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ORIGINAL ARTICLE

Core Motivations of Childhood Obsessive-Compulsive Disorder: The Role of Harm Avoidance and Incompleteness

Meghan Schreck[1] · Christopher Georgiadis[2] · Abbe Garcia[3] · Kristen Benito[3] · Brady Case[3] · Jennifer Herren[3] · Michael Walther[3] · Jennifer Freeman[3]

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Abstract

In an effort to improve patient conceptualization and targeted treatment, researchers have sought to accurately classify OCD subtypes. To date, the most common form of OCD classification has used the content of symptom topography as opposed to functional links between symptoms to categorize OCD. The aim of the current study was to explore the associations between these two forms of OCD classification. Participant topographical symptoms were self-reported using the Obsessive-Compulsive Inventory-Child Version (OCI-CV). Clinicians assessed whether participant symptoms were motivated by harm avoidance and/or incompleteness. Structural equation modeling was employed to explore the associations between harm avoidance and incompleteness and symptom dimensions in youth with OCD. Results showed that harm avoidance was significantly associated with doubting/checking, obsessing, and neutralizing symptoms, whereas incompleteness was associated with doubting/checking, ordering, and neutralizing symptoms. Findings are consistent with child and adult literature and highlight the importance of assessing the underlying function of OC behaviors.

Keywords OCD · Harm avoidance · Incompleteness

Introduction

Pediatric obsessive-compulsive disorder (OCD) is a heterogeneous and disabling disorder that affects 1% to 4% of children and adolescents [1, 2]. When left untreated, OCD in youth may persist and be associated with long-term sequelae such as additional anxiety and mood concerns [3]. Cognitive-behavioral therapy (CBT) and medication are effective treatments for childhood OCD, yet up to 58% of youth with OCD do not attain symptom remission following a standard course of CBT [4]. To improve the treatment of OCD and the understanding of its etiology, researchers have sought to accurately and meaningfully classify heterotypic symptom clusters within OCD.

Researchers seeking to categorize OCD phenotypes in adults [5, 6] and in children [7] have typically employed factor or cluster analytic techniques to identify OCD dimensions or subtypes based on the topographic qualities of obsessions and compulsions [8–10]. Within the OCD literature, topography has been defined as the structure or form of a behavior (e.g., "washing"), whereas function refers to the "purpose" or underlying motivation of a behavior (e.g., "to avoid contracting an illness") [11–13]. Topographical dimensions most commonly derived in adult samples include four factors: cleanliness/washing, symmetry/ordering, obsessions (e.g., harm and repugnant obsessions)/checking, and hoarding [6, 14]. Four topographical dimensions are also commonly found in child samples (i.e., compulsions, sexual/aggressive obsessions, superstitions, hoarding/ordering/somatic concerns), though these factors differ in content and are less thematically consistent when compared with adult factors [15].

Studies that characterize the topography of OCD further our understanding of the *observable* features of obsessions and compulsions, however they tell us less about how

✉ Meghan Schreck
mschreck@partners.org

[1] Obsessive-Compulsive Disorder Institute, McLean Hospital/Harvard Medical School, 115 Mill St., Belmont, MA 02478, USA

[2] Department of Psychology, Florida International University, Miami, FL, USA

[3] Pediatric Anxiety Research Center, Bradley Hospital, Alpert Medical School of Brown University, East Providence, RI, USA

symptoms might be *functionally* connected. Given the central importance of the functional relationship between obsessions and compulsions in the cognitive-behavioral model of OCD [16, 17], categorization of symptoms must take the function or motivation of compulsive behavior into close consideration. Findings from research by Storch et al. [18] highlight the limitations of a topographical model of OCD classification by demonstrating that OCD dimensions in youth predict several distinct symptoms of OCD and can be driven by unique underlying motivators. As such, conceptualization frameworks that consider the infinite ways in which rituals of similar topographical content (e.g., touching, tapping, or rubbing) can be related to distinct motivators (e.g., to prevent harm to someone else vs. to achieve a "just right" feeling) are needed for more incisive behavioral assessment.

Alternative classification methods and assessment measures have attempted to incorporate functional relationships between obsessions and compulsions to better conceptualize patient phenomenology. For example, some cognitive models of OCD consider misappraisals of unwanted thoughts and OCD-related beliefs that motivate resulting compulsive behaviors [19–21]. Within such models, cognitive dimensions, such as increased sense of responsibility, overestimation of threat, and over-valuing the importance of thoughts, may influence the type of compulsive behaviors performed to quell obsessive thinking [22–25]. Although cognitive models may better capture the underlying function of OCD symptoms compared to topographical models, they do not readily account for "not just right experiences" (NJREs) or feelings of incompleteness that drive compulsive behaviors in OCD [26, 27]. This limitation is particularly important in youth populations, where NJREs are prevalent and awareness of cognitive motivators of behavior may be less common relative to adults [18, 28]. Additionally, the Dimensional Yale-Brown Obsessive Compulsive Scale (DY-BOCS) [29] and the Dimensional Obsessive Compulsive Scale (DOCS) [30] incorporate NJREs and function into their assessment of OC symptoms by clustering functionally similar symptoms and linking compulsions to obsessions (e.g., "I check or take other measures to prevent or avoid harm coming to myself or others" and "Mentally performing an action or saying prayers to get rid of an unwanted or unpleasant thought"). Although these measures do a better job of assessing the functional relation between obsessions and compulsions, they do so about specific symptom clusters, and therefore, could miss certain symptom combinations.

There is undeniable merit in models that measure observable OC symptoms; however, an assessment of underlying motivation is crucial to adequately target the patient's core fear in treatment. The Core Dimensions Model of OCD, which proposes that compulsions are motivated by either harm avoidance or feelings of incompleteness, has helped to inform the development of more nuanced assessment tools [31]. *Harm avoidance* (HA) refers to symptoms that function to avoid harm to oneself or others (e.g., contracting illness or unintended aggression). *Incompleteness* (INC) refers to symptoms that are associated with "an inner sense of imperfection, connected with the perception that actions or intentions have been incompletely achieved [27 p. 1156]" and is similar to NJREs. The Core Dimensions Model was developed from the Motivation Model of OCD by Rasmussen and Eisen who subtyped individuals with OCD according to risk assessment, pathologic doubt, and incompleteness [32]; however, Summerfeldt et al. [31] adjusted the Motivation Model to capture motivations more dimensionally, rather than categorically. In both models, the same OC behavior may serve distinct ritualistic functions across individuals. For example, in two children with OCD, one child may engage in ritualized hand washing to remove germs, whereas another child may do so until it feels "just right" or "even" across hands [33]. Similarly, the model accounts for the common occurrence of two topographically distinct behaviors sharing the same ritualistic function. For example, to reduce anxiety about getting sick, one teenager might check the internet for symptoms of an illness whereas another might wash their hands repeatedly [31]. In this way, a model including HA and INC as underlying motivations of OCD emphasizes the functional relationship between obsessions and compulsions rather than focusing solely on the content of symptoms or within predefined symptom clusters.

Research investigating core motivations of OCD has been conducted in adults [33, 34]. However, despite efforts to encourage the measurement of HA and INC in youth with OCD and to link these constructs to OC symptom topography [11], there have been few studies that have empirically tested these relations in youth with OCD. The recent work of Cervin and Perrin [35] adapted and validated the Obsessive-Compulsive Trait Core Dimensions Questionnaire (OCTCDQ) and the Obsessive-Compulsive Core Dimensions Interview (OC-CDI) [31] for clinically referred youth with OCD and anxiety disorders [35]. In a separate study examining differences in HA, INC, and disgust in youth with OCD, anxiety disorders, and no psychiatric disorder, these researchers found that HA was significantly associated with doubting/checking, obsessing, and washing, whereas INC was significantly associated with doubting/checking, ordering, and neutralizing [36]. Doubting/checking was the only OCD dimensions motivated by both HA and INC, which supported findings in adults [33].

The present study extends the work of Cervin et al. [36] by examining the relations between two core motivations of OCD (i.e., HA and INC) and OCD dimensions in a sample of youth seeking intensive outpatient treatment for severe OCD. We hypothesized that HA would be positively and significantly associated with doubting/checking, obsessing, and washing, whereas INC would be significantly and

positively associated with doubting/checking, ordering, and neutralizing.

Method

Participants and Procedure

One hundred seventy children and adolescents seeking intensive outpatient services at a children's psychiatric hospital in the Northeast United States were recruited for the present study. All participants received diagnoses from a licensed child psychiatrist or licensed psychologist during the standard intake assessment, and diagnoses were extracted from participant electronic medical records for the present study. Research was conducted in a naturalistic, intensive clinical setting. As part of standard clinical care, all participants completed a battery of questionnaires during their initial day of services. The treating psychologist completed clinician-rated measures (e.g., CY-BOCS, Core Obsessional Theme form) within the first week of admission. Patients were included in the study if they received a diagnosis of OCD and their clinician completed the Core Obsessional Theme form. One hundred forty-three participants (84.1%) received a primary diagnosis of OCD and 27 participants (15.9%) received a secondary diagnosis of OCD. Of the 27 participants with OCD as a secondary diagnosis, primary diagnoses were as follows: Social Anxiety Disorder (N = 12), Generalized Anxiety Disorder (N = 5), Post-Traumatic Stress Disorder (N = 2), Tourette Syndrome (N = 1), Excoriation Disorder (N = 2), Major Depressive Disorder (N = 1), Attention-Deficit Hyperactivity Disorder (N = 1), and Autism Spectrum Disorder (N = 3). There were no significant differences on any study variables between patients who had completed data vs. missing data on the Core Obsessional Theme form. Participants were aged 6 to 18 years (M = 12.23, SD = 3.13) and were 53.5% female. Participant ethnicity was 92.9% White/Not Hispanic and 5.3% Hispanic/Latino. Participant race was 90.6% White, 2.4% Black, 1.2% as Asian or Pacific Islander, 2.4% Hispanic, 1.2% as Multiracial, and 1.2% as Other. Three participants (1.8%) had missing data for ethnicity and two participants (1.2%) had missing data for race.

Measures

Obsessive Compulsive Inventory: Child Version (OCI-CV) [37]

The OCI-CV is a 21-item self-report measure that assesses past-month obsessive compulsive symptoms in children and adolescents ages 7–17. The OCI-CV has six empirically derived subscales, which include doubting/checking, obsessing, hoarding, washing, ordering, and neutralizing. The sum of subscales yields a total score. The OCI-CV has adequate psychometric properties [37, 38]. In the current study, the OCI-CV has strong internal consistency ($\alpha = 0.86$).

Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) [39, 40]

The CY-BOCS is a well-known 10 item semi-structured clinician-rated interview that is comprised of two parts. The CY-BOCS Symptom Checklist (CY-BOCS-SC) assesses the presence and topography of obsessions and compulsions over the past week. The CY-BOCS-SC is composed of several symptom dimensions, including, but not limited to, contamination, aggressive, and sexual obsessions and washing, checking, and ordering compulsions. The CY-BOCS Severity Scale (CY-BOCS-SS) measures obsession and compulsion symptom severity over the past week, based on the symptoms endorsed on the checklist. On the CY-BOCS-SS, obsessions and compulsions are rated on 0–4 point-scales, ordered in severity, in five dimensions (time, interference, distress, resistance, control). The CY-BOCS-SS yields a total obsession score (0–20), a total compulsion score (0–20), and a combined total score (0–40). Adequate reliability and validity have been demonstrated for both the Severity Scale and Symptom Checklist [39–42]. In the current study, the CY-BOCS-SS had strong internal consistency ($\alpha = 0.86$).

Core Obsessional Theme

Clinicians completed the Core Obsession Theme form, a 4-item checklist capturing clinician impressions of underlying motivations of compulsive behavior. Children were classified as having HA or INC symptoms based on global clinical impression of symptoms, which was determined by both formal (i.e., functional assessment of symptoms during CY-BOCS administration) and informal assessment during the first week of admission. Given that it is common for youth to have both HA and INC, clinicians reported on whether compulsions were driven *primarily* by HA or INC. For example, if a child spent most of his time washing his hands because of fear of germs, but was also occasionally driven to step over cracks in the sidewalk to avoid feelings of incompleteness, a clinician would endorse both HA and INC, with an HA primary specifier and an INC secondary specifier. Alternatively, if a child spent most of his time ordering and arranging items in his room because of feelings of incompleteness or not just right experiences, but also occasionally spent time checking the stove to prevent harm towards others, a clinician would endorse both HA and INC, with an INC primary specifier and an HA secondary

specifier. A primary specifier could only be given to HA or INC, not both. Only the absolute values of core motivators were used in the present study and HA and INC were scored separately, such that 0 = no presence of core motivator and a score of 1 = presence of core motivator, regardless of primary or secondary nature. Therefore, a given participant could have been rated as having both HA and INC, HA only, INC only, or neither HA nor INC as core motivators of their OCD symptoms. This form was originally created for clinical purposes to help clinicians determine the underlying function of OC behaviors in the context of assessing for OC topography (i.e., contamination fears, checking rituals, etc.)

Data Analytic Plan

Means, standard deviations, and/or proportions for OCI subscales, OCI total score, CY-BOCS-SS total score, HA, INC, and demographic variables were computed using SPSS version 24.0. Structural equation modeling (SEM) using Mplus, version 7.4 was used to conduct statistical analyses for the present study [43]. A robust weighted lease squares estimator (WLSMV) was used to account for non-normal distribution of variables and missing data. The WLSMV also provides a good option for modeling categorical or ordered data [44]. The structural equation model was evaluated using three fit statistics, including the root mean square error of approximation (RMSEA), comparative fit index (CFI), and Tucker-Lewis index (TLI). For the RMSEA, values approximating between 0.05 and 0.08 reflect reasonable fit and values less than 0.05 suggest a good fit. For the CFI and TLI, values 0.90 or greater suggest acceptable fit and values 0.95 or greater are considered a good fit. Main hypotheses were estimated using structural equation modeling. Paths were estimated from HA and INC to the six OCI-CV factors (i.e., doubting/checking, obsessing, washing, hoarding, ordering, neutralizing).

Results

Descriptives

HA *and* INC were identified as core motivations of OC symptom topography for most participants (56%). HA-only was a core motivation for 25% of participants and INC-only was a core motivation for 18% of participants. Only one percent of participants had neither HA nor INC identified as core motivations of their OC symptoms (See Table 1). Means and standard deviations for OCI Total, OCI factors, and CY-BOCS-SS can be found in Table 1. Mean OCD severity fell within the severe range (M = 27.83).

Structural Model

Overall model fit displayed optimal properties [CFI = 0.97, TFI = 0.97, RMSEA = 0.05, CI 0.04 to 0.06]. HA was positively and significantly associated with doubting/checking, obsessing, and neutralizing, whereas INC was positively and significantly associated with doubting/checking, ordering, and neutralizing. Neither HA nor INC were significantly associated with hoarding or washing. HA was negatively and significantly associated with INC. Model paths are illustrated in Fig. 1. Path coefficients with confidence intervals are illustrated in Table 2.

Table 1 Descriptive statistics of study variables

Continuous/ordinal variables	M (SD)
OCI-CV total (N = 156)	15.55 (7.81)
OCI-CV doubting/checking (N = 163)	3.49 (2.47)
OCI-CV obsessing (N = 164)	4.24 (2.35)
OCI-CV hoarding (N = 165)	1.47 (1.56)
OCI-CV washing (N = 167)	2.30 (2.14)
OCI-CV ordering (N = 165)	2.44 (1.93)
OCI-CV neutralizing (N = 168)	1.45 (1.46)
CY-BOCS severity scale (N = 144)	27.83 (5.02)
Categorical variables	**N (%)**
Core obsessional theme	170 (100%)
Only harm avoidance	42 (24.7%)
Only incompleteness	31 (18.2%)
Both harm avoidance and incompleteness	95 (55.9%)
Neither harm avoidance nor incompleteness	2 (1.2%)

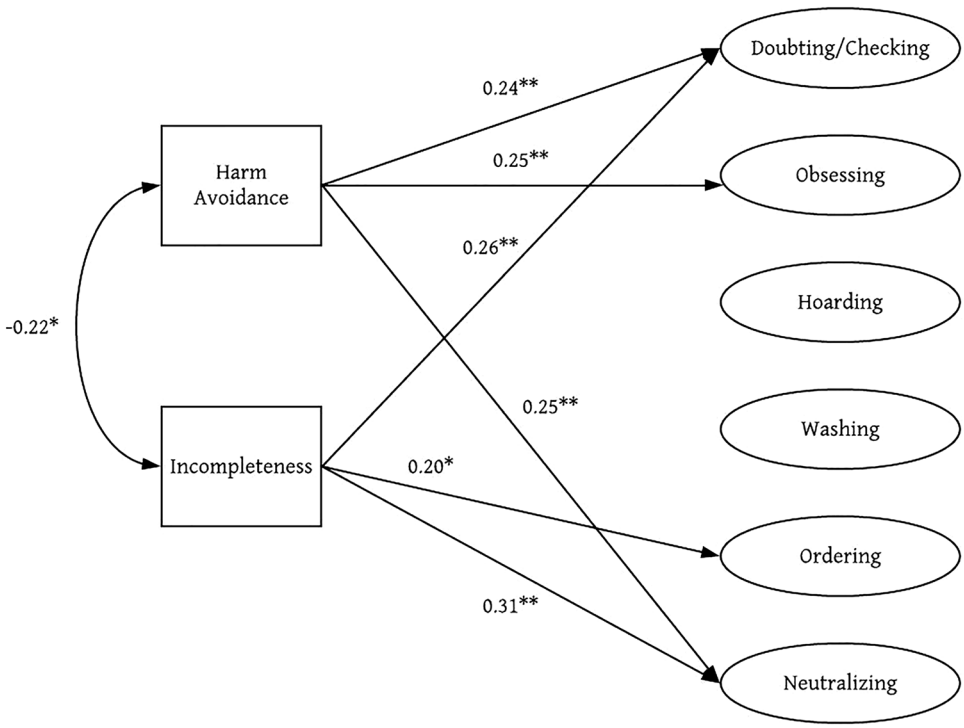

Fig. 1 SEM path diagram of associations between harm avoidance (HA) and incompleteness (INC) and OCD symptom dimensions. *Note.* Only statistically significant paths are shown. *SEM* structural equation modeling. * Indicates $p < .05$, ** indicates $p < .01$

Table 2 Standardized path coefficients (β) and 95% confidence intervals (CI) for the path coefficients for SEM analyses

	Doubting/checking β (95% CI)	Obsessing β (95% CI)	Hoarding β (95% CI)	Washing β (95% CI)	Ordering β (95% CI)	Neutralizing β (95% CI)
Harm avoidance	0.24** (0.06, 0.42)	0.25** (0.10, 0.40)	0.16 (− 0.02, 0.35)	0.14 (− 0.04, 0.32)	0.04 (− 0.12, 0.21)	0.25** (0.07, 0.43)
Incompleteness	0.26** (0.09, 0.42)	0.01 (− 0.16, 0.18)	0.17 (− 0.02, 0.47)	0.08 (− 0.12, 0.27)	0.20* (0.02, 0.37)	0.31** (0.13, 0.49)

SEM structural equation modeling

*indicates $p < .05$, ** indicates $p < .01$

Discussion

The present study investigated the unique relations between two core motivations of OCD, HA and INC, and symptom dimensions in pediatric OCD (doubting/checking, obsessing, hoarding, washing, ordering, neutralizing), as measured by the Obsessive-Compulsive Inventory-Child Version (OCI-CV). In the current sample, the majority of youth exhibited both HA and INC as underlying core motivations of their OC symptoms.

Results from the structural model revealed that core motivations of OCD are uniquely and differentially related to OCD topography. Consistent with our hypotheses and findings from child [36] and adult samples [33], our results support the motivational heterogeneity of doubting/checking and neutralizing and the motivational homogeneity of ordering and obsessing. HA and INC were each significantly associated with doubting/checking and neutralizing, whereas HA alone was uniquely related to obsessing and INC was uniquely related to ordering. Neither washing nor hoarding were related to HA or INC. There is evidence that doubting and checking play a strong central role in all other OCD symptoms in children and adolescents [45]. Cervin et al. [45] conducted a network analysis of OCD symptom dimensions using the OCI-CV and found that the doubting/checking factor was a highly central node in the interconnectedness of OCD symptoms. It is possible that the centrality of doubting/checking is partially explained by its motivational heterogeneity. Furthermore, these findings warrant further exploration into whether HA and INC predict treatment outcome above and beyond OC symptoms, and call for experimental studies in youth with OCD whereby HA and INC are elicited and compulsive

behaviors are measured [e.g., 46, 47]. Clinical assessment and treatment implications of these findings are discussed below.

Clinical Implications

Assessment

Evidence-based treatment starts with evidence-based assessment. The findings from the current study demonstrate a relation between two core motivations of OCD and OCD symptom themes. Assessing core motivation of OCD identifies the function of OC symptoms, which is central to developing effective treatments. Enhancing evidence-based assessment measures of OCD to include the assessment of core motivational themes would aid in designing more targeted treatment plans for patients with OCD. For example, Conelea and colleagues [11] offered a two-level assessment approach to identify core motivational theme in addition to symptom theme, using the Y-BOCS/CY-BOCS. Summerfeldt et al. [31] developed an interview-rated measure of HA and INC, which has been adapted for use with children (35). Additionally, Boisseau and colleagues [48] recently developed the Brown Incompleteness Scale (BINCS), which is a multifaceted clinician-administered measure of incompleteness. These tools can be used in conjunction with measures for OC symptom topography to assess for function and inform more effective exposures.

Treatment

In designing an exposure, a clinician must understand the functional relation between symptoms; in other words, "why" an individual is engaging in a behavior (e.g., to avoid harm), not simply knowing "what" the behavior looks like (e.g., checking). Understanding the function of symptoms is especially important when there is motivational heterogeneity of a symptom theme in OCD as is the case with doubting/checking and neutralizing in the current study. For example, a child with OCD may repeatedly turn a light switch on and off, which may be functionally linked to the obsession, "my parent will get sick [if I do not turn on and off the light]." This is an example of "magical thinking" whereby the child believes an action is linked to an unrelated event [49]. In this case, the core motivation is HA. Alternatively, this repetitive behavior could be linked to the obsession "I have to keep doing this until it feels just right" where the core motivation is INC.

Knowing the core motivation of symptoms determines "what happens" during an exposure in terms of the thoughts and feelings that are to be experienced, and the nuances of the rituals that are to be prevented [11]. For example, in the case of a child turning on and off a light switch to prevent a parent from getting sick, the exposure would entail the child resisting repetitive light switching all together and allowing unwanted thoughts and feelings about the possibility of parent sickness to be there without attempting to eliminate them. In the case of incompleteness motivating repetitive light switching, the child would be encouraged to turn on and off the light switch the "wrong way" or to "mess up" the ritual and turn it off quickly and carelessly. The child would also be instructed to allow "not just right experiences" to be there without doing anything to alleviate the discomfort from performing the behavior "incorrectly."

Furthermore, therapists' own behaviors play an important role in the execution of exposure therapy. Benito and colleagues [50] studied the relation between fear increasing (e.g. encourage approach, intensify), fear neutral (e.g., teaching), and fear decreasing (e.g., accommodation, unrelated talk) therapist behaviors during exposure therapy for children. Findings showed that several behaviors relate to clinical outcomes in exposure therapy and that these relations depend on patient fear level. In this study, "fear" included other forms of acute distress that are elicited during exposure therapy, including incompleteness and disgust. Knowing the core "fear" or motivation of OCD symptoms is essential for therapists to appropriately implement these behaviors during treatment. For example, without knowing a patient's core motivation of symptoms, a therapist would not know what to encourage approach towards or to intensify.

Our null finding for hoarding is consistent with similar studies in both children and adults. The DSM-5 now conceptualizes hoarding as distinct from OCD, due in part to findings like these that demonstrate differences between hoarding and other OCD symptom themes. Although there is evidence that individuals with hoarding disorder often exhibit additional INC-related symmetry obsessions and repeating and ordering compulsions [51], prior studies show a nonsignificant relation between INC and hoarding. Our results further support the distinction between OCD and hoarding. Avoidance of grief is an additional underlying motivation that may be related to hoarding and worthy of further investigation [52].

Surprisingly, washing was not significantly related to either core motivation. Our results indicate that other motivators (e.g., disgust) may be particularly important to consider as motivators for compulsive behavior. Other studies have suggested that disgust may be particularly important in the conceptualization of contamination fear and washing symptoms [53]. Additionally, the washing questions on the OCI-CV are specific to contamination concerns and the excessive nature of handwashing (i.e., "I feel like I must wash and clean over and over again," "I worry a lot about things being clean," "I wash my hands more than other kids"). However, washing is a ritual that also occurs outside of contamination obsessions and is not always excessive, but

rather routinized or following a pattern, even if completed quickly. Furthermore, children with poor insight completing this measure may not view their own behavior as excessive.

Finally, HA and INC were significantly and negatively correlated ($r = -0.22$, $p < 0.05$), which is consistent with previous findings in adults [31]. This finding further supports HA and INC as distinct, but co-occurring constructs with some mutual exclusivity. The direction and size of this correlation supports findings using the OC-CDI, the semi-idiographic interview–rated method of assessment of HA and INC, which was designed to closely follow Rassmusen and Eisen's model [31]. Significant positive correlations have been observed using the OC-CDQ self-report questionnaire [31].

Limitations

The current study is limited in several important ways. First, the current measure of HA and INC is a clinician report questionnaire of childhood HA and INC that is not yet validated. Although the measure used in the current study does not mutually exclude the two core motivations, it is dichotomous rather than dimensional. However, this measure might offer a "quick and dirty" assessment of OCD function, which could aid in efficient and effective treatment planning. Nonetheless, future research would benefit from using the adapted child versions of the OCTCDQ and OC-CDI to measure trait and state HA and INC in youth [31, 35]. Additional validation studies of these measures and careful consideration of how youth may interpret these items is important. For example, item 9 of the OCTCDQ states "If I don't do things in a certain way, something harmful or bad may result." A child reading this statement may interpret something "bad" as a "not just right feeling." In this case, what was categorized as a HA item could be understood as an INC item. Developing valid and reliable measures of core motivations of OCD in youth presents a challenge given lower insight into OCD symptoms among children [18]. Second, although the current study aimed to establish a relationship between topographical symptoms and the most commonly cited motivations of OC behavior, there may be additional core motivations of OCD in youth worthy of investigation, such as fear [54], disgust, [36, 53] and sensory experiences [55]. For example, Rozenman et al. [54] found that two types of fear predicted different OC symptoms, such that separation fears were related to aggressive/sexual/religious/checking symptoms and somatic/autonomic fears were related to symmetry obsessions and ordering, counting, and repeating compulsions [54]. Additionally, current measures of disgust and fear are limited in that they often conflate disgust and fear with HA. It is recommended that future studies investigate the unique role of fear and disgust, above and beyond that of HA and INC. Third, the current study included children ranging from age 6 to 18 years old. There are likely developmental differences at different ages within this range that warrant investigation. For example, younger children have a harder time verbalizing HA and overall less insight than older children.

Summary

In conclusion, this is one of the first studies to explore the relation between core motivations of OCD and symptom dimensions in youth with OCD. Our hypotheses were largely supported and suggest that HA and INC are *both* significantly associated with doubting/checking and neutralizing symptoms in OCD, whereas HA is uniquely associated with obsessing, and INC is uniquely associated with ordering. Based on these findings, it is recommended that clinicians assess the underlying function of rituals, not simply assess symptom topography, to develop the most effective exposures and treatment plans for individuals.

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Compliance with Ethical Standards

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

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