Principal Investigator: Blakeley-Smith, Audrey

COMIRB No: 20-3142

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Study Title: Group Cognitive Behavioral Treatment for Anxiety in Adolescents with ASD and Intellectual Disability: A Randomized Controlled Trial.

You/your child are/is being asked to be in a research study. This form provides you/your child with information about the study. A member of the research team will describe this study to you/your child and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

You/your child are/is being asked to take part in a research study of a treatment program for emotion regulation and anxiety in adolescents. Problems with emotion regulation and anxiety are fairly common in children with developmental disabilities. This research project uses treatment for anxiety that has been shown to be successful in general pediatric practice. The treatment does not use medication, but instead uses a type of psychotherapy.

You/your child are/is being asked to be in this study because you/your child

(1) have/has a diagnosis of Autism Spectrum Disorder (ASD) and Intellectual Disability (ID)
(2) have/has symptoms of anxiety;
(3) are/is between 12 and 18 years old, and
(4) have/has adaptive behavior below 70.

Other people in this study

Up to 72 adolescents from your area will be asked to participate in this study.

What happens if I join this study?

If you/your child will join the study you will meet with the research team to learn about the study and, if you choose to participate, sign the consent forms. In addition to signing the consent form to participate in this study, you will be asked to sign forms that will allow the researchers to gather medical and intervention records for you/your child. If you are in possession of your child's current Individualized Education Program (IEP), you will be requested to share this with the research team. You can choose to not share the IEP. If the IEP is not in your possession, you will not be requested to obtain it. The purpose of the research team obtaining the IEP is to document your child's current therapeutic supports. Furthermore, if you are in possession of a previous evaluation where your child has completed a standardized adaptive behavior measure and/or a standardized cognitive measure within 3 years of the baseline visit, you will be requested to share this with the research team. You can choose to not share these documents. If these documents are not in your possession, you will not be requested to obtain them. The purpose of the research team obtaining any previous evaluation completed within 3 years of the baseline visit is to document your child's adaptive functioning scores and cognitive scores without repeating these tests.

The second step of the study involves administering tests to evaluate your/your child's current developmental level, social, and communication skills. At the same time that we are working

with you/your child, we will interview you (caregiver) on your child's anxiety and will complete forms on their adaptive behavior, emotion regulation, and anxiety. In addition, you (caregiver) will be given forms to fill out. Forms will include questions about the physical and mental health of family members, educational and employment information, and ethnic/racial identity. The evaluation will take place at JFK Partners and will last about 2-3 hours. Filling out the forms should take another 1-2 hours or so. The information from this testing session will be used to determine if you/your child are/is appropriate and eligible for this particular type of cognitive behavior therapy. If you/your child are/is found not to be eligible for the study (either because he/she does not have ASD or ID, or does not have significant symptoms of anxiety), then we will tell you this immediately following the testing. We will also work with you to find another, more appropriate intervention that meets yours/your family needs.

If you/your child meet/meets the eligibility requirements for the study, you will be enrolled in a treatment group. You will be assigned randomly to the treatment group (A,B,C, or D) but may need to wait for a period for the treatment group to begin. All eligible participants will be able to participate in treatment, however, the start date of the when you will be able to begin the treatment will differ depending on your group number. While you are waiting to being the treatment group, you will be asked monthly to inform the research staff about outside therapies that your child receives. You will not wait longer than 6 months to begin the intervention.

Then, you/your child will be asked to come to JFK Partners for assessments. Assessments will total between 4-5 hours. During these assessments, professional research staff will ask you (caregivers) questions about the child's symptoms of anxiety and how those symptoms are affecting him/her and the family. You (caregivers) will also be asked about the child's current use of skills to manage anxiety such as deep breathing and helpful thoughts. Research staff will also assess you/your child for Autism and Intellectual Disability Further observe you/your child in a situation that causes anxiety to better understand the behavior you/they display when anxious. Paperwork will also be provided to you (caregivers) to complete regarding the child's behavior, family management of anxiety, quality of life, and outside therapies that your child receives. If you (caregivers) wait for more than 16 weeks to begin treatment, this assessment will be repeated within 3 weeks of the start of treatment.

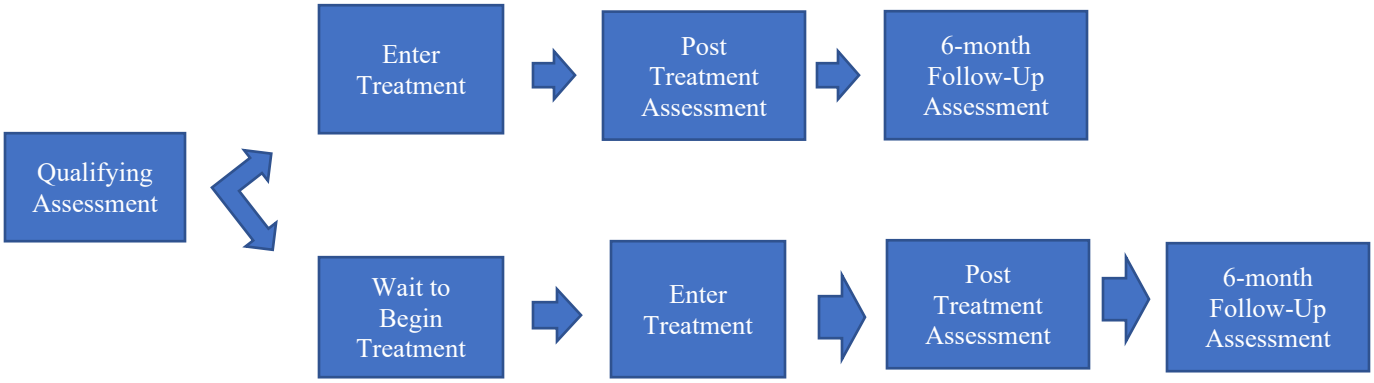
You (adolescent and caregivers) will be asked to attend weekly 60-90 minute group therapy sessions for 14 weeks. Therapy sessions will be hosted in person at JFK Partners or via Zoom as needed. In case a treatment session will be hosted online via zoom, the research personnel will create a zoom meeting with the university account. The zoom meeting will be accessible only with a passcode. The research team will send the link to access and the passcode to the meeting via email. The link and the passcode to access the meeting will be sent to all the treatment participants, the therapists hosting the session, and the PI. Intervention sessions will be conducted by a minimum of two therapists—at least one of the therapists will be a licensed clinical psychologist with experience in cognitive behavioral therapy. Other therapists will be post-doctoral fellows in clinical psychology, pre-doctoral interns in clinical psychology, and advanced graduate students in clinical psychology. Sessions will be videotaped (with permission of group members). The first 3 sessions will be for parents only and will be 90 minutes. Then, the next 9 sessions will be for adolescents and caregivers to attend together and each session will be 60 minutes. Parent sessions will cover parenting challenges associated with the management of emotion regulation difficulty and anxiety in adolescents with ASD and ID. Parenting supports will be discussed in addition to understanding how you/your child may show anxiety. The 9 sessions in which adolescent and caregivers will attend will cover topics such as:

(1) what makes you/your adolescent anxious,
(2) what do/does you/your adolescent do/look like when anxious,
(3) tools to support emotion regulation and manage anxiety, and
(4) active coaching to use coping skills while facing fears.

There will be homework assignments, meaning you (adolescent and caregivers) will be expected to practice strategies learned in group at home. Missed sessions may not be able to be rescheduled. You (caregivers) will also be asked to inform the research staff about outside therapies that your child receives and will be asked to update the staff on a monthly basis.

You (adolescent and caregivers) will be asked to come to the JFK Partners for up to 2 appointments immediately following treatment, and 2 appointments 6 months after treatment. During these appointments, our research staff will ask you (caregivers) about your child's symptoms of anxiety and how those symptoms are affecting your child and your family. We will also ask you (caregivers) about your experiences in the treatment group so that we can begin to understand what parents and adolescents see as most helpful and least helpful.

All adolescents will participate in the intervention within 6 months of enrolling in the study. Each adolescent will be randomly assigned to a treatment group (either A,B,C, or D). The start date of your/your child's group will be determined by the letter assigned to you/him/her. If your child needs to wait to begin group, they will continue with the treatment they would normally receive in the community. They will then be asked to join the treatment group after approximately 6 month There will be 3-4 other adolescents in your/your child's group. Each group will participate in the same basic treatment model. Please see the below diagram to understand the treatment assignment process:



What are the possible discomforts or risks?

You will be randomly assigned to begin the treatment group immediately, or wait approximately 6 months before beginning the treatment group. During the time you are waiting, you may continue the treatment that you would usually receive. Waiting to begin the treatment may be difficult, particularly if you feel your usual treatment is not sufficiently treating your anxiety. However, there is also a risk that the treatment may not be as good as your usual treatment. There is a risk that people outside of the research team will see your child's research information. We will do all that we can to protect your information, but it cannot be guaranteed. In addition, the study may include risks that are unknown at this time. Coming to JFK Partners at least one time weekly, and carrying out home interventions may be inconvenient and time consuming. If the treatment seems to have a negative impact on your family or your child, your,

his or her participation may be discontinued by the principal investigator or by you, the parent. If at any point in the study you feel your/your child's symptoms are getting worse, you may contact the principal investigator and/or the Colorado Crisis hotline at 1-844-493-8255.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the effectiveness of this CBT intervention relative to treatment that your child would typically receive in the community.

This study is not designed to treat any illness or to improve your health.

Are there alternative treatments?

There are other treatments for treating emotion regulation problems and reducing symptoms of anxiety in individuals with ASD and ID. These treatments include traditional psychotherapy, medication, and making lifestyle changes. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This study is funded by the Department of Defense.

Will I be paid for being in the study?

You will be provided a $20.00 gift card for each assessment and evaluation visit in this study. This will add up to a total of $140.00 if you enter treatment immediately or up to $180.00, if you need to wait to enter treatment since you will then be required to repeat an assessment immediately prior to entering treatment. There are no gift cards provided for treatment sessions. Gift cards will be distributed in-person following live appointments or mailed to your preferred address.

If you leave the study early, or if we have to take you out of the study, you will be provided gift cards only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission, if the study doctor thinks that being in the study may cause you/your child harm, or for any other reason. Also, the sponsor may stop the study at any time.

Who do I call if I have questions?

The researcher carrying out this study is Audrey Blakeley-Smith, Ph.D. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Audrey Blakeley-Smith at 303-724-7630. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Audrey Blakeley-Smith, Ph.D. with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

Recorded Information

In this study we will be recording the following assessment evaluations: Autism Diagnostic Observation Schedule, the Anxiety Disorders Interview Schedule-Autism Spectrum Addendum, and the Behavior Approach Task. The purpose of recording these sessions is for diagnostic reliability. We will also record all group treatment sessions so that our research team can do quality checks on the clinicians' delivery of the intervention. Video recordings will be uploaded and stored on the university HIPPA protected share drive. We will keep this information secure and private. We will store it for 7 years following the end of the study. At the end of that time, we will destroy it.

The use of any recordings will be for the following purposes (initial all approved uses):

1) for research (e.g., diagnostic reliability, treatment checks to ensure that facilitators are implementing the program)
_____Initials

2) for the training of research personnel, or pre-professional students.
_____Initials

All video recordings will be kept under lock and key. All recordings will be protected and used only for the purposes for which you have given permission as indicated above.

The use of any recordings will be done in a legitimate manner which is not intended to cause embarrassment or harm, and your confidentiality will be maintained.

All recordings will be held and used for only the above purposes. The recordings, as mentioned above, will be stored for 7 years following the end of the study.

Being placed on a recruitment list for future studies

We may be doing other studies in the future, and would like to make a list of people who are interested in doing more studies. If you decide now that we can keep your name on a list, you can change your mind anytime. If you change your mind, contact Dr. Audrey Blakeley-Smith and she will remove your name from the list.

I would like to be included on a list of people who will be contacted about future studies.
_____ Initials

I would not like to be included on a list of people who will be contacted about future studies.
_____ Initials

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- JFK Partners

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Audrey Blakeley-Smith, Ph.D.
JFK Partners, University of Colorado School of Medicine
13121 E. 17th Ave. C234
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research

- The study doctor and the rest of the study team.
- The *Department of Defense,* the agency paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

▪ Some things we cannot keep private. If you give us any information about being abused pr neglected/your child abuse or neglect, we have to report that to state Social Services. Also, if we get a court order to turn over your study records, we will have to do that.

▪Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we have to report that to the local and/or State police or state Social Services. Also, if we get a court order to turn over your study records, we will have to do that.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number (this will be used for participant payment)
- Portions of your previous and current Medical Records that are relevant to this study, including diagnosis(es),
- Research Visit and Research Test records
- Psychological and mental health tests

What happens to Data that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____
Parent

Printed Name:_____

Signature:_____ Date:_____
Participant (If applicable)

Printed name (If applicable):_____

Consent form explained by:_____ Date:_____

Printed Name:_____

Signature:_____ Date:_____
Legally Authorized Representative

Printed Name:_____

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature ☐

Witness of consent process ☐