Parent-based Treatment for Youth With Anxiety and Obsessive-compulsive Disorder

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Section Aa: Title & PI

A1. Main Title

PARENT-BASED TREATMENT FOR YOUTH WITH ANXIETY AND OBSESSIVE-COMPULSIVE DISORDER

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

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A5. Funding Source:

Organization: GILLSON LONGENBAUGH FOUNDATION

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Anxiety and obsessive-compulsive disorders are the most common mental health disorders in childhood and adolescence (Merikangas et al., 2010). Parental accommodation of their children's avoidance, escape, safety behaviors are a set of parenting behaviors that have been most strongly associated with child anxiety and obsessive-compulsive disorder (Kagan et al., 2016). Developing and testing parent-led interventions that target accommodation and parenting styles associated with anxiety has the potential to improve treatment outcomes and reach families who may not otherwise access care (for

example, for youth who refuse to attend therapy). A parenting intervention for youth with anxiety has been recently developed to address these goals called Supportive Parenting of Anxious Childhood Emotions ("SPACE"). In this intervention, therapists meet individually with parents to help them reduce accommodation and support adaptive behaviors in their children. SPACE was recently shown to be noninferior to individual cognitive-behavioral therapy with 88% of youth being classified as responders to SPACE (Lebowitz et al., 2020).

The purpose for the proposed study is to demonstrate the treatment efficacy of SPACE compared to a low-contact, therapist-supported bibliotherapy version of this intervention, providing efficacy evidence for SPACE as delivered by an independent investigatory group.

Section D: Purpose and Objectives

The purpose of this study is to implement a parenting intervention based on a cognitive-behavioral approach to anxiety and OCD for children and adolescents aged 7-17. We will compare standard Supportive Parenting for Anxious Childhood Emotions (SPACE) to a low-contact, therapist-supported bibliotherapy version of SPACE using the book "Breaking Free of Child Anxiety and OCD."

Specifically, our aims are as follows:

1. To provide evidence of treatment efficacy for the full standard version of SPACE relative to a low therapist contact bibliotherapy version of SPACE (Lebowitz, 2020).

2. To determine pre-treatment predictors of treatment outcome, especially those that showed a moderate response to the low therapist contact bibliotherapy SPACE group compared to the standard SPACE group.

3. To compare treatment adherence between the standard SPACE group and the low therapist contact bibliotherapy SPACE group.

4. To explore treatment satisfaction, preferences, and feasibility of standard SPACE and low therapist contact bibliotherapy SPACE, overall and as a function of group status.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 2: Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Adult (18-64 yrs), Child (3-12 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Both patients and healthy, non-patient, normals

Which if any of the following vulnerable populations will be recruited as subjects?
Children, Mentally ill

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
There are two types of participants in this study. First, parents of children anxiety and/or OCD will provide informed consent, and only those adults with decisional capacity will be eligible for participation. These participants (i.e., parents) are not considered a vulnerable population. Second, children with anxiety and/or OCD are considered a vulnerable population. Therefore, their parents are required to provide consent and the child will be asked to provide assent. Information provided to children will be suitable for their developmental level. Further, we have exclusion criteria related to low IQ to ensure children are able to understand the purpose and nature of the study.

Overall, all participants will be provided with all relevant information and will be given as much time as needed to decide whether to participate. Participants will be informed that their participation or absence of participation will not have any influence on the clinical services received at BCM or any other institution. Informed consent/assent will be obtained prior to proceeding with any study procedures. We will take all appropriate steps to protect participants' identities. Participants will be assigned a unique alphanumeric identifier that will enable the research team to manage the participant data while maintaining the participant's confidentiality. All study data will also be coded with the participants' unique identifier. The coded data will be stored on servers managed by the institutional IT programs and/or departmental system administrators. Any physical data will be examined in a secure and private environment. When not in use, the physical data will be locked in a filing cabinet located in the research team's office, where only the research team has access. We will collect the minimum amount of information needed for the purposes of this study. Only approved study personnel will have access to this data, and all of the information gathered will be used for this study, only unless data has clinical relevance to the patient's treatment, in which case will be shared with the clinical team.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

A total of 120 children-parent dyads will participate and will be randomized in a 1:1 ratio into one of two groups: (1) the standard SPACE group and 2) the bibliotherapy, low therapist contact SPACE group.

Inclusion Criteria:

1) The child is between the ages of 7 to 17 at enrollment

2) The child has clinically significant symptoms of anxiety and/or OCD, as indicated by a score of 12 or higher on the Pediatric Anxiety Rating Scale (PARS).

3) The child is appropriate for anxiety-focused treatment (e.g., anxiety is the primary problem as diagnosed using the Kiddie Schedule for Affective Disorder and Schizophrenia (K-SADS), and if secondary psychopathology is present it will not interfere with treatment).

4) One parent/guardian is able and willing to participate in assessment and treatment (e.g., has sufficient English fluency, the decisional capacity to participate, and can commit to treatment duration).

5) The participating parent/guardian lives with their child at least 50% of the time.

6) Both parent and child are able to read and understand English.

7) The child has the intellectual and communication skills to engage in CBT, as judged by an experienced supervising clinician.

8) Participants must reside in Texas and parents must be in the state of Texas when taking calls.

Exclusion Criteria:

1) the child has a diagnosis of child lifetime bipolar disorder, drug or alcohol abuse, psychotic disorder, or conduct disorder.

2) the child has severe, current suicidal/homicidal ideation and/or self-injury requiring medical intervention (referrals will be made for appropriate clinical intervention).

3) the child is receiving concurrent evidence-based psychotherapy for anxiety, involving exposure therapy in at least 50%

of sessions.

4) New Treatments: Initiation of an antidepressant within 12 weeks before study enrollment OR 6 weeks for an antipsychotic, benzodiazepine, or ADHD medication before study enrollment. Established Treatment changes: Any change in established psychotropic medication (e.g., antidepressants, anxiolytics, alpha agonist) within 6 weeks before study enrollment (4 weeks for antipsychotic, anti-anxiety, benzodiazepine, or ADHD medication). Any medications must remain stable during treatment; downward adjustments due to side effects may be acceptable.

F2. Procedure

RECRUITMENT. A total of 120 child-parent dyads will be recruited through different methods. The primary sources will be through the Baylor Psychiatry Clinic, social media, and various anxiety and OCD-related organizations, professionals, clinics, and resources.

Study advertisements will be circulated through other relevant sources (e.g., social media, including Facebook ads and videos of the PI talking about the study; websites; listservs; newsletters; research participant databases; word of mouth; other sources that would provide a diverse sample to enhance enrollment and subject generality.

We will contact social service/community organizations (e.g., private clinics, educational support/other social emotional learning services, schools, advocacy groups, resources, nonprofits) to distribute flyers.

Standard disclaimer language from the organization distributing the study flyer may be included on the flyer (these disclaimers state that the flyer content isn't coming from the organization; see example in Section S).

Interested people will be asked to contact the coordinator by email/phone.

PHONE SCREEN. Parents will be given a 20-minute telephone screening to elicit preliminary inclusion/exclusion information, confirm potential interest, and answer questions the parent may have about the study. A screening form will be used to collect pertinent information including contact information, basic demographics (age, race, gender, ethnicity), and questions relating to mood and health. Individuals who meet basic eligibility requirements during the phone interview and remain interested will be invited for a screening visit (i.e., baseline assessment), at which point a member of the research team will obtain informed consent/assent from the parent and child.

INFORMED CONSENT. There are three possibilities for obtaining consent if and when a potential participant chooses to participate in this study.

1) Consent will be obtained in-person. Participants will be provided with all relevant information and will be given as much time as needed to decide whether to participate. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a quiet and private room, and participants may take as much time as needed to make a decision about their participation. Members of the research team will be available to answer questions or explain any details further. Participants will be informed that their participation or absence of participation will not have any influence on the clinical services received at BCM (or any other institution). Informed consent/assent will be obtained prior to proceeding with any study procedures. A copy of the informed consent form will be given to the subject to take home with them. All participants will also be informed that they do not have to answer any specific questions if they do not wish to do so.

2) Consent will be obtained using an electronic process. All regulatory consent procedures explained above will be followed when using e-consent protocol i.e. provided all relevant information and be given as much time as needed. A member of the research team will schedule an informed consent via HIPAA compliant video conferencing software, ZOOM. Participants will be provided an electronic copy of the consent to read prior to the call. Research staff will send the participant a secure e-mail link to an online consent form via Redcap. We will also provide 'key points' to the study, to aid in the parents explanation of the study to their child so that the child has an understanding of the study, requirements, and components prior to the scheduled call. During the scheduled call, participant and research team member(s) will thoroughly review the consent to ensure comprehension, answer any questions, and address any concerns. Participants will be able to agree to participate, and sign the consent form with a stylus, mouse, or finger and submit it to the research staff. The participant will also be able to download a copy of their signed consent form as a PDF through REDCap.

3) Consent will be obtained via mail. Alternatively, participants have the option of receiving the informed consent in hard-copy via mail. The research team will mail 2 consent forms to the participant. The consent discussion will be conducted over the phone before the participant signs the forms. Members of the research team will be available to answer questions or explain any details further. The participant will be instructed to sign both, keep one for their records, and mail back the second using the self-addressed stamped envelope included in the mailing. Informed consent will be obtained prior to proceeding with any study procedures.

TREATMENT. All participants will receive the Supportive Parenting of Anxious Childhood Emotions (SPACE) intervention, a parenting intervention based on a cognitive-behavioral approach to anxiety. In SPACE, parents learn to support their children through instilling a message of support and encouragement; that they acknowledge their child's difficult experience with anxiety while conveying confidence that they can cope with stressful situations. This is done through specifically identifying parental accommodation behaviors they currently use and steadily reducing engagement in those behaviors. In the therapist-led SPACE group, therapists will follow the SPACE treatment manual, "Treating Childhood and

Adolescent Anxiety." In the low therapist contact bibliotherapy SPACE group, treatment will be provided using "Breaking Free of Child Anxiety and OCD," which is a parent-oriented book adaptation of the SPACE program for child and adolescent anxiety and/or OCD.

Treatment will take place over 12-24 weeks through telemedicine technology (video-conferencing) which, given recent changes in Texas legislation, provides a sustainable platform for disseminating services to those in underserved areas. Treatment begins with psychoeducation about childhood anxiety and how parenting behaviors can contribute to the development and maintenance of anxiety. Subsequently, each week, parents learn tools to increase supportive communication that conveys a message of support (i.e., that they understand and accept their child¿s distress) and encouragement (i.e., that they are confident in their children's ability to cope). One core aspect of treatment will be parents identifying and steadily reducing specific accommodation behaviors. For example, parents who routinely speak for their child at family gatherings due to their child's social anxiety may tell their child they do not plan on answering questions directed to their child from specific family members, and subsequently resist providing answers when their child is asked questions. Alternatively, parents of children with separation anxiety who usually accompany them on trips outside the house may go on incrementally longer errands while the child is safe at home. These exercises serve as parent-led exposures, the key component of therapy for anxiety.

All relevant information regarding parent-led exercises will be detailed in the treatment manuals/parent-directed books. Therapists will review progress with parents during video-conferencing sessions.

Families will be randomized in a 1:1 ratio into either the low therapist contact bibliotherapy SPACE group or the standard SPACE group. Treatment will be guided by a licensed psychologist/therapist or trainee under the supervision of a licensed psychologist. All treatment will be provided via Zoom, which is HIPAA compliant and secure video-conferencing software.

In addition to posttreatment assessments at the end of the 12-week protocol, a one-month follow-up will assess the sustainability of improvement over a short period. Participants in the low therapist contact bibliotherapy SPACE group who do not reach treatment responder status as assessed at the one-month follow-up will be invited to receive up to additional 8 additional weekly sessions of standard SPACE treatment.

LOW THERAPIST CONTACT BIBLIOTHERAPY SPACE GROUP (LTC-SPACE group). Families randomized to the LTC-SPACE group will receive four 45-minute supportive video calls with a therapist over the first 12 weeks of treatment. Participating families will receive a copy of the book 'Breaking Free of Child Anxiety and OCD' to use at home and in-session with the therapist. During each of the four video-conferencing sessions, therapists will serve to provide encouragement and support as the parent works through the program independently, consistent with previous bibliotherapy research (Rapee et al., 2008) and our ongoing work with parent-led bibliotherapy interventions. Treatment-responder status will be determined based on the 1-month follow up assessment (described below), and treatment non-responders will be offered the chance to receive up to eight additional sessions of standard SPACE treatment. Treatment responders will not receive this additional treatment.

STANDARD SPACE GROUP. Families randomized to the standard SPACE group will receive twelve parent-only, once-weekly, 60-minute video calls with a therapist. During each of the twelve videoconferencing sessions, therapists will guide the parent through the implementation of the program, including providing psychoeducation, discussing and practicing supportive communication, identifying accommodation behaviors, and developing weekly goals related to reducing accommodation. Participants in this group will not be offered an additional 8-week course of standard SPACE regardless of treatment-responder status determined at the 1-month follow up assessment.

ASSESSMENTS. All participants will be asked to cooperate in assessments that will occur at pre-treatment (baseline before treatment), post-treatment (at the end of the twelve weeks), and 1-month follow up (4 weeks after first 12 weeks of treatment have concluded). Non-responders to bibliotherapy (assessed at 1-month follow-up) who choose to participate in therapist-led SPACE will complete an additional post-treatment assessment following up to eight additional sessions of SPACE (up to 8 weeks later). The three assessments include a battery of questionnaires and measures at these three timepoints. Depending on group assignment (LTC-SPACE or standard SPACE), measures will also be completed at session visits. Treatment responder status will be assessed at the 1-month follow up, and whether participants in the LTC-SPACE group receive up to 8 additional weeks of standard SPACE will be determined based on the 1-month follow up assessment.

The IE will be an experienced clinician, trained professional, or advanced graduate trainee (supervised by a clinician). The measures that will be administered will include both IE-rated and participant-rated scales (please see attachment in section S). Measures will be completed either in-person or by secure connection (Zoom) and Qualtrics, to reduce burden.

TREATMENT FIDELITY/INTEGRITY. All clinician and assessment sessions, in both conditions, will be audio-recorded or video-recorded (with parent consent). These recordings will be used for research purposes, to monitor ongoing fidelity, to quantify treatment adherence, as well as to assess inter-rater reliability and rater drift. If concerns are noted, the clinician and/or IE will not conduct another assessment until procedures have been reviewed. Clinicians will upload audio and video recordings to a web-secure, HIPAA-compliant storage (Box). Fidelity measures have been developed in our pilot work and adapted for use in this project: [1] The Parent Completion and Effort Rating (PCER); and [2] The Treatment Adherence, Content, and Competence Checklist. We will also use treatment fidelity checklists for each session following Lebowitz et al. (2020).

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 240 Worldwide: 240

Please indicate why you chose the sample size proposed:

We will enroll 120 parent-child dyads (n = 240 total children and parents), we anticipate 90 dyads will be eligible (n = 180), in order to meet an intent-to-treat sample size of 45 parent-child dyads per group, accounting for screen-fail rates. This exceeds our anticipated needs of 34 parent-child dyads per group to detect statistical significance in response rates on the CGI-I, the primary outcome measure. The power analysis assumed α = .05, power = .95, as well as a 24% response are for the parent self-guided intervention (based on our previous work with a similar approach; Storch et al., under review) and a 66% response rate for individual SPACE based on the Lebowitz et al. (2020) trial. We also anticipate the target sample size will be more than enough to detect differences in reductions on the Pediatric Anxiety Rating Scale (PARS), our other primary outcome, based on the Lebowitz et al. (2020) trial and our own preliminary analysis (Storch et al., under review). For this outcome, we anticipate needing 16 participants to detect statistically significant differences. This assumes an effect size of f = .845, α = .05, power = .95, and a correlation among repeated measures of r = .33.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Descriptive statistics on all randomized participants will be analyzed and if any key variables (e.g. anxiety severity) differ across groups, they will be controlled for in analytic models via inclusion as a covariate. Violations of distributional assumptions will be addressed (e.g. robust sandwich estimators and interval smoothing for continuous variables, and exact logistic regression) in the case of sparely distributed dichotomous dependent variables.

Study Aims 1-4 address pre-post group differences as a result of treatment, statistical moderation of pre-post treatment effects, and evaluation of additional observed change from post-treatment to 1-month follow up. Chi-square analyses will compare dichotomous outcomes (i.e., treatment response rates). Mixed within-between (time by treatment group) analysis of covariance (ANCOVA) will be used to assess pre-post and post-1-month follow up changes in continuous outcomes (i.e., symptom severity). Within-group change on continuous measures from post-treatment to 1-month follow up will assessed by dependent t-tests for each treatment group. Between group differences in study dropout will be assessed by logistic regression.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Overall, the risks of this study are considered relatively minor. One potential risk of participating in this study is discomfort associated with the psychiatric evaluation and completion of rating scales-- either due to the discussion of subjectively difficult topics or due to the length of time required for the interviews and questionnaires. However, we have found that most people welcome the opportunity to discuss their experiences with a trained clinician; and breaks will be given as much as possible to decrease boredom and physical/psychological discomfort. In rare cases, psychotherapy may exacerbate anxiety symptoms. Should a child's symptoms increase significantly (linked to treatment or not) and require study discontinuation, we will discuss alternative treatment options including psychotropic medication and more intensive psychotherapy. We will implement very strict rescue criteria should a child's symptoms worsen significantly; he/she requires a higher standard of care (i.e., inpatient); and/or the child experiences suicidality or significant side effects. Should a participant's symptoms markedly worsen, and/or the individual experience suicidality or significant side effects, he/she will be immediately withdrawn from the study and provided with the standard of care, which may include hospitalization, if necessary. Dr. Storch and Dr. Palo (or a covering clinician) will be available at all times to study participants in the event of a clinical emergency. Both this availability and how to reach the investigators in an emergency will be clearly communicated orally and in writing to study participants.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

Yes

NOTE: The answer to the questions in H2 requires the completion of the form: 'Section H â€“ Data and Safety Monitoring Plan' as an attachment in Section S.

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There are several anticipated benefits associated with study participation, including improved access to care, extensive psychiatric evaluation and psychological treatment. As a result of the latter, subjects may experience improvements in both quality of life and psychosocial functioning, as well as reductions in symptoms presentation and related impairment.

Describe potential benefit(s) to society of the planned work.

Participation will provide valuable treatment outcome data, which may benefit future families by helping faculty and staff better evaluate and improve treatment and care for individuals anxiety and/or OCD. Overall, understanding the effectiveness of a lower therapist contact model may also have dramatic benefits for improving access, allocating more intensive services for those most in need, and reducing barriers (e.g., distance).

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The benefits of participation far outweigh the relatively minor risks of participation. The treatment provided has demonstrated non-inferiority to CBT (considered standard-of-care) in a rigorous randomized controlled trial, with 88% of participants being classified as treatment responders (n=42/48). In addition, it is possible that treatment may be rendered faster when participating in the research study given the typical wait-list period when being seen through a standard clinic.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

The waiver of written consent is required for the pre-screening portion of the study. Verbal consent will be obtained before the pre-screening, and written informed consent will be obtained before proceeding with further study activities. Please see the script for obtaining verbal consent before the pre-screening, attached in Section S.

Collecting basic information (e.g. name, DOB, contact information, reason for seeking treatment) to determine study eligibility criteria involves no more than minimal risk to the subject. Patient information is routinely reviewed by clinicians when determining eligibility for treatment after receiving a verbal consent, and access to such information is strictly monitored. Only individuals who have been trained in health information privacy protocols are allowed to review patient information, and all investigators conducing screenings will receive the same training. Thus, a standard protocol for protecting patient's privacy rights already exists. We will review subjects' information to confirm subject eligibility. We will also review any pertinent documentation regarding prior testing (e.g., any anxiety disorder or autism spectrum disorder diagnostic assessments, IQ, genetic-testing) in order to verify subject eligibility.

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Parents will be given a 20-minute telephone screening to elicit preliminary inclusion/exclusion information, confirm potential interest, and answer any questions the parent may have about the study. A screening form will be used to collect pertinent information including contact information, basic demographics (age, race, gender ethnicity), and questions relating to mood and health. Individuals who meet basic eligibility requirements during the phone interview and remain interested will be invited for a screening visit (i.e., baseline assessment), at which point a member of the research team will obtain informed consent/assent from the parent and child.

INFORMED CONSENT. There are three possibilities for obtaining consent if and when a potential participant (e.g., parent and child) chooses to participate in this study.

1) Consent will be obtained in-person. Participants will be provided with all relevant information and will be given as much time as needed to decide whether to participate. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a quiet and private room, and participants may take as much time as needed to make a decision about their participation. Members of the research team will be available to answer questions or explain any details further. Participants will be informed that their participation or absence of participation will not have any influence on the clinical services received at BCM (or any other institution). Informed consent/assent will be obtained prior to proceeding with any study procedures. A copy of the informed consent form will be given to the subject to take home with them. All participants will also be informed that they do not have to answer any specific questions if they do not wish to do so.

2) Consent will be obtained using an electronic process. All regulatory consent procedures explained above will be followed when using e-consent protocol i.e. provided all relevant information and be given as much time as needed. A member of the research team will schedule an informed consent via HIPAA compliant video conferencing software, ZOOM. Participants will be provided an electronic copy of the consent to read prior to the call. Research staff will send the participant a secure e-mail link to an online consent form via Redcap. We will also provide 'key points' to the study, to aid in the parents explanation of the study to their child (attached in Section S) so that the child has an understanding of the study, requirements, and components prior to the scheduled call. During the scheduled call, participant and research team member(s) will thoroughly review the consent to ensure comprehension, answer any questions, and address any concerns. Participants will be able to agree to participate, and sign the consent form with a stylus, mouse, or finger and submit it to the research staff. The participant will also be able to download a copy of their signed consent form as a PDF through REDCap. A PDF of the online survey can be found in Section S. Also attached is a copy of the last page where name, signature, and date are collected.

3) Consent will be obtained via mail. Alternatively, participants have the option of receiving the informed consent in hard-copy via mail. The research team will mail 2 consent forms to the participant. The consent discussion will be conducted over the phone before the participant signs the forms. Members of the research team will be available to answer questions or explain any details further. The participant will be instructed to sign both, keep one for their records, and mail back the second using the self-addressed stamped envelope included in the mailing. Informed consent will be obtained prior to proceeding with any study procedures.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
Yes

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
No

At what institution will the physical research data be kept?
Baylor College of Medicine

How will such physical research data be secured?
Any physical data will be examined in a secure and private environment. When not in use, the physical data will be locked in a filing cabinet in the research team's office where only the research team will have access. The physical data will be disposed of in a responsible manner that is consistent with BCM policy.

At what institution will the electronic research data be kept?
Baylor College of Medicine.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
The information collected will be entered into a database that will be password-protected for confidentiality. The database will be stored on the BCM network. Per BCM policies, the confidential information will be stored on servers managed by the institutional IT programs and/or departmental system administrators. When not in use, the physical data will be locked in a filing cabinet in the research teams¿ office where only the research team has access. The physical data will be disposed of in a responsible manner that is consistent with BCM policy. All identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research. As participants are enrolled, they will each be assigned a unique alphanumeric identifier that will enable the research team to manage the participant data while maintaining the participant's confidentiality. All study data will also be coded with the participant's unique identifier. The coded data will be stored on

servers managed by the institutional IT programs and/or departmental system administrators. Only the PI and Co-Is will have knowledge of the subject's actual identity. Once the subject is assigned a unique identifier, they will only be identified by that code. Electronic data, including audio-video recordings and biosensor data, will be uploaded and maintained secure on the web-secure, HIPAA compliant storage system (Box). Only the members of the investigative team will access this information. No information will be disclosed outside of the research setting.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

N/A

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

Participants will receive free treatment but will not be compensated otherwise. Neither subjects nor subjects' insurance will be responsible for research related costs.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

N/A

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Other: Flyer, website, social media

Exact language of Advertisement:

Are you the parent of a child aged 7 to 17 with anxiety or OCD symptoms? Join a free treatment study!

What is this study about? Baylor College of Medicine is conducting a research study that provides a free scientifically backed, parent-based treatment program for anxiety and OCD in children and adolescents (ages 7-17 years old). This program is delivered over videoconferencing to your home.

What's involved? --A free 12-week course of parent-based therapy for children with anxiety or OCD with sessions delivered via video conferencing -- a total of 3 assessments conducted over video-conferencing

Participants will receive: --Free parent-based therapy for children and teens with anxiety and OCD

Is this study right for me? --Do you have a child between the ages of 7 and 17 years old with anxiety and/or OCD? --Can your child communicate verbally? --Do you and your child speak English? --Do you currently reside in Texas?

If you're interested or unsure if you meet the requirements, contact a member of the study team at:

XXX@bcm.edu 713-798-8563

NOTE: Health information shared online is not secure. Please do not comment on this post with any private or personal health information.

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Parent's Consent to Participate in the Research and Permission to Allow Child to Participate in Research

H-49809- PARENT-BASED TREATMENT FOR YOUTH WITH ANXIETY AND OBSESSIVE-COMPULSIVE DISORDER

Concise and Focused Presentation

You and your child are invited to take part in a research study looking at the effectiveness of two parenting interventions for anxiety and OCD in youth that are based on a cognitive-behavioral approach to anxiety and delivered via teletherapy. The first is a therapist-led treatment called Supportive Parenting for Anxious Childhood Emotions (SPACE), and the second is a low therapist contact bibliotherapy version of SPACE using the book "Breaking Free of Child Anxiety and OCD." Cognitive behavioral strategies focus on how your child's thoughts, beliefs, and attitudes affect feelings and behavior and teaches coping skills for dealing with different problems. Teletherapy is providing therapy through a live connection over the internet (most commonly using video software).

All families who meet eligibility criteria will receive a parenting intervention based on a cognitive-behavioral approach to anxiety. However, the amount of contact you have with your therapist will vary depending on the type of treatment. You and your child will be randomized, like a flip of a coin, to one of the two interventions: 1) low therapist contact bibliotherapy treatment, where you will receive four 45-minute supportive video calls over the 12 weeks of treatment; or 2) therapist-led standard SPACE treatment, where you will receive twelve 60-minute sessions with your therapist. If you complete the low therapist contact bibliotherapy treatment and it is determined that your child would benefit from further treatment, you will be invited to receive up to eight additional therapist-led sessions.

If you decide to participate in this study and to allow your child to participate, you will be asked to provide your signature at the end of this document. Please take all the time you need to go over the information in this document and ask questions as needed. Once you provide written consent for the procedures detailed below, you and your child will be asked to participate in a "screening" visit (also known as the pre-treatment assessment) to determine your eligibility for the study. If you qualify, your participation in the study will last approximately 16-24 weeks (i.e., 12 weeks of treatment, a follow-up assessment 4 weeks after treatment ends, and up to 8 weeks of additional treatment if you were in the low therapist contact bibliotherapy group).

In order to decide whether or not you wish to participate in this research study, you should know enough about the risks and benefits to make an informed decision. Possible risks involved with the study include discomfort, frustration, or fatigue from completing questionnaires and clinical interviews that are sensitive in nature. As your child begins treatment, they may experience a slight increase in anxiety and discomfort. This should be short-lived, and therapy should reduce those effects over the long term. It is also possible, although unlikely, that your child's anxiety may worsen during participation. Your child's progress will also be regularly monitored, and should your child show worsening symptoms, the PI may see fit to withdraw your child from the study and help you seek more appropriate or intensive services. Your child may be offered the opportunity for off-protocol treatment, in which case you would be responsible for associated fees/costs.

Potential benefits include better access to care, psychological evaluation, and psychotherapy treatment that may reduce symptoms and impairment.

You and your child's participation in this study is completely voluntary, and your decision to not participate, not allow your child to take part in this study, or to stop participation at any point will not affect the care they receive at BCM or at any institution. Alternative treatments are available if you choose not to participate in this study, such as seeking care through your insurance (e.g., primary care doctors, anxiety or OCD specialists as applicable).

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study. This document is called an informed consent form. The nature of the study, benefits, risks, and other important information about the study are detailed below. Because both children and parents can join this study, please take note that the word "you" in this consent form refers to both you and your child.

We are asking you to take part in a research study called Parent-Based Treatment for Youth with Anxiety and Obsessive-Compulsive Disorder. The person who is in charge of this research study is Dr. Eric Storch, Ph.D. This person is called the Principal Investigator. However, other research staff may also be involved and can act on behalf of the person in charge.

Children between the age of 7 and 17 who experience impairing anxiety and their caregivers may join the study.

This research study is funded by Gillson-Longenbaugh Foundation.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

This research is being done to compare the effectiveness of two parenting interventions for anxiety and OCD in youth that are based on a cognitive-behavioral approach to anxiety. The first is a therapist-led treatment called Supportive Parenting for Anxious Childhood Emotions (SPACE), and the second is a low therapist contact bibliotherapy version of SPACE using the book "Breaking Free of Child Anxiety and OCD."

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine.

WHAT WILL HAPPEN IF YOUR CHILD JOINS THIS STUDY?

If you agree to allow your child to take part in this study, we will ask you and your child to do the following things:

Once enrolled, both you and your child will be randomized into one of two treatment groups, like a flip of

a coin. There is a 50% chance that you and your child will be randomly chosen to receive the therapist-led Supportive Parenting of Anxious Childhood Emotions (SPACE) intervention, and a 50% chance that you and your child will be assigned to receive the low therapist contact bibliotherapy version of SPACE.

If you are randomized to the therapist-led SPACE group, you will receive the standard SPACE protocol. If you are randomized to the low therapist contact bibliotherapy group, treatment will be provided to you using 'Breaking Free of Child Anxiety and OCD: A Scientifically Proven Program for Parents', which is a parent-oriented book adaptation of the SPACE program for child and adolescent anxiety and/or OCD. Treatment will take place over 12-24 weeks through video-conferencing sessions.

Regardless of condition, your child will receive a parenting intervention based on a cognitive-behavioral approach to anxiety and/or OCD via teletherapy. Cognitive behavioral strategies focus on how your child's thoughts, beliefs, and attitudes affect feelings and behavior and teaches coping skills for dealing with different problems. In these parenting interventions, parents learn to support their children through instilling a message of support and encouragement and acknowledging their child's difficult experience with anxiety while conveying confidence that they can cope with stressful situations. This is done through specifically identifying parental accommodation behaviors they currently use and steadily reducing engagement in those behaviors.

Each week, you will learn tools to increase supportive communication that conveys a message of support and encouragement to your child. One core aspect of treatment will be identifying and steadily reducing specific accommodation behaviors. For example, parents who routinely speak for their child at family gatherings due to their child's social anxiety may gently let their child know that they will no longer do so. These exercises serve as parent-led exposures, the key component of therapy for anxiety.

LOW THERAPIST CONTACT BIBLIOTHERAPY GROUP:

If you and your child are randomized to the low therapist contact bibliotherapy group, you will receive four 45-minute supportive video calls with a therapist over the first 12 weeks of treatment. Sessions will occur approximately at weeks 1, 4, 6, and 9. You will receive a copy of the book "Breaking Free of Child Anxiety and OCD" to use at home and in-session with the therapist. During each of the four video-conferencing sessions, therapists will serve to provide you with encouragement and support as you work through the program independently with your child.

One month after the twelfth week of treatment, participants in the low therapist contact bibliotherapy SPACE group will be assessed to determine whether their children have responded to the treatment. If it is determined that your child would benefit from further treatment, you will be invited to receive up to 8 additional weekly sessions of therapist-led standard SPACE treatment.

STANDARD SPACE GROUP:

If you and your child are randomized to the standard SPACE group, you will receive twelve 60-minute

supportive video calls with a therapist over the 12 weeks of treatment. Sessions will occur approximately weekly. During each of the twelve videoconferencing sessions, therapists will guide you through the implementation of the program, including explaining materials, discussing and practicing supportive communication, identifying accommodation behaviors, and developing weekly goals related to reducing accommodation. Additional treatment beyond the initial 12 weeks will not be available for participants in the standard SPACE group.

ASSESSMENTS:

In addition to treatment, you and your child will participate in a total of 3-4 assessment visits. These visits will take place as follows: (1) Pre-treatment assessment (approximately 3 hours); (2) Post-treatment assessment (after the 12 weeks of treatment; approximately 2-3 hours); (3) one-month follow-up assessment (1 month after your post-assessment; about 2-3 hours). If you are in the low therapist contact bibliotherapy group and receive the additional therapist-led sessions, you will participate in a fourth assessment after your last session.

Follow-up assessments will be completed through Zoom video conferencing or over the phone. These assessments will be administered to you by an independent evaluator (IE) and include measures assessing mental health problems or disorders, mood, functioning, related impairment, etc. The IE is an experienced clinician, a trained professional, or an advanced graduate trainee (supervised by an experienced clinician).

All treatment sessions and assessments will be audio- and/or videotaped to make sure that therapists and IEs are providing a high quality of care. These audio files are for research purposes only and will only be shared with research staff affiliated with this project. You or your child will generally not have access to these files. However, if files are necessary to your care, they will be shared with you or your physician.

At the start of the study, we will assign a special number or code to your and your child's study data, which will not contain any personal information (e.g., your name, your child's name, your child's date of birth) that could identify you or them. The document that links the coded information to their identifiers will be stored separately and will only be accessible to the investigators in this study. All data being collected will be stored in a locked file cabinet, and only the PI or a member of the study staff will be able to access them.

YOUR CHILD SHOULD NOT PARTICIPATE IN THIS STUDY IF ANY OF THE FOLLOWING APPLY:

[1] You child is receiving psychotherapy for anxiety, involving exposure therapy in at least half of the sessions, at the same time as the study treatment.

[2] Your child has started or changed an antidepressant medication within 4 weeks before study enrollment or a stimulant or benzodiazepine medication 2 weeks before study enrollment.

[3] Your child has severe current suicidal/homicidal ideation and/or self-injury requiring medical intervention. This is to ensure that we are providing the appropriate level of care for youth.

FUTURE CONTACT

Research is always an ongoing process and new questions arise every day. That is why we are asking families in this study if they would be willing to be contacted in the future about research related to this or other studies. If you do not wish to be contacted, in no way will it affect your involvement in this study, in other studies, or in any other services you currently receive or may receive in the future at BCM (or other institutions).

Please review the two statements below and then INITIAL & DATE next to the statement that is right for you.

_____ /_____ YES, I agree to be contacted in the future about research related to this or other studies.

_____ / _____ NO, I do not agree to be contacted in the future about research related to this or other studies.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, and GILLSON LONGENBAUGH FOUNDATION and their representatives.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine is required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, GILLSON LONGENBAUGH FOUNDATION and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Eric Storch, Ph.D., Menninger Department of Psychiatry and Behavioral Sciences 1977 Butler Blvd, Suite 4-197 Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is

removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

Researchers will take appropriate steps to protect any information they will collect about your child. However, there is a slight risk that information about him or her could be revealed inappropriately or accidentally. Similarly, your child's assessments and therapy sessions may be audiotaped or videotaped. Only the PI and the research team will have access to these audio and video files and they are for quality assurance and research purposes. You will not be able to review the audio and video files, which will be kept on BCM's secure network drive. Although they will be stored securely, there is some risk that the files could be redisclosed.

Other possible risks to you or your child child may include the psychiatric evaluation and administration of rating scales and participation in parenting interventions for anxiety and OCD that are based in cognitive-behavioral strategies.The main risk of the psychiatric evaluation and administering of rating scales is that you and your child may experience mild discomfort due to the discussion of subjectively difficult topics. However, our experience shows that most people appreciate the opportunity to discuss their experiences with a trained clinician. The length of time required for the interviews and questionnaires is a possible discomfort. You and your child will be given as many breaks as needed during that time. You you and your child also do not have to answer any questions if you or they do not want to.

As your child begins treatment, they may experience a slight increase in anxiety and discomfort. This should be short-lived and therapy should reduce those effects over the long term. Your child may also experience distress during exposure exercises. It is also possible, although unlikely, that your child's anxiety may worsen during participation. In the instance that your child's symptoms worsen, they may be offered the opportunity for off-protocol treatment, in which case you will be responsible for associated fees/costs.

Participation in more than one research study or project may further increase the risks to your child. If your child is already enrolled in another research study, please inform the PI or the person reviewing this consent with you before enrolling your child in this or any other research study or project.

If you or your child wish to discuss the information above or any discomforts you may experience, please ask questions now or call Dr. Storch at 713-798-3579.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: your child experiencing improvements in both quality of life and psychosocial functioning, as well as reductions in symptoms presentation and related impairment. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: Participants will be free to seek care through their insurance (e.g., primary care doctors, anxiety or OCD specialists as applicable).

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another state, or if you are unable to keep appointments) or because the entire study is stopped. The sponsor, investigator, or Institutional Review Board may stop the study at any time.

Your child may be removed from the study without your consent if:

- Your child does not qualify to be in the study because he or she does not meet the study requirements. Ask the PI if you would like more information about these requirements.

- Your child needs a medical treatment or a higher level of care not allowed in this study (e.g., suicidality).

- The investigator decides that continuing the study would be harmful to your child.

- Study treatments have a bad effect on your child.

- Your child is unable to keep appointments as directed (you do not attend or are not responsive to scheduling assessments or sessions if you cancel within 24 hours or no-show one or more assessments or sessions. The investigator may determine that missed or canceled sessions may count towards the sessions provided.

- The study is canceled and/or other administrative reasons.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, ERIC STORCH, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: ERIC STORCH at 713-798-3579 during the day. You will receive a return call within two business days. This is not an emergency number. If there is an emergency, please call 911 or go to the nearest emergency room.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here _____

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Legally Authorized Representative Parent or Guardian	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date