect on treatment trajectory. Symptom severity and functional impairment were included as outcomes due to previous literature demonstrating strong cross-sectional links between accommodation and these variables. We are unaware of work to date that examines the *predictive* nature of FA in relation to symptom severity and functional impairment in a sample of young children with OCD and therefore this is a pilot examination of these constructs within the Pediatric Obsessive-Compulsive Disorder Treatment Study for Young Children (POTS Jr.) treatment study. The present study aimed to examine whether FA levels early in treatment predict symptom severity and functional impairment at subsequent time points or alternatively, if early changes in symptom severity and functional impairment predict FA at subsequent time points. Although exploratory, we hypothesized based on preliminary evidence [29], that greater reductions in FA levels early in treatment would predict greater improvement in symptom severity and functional impairment at subsequent time points.

## Methods

### Design

This study used data from the POTS Jr. trial, a 14-week randomized controlled trial comparing family-based CBT (FB-CBT) for youth with early-onset OCD to family-based relaxation therapy [10]. The study rationale, sample characteristics, methods, description of treatment and primary outcomes have been detailed elsewhere [10, 14]. Participants were recruited across three study sites (Brown University, Duke University and University of Pennsylvania) and randomized across the two treatment conditions. The current study only includes participants (N = 63) randomized to the FB-CBT group, as we are interested in the timing of FA change in response to a CBT intervention that included a focus on exposure and specific instruction in reducing FA. Institutional Review Board approval was obtained at each study site. Parents provided written informed consent and children provided written assent. The Consolidated Standards of Reporting Trials diagram was originally reported in Freeman et al. [10].

Independent evaluators were all doctoral-level psychologists who were trained to reliability on the Clinical Global Impression-Severity (CGI-S) and -Improvement (CGI-I)

scales [34] and the CYBOCS [35] through joint interviews, videotape reviews, and participation in monthly cross-site supervision conferences. Reliability was routinely checked on a random selection of videotapes, and independent evaluators were retrained if they fell below 80% agreement.

## Participants

The sample consisted of 63 youth aged 5 to 9 years ( $M_{\text{age}} = 7.40$ ,  $SD = 1.18$ ). To be eligible, participants were ages 5–8, had a primary diagnosis of OCD and a score of 16 or higher on the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS). Descriptive statistics of demographic characteristics and baseline study variables are presented in Table 1.

## Measures

### Symptom Severity

Two measures of youth symptom severity were included. The Clinical Global Impressions-Severity scale (CGI-Severity; CGI-S) [34] is a clinician-rated measure of global symptom severity. The CGI-S is rated on a scale of 1 (normal, not at all ill) to 7 (among the most extremely ill patients). The scores at baseline, week 5, week 9, and post-treatment (week 14) were used to represent global symptom severity. The Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) [35] was included as a measure of youth OCD specific symptom severity. The CY-BOCS is a well-established clinician-rated measure of OCD severity for youth [35–37]. The measure is composed of symptom checklists for both obsessions and compulsions and 10 severity items

regarding time spent, interference, distress, resistance, and control. The items are rated on a scale of 0 (no symptoms) to 4 (extreme symptoms), with higher scores indicating higher severity. Independent evaluators completed the CY-BOCS at baseline, week 5, week 9 and post-treatment (week 14). The CY-BOCS has demonstrated adequate convergent and divergent validity [35–37].

### Functional Impairment

Parents completed the Child Obsessive Compulsive Impact Scale-Revised, Parent-report (COIS-RP) [38]. The COIS-RP is a parent-report of the impact that OCD symptoms have on youth psychosocial functioning. The 33-item measure assesses functioning across social, school, and home domains. Items are rated on a 4-point scale with a range of 0 (not at all) to 3 (very much). The total score was used as an indication of functional impairment, with higher scores reflecting increased impairment. The COIS-R has demonstrated excellent internal consistency and satisfactory concurrent validity [38].

### Family Accommodation

Family accommodation was assessed using the Family Accommodation Scale-Parent-Report (FAS-PR) [39]. The FAS-PR is a parent-report version of the original clinician-rated FAS [39]. This 13-item measure examines parent accommodation of their children's OCD symptoms, associated distress, and related impairment. Items are rated on a 5-point scale with a range of 0 (never) to 4 (daily). An overall accommodation score was calculated based on the first nine items in line with previous studies [17, 40]. The FAS is psychometrically sound in use with youth [16, 41].

**Table 1** Sample baseline characteristics

Study variable	Mean (SD)
Age	7.40 (1.18)
Female gender, N (%)	39 (62%)
Hispanic or Latinx	3 (4.7%)
Race, N (%)	
White	59 (93.7%)
Black	1 (1.6%)
Mixed race	1 (1.6%)
Not reported	2 (3.2%)
CY-BOCS	25.13 (4.46)
FAS	23.15 (15.04)
CGI	4.71 (0.89)
COIS-RP	23.97 (16.43)

*CY-BOCS* Children's Yale Brown Obsessive Compulsive Scale, *FAS* Family Accommodation Scale, *CGI-S* Clinical Global Impression-Severity, *COIS-R* Child Obsessive Compulsive Impact Scale-Revised, Parent Report

### Outline of FB-CBT Treatment Components

FB-CBT focused on providing the child and parent with tools to understand, manage, and reduce child OCD symptoms. In addition to exposure, the primary components included (1) psychoeducation, (2) behavior management skills training (3) externalizing OCD and ERP, and (4) family process components [10]. The following section will outline treatment components by session(s) in order to provide context through which to view the results. Additional FB-CBT treatment information has been detailed elsewhere [10, 13].

**Sessions 1–2** The first two sessions only involved the parents and focused on providing parents with psychoeducation about pediatric OCD and family involvement in the treatment process. Additional topics included build-

ing a symptom hierarchy and introducing several behavior management strategies (differential attention, creation of a reward plan).

**Session 3** Parents and children participated in the session together. Children were introduced to the feelings thermometer (used to rate distress) and symptom monitoring. Parents were introduced to the behavior management strategies of differential attention and use of praise and encouragement.

**Session 4** Parents and children participated in the session together. Children were introduced to the concept of cognitive strategies (“bossing back” OCD) and ERP. Family disengagement from child symptoms (reducing family accommodation) was discussed.

**Session 5–6** Parents and children participated in sessions together. Children continued practicing “bossing back” and ERP and parents were encouraged to continue disengaging from child symptoms. Parents were introduced to the concept of modeling as well as scaffolding (learning how to guide exposure activities and responding to child distress in ways that are consistent with an exposure-based treatment model).

**Session 7–12** Parents and children participated in sessions together. Children continued practicing “bossing back” and ERP. Parents continued to practice scaffolding and engaging in problem-solving as needed. Maintenance and relapse prevention strategies were reviewed in later sessions.

### Data Analytic Strategy

All data management and analyses were carried out in R and MPlus, using the MPlusAutomation package [42, 43]. Data were examined for normality and patterns of missingness were evaluated. Missing data were handled in MPlus using full-information maximum likelihood (FIML) estimation. A series of three cross-lagged panel models (CLMPs) were tested to examine FAs relationships with symptom severity and functional impairment at baseline, week 5, week 9, and week 14. The first model examined the relationship between FA (FAS-PR) and OCD symptom severity (CY-BOCS). The second model examined the relationship between FA (FAS-PR) and global severity of psychopathology (CGI-S). Finally, the third model examined the relationship between FA (FAS-PR) and functional impairment specific to OCD (COIS-RP). Model fit was evaluated using recommended cutoffs (e.g., nonsignificant  $\chi^2$ ,  $RMSEA \leq 0.08$ ,  $CFI \geq 0.95$ ,  $TLI \geq 0.95$ ,  $SRMR \leq 0.08$ ). Models were still considered to have acceptable fit if the majority of fit indices met this threshold.

## Results

### Associations Between FA and OCD Symptom Severity

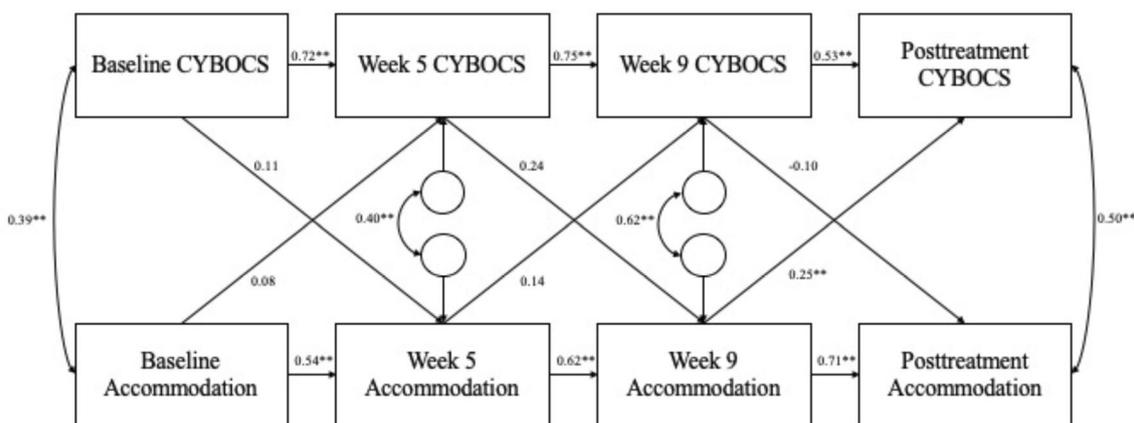
The first CLPM examined the relationship between FA and OCD symptom severity. Model fit was acceptable,  $\chi^2[12] = 19.82$ ,  $p = 0.07$ ,  $RMSEA = 0.10$ ,  $CFI = 0.97$ ,  $TLI = 0.94$ ,  $SRMR = 0.06$ ). All autoregressive parameters were significant (i.e., variables at time  $T - 1$  predicted the same variable at time  $T$ ). Additionally, FA and OCD symptom severity were significantly correlated at each timepoint (all  $p$ 's  $< 0.05$ ). In regard to the cross-lagged associations, the path from FA at week 9 to symptom severity at week 14 was the only significant cross-lagged effect ( $b = 0.25$ ,  $p = 0.003$ ), suggesting that reductions in accommodation precipitate decreases in OCD symptoms severity towards the end of treatment. A path diagram of the full CLPM that includes all path coefficients is presented in Fig. 1.

### Associations Between FA and Global Symptom Severity

The second CLPM examined the relationship between FA and global symptom severity. Model fit was acceptable,  $\chi^2[12] = 20.40$ ,  $p = 0.06$ ,  $RMSEA = 0.10$ ,  $CFI = 0.97$ ,  $TLI = 0.92$ ,  $SRMR = 0.06$ . Similar to the model examining OCD symptom severity, all variables at time  $T - 1$  predicted themselves at time  $T$ . Additionally, FA and global symptom severity were correlated with each other at each timepoint (all  $p$ 's  $< 0.05$ ). The cross-lagged effect of FA at week 5 predicting global symptom severity at week 9 was significant,  $b = 0.03$ ,  $p = 0.02$ . Similarly, the cross-lagged effect of FA at week 9 predicting global symptom severity at week 14 was significant,  $b = 0.04$ ,  $p = 0.03$ , suggesting that reductions in accommodation precipitate decrease in global symptom severity. A path diagram of the full CLPM that includes all path coefficients is presented in Fig. 2.

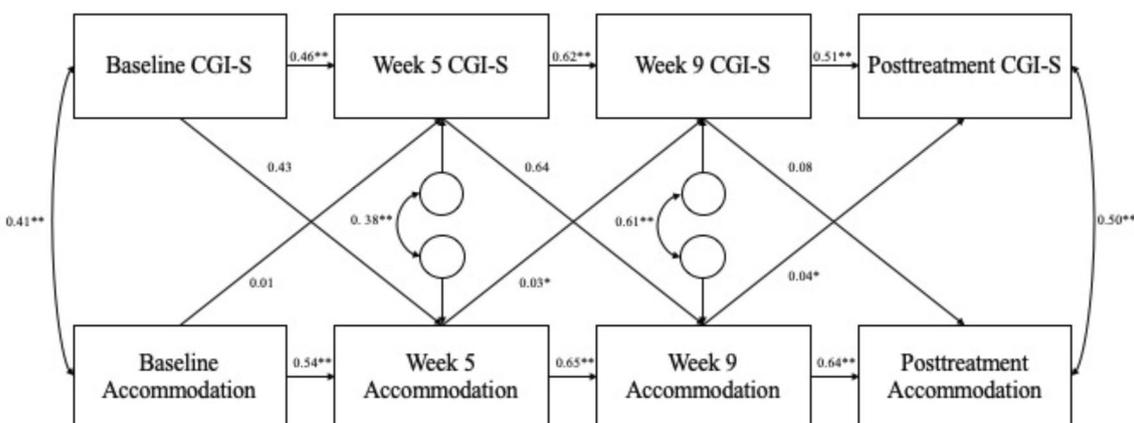
### Associations Between FA and Functional Impairment

Finally, the last CLPM examined the relationship between FA and functional impairment. This model fit the data well,  $\chi^2[12] = 18.73$ ,  $p = 0.10$ ,  $RMSEA = 0.10$ ,  $CFI = 0.98$ ,  $TLI = 0.96$ ,  $SRMR = 0.05$ . All autoregressive effects (variables at time  $T - 1$  predicting the same variable at time  $T$ ) were statistically significant. Additionally, functional impairment was significantly correlated with FA at all assessment points except for week 5 where the correlation approached significance ( $\Psi = 0.29$ ,  $p = 0.07$ ). The cross-lagged effect of



**Fig. 1** Path diagram of CLPM examining temporal relationships between OCD symptom severity (CYBOCS) and parental accommodation. *CYBOCS* Children’s Yale Brown Obsessive Compulsive Scale. Path coefficients represent unstandardized coefficients *except*

covariances between variables at each time point were converted to standardized correlation coefficients for ease of interpretation. \* $p < 0.05$ ; \*\* $p < 0.01$



**Fig. 2** Path diagram of CLPM examining temporal relationships between global symptom severity (CGI-S) and parental accommodation. *CGI-S* Clinical Global Impression-Severity. Path coefficients

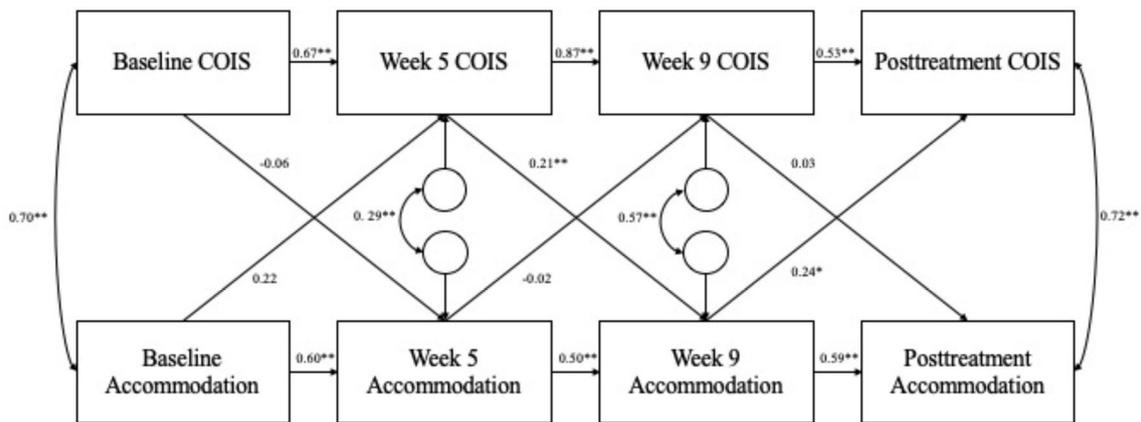
represent unstandardized coefficients *except* covariances between variables at each time point were converted to standardized correlation coefficients for ease of interpretation. \* $p < 0.05$ ; \*\* $p < 0.01$

functional impairment at week 5 predicting FA at week 9 was significant,  $b = 0.21, p < 0.01$ , suggesting decreases in impairment are prospectively associated with decreases in accommodation early in treatment. Additionally, the cross-lagged effect of FA at week 9 predicting functional impairment at week 14 was significant,  $b = 0.24, p < 0.05$ , suggesting decreases in family accommodation later in treatment predict later changes in functional impairment. A full path diagram of this CLPM that includes all path coefficients is presented in Fig. 3.

### Discussion

This study examined the relationship between FA, youth symptom severity and functional impairment in a sample of youth receiving family-based CBT for early onset OCD.

Specifically, these constructs were examined at multiple time points across treatment in order to examine effect on treatment trajectory. In line with previous findings [29], at baseline, FA was related to symptom severity and impairment such that higher levels of FA were associated with greater symptom severity and functional impairment. We expanded on these findings by demonstrating that this relationship is consistent across the course of treatment. Results also indicated that reduction in FA predicted improved symptom severity and impairment at subsequent time points, although how well FA predicted improvement across different outcome measures depended on when in treatment FA improved. These findings highlight the importance of targeting FA in order to affect change in symptom severity and impairment, particularly in the latter half of treatment.



**Fig. 3** Path diagram of CLPM examining the temporal relationship between functional impairment (COIS-RP) and parental accommodation. *COIS-RP* Child Obsessive Compulsive Impact Scale-Revised, Parent Report. Path coefficients represent unstandardized coefficients

except covariances between variables at each time point were converted to standardized correlation coefficients for ease of interpretation. \* $p < 0.05$ ; \*\* $p < 0.01$

In regard to youth OCD symptom severity, symptom severity at baseline was associated with symptom severity at each subsequent time point, suggesting that youth with more severe symptom presentations at the beginning of treatment were likely to have higher levels of symptoms throughout treatment. This same pattern was found for FA, such that parents who engaged in higher levels of FA at the beginning of treatment were likely to engage in greater FA throughout. This is consistent with previous treatment studies finding that higher baseline symptom severity and FA predict poorer treatment outcomes [20, 21]. In relation to each other, results suggested that although FA and OCD symptom severity were associated with each other at each individual time point, their predictive relationship across time was less consistent. In the first half of treatment, FA did not predict symptom severity at subsequent time points and symptom severity did not predict FA at subsequent time points. However, FA at week 9 predicted symptom severity at post-treatment (week 14) whereas symptom severity at week 9 did not predict FA at post-treatment. This suggests that in the later stages of treatment, improvement in FA is an important driver of symptom improvement but symptom improvement does not drive improvement in FA. This is in line with previous findings demonstrating that changes in FA precede symptom improvement [29].

Similar findings were found for youth global symptom severity, such that changes in FA later in treatment preceded improvement in global symptom severity. Results also indicated that changes in FA *earlier* in treatment preceded subsequent changes in global symptom severity. Conversely, changes in global symptom severity were not predictive of changes in FA at any subsequent time points. The discrepancy between timeliness of change in FA and its relation to changes in symptoms may be due to the specificity of

the symptom measure. The CGI-S measures overall symptom severity whereas the CYBOCS measures OCD specific symptom severity. It may be that change in FA earlier in treatment has a greater impact on broader indices of youth psychopathology rather than OCD symptoms specifically. The content of earlier sessions consists of psychoeducation and aspects of parent training (e.g. active ignoring, use of rewards) that are important, but not exclusively relevant to OCD symptoms. It may be that parents who effectively reduce their level of accommodation early on in treatment are those who are also able to apply these principles to a broader range of youth behavior, such as externalizing behaviors. Thus, parents who are most adept at flexibly using the treatment principles early in treatment are also likely to see improvement in other areas besides OCD symptoms. This would also make sense given that direct youth exposure work has only just started by week 5 and therefore changes in FA at this point are less likely to coincide with more immediate changes in OCD specific symptom severity. It is not until later in treatment when exposure work is more underway that the relationship between FA and OCD severity becomes more apparent. It should be noted that the effect size for changes in global symptom severity and accommodation was relatively small compared to OCD symptom severity and functional impairment and thus results should be replicated with a larger sample.

Improvement in FA also preceded subsequent improvement in functional impairment in the latter part of treatment, consistent with findings related to symptom severity. However, some differences were found for the relationship between FA and functional impairment earlier in treatment. Unlike changes in symptom severity, changes in functional impairment preceded subsequent changes in FA in the beginning part of treatment. This suggests that if there is a

significant shift in functioning related to OCD symptoms, parents may find it easier to reduce their accommodation of these symptoms. Perhaps when youth are functioning better across certain domains (home, school, social), parents are less pulled to accommodate either due to reductions in the child's overall distress or the parents own stress. This finding may also be due to the fact that parents reported on functional impairment whereas independent evaluators reported on symptom severity. This raises an important question of parent perception of child distress/functioning and the impact this has on FA. Prior research suggests that parental perception of child distress and beliefs about ramifications of child distress relate to engagement in FA [44–46]. It will be important for future work to examine changes in parent perception and beliefs about child distress/functioning and accommodation over the course of treatment.

Taken together, these findings highlight the importance of family involvement in treatment. For younger children, change in parent behavior is crucial, especially in the latter half of treatment. Parents who struggle to reduce FA by the end of treatment may find it difficult to aid youth in completing between-session exposure practices, a particularly important ingredient to treatment success for younger children. For parents who struggle to reduce accommodation, our findings underscore the importance of additional intervention that addresses barriers to change in FA. Prior research suggests that parental engagement in accommodation is related to their own distress or beliefs about their child's symptoms or ability to change [44, 45] and preliminary evidence suggests that targeting parental beliefs is one avenue by which to change parent behavior in response to child distress [46]. Additional studies are needed that examine barriers to parent behavior change as they relate to treatment outcomes. Our results also shed further light on the debate of whether youth improvement makes it easier for parents to change their behavior or whether changes in parent behavior drive youth improvement. Generally, our results support parent behavior change being important to youth improvement, but also suggest that targeting functional impairment related to OCD symptoms early in treatment may be important given that changes in this domain predicted subsequent changes in FA.

This study has several strengths, including data collection at multiple assessment points throughout treatment and psychometrically sound outcome measures that include both clinician and parent-report. However, there are limitations that require comment. Although this study utilized data from a rigorously designed randomized controlled trial, only participants in the FB-CBT group were included in analyses. As such, the final sample size was modest and results should be replicated in a larger sample. Data from the larger controlled trial included follow-up assessments, but because we were most interested in examining changes in accommodation as

it related to specific phases of active treatment and session content, we chose not to include follow-up data. Given the pilot nature of examining accommodation in this way, future studies should include follow-up time points to understand the longevity of these effects. The sample was also homogenous in regards to age and demographics. These results may not generalize to older youth, especially given the variability in parent involvement in treatment among adolescents. FA has been proven to be important in older youth, both in terms of symptom severity and treatment outcomes [19, 21], but it may be that FA in older age groups does not precede symptom improvement. Older children and adolescents may be more capable of completing at-home exposure practices independently relative to younger children and therefore treatment outcomes may not be as closely tied to changes in parent behavior. The sample was also fairly homogenous in terms of race/ethnicity and income. FB-CBT requires significant parent involvement, which may not be possible for some families and future research should examine accommodation changes in relation to treatment outcomes in more demographically diverse participant samples. Lastly, accommodation was measured via parent-report only. High concordance rates have been found between parent and clinician ratings of FA [47], but given issues with retrospective reporting bias, future studies should include a broader range of assessment tools related to FA (clinician and child-ratings, ecological momentary assessment).

## Summary

FA is an important treatment target in pediatric OCD treatment, yet few studies have examined change in FA at different stages of treatment as it relates to improvement in youth symptom severity and impairment. The current study sought to examine the trajectory of change in FA and its association with changes in youth symptom severity (OCD specific and global) and functional impairment in a sample of youth receiving a family-based intervention for early-onset OCD. These constructs are particularly important to examine in young children with OCD given the crucial role parents play in skill acquisition and supporting intervention implementation at home. Results showed that changes in FA in the beginning stages of treatment preceded global symptom improvement (but not OCD specific improvement) whereas changes in functional impairment preceded changes in FA. This suggests that meaningful improvement in youth functioning may be an important early driver of reductions in FA, perhaps through reduced overall burden on the family system. Additionally, early reductions in FA may translate to improvement across broader indices of youth symptoms. Results related to the latter half of treatment showed that changes in FA preceded improvement in global and OCD

specific symptom severity as well as functional impairment. These findings highlight the importance of targeting FA when treating early-onset OCD, paying particular attention to FA that has not attenuated by the later stages of treatment. Future research should aim to understand barriers to change in FA in order to optimize treatment outcomes in this population.

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## Declarations

**Conflict of interest** The authors declare they have no conflict of interest.

**Research Involving Human Participants** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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