STUDY PROTOCOL AND METHODS ADVANCEMENT

A Team-Based Partner-Driven Model for Delivering Outpatient Exposure Treatment for Pediatric Anxiety and OCD

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Objective: Anxiety disorders are among the most common and earliest forms of psychopathology, yet few providers in community practice settings use or are trained in evidence-based treatments (EBTs) for pediatric anxiety. Delivery of EBTs is further limited by the "provider-centered" manner in which they are often administered (ie, office-based). This paper presents the rationale, design, and methods for a team-based approach to the treatment of pediatric anxiety that was developed with substantial patient, caregiver, and community partner involvement, and that addresses quality and workforce issues inherent in the current child mental health crisis.

Method: This study aims to compare team-based community delivered cognitive behavioral treatment (CBT) and office-based CBT for pediatric anxiety and obsessive-compulsive disorder (OCD) in a sample of 333 children and adolescents 5 to 18 years of age. Rather than reporting outcomes, the purpose of this paper is to spotlight study design, methods, and procedures, including processes for fostering and maintaining strong partner engagement, training strategies, supervision structures, and implementation of quality and fidelity monitoring tools.

Discussion: Treatment delivered outside of a traditional office setting using a team-based approach has the potential to increase patient access to care. In addition to describing specific design considerations, we provide a roadmap for the integration of community-based partners and for rigorous supervision and quality monitoring. Future directions are discussed, particularly in the context of lack of access to care that has a longstanding disproportionate impact on youth of color and youth from low-income communities.

Clinical trial registration information: Improving Access to Child Anxiety Treatment (IMPACT); https://clinicaltrials.gov/study/NCT03528109; NCT03528109.

Diversity & Inclusion Statement: We worked to ensure sex and gender balance in the recruitment of human participants. We worked to ensure race, ethnic, and/or other types of diversity in the recruitment of human participants. We worked to ensure that the study questionnaires were prepared in an inclusive way. One or more of the authors of this paper self-identifies as a member of one or more historically underrepresented sexual and/or gender groups in science. We actively worked to promote sex and gender balance in our author group.

Key words: anxiety; obsessive-compulsive disorder; exposure treatment; team-based treatment; treatment access

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Anxiety disorders are among the most common and earliest emerging forms of psychopathology, affecting 14% to 30% of youth and young adults.[1–5] Anxiety in childhood leads to broad impairment, with particularly devastating effects on academic functioning and peer relationships.[6] Without treatment, such impairments have been shown to compound over time[7] and predict depression, substance abuse, suicide attempts, and further disability into adulthood.[5,6,8–10] The Coronavirus Disease 2019 (COVID-19) pandemic has contributed to an estimated 25.6% increase in the prevalence of anxiety disorders globally, with a disproportionately higher rate of change among individuals in younger age groups.[11] Increased prevalence rates have combined with a national shortage of child mental health professionals to create an unprecedented child mental health crisis, leaving many service-seeking families without options for quality treatment.[12,13]

To address the current state of emergency in child mental health, novel approaches must be developed[14] and focus on both rapidly expanding the mental health workforce and increasing access to high-quality, evidence-based care. The sustainability of such efforts relies on the collaboration of several key players in the youth mental health landscape, including third-party payers, service delivery providers, patients, and caregivers. This Study Protocol and Methods Advancement paper presents a team-based service model with the potential to address workforce and access issues in the context of childhood anxiety disorders, and describes a partner engagement approach to increase the

patient-centeredness and longevity of this work moving forward.

Treatment for Anxiety and Obsessive-Compulsive Disorder

The gold standard psychosocial treatment for youth with anxiety is cognitive–behavioral therapy (CBT). CBT typically includes multiple components, of which exposure has robust empirical support as a primary and necessary ingredient.[15–19] Exposure involves gradually approaching situations or objects that evoke distress, which creates opportunities to correct maladaptive anxiety thoughts and behaviors with new learning.[20] CBT with exposure is considered a "well-established" treatment for pediatric anxiety and OCD, consistently demonstrating symptom reduction and improvements in functional impairments with large effect sizes.[21–23]

Despite the strong support for CBT as a frontline treatment, only 20% of youth with anxiety and related disorders (including obsessive-compulsive disorder [OCD]) receive evidence-based care in community settings,[1] and average wait times are long.[24] Even when able to access CBT, these youth rarely receive exposure—the most efficacious CBT ingredient[25]—due in large part to low rates of exposure training and use among providers.[26,27] Although exposure trainings have recently become more available online and at the graduate level,[28,29] studies have found that ongoing supervision and consultation is essential to the adoption and sustained practice of exposure, which may hinder its wide implementation.[30]

The availability of exposure-based CBT is further limited by the "provider-centered" manner in which it is often delivered (ie, office-based weekly, hour-long meetings with a licensed clinician). This configuration of services introduces structural barriers related to transportation and scheduling and is less ideal for historically marginalized youth and families with characteristics/experiences that put them at risk for poorer health care access and/or mental health outcomes (eg, based on race/ethnicity, income, LGBTQ+, or symptom acuity). Patients and families receiving care in the community also experience a higher proportion of life stressors (eg, caregiver mental health concerns, family conflict) that further compromise their ability to regularly attend office-based scheduled visits.[31,32] Furthermore, patients and families holding marginalized identities may have historically justified reservations about seeking services in mental health facilities.[33–35]

Barriers to engaging and retaining children in treatment are a primary reason for the disparity between need and actual service use.[36–38] No-show rates for initial pediatric mental health intake appointments range from 48% to 62%,[39,40] and half of children who initiate outpatient mental health services do not complete an adequate dose of treatment.[31] As such, the field of mental health has been challenged to transport what works to where it works most effectively.[41,42]

Team-Based CBT Can Increase Treatment Access and Quality

Team-based treatment models, which pair licensed providers with highly trained non-licensed individuals (eg, community health workers or lay health workers), represent a well-established means for expanding treatment access while maintaining effectiveness.[43–45] Such models are well established across pediatric settings (ie, asthma, diabetes) to address complex needs of patients and families and to coordinate care across individuals with varying educational and professional backgrounds.[46] Team-based models have also been used across health systems (eg, primary care, community mental health) to leverage the expertise of external organizations and to increase the availability of and access to specialty care.[45] The model of team-based care that coordinates treatment activities among both licensed and non-licensed individuals is a form of "task-sharing" and is supported by numerous systematic reviews as a means to increase the availability of specialty mental health services across low- and high-resource settings.[45,47–49]

A unique and important feature of team-based models is the potential for sessions with a non-licensed provider to occur in patients' homes and the community, which is typically infeasible for licensed providers because of time constraints, capacity, and billing restrictions. Paradigms for incorporating home-based care into traditional child outpatient services have existed for decades,[50] and child anxiety disorders are especially responsive to home-based services.[51] Providing services in the home and community allows patients to engage with services in trusted spaces and reduces most of the aforementioned structural barriers. Home-based delivery also promotes more family involvement in care, which is a known predictor of better CBT outcomes for youth with anxiety.[52]

Team-based CBT in the home and community also offers unique advantages for the delivery of exposure therapy. A review of 37 trials of home-based mental health interventions found that among common psychosocial treatment elements including anger management, functional analysis, and problem solving, exposure was the most effective.[53] Home-based care allows access to settings in which patients and families experience their symptoms and provides rich observational data about the factors maintaining anxiety at home. The ability to access naturalistic situations that are difficult to recreate in the office (ie,

"treating anxiety where it lives"), with staff providing hand-over-hand assistance during real-life situations, makes this model of care especially potent in the delivery of exposure therapy.

Given the alarming gap between the need for mental health services—particularly anxiety services—and the growing shortages in our mental health workforce,[54,55] there has been a strong push to scale up service models that pair non-licensed health workers with licensed providers as a feasible strategy for bridging the gap with quality services.[56] In particular, evidence supports the use of a team-based model for delivering CBT for individuals with anxiety and mood disorders and provides a framework for further expanding this efficient service model.[43,57–59] In addition to demonstrating initial efficacy, team-based models have been shown to effectively double the number of cases that can be seen by a licensed provider.[59] Thus, team-based exposure delivery offers a promising and scalable model for addressing access barriers for youth with anxiety while rapidly diversifying the composition of the workforce.

Quality of Team-Based Care Is Contingent Upon Training, Supervision, and Quality Monitoring

Despite the promise of team-based care as a workforce shortage solution, several existing barriers limit the effectiveness and broad implementation of such models for pediatric mental health concerns. For example, reports of training have been highly variable in previous task-sharing models of mental health service delivery, and most lay workers in these models have noted a desire for increased supervision and consultation.[49,60] Implementation trials have consistently demonstrated that a combination of intensive workshop training followed by ongoing consultation is an essential support strategy for promoting the adoption and long-term use of a new evidence-based practice.[61–63] As such, the standardization and validation of training and supervision strategies for team-based models are urgently needed to promote their scalability while maintaining high treatment quality.

Within the context of provider (both licensed and non-licensed staff) training in CBT, studies have demonstrated that lack of exposure-specific training is a primary barrier to its sustained use in practice.[64] Another potential barrier includes provider beliefs that exposure therapy may be harmful to patients and may exacerbate anxiety-related distress, given the emphasis on approaching feared situations and stimuli.[65–67] As such, in addition to providing psychoeducation about the rationale for exposure to target anxiety and OCD concerns, provider training should focus on experiential exercises to demonstrate that exposure is tolerable and effective.[68,69] Furthermore, given the relatively low rates of sustainability in the use of exposure practices post training,[70] supervision practices that promote the long-term adoption of exposure practices are warranted. There may also be barriers specifically related to provider-level (licensed vs non-licensed) that affect training and sustained use of exposure, including differences in lived experience, access to resources, and prior training experiences. Provider-level barriers that potentially differ based on license status should be considered in building sustainable training practices.

Measures of quality—that is, the degree to which an intervention is delivered to maximize patient improvement—are essential to implementation of evidence-based treatments in typical service settings,[71–73] and facilitate practice sustainment and support tailored supervision practices. The use of "process" quality measures (ie, those that assess aspects of delivery) allow for a "feedback loop" to directly inform delivery changes when needed, and can help identify reasons for implementation success or failure. Treatment quality has been shown to strongly predict response in controlled trials of CBT for anxiety, and variation in quality has been observed even among highly trained/experienced PhDs. Moreover, evidence suggests that therapists who are trained to use quality measures to guide exposure delivery may have improved patient outcomes (compared with therapists receiving standard training[74]). This underscores the importance of ongoing quality monitoring and strong communication among providers as key components of team-based service models that provide services in the home and community. In order for quality monitoring tools to be used sustainably at scale in the community, they must be practical, while still accurately assessing aspects of delivery that relate to outcomes. Taken together, the advancement of mental health service innovations is contingent upon the dynamic interplay between rigorous and interactive training practices, supervision, and quality monitoring tools that are tailored to the unique context of team-based care.[75]

The Current Study

This Study Protocol and Methods Advancement paper describes a trial in progress comparing a team-based CBT model of care to a traditional office-based CBT model in an outpatient specialty clinic for youth with anxiety and/or OCD using "exposure coaches" (ECs). The impetus for developing and testing this model came from patients and families receiving a combination of hospital- and home-based services in our partial hospitalization program, in which home-based services were integrated into routine care.[76] Patients and families stepping down from the partial program would often ask if they could continue to receive services in their home/community at the outpatient level of

care, given a preference for home-based exposures; however, a lack of applicable billing codes made this service impossible to implement for all youth with public and commercial insurance. The current study was funded by the Patient-Centered Outcomes Research Institute (PCORI) and was developed in concert with key partners with varying lived experience and content expertise, including patients and families, experts in home-based care, patient advocates, hospital leadership, and regional insurance providers. The broad goals of the project include the following: (1) developing and validating the team-based CBT model with meaningful involvement from key partners; (2) examining "what works best for whom" in our group comparisons (ie, predictors of differential responding in each condition); and (3) working with regional payers to create a billable and sustainable service option for all youth. Specific aims are as follows:

Aim 1. To compare the relative effectiveness of patient-centered team-based CBT ("home/community") vs provider-centered CBT ("office") treatment for the following:

1a. Improving family treatment engagement/satisfaction

1b. Reducing anxiety symptoms (Primary/Partner Key Outcome)

1c. Reducing associated disability (quality of life and functional impairment)

Aim 2. To understand predictors of treatment response, including severity of illness, caregiver burden, barriers to treatment access, and family accommodation.

Aim 3. To explore group differences in time course of response, durability of treatment gains, provider volume/capacity, and efficiency in patient-centered vs provider-centered treatment.

The purpose of this paper is to provide an in-depth account of the study design and procedures for developing and validating an innovative care model that addresses quality and workforce issues inherent in the current child mental health crisis. Rather than reporting outcomes, the purpose is to spotlight study methods and procedures, including processes for fostering and maintaining strong partner engagement, training strategies, supervision structures, and implementation of quality monitoring tools. In the Discussion, we address the impact of the pandemic on this study (eg, use of telehealth) and the resulting challenges and successes. Finally, implications for scaling the team-based CBT model to increase equitable access to high-quality mental health services for all youth are discussed.

METHOD

Study Participants

The study is ongoing and plans to enroll a total of 333 youth (167 youth randomly assigned to the patient-centered team-based condition and 167 youth randomly assigned to the provider-centered office condition) with expected study completion in December 2024. All procedures are conducted as part of an institutional review board (IRB)–approved protocol, and all participants sign an Informed Consent Form and Child Assent Form (ages 8+) before enrolling in the study.

Eligibility Criteria. Inclusion criteria are as follows: (1) age 5 to 18 years inclusive; (2) primary or co-primary *DSM-5* diagnosis of generalized anxiety disorder, separation anxiety disorder, specific phobia, social anxiety disorder, panic disorder, agoraphobia, unspecified anxiety disorder, selective mutism, or OCD; (3) symptom duration of at least 3 months; (4) requirement of outpatient (not partial hospital or inpatient level of care) treatment; and (5) presence of a stable caregiver who can participate in treatment. Although we require a primary or co-primary diagnosis of anxiety or OCD, we include participants with most comorbid diagnoses (including youth who have a previously diagnosed autism spectrum disorder [ASD]) to increase the generalizability of our findings and to maximize access to care. Of note, we do not conduct formal ASD diagnostic assessment as part of this study, and therefore we are limited in the conclusions that we can draw about this specific subset of youth and their treatment outcomes. We also include youth on stable doses of psychotropic medications, given the high use of these medications in our population of interest, and feedback from patient and caregiver partners that exclusion for medication use would limit the relevance of findings. With respect to serotonin reuptake inhibitors (SRIs), atypical antipsychotics, and buspirone, a stable dose is defined in the current study as no medication initiation or discontinuation within 4 weeks, and no dose change within 2 weeks of baseline symptom assessment. For benzodiazepines and other fast-acting anxiolytics, a stable dose is defined as no medication initiation or discontinuation within 2 weeks of and no dose change within 1 week of baseline symptom assessment.

Exclusion Criteria. Exclusion criteria are as follows: (1) other primary or co-primary psychiatric disorder that requires initiation of different active treatment; (2) documented intellectual disability that would interfere with a child's ability to participate in treatment (ie, nonverbal); (3) thought disorder or psychotic symptoms; (4) conduct disorder; (5) current and/or acute suicidality; (6) concurrent

psychotherapy for anxiety or OCD; (7) chronic medical illness that would preclude active participation in treatment; and (8) treatment with psychotropic medication that is not stable. The designation of primary and co-primary diagnoses is based on clinical information (eg, symptom severity, degree of functional impairment) collected during the initial diagnostic interview and agreed upon by a study supervisor.

Study Setting

The study is being conducted at an academic medical center in the northeastern United States. The study setting is a nationally recognized, integrated research and clinical program encompassing outpatient services and a range of partial hospital programs. For participants in the team-based condition, treatment is conducted both in an outpatient hospital setting as well as in the home and community.

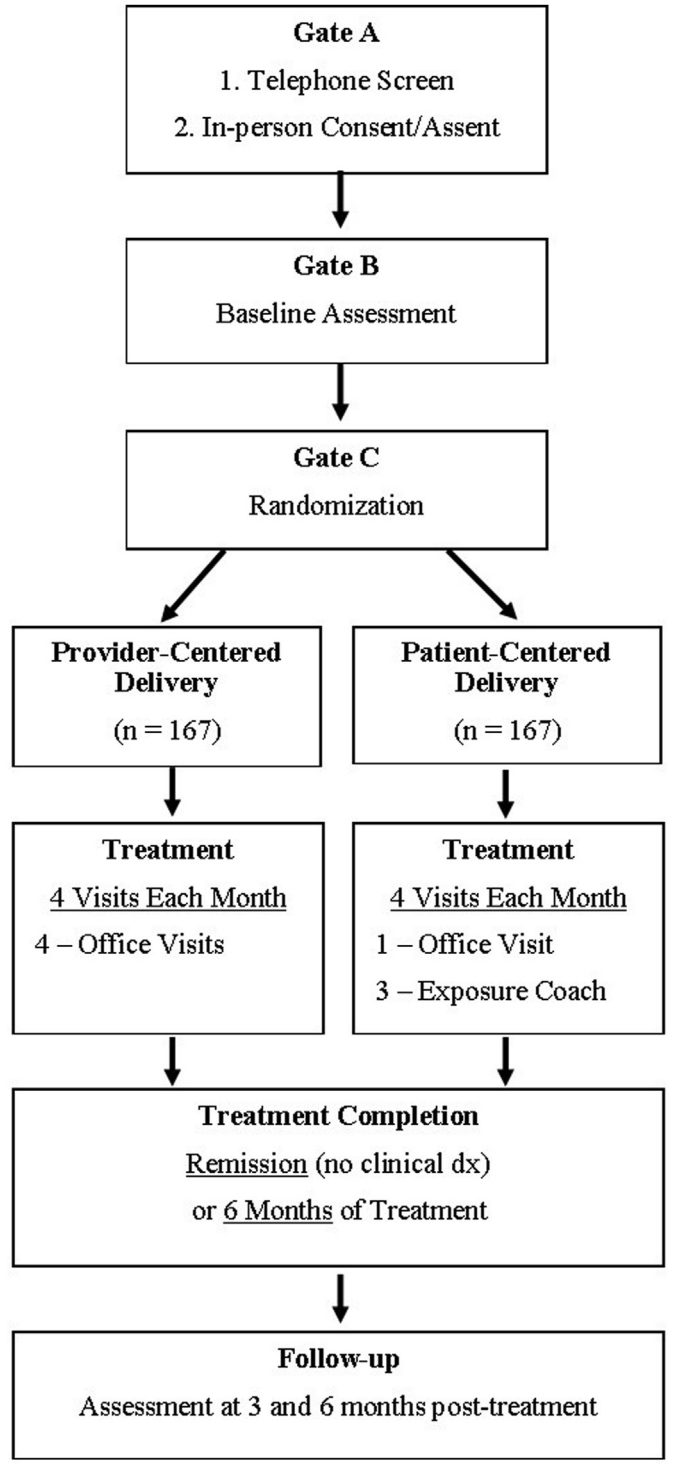
Recruitment Procedure

Participants are referred to the study via a number of mechanisms that are developed in concert with our partner groups. This engagement strategy is influential across many recruitment domains, ranging from identifying specific recruitment locations (eg, local clinics serving historically marginalized youth) to helping to develop recruitment materials. Providers with whom the clinic has existing relationships (eg, local pediatricians and mental health professionals) act as recruitment partners for the study. Some participants may find the study through searching the Internet (ie, clinicaltrials.gov). In addition, the study team uses flyering at community health and mental health centers, recreation centers, libraries, and churches, and posts recruitment advertisements on social media (eg, on Facebook and Instagram) and hospital websites.

Sample Selection

We use a 3-gate assessment (Figure 1) procedure to screen participants for eligibility and interest in participating in the study as per the methods of prior clinical trials and to reduce participant/family burden[77–79] and follow the Consolidated Standards of Reporting Trials (CONSORT)[80] reporting guidelines. Gate A consists of a telephone screening interview to assess participants' preliminary eligibility and family interest, and lasts 15 to 30 minutes. If a family is interested, brief follow-up questions assess initial inclusion and exclusion criteria. If initial inclusion criteria are met, an in-person meeting or virtual meeting (ie, via Zoom) is scheduled (Gate B). Gate B consists of a meeting in which a research team member first obtains written participant assent and parental consent. Next, the independent evaluator (IE) conducts an eligibility assessment including a systematic diagnostic evaluation with the caregiver(s)/guardian(s) and child. This visit takes approximately 120 minutes. The research team reviews all data to establish suitability for study entry. Eligible participants proceed to Gate C, in

FIGURE 1 Study Flow Diagram



Note: *dx = diagnosis.*

TABLE 1 Engagement Principles

Principle	Definition
Reciprocal relationships	Demonstrated when the roles and decision-making authority of all research partners, including the patient and other partners, are defined collaboratively and clearly stated.
Co-learning	Demonstrated when researchers help patient and partners understand the research process. Likewise, the research team will learn about patient-centeredness and patient/other partner engagement, and will incorporate the patient and other partners into the research process.
Partnerships	Demonstrated when time and contributions of patient and other partners are valued and demonstrated in fair financial compensation, as well as in reasonable and thoughtful requests for time commitment by patient and other partners.
Transparency, honesty, trust	Demonstrate when major decisions are made inclusively and information is shared readily with all research partners. Patients, other partners, and researchers are committed to open and honest communication with one another.

which symptoms and functioning are briefly reviewed with an IE to confirm baseline severity (approximately 15-30 minutes). Within 1 week of this visit, although most often on the same day, families have their first treatment visit with their assigned licensed clinician regardless of condition. At this first treatment visit, families are informed of randomization and meet their EC if assigned to the team-based condition. Throughout the assessment process, participants/families who are deemed ineligible or who decline participation are referred for appropriate clinical services. In addition, to respond to inequity in terms of access to care and systemic racism, we gave prioritized status to youth from historically marginalized backgrounds on our waitlist (eg, spots at the top of our waitlist were reserved).

Partner Engagement

Our comprehensive engagement plan was built on our funder's engagement principles (Table 1), synthesis of existing guidelines,[81] and systematic reviews of community engagement.[82,83]

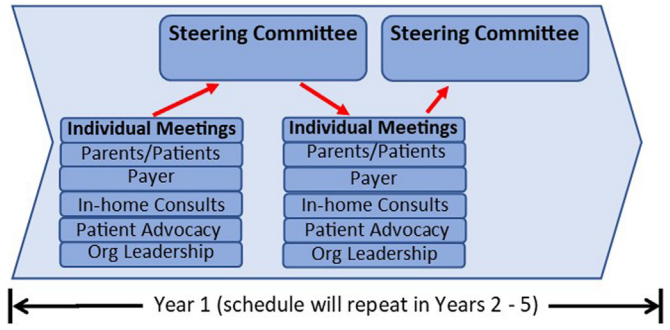
Partners. The development of the current study was based on frequent communication and collaboration with a number of key partners who had a focused interest in developing an outpatient team-based model of care. This included caregivers and families, hospital administration, and service providers in a partial hospitalization program for anxiety and OCD located in the northeastern region of the United States. Patients and families often communicated that the "step down" from the partial level of care to traditional, office-based outpatient services felt challenging, particularly the transition of no longer having support in the home setting, where symptoms are typically most severe.

As a family-driven response to this apparent need, a group of caregivers whose children received care in our partial program organized a Parent Advisory Council. A primary focus of their advocacy efforts was to facilitate the development of a home-based outpatient model of anxiety services to more effectively "step down" from the partial level of care. Their advocacy was the impetus for the current study, and for nearly a year before submitting for funding, the research team identified and recruited additional relevant partner groups and outlined a plan for aligning partner skills and experience with aspects of implementing, optimizing, and sustaining the team-based model. Patient and caregiver partners were identified following participation in our clinical programs (both partial programs and outpatient programs). Other partners were identified and recruited based on existing established clinical, research, and administrative relationships with the team.

Partners (n = 30) are organized into the following groups: (1) "Patients and Caregivers" who provide input on service design and implementation; (2) "Home-Based Consultants" who inform practical implementation planning and supervision/quality monitoring procedures; (3) "Patient Advocates" who assist with recruitment and raising study awareness in the community; (4) "Hospital Administration" personnel who assist with service implementation (eg, integration of a new service line into electronic medical record) and sustainment (eg, payer contracting); and (5) "Payer" representatives from a commercial insurance company who focus on increasing access to quality anxiety services and evaluating the utility of contracting to make the service available in-network. Two years into the project, additional internal grant funds were received to develop a Diversity, Equity, and Inclusion–focused partner group to inform equitable recruitment and enrollment procedures as well as to raise awareness about anxiety diagnoses and services for youth who have been economically/socially marginalized and/or historically underrepresented in clinical science and underserved in clinical practice.

Engagement Structure and Procedures. Each individual partner group meets twice per year for 60 minutes, with group meetings focused on the specific aspects of study operations or planning that fit the group's set of skills and

FIGURE 2 Annual Schedule of Partner Meetings



Note: org = organization.

expertise. For instance, barriers related to developing a new note template in the hospital electronic medical record were specifically brought to the Hospital Administration group, whereas barriers to engaging study participants were brought to the Patient and Family group. Between each round of partner group meetings, we also convene a Steering Committee (SC) twice annually for 90-minute meetings. The SC consists of 1 or 2 representatives from each partner group to provide a balance of all partner perspectives on higher-order study considerations, such as retooling procedures during the COVID-19 pandemic.

There are several advantages to alternating individual partner group meetings with those of the steering committee (Figure 2). First, we can triage specific study items to suit the unique expertise of each group, which promotes meaningful engagement and demonstrates to partners that we recognize and value their skills. Second, we can sequence group meetings in some instances to build toward a solution that involves the expertise of multiple partners.

The steering committee meetings are also intended to be mutually beneficial to the research team and partners; specifically, partners have been able to advance initiatives outside of the study as a result of connections with fellow committee members. The structure and spirit of partner and steering committee meetings is specifically designed to promote 6 engagement principles: (1) reciprocal relationships are promoted by explicitly eliciting and leveraging the expertise and opinions of partners to inform the development and execution of study procedures; (2) co-learning is facilitated by creating a shared agenda whereby researchers provide updates on study design and procedures, and partners are provided space to offer insight and feedback; (3) partnerships are developed by balancing individual partner meetings with steering committee meetings to prevent undue burden on individuals while facilitating open communication across partner groups; and (4) transparency, honesty, and trust are promoted across relationships by providing updates on study activities and decisions to all partner groups, both during meetings and in the interim.

Our study team also includes a number of process researchers (researchers examining how something works), and it is through this lens that we not only evaluate whom to engage as a partner and what tasks suit their interests/expertise, but also how to create meaningful engagement. We know that defining roles and responsibilities is a foundational element for active partner involvement; when partners know why they have been asked to participate, and when their roles and responsibilities are collaboratively defined, they feel confident about how to contribute in a way that is fulfilling to them. Meeting frequency, duration, and structure were carefully honed to promote engagement and have resulted in 100% retention of partners over the past 5 years.

Treatment

The primary question in the current study relates to the use of a team-based service model vs a traditional in-office model of care for exposure therapy for youth with anxiety. Participants receive the same treatment content (ie, exposure therapy) in 1 of 2 treatment conditions representing 2 distinct models of outpatient care: (1) provider-centered "office" CBT consists of weekly 45- to 60-minute in-person office visits with a licensed psychologist; and (2) patient-centered team-based "home/community" CBT consists of 45- to 60-minute in-person office visits with a licensed psychologist once per month and a 90-minute in-person home or community visit with an EC 3 times per month for a total of 4 visits per month (once per week). EC visits in the home/community are longer than office visits based on pilot data and partner feedback about the need for some additional time for logistics (eg, putting pets in another room, situating younger children) and for families to acclimate to having staff in their home (eg, greetings are more extended in the home). The number of treatment sessions (once per week) does not differ between the 2 conditions.

Use of Telehealth. Because of COVID-19–related changes in hospital policy and to maintain patient and staff safety, we temporarily halted in-person treatment for this study in March 2020. We subsequently received a COVID-19 enhancement award from PCORI to conduct an open pilot trial of this team-based CBT model occurring fully remotely. This pivot caused by the pandemic allowed for the examination of the novel combination of a team-based treatment model with a telehealth delivery modality. The results of this study are reported elsewhere.[59]

Following the lifting of COVID-19 restrictions on in-person care, we resumed enrollment in the main study. To continue to follow hospital and public health guidelines, we allow for a limited number of telehealth sessions in the home/community and office conditions so as to preserve continuity of care. The use of telehealth is limited to situations in which a family or provider is required to isolate as a result of a COVID-19 infection or exposure. In practice, the number of telehealth sessions across both conditions is small relative to the number of in-person sessions. Although we do not expect use of telehealth to differ by condition, when conducting final analyses, we will look to see whether there are any differences in the number of telehealth sessions across conditions.

Treatment Protocols. The primary intervention ingredient is exposure therapy and follows the treatment principles covered in our team's exposure training program (Supplement 1, available online). As part of this training program, we include supplementary training materials (Supplement 2, available online) that providers can reference after they complete the initial training. This supplementary training material covers general reminders about principles and structure of treatment sessions, and specific guidance for using CBT for anxiety and OCD, focusing on (1) psychoeducation, (2) hierarchy building, (3) exposure, and (4) relapse prevention. Both participants and their caregivers (if possible) play active roles in the treatment sessions. Participants and their caregivers (if possible) also complete treatment "homework" outside of the session to increase treatment dose and to support generalization of skills gained.

The initial exposure treatment training and supplementary training materials were designed to be used flexibly to enhance tailoring for participant needs and future implementation (as evidence suggests is beneficial; eg, see Weisz *et al.*[84]). For example, sessions do not need to be implemented in a prescriptive order, and typically involve many repetitions of the "Exposure Session" before proceeding to relapse prevention at the end of treatment. Given the heterogeneity of anxiety and OCD concerns, exposure sessions are inherently tailored to target participant "core fears," and guidance is provided within the manual to effectively titrate exposure difficulty. All sessions also include caregiver involvement to the degree that it is clinically indicated. Furthermore, given the wide age range in our sample, both our provider training and the use of supplementary training materials facilitate developmental tailoring.

Treatment Duration. Active treatment (regardless of treatment condition) continues for 6 months, or until one of the following occurs: (1) the participant achieves symptom remission (defined as no longer meeting *DSM-5* diagnostic criteria); (2) the participant/family decides that they have met their goals; or (3) the family drops out of treatment (whichever comes first). This definition of treatment response is determined by the treating clinician and family, as is consistent with typical clinical practice. A number of factors are taken into consideration when making this determination, including symptom severity, functional impairment, and need for weekly treatment as viewed by both the family and clinical team.

Adverse Events. If a youth has active suicidality (eg, with plan, intent, or recent attempt) when being assessed for this study, they are not eligible for the study. At initial assessment and throughout treatment (including at the 3-month and 6-month follow-up timepoints), a child's psychiatric symptoms, including depressive symptoms and possible suicidal ideation, are assessed by the IE using queries based on the Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI-Kid) Version 7.0 screening questions/modules.[85] Because the MINI-Kid suicidality module does not have screening questions, after the initial eligibility assessment (during which the full module is administered), we take relevant questions from this module (ie, those that assess for passive suicidal ideation, non-suicidal self-injury, and plan or intent) and ask them at all assessment time points (this is in addition to monitoring from the clinical team during active study treatment). If a participant endorses any risk in response to these initial questions, extensive follow-up questions are asked, and a safety plan (as is practice in our hospital setting) is created. If a child develops suicidal ideation at any point during the study, and it is the clinical judgment of the licensed clinician and study team that this suicidal ideation cannot be managed through the child's assigned treatment arm, the study team will remove the child from the study and will make sure that the child receives appropriate assessment and treatment for these symptoms. The licensed clinician for each case (or another licensed supervisor) is available at all times to ECs conducting home visits in the event that there is any concern about a participant's risk status.

Clinician Supervisors. Licensed PhD-level clinicians ($n = 7$) provide services in both treatment conditions. In the team-based condition, the licensed clinician holds the case and works in tandem with an EC assigned to the case (ie, clients met with the same licensed provider and EC team throughout treatment). Licensed providers include faculty with specialty training in pediatric anxiety and exposure therapy, as well as advanced postdoctoral fellows.

Exposure Coaches. Exposure coaches (ECs) are selected from a pool of college-educated (ie, BA, BS) candidates recruited for a dual exposure coach/research assistant position in our center, as per past hiring protocols for this position and in conjunction with our hospital human resources procedures for selection, interviewing, and onboarding. ECs each have a caseload of up to 12 participants at a time, depending on their study role.

Exposure Coach Training. All ECs complete a 12-hour training that includes didactic and experiential training components. Didactic content is distributed across 14 modules and has been used in multiple National Institutes of Health (NIH)–funded grants. Didactic content aligns with the principle-based treatment protocol described above, and covers such topics as the following: (1) diagnostic considerations for anxiety disorders and OCD; (2) psychoeducation; (3) the CBT model of anxiety and maintenance processes; (4) functional assessment; (5) exposure therapy rationale and principles for optimizing delivery; and (6) orientation to quality monitoring tools (ie, Exposure Guide [EG]).[74] Experiential learning strategies include role plays, evaluation of videotaped sessions, and participation in self-exposure tasks, which is consistent with the literature on integrating active strategies to promote therapist learning.[86,87] ECs receive an additional 2 hours of training on procedures related to conducting exposures in the home (eg, safety issues, motivation, and documentation). The training, directed by clinicians, reflects existing hospital and clinic practices. After completing a total of 12 hours of modular training, coaches join previously trained ECs for a minimum of 3 visits until a supervisor approves their leading a home/community exposure visit independently.

Quality Assurance Procedures

Quality Monitoring. The quality assurance procedure was developed and validated over the course of 4 therapist training studies, including 165 therapist participants. Participating therapists practicing in diverse practice settings, including 12 community mental health clinics and 7 private practices, were deliberately recruited to increase the generalizability of training and supervision procedures. The quality monitoring tool, the Exposure Guide (EG), was developed through these studies[74,88–90] and designed to support therapists in measuring and calibrating their own behaviors during exposure sessions. Studies involved microanalytic coding of therapy sessions to identify therapist delivery behaviors associated with differential treatment response, development and iterative revision of the EG in collaboration with partners, and implementation and evaluation of the EG across diverse and varied mental health service settings. Findings have demonstrated that therapists using the EG in practice have produced a 23.3% higher rate of treatment response relative to therapists using a general adherence-based monitoring form that assesses the presence or absence of various treatment components and does not highlight the functional link between delivery behavior and patient anxiety levels.

The result of the studies outlined above is a well-validated quality monitoring measure that also promotes optimization of therapist delivery behaviors. Both licensed and unlicensed providers have demonstrated ongoing reliability on this tool. Within the current study, providers (both licensed and non-licensed) complete the EG after each treatment session, which takes approximately 2 to 5 minutes. This process prompts therapist reflection about delivery behaviors during exposure, with supporting contextual information to help therapists evaluate the function of their own behavior and to problem-solve barriers to using the recommended behaviors. The first page uses a "skip out" procedure to determine whether an exposure took place. If an exposure did not occur, therapists are asked to consider which barriers were present. If an exposure occurred, therapists proceed to check items for exposure preparation, therapist behaviors during exposure, and post-exposure reflection. The final page of the EG provides brief troubleshooting related to common problems that can affect therapist behaviors. For example, if an exposure was "too hard," suggestions are provided to address this in the next session without use of fear-decreasing behaviors (eg, using intensifying behaviors judiciously, revisiting the hierarchy to find an easier exposure). The organizing framework of the EG incorporates scientific input (eg, EG items and structure) in conjunction with real-time treatment decisions based on a therapist's context-specific observations, which follows recommendations for coordinated strategic action.[90] All therapy sessions in the current trial are audio- and/or video-taped to facilitate ongoing EG tailoring to the team-based model and to ensure high-quality delivery. Using these recordings, study staff will double-rate the EG for a randomly selected 20% of all treatment sessions.

Supervision. After initial training, ECs attend supervision with the licensed provider holding the case(s) along with other ECs sharing a case with that licensed provider (Figure 3). Approximately 10 to 15 minutes are allocated for supervision of each case depending on case complexity, which leads to discussion of 4 to 6 cases within an hour of supervision. We have found over time that this level of supervision is of crucial importance for appropriate clinical

FIGURE 3 Monthly Structure of Sessions Presented by Provider, Location, Duration, and Accompanying Quality Assurance Procedures

Wk 1 Visit	Wk 2 Visit	Wk 3 Visit	Wk 4 Visit
Licensed Clinician --- Office --- 60 mins	EC --- Home/ Community --- 90 mins	EC --- Home/ Community --- 90 mins	EC --- Home/ Community --- 90 mins
Wk1 QA	**Wk 2 QA**	**Wk 3 QA**	**Wk 4 QA**
EC Update 15 min/case	EC Supervision 15 min/case --- EG review	EC Supervision 15 min/case --- EG review	EC Supervision 15 min/case --- EG review

Note: *EC = exposure coach; EG = exposure guide; QA = quality assurance.*

oversight and maintenance of quality in team-based models. Based on supervisors' reports, the most frequent topics brought to supervision include the following: (1) troubleshooting and addressing barriers to exposure; (2) understanding the function of symptoms, functional hierarchy development, and exposure principles; (3) exposure selection and planning; (4) delivery processes; (5) boundary issues; (6) motivation; and (7) aspects of family context. Consistent with training procedures, supervision also emphasizes active learning strategies and cultural responsiveness, including awareness of one's own identities and possible biases, and of individual differences and situations that would be inappropriate for exposure (eg, a realistic fear; see Falender *et al.*[91] for a thorough review). We believe that this type of self-exploration in supervision for both licensed and non-licensed providers strengthens alliance and team functioning. Centering relationships and working collaboratively are key to the effectiveness of this model, although we did not formally measure these factors in this study.

Assessment Procedures

We use a multi-gate screening process to reduce participant burden (see "Sample Selection" above for details of screening procedures). Assessments map directly onto the primary outcomes and study aims. Study measures are summarized in Table 2,[92–104] which specifies the relationship between measures, corresponding symptom domains/specific aims, source of rating and timing of administration. Consistent with an intent-to-treat approach, all participants are assessed at all time points.

Over the course of active treatment, a participant's symptoms are assessed at baseline and weeks 6, 12, 18, and 24 (or post treatment). Following acute treatment, all study participants participate in naturalistic follow-up (FU) assessments at 3- and 6-months post treatment. Symptoms are assessed by an independent evaluator (IE) who is masked to treatment condition at each timepoint. Assessments last approximately 30 to 60 minutes and occur in-person in the office or remotely (via Web-based platform or telephone).

Weekly Clinician-, Caregiver-, and Child-Rated Measures. Each week, after a treatment session, clinicians and ECs allow 5 minutes for caregivers and youth (8+ years of age) to complete brief self-report questionnaires assessing therapeutic alliance. These questionnaires are completed on paper or electronically through Research Electronic Data Capture (REDCap). After the treatment session has ended, clinicians and ECs complete weekly clinician-rated measures measuring exposure completion and family homework compliance.

Independent Evaluator–Conducted Symptom Assessments. All IEs are trained to a reliable standard on the diagnostic and interviewer-delivered measures through joint interviews, videotape reviews, and formalized training. Similar to procedures implemented in prior large trials, training includes orientation to the measures, conducting assessment procedures, and IE observation of training tapes. To be certified, IE trainees must code previously certified tapes with acceptable inter-rater reliability (ie, 0.85).

TABLE 2 Patient-Level Measures and Timing of Administration

				Administration time							
Measure	**Purpose**	**Aim**	**Reporter**	**Baseline**	**Weekly**	**6 wk**	**12 wk**	**18 wk**	**24 wk**	**3 moFU**	**6 mo FU**
MINI Kid Version 7.0[84]	*DSM-5* diagnoses	Inc./Exc.	IE	X							
Children's Yale–Brown Obsessive Compulsive Scale[92] or Pediatric Anxiety Rating Scale[93]	Symptom severity	Inc./Exc. 1b	IE	X		X	X	X	X	X	X
Client Satisfaction Questionnaire[94]	Treatment satisfaction	1a	Parent, participant			X	X	X	X	X	X
Therapeutic Alliance Scale for Caregivers and Parents; Therapeutic Alliance Scale for Children[95,96]	Treatment alliance	1a	Parent, participant		X						
Homework Compliance[97]	Treatment engagement	1a	Clinician		X						
Clinical Global Impression Scales (CGI)[98]	Treatment response	1b, 2	IE	X		X	X	X	X	X	X
Pediatric Quality of Life Enjoyment & Satisfaction Questionnaire[99]	Quality of life	1c	Parent, participant	X		X	X	X	X	X	X
Child Sheehan Disability Scale[100]	Disability	1c	Parent, participant	X		X	X	X	X	X	X
Top Problems Assessment[101]	Consumer improvement	1c	Parent, participant	X		X	X	X	X	X	X
Caregiver Strain Questionnaire[102]	Predictors	2	Parent	X		X	X	X	X	X	X
Barriers to Treatment Questionnaire[103]	Predictors	2	Parent	X					X	X	X
Pediatric Accommodation Scale– Parent Report[104]	Predictors	2	Parent	X		X	X	X	X	X	X
Demographics/ (Caregiver and Youth versions)	Predictors	2	Parent, participant	X							

Note: *Exc.= exclusion; FU = follow-up; IE = independent evaluator; Inc.= inclusion; MINI KID = Mini–International Neuropsychiatric Interview for Children and Adolescents.*

Study Measures

Included measures were selected to map onto specific aims developed collaboratively by investigators and partners. Specifically, Aim 1a measures evaluate the following: (1) satisfaction with the treatment program and assigned condition; (2) engagement in between-session treatment activities (ie, homework) and study procedures (eg, follow-up assessments); and (3) alliance and relationship with treatment providers. Aim 1b measures assess anxiety symptoms, including overall number of symptoms, functional impairment, and level of associated distress. Relatedly, Aim 1c measures examine global functioning and quality of life (ie, functioning above and beyond anxiety-related impairment). Aim 2 measures were selected to identify key predictors of treatment response, including the following: (1) severity of illness at baseline; (2) barriers to treatment participation (eg, logistical and structural barriers to treatment access and engagement); (3) caregiver accommodation (ie, caregiver behaviors intended to alleviate participant anxiety symptoms in the short term); and (4) demographic factors (eg, socioeconomic status, race, or ethnicity). Table 2 provides a complete list of included measures.

Power and Sample Size

Power was estimated for the primary outcome of treatment response based on the Clinical Global Impression—Improvement (CGI-I) scale (Aim 1b, responder status; CGI-I $\leq$2), given that this outcome is a top priority to all partners and has been widely used as an outcome in prior clinical trials. In prior clinical trials of office-based CBT for youth with anxiety, the proportion of responders has ranged from 59% to 72%.[22,105] We anticipate that our sample will differ from those in prior studies in 2 important ways: (1) inclusion of youth with ASD; and (2) a larger subset of families with significant barriers to office-based care, who may have self-selected out of prior trials requiring office-based CBT. Therefore, we conservatively estimate a 59% response rate in the Provider-Centered treatment arm. An *a priori* threshold of 20% difference in response rate was determined by the research team to be clinically meaningful and also sensitive to the concerns of community partners.[106] Therefore, power was calculated using G*Power Version 3.1.2 for testing a between-group difference of 20% in the primary outcome (responder status; CGI-I $\leq$2). With a total randomized sample of 333, our main analysis has 95.7% power to detect a 20% treatment response (aim 1b), and the minimum detectable treatment response difference with 80% power is 15.6%. Within pre-planned stratified analyses that are expected to evenly divide the sample (by gender/sex, severity, age), we will have adequate power (80%) to detect a 20.4% treatment response difference. This sample also allows us to engage in meaningful subgroup analysis examining participant groups who may not benefit to the same degree as other members of the sample. Participants are considered randomized when they learn of their assignment to condition after the baseline assessments.

Statistical Analysis

Primary analyses will use an intent-to-treat approach, meaning that all persons randomized will be included in the outcome analysis. Missing data will be imputed using multiple imputation procedures.[107,108] Outcome analysis will use generalized linear models, choosing appropriate link functions (eg, identity for continuous outcomes, logit for binary outcomes) given the scale of the dependent variables. Outcomes will be follow-up values on outcome measures, and baseline (pre-treatment) measures will be used as covariates in an analysis of covariance (ANCOVA) regression framework as appropriate. This is a powerful approach to evaluating randomized trials.[107] For aim 3, we will use a discrete time survival analysis framework to compare time to treatment response. Consistent with CONSORT guidelines, we have selected *a priori* covariates in our main analysis, which include factors used in the randomization procedure (age, gender/sex, baseline severity) as well as participant race/ethnicity. Because we include youth on stable doses of psychotropic medications (see Inclusion and Exclusion Criteria), we will also include medication status as a covariate using indicators regarding the use of psychostimulants (yes/no) and of serotonin reuptake inhibitors (SRIs) (yes/no).

Missing Data

Although attrition may be lower in this study, particularly in the patient-centered team-based treatment arm, we conservatively estimate a 15% attrition rate for final sample size. Multiple imputation (MI) techniques appropriate for missing data type (categorical, continuous, or both) will use covariates identified *a priori,* observed outcome variables, and treatment assignment data to generate imputation models. A total of 20 complete imputation data sets will be created for each aim. Sensitivity analyses will describe the extent to which our MI-based inferences are subject to violations of the assumption that the missing data mechanism is not random with respect to the value of the outcome that would have been observed, had it been observed, conditional on observed data.

DISCUSSION

We are in the midst of an unprecedented nationwide children's mental health crisis in the wake of the COVID-19 pandemic, with anxiety symptoms having doubled in

youth[109] and a rapid corresponding increase in demand for services.[110–112] This is coupled with a national shortage of child mental health professionals predating the pandemic, which means that difficulty accessing care and extremely long wait times have only gotten worse, particularly for historically marginalized youth.[113,114] Even youth with anxiety who are engaged in treatment are not likely to be receiving high-quality exposure-based CBT, as few providers outside of academic medical centers are trained in this approach.[64] In addition, the delivery of this treatment most often involves weekly office visits, which can create additional barriers such as limited accessibility (ie, transportation issues, work conflict) or difficulties translating therapeutic exercises to the home. For youth from historically marginalized backgrounds and those living in poverty, these barriers are significantly greater and amplify difficulty in accessing quality care.[33–35] This Study Protocol and Methods Advancement paper presents an innovative method for applying a patient-centered (treatment occurring in the home/community) team-based model of exposure-based CBT for youth with anxiety disorders and/or OCD, which holds promise to improve access to this gold-standard treatment for anxiety disorders for a larger number of patients. Specifically, in the current study, bachelor's degree–level staff (ECs) and licensed psychologists use a task-sharing approach to a principle-guided treatment to increase psychologist capacity and in turn to increase patient access to care. In addition to the use of an evidence-based practice (exposure-based CBT), our model includes specific empirically tested tools for ongoing staff training, supervision, and quality monitoring as well as a roadmap for community partner involvement.

Above and beyond addressing a shortage in the mental health workforce, the current study aims to maintain and promote high-quality, evidence-based services within the team-based framework. There is consensus in the task-sharing literature that ongoing supervision and quality monitoring is essential for maintaining best practices[44,115–117]; however, there is relatively little information about how quality assurance procedures are developed and tailored to support the successful implementation and scalability of team-based models. Treatment quality predicts clinical outcomes in controlled trials of CBT for anxiety, and variation in delivery quality has been observed even among highly trained and experienced psychologists.[88] Although studies have generally not shown poorer outcomes for patients receiving care under less experienced providers,[118,119] reliance on less highly trained providers to deliver CBT risks reducing treatment effectiveness relative to provider-centered delivery.

To address such barriers, this model uses staff training and supervision methods that have been used in prior studies[74,88–90] designed to disseminate exposure-based CBT in a variety of settings, and with providers with different levels of training. As detailed above, all clinical staff are initially trained using a flexible, principle-guided treatment protocol that focuses on the broad principles of exposure that lead to therapeutic change, such as challenging one's core fears in a gradual way using titration and hierarchy development, instead of following a standardized procedure for each session. Treatment quality control is ongoing and is achieved in 2 main ways: (1) through the use of specific supervision practices; and 2) through the use of the EG.[74,88,120] Without a robust and thoughtfully developed supervision and quality control strategy, such team-based models are likely to have much greater variation in fidelity and overall effectiveness.

It is difficult to describe fully in words how the development of long-term relationships with multiple key partner groups has meaningfully informed and altered the conduct and roadmap of this study over a period of many years. By listening carefully to the voices of individual partners, content-specific partner groups, and the collective steering committee, we have honed our approach to facilitating and maintaining active partner engagement over the years, which has led to 100% retention of group members. The contributions of the 30 partners across 6 groups (patients and family, home-based providers, patient advocates, hospital administration, payer, and diversity, equity, and inclusion [DEI] experts) have solved practical and pragmatic problems and have made significant contributions throughout the project to support outreach and recruitment, particularly of youth who have been economically/socially marginalized and/or historically underrepresented in clinical science and underserved in clinical practice, and have helped to identify the ways in which access is still limited for many families. For example, at the onset of the COVID-19 pandemic, hospital administrative partners helped facilitate a temporary transition to a telehealth-based delivery model to prevent the suspension of services for families. This support included helping the study team identify different ways for families to use available devices for sessions and to navigate issues of Internet availability, and ultimately led to supplemental funding to develop and pilot a telehealth model of a team-based treatment.[59]

One of the most significant achievements of the ongoing collaboration with partners has been the development of a billing protocol to cover this team-based model of care through insurance prior to the completion of the study. Thanks to the collaboration with our regional payer partner, we successfully negotiated a contract to fully cover the team-

based model of care, including exposure coaching, in our hospital outpatient department. This initial success is helping pave the way for developing a similar billing protocol with a broader range of insurers, including publicly funded ones, which is an effort that is currently underway. Although we suspect that team-based models of care will decrease barriers, meet family needs, and improve office-based outcomes for many families in outpatient care, payer level factors are likely a primary barrier to scaling up and disseminating widely the "patient-centered" service model examined in this study. The development of additional agreements will have a broad impact on accessibility of services in different contexts and for a more diverse set of patients and families to ensure that products from the study have a sustained impact through systemic adoption in outpatient care.

The team-based model of care proposed in this study also has the potential to work with other types of evidence-based practices (eg, parent behavioral training) and provider teams, thus helping address the critical lack of mental health providers, while also supporting increased workforce diversity. Recent federal reports suggest that inequity persists due to "an inadequate workforce to meet the mental health needs of the population[121]" and suggest that the deployment of Community Health Workers (CHWs) offers a promising and scalable model for addressing the current treatment gap while also rapidly diversifying the composition of the workforce.[122] As CHWs are typically members of the communities that they serve, they are uniquely well suited to build trust and to address community-specific barriers such as structural complications (eg, lack of transportation), culturally bound conceptualizations of mental health, low mental health literacy, mental health stigma, and negative perceptions of mental health care.[123] Although the current study used PhD-level licensed psychologists and bachelor's degree–level ECs, future work can and should evaluate the model among other provider types, including master's degree–level clinicians and CHWs.

Although this service model has the potential to reduce access barriers, we would be remiss not to comment on the fact that this study takes place in an academic medical setting and thus is restricted to youth who typically receive care in such settings. There is a resounding call from systematic research reviews, advocacy groups, and our extensive group of partners to prioritize the inclusion of youth who have been historically underserved and marginalized (eg, based on race, ethnicity, or income) in comparative effectiveness trials. This is in response to the staggering and longstanding failure to include these youth in clinical trials (virtually all trials have been conducted with disproportionately White, non-Latino/a/e samples of moderate to high economic means) as well as the clear need to tailor treatment to better address barriers to access, quality, and clinical improvement for these groups. Despite efforts to include a more diverse sample by working closely with community partners (eg, pediatric practices, advocacy groups, schools, community engagement experts) who serve these youth and families and by prioritizing them on our waitlist, the setting of an academic medical center located on the outskirts of an urban metropolitan area remains a barrier in many ways (eg, transportation, lack of diversity among licensed staff). The study sample to date is already much more diverse in terms of race and ethnicity than multiple previous randomized controlled trials (RCTs) in anxiety/OCD,[77–79,124] and it is imperative to continue to improve upon this.

We would be remiss not to comment on the way in which the COVID-19 pandemic affected this study and the overall field of mental health. The study was designed prior to 2020, when telehealth was not considered routine care. As mentioned above, the study team received a supplemental grant to conduct an open trial of team-based CBT delivered via telehealth in 2020, and telehealth sessions are used sparingly in the larger trial to meet the needs of families while following public health and hospital guidelines. Although we cannot fully test a telehealth-delivered team-based treatment arm as part of this study, we recognize that in the wake of the pandemic, many mental health clinics have transitioned to offering some or all services via telehealth.[125] Although systematic reviews consistently show comparable outcomes for in-person vs telehealth treatment of anxiety,[126–128] there are noted instances when subgroups of patients respond better to one modality than the other. For instance, individuals with low motivation tend to struggle more with engagement during telehealth services, and those with limited technology resources struggle to reliably use telehealth.[129] All of these systematic reviews highlight the need for comparative research to fill critical gaps in understanding which subgroups are more likely to benefit from telehealth or in-person delivery modalities. More research is needed that considers individual-level characteristics such as needs, preferences, and digital skills, to better inform care modality decisions in typical practice settings. Treatment modality has significant implications for the effectiveness of treatment, as it can mitigate or exacerbate treatment barriers,[130] particularly for vulnerable youth.[131]

Despite its limitations, results of this study will provide important information on the effectiveness of a team-based patient-centered model that has the potential to increase provider capacity and reduce barriers to access to care. To our knowledge, this study will be among the very largest single-site effectiveness studies in pediatric OCD and

anxiety and will be especially notable in terms of the innovative service delivery model, the diversity of the sample (eg, in terms of demographic characteristics, identities held by participants and families, and comorbid diagnoses such as ASD), the use of empirically derived quality assurance and supervision strategies, and the purposeful long-term engagement of a network of study partners. Yet, there is still a gap in information about how to integrate in sustainable and culturally responsive ways these innovative service models in community settings where services are needed most. It is of critical importance that we examine how team-based outpatient service models of youth anxiety treatment work best to improve functioning and promote access and engagement in real-life community settings, while maintaining high quality. Future initiatives must include further exploration of the use of team-based models to deliver exposure-based treatment in community mental health settings where youth have not typically had access to high-quality care. These initiatives should balance the inclusion of necessary quality monitoring with meaningful, ongoing partner engagement to ensure equitable access to care for all youth, and to develop effective and inclusive strategies to optimize and sustain treatment access, quality, and outcomes.

CRediT authorship contribution statement

Jennifer Freeman: Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Joshua Kemp:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Erin O'Connor:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Data curation. **Jennifer Herren:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Christopher Georgiadis:** Writing – review & editing, Writing – original draft, Funding acquisition, Conceptualization. **Giulia Righi:** Writing – review & editing, Writing – original draft, Supervision. **Kristen Benito:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

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