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FINAL RESEARCH REPORT

Using Team-Based Behavioral Therapy by Telehealth to Treat Youth with Anxiety and Obsessive-Compulsive Disorder

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ABSTRACT

Background: This report presents the preliminary results of a 1-year, single-arm open (ie, nonrandomized) trial of a novel telehealth cognitive behavior therapy (CBT) for pediatric patients with anxiety and obsessive-compulsive disorder (OCD) awarded alongside an existing comparative effectiveness study (referred to hereafter as the "main study"). Use of CBT for anxious youth is an established, evidence-based intervention and the first-line treatment for child anxiety. Exposure therapy is the primary component of CBT for anxious youth and involves learning to gradually face fears. The main study seeks to test a novel home-delivery model using bachelor's degree–level staff to provide adjunctive treatment under PhD psychologist supervision. The comparison arm is standard outpatient treatment with a psychologist ("office"). Because of the COVID-19 pandemic and associated changes in hospital policy, we temporarily halted participant recruitment to these 2 in-person treatment arms in March 2020 and opened enrollment to patient-centered telehealth treatment (N = 46), modeled after our home treatment arm but occurring fully remotely.

Objectives: Although traditional telehealth treatments can address barriers associated with in-person treatment, they have yet to be employed to increase service capacity by using bachelor's degree–level staff to provide treatment services directly under the supervision of PhD-level psychologists. This supplemental project aimed to provide preliminary data for a telehealth delivery system that addresses patient-stakeholder needs, extends the reach of services to relevant contexts outside the office, and expands the labor pool of available clinicians. The aims of this supplement followed those of the main study but emphasized engagement and satisfaction as the primary aims. Secondary and exploratory aims were intended to inform future large-sample comparative effectiveness research:

- *Supplement aim 1:* Describe stakeholder-driven outcomes during telehealth-based treatment, including patient and caregiver treatment engagement and satisfaction (aim 1a; primary aims), course of anxiety/OCD symptoms and treatment response (aim 1b; secondary aim), and associated disability (aim 1c; secondary aim).
- *Supplement aim 2:* Examine predictors of treatment response, including illness severity, barriers to treatment, caregiver strain, and caregiver accommodation (exploratory aim).
- *Supplement aim 3:* Describe clinician capacity and the efficiency of the patient-centered telehealth model (exploratory aim).

Methods: This study was a single-arm, open trial of a novel patient-centered telehealth treatment. Participants included 46 youth between the ages of 5 and 18 years diagnosed with primary anxiety or OCD who received CBT through the novel telehealth model, whereby patients meet monthly with a supervising PhD and with bachelor's degree–level staff all other weeks of the month. Participants received treatment for up to 6 months and completed symptom assessments every 6 weeks throughout treatment. Preliminary descriptive pre-post analyses were conducted for primary and secondary aims. Clinician capacity was measured using the number of psychologist hours for clinical activities, and efficiency was modeled using a Kaplan-Meier survival analysis.

Results: A total of 46 participants were entered into patient-centered telehealth treatment and received treatment. Participants were 5 to 18 years old (mean [SD], 11.3 [3.5] years). Half the participants (50%) reported that their biological sex was female, and half reported that their biological sex was male. The majority of participants (87%) reported their race as White. Preliminary descriptive results demonstrated high patient and caregiver treatment engagement (mean, 19 of 24 sessions attended) and satisfaction (mean, 38.4 patient report and 45.0 caregiver report of 48 possible points on the Therapeutic Alliance Scale, indicating high therapeutic alliance; mean, 28.8 patient report and 29.6 caregiver report of 32 possible points on the Client Satisfaction Questionnaire-8 after treatment, indicating high treatment satisfaction) during telehealth treatment. Moreover, results indicated that anxiety and OCD symptoms decreased significantly from baseline to after treatment. In total, 68% of participants were classified as treatment responders after treatment, as measured by the Clinical Global Impression–Improvement scale. Patient- and caregiver-reported top problems, patient-reported functional impairment, and caregiver-reported quality of life improved significantly from baseline to after treatment. Clinical psychologist capacity increased more than 2-fold by using bachelor's degree–level staff.

Conclusions: Patient-centered telehealth treatment demonstrates preliminary feasibility and acceptability based on high rates of treatment engagement and satisfaction. Preliminary results also suggest significant symptom reductions and improvement in disability associated with anxiety/OCD symptoms. This novel telehealth delivery model using bachelor's degree–level staff to provide adjunctive treatment has the potential to increase clinician capacity and reduce barriers to mental health care access for youth during and beyond the COVID-19 pandemic.

Limitations: Study limitations include the single-arm, open trial design, which limits our ability to draw conclusions about the causality of symptom improvement and the small sample size that limited statistical power. A lack of racial and ethnic diversity in the study sample limited the generalizability of the findings. The study setting (an anxiety specialty clinic) also limited generalizability. From a measurement standpoint, certain measures were not administered to patients who were too young to complete them, and some families missed symptom assessments, further limiting statistical power. Also, most but not all outcome measures have definitions of clinically meaningful change. Finally, although we had significant stakeholder input throughout the study, the short time in which the award application was written and funded limited the amount of initial stakeholder feedback and collaboration in developing the proposal.

BACKGROUND

Evidence-based delivery models that optimize remote access to care are desperately needed given the mental health burden of the COVID-19 pandemic.[1,2] The pandemic has only exacerbated the ways in which our current outpatient model does not meet the needs of families with anxious children (eg, access barriers, therapist shortages). Additionally, there is an increasing need for behavioral health treatments focused on helping patients with anxiety related to the pandemic itself. Telehealth treatment models are a necessary health system adaptation in the pandemic health crisis but also may improve access to care after the pandemic. Data about novel telehealth delivery models are both highly informative and relevant for the future mental health care landscape.

A growing body of research indicates that telehealth-delivered cognitive behavior therapy (CBT) is effective for youth with anxiety and obsessive-compulsive disorder (OCD) when the services are provided by a doctoral-level clinician, with treatment responder rates ranging from 73% to 82%.[3-5] Use of CBT for anxious youth is an established, evidence-based intervention and the first-line treatment for child anxiety. Exposure therapy is the primary component of CBT for anxious youth and involves learning to gradually face fears or approach anxiety-provoking stimuli. Such treatments are usually provided by a PhD-level psychologist in an individual or family-based format, and the average duration of treatment is approximately 3 to 4 months. Although traditional telehealth treatments can address barriers associated with face-to-face treatment, they have yet to be used to increase service capacity. Using a team-based delivery model wherein bachelor's degree–level staff provide adjunctive exposure therapy under the supervision of a PhD-level psychologist is an innovative service design and has the potential to radically expand treatment capacity.

We are currently completing a 5-year randomized trial to compare the effectiveness of 2 models of CBT—patient-centered (home) delivery vs clinician-centered (office) delivery—for 333 youth aged 5 to 18 years with anxiety and OCD. This trial (referred to as the "main study" in this report) was funded in 2018 as part of PCORI's Improving Healthcare Systems funding announcement. Use of CBT for anxious youth is an established, evidence-based intervention,

but our main study seeks to test a novel home-delivery model combining doctoral-level clinicians with bachelor's degree–level clinicians (called *mobile exposure coaches*) who can provide care outside the office setting. Long-term outcomes of the main study include establishing a service delivery model with payer buy-in and potential for sustainability.

Because of COVID-19–related changes in hospital policy, to maintain patient and staff health and to respond to our multiple stakeholder groups, we temporarily halted participant recruitment for our main study in March 2020. We received a COVID-19 enhancement award to conduct an open trial of an additional treatment arm: patient-centered telehealth (N = 46) modeled after our patient-centered home treatment and using bachelor's degree–level clinicians but occurring fully remotely. This supplemental project fully used the infrastructure, staffing, and stakeholder groups of our main study and provides preliminary data supporting a telehealth delivery system that addresses patient needs, extends the reach of services to relevant contexts outside the office, and expands the labor pool of available clinicians. Primary outcomes were patient and caregiver treatment engagement and satisfaction. Secondary outcomes were change in anxiety and OCD symptoms and associated disability. Exploratory analyses included predictors of treatment response, time course of response, and clinician capacity and efficiency.

Of note, at the time the supplement application was written and funded (April-May 2020), we had limited information about what would become the lengthy course of the pandemic. We anticipated reopening in-person recruitment for the main study before completion of the supplement and temporarily randomizing participants to 3 groups (ie, home, office, and telehealth), but because of the extended length of the public health crisis, all telehealth participants were enrolled before we reopened our main study (which later reopened on March 17, 2021). Thus, this report outlines preliminary results from a single-arm, open trial of patient-centered telehealth. This report does not include results of the ongoing main study.

Supplement Aim 1

In this aim, we described stakeholder-driven outcomes during telehealth-based treatment, including (1a) patient and caregiver treatment engagement and satisfaction, (1b) course of anxiety/OCD symptoms and treatment response, and (1c) associated disability:

- **Supplement aim 1a: patient and caregiver treatment engagement and satisfaction.** Describe patient and caregiver treatment engagement and satisfaction during patient-centered telehealth-based treatment (primary aim).

- **Supplement aim 1b: course of anxiety/OCD symptoms and treatment response.** Describe the course of anxiety/OCD symptoms and the percentage of participants who achieved responder status during patient-centered telehealth treatment (secondary aim).

- **Supplement aim 1c: associated disability.** Describe disability associated with anxiety/OCD symptoms, including patient- and caregiver-identified top problems, functional impairment, and quality of life (QOL), over the course of patient-centered telehealth treatment (secondary aim).

Supplement Aim 2

In this aim, we examined predictors of treatment response, including illness severity, barriers to treatment, caregiver strain, and caregiver accommodation (exploratory aim).

Supplement Aim 3

In this aim, we described clinician capacity and the efficiency of the patient-centered telehealth model (exploratory aim).

PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

Five distinct stakeholder groups—Patient and Family, Payer, Hospital Leadership, Mobile Therapist, and Patient Advocate—each met every 6 months for 60 minutes during the supplemental project period (2 meetings). An additional group—the Study Steering Committee group—which consisted of representative members from each individual stakeholder group, met every 6 months for 90 minutes (2 meetings). There were 23 total stakeholders, including 9 parent stakeholders, 3 patient stakeholders, 2 payer stakeholders, 3 mobile therapist stakeholders, 3 hospital leadership stakeholders, and 3 patient advocate stakeholders. Stakeholders played a significant role in designing the structure (eg, visit time, training, and supervision protocols) of the patient-centered (home) delivery model, which was converted from an in-person format in the main study to the telehealth format for the current supplement. As such, the stakeholders guiding execution of the telehealth supplement had contributed to the overall structure of the service; through ongoing stakeholder meetings, they expressed relief and gratitude that the model could continue in a telehealth format to meet patient needs for care during the COVID-19 pandemic.

The robust stakeholder infrastructure used throughout the telehealth supplement was originally developed for our main study and purposely employed for the current project. Patient and parent stakeholders were identified through their past involvement in either outpatient or partial hospitalization care in our Pediatric Anxiety Research Center (PARC) at Bradley Hospital. Payer stakeholders were identified from previous collaborative work related to quality improvement metrics in outpatient care. Hospital Leadership stakeholders were Bradley Hospital's president, director of inpatient and intensive services, and the chief medical officer/director of outpatient services. Two mobile therapist stakeholders were identified by their leadership roles as mobile exposure coaches in our partial hospitalization program at PARC, and a third was identified from her role as director of Bradley Hospital's home-based intensive behavioral treatment program for children with autism spectrum disorder. Patient advocate stakeholders were identified by colleagues and through prior collaborative work related to health care public policy, health disparities, and pediatric medicine. We have had no

difficulty retaining stakeholders and have received ongoing positive feedback about their participation in meetings. Stakeholders are compensated for attending meetings, except for hospital administrative and payer stakeholders.

During this project, we were continuously impressed by the dedication and expertise of our varied stakeholder members. All stakeholder meetings were held virtually (via Zoom), and we were encouraged by the high attendance rate and engagement during this confusing transitional period of the pandemic. As a result of these stakeholder meetings being previously scheduled as part of the main study, the Payer and Mobile Therapist groups were held once during the planning phase before we received our telehealth supplement and once during the supplement. The Patient and Family, Hospital Leadership, and Patient Advocate meetings were all held right after we formally began our supplemental project and again in fall/winter 2020 during the active treatment phase of the study.

Before starting the telehealth supplement, we received feedback from our Payer stakeholder and Study Steering Committee members regarding insurance coverage of telehealth, patient preferences surrounding telehealth, and potential barriers from technology and internet access for certain families. Feedback specific to telehealth acceptability was collected during 2 cycles of stakeholder meetings that took place from April to December 2020. Stakeholders in all 6 of our groups (Hospital Leadership, Home-based Therapist, Patient Advocate, Patient and Family, Payer, and the Steering Committee) expressed strong support for a telehealth model that could address both access and capacity issues. Overall, all stakeholder groups discussed positive perceptions or experience with exposure treatment delivered through telehealth and viewed the current model of combining a PhD-level psychologist and a bachelor's degree–level clinician as acceptable and necessary in the current public health crisis.

Specifically, several stakeholders emphasized the importance of telehealth as a delivery method, noting that examining telehealth is "relevant, timely and like it has a lot of benefits" given the changing mental health landscape resulting from the COVID-19 pandemic. Numerous stakeholders across groups felt that telehealth is a great option for many underserved families that may not be able to access in-person treatment because of unpredictable parent work

schedules and transportation barriers and that it may increase access to historically underrepresented patient populations. One parent stakeholder drew from her professional experience: "As a public-school educator for underfunded schools, I can think of lots of families where both families work, and it would be hard to make it to treatment sessions in person. This might also improve the diversity of the study sample." Although home-based clinical stakeholders highlighted their experience delivering telehealth and its ability to increase patient access, they noted, "We have gotten a lot of kids from out of state that we normally can't treat, and exposures have been going well. We can help kids transition to classes (on a call with us on a device)." Furthermore, our payer stakeholder expressed interest in understanding how well telehealth works for their customers: "As we continue to see behavioral health services rise during COVID, there is going to be a point at which employer groups are asking, 'What am I paying for? Is this [telehealth] what my employee actually needs?'" Overall, study stakeholders from all groups expressed strong support for telehealth treatment and its acceptability.

Stakeholders also provided vital insight into changes in licensing of telehealth services, family comfort with the different treatment formats, and patient barriers to treatment access. Before the project started, Payer and Mobile Therapist stakeholders primarily discussed the need for new hospital and IRB approval for virtual treatment. The Mobile Therapist group focused on limited clinician access to personal protective equipment, provided updates on the challenges and benefits other clinicians have experienced while transitioning to telehealth, and provided suggestions for telehealth opportunities for training new hires in exposure therapy delivery. During the project, members of the Patient and Family stakeholder group discussed their own experiences transitioning to telehealth treatment and provided insight into which teleconferencing programs they found most user friendly. Members of our Payer, Hospital Leadership, and Patient Advocate groups discussed the statewide telehealth insurance coverage policies and possible barriers to insurance coverage for telehealth. Based on Payer group stakeholder feedback, we collected insurance information for study participants to inform sustainability planning for this model. Throughout the project period, study stakeholders provided support for telehealth treatment, helped inform methodological choices that made sense for patients and families (eg, virtual assessments, Zoom vs other platforms, appointment

scheduling in conjunction with virtual school) and expressed interest in our combined clinician model of telehealth as an accessible means of delivering therapy and increasing access to care, even after the COVID-19 pandemic ends.

METHODS

Study Overview

This study aimed to obtain initial data for a single-arm, patient-centered telehealth open trial with a pre-post design to enhance our main study of comprehensive patient-centered vs traditional clinician-centered delivery. The telehealth condition mirrored our main study's "home" condition, whereby patients met monthly with a supervising PhD (virtually) and with a bachelor's degree–level staff member once per week on all other weeks of the month (virtually). A total of 46 youth aged 5 to 18 years received exposure therapy for anxiety or OCD by telehealth using a HIPAA-compliant video platform (ie, Zoom). A trained bachelor's degree– or PhD-level independent evaluator assessed patient and caregiver treatment engagement and satisfaction (aim 1a; primary), anxiety and/or OCD symptom severity (aim 1b; secondary), and associated disability (ie, patient- and caregiver-identified problem severity, functional impairment, and QOL; aim 1c; secondary) at baseline and during active treatment at weeks 6, 12, 18, and 24. Illness severity, barriers to treatment, caregiver strain, and caregiver accommodation data collected at baseline were used as predictors of treatment response (aim 2; exploratory). Clinician capacity was described using the number of patients a given clinician could treat and the number of sessions until patient discharge. Clinician efficiency was analyzed using a Kaplan-Meier survival model to examine time course to treatment response (aim 3; exploratory).

Study Setting

The PARC is an integrated research and clinical program encompassing outpatient services and a range of partial hospitalization programs. The mission of PARC is to provide state-of-the-art assessment as well as behavioral and pharmacologic treatment to children and adolescents with anxiety disorders and OCD. Research on the etiology, phenomenology, and treatment of child anxiety and OCD is also conducted at PARC, and there have been ongoing grant-funded projects since 1999. PARC's mission is to achieve excellence in its roles as (1) caregivers dedicated to the application of effective treatment in the real places where children and families struggle most, tailored to their needs and values; (2) researchers developing and

testing new strategies to improve outcomes and extend the reach of effective care; (3) teachers training psychologists, physicians, and other clinicians to improve care and grow the workforce; (4) advocates improving public understanding, reducing stigma, and securing resources; and (5) colleagues supporting one another with the respect that guides our work with patients and families. The connections made with patients and families as part of our clinical service—and in particular our partial programs—have greatly expanded our presence in local and national patient and family advocacy networks and created the stakeholder impetus for both our main study and this current project.

We selected PARC for this COVID-19 supplement open trial given that it was the existing location for the main study and because it is where we first developed the mobile exposure coach role. Our patient-centered home treatment model grew out of feedback from patients and caregivers who had been treated by mobile exposure coaches as part of their care in our PARC partial hospitalization program. These families wished to continue having visits from a bachelor's degree–level clinician (referred to as a *mobile exposure coach*) in addition to a doctoral-level psychologist but at an outpatient level of care. For the current telehealth supplement, we used both existing hospital-level infrastructure (eg, bachelor's degree–level exposure coach model from our partial hospital program) and infrastructure from the main study (eg, intake procedures, payment processes, staff supervision groups).

Participants

Study participants were individuals and caregivers who called PARC looking for services for youth with anxiety or OCD concerns. The majority of participants were referred to the study from health care professionals (eg, pediatricians, mental health clinicians in the community) who were existing recruitment partners of PARC in the region. Some patients found the study by searching the internet or ClinicalTrials.gov or through KidsLink, our hospital's child mental health referral hotline. Interested callers completed a phone-based consent and eligibility screen; those who consented, met preliminary inclusion criteria, and identified as primarily seeking treatment for anxiety or OCD symptoms were eligible for the waitlist. When they reached the top of the waitlist, participants completed the informed consent and assent

process and had a more in-depth eligibility assessment with an independent evaluator, including a diagnostic interview (using the Mini-International Neuropsychiatric Interview for Children and Adolescents [MINI-KID]) and symptom-specific interviews (using the Pediatric Anxiety Rating Scale [PARS] and Children's Yale-Brown Obsessive Compulsive Scale [CY-BOCS] for anxiety and OCD, respectively). Independent evaluators were bachelor's degree– or PhD-level clinicians who underwent didactic training at PARC and were determined to be reliable assessors (eg, trainee ratings were consistent with established independent evaluator ratings). The cases were discussed in conference with the principal investigator or a study psychologist to determine whether the case was appropriate and eligible for the study in terms of severity and diagnoses.

To be included in this study, participants needed a primary or co-primary diagnosis of any anxiety disorder or OCD, although we included patients who also presented with other comorbid psychiatric diagnoses (including autism spectrum disorder) to increase the generalizability of our findings. We also included youth on stable doses of psychotropic medications, given high utilization of these medications in our population of interest and feedback from family stakeholders that exclusion for medication use would limit the relevance of findings. We felt that it was best to err on the side of being more inclusive and casting a wide net. Psychiatric conditions and symptoms likely to interfere with treatment (eg, psychosis and suicidality), however, served as exclusion criteria to test the treatment effectively and ensure that patients got the best possible care.

Inclusion criteria were (1) aged 5 to 18 years, inclusive; (2) primary or co-primary *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) *(DSM-5)* diagnosis of separation anxiety disorder, specific phobia, social anxiety disorder, panic disorder, generalized anxiety disorder, selective mutism, agoraphobia, or OCD (using the MINI-KID); (3) symptom duration of at least 3 months; (4) outpatient; and (5) presence of a stable parent or guardian who could participate in treatment.

Exclusion criteria were (1) other primary or co-primary psychiatric disorder that requires initiation of other active current treatment, (2) documented intellectual disability

(eg, nonverbal), (3) thought disorder or psychotic symptoms, (4) conduct disorder, (5) acute suicidality, (6) concurrent psychotherapy, (7) chronic medical illness that would preclude their active participation in treatment, and (8) treatment with psychotropic medication that was not stable (defined as no medication initiation or discontinuation within 4 weeks and no dose change within 2 weeks of baseline assessment).

Intervention

The patient-centered telehealth treatment model was based on our existing patient-centered home treatment model. Both patient-centered models use a novel, team-based delivery approach wherein treatment is delivered to each patient individually by 1 PhD-level psychologist (1 weekly visit per month) and 1 bachelor's degree–level mobile exposure coach (once per week on all other weeks of the month). Both models use existing hospital infrastructure (eg, for scheduling clinical visits, billing). The only difference between patient-centered telehealth treatment and the original patient-centered home-based model was the use of an online platform (in patients' homes and in the community via telehealth vs actually in person in patients' home and in the community). Telehealth-based treatment was deemed patient centered because it responded to patient and family needs (eg, by offering a viable treatment option within the context of the COVID-19 pandemic when in-person services were closed, increasing clinician capacity, reducing transportation barriers, and allowing for flexible scheduling).

The primary intervention delivered in this study was exposure therapy, the primary component of CBT that involves teaching patients gradually to approach feared stimuli. Treatment followed the exposure therapy for anxiety treatment manual, *Cognitive Behavioral Therapy for Anxiety and OCD,* written by the study team. It is based on manuals previously developed by Jennifer Freeman, PhD, and colleagues; has been used in our prior trials; and was designed for optimal flexibility. The manual incorporates community therapist feedback and is the standard of care in our PARC outpatient and partial hospital programs. The manual provides guidelines for CBT in anxious youth, including general reminders about principles and structure of treatment sessions, and specific guidance for using CBT with exposure for anxiety and OCD,

focusing on the basic skills of (1) psychoeducation, (2) hierarchy building, (3) exposure, and (4) relapse prevention. Both patients and their caregivers (if possible) play active roles in the treatment sessions. Patients and their caregivers (if possible) also complete treatment "homework" outside the session to increase treatment dose and support generalization of skills gained. An optional session for using rewards is also provided. This manual was designed to be used flexibly, does not need to be implemented "in order," and might involve many repetitions of the exposure session before proceeding to relapse prevention at the end of treatment. Based on our research, this flexible and theory-based approach contrasts with prior therapist training programs that required clinicians to follow a linear, sequential pattern; used a separate manual for each disorder; and largely ignored comorbidity or environmental barriers to treatment. Theory-based manuals allow for flexible integration of skills with existing practices rather than requiring session-by-session administration of techniques and are ideally suited for standardizing an intervention across settings. This flexibility is especially important for this population because studies suggest that 56% to 92% of patients with OCD have other comorbid mental health disorders.[6-9]

Participants received individual once-weekly treatment for up to 24 weeks, with some participants discharging early because of fully addressing anxiety/OCD targets. Once per month, participants met with a PhD-level psychologist on Zoom for 60 minutes. Participants met with their exposure coach, who delivered weekly, individual sessions that lasted 90 minutes on Zoom all other weeks of the month. Session content and intervention dose did not differ by clinician type. In other words, both sessions led by PhD psychologists and sessions led by mobile exposure coaches delivered the same treatment intervention (ie, exposure therapy). The once-monthly session with the PhD-level psychologist also tended to include more "big-picture" exposure planning, addressing family conflict and specific comorbidity, case conceptualization, discussion of parental concerns, and problem solving for specific barriers to treatment compliance. All sessions included family involvement to the degree that it was clinically indicated. PhD-level psychologists and mobile exposure coaches provided technical support with the online platform for patients and caregivers when needed.

PhD-level psychologists were existing staff psychologists at PARC based at Bradley Hospital. Mobile exposure coaches were selected from a national pool of candidates recruited for a dual exposure coach/research assistant position in our center per past hiring protocols for this position and in conjunction with our hospital human resources procedures for selection, interviewing, and onboarding. They were required to have a college degree. Four primary mobile exposure coaches each had a maximum caseload of 5 participants at a time, while 3 additional mobile exposure coaches had a caseload of 2 participants each.

All study therapists (PhD-level psychologists and mobile exposure coaches) took part in a 2-day training session conducted by study investigators (our team has used this training in 2 other NIH funded grants) to orient them to the treatment manual and Exposure Guide (EG). Training emphasized active learning strategies (eg, role plays, group participation in exposure task) consistent with the literature on therapist learning.[10,11] Day 1 provided training on exposure implementation and the principle-based treatment manual. Day 2 oriented study therapists to the content and principle-based rationale for EG items as well as definitions and use of the EG manual as a reference, if desired. In addition, all mobile exposure coaches participated in a series of training modules led by the study investigators. These modules included didactic and interactive sessions 60 to 120 minutes in length on the following topics:

- Introduction and Orientation

- Home Visit Safety

- Symptom Overview

- CBT Model and Exposure Rationale

- Foundational Therapeutic Skills

- Treatment Overview and Psychoeducation

- Core Fear and Hierarchy

- Exposure Delivery

- Supervision Documentation

- Risk Assessment and Reporting

Mobile exposure coaches received additional training on procedures related to conducting exposures by telehealth (eg, safety issues, motivation, and documentation). The trainings reflected existing Bradley Hospital and PARC program practices. Given the importance of testing valid supervision procedures for the patient-centered telehealth model, the treating PhD-level clinician also provided weekly group supervision for exposure coaches. Supervision focused on (1) understanding the function of symptoms, hierarchy development, and exposure principles; (2) discussion of exposure selection; (3) what coaches should be doing and saying during exposure; (4) boundary issues; (5) motivation; (6) underscoring the collaborative process of fighting anxiety as part of a team with respect for patients and families; and (7) addressing issues specific to the telehealth platform (eg, limits to exposure selection and practice, privacy, distractions, going off camera, child engagement).

Study Outcomes

Below are descriptions of the measures used.

Demographics

Demographic information was collected from caregivers and youth (aged ≥12 years) during the baseline assessment using a standardized demographics questionnaire.

Diagnostic and Inclusion Criteria Measures

Psychiatric diagnosis: MINI-KID.[12] The MINI-KID is a brief, structured, clinician-rated diagnostic interview that can be used with patients aged 4 to 18 years and their caregivers.[13] It is designed to assess the presence and severity of psychiatric disorders according to *DSM-5* and *International Statistical Classification of Diseases, Tenth Revision* criteria. Questions are organized into diagnostic modules and delivered in a yes/no format. The measure has demonstrated adequate reliability and validity.[12,13] Primary, co-primary, and secondary diagnoses were determined using the MINI-KID based on which presenting symptoms the

patient, caregivers, and evaluator felt were causing the most distress and interference. After an independent evaluator completed the diagnostic assessment with a family, the case was discussed in conference with PhD-level supervisors to review the results and establish consensus for assigned diagnoses.

Measures for aim 1a (primary aim). The measures for this aim were patient and caregiver treatment engagement and satisfaction.

Treatment engagement: attendance. Treatment attendance was measured by the number of sessions patients or their caregivers attended during active treatment. We also recorded session cancellations, treatment drop-outs (family lost to contact), and premature terminations (eg, because of symptom improvement, symptom worsening, or desire to pursue other treatment).

Treatment engagement: homework compliance. The homework compliance measure asks clinicians to rate both the quality and the quantity of patient and caregiver homework completed between treatment sessions. The measure asks clinicians to rate patient and caregiver homework compliance on a scale from 1 (indicating no compliance) to 7 (indicating excellent compliance). Our research group has used this form previously in multiple large-scale treatment trials, and it has been helpful in determining barriers to homework completion.[14]

Treatment satisfaction: Therapeutic Alliance Scale for Caregivers and Parents and Therapeutic Alliance Scale for Children–Revised. The Therapeutic Alliance Scale for Caregivers and Parents[15] is a 12-item measure of therapeutic alliance between caregivers and their child's therapist. This measure assesses the bond and collaboration between caregiver and therapist. Each item is rated using a scale from 0 ("not true") to 4 ("very much true"). Higher scores indicate stronger therapeutic alliance. The measure has demonstrated excellent reliability and validity.[15] The Therapeutic Alliance Scale for Children–Revised[16,17] is a 12-item measure of therapeutic alliance between a children/patients and their therapist, collected from

patients 8 years of age and older. This measure assesses the degree of affective bond between patient and therapist as well as the level of therapeutic task collaboration. Each item is rated using a scale from 0 ("not true") to 4 ("very much true"). This measure has demonstrated excellent reliability and validity.[16,17]

Treatment satisfaction: Client Satisfaction Questionnaire–8 Item. The Client Satisfaction Questionnaire–8 Item (CSQ-8)[18] is an 8-item patient- and caregiver-report questionnaire assessing consumer satisfaction with mental health services. The dimensions of consumer satisfaction include: physical surroundings, treatment staff, quality of service, outcome of service, and procedures. Each item is rated using a scale from 0 to 4, with higher scores indicating greater satisfaction with services. Youth 8 years of age and older and their caregivers each completed this measure.

Measures for aim 1b (secondary aim). The measures for this aim were course of anxiety/OCD symptoms and treatment response.

Anxiety symptoms: PARS. The PARS[19] is a clinician-administered measure for assessing the frequency, severity, and impairment of common anxiety disorders. The measure includes a checklist of specific symptoms as well as a severity rating scale that can be used to assess a variety of anxiety-related concerns. The measure provides an index of overall anxiety severity and has demonstrated adequate reliability and validity as the primary outcome measure in large clinical trials of anxiety disorder treatments.[20,21] The cutoff for a clinical level of anxiety symptoms is a score of 17.5 out of 35 possible points,[22] but this was not used to determine inclusion for the study, which was determined by our diagnostic interview (MINI-KID). Higher total scores indicate greater symptom frequency, severity, and impairment. The PARS was collected at participants' initial appointment and every 6 weeks throughout treatment to assess their anxiety symptom severity.

OCD symptoms: CY-BOCS. The CY-BOCS is a clinician-administered, "gold-standard" assessment of OCD symptom severity with excellent psychometric properties.[23] The measure consists of a symptom checklist and a 10-item rating scale. Each item is rated on a scale of 0 to

4 such that total severity scores range from 0 (no symptoms) to 40 (severe).[25] A score of 16 on the CY-BOCS is generally considered the cutoff for clinically significant symptoms.[14,25,26] The CY-BOCS was not used to determine eligibility, however. Rather, it was collected at participants' initial appointment and every 6 weeks throughout treatment to assess their OCD symptom severity. Participants completed the PARS (for primary anxiety disorder), CY-BOCS (for primary OCD), or both the PARS and the CY-BOCS for comorbid anxiety disorder and OCD.

Global symptom severity and treatment response: Clinical Global Impression–Severity and –Improvement scales. The Clinical Global Impression (CGI) scale[27] consists of 2 brief, clinician-rated measures of global severity and improvement in treatment for children and adults. The CGI–Severity (CGI-S) scale was used to rate clinical symptom severity alongside the MINI-KID, which was used to determine specific diagnoses at study entry. The CGI– Improvement (CGI-I) scale was the primary measure of treatment response in this study. The CGI-I scale is a single-item scale that ranges from 1 ("very much improved") to 7 ("very much worse"). Previous large-scale clinical trials[26] have defined clinically meaningful treatment response using this measure such that scores of 1 ("very much improved") and 2 ("much improved") indicate treatment response and all other scores from 3 ("minimally improved") to 7 ("very much worse") indicate treatment nonresponse. We used the same convention to define treatment response in this study. This measure has good psychometric properties.[28]

Measure for aim 1c (secondary aim). The measure for this aim was associated disability of anxiety/OCD symptoms.

Patient- and caregiver-identified top problems: Top Problems Assessment. The Top Problems Assessment[29] asks patients (all ages) and their caregivers together to collaboratively identify the top 3 problems that they feel are most important to address in treatment and rate the severity of these problems throughout treatment. This idiographic measure of impairment is driven by the individual needs and desires of the consumer. Respondents rate how much each problem bothers them from 0 ("not at all") to 10 ("very, very

much"). This measure has demonstrated strong reliability, validity, and sensitivity to change during treatment.[29]

Functional impairment: Sheehan Disability Scale–child and parent versions.
The Sheehan Disability Scale (SDS)[30] measures the extent to which anxiety or OCD symptoms interfere with a patient's daily functioning. The SDS assesses the influence of anxiety or OCD symptoms on school, social, and family functioning domains. Items are rated on an 11-point scale, ranging from 0 ("not at all") to 10 ("very, very much"). Higher scores indicate greater functional impairment. This measure was administered to both patients (9 years of age and older) and caregivers. This measure has demonstrated acceptable validity and reliability.[30]

QOL: The Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire.
The Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q)[31] is a 13-item patient- and caregiver-report measure of patient functioning in life that uses a 5-point ratings scale, with higher scores indicating better QOL. This measure was completed by both patients (6 years of age and older) and caregivers. The measure assesses the quality of the patient's life in a variety of domains. Versions of this measure have been used in our group's prior Pediatric OCD Treatment Study trials and demonstrate good psychometric properties for the age range of our study.[32]

Measure for aim 2 (exploratory aim). The measure for aim 2 was predictors of treatment response.

Illness severity. Baseline illness severity as measured by the CGI-S scale was dichotomized (CGI-S 1-4 = low, 5-7 = high) for use as a predictor of response.

Barriers to treatment: Barriers to Treatment Questionnaire–Parent version.
The Barriers to Treatment–Parent (BTQ-P)[33] is a 28-item measure adapted from the BTQ to assess caregiver perceptions of barriers to accessing treatment for their child's anxiety.[34] The measure was completed at the outset of treatment and assesses domains such as logistic and

financial barriers, stigma, and aspects of treatment. Items are rated on a 0 ("not at all true") to 2 ("mostly true") scale. The measure has demonstrated acceptable psychometric properties.[33]

Caregiver strain: CSQ. The CSQ[35] assesses caregiver perceptions of the extent to which caring for a child with emotional problems affects several domains, including family life and relationships, demands on time, financial strain, disruption of social life, worry, guilt, and fatigue. This is a 21-item self-report measure that calls for caregivers to rate the extent of strain for each item using a 0 ("not at all") to 4 ("very much") scale. Higher scores indicate greater caregiver strain. The CSQ has exhibited sound psychometric properties.[35]

Caregiver accommodation: Pediatric Accommodation Scale–Parent Report. The Pediatric Accommodation Scale–Parent Report (PAS-PR)[36] is a 5-item questionnaire that assesses the frequency and interference associated with accommodating a patient's anxiety. Each item is followed by a series of common examples to illustrate the principle of accommodation for caregivers. Responses for frequency are 0 ("never"), 1 ("rarely"), 2 ("occasionally"), 3 ("often"), and 4 ("always"). Response options for interference caused by accommodation are 0 ("none"), 1 ("mild"), 2 ("moderate"), 3 ("severe"), and 4 ("extreme"). Higher scores indicate greater caregiver accommodation. The PAS was developed by our research group and has sound psychometric properties.[36]

Measures for supplement aim 3 (exploratory aim). Measure for this aim were clinician capacity and efficiency.

Clinician capacity. Clinician capacity was described as the number of cases that 1 individual psychologist was able to treat within the novel, patient-centered telehealth model using bachelor's degree–level staff compared with a theoretical traditional office model in which the same psychologist sees 1 patient for 60 minutes per week without the support of bachelor's level–level staff. Clinician time used in this calculation included time spent with a patient in session as well as time spent on other clinical-related activities, such as clinical supervision and writing clinical notes.

Clinician efficiency. Clinician efficiency was assessed using a Kaplan-Meier survival analysis to examine time course to treatment response. Time to response was measured in weeks, and response was defined as CGI-I 1 ("very much improved") or 2 ("much improved"), the same as for aim 1b.

Sample Size Calculations and Power

As mentioned earlier, this single-arm, open trial of patient-centered telehealth treatment is nested within our main study, a randomized trial of patient-centered, home-based vs clinician-centered, office-based treatment. The sample size of this open trial (N = 46) was determined using existing data about clinician capacity and efficiency from our main study (ie, how many patients we anticipated being able to treat within the 1-year time limit of the supplement award) and by a desire to compare treatment response between the telehealth and office treatment arms in future exploratory analyses.

In this supplemental project report, we focus on patient and caregiver engagement and satisfaction during telehealth-based treatment and plan to use this preliminary telehealth data to inform future comparative effectiveness research. In this report, we conducted preliminary, descriptive analyses that follow the aims outlined for the main study, including aims to examine treatment response and predictors of symptom change. These aims may involve analyses for which we have low power given the small sample size of this single-arm supplement study. Nevertheless, this preliminary data can be used to inform future grants examining the use of telehealth treatment models to improve access to care.

Time Frame for the Study

Participants were offered up to 24 weeks of telehealth-based treatment within the context of the study. Recruitment of the telehealth sample began in June 2020, and all 46 participants were entered into treatment by December 2020. Following patients' last treatment session, patients and their families completed a post-treatment assessment during which they answered questions and completed surveys about their symptoms. All post-treatment

assessments were completed by July 2021, which was the projected treatment completion date for the supplement.

Data Collection and Sources

Participants completed assessments with independent evaluators every 6 weeks throughout treatment. All families were given the option to complete assessments either over Zoom or over the phone to accommodate their preferences and schedule. Families could complete their post-treatment assessment 1 to 2 weeks after their last treatment session. If families did not answer phone calls, follow-up voicemail messages and emails were sent. Families were also sent reminder calls the day before their scheduled assessment.

Individuals could decline to participate in the study (withdraw) at 3 separate times before their first treatment session:

- **Gate A.** Phone consent (ie, verbal consent to be preliminarily assessed for study eligibility over the phone)

- **Gate B.** In-person consent and eligibility assessment

- **Gate C.** After consent and eligibility but before their first treatment session

Participants can be found ineligible at 2 time points: during the initial phone screen process (gate A) and after the consent and eligibility assessment (gate B). Whenever individuals declined to enroll in our project (declined consent) or withdrew consent, their refusal and their provided reason were documented in a tracking datasheet. Similarly, after multiple weeks of attempting to contact a participant's family using multiple different modes of communication (eg, email, phone calls, voice messages), the participant was marked as lost in a tracking datasheet.

Analytical and Statistical Approaches

Supplement Aim 1. Describe Stakeholder-Driven Outcomes During Patient-Centered Telehealth-based Treatment

Supplement aim 1a (primary aim): patient and caregiver treatment engagement and satisfaction. We conducted descriptive analyses to report on treatment engagement (session attendance and homework compliance) and satisfaction (patient and caregiver therapeutic alliance on the Therapeutic Alliance Scales and satisfaction on the CSQ-8) during patient-centered telehealth treatment. We used multiple imputation (ie, using IBM SPSS Statistics software to generate estimates using data from the patient's other assessments and from other patients' assessments) to address missing data (for missing select items on 1 questionnaire or missing full questionnaires) on patient- and caregiver-report measures (ie, Therapeutic Alliance Scales and CSQ-8).

Supplement aim 1b (secondary aim): course of anxiety/OCD symptoms and treatment response. We conducted descriptive analyses to report on independent evaluator–measured anxiety/OCD symptoms and treatment response at each assessment time point (ie, baseline, week 6, week 12, week 18, post-treatment) across treatment. We used multiple imputation to address missing data for patients who missed study assessments. We conducted paired-samples *t* tests to examine change in mean PARS and CY-BOCS scores, respectively, from baseline to after treatment. We also conducted paired-samples *t* tests to examine change in mean CGI-S score from baseline to after treatment. The percentage of study participants labeled as treatment responders was defined using the CGI-I (CGI 1 ("very much improved") or 2 ("much improved"), classified as responders, and values 3 to 7, classified as nonresponders.

Supplement aim 1c (secondary aim): change in associated disability of anxiety/OCD symptoms. We conducted descriptive analyses to describe patient- and caregiver-reported associated disability at each assessment time point across treatment. We

used multiple imputation to address missing data (ie, missing select items on 1 questionnaire or missing full questionnaires). We conducted paired-samples *t* tests to examine change in mean scores on measures of associated disability from baseline to after treatment. We conducted this analysis separately for each outcome variable of interest: patient- and caregiver-identified top problems (Top Problems Assessment severity scores), functional impairment (SDS total scores), and QOL (PQ-LES-Q total scores).

Supplement Aim 2 (Exploratory Aim): Predictors of Treatment Response

We selected patient and caregiver baseline characteristics of interest by determining which characteristics have predicted improved/attenuated treatment response in prior studies of office-based treatment (illness severity, caregiver strain, caregiver accommodation) and barriers to treatment (using feedback from patient stakeholders about important barriers to office-based treatment, such as "could not get off of work," "transportation/scheduling problems," "could not get an appointment," "unsure of who to see or where to go," "childcare barriers"). Before analysis, we classified individual families as "low" or "high" on characteristics of interest as follows: (1) baseline illness severity (low = CGI-S 3-4, indicating mild to moderate severity; high = CGI-S 5-7, indicating marked or extreme severity); (2) barriers to treatment access (BTQ-P: median split to determine low/high group status); (3) caregiver strain (CSQ: median split to determine low/high group status); and (4) caregiver accommodation (PAS-PR: median split to determine low/high group status). We conducted descriptive analyses to describe responses on predictor measures at baseline and after treatment. We used multiple imputation to address missing data (ie, missing select items on 1 questionnaire or missing full questionnaires). We conducted logistic regression analyses individually for each predictor variable to examine the relationships between baseline (week 0) variables and treatment response (defined by CGI-I <3).

Supplement Aim 3 (Exploratory Aim): Clinician Capacity and Efficiency

Clinician capacity was measured using the number of cases that 1 individual psychologist could treat within the novel patient-centered telehealth model using bachelor's

degree–level staff compared with a theoretical traditional office model in which the same psychologist sees 1 patient for 60 minutes per week, without the support of bachelor's degree–level staff. Estimates of clinician capacity for each model are based on average clinician caseloads within our clinic. Clinician time used in this calculation included time spent with a patient in session and staff psychologist-reported time spent on other clinical-related activities, such as clinical supervision and writing clinical notes. We estimated the number of cases treated at a given time and number of clinician hours per participant in 24 weeks of treatment. To assess clinician efficiency, we used a Kaplan-Meier survival analysis to examine time course to treatment response.

All analyses were conducted in IBM SPSS Statistics, version 26, software. For all analyses (primary, secondary, and exploratory), statistical significance was inferred for analyses that resulted in $P < .05$, as is convention within the clinical psychology field. We opted not to employ a correction for multiple testing given that this is a primarily descriptive report of a single-arm, open trial.

Changes to the Original Study Protocol

During this supplement, we sought and received approval from the IRB to (1) remove English fluency as an inclusion criterion to enroll Spanish-speaking participants; (2) modify our protocol and consent forms to reflect changes in COVID-19 procedures, when applicable; (3) modify the caregiver-report "Demographics" measure to include new options for caregivers to report patient gender identity; and (4) add a "Youth Demographics" measure for youth participants (12 years of age and older) to complete upon enrollment in the study.

RESULTS

Study Sample

For an overview of participant flow through the study supplement, please refer to the participant flow diagram in Figure 1. Of the final sample, 33 people were determined eligible during recruitment for the telehealth supplement (starting June 2020), while 13 participants were determined eligible for in-person outpatient anxiety/OCD treatment before recruitment for the telehealth supplement (during recruitment for the main study office and home conditions) but were instead offered and accepted enrollment in the telehealth treatment arm because of COVID-19 restrictions. All participants included in the participant flow diagram were entered into telehealth treatment, declined to participate in the study, or were lost by the research team before they could start treatment.

Figure 1. Participant Flow, June-December 2020

Gate A2: Phone Screen & Eligibility Checklist
(n = 64)
Phone screens eligible (n = 48)
Ineligible (n = 6)
Withdrew (n = 10)

Gate A2
Ineligible (n = 6)
   Anxiety is not the primary concern (n = 6)
Withdrew (n = 10)
   Want to pursue other services (n = 6)
   No longer pursuing services (n = 2)
   Financial/insurance barrier (n = 1)
   Lost to research team (n = 1)

Gate B: In-person Consent &
Assessment (n = 48)
Withdrew before consent (n=7)
Consented: Eligible (n = 33)
Consented: Ineligible (n =5)
Withdrew: after consent (n = 3)
N = 13 entered treatment in telehealth after being determined eligible before June 2020 (our official recruitment start)

Telehealth Patient-Centered (n = 46)
Withdrew from study after 1st session (n = 3)
Week 6 Assessment completed (n = 43)
Week 12 Assessment completed (n = 40)
Week 18 Assessment completed (n = 32)*
Post Assessment completed (n = 44)
*__Note:__ Some participants did not complete their assessments due to discharging from treatment early
Discharged before Week 6 (n = 1)
Discharged before Week 12 (n=4)
Discharged before Week 18 (n = 6)
Total discharged prior to 6 months (n =18)

Participants Who Provided Consent, Then Were Determined to Be Ineligible (n = 5)

Five participants who consented to taking part in the study were found to be ineligible during recruitment for the telehealth supplement (from June 22, 2020, through December 3, 2020). Three of these participants were ineligible because anxiety was not their primary mental health concern, 1 participant was ineligible because they did not meet criteria for an anxiety

disorder, and 1 participant was ineligible because they needed further mental health assessment before accessing treatment. These participants were not included in our final sample of 46.

Participants Who Withdrew From Treatment (n = 6)

Three participants (not included in the total 46) withdrew from the study before starting treatment. Two of these participants withdrew because they no longer wanted services, and 1 participant withdrew to seek services for a presenting mental health concern other than anxiety or OCD. Three participants withdrew from the active treatment phase of the study but were still included in our 46-patient sample. One participant withdrew from treatment because they longer wanted services. One participant ended treatment early because of hospitalization related to self-injurious behaviors and was referred to a higher level of care afterwards. One additional participant was admitted to a higher level of care following attempted self-injury that did not require medical attention.

Participants Who Did Not Complete a Post-treatment Assessment (n = 2)

Two participants of the total telehealth sample (N = 46) did not complete their post-treatment assessment (95.7% completion rate).

Final Sample

A total of 46 participants were entered into patient-centered telehealth treatment and received treatment. Participants were 5 to 18 years old (mean [SD], 11.3 [3.5] years). Half of the participants (50%) reported that their biological sex was female, and half reported that their biological sex was male. The majority of participants (87%) reported their race as White.

Most participants (44 [95.6%]) had health insurance coverage. The majority of participants (74%) had received previous treatment for mental health concerns, but 72% had not received exposure therapy. Twenty-two participants (48%) were receiving medication upon enrollment in telehealth treatment. See Table 1 for additional demographic information.

Table 1. Demographic Characteristics of the Study Sample

Characteristic	Frequency/N	Percentage
Patient race		
White	40/46	87
Black	1/46	2
Multiracial	3/46	7
Asian	1/46	2
Hawaiian, Pacific Islander, Alaska Native	1/46	3
Patient ethnicity		
Non-Hispanic	42/46	91
Hispanic	4/46	9
Patient biological sex		
Male	23/46	50
Female	23/46	50
Household annual income		
<$5000	1/46	2
$15 000-$24 999	1/46	2
$25 000-$49 999	2/46	4
$50 000-$74 999	6/46	13
$75 000-$99 999	5/46	11
$100 000-$149 999	16/46	35
≥$150 000	6/46	13
Missing	9/46	20
Insurance provider type		
Blue Cross Blue Shield	25/46	54
United Health Care	8/46	17
Tufts	3/46	7
Aetna	3/46	7
Neighborhood Health Plan	3/46	7
Tricare	1/46	2
Cigna	1/46	2
None or self-pay	2/46	4
Patient primary diagnosis[a]		
Any anxiety disorder		
GAD	29/46	63
Social anxiety disorder	16/46	35
Separation anxiety disorder	5/46	11
Specific phobia	3/46	7
Unspecified anxiety disorder	6/46	13
OCD	1/46	2
Patients diagnosed with co-primary OCD and an anxiety disorder	24/46	52
Other co-primary or secondary diagnoses	7/46	15

Characteristic	Frequency/N	Percentage
ADHD	16/46	35
ADHD–inattentive type	6/46	13
ADHD–hyperactive type	2/46	4
ADHD–combined type	8/46	17
ASD	1/46	2
Tourette disorder	4/46	9
Motor tic disorder	2/46	4
Vocal tic disorder	1/46	2
Excoriation disorder	1/46	2
Trichotillomania	1/46	2
Unspecified mood disorder	1/46	2

Abbreviations: ADHD, attention-deficit/hyperactivity disorder; ASD, autism spectrum disorder; GAD, generalized anxiety disorder; OCD, obsessive-compulsive disorder.

[a]Diagnostic data sum to more than the total sample size (N = 46) because of comorbidity (ie, 1 patient may have multiple co-primary diagnoses).

Primary Outcomes

Supplement Aim 1: Describe Stakeholder-Driven Outcomes During Patient-Centered Telehealth-based Treatment

Supplement aim 1a (primary aim): treatment engagement and satisfaction—attendance. Participants completed between 1 and 24 treatment sessions (mean [SD], 19.0 [5.5] sessions) of patient-centered telehealth-based treatment. Number of treatment session cancellations during active treatment ranged from 0 to 6 (mean [SD], 2.2 [1.7] cancellations). See Table 2 for descriptions of reasons for treatment session cancellation.

Table 2. Clinician-Reported Reasons for Treatment Session Cancellation

Reason	Frequency/N	Percentage
Patient sick	7/119	6
Caregiver sick	5/119	4
Clinician sick	3/119	3
Transportation	1/119	1
Weather	1/119	1
Holiday	22/119	19
Family away	11/119	9
Other family commitment	32/119	3
No call/no show	18/119	15
Planned cancellation because wrapping up services	5/119	4

Other
    COVID-19
    Family emergency
    Family wanted to wait until after an evaluation
    Insurance stopped covering telehealth
    Clinician emergency
    Clinician away on vacation
    Power outage
	14/119
	2/119
	2/119
	1/119
	1/119
	2/119
	5/119
	1/119
		12
		2
		2
		1
		1
		2
		4
		1

A majority of patients (61%) completed the full 24-week course of treatment. Some patients (39%) terminated treatment before 24 weeks. Of the patients who terminated treatment before 24 weeks, the largest portion (39%) did so because of symptom improvement. See Table 3 for information about reasons for treatment termination.

Table 3. Clinician-Reported Reasons for Treatment Termination

Reason	Frequency/N	Percentage
Reason for discontinuation		
End of 6-mo study participation	28/46	61
Discontinuation before 6 mo	18/46	39
Of those who discontinued before 6 mo (n = 18)		
Agreed upon termination of services	15/18	83
Dropout	3/18	17
Of those whose early discontinuation was agreed upon (n = 15)		
Symptoms improved	7/15	47
Symptoms worsened, needed higher level of care	1/15	7
Treatment target shifted from anxiety to other concern	3/15	20
Nearing end of study participation	2/15	13
Dislikes exposure	2/15	13
Of those whose early discontinuation was the result of dropout (n = 3)		
Connection with treatment team	1/3	33
Prefer alternative treatment	1/3	33
Missing	1/3	33

Treatment engagement: homework compliance. Average (SD) patient homework compliance across all treatment sessions was rated as 12.8 (3.4) out of 21 possible points. Average (SD) caregiver homework compliance across all treatment sessions was rated as 13.6 (3.5) out of 21 possible points, indicating moderate levels of homework compliance.

Treatment satisfaction: therapeutic alliance. The average (SD) therapeutic alliance score for patients was 38.4 (4.2) out of 48 possible points, indicating moderate to strong therapeutic alliance. The average (SD) therapeutic alliance score for caregivers was 45.0 (3.6) out of 48 possible points, indicating strong therapeutic alliance.

Treatment satisfaction: client satisfaction. Patients reported high treatment satisfaction at week 6 (mean [SD], 27.4 [3.6]), week 12 (mean [SD], 27.4 [4.2]), week 18 (mean [SD], 28.5 [4.8]), and after treatment (mean [SD], 28.8 [4.5]). Caregivers also reported high satisfaction at week 6 (mean [SD], 29.1 [3.1]), week 12 (mean [SD], 29.6 [3.2]), week 18 (mean

[SD], 29.8 [3.3]), and after treatment (mean [SD], 29.6 [3.7]). See Table 4 for descriptive statistics of outcome variables for aim 1a.

Table 4. Descriptive Statistics of Outcome Variables for Aim 1a

Outcome variable	Time point	No.	Mean (SD)
Patient homework compliance (clinician rated)	Average weeks 1-24	45[a]	12.8 (3.4) out of 21 possible points
Caregiver homework compliance (clinician rated)	Average weeks 1-24	41[b]	13.6 (3.5) out of 21 possible points
Patient therapeutic alliance (measured by the TASC-r	Average weeks 1-24	40[c]	38.4 (4.2) out of 48 possible points
Caregiver therapeutic alliance (measured by the TASCP	Average weeks 1-24	46	45.0 (3.6) out of 48 possible points
Patient treatment satisfaction (measured by the CSQ-8–Child version)	Week 6 Week 12 Week 18 After treatment	40[c] 40[c] 40[c] 40[c]	27.4 (3.6) out of 32 possible points 27.4 (4.2) out of 32 possible points 28.5 (4.8) out of 32 possible points 28.8 (4.5) out of 32 possible points
Caregiver treatment satisfaction (measured by the CSQ-8–Parent version)	Week 6 Week 12 Week 18 After treatment	46 46 46 46	29.1 (3.1) out of 32 possible points 29.6 (3.2) out of 32 possible points 29.8 (3.3) out of 32 possible points 29.6 (3.7) out of 32 possible points

Abbreviations: CSQ-8, Client Satisfaction Questionnaire–8 Item TASC-r, Therapeutic Alliance Scale for Children–Revised ; TASCP, Therapeutic Alliance Scale for Caregivers and Parents.
[a]Missing data because of patient early discharge from treatment (n = 1).
[b]Missing data because of lack of caregiver presence in treatment sessions (n = 5).
[c]Missing data because of patients being too young to complete the survey (n = 6).

Secondary Outcomes

Supplement Aim 1b: Course of Anxiety/OCD Symptoms and Treatment Response

Course of anxiety symptoms. A paired-samples *t* test indicated that independent evaluator–rated anxiety symptoms decreased significantly from baseline (mean [SD], 13.8 [2.8]) to after treatment (mean [SD], 7.4 [4.5]; t_{542} = 6.3; *P* < .001). This average PARS score following treatment demonstrates that anxiety symptoms decreased to a nonclinical level.

Course of OCD symptoms. A paired-samples *t* test indicated that independent evaluator–rated OCD symptoms decreased significantly from baseline (mean [SD], 23.23 [2.66]) to after treatment (mean [SD], 17.2 [7.0]; $t_{2989307}$ = 4.7; *P* < .001). Although participants demonstrated a significant decrease in OCD symptoms over the course of treatment, the average CY-BOCS score after treatment just surpassed a clinical level of OCD symptoms (ie, a score of 16, which marks more than mild symptoms on the CY-BOCS). See Table 5 for descriptive statistics of OCD symptom severity (CY-BOCS) and anxiety symptom severity (PARS) measures.

Table 5. Descriptive Statistics of Anxiety and OCD Symptom Variables for Aim 1b

Outcome variable	Time point	No.	Mean (SD)
Anxiety symptoms (measured by the PARS)	Baseline	37[a]	13.8 (2.8) out of 25 possible points
	Week 6	37[a]	10.2 (4.4) out of 25 possible points
	Week 12	37[a]	9.8 (4.9) out of 25 possible points
	Week 18	37[a]	8.8 (4.6) out of 25 possible points
	After treatment	37[a]	7.4 (4.5) out of 25 possible points
OCD symptoms (measured by the CY-BOC)	Baseline	26[b]	23.2 (2.7) out of 40 possible points
	Week 6	26[b]	21.9 (3.5) out of 40 possible points
	Week 12	26[b]	20.2 (4.2) out of 40 possible points
	Week 18	26[b]	18.2 (5.3) out of 40 possible points
	After treatment	26[b]	17.2 (7.0) out of 40 possible points

Abbreviations: CY-BOC, Children's Yale-Brown Obsessive Compulsive Scale; OCD, obsessive-compulsive disorder; PARS, Pediatric Anxiety Rating Scale.
[a]Missing because of patient not diagnosed with an anxiety disorder (n = 9).
[b]Missing because patient was not diagnosed with OCD (n = 20).

Treatment response. A paired-samples *t* test indicated that independent evaluator–rated global symptom severity, as measured by the CGI-S scale, decreased significantly from baseline (mean [SD], 4.7 [0.5], indicating moderate to marked severity) to after treatment (mean [SD], 3.7 [1.2], indicating mild to moderate severity; t_{2031} = −5.9; *P* < .001). Moreover, using the CGI-I scale, 11% of patients responded to treatment by week 6, an additional 19% of patients who did not respond by week 6 responded by week 12 (cumulative response, 30%), an additional 30% of patients who did not respond by week 12 responded by week 18 (cumulative response, 61%), and an additional 7% of patients who did not respond by week 18 responded

after treatment. Overall, 68% of patients were classified as treatment responders. Alternatively, 32% of patients did not achieve responder status at any point during treatment. See Tables 6 and 7 for descriptive statistics for CGI-S and CGI-I scores, respectively, across all time points.

Table 6. Descriptive Statistics for Clinical Global Impression–Severity Across Treatment

CGI-S score	Frequency/N	Percentage
Baseline		
"Normal, not at all ill"	0/46	0
"Borderline mentally ill"	0/46	0
"Mildly ill"	0/46	0
"Moderately ill"	15/46	33
"Markedly ill"	31/46	67
"Severely ill"	0/46	0
"Among the most extremely ill patients"	0/46	0
Week 6		
"Normal, not at all ill"	0/46	0
"Borderline mentally ill"	0/46	0
"Mildly ill"	3/46	7
"Moderately ill"	18/46	39
"Markedly ill"	24/46	52
"Severely ill"	1/46	2
"Among the most extremely ill patients"	0/46	0
Week 12		
"Normal, not at all ill"	1/46	2
"Borderline mentally ill"	0/46	0
"Mildly ill"	6/46	13
"Moderately ill"	21/46	46
"Markedly ill"	18/46	39
"Severely ill"	0/46	0
"Among the most extremely ill patients"	0/46	0
Week 18		
"Normal, not at all ill"	1/46	2
"Borderline mentally ill"	2/46	4
"Mildly ill"	12/46	26
"Moderately ill"	20/46	43
"Markedly ill"	11/46	24
"Severely ill"	0/46	0
"Among the most extremely ill patients"	0/46	0
After treatment		
"Normal, not at all ill"	4/46	9

CGI-S score	Frequency/N	Percentage
"Borderline mentally ill"	1/46	2
"Mildly ill"	13/46	28
"Moderately ill"	15/46	33
"Markedly ill"	13/46	28
"Severely ill"	0/46	0
"Among the most extremely ill patients"	0/46	0

Abbreviation: CGI-S, Clinical Global Impression–Severity.

Table 7. Descriptive Statistics for Clinical Global Impression–Improvement Across Treatment

CGI-I score	Frequency/N	Percentage
Week 6		
"Very much improved"	0/46	0
"Much improved"	5/46	11
"Minimally improved"	29/46	63
"No change"	12/46	26
"Minimally worse"	0/46	0
"Much worse"	0/46	0
"Very much worse"	0/46	0
Week 12		
"Very much improved"	2/46	4
"Much improved"	12/46	2
"Minimally improved"	28/46	61
"No change"	3/46	7
"Minimally worse"	1/46	2
"Much worse"	0/46	0
"Very much worse"	0/46	0
Week 18		
"Very much improved"	4/46	9
"Much improved"	24/46	52
"Minimally improved"	16/46	35
"No change"	2/46	4
"Minimally worse"	0/46	0
"Much worse"	0/46	0
"Very much worse"	0/46	0
Post-treatment		
"Very much improved"	9/46	20
"Much improved"	22/46	48
"Minimally improved"	13/46	28
"No change"	2/46	4
"Minimally worse"	0/46	0
"Much worse"	0/46	0

CGI-I score	Frequency/N	Percentage
"Very much worse"	0/46	0

Abbreviation: CGI-I, Clinical Global Impression–Improvement.

Supplement Aim 1c: Change in Associated Disability of Anxiety/OCD Symptoms

Patient- and caregiver-identified top problems. Patient- and caregiver-reported top problem umbers 1 (t_{1352} = 8.6; P < .001), 2 (t_{556} = 6.8; P < .001), and 3 (t_{507} = 7.1; P < .001) problem severity decreased significantly from baseline to after treatment.

Functional impairment. On average, patients reported mild functional impairment related to anxiety or OCD symptoms at baseline (mean [SD], 13.1 [6.5]), week 6 (mean [SD], 10.8 [6.4]), week 12 (mean [SD], 10.6 [5.9]), week 18 (mean [SD], 9.9 [8.6]), and after treatment (mean [SD], 8.6 [7.1]). On average, caregivers reported mild to moderate functional impairment related to anxiety or OCD symptoms at baseline (mean [SD], 17.3 [9.8]), week 6 (mean [SD], 17.5 [11.9]), week 12 (mean [SD], 15.4 [11.4]), week 18 (mean [SD], 13.3 [11.6]), and after treatment (mean [SD], 14.4 [10.9]). Paired-samples t tests indicated that patient-rated (t_{409} = 2.8; P = .006) but not caregiver-rated (t_{426} = 1.6; P = .102) functional impairment decreased significantly from baseline to after treatment.

Quality of life. On average, patients reported fair to good QOC at baseline (mean [SD], 48.5 [6.5]), week 6 (mean [SD], 48.1 [7.7]), week 12 (mean [SD], 49.2 [6.4]), week 18 (mean [SD], 50.6 [6.2]), and after treatment (mean [SD], 51.9 [7.9]). Similarly, on average, caregivers reported fair to good QOL at baseline (mean [SD], 48.7 [6.9]), week 6 (mean [SD], 49.1 [7.1]), week 12 (mean [SD], 48.2 [9.6]), week 18 (mean [SD], 52.8 [7.9]), and after treatment (mean [SD], 52.4 [8.4]). Paired-samples t tests indicated that caregiver-reported (t_{363} = −2.9; P = .004) but not patient-reported (t_{140} = −1.9; P = .054), QOL improved significantly from baseline to after treatment. See Table 8 for descriptive statistics of outcome variables for aim 1c, and see Table 9 for paired-samples t tests of all analyses conducted for aim 1.

Table 8. Descriptive Statistics of Outcome Variables for Aim 1c

Outcome variable	Time point	No.	Mean (SD)
Patient- and caregiver-reported problem 1 (measured by the TPA)	Baseline Week 6 Week 12 Week 18 Post-treatment	46 46 46 46 46	8.1 (1.7) out of 10 possible points 6.2 (2.4) out of 10 possible points 6.4 (2.3) out of 10 possible points 4.9 (2.8) out of 10 possible points 4.0 (2.8) out of 10 possible points
Patient- and caregiver-reported problem 2 (measured by the TPA)	Baseline Week 6 Week 12 Week 18 Post-treatment	46 46 46 46 46	7.2 (1.8) out of 10 possible points 6.2 (2.6) out of 10 possible points 5.0 (2.3) out of 10 possible points 5.2 (2.5) out of 10 possible points 4.3 (2.6) out of 10 possible points
Patient- and caregiver-reported problem 3 (measured by the TPA)	Baseline Week 6 Week 12 Week 18 Post-treatment	46 46 46 46 46	6.8 (2.1) out of 10 possible points 5.4 (2.9) out of 10 possible points 4.9 (2.9) out of 10 possible points 4.6 (2.9) out of 10 possible points 3.7 (2.9) out of 10 possible points
Patient-reported functional impairment (measured by the SDS–Child version)	Baseline Week 6 Week 12 Week 18 Post-treatment	36[a] 36[a] 36[a] 36[a] 36[a]	13.1 (6.5) out of 30 possible points 10.8 (6.4) out of 30 possible points 10.6 (5.9) out of 30 possible points 9.9 (8.6) out of 30 possible points 8.6 (7.1) out of 30 possible points
Caregiver-reported functional impairment (measured by the SDS–Parent version)	Baseline Week 6 Week 12 Week 18 Post-treatment	46 46 46 46 46	17.3 (9.8) out of 50possible points 17.5 (11.9) out of 50possible points 15.4 (11.4) out of 50possible points 13.3 (11.6) out of 50possible points 14.4 (10.9) out of 50possible points
Patient-reported QOL (measured by the PQ-LES-Q–Child version)	Baseline Week 6 Week 12 Week 18 Post-treatment	42[b] 42[b] 42[b] 42[b] 42[b]	48.5 (6.5) out of 65 possible points 48.1 (7.7) out of 65 possible points 49.2 (6.4) out of 65 possible points 50.6 (6.2) out of 65 possible points 51.9 (7.9) out of 65 possible points
Caregiver-reported patient QOL (measured by the Pediatric Q-LES-Q–Parent version)	Baseline Week 6 Week 12 Week 18 Post-treatment	46 46 46 46 46	48.7 (6.9) out of 65 possible points 49.1 (7.1) out of 65 possible points 48.2 (9.6) out of 65 possible points 52.8 (7.9) out of 65 possible points 52.4 (8.4) out of 65 possible points

Abbreviations: PQ-LES-Q, Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire; QOL, quality of life; SDS, Sheehan Disability Scale; TPA, Top Problems Assessment.
[a]Missing data because patients were too young to complete the survey (n = 10).
[b]Missing data because patients were too young to complete the survey (n = 4).

Table 9. Paired-Samples *t* Tests of Baseline to Post-treatment Change in Outcome Variables

Outcome variable	Paired differences						
	Mean	SE	95% CI	*t*	*df*	*P* value	Cohen *d*
Change in anxiety symptoms (measured by the PARS)	6.40	1.02	(4.39-8.41)	6.3	542	< .001[a]	1.0
Change in OCD symptoms (measured by the CY-BOCS)	5.99	1.28	(3.49-8.50)	4.7	2 989 307	< .001[a]	0.9
Change in global symptom severity (measured by the CGI-S scale)	0.99	0.17	(0.66-1.32)	5.9	2031	< .001[a]	0.9
Change in patient- and caregiver-reported problem 1 (measured by the TPA)	4.11	0.48	(3.2-5.0)	8.6	1352	< .001[a]	1.3
Change in patient- and caregiver-reported problem 2 (measured by the TPA)	2.91	0.43	(2.1-3.8)	6.8	556	< .001[a]	1.0
Change in patient- and caregiver-reported problem 3 (measured by the TPA)	3.11	0.44	(2.2-3.9)	7.1	507	< .001[a]	1.0
Change in patient-reported functional impairment (measured by the SDS–Child version)	4.52	1.64	(1.29-7.74)	2.8	409	.006[a]	0.5
Change in caregiver-reported patient functional impairment (measured by the SDS–Parent version)	2.88	1.76	(−0.57 to 6.34)	1.6	426	.102	0.2
Change in patient-reported QOL (measured by the PQ-LES-Q–Child version)	−3.43	1.77	(−6.91 to 0.59)	−1.94	140	.054[a]	0.3
Change in caregiver-reported patient QOL (measured by the PL-LES-Q–Parent version)	−3.75	1.29	(−6.27 to −1.21)	−2.9	363	.004[a]	0.4

Abbreviations: CGI-S, Clinical Global Impression–Severity; CY-BOCS, Children's Yale-Brown Obsessive Compulsive Scale; df, degrees of freedom; OCD, obsessive-compulsive disorder; PARS, Pediatric Anxiety Rating Scale; PQ-LES-Q, Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire; QOL, quality of life; SDS, Sheehan Disability Scale; TPA, Top Problems Assessment.
[a]Indicates statistical significance.

Exploratory Outcomes

Supplement Aim 2: Predictors of Treatment Response (Exploratory)

Illness severity. In our sample, baseline illness severity, as measured by CGI-S, did not predict treatment response, as measured by CGI-I, after treatment ($\beta = -1.5$; *P* = .079).

Barriers to treatment. In our sample, caregiver-reported barriers to treatment at baseline, as measured by the BTQ-P questionnaire, did not predict treatment response, as measured by the CGI-I scale, after treatment ($\beta = .5$; *P* = .483). This finding may be because of a restricted range on the independent variable as most participants reported few barriers to treatment. In this vein, the average BTQ-P score at baseline was a 7.1 out of 56 possible points, and the highest score reported was a 19 out of 56 possible points.

Caregiver strain. In our sample, caregiver-reported caregiver strain at baseline, as measured by the CSQ, did not predict treatment response, as measured by the CGI-I, after treatment ($\beta = .6$; *P* = .389). On average, caregivers reported low to moderate caregiver strain at baseline (mean, 27.6 out of 84 possible points).

Caregiver accommodation. In our sample, caregiver-reported accommodation at baseline, as measured by the PAS-PR, did not predict treatment response, as measured by the CGI-I after treatment ($\beta = -.2$; *P* = .731). On average, caregivers reported low to moderate caregiver accommodation at baseline (mean, 10.9 out of 40 possible points).

See Table 10 for descriptive statistics of predictor variables for aim 2. See Table 11 for frequencies of predictor variable median splits for aim 2. See Table 12 for results of regression analyses for aim 2.

Table 10. Descriptive Statistics for Predictor Variables for Aim 2[a]

Predictor variable	Time point	No.	Mean (SD)
Barriers to treatment (measured by BTQ-P)	Baseline Post-treatment	46 46	7.1 (4.8) out of 56 possible points 5.2 (3.9) out of 56 possible points
Caregiver strain (measured by the CGSQ–Caregiver report)	Baseline Post-treatment	46 46	27.6 (15.1) out of 84 possible points 22.1 (15.9) out of 84 possible points
Caregiver accommodation (measured by the PAS-PR)	Baseline Post-treatment	46 46	10.9 (8.1) out of 40 possible points 7.9 (8.4) out of 40 possible points

Abbreviations: BTQ-P, Barriers to Treatment–Parent; CGI-S, Clinical Global Impression–Severity; CGSQ, Caregiver Strain Questionnaire; PAS-PR, Pediatric Accommodation Scale–Parent Report.
[a]Table excludes illness severity (CGI-S) as these descriptives are presented under aim 1b.

Table 11. Descriptive Statistics of Predictor Variables for Aim 2 (Predictors of Treatment Response)

Outcome variable	Category	Frequency/N	Percentage
Illness severity (measured by the CGI-I scale), median split	High Low	31/46 15/46	67 33
Barriers to treatment (measured by BTQ-P), median split	High Low	23/46 23/46	50 50
Caregiver strain (measured by CGSQ–Caregiver report), median split	High Low	23/46 23/46	50 50
Caregiver accommodation (measured by PAS-PR), median split	High Low	22/46 24/46	48 52

Abbreviations: BTQ-P, Barriers to Treatment–Parent; CGI-I, Clinical Global Impression–Improvement; CGSQ, Caregiver Strain Questionnaire; PAS-PR, Pediatric Accommodation Scale–Parent Report.

Table 12. Regression Analyses Examining Predictors of Treatment Response (Aim 2)

Predictor	β	SE	df	P value	95% CI
Illness severity (measured by the CGI-S scale)	−1.5	0.9	1	.740	(0.99-1.00)
Barriers to treatment (measured by BTQ-P)	.5	0.8	1	.483	(0.39-7.43)
Caregiver strain (measured by CGSQ–Caregiver report)	.6	0.7	1	.389	(0.47-7.01)
Caregiver strain (measured by CGSQ	−.2	0.7	1	.731	(0.21-3.01)

Abbreviations: BTQ-P, Barriers to Treatment–Parent; CGI-S, Clinical Global Impression–Severity; CGSQ, Caregiver Strain Questionnaire; df, degrees of freedom.

Supplement Aim 3: Describe Capacity and Efficiency (Exploratory)

Clinician capacity. Within the patient-centered telehealth delivery model, a single staff psychologist had the capacity to treat a greater number of patients than they would be able to in a traditional weekly office-based outpatient model because of the use of bachelor's degree–level staff to provide adjunctive treatment sessions. During this telehealth supplement, staff psychologists spent an estimated 15.5 clinical hours over the course of treatment per patient treated via patient-centered telehealth compared with an estimated 38 hours required of psychologists per patient treated via a traditional weekly office-based model. These estimates are based on a theoretical model in which patients receive 24 total treatment sessions delivered one per week. Estimates include psychologist time spent in session with a patient as well as conducting other clinical-related activities (ie, clinical supervision and writing clinical notes). See Table 13 for more detail.

Table 13. Calculation of Clinician Capacity in Patient-Centered Telehealth Compared With a Theoretical Clinician-Centered Office Delivery Model (Aim 3)

Clinician hours spent per patient	Traditional office model	Telehealth model
No. of treatment sessions delivered by psychologist	24 sessions	6 sessions[a]
Psychologist time spent per treatment session	1 h	1 h
Total No. of psychologist-hours spent in session per patient	24 sessions[b] at 1 h/each = 24 h	6 sessions[b] at 1 h/each = 6 h
Total psychologist time spent in clinical supervision across 24 wk of patient's treatment	2 h	6.5 h[b]
Psychologist time spent on other clinical-related activities (eg, writing clinical notes, completing administrative forms)	12 h	3 h
Total no. of psychologist-hours required per delivery model	38 h	15.5 h

[a]Additional 18 sessions provided by bachelor's degree–level staff.
[b]Increased supervision time based on providing clinical supervision to bachelor's degree–level staff.

In a theoretical traditional office-based outpatient treatment model, assuming a 40-hour workweek, 1 psychologist would be able to treat approximately 27 patients in a 6-month (1008-hour) time period (calculated as 1008 hours / 38 hours per patient). In contrast, in the novel patient-centered telehealth delivery model using bachelor's degree–level staff in conjunction with psychologists, 1 psychologist would be able to treat approximately 65 patients in the same 6-month (1008-hour) time period (calculated as 1008 hours / 15.5 hours per patient). In other words, psychologists delivering care through this patient-centered telehealth model would be able to treat more than twice as many patients at a time compared with those delivering care via a traditional outpatient office model.

Clinician efficiency. A Kaplan-Meier survival model indicated that the average (SE) time to treatment response was 22 (0.5) weeks (95% CI, 21.20-23.23). See Figure 2 for the model indicating cumulative rate of treatment response and time to treatment discharge.

Figure 2. Kaplan-Meier Survival Curve of Time to Treatment Response or Discharge (Aim 3)
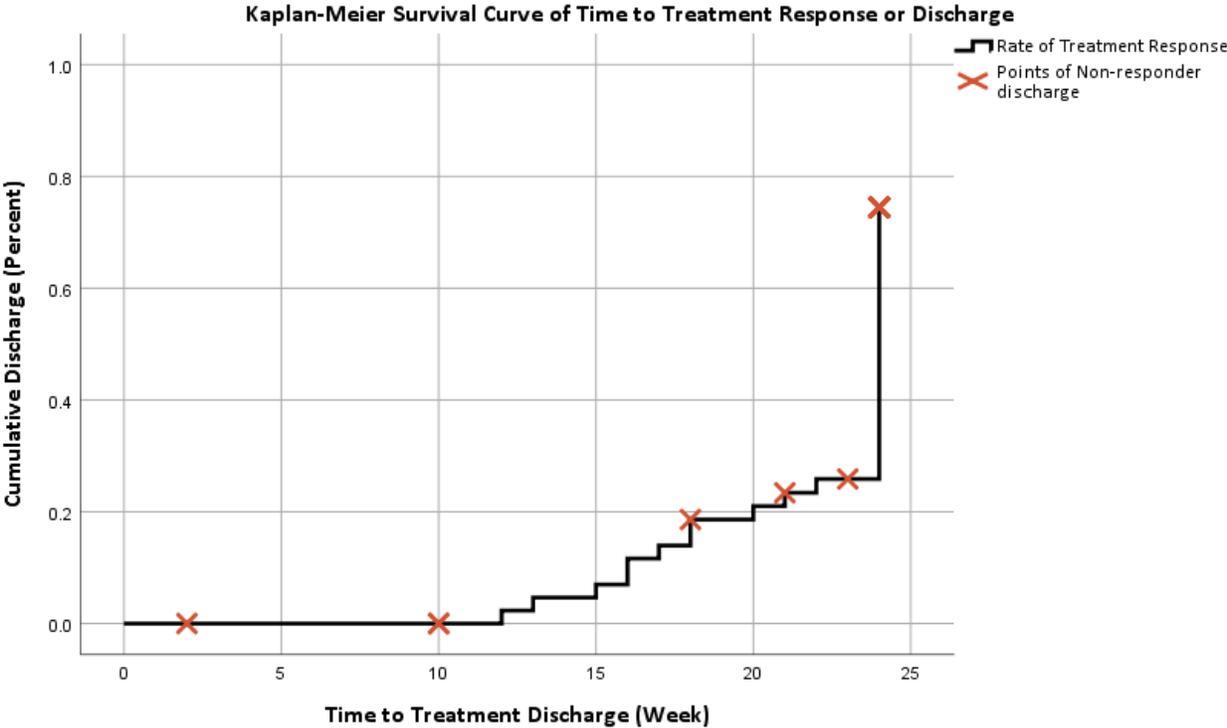
DISCUSSION

Summary of Results

The current study's descriptive results provide preliminary data to support this novel team-based, patient-centered telehealth treatment for pediatric anxiety and OCD. Patients and families demonstrated high treatment engagement and satisfaction. Independent evaluator–rated anxiety and OCD symptoms decreased significantly throughout treatment. The majority of participants (68%) were classified as treatment responders after treatment, and rates of treatment response were similar to those of previous telehealth studies.[3-5] Further, patient- and caregiver-identified top problem severity, patient-reported functional impairment, and caregiver-reported QOL improved over the treatment course. During the telehealth supplement, PhD-level psychologists were able to treat a larger caseload of patients in less time given that mobile exposure coaches conducted most sessions with patients. The average time to treatment response was 22 weeks. Stakeholders from a variety of groups (eg, families, payers, clinicians) strongly approved of the telehealth treatment option.

Results in Context

Patient-centered telehealth treatment delivery for youth with anxiety and OCD, using a team-based model delivered by bachelor's degree–level staff and PhD-level psychologists, was acceptable to patients and caregivers and led to anxiety and OCD symptom improvement in the context of the COVID-19 pandemic, when in-person services were not feasible. This treatment delivery method allowed for increased caseloads of PhD-level psychologists. Patients also experienced reduced symptom severity and associated disability over the course of treatment. Although not part of our formal analyses, it is worth noting that this sample had high levels of illness severity at the start of treatment. Based on the CGI-S scale, 67% of the sample was "markedly ill" at baseline vs 28% of the sample that was "markedly ill" after treatment. This shift in CGI-S scores represents a clinically meaningful shift in the life of patients and caregivers.

Potential to Affect Health Care Decision-making

Providing patient-centered treatment via telehealth may be a good option for families with barriers to accessing office- or home-based services, particularly during the COVID-19 pandemic. In addition, our health system currently faces a national shortage of mental health professionals.[37,38] In our region, it is nearly impossible to find outpatient psychologists with openings, and youth are spending multiple nights "boarding" in our Children's Hospital emergency department as they wait for mental health care. This type of telehealth service delivery model may be particularly effective when the demand for youth anxiety/OCD treatment is higher than the number of available licensed practitioners because mobile exposure coaches delivering treatment can increase PhD caseload. This telehealth service delivery model was supported by our payer stakeholders, and the results of this study align with payer-driven outcomes (eg, high client satisfaction, reductions in client symptoms, increased clinician capacity), providing preliminary support for this model to be covered by payers and available to all patients and caregivers.

Generalizability

The results of this study are best generalized to other anxiety and OCD specialty clinics that provide outpatient services with similar organizational models. The study included youth aged 5 to 18 years, so the results can be generalized to both youth with early-onset anxiety or OCD symptoms as well as older teens. The current supplement project sample lacks racial and ethnic diversity, though, limiting the generalizability. For context, local census data from 2021 demonstrates that 71.4% of Rhode Island's population is White non-Hispanic, 16.3% is Hispanic, and 8.5% is Black.[39] In the PARC partial hospital program at Bradley Hospital, 97% of participants who consented to research before the COVID-19 pandemic were White, 1% were Black, 1% were Asian, and 1% declined to answer; 95% were non-Hispanic, while 5% were Hispanic.

Subgroup Analyses or Heterogeneity of Treatment Effects

Although we conducted an examination of predictors of treatment response (aim 2), this analysis was exploratory given our small sample size and inability to compare this

telehealth treatment arm with our main study clinician-centered office arm in this report. We were unable to conduct inferential subgroup or moderator analyses in this report given that our small sample (N = 46) did not provide adequate power for such analyses.

Study Limitations

Primary study limitations include the single-arm, open trial design, which limits our ability to draw conclusions about whether the intervention caused the symptom improvement, and the small sample size limited statistical power for examining potential predictors of treatment response. This study is also limited in that we did not use certain outcome measures with patients who were too young to complete them. In addition, some families missed study assessments, perhaps weakening our ability to detect the effect of the intervention. A lack of racial and ethnic diversity in the study sample limited the generalizability of the findings. That the study setting was an anxiety specialty clinic rather than a community mental health center that treats many referred participants also contributed to a study sample biased toward participants who are well equipped with resources, motivated to participate, and had higher levels of illness severity. Although we were able to compare change on our aim 1b measures (global improvement) to that defined as clinically meaningful change in previous studies (and found similar rate of treatment response as past studies[3-5]), we were unable to compare change on our aim 1c (idiographic top problems, disability, QOL) measures with that of previous studies because no literature currently exists that defines clinically meaningful change on these measures. Finally, although we had significant stakeholder input throughout the study, the short time in which the grant was written and funded limited the amount of initial stakeholder feedback to and collaboration on the proposal.

Future Research

A fully powered (large sample), patient-centered, team-based comparative telehealth trial would provide a more rigorous evaluation of this treatment model compared with existing treatment models (eg, home and office based). Future research should also aim to examine differences in responses to a given treatment model among subgroups of participants (eg, those with more severe illness, those with certain comorbidities) to aid in efforts to better

understand which treatment model works best for whom. It is imperative that subsequent studies include a more racially and ethnically diverse and representative sample of patients and caregivers. As such, future efforts must involve taking this model of care outside of specialty clinic/hospital settings, assessing its application to the treatment of other psychiatric disorders, and collaborating with local community mental health clinics/federally qualified health centers. Moving forward, this work also could be expanded to examine emerging adults, especially because telehealth is accessible for both families and young adults while going through transitions (eg, moving out, attending college). Finally, future studies should ensure that patients and other stakeholder groups are involved in all phases of the development of telehealth and other novel treatment models to ensure that the services provided respond to patient and stakeholder needs.

CONCLUSIONS

This supplemental study provides preliminary data to evaluate the feasibility and acceptability of a novel, team-based, patient-centered telehealth treatment for pediatric anxiety and OCD during the COVID-19 pandemic. Descriptive results suggest high rates of patient and caregiver engagement, satisfaction, and improvement in symptom specific as well as functional outcomes. The treatment model also increased clinician capacity; improved access to care for patients and families; and was strongly supported by a wide range of patient, hospital administrative, payer, and community stakeholders. This telehealth supplemental project provides a unique perspective of patients', families', and other stakeholders' receptiveness to a novel model of telehealth-delivered exposure-based CBT.

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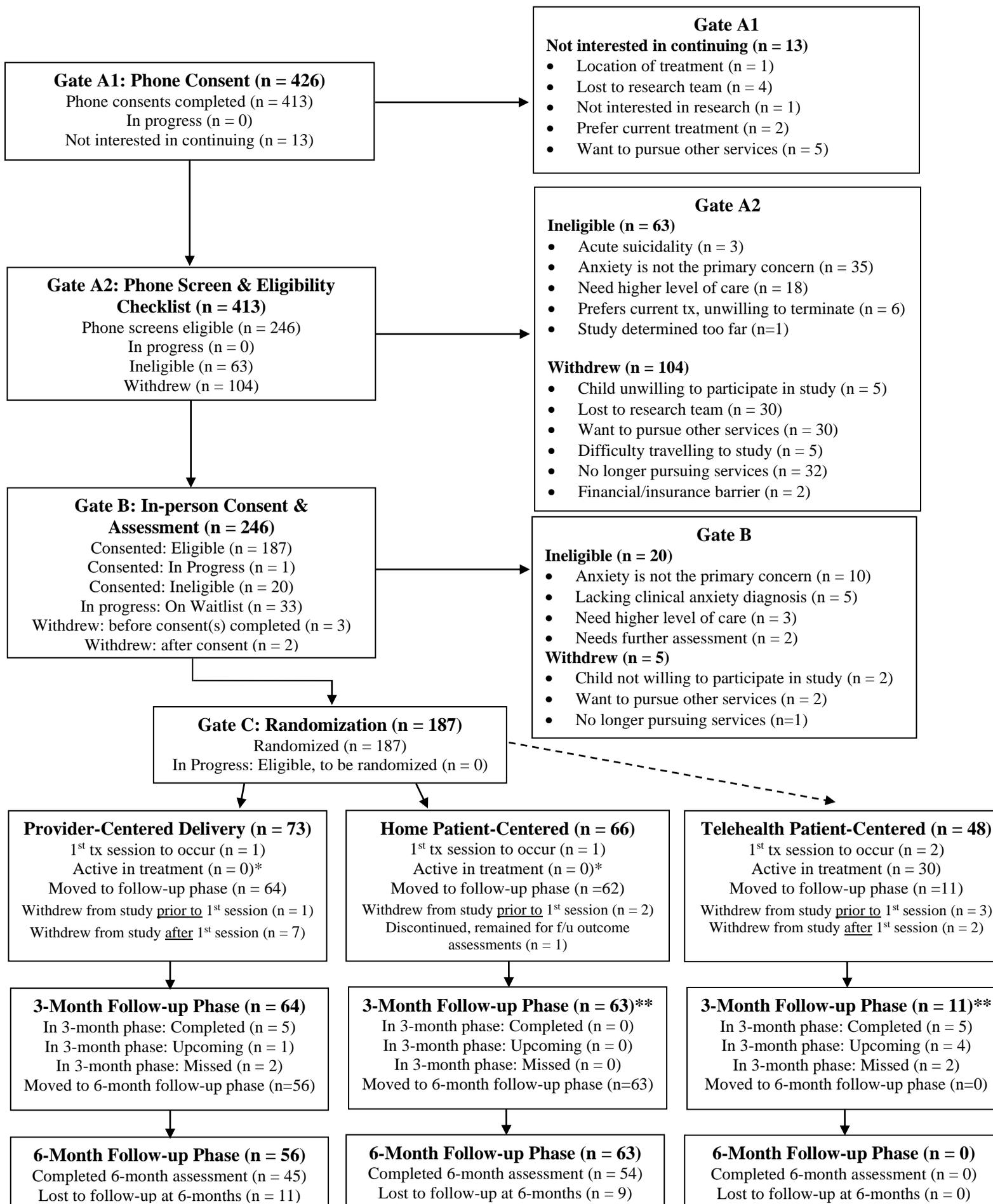39.   US Census Bureau. QuickFacts: Rhode Island. Accessed April 12, 2022. https://www.census.gov/quickfacts/fact/table/RI/PST045221#qf-headnote-b

ACKNOWLEDGMENTS

APPENDIX: DECEMBER 2020 CONSORT DIAGRAM

"Comparison of Patient-Centered versus Provider-Centered Delivery of Cognitive Behavioral Treatment (CBT) for Pediatric Anxiety and Obsessive-Compulsive Disorder (OCD)"

CONSORT DIAGRAM: Kick-off through December 2020

Gate A1: Phone Consent (n = 426)
Phone consents completed (n = 413)
In progress (n = 0)
Not interested in continuing (n = 13)

→

Gate A1
Not interested in continuing (n = 13)
- Location of treatment (n = 1)
- Lost to research team (n = 4)
- Not interested in research (n = 1)
- Prefer current treatment (n = 2)
- Want to pursue other services (n = 5)

Gate A2: Phone Screen & Eligibility Checklist (n = 413)
Phone screens eligible (n = 246)
In progress (n = 0)
Ineligible (n = 63)
Withdrew (n = 104)

→

Gate A2
Ineligible (n = 63)
- Acute suicidality (n = 3)
- Anxiety is not the primary concern (n = 35)
- Need higher level of care (n = 18)
- Prefers current tx, unwilling to terminate (n = 6)
- Study determined too far (n=1)

Withdrew (n = 104)
- Child unwilling to participate in study (n = 5)
- Lost to research team (n = 30)
- Want to pursue other services (n = 30)
- Difficulty travelling to study (n = 5)
- No longer pursuing services (n = 32)
- Financial/insurance barrier (n = 2)

Gate B: In-person Consent & Assessment (n = 246)
Consented: Eligible (n = 187)
Consented: In Progress (n = 1)
Consented: Ineligible (n = 20)
In progress: On Waitlist (n = 33)
Withdrew: before consent(s) completed (n = 3)
Withdrew: after consent (n = 2)

→

Gate B
Ineligible (n = 20)
- Anxiety is not the primary concern (n = 10)
- Lacking clinical anxiety diagnosis (n = 5)
- Need higher level of care (n = 3)
- Needs further assessment (n = 2)
Withdrew (n = 5)
- Child not willing to participate in study (n = 2)
- Want to pursue other services (n = 2)
- No longer pursuing services (n=1)

Gate C: Randomization (n = 187)
Randomized (n = 187)
In Progress: Eligible, to be randomized (n = 0)

Provider-Centered Delivery (n = 73)
1st tx session to occur (n = 1)
Active in treatment (n = 0)*
Moved to follow-up phase (n = 64)
Withdrew from study prior to 1st session (n = 1)
Withdrew from study after 1st session (n = 7)

Home Patient-Centered (n = 66)
1st tx session to occur (n = 1)
Active in treatment (n = 0)*
Moved to follow-up phase (n =62)
Withdrew from study prior to 1st session (n = 2)
Discontinued, remained for f/u outcome assessments (n = 1)

Telehealth Patient-Centered (n = 48)
1st tx session to occur (n = 2)
Active in treatment (n = 30)
Moved to follow-up phase (n =11)
Withdrew from study prior to 1st session (n = 3)
Withdrew from study after 1st session (n = 2)

3-Month Follow-up Phase (n = 64)
In 3-month phase: Completed (n = 5)
In 3-month phase: Upcoming (n = 1)
In 3-month phase: Missed (n = 2)
Moved to 6-month follow-up phase (n=56)

3-Month Follow-up Phase (n = 63)**
In 3-month phase: Completed (n = 0)
In 3-month phase: Upcoming (n = 0)
In 3-month phase: Missed (n = 0)
Moved to 6-month follow-up phase (n=63)

3-Month Follow-up Phase (n = 11)**
In 3-month phase: Completed (n = 5)
In 3-month phase: Upcoming (n = 4)
In 3-month phase: Missed (n = 2)
Moved to 6-month follow-up phase (n=0)

6-Month Follow-up Phase (n = 56)
Completed 6-month assessment (n = 45)
Lost to follow-up at 6-months (n = 11)

6-Month Follow-up Phase (n = 63)
Completed 6-month assessment (n = 54)
Lost to follow-up at 6-months (n = 9)

6-Month Follow-up Phase (n = 0)
Completed 6-month assessment (n = 0)
Lost to follow-up at 6-months (n = 0)

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*Note: Participants in the home condition during COVID-19 restrictions are counted towards the total sample (either home or telehealth) depending on which medium they had >50% sessions. Those in provider-centered delivery count towards their condition if >50% of their sessions were in-person. All but n=2 received a hybrid of in-person tx and telehealth.

**Note: the number of participants at 3-month follow-up consists of those who "Moved to follow-up phase" and "Discontinued, remained for outcome assessments "