Stepped-Care Cognitive-Behavioral Treatment for Youth With ASD and Anxiety

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H-44081- PARENT-LED STEPPED-CARE CBT FOR YOUTH WITH AUTISM SPECTRUM DISORDER AND CO-OCCURRING ANXIETY

Background

You and your child 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.

We are asking you and your child to take part in a research study called: PARENT-LED STEPPED-CARE COGNITIVE-BEHAVIORAL TREATMENT FOR YOUTH WITH ASD AND CO-OCCURRING ANXIETY. 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 4 and 14 who meet criteria for an autism spectrum disorder (ASD) and experience impairing anxiety may join the study. Parents may also join the study to provide information about their child.

This research study is funded by Texas Higher Education Coordinating Board.

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 implement and evaluate how effective a parent-led, stepped-care cognitive behavioral intervention is for treating anxiety in children with ASD.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and TCH: Texas Children's Hospital.

WHAT WILL HAPPEN IF YOUR CHILD JOINS THIS STUDY?

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

Once enrolled, your child will receive stepped-care cognitive-behavioral therapy (SC-CBT). Cognitive behavioral therapy (CBT) focuses on how your child's thoughts, beliefs, and attitudes affect feelings and behavior and teaches coping skills for dealing with different problems. The type of CBT is a specialized cognitive-behavioral treatment program for children and adolescents with ASD and comorbid anxiety. This type of treatment will be delivered using a stepped-care model, which provides therapy in "steps" that vary by intensity. Treatment is "stepped-up" until your child begins to make progress, beginning first with the lowest intensity treatment (e.g., fewer in-person appointments, parent-led exposures) to more intensive (e.g., weekly in-person sessions, therapist-led exposures), as needed. SC-CBT consists of two main steps: Step One and Step Two.

Your child will start with STEP ONE, which includes 4 parent-led, therapist-assisted sessions (each lasting 45 minutes) over a 12-week period. An important part of therapy involves facing feared situations, places, or objects; a process called exposure. Exposure involves gradually and repeatedly going into feared situations until you feel less anxiety. For example, an exposure for a child who is afraid of dogs may begin by looking at pictures of dogs and standing across the park from a dog on a leash, to eventually petting a dog. At each of the 4 sessions, the therapist will review with you how to use exposures with your child, so that they may gradually face their fears and learn to cope with their anxiety. You will also receive a workbook, offering step-by-step instructions on how to provide treatment at home. With the skills learned from the workbook, you will lead treatment with your child. Brief phone calls between you and study personnel will also be provided for support, coaching, and motivation.

After the 12-weeks, Step One will be complete and your child will participate in a brief assessment, which is used to determine if more therapy is needed. If your child meets treatment response status, then you and your child will proceed to the Maintenance Phase. During this Maintenance Phase, you will be encouraged to continue using the tools learned in Step One, continue using the workbook as a guide, and continue practicing the skills at home. If your child is determined to need more therapy at the end of Step One, then you will be 'stepped up' to receive STEP TWO of SC-CBT, which consists of 10 therapist-led, parent-supported sessions (each lasting 60-90 minutes) over the course of 12 weeks.

In addition to receiving SC-CBT, your child will participate in 4 assessments total throughout the course of the study. The time points for these assessments will be as follows: [1] Screening/Baseline, which is conducted before the beginning of treatment; [2] Mid-treatment, which is conducted after Step One to determine if more therapy is needed; [3] Post-Treatment, which is conducted approximately 12 weeks after your completion of the mid-assessment; and [4] Three-month Follow-up, which is conducted 3 months after the completion of your post-assessment. Post and follow-up assessments will be administered through a secure and HIPAA compliant video-conferencing software (Zoom) in order to reduce burden. These assessments will be administered to you by an independent evaluator (IE). The IE is an experienced clinician, a trained professional, or an advanced graduate trainee (supervised by an experienced clinician).

We will also ask your child to participate in several objective assessment tasks, which will look at your child's physiological and motor characteristics. These tasks will be given at baseline and at post-treatment and will look at your child's gait performance (e.g., gait speed) and balance (e.g., center of mass sway) through use of small body-worn sensors. These body-worn sensors are safe, valid for use in children, and will measure your child's gait and balance. Your child may be asked to walk, stand, sit, or lie while wearing the body-worn sensor. Objective assessment tasks will be conducted on-site (during the visit).

In addition to the objective assessment tasks, all treatment sessions, interviews, and assessments will be audiotaped on a digital recorder or videotaped on a camcorder 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 child's study data, which will not contain any personal information (e.g., your child's name, date of birth) that could identify 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 Dr. Storch or a member of the study staff will be able to access them.

At the end of your participation in the study you will receive a brief summary about research assessment findings and treatment. Summaries provided to you will detail RESEARCH findings and will not be equivalent or a substitution of a clinical evaluation. Summaries will be shared with you by 1) secure email, 2) postal mail, or 3) in person.

For those individuals who participated in the SPARK study,) we are asking your consent for the SPARK study, hosted by the Simons Foundation, to share with Baylor College of Medicine the clinical, demographic and genetic data collected during your participation in SPARK. This information will be shared using your linked research ID number and using a secure transfer system. We are also asking for your consent to share the data we collect during the study here at Baylor College of Medicine with SPARK in order to add to the information that was collected during your participation in SPARK. Please note that because you are a participant in both studies, SPARK and this study will be able to share and link your identifying information as well as any future data you may contribute to either project.

The Simons Foundation funds innovative research and provides coded data access (data with your identifying information removed) to qualified researchers. Researchers can file an application with the Simons Foundation to obtain access to your study data for research purposes. Experts at the Simons Foundation who protect health and science information will look at every request carefully to minimize risks to your privacy.

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

[1] Your child is receiving psychotherapy, certain forms of social skills training, or certain behavioral interventions that target anxiety (e.g., applied behavior analysis) at the same time as CBT. You can stop these interventions if you would like and it would not harm your child to do so.

[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

For non-SPARK participants:

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/TCH (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.

HEALTH INFORMATION AND/OR DATA FOR USE IN OTHER RESEARCH STUDIES

In the future, we may also like to use the information we collect about your child for other research studies. Your child's information will only be released to other investigators for a specific study that has been approved by the Institutional Review Board (IRB). The IRB ensures that research involving human subjects is conducted ethically and that the rights and safety of study participants are protected. If released, your child's health information and/or study data will be stripped of any personal information (such as your child's name, date of birth, medical reference number) and appropriate steps will be taken to protect his/her identity. However, there is a slight risk that your child's information and/or study data could be revealed inappropriately or accidentally.

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

_____ /_____ YES, I agree to allow my child's health information and/or study data to be used in other research studies.

_____ / _____ NO, I do not agree to allow my child's health information and/or study data to be used in other research studies.

STUDY INVOLVEMENT

Please review the following study involvement information, and INITIAL & DATE at the bottom.

I understand that involvement in this study involves:

-Attending 4 sessions during the initial 12 weeks of the project.
-If it is clinically indicated, attending 10 parent and child sessions during the next 12-week period.
-4 assessments (including the one today)

INITIAL & DATE: _____ / _____

COVID-19 STATEMENT

Due to the COVID-19 outbreak, the research team has taken measures to ensure the safety and wellbeing of participants, while also prioritizing continuity of care. We now offer this study in a fully remote format in order to comply with social distancing guidelines. This option is available and will be offered when appropriate. Remote appointments will be through Zoom, a HIPAA compliant video-conferencing platform.

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 and TCH: Texas Children's Hospital 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.)
- Full Social Security #
- 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, TCH: Texas Children's Hospital, and TEXAS HIGHER EDU COORD. BRD 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 and TCH: Texas Children's Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and TCH: Texas Children's Hospital 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 and TCH: Texas Children's Hospital 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 and TCH: Texas Children's Hospital 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 and TCH: Texas Children's Hospital.

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, TEXAS HIGHER EDU COORD. BRD and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, and TCH: Texas Children's Hospital 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 4-400 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 in-person assessments and therapy sessions may be audiotaped or videotaped. Only Dr. Storch 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 your child may include the psychiatric evaluation and administration of rating scales and participation in cognitive-behavioral psychotherapy.

The main risk of the psychiatric evaluation and administering of rating scales is that 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. Your child will be given as many breaks as needed during that time. Your child also does not have to answer any questions if s/he does not want to.

As your child begins stepped-care CBT, s/he 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, he/she will be offered the opportunity for off-protocol treatment in which 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 he or she is already enrolled in another research study, please inform Dr. Storch 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 713-798-4945.

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: 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.. However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

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 Principal Investigator 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 and your child will be compensated $40 for each completed assessment (i.e., baseline, mid-treatment, post-treatment, follow-up), for a total of $160 per parent-child dyad. Payment will be provided to you via ClinCards. You can decline payment if you so desire. You will only be compensated when you complete each respective assessment. Therefore, if you withdraw or drop out, you will not be compensated for any uncompleted assessments. All research study interventions will also be provided free of cost.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or legally authorized representative (LAR) reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. All information collected will be safely stored in a locked cabinet, to which only members of the research team will have access to. This information will only be used to process compensation for study participation, not for research purposes. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, Baylor will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

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: Dr. Eric Storch at 713-798-4945 during the day.

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 _____

H-44081- PARENT-LED STEPPED-CARE CBT FOR YOUTH WITH AUTISM SPECTRUM DISORDER AND CO-OCCURRING ANXIETY

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

H-44081- PARENT-LED STEPPED-CARE CBT FOR YOUTH WITH AUTISM SPECTRUM DISORDER AND CO-OCCURRING ANXIETY

Background

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We are asking you and your child to take part in a research study called: PARENT-LED STEPPED-CARE COGNITIVE-BEHAVIORAL TREATMENT FOR YOUTH WITH ASD AND CO-OCCURRING ANXIETY. 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 4 and 14 who meet criteria for an autism spectrum disorder (ASD) and experience impairing anxiety may join the study. Parents may also join the study to provide information about their child.

This research study is funded by Texas Higher Education Coordinating Board

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 implement and evaluate how effective a parent-led, stepped-care cognitive behavioral intervention is for treating anxiety in children with ASD.

Procedures

The research will be conducted at the following location(s):
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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.

HEALTH INFORMATION AND/OR DATA FOR USE IN OTHER RESEARCH STUDIES

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_____ /_____ YES, I agree to allow your health information and/or study data to be used in other research studies.

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STUDY INVOLVEMENT

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I understand that involvement in this study involves:

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-If it is clinically indicated, attending 10 parent and child sessions during the next 12-week period.
-4 assessments

INITIAL & DATE: _____ / _____

COVID-19 STATEMENT

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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 and TCH: Texas Children's Hospital 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.)
- Full Social Security #
- 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, TCH: Texas Children's Hospital, and TEXAS HIGHER EDU COORD. BRD 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 and TCH: Texas Children's Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and TCH: Texas Children's Hospital 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 and TCH: Texas Children's Hospital 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 and TCH: Texas Children's Hospital 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 and TCH: Texas Children's Hospital.

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, TEXAS HIGHER EDU COORD. BRD and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, and TCH: Texas Children's Hospital 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 4-400 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 you. However, there is a slight risk that your information could be revealed inappropriately or accidentally. Similarly, your child's in-person assessments and therapy sessions may be audiotaped and/or videotaped. Only Dr. Storch and the research team will have access to these audio and video files and they are for quality assurance 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 may include the psychiatric evaluation and administration of rating scales and participation in cognitive-behavioral psychotherapy.

The main risk of the psychiatric evaluation and administering of rating scales is that you 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 will be given as many breaks as needed during that time. You also do not have to answer any questions if you do not

want to.

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

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call Dr. Storch at 713-798-4945.

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

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand your child experiencing improvements in both quality of life and psychosocial functioning, as well as reductions in symptoms presentation and related impairment..

Alternatives

You may choose to not participate in this study.

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 city, or if you are unable to keep appointments as directed) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

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

You and your child will be compensated $40 for each completed assessment (i.e., baseline, mid-treatment, post-treatment, follow-up), for a total of $160 per parent-child dyad. Payment will be provided to you via ClinCards. You can decline payment if you so desire. You will only be compensated when you complete each respective assessment. Therefore, if you withdraw or drop out, you will not be compensated for any uncompleted assessments. All research study interventions will also be provided free of cost.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or legally authorized representative (LAR) reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. All information collected will be safely stored in a locked cabinet, to which only members of the research team will have access to. This information will only be used to process compensation for study participation, not for research purposes. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, Baylor will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

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: Dr. Eric Storch at 713-798-4945 during the day.

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.

H-44081- PARENT-LED STEPPED-CARE CBT FOR YOUTH WITH AUTISM SPECTRUM DISORDER AND CO-OCCURRING ANXIETY

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

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-44081
Status: Approved
Initial Submit Date: 8/31/2018
Approval Period: 3/25/2020 - 3/24/2021

Section Aa: Title & PI

A1. Main Title

PARENT-LED STEPPED-CARE CBT FOR YOUTH WITH AUTISM SPECTRUM DISORDER AND CO-OCCURRING ANXIETY

A2. Principal Investigator

Name:	ERIC STORCH	Phone:	713-798-4945
Id:	201198	Fax:	
Department:	PSYCHIATRY & BEHAVIORAL SCIENCES	Email:	storch@bcm.tmc.edu
Center:		Mail Stn:	BCM350

A3. Administrative Contact

Name:	SEAN OLSEN	Phone:	3109713119
Id:	233474	Fax:	
		Email:	233474@bcm.edu
		Mail Stn:	BCM-412

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

A4. Co-Investigators

Name:	ROBIN KOCHEL	Phone:	832-824-3390
Id:	152719	Fax:	
Department:	PEDIATRICS: PSYCHOLOGY	Email:	kochel@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	LEANDRA BERRY	Phone:	832-822-3700
Id:	164463	Fax:	
Department:	PEDIATRICS: PSYCHOLOGY	Email:	lberry@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	KATRINA RUFINO	Phone:	713-275-5355
Id:	174545	Fax:	
Department:	PSYCHIATRY & BEHAVIORAL SCIENCES	Email:	rufino@bcm.tmc.edu
Center:		Mail Stn:	BCM350
Name:	MICHELLE PATRIQUIN	Phone:	713-275-5229

A5. Funding Source:

Organization: TEXAS HIGHER EDU COORD. BRD

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

BCM: Baylor College of Medicine
TCH: Texas Children's Hospital

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. ClinicalTrails.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:
NCT03720795

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Autism spectrum disorder (ASD) affects as many as 1 out of 59 individuals, with many higher-functioning youth not diagnosed until school-age or later. This equates to ~102,000 children under the age of 14 years in the state of Texas alone. Significant impairment in social and adaptive functioning are common, as are comorbid behavioral health disorders, with anxiety disorders affecting between 50¿80% of youth with ASD. Given the relative frequency of anxiety disorders among children with ASD, the associated impairment, and worsening trajectory over time without intervention, there is a great need for treatment that specifically addresses anxiety-related symptoms in ASD.

Cognitive behavioral therapy (CBT) has demonstrated efficacy in a number of studies. However, existing treatment

protocols are delivered by therapists as ¿full-packages¿ (i.e., 12-16 clinic sessions), which can be therapist-intensive, costly, impractical for families, and not responsive to parental preferences. Alternative approaches, such as parent-led, stepped-care models that improve accessibility, are efficient, provide personalized care, and lower mental health treatment cost, are greatly needed. Stepped-care models provide a lower-intensity first step (e.g., parent-led, less costly, and more convenient for parents) as the initial treatment with the assumption that a proportion of individuals will respond to the first step and others will need to step up to more intensive treatment. Matching treatment to families¿ needs and tailoring subsequent treatment may be an efficient and effective approach, as well as consistent with parents¿ desire to help their child. Given this, together with the substantial impairment associated with clinical anxiety in individuals with ASD across the age span, this study proposes to implement a parent-led, flexible, individually-tailored cognitive-behavioral intervention for children with ASD and anxiety.

Section D: Purpose and Objectives

The purpose of this study is to implement a parent-led, stepped-care cognitive behavioral therapy to children with ASD and anxiety. Specifically, we will (1) examine the effectiveness of Stepped-Care CBT (SC-CBT; e.g., starting with Step One parent-led, therapist-assisted treatment and then either maintenance or Step Two therapist-directed CBT), (2) examine the potential predictors of response to Step One that could be used as baseline tailoring variables to match children to the best level of care (i.e., Step One or CBT), and (3) examine the economic value of using a cost-effectiveness approach of SC-CBT. We expect that through Stepped-Care CBT, children¿s anxiety levels will lessen.

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)

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?

We will seek consent from all participants who wish to participate in this study. If and when a potential participant chooses to participate in this study, written informed consent will be obtained. 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, TCH, or any other institution. Informed consent 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:

d) Questionnaire/survey/interview

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 200 children (aged 4-14) with a diagnosis of ASD and co-occurring anxiety and their parent/legal guardian will participate and receive SC-CBT treatment. In addition, all participants will be asked to cooperate in assessments that will occur at baseline, mid-treatment, post-treatment, and 3-month follow-up.

Inclusion Criteria:

1) The child is between the ages of 4 to 14 upon enrollment with a) an established diagnosis of ASD made by a standardized assessment (e.g., Autism Diagnostic Observation Schedule-Second Edition; Childhood Autism Rating Scale-Second Edition); and/or b) a score of 65and above on the Social Responsiveness Scale-Second Edition (SRS-2).

2) The child has clinically elevated symptoms of anxiety and/or OCD as indicated by a Clinical Severity Rating of ≥4 from the Anxiety Disorders Interview Schedule (ADIS), made on diagnoses endorsed on the Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI-Kid) at baseline assessment, and the Pediatric Anxiety Rating Scale>12.

3) Anxiety and/or OCD is the primary presenting problem and the independent evaluator (IE) determines that the child is appropriate for the intervention focus.

4) One parent/guardian is able and willing to participate (i.e., parent-led therapist assisted treatment, attend study assessments).

5) The child has a Full Scale and Verbal Comprehension IQ>70 as assessed on the Differential Ability Scales-Second Edition (DAS-II) or Wechsler Abbreviated Scale of Intelligence-Second Edition (WASI-II). This level of intellectual ability is frequently used to demark the boundary of ¡°high functioning¡± ASD, and we and others have adopted this in our CBT trials for children with ASD to achieve acceptable external validity.

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

Exclusion Criteria:

Participants will be excluded if (1) the child has a diagnosis of child lifetime DSM-5 bipolar disorder, psychotic disorder, and/or intellectual disability; (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 psychotherapy for anxiety; (4) child has initiated or changed dosage of psychotropic medications within 4 weeks before study enrollment OR stimulant or benzodiazepine medications within 2 weeks before study enrollment. If appropriate, the child may be enrolled in the study once medication dosage has stabilized (i.e., 4 weeks for psychotropic medication or 2 weeks for stimulant/benzodiazepine medication).

F2. Procedure

RECRUITMENT

A total of 200 child-parent dyads will be recruited through different methods. The primary sources will be through the TCH Autism Center, which sees at least 90 patients per month between the ages of 4-14 years with ASD, and through the Autism Center Research Database (ARCD), which has more than 1,700 families enrolled with the vast majority consenting to be recontacted for new study opportunities such as this one. Although it is anticipated that most of the study recruitment will occur through TCH Autism Center's normal patient flow and the ARCD, study advertisements will also be circulated through relevant sources (e.g., social media, websites, newsletters) to enhance enrollment and subject generality. As well, we will contact clinicians and professionals working with children with anxiety (e.g., private clinics, community organizations) to distribute advertisement flyers to potential participants. Interested potential participants will be asked to contact the research coordinator by email or telephone.

Recruitment will also be done through SPARK (Simons Foundation Powering Autism Research for Knowledge) which is a) which is a landmark autism research project with the mission of speeding up research and advancing the understanding of autism. SPARK's goal is to recruit 50,000 individuals in North America with a professional diagnosis of autism, and their family members, into an online research cohort. Approved researchers are allowed to recruit already enrolled SPARK families for additional studies. The Co-I, Dr. Robin Kochel, and the study have been approved for recruitment through SPARK. Eligible SPARK participants will receive an invitation email with a link that directs them to an authorization page, where they can select yes or no to authorizing the research team to contact them. Three reminder emails are sent if there is no response. There are also 2 sequence reminders sent if families indicate interest but do not complete the authorization When families authorize and provide contact information to reach them, SPARK will share their contact information with the research coordinator through a secure admin portal, giving her unique credentials to access it. Language for invitation email, reminder email, and authorization form can be found on section S.

INITIAL PHONE SCREEN.

Parents will be given a 20-minute telephone screening to elicit preliminary inclusion/exclusion information. 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 from the parent and child.

INFORMED CONSENT

If and when a potential participant chooses to participate in this study, informed consent will be obtained. 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 TCH (or any other institution). Informed consent will be obtained prior to proceeding with any study procedures. All participants will also be informed that they do not have to answer any specific questions if they do not wish to do so. After obtaining consent, participants will complete the baseline assessment and begin treatment.

TREATMENT

All participants will receive parent-led, stepped-care cognitive-behavioral therapy (SC-CBT). CBT focuses on how a child's thoughts, beliefs, and attitudes affect feelings and behavior and teach children coping skills for dealing with different problems. The type of CBT that will be used is a specialized program for children and adolescents with ASD and comorbid anxiety. This type of treatment will be delivered using a stepped-care model, which provides therapy in "steps" that vary by intensity. Treatment is "stepped-up until the child begins to show improvement in anxiety symptoms, beginning first with the lowest intensity (e.g., fewer in-person appointments, parent-led exposures) to more intensive (e.g., weekly in-person sessions, therapist-led exposures), as needed. SC-CBT consists of two main steps (detailed below). Each participant will be treated by a licensed psychologist/therapist or trainee under the supervision of a licensed psychologist. At the end of study participation, a standardized summary of assessment and treatment will be provided to research participants. Assessment summaries will contain information about inclusion criteria (e.g. SRS score, CSR score, PARS score, whether they met IQ cut off, etc.). It will be specified that this summary details research findings, and that our assessment is not equivalent or a substitution of a clinical evaluation. Treatment summaries will contain information about how many therapy sessions participants attended. Summaries will be reviewed and signed by PI before sharing them with research participants. Summaries will be shared through secure email, postal mail, or in person.

STEP ONE. All participants will start with Step One, which includes 4 parent-led, therapist-assisted sessions over a 12-week period. Parents will receive a parent-child workbook to use in session with the therapist, and at home. During each of these 4 sessions, the therapist will review with parents the necessary skills for conducting exposures and will provide guidance in the delivery of exposures. Exposures, a hallmark of CBT for anxiety are used to gradually and repeatedly confront feared stimuli. For example, exposure therapy for a child fearful of dogs may begin with looking at pictures of dogs and standing across the park from a dog on a leash, to eventually petting a dog. Outside of session, parents will lead therapy using the provided workbook, which consists of a step-by-step approach for parents written on a 6th-grade level. Brief phone contacts between parent and staff will also be provided for support, coaching, and motivation. After completing Step One, a brief assessment will occur (i.e., the mid-treatment). If the child meets treatment response status, then the parent and child end treatment and proceed to the Maintenance phase, where parents and children will be encouraged to continue using the workbook and tools that they learned in Step One. If the child does not meet treatment response (i.e., does not improve), then s/he will 'step up' to Step Two.

STEP TWO. For those children who do not respond to Step One, they will be 'stepped up' to Step Two, which consists of 10 therapist-led, parent-supported sessions, each lasting 60-120 minutes over the course of 12 weeks. During Step Two, therapists will lead exposure tasks and teach children response strategies. These strategies will focus on providing children with anxiety-coping skills. In addition, parents will be taught (in weekly sessions) to support children in learning and maintaining anxiety-coping skills, especially when outside of sessions. These skills are encouraged to be practiced at school, in the community, and in peer-group settings. After completing Step Two, participants will end treatment and the post-assessment will occur. For those participants in the maintenance phase (i.e., treatment responders at Step One), the post-assessment will occur approximately 12 weeks after the completion of the mid-treatment (for consistency with procedures in Step Two). All participants will then be re-assessed 3-months, after completion of the post-treatment.

ASSESSMENTS

All participants will be asked to cooperate in assessments that will occur as described above. All assessments will be conducted with an independent evaluator (IE). 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). To reduce burden for families, post-assessment and 3-month follow-up measures will be completed through a secure connection using video-conferencing software (Zoom). Zoom is a secure HIPAA-compliant video-conferencing software.

In addition to completing rating scales, participants will be asked to participate in several objective assessment tasks, examining physiological and motor characteristics. These tasks will be given at baseline and at post-treatment, and will measure the participants gait performance (e.g., gait speed) and balance (e.g., center of mass sway). Both gait performance and balance will be assessed on-site during the in-person visits through the use of wearable sensors. Sensors transmit data to a BCM encrypted laptop via Bluetooth function (wireless), and data are saved in the laptop automatically. The sensor data will not include identifiable information such as name and date of birth. We will use HIPAA compliant BCM Box for transmitting the collected data and for storage. Data collected for each participant will be coded to ensure confidentiality. Only study personnel will have access to subjects' records. Data may also be shared with study's co-investigators (on this IRB protocol) through BCM Box. However, data that could in any way identify subjects will not be made public or shared. All of the outcomes in these tasks will be measured using previously validated wearable sensors (more information attached in section S).

TREATMENT FIDELITY/INTEGRITY

All clinician and assessment sessions, in both conditions, will either be audio-recorded or video-recorded (with parent consent). These recordings will be used for research purposes, to monitor ongoing fidelity in Steps One and Two, to quantify treatment adherence, as well as to assess the 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 recordings to a web-secure, HIPPA-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); [2] The Adaptation Checklist-Child; [3] The Step One Treatment Checklist; [4] The Treatment Adherence, Content, and Competence Checklist.

TEMPORAL CHANGES DUE TO COVID-19

Please see procedural changes due to COVID-19 attached in Section S (due to limited remaining characters)

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 200 Worldwide: 200

Please indicate why you chose the sample size proposed:

We will enroll a total of 200 participants, which achieves sufficient power for the primary and secondary aims. Although we expect slight attrition, the below-mentioned analyses allow for attrition without the loss of data. While MLM does not provide for specific power analyses, the suggested power rules range from 20 participants per group, per level. As such, to be conservative with our power estimates, we aim to enroll 200 participants to ensure we are sufficiently powered for our analyses, accounting conservatively for attrition (~7% at Step One; ~15% at Step Two).

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?

Data analysis will involve Multilevel Modeling (MLM) because of the ¿nested¿ nature of the variables. More specifically, because the measures are repeated, the measures are considered the first level of the hierarchy, the individual children are considered the second level, and the treatment groups are considered the third level. A major advantage of MLM is its ability to handle missing data. While more traditional analyses use listwise deletion if a single time point is missing, MLM uses parameter estimates to maximize the use of existing data. Furthermore, the present study will implement a regression discontinuity analysis, which is an application of mixed models within MLM. This will allow us to examine the impact of treatment, without the use of random assignment, as this method allows for the use of groups that are similar at baseline, but then are designated by a predetermined selection cut point.

After assessing responder status and determining which participants receive Step Two treatment and which participants move to the maintenance phase, binary logistic regression will be utilized in an attempt to determine if there are factors significantly predicting group membership. Possible predictors include variables such as age, anxiety severity, internalizing/externalizing problems, and parent characteristics.

Cost-effectiveness analysis examines the relative value of SC-CBT (relative to CBT). CEA is performed from a societal perspective, meaning the costs to the healthcare system and the patient/parents are included. Treatment costs include

direct (e.g., cost of therapy session), indirect (e.g., travel costs, missed work), and opportunity costs (e.g., value of lost time; see above for cost measures). CEA often incorrectly omits the opportunity cost of patient/parent time spent on therapy, phone support, and at-home parent-child meetings. Non-study, mental-health service costs include inpatient, outpatient, and school-based services and will be priced using the Texas Medicaid fee schedules. Research-specific costs (e.g., screening, research consent) for patients and staff are excluded. Incremental cost-effectiveness ratios (ICER) are computed as incremental costs divided by incremental changes in morbidity/outcomes (symptom reduction and change in impairment/functioning). If outcomes differ significantly, a non-parametric bootstrap with replacement method is used to generate a joint distribution of differential costs and outcomes. If outcomes do not differ, cost-effectiveness is determined by examining treatment costs. Mean and median ICER ratios are reported, as well as 95% confidence intervals. Cost-effectiveness acceptability curves examine the probability of falling below a variety of cost-effectiveness thresholds. In addition to the ICER approach, the net-benefit approach will be used to determine if findings are sensitive to method.

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 intense 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 (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 – 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 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 with ASD and co-occurring anxiety.

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

The benefits of participation far outweigh the relatively minor risks of participation. As the treatment provided is considered standard-of-care, quality of intervention is not in question. 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?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A waiver of consent is required to collect subjects' health information via EPIC, prior electronic medical record systems, and/or hard copy records of those subjects associated with Texas Children's Hospital and TCH Autism Center, in order to determine subject eligibility. Pertinent clinical information will be collected from the medical records regarding identifying information such as name, telephone, date of birth, medical record number, demographics, and diagnoses. Any pertinent documentation regarding prior testing (e.g., any ASD and anxiety disorder diagnostic assessments, IQ, genetic-testing) will also be reviewed and collected from interested families in order to verify subject eligibility.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

Use of patient's charts involves no more than minimal risk to the subject. Subjects charts are routinely reviewed by clinicians and their access is strictly monitored. Only individuals allowed access to patient's charts (e.g., EPIC) are allowed to review patient information. Thus, a standard protocol for protecting patient's privacy rights already exists. We will review subjects' charts to identify and contact potential participants, as well as to confirm subject eligibility.We will also review any pertinent documentation regarding prior testing (e.g., any ASD and anxiety disorder diagnostic assessments, IQ, genetic-testing) in order to verify subject eligibility.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

Reviewing medical charts is part of standard clinical practice and necessary to ascertain diagnoses and other medical information. Patients' contact and medical information will only be used to identify and contact potential participants. Pertinent documentation regarding prior testing will also only be used to verify subject eligibility. Only the members of the investigative team will have access to this information. No information will be disclosed outside of the research setting.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Accessing patients' contact and medical information is necessary to identify potential participants for the study. Accessing interested families documentation regarding prior testing is also necessary to confirm eligibility prior to enrolling. Without the waiver and thus without access to participants, it would be impossible to effectively conduct the research. In addition, scientific validity would be compromised if not all the records can be analyzed.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

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. Any physical data will be examined in a secure and private environment. When not in use, physical data will be locked in a filing cabinet in the research team's 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 each subject is enrolled, he or she will be assigned a unique participant number (e.g. 1-100) to protect the subject's identity. A password-protected document will be created that will contain the subject's participant number, as well as their identity. Per BCM policies, confidential information will be stored on servers managed and maintained by the institution IT programs and/or department system administrators. Only the PI and Co-Is will have knowledge of the subject's actual identity. Once the subject is assigned a participant number, he or she will only be identified by their participant number and all other identifying information (i.e. name, medical record number, address, etc...) will be removed from the study database.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

All identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research and local IRB requirements, and participants will only be identified through their unique participant number.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Written assurances exist on the consent form, stating that any PHI will not be reused or disclosed with any other person or entity, except as requested by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule. All data collected will be entered into a database that will be password-protected and stored on the secure BCM network. Any physical data collected will also be kept and stored in a secure, locked filing cabinet in the research team's office where only the research team has access. Any collected identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research and local IRB

requirements. Any PHI obtained from collected documentation will be redacted and relabeled using unique study IDs. All documentation provided by the participants will be stored in a locked filing cabinet.

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:
No

Other:
No

Will additional pertinent information be provided to subjects after participation?
Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.
Upon request, we will provide information on published outcomes of the study.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
No

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.

Children with ASD and co-occurring anxiety, and their parents/legal guardians will be recruited through different methods. The primary sources will be through the TCH Autism Center, which sees at least 90 patients per month between the ages of 4-14 years with ASD, and through the Autism Center Research Database (ARCD), which has more than 1, 700 families enrolled with the vast majority consenting to be recontacted for new study opportunities such as this one. Although it is anticipated that most of the study recruitment will occur through TCH Autism Center's normal patient flow and the ARCD, study advertisements will also be circulated through relevant sources (e.g., social media, websites, newsletters) to enhance enrollment and subject generality. As well, we will contact clinicians and professionals working with children with anxiety (e.g., private clinics, community organizations) to distribute advertisement flyers to potential participants. Interested potential participants will be asked to contact the research coordinator by email or telephone.

Parents will be given a 20-minute telephone screening to elicit preliminary inclusion/exclusion information. 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 from the parent and child.

If and when a potential participant chooses to participate in this study, informed consent will be obtained. 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 TCH (or any other institution). Informed consent will be obtained prior to proceeding with any study procedures. All participants will also be informed that they do not have to answer any specific questions if they do not wish to do so. Due to COVID-19 outbreak, consent will be obtained using an electronic process when appropriate. 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.

Appropriate steps will be taken 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.

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 #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

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

Other:
No

At what institution will the physical research data be kept?
TCH Autism Center

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. Information (i.e. full social security number, address, date of birth, and language of preference) collected with the sole purpose of providing compensation through ClinCard will be safely stored in a locked cabinet, to which only members of the research team will have access to. This information will only be used for compensation purposes, not for the research study. 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:
Yes, (describe below):
Audio-video recordings and biosensor data will be uploaded and maintained secure on a web-secure, HIPPA compliant storage system (Box Sync).

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. Information collected with the sole purpose of providing compensation through ClinCard will be safely stored in a locked cabinet, to which only members of the research team will have access to. This information will only be used for compensation purposes, not for the research study. 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, HIPPA compliant storage system (Box Sync). No information will be disclosed outside of the research setting. The sensor data will not include identifiable information such as name and date of birth, etc. Data collected for each participant will be coded to ensure confidentiality. Sensor data will be transmitted via Bluetooth function connected to the BCM network onto a BCM encrypted laptop. Only the members of the investigative team will access this information.

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 be compensated $40 for each assessment completed (i.e., baseline, mid-treatment, post-treatment, follow-up), for a total of $160 per parent-child dyad. Participants can decline payment if they so desire. Participants will only be compensated when they complete the respective assessment. Therefore, participants who withdraw or drop will not be compensated for uncompleted assessments. All study interventions will be provided free of cost.

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:

160

Distribution Plan:

Participants will be paid upon completion of each assessment (i.e., baseline, mid-treatment, post-treatment, follow-up). Participants will be dispensed payments via ClinCards. Information such as full social security number, address, date of birth, and language of preference will be collected from parents and legal guardians for the sole purpose of providing compensation via ClinCard. This information will only be used to process compensation, not for the research purposes. ClinCards will be mailed to those participants completing the initial assessment via Zoom. Upon confirmation of receipt of card, payments will be dispensed following completion of assessments.

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)

Parent's Permission to Allow Child to Participate in Research

Parent's Consent to Participate in Research

Section R: Advertisements

Mode of Advertising: Internet

Exact language of Advertisement:

FREE Therapy for Children with ASD and Co-Occurring Anxiety! Is your child between the ages of 4 and 14? Has your child received a diagnosis of autism spectrum disorder? Does your child experience impairing anxiety? Baylor College of Medicine and Texas Children¿s Hospital are conducting research on a parent-led cognitive behavior therapy (CBT). This particular treatment has been tailored to meet the needs of children WITH HIGH-FUNCTIONING ASD who also experience anxiety symptoms. Therapy is FREE of cost and incentives will be provided upon completion of several parts of the study. **Therapy in this study is NOT meant to address problem behavior** If you are interested in learning more about this study please contact Ana Ramirez at ana.ramirez@bcm.edu or 832-824-8372.

Mode of Advertising: Other: Flyer

Exact language of Advertisement:

FLYER 1

Parent-Led Stepped-Care CBT for Youth with ASD and Co-occurring Anxiety

Is your child between the ages of 4 and 14? Has your child received a diagnosis of autism spectrum disorder (ASD)? Does your child experience impairing anxiety?

Baylor College of Medicine and Texas Children's Hospital are conducting research on a parent-led, stepped-care cognitive-behavioral treatment protocol (SC-CBT) for anxiety in youth with ASD.

Eligible participants will receive therapy at no cost. In addition to therapy, you/your child would have to attend a total of four assessment sessions: 1) baseline, 2) mid-treatment, 3) post-treatment, 4) three-month follow-up. You will be compensated $40 for each completed assessment session.

For more details, please contact the study coordinator, Ana Ramirez at (832) 824-8372 or email Ana.Ramirez@bcm.edu

FLYER 2

Do you have a child with ASD and Anxiety?

Researchers at Baylor College of Medicine and Texas Children's Hospital are looking for parents of children ages 4-14 with ASD and anxiety symptoms (worries and fears) to participate in a research study. You may be eligible to qualify for treatment at no cost!

To learn more about current projects and eligibility contact us at: anxietyandASD@bcm.edu

FLYER 3 (COVID-19 EDIT)

FLYER 1

Parent-Led Stepped-Care CBT for Youth with ASD and Co-occurring Anxiety

Is your child between the ages of 4 and 14? Has your child received a diagnosis of autism spectrum disorder (ASD)? Does your child experience impairing anxiety?

Baylor College of Medicine and Texas Children's Hospital are conducting research on a parent-led, stepped-care cognitive-behavioral treatment protocol (SC-CBT) for anxiety in youth with ASD.

Eligible participants will receive therapy at no cost. In addition to therapy, you/your child would have to attend a total of four assessment sessions: 1) baseline, 2) mid-treatment, 3) post-treatment, 4) three-month follow-up. You will be compensated $40 for each completed assessment session. Remote assessment and treatment available to comply with social distancing guidelines.

For more details, please contact the study coordinator, Ana Ramirez via email anxietyandASD@bcm.edu

Mode of Advertising: BCM Clinical Trials Website

Exact language of Advertisement:

Listing Title - "Parent-Led Stepped-Care CBT for Youth with ASD and Co-occurring Anxiety" Categories: Psychiatry and Behavior Study Contact: Ana Ramirez Phone:(832) 824-8372 Email: Ana.Ramirez@bcm.edu Is your child between the ages of 4 and 14? Has your child received a diagnosis of autism spectrum disorder (ASD)? Does your child experience impairing anxiety? Baylor College of Medicine and Texas Children's Hospital are conducting research on a parent-led, stepped-care cognitive-behavioral treatment protocol (SC-CBT) for anxiety in youth with ASD. Eligible participants will receive therapy at no cost. You/your child would have to attend a total of four assessment sessions: 1) baseline, 2) mid-treatment, 3) post-treatment, 4) three-month follow-up. You will be compensated $40 for each completed assessment session. If you are interested, would like more information, or would like to see if you qualify, please contact the study coordinator, Ana Ramirez at (832) 824-8372 or email Ana.Ramirez@bcm.edu.