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Baseline Characteristics of Participants in the IMPACT Trial for Youth with Anxiety and OCD

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Abstract

Anxiety disorders are the most common mental health diagnoses among youth, yet many are unable to access exposure-based Cognitive Behavioral Therapy (CBT). A team-based, community delivered approach, pairing a licensed provider with a non-licensed provider, may address barriers to receiving CBT. This paper presents the baseline sample characteristics of youth and families participating in a large randomized controlled trial comparing team-based, community delivered CBT (IMPACT-CBT) and traditional office-based CBT for pediatric anxiety and Obsessive Compulsive Disorder (OCD). This study aims to describe baseline characteristics of treatment-seeking youth ages 5 to 18 (N = 335) enrolled in the IMPACT trial, highlighting demographic characteristics, symptoms and diagnoses, and youth and family functioning. This clinically complex sample offers an opportunity to better understand characteristics of youth with pediatric anxiety and OCD. Findings highlight the need for increased access to exposure-based CBT.

Introduction

Anxiety disorders are the most common mental health diagnoses among children and adolescents (Cartwright-Hatton et al., 2006; Merikangas et al., 2010). Since the COVID-19 pandemic, rates of anxiety and other mental health conditions have risen considerably among youth (US Preventative Services Task Force, 2022). A meta-analysis of 29 studies reporting on youth mental health prevalence rates showed a pooled prevalence of clinically elevated anxiety of 20.5% during the COVID-19 pandemic – nearly double the pre-pandemic rate (Racine et al., 2021). Furthermore, untreated anxiety disorders in youth have been associated with continued impairment in academic and social functioning later in life (Asselmann et al., 2018), and can result in the development of additional mental health disorders (Kendall et al., 2004). Child anxiety often precedes the development of depressive disorders and is a risk factor for suicidality and substance use disorders (Biederman et al., 1995; Compton et al., 2002).

With the concerning increase in rates of youth anxiety and long-term implications for functioning, access to evidence-based treatments is of the utmost importance. Cognitive behavioral therapy (CBT) has been established as the gold-standard treatment for child anxiety and obsessive compulsive disorder (OCD). Specifically, the exposure component of CBT has been shown to be the “active ingredient” associated with the most treatment gains for child anxiety and OCD (Chu & Harrison, 2007; Freeman et al., 2014). Exposure involves gradually approaching feared situations or stimuli which creates new learning opportunities and increased ability to tolerate distress (Craske et al., 2014). Despite the availability of CBT, access for many children and families remains challenging. The treatments that youth are most likely to access in the community are often not evidence-based or do not always adhere to treatment fidelity (Cho et al., 2019; Bitsko et al., 2022). Even if youth do access evidence-based treatment, they often face long waitlists due to high need (Reardon et al., 2020). Moreover, despite exposure-based treatment leading to the most robust and consistent treatment outcomes for pediatric anxiety and OCD (Higa-McMillan et al., 2016), there is a notable dearth of providers trained in exposure-based therapy (Weissman et al., 2006), creating an even greater bottleneck for access to care. For youth and families

who are able to identify exposure-based services, there are structural barriers related to traditional office-based treatment (e.g., transportation barriers, child care difficulties, travel time) that may further hinder a family's ability to pursue treatment.

One potential avenue to address treatment access issues is the utilization of a team-based approach to care in which a licensed provider is paired with a non-licensed provider who provides services in the home and/or community. This approach increases the number of youth able to be treated at one time and reduces barriers related to traditional office-based models of care. The present study describes the baseline characteristics of treatment-seeking youth ages 5–18 (N = 335) who were part of a large randomized controlled trial comparing team-based patient-centered home/community delivered exposure-based CBT (IMPACT-CBT) and single provider office-based CBT for pediatric anxiety and OCD in an academic medical center setting. The methodology of the larger trial is described in detail elsewhere (Freeman et al., 2025).

Consistent with the engagement principles of the funder, the Patient-Centered Outcomes Research Institute (PCORI), this study was developed in partnership with caregivers/youth, payers, in-home clinicians, patient advocates, and organization/hospital leadership. As such, methodology and study design decisions, including sample characteristics, were developed in concert with voices not traditionally centered in academic research spaces. Specifically, based on feedback from study partners, exclusion criteria were kept to a minimum in order to increase the generalizability of findings. The sample included a range of clinical anxiety presentations, including comorbid presentations (e.g., youth with autism, depression) that were historically excluded from tightly controlled anxiety treatment trials (Compton et al., 2010) yet are common comorbid presentations in typical outpatient settings. In addition to comorbidity, the sample included a range of anxiety and OCD severity based on intentional inclusion of youth stepping down from partial hospitalization levels of care (i.e., specific study spots were held for youth stepping down to an outpatient level of care from our clinic's partial hospitalization program). Some youth presenting to outpatient clinics are doing so after participating in higher levels of care and may present with greater degrees of functional impairment and comorbidity (Hugunin et al., 2023), making it important to represent this upper range of severity. Relatedly, given high utilization of psychotropic medication in youth with anxiety and OCD, youth on stable doses of medication were also included to further support the relevance of findings. Once enrolled, youth were allowed to initiate, discontinue or change medication dose as determined by their prescriber as is commonplace in outpatient practices. All medication changes were carefully documented throughout the course of the study although only medications at baseline will be reported here.

In addition to few exclusionary criteria, specific attention was paid to recruit historically underserved and marginalized youth based on the failure of past clinical trials to adequately include these youth. Youth from historically marginalized backgrounds were prioritized on the study waitlist and the study team worked closely with community partners to more closely mirror the surrounding community and represent greater racial and ethnic diversity. Description of the sample provided in this paper will offer greater insight into the generalizability of IMPACT-CBT and improving access to evidence-based

treatment. Below, we will briefly present the methods of the larger randomized trial (for more detailed methods refer to Freeman et al., 2025), outline the assessment measures included, present baseline characteristics of the sample (e.g., demographics, symptom severity, functional impairment, medication status) and discuss the findings as well as limitations of recruitment strategies.

Methods

Participants

A total of 335 youth aged 5 through 18 years participated in the study. In the final sample, 163 youth were randomly assigned to the single provider office condition and 172 youth were randomly assigned to the IMPACT-CBT condition. All study procedures were conducted as part of an institutional review board (IRB)–approved protocol, and all participants signed an Informed Consent Form and Child Assent Form (ages 8+) before enrolling in the study. Recruitment of participants took place between 2018–2024 with a pause in enrollment during the COVID-19 pandemic (Freeman et al., 2024). A variety of community-based recruitment methods were used; details of recruitment methods are described elsewhere (Freeman et al., 2025).

To assess eligibility and interest in study participation, a three-gate assessment procedure was used. During a 30-minute telephone screen (Gate A), a trained research assistant described the study, and interested caregivers were asked about their child's presenting symptoms to assess for initial study eligibility. After conferring with a licensed psychologist, preliminarily eligible participants and their caregiver(s) were invited to complete the consent process and a diagnostic assessment (Gate B). This assessment was administered by an independent evaluator (IE) and conferenced with a licensed psychologist to determine study eligibility. Immediately prior to their first treatment session, and within one week of their Gate B assessment, eligible participants completed a briefer assessment (Gate C) with an IE to determine baseline symptom level severity and ensure eligibility criteria were still met.

Study inclusion criteria were: a) age 5–18, inclusive, at the start of treatment, b) primary or co-primary Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of generalized anxiety disorder (GAD), separation anxiety disorder, specific phobia, social anxiety disorder, panic disorder, agoraphobia, selective mutism, unspecified anxiety disorder or OCD, c) symptom duration of 3 months or more, d) appropriateness for outpatient treatment, and e) presence of a caregiver who could consistently participate in treatment if needed. Study exclusion criteria were a) other primary or co-primary psychiatric disorder that required initiation of other treatment, b) intellectual disability, c) thought disorder or psychotic symptoms, d) conduct disorder, e) acute suicidality, f) concurrent psychotherapy, g) chronic medical illness that would interfere with a child's ability to participate in treatment, and h) treatment with psychotropic medication that was not stable (defined as no medication initiation or discontinuation within four weeks and no dose change within two weeks of baseline assessment for SRIs, atypical antipsychotics and buspirone; defined as no medication initiation or discontinuation within

two weeks and no dose change within one week of baseline assessment for benzodiazepines and other fast-acting anxiolytics).

Assessment Measures

The baseline assessment consisted of ratings completed by IEs at Gates B and C, as well as youth and caregiver questionnaires completed at Gate C.

Demographics were collected via caregiver and youth report and included questions around age, gender, race, ethnicity, socioeconomic status, type of health insurance (commercial, public, military), family mental health history, treatment history and medication status.

Anxiety/ OCD symptoms and severity were measured using the Pediatric Anxiety Rating Scale (PARS), Children's Yale-Brown Obsessive Compulsive Scale (CYBOCS), and the Clinical Global Impression Severity scale (CGI-S). The PARS is an IE-administered scale which assesses severity across anxiety disorders and demonstrates adequate reliability and validity (Walkup et al., 2002). The measure consists of a 50-item symptom checklist and a 7-item rating scale. Each item is rated on a 0 to 5 scale. The present study summed 5 of the 7 subscales (excluded number of symptoms and physical symptoms items consistent with prior studies (Johnco et al., 2015), such that total severity scores range from 0 to 25, with higher scores indicating greater severity. The PARS severity scores showed acceptable (α = .78) internal consistency in the current sample. The CYBOCS is an IE-administered scale yielding a combined severity score for obsessions and compulsions and demonstrating adequate reliability and validity (Scahill et al., 1997). The measure consists of a symptom checklist and a 10-item rating scale. Each item is rated on a 0 to 4 scale such that total severity scores range from 0 (no symptoms) to 40 (severe). The internal consistency for the severity scale for the current sample was acceptable (α = .77). IEs administering the assessments were trained to use developmentally appropriate anchors and probes. The CGI is a two-item measure consisting of severity (CGI-S) and improvement (CGI-I) scales ranging from determined by the IE. The CGI-S was used to assess baseline global severity on a 7-item scale that ranges from 1 (normal, not at all ill) to 7 (among the most extremely ill patients). The CGI shows adequate reliability and validity (Guy, 1976; Skriner et al., 2016).

Functional impairment was measured using the Child Sheehan Disability Scale (CSDS). The CSDS, a measure assessing disruption in functioning, was administered to caregivers as a 5-item scale, and to youth ages 8 + as an abbreviated 3-item self-report. Items are rated on an 11-point scale ranging from 0 (not at all) to 10 (very, very much). Each version of this measure demonstrates adequate reliability and validity (Whiteside, 2009). Internal consistency in the present sample was good (α = .87) for youth self-report and acceptable (α = .73) for caregiver report.

Comorbidity was measured using the Mini International Neuropsychiatric Interview for Children and Adolescents (MINI-KID) version 7.0. The MINI-KID is a structured diagnostic interview, administered by the IE, which yields DSM-5 diagnoses, and demonstrates adequate reliability and validity (k = .75 – 1.00).

The interview was administered to the youth participant and their caregiver(s), although youth varied in their ability to participate depending on their age and development. The MINI-KID has been validated for use with children between the ages of 6–17 (Sheehan et al., 2010) and has been used successfully in prior studies with 5- and 18-year-olds (Sheehan et al., 2010).

Quality of life was measured using the Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q), a 13-item scale measuring quality of life across domains ranging from 1 (very poor) to 5 (very good), administered via caregiver-report and youth self-report for youth ages six and above. Both versions of this measure demonstrate adequate reliability and validity (Wellen et al., 2017). Internal consistency in the present sample was good for youth self-report (α = .89) and caregiver report (α = .89).

Caregiver burden was measured using the Caregiver Strain Questionnaire (CSQ), a 21-item self-report measuring caregiver strain attributable to having a child with emotional and or behavioral health concerns using a 1 (“not at all”) to 4 (“very much”) scale. The CSQ was administered via caregiver-report and has adequate reliability and validity (Brannan et al., 1997). Internal consistency in the present sample was excellent (α = .95).

Family accommodation was measured using the Pediatric Accommodation Scale-Parent Report (PAS-PR), a 5-item caregiver-report measure designed to measure frequency and impact of caregiver accommodation on youth. Responses for frequency include 0 (never), 1 (rarely), 2 (occasionally), 3 (often), and 4 (always). Response options for interference due to accommodation include 0 (none), 1 (mild), 2 (moderate), 3 (severe), and 4 (extreme). The PAS-PR demonstrates adequate reliability and validity (Benito et al., 2015). Internal consistency in the present sample for the frequency subscale was good (α = .85), internal consistency for the parent impact subscale was good (α = .81), and internal consistency for the child impact subscale was good (α = .81).

Barriers to accessing treatment were assessed using the Barriers to Treatment Questionnaire – Parent Version (BTQ-P), a 28-item scale assessing the impact of specific barriers (e.g. stigma, shame, finances, and waitlists) in a caregiver’s ability to access mental health care for their child. Items are rated on a 0 (“not at all true”) to 2 (“mostly true”) scale. The BTQ-P demonstrates adequate reliability and validity (Tomás et al., 2016). The internal consistency for this scale was excellent (α = .92).

Quality Assurance

Quality assurance was ensured through rigorous training and supervision processes. IEs were trained to reliability on the MINI-KID and reviewed each assessment with a licensed psychologist to determine diagnoses and ensure diagnostic reliability. IEs were also trained to reliability on the PARS, CYBOCS and CGI. Assessment scores were reviewed by a licensed psychologist. Assessments were recorded, and 20% of tapes were randomly selected to be reviewed by another IE to ensure consistent, standardized assessment. Reliability was excellent across all IE-administered measures (*k* = .81-.82).

Data Analysis

Means, standard deviations, ranges and medians are used to present continuous variables; percentages and frequencies are used to present categorical data. The final sample of *N* = 335 was used except in cases of missing data, in which case the n varies based on missingness. All data tables include Ns from which descriptive statistics were calculated. Note that completion of youth-report measures varied by age; the CSDS was completed by youth age 8+ (*n* = 217; 64.8%); the PQLES-Q was completed by youth age 6+ (*n* = 242; (72.2%). The PQLES-Q (caregiver) was inadvertently not administered to a small number of caregivers early in the study, for a total of *n* = 272 caregivers (81.2%) who completed it.

Results

Demographic Characteristics

Detailed demographic information can be found in Table 1. A slight majority of participants were female (57.9%), and most identified as White (81.5%) and not Hispanic or Latino (91.0%). The majority of families had commercial health insurance (84.8%). Family history was notable such that 71.3% of families reported a family history of anxiety, followed by depression (57.6%). Over half of youths (66.6%) had received previous mental health treatment, and a large minority (41.2%) were taking medication at baseline, with the most common medication being SRI followed by stimulants.

Table 1
Demographic Characteristics of Study Sample (N = 335)

Youth Baseline Demographics	**Total (*n*)**	***n* (%)**	***M* (*SD*)**
Youth age (years)			11.2 (3.4)
Youth gender			
Male	137	40.9	
Female	194	57.9	
Gender queer/gender non-conforming	3	0.9	
Prefer not to answer	1	0.3	
Unknown or unreported	0	0	
Youth Ethnicity			
Not Hispanic or Latino	305	91.0	
Hispanic or Latino	17	5.1	
Unknown or unreported	13	3.9	
Youth Race			
White	273	81.5	
Black or African American	11	3.3	
Asian	4	1.2	
Other or Multiple	33	9.9	
Unknown or unreported	14	4.2	
Past Mental Health Treatment			
Yes	223	66.6	
No	101	30.1	
Unknown or unreported	11	3.2	
Past Exposure Therapy			
Yes	95	28.4	
No	228	68.1	
Unknown or unreported	12	3.6	
Past Medication for Mental Health Concerns			
Note. SRI = Serotonin Reuptake Inhibitor; OCD = Obsessive Compulsive Disorder			

Youth Baseline Demographics	**Total (*n*)**	***n* (%)**	***M* (*SD*)**
Yes	138	41.2	
No	184	57.1	
Unknown or unreported	13	3.9	
Current Medication for Mental Health Concerns			
None	203	60.6	
SRI	109	32.5	
Stimulant	26	7.8	
Antipsychotic	11	3.3	
Benzodiazepine	17	5.1	
Other	26	7.8	
Unknown or unreported	0	0	
Family/Caregiver Baseline Demographics			
Insurance			
Public	26	7.8	
Secondary public	10	3.0	
Military	5	1.5	
Commercial	284	84.8	
Unknown or unreported	10	3.0	
Family Perceived Economic Status			
“We live very well”	26	7.8	
“We live comfortably”	210	62.7	
“We live from check to check”	79	23.6	
“We are almost poor”	2	0.6	
“We are poor”	1	0.3	
Unknown or unreported	17	5.1	
Government Assistance			
Yes	31	9.3	
Note. SRI = Serotonin Reuptake Inhibitor; OCD = Obsessive Compulsive Disorder			

Youth Baseline Demographics	Total (*n*)	*n* (%)	*M* (*SD*)
No	159	47.5	
Prefer not to answer	6	1.2	
Unknown or unreported	139	41.5	
Family Mental Health History			
OCD	85	25.4	
Tics/Tourette's	15	4.5	
Anxiety	239	71.3	
Depression	193	57.6	
Drugs/Alcohol	82	24.5	
Schizophrenia	31	9.3	
Bipolar Disorder	62	18.5	
None	54	16.1	
Unknown or unreported	7	2.1	
Note. SRI = Serotonin Reuptake Inhibitor; OCD = Obsessive Compulsive Disorder			

Symptoms and Diagnoses

Detailed symptom and diagnostic data are presented in Table 2. The most common primary diagnoses were OCD (41.9%), GAD (35.3%), and social anxiety disorder (12.9%). Average global symptom severity was on the high end of the moderate range (CGI-S *M* = 4.7, *SD* = 0.6).

Table 2
Descriptive Statistics for Baseline Diagnoses and Symptom Severity (N = 335)

Youth Diagnoses	**Mean (SD)**	***n* (%)**
Number of Diagnoses		
1		128 (38.2)
2		137 (40.9)
3+		70 (20.9)
Symptom Severity		
OCD Symptoms (CYBOCS)	21.7 (4.3)	
Anxiety Symptoms (PARS)	14.2 (3.4)	
Global Symptom Severity (CGI-S)	4.7 (0.6)	
Primary Diagnoses		
Obsessive Compulsive Disorder		140 (41.8)
Generalized Anxiety Disorder		119 (35.5)
Social Anxiety Disorder		43 (12.8)
Selective Mutism		18 (5.4)
Separation Anxiety Disorder		17 (5.1)
Specific Phobia		16 (4.8)
Other		26 (7.8)
Baseline Comorbidities		
Anxiety		64 (19.1)
Obsessive Compulsive Disorder		20 (6.0)
Attention Deficit Hyperactivity Disorder		88 (26.3)
Depressive disorder		15 (4.5)
Tics		27 (8.1)
Rule out Autism Spectrum Disorder		23 (6.9)

Note. CY-BOCS = Children's Yale Brown Obsessive Compulsive Scale; PARS = Pediatric Anxiety Rating Scale; CGI-S = Clinical Global Impression - Severity

A majority of the sample (61.7%) had two or more diagnoses; the most common secondary comorbid diagnoses were attention-deficit/hyperactivity disorder (ADHD;26.3%), followed by anxiety disorders

(19.1%). Although autism spectrum disorder (ASD) diagnoses were not formally assessed as part of study procedures, 6.9% of youth endorsed elevated ASD symptoms and/or had a prior diagnosis of ASD.

Youth and Family Functioning

Youth anxiety-related quality of life was rated between “fair” and “good” by both caregivers (*M* = 3.7; *SD* = 0.6) and youth (*M* = 3.7; *SD* = 0.6; see Table 3). In terms of anxiety-related disability, parent participants reported that their child’s symptoms have moderately disrupted their child’s schooling (*M* = 4.8; *SD* = 3.1), moderately disrupted their child’s social life (*M* = 5.3; *SD* = 3.0), mildly disrupted their own work (*M* = 3.3; *SD* = 2.9), mildly disrupted their own social life (*M* = 3.4; *SD* = 2.9), and mildly disrupted their own family life/home responsibilities (*M* = 4.1; *SD* = 3.0). Child participants reported that their symptoms have “messed up things with school and homework” “some” (*M* = 4.7; *SD* = 3.0), “messed up things with friends” “some” (*M* = 3.3; *SD* = 2.9), and “messed things up at home” “some” (*M* = 5.0; *SD* = 3.0).

Table 3
Mean and Standard Deviations for Youth and Family Functioning

Youth Functioning	**Total completed (*n*)**	**Mean**	**SD**
Anxiety-related disability (CSDS Caregiver)	285	4.14	2.33
Anxiety-related disability (CSDS Youth)	217	4.34	2.30
Quality of life (PQLES-Q Caregiver)	272	3.67	0.60
Quality of life (PQLES-Q Youth)	242	3.73	0.64
Family Functioning			
Caregiver strain (CSQ Caregiver)	284	29.8	15.3
Caregiver Accommodation (PAS-PR Caregiver)	283	1.67	0.83

Note. CSDS = Child Sheehan Disability Scale; PQLES-Q = Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire; CSQ = Caregiver Strain Questionnaire; PAS-PR = Pediatric Accommodation Scale – Parent Report

Table 4
Commonly Endorsed Barriers to Treatment

Barriers (BTQ)[a]	***n (%)***
Unsure of who to see or where to go	175 (63.2)
Couldn't get an appointment	133 (48.0)
Child not comfortable discussing problems with a health professional	125 (45.1)
Child felt ashamed of his/her problems	106 (38.3)
Parent was concerned that child would be put on medication	97 (35.0)
Transportation/scheduling problems	92 (33.2)
Parent did not know that child's problem was a genuine mental health condition	86 (31.0)
Child felt ashamed of needing help	86 (31.0)
Worried about the cost	86 (31.0)
[a]N= 277	

Note. BTQ = Barriers to Treatment Questionnaire

In terms of caregiver strain, caregivers reported that their child's symptoms caused interruption of personal time (86.6%), disruption of family routines (84.1%), disruption of their family's social activities (72.2%), missing work or neglecting other duties (70%), and paying less attention to other family members (70.1%). Caregivers also reported worrying about their child's future (95.0%), feeling sad or unhappy (91.9%), feeling tired or strained (88.0%) and feeling guilty about their child's emotional or behavioral problem (78.9%). Nearly all caregivers (98.9%) reported relating to their child and that their child's difficulties had taken a toll on their family in general (93.0%) within the past 6 months.

In terms of caregiver accommodation, caregivers reported providing reassurance (98.9%), experiencing distress when helping their child with anxiety (77.0%), helping their child avoid anxiety triggers (75.1%), and changing the family's routine to reduce their child's anxiety (72.1%). Parents also reported that the child's need for reassurance from family members interfered with daily functioning (70.9%) and the child became upset when accommodation was not provided (71.1%).

Discussion

To our knowledge, this study represents the largest single-site randomized controlled effectiveness trial for youth with anxiety or OCD. Baseline participant characteristics reflect the overall trial emphasis on external validity and suggest a more clinically varied sample than has typically been included in prior large-scale efficacy trials. The most common primary diagnoses were OCD and GAD; together, these comprised just over three-quarters of the present sample. Importantly, most participants had at least

one additional comorbid diagnosis. This is consistent with clinical practice settings broadly, where comorbidity is the rule rather than the exception (Kendall et al., 2001; Garcia et al., 2010). It is also consistent with overall comorbidity rates in prior efficacy trials (Compton et al., 2010; Piacentini et al., 2014; Pediatric OCD Treatment Study [POTS] Team, 2004). In contrast to those trials, the present sample includes a higher percentage of youth with comorbid ADHD; more than one quarter of the present sample met ADHD criteria, which is consistent with population prevalence rates among youth with anxiety and OCD (Masi et al., 2010). The present study included youth with comorbid ASD, which is also a departure from prior efficacy trials. Such inclusion is particularly relevant given evidence of high comorbidity between OCD and ASD (Martin et al., 2020), and the prevalence of OCD symptoms among youth with ASD (Pazuaniak & Perkrul, 2020). Additionally, more than 40% of youth in this study were already taking a stable psychotropic medication for mental health concerns at baseline, consistent with medication use patterns observed in outpatient settings (Comer et al., 2011; Weber et al., 2016;). With the exception of the POTS II OCD trial, in which medication partial responders were the population of interest (Freeman et al., 2009), prior trials have either largely excluded youth taking psychotropic medications for anxiety or OCD (e.g., POTS, 2004) or had more significant exclusion criteria related to psychotropic medication (e.g., Compton et al., 2010, Freeman et al., 2014). Despite these differences, global symptom severity in this study was in the moderate-severe range and broadly similar to that observed in prior trials (POTS, 2004; Compton et al., 2010). Consistent with this level of symptom severity, youth and caregiver report suggests moderate levels of functional impairment and disability. Overall, baseline clinical characteristics (severity, comorbidity, medication use) suggest that youth in the present study are largely representative of those seen in typical outpatient settings.

Despite moderate levels of severity and impairment on average, caregivers reported high levels of disruption in overall family functioning, caregiver strain, and family accommodation. A large majority reported symptom-related disruptions across multiple domains of family functioning including disruption of personal time, family routines, family social activities, missing work or neglecting other duties, and paying less attention to other family members. Virtually all caregivers also reported worrying about their child's future, feeling sad or unhappy as a result of their child's emotional or behavioral problems, feeling tired or strained, and that their child's difficulties had taken a toll on their family. Similarly, nearly all caregivers reported providing accommodation related to youth symptoms within the past week, and nearly three-quarters reported that the child's need for reassurance from family members interfered with the child's daily functioning and that the child became upset when accommodation was not provided. This level of accommodation is common among treatment-seeking youth with anxiety or OCD (Lebowitz et al., 2016), as family members often attempt to manage distress by helping their child avoid anxiety-provoking situations. These findings underscore the impact that anxiety and OCD have on caregivers and families, particularly causing disruptions to daily functioning and emotional distress (e.g., worry, guilt, and fatigue). When caregiver strain is considered alongside accommodation, it paints a picture of caregivers frequently attempting to manage child anxiety, resulting in strain within the family system. When a family engages in "errors of kindness" or repeated rescues from anxiety provoking situations, anxiety declines in the short-term, but this can cause families to become stuck in cycles in the

long-term leading to caregiver burden described by the present sample. Moreover, family accommodation is an important treatment target, with changes in accommodation preceding symptom improvement (O'Connor et al., 2023) and high levels of accommodation at baseline relating to poorer treatment outcomes (Salloum et al., 2018). IMPACT-CBT may provide unique opportunities for addressing family accommodation given that treatment may take place in the home. The larger study will allow for further examination of these mechanisms.

Approximately two-thirds of youth in the sample had received previous mental health treatment. However, fewer than 30% had previously received any form of exposure therapy, the gold-standard intervention for anxiety and OCD. This is broadly consistent with prior research demonstrating that exposure-based CBT is rarely available in clinical practice settings (Reid et al., 2018;), often the result of a shortage of community clinicians trained in exposure therapy and persistent misconceptions about the safety and acceptability of exposure-based treatment across settings (Kemp et al., 2024; Deacon et al., 2013). Notably, many participants were referred to the study by local providers already familiar with our outpatient clinic, including those within our clinic's partial hospitalization program, suggesting possible higher than typical rates of treatment utilization prior to entering care. This indicates that awareness of exposure-based CBT may be clustered within particular referral networks rather than widely distributed across community settings. This pattern highlights prior findings (Frank et al., 2023) of unequal access to evidence-based care and suggests that families without connection to specialty systems may be less likely to receive appropriate treatment recommendations. These findings underscore the need for broader dissemination, provider training, and public awareness efforts to increase access to exposure-based interventions for youth with anxiety and OCD in typical community settings.

Caregiver-reported barriers to treatment further illustrate the substantial challenges families face in accessing mental health care. Virtually all caregivers endorsed at least one barrier to treatment. Most frequently, caregivers reported that they were unsure of who to see or where to go for mental health treatment for their child. This aligns with previous effectiveness trials reporting similar rates of such barriers (Salloum et al., 2016) and is especially common among African American families (Williams et al., 2012). Additional commonly reported barriers included difficulty securing an appointment and children feeling uncomfortable discussing their concerns with health professionals. Interestingly, in the present sample, a greater proportion of caregivers reported difficulties obtaining an appointment than those in comparison trials, which occurred pre-COVID-19 pandemic (Salloum et al., 2016; Williams et al., 2012). These findings are not unexpected, given evidence of increasing anxiety symptoms in youth since the onset of the COVID-19 pandemic (Racine et al., 2021), which has resulted in fewer openings for new patients and longer average wait times.

IMPACT-CBT may be particularly well suited for families endorsing these barriers to treatment. This model has the potential to reduce wait times by expanding the capacity of licensed providers, thereby allowing a greater number of patients to receive care. It may also help with youth's apprehension about discussing mental health concerns with professionals by providing treatment in familiar community environments (e.g., the family's home and/or community) rather than traditional academic medical

centers, which may pose additional barriers for some patients and families. Several efforts were undertaken to reduce potential barriers to participation in the present study, including accepting all forms of insurance coverage and intentionally prioritizing the inclusion of youth who have been historically underrepresented in efficacy trials (e.g., based on comorbidity, treatment history, and medication use).

Although the present sample is relatively diverse with respect to clinical features, the overall demographic characteristics remain largely consistent with those in prior large-scale efficacy trials (Skriner et al., 2016, Treatment for Adolescents with Depression Study [TADS] Team, 2005). The sample was predominantly White, with limited representation from other racial groups, and most identified as non-Hispanic or Latino. This is consistent with state racial demographics, but underrepresents minoritized racial groups compared with national rates (U.S. Census Bureau, 2021). Moreover, Hispanic/Latino youth were underrepresented relative to past trials as well as Census data (Weersing et al., 2017; U.S. Census Bureau, 2021). The sample also reflected a range of socioeconomic backgrounds, though most participants reported “We live comfortably,” consistent with patterns of high socioeconomic status (SES) observed in previous trials (POTS Jr.; Skriner et al., 2016; TADS Team, 2005). Additionally, most participants (84.8%) reported having commercial insurance although public insurance was accepted. This is in line with national data showing that commercial insurance is more common than public coverage, although rates of commercial insurance were higher in this study compared to national data (65.4%) (U.S. Census Bureau, 2024). Overall, the study sample demonstrates limited racial and ethnic diversity, particularly among Hispanic/Latino youth. The limited diversity of the sample is particularly notable given the use of specific community-informed recruitment strategies (e.g., partnering with schools and advocacy groups, bilingual staffing and prioritization of youth with self-identified marginalized identities on the waitlist). This likely reflects the significant and multiple barriers that exist to accessing treatment in an academic medical center setting. These include geographic barriers (e.g., location of the academic medical center, limited public transportation), limited racial and ethnic diversity among licensed staff, stigmatizing beliefs about mental illness (Alvidrez et al., 2008), and concerns about providers or treatment processes (Williams et al., 2012; Suite et al., 2007). The limited racial and ethnic diversity of the sample represents a limitation of the study and restricts the generalizability of findings, particularly from urban and historically underserved populations. Addressing these structural and systemic barriers, as well as perceptions regarding mental health problems and services, will be essential for future trials and for improving equitable access to evidence-based care for anxiety and OCD. IMPACT-CBT offers a promising framework for addressing these gaps.

Summary

The present research offers an opportunity to better understand the characteristics of treatment-seeking youth with pediatric anxiety and OCD within real-world outpatient settings. The clinically complex nature of this sample marked by elevated symptom severity, high rates of comorbidity, substantial medication use, significant caregiver burden and accommodation, combined with the minimal exclusion criteria, provides a more representative clinical sample of outpatient youth with anxiety and OCD. Accordingly,

findings from this comparison of IMPACT-CBT and single-provider office-based CBT may generalize to broader outpatient populations, though the limited racial and ethnic diversity within the sample should be considered. Baseline characteristics also reveal severe symptomology and high comorbidity despite many participants having received prior mental health treatment, yet relatively few having received exposure therapy. This finding highlights the need to increase awareness of and access to evidence-based exposure therapy, as well as flexible, scalable treatment approaches capable of reaching youth with diverse clinical and contextual needs. These concerns are being addressed in our ongoing work, which involves partnering with community mental health agencies across the state to bring anxiety and OCD treatment directly to youth and families within the communities where they live.

Declarations

Compliance with Ethical Standards

Conflict of Interest

The authors declare they have no conflicts of interest.

Informed Consent

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

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.

Note

BTQ = Barriers to Treatment Questionnaire

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Author Contribution

Authors E.O., K.B., and J.F made substantial contributions to the conception and design of the work, the acquisition, analysis and interpretation of data and wrote the main manuscript text. Author R.J, made substantial contributions to the analysis and interpretation of the data.Authors J.H., and J.K., made substantial contributions to the conception and design of the work and the acquisition, analysis and interpretation of the data.Authors E.P., C.M., J.S., and K.R., prepared Tables 1-4 and contributed to the writing of the main manuscript text. All authors reviewed the manuscript.

Data Availability

This study was funded before the implementation of the PCORI requirement for data submission to its data repository. Therefore, the study data are not available in a repository. De-identified data may be made available to qualified investigators who request access through appropriate channels and enter into a fully executed data use agreement.

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