NCT05430022
GROUP DEPRESSION TREATMENT FOR AUTISTIC YOUTH
July 15, 2021

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Jessica Schwartzman, Ph.D. **Revision Date: 06/24/2021**
Faculty Advisor: Blythe Corbett, Ph.D.
Study Title: Adapted Cognitive Behavioral Therapy for Depression in Youth with Autism
Institution/Hospital: Vanderbilt University

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully. Please ask any questions you may have about this study and the information below. You will have an opportunity to ask questions, and your questions will be answered. You will also receive a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This study aims to measure the effects of a new Cognitive Behavioral Therapy (CBT) for depression among adolescents (10-17 years old) with Autism Spectrum Disorder (ASD). To participate in research, adolescents and one of their parents attend three research visits (2 hours each including breaks). Study visits will be conducted outside of the CBT clinical sessions. Participants must be enrolled in the CBT clinical groups at VUMC to participate in the study. However, participants can participate in the CBT clinical groups without participating in the study. Families may not benefit from participating in the study. However, some of the possible benefits include learning about mood and emotions by completing questionnaires and interviews with a clinician. There are no expected risks to participating. Families will be compensated $30 per study visit, and families can earn $90 for completing all study visits. You and your child may participate in this study for about 8 months.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You and your child are being asked to participate in a research study because your child has autism, depressive symptoms, and is enrolled in clinical groups at the Department of Psychiatry and Behavioral Sciences. You and your child will participate by filling out questionnaires about your child and your parenting experiences. You will have interviews with study clinicians and adolescents will complete some psychological testing. We hope to learn about cognitive behavior therapy to improve mood in children with autism.

You do not have to be in this research study. This research study is separate from the clinical treatment groups at the Department of Psychiatry and Behavioral Sciences. Participation in this research study is voluntary and does not affect your child's enrollment in the clinical groups. You may choose to not be in this study and to get other treatments. These will not change your healthcare, services, or other rights. You can stop being in this study at any time. You will be told if we learn something new that may affect the risks or benefits of this study. You can decide if you want to till be in the study or not.

Procedures to be followed and approximate duration of the study:
Participation in this study is voluntary and separate from the clinical groups at the Department of Psychiatry. If you choose to enroll in the study, you would participate three research visits (2 hours each including breaks). More details are in the next section. The total length of your study participation is about 8 months.

3. If you decide to volunteer, you will undergo the following procedures:

The table below summarizes all of the study activities for you and your child.

	Study Visits
Adolescents	Adolescents will attend three research visits (2 hours each including breaks): 1. Visit 1 – In person: Before clinical groups. 2. Visit 2 – Remote: After final clinical group session. 3. Visit 3 – Remote: 12 weeks after Visit 2. During all study visits, adolescents will fill out questionnaires about their mood, behaviors, and friendships. Adolescents will be interviewed by study clinicians at all study visits. Two eligibility assessments (ADOS-2, WASI-II) to measure autism symptoms and intellectual ability may be given if they were not done in the past 24 months. Total time for research visits is 5-6 hours.
Parents	One parent of each adolescent with ASD will also attend the same three research visits (2 hours each including breaks): 1. Visit 1 – In person: Before treatment. 2. Visit 2 – Remote: After final clinical group session. 3. Visit 3 – Remote: 12 weeks after Visit 2. During all research visits, parents will fill out questionnaires about their child's mood, behaviors, and friendships. Parents will also fill out questionnaires about their parenting experiences. Total time for research visits is 5-6 hours.

Below is more information about activities during study visits:

- Baseline (Visit 1): At the first research visit, you and your child will complete the consent and assent process. You will fill out some questionnaires about your child's diagnostic history. Together, you and your child will have an interview with a clinician. Your child may complete two diagnostic assessments – one for measuring autism symptoms, and the other for measuring intellectual abilities – if they have not been done in the past 24 months. Also, parents and adolescents will complete more questionnaires about your child's mood and behaviors, and about your parenting experiences. For example, adolescents may be asked about loneliness and experiences with teasing/bullying. Three of the questionnaires will be administered aloud by study staff and answers will be audio recorded. The audio recording will be used for coding language responses. This audiotape will be destroyed upon completion of the study. You will be notified if you are eligible for the study at the end of this visit. This visit takes about 2 hours. If your child is not eligible, you and your child will be withdrawn from the study.

- Post-Treatment (Visit 2): After the final clinical group session, you and your child will complete the same questionnaires from the beginning of the study. Questionnaires ask about your child's thoughts, emotions, and behaviors. Additionally, parents will repeat the same questionnaires from the beginning of the study about your parenting experiences. Two of the questionnaires will be administered aloud by study staff and answers will be audio recorded. The audio recording will be used for coding language responses. This audiotape will be destroyed upon completion of the study. This visit takes about 2 hours.

- Follow-Up (Visit 3): In order to measure long-term changes that your child may make, you and your child will be invited to attend a final research visit. This will occur 12 weeks after the post-treatment visit (Visit 2). In this visit, your child will complete the same questionnaires from the beginning of the study. Parents will complete the same questionnaires about parenting experiences. Two of the questionnaires will be administered aloud by study staff and answers will be audio recorded. The audio recording will be used for coding language responses. This audiotape will be destroyed upon completion of the study. This visit takes about 2 hours.

No medication or pharmaceutical agent is administered at any time in this study.

Expected costs:
You may have transportation costs for participating in the first study visit.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:
There are minimal risks associated with your participation in this study. Everyone in the study will be watched carefully for any side effects. At times, study visits may be tiresome or cause mild frustration or anxiety. However, we will give you and your child breaks whenever needed. Refusal to attend study visits, threatening behavior towards others, or any verbal protest indicating that you or your child do not want to continue in the study are signs that you do not want to continue in the study. Overall, study procedures should be no more stressful than coming to a new clinic for routine medical procedures. Therefore, the likelihood of any lasting effects from completing questionnaires would be minimal.

Good effects that might result from this study:

a) **The benefits to science and humankind that might result from this study.**
The information we get from this study may help us to learn more about how children with autism understand and manage low mood and depressive symptoms. It may also show how autism-adapted interventions can improve areas of well-being.

b) **The benefits you might get from being in this study.**
It is possible that you and your child will not benefit directly by participating in this study. It is also possible that your child may learn about their mood and emotions by completing questionnaires.

Study Results:
At the end of the study, de-identified data from participants will be published in a manuscript. Data will be published in a group without any identifying information about families. The research team will share the manuscript with all families at the end of the study.

Compensation for participation:
To compensate you for time and effort during study visits, adolescents and one of their parents will each be given $15 per study visit (up to $30 per family per visit). Therefore, families can earn $90 for completing all three study visits.

Alternative treatments available:
Participants in this study must be enrolled in ongoing clinical groups at the Department of Psychiatry and Behavioral Sciences in order to be eligible for and participate in this study. Thus, all participants will receive treatment. There are no alternative treatments in this study.

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Circumstances under which the Principal Investigator may withdraw you from study participation:
First, the Principal Investigator may withdraw you or your child if you become very upset or uncomfortable with the study procedures or experience. Study activities include three research visits (2 hours each including breaks). Second, you and your child may be withdrawn from the study for missed study visits that are not rescheduled. Third, if you and/or your child show severe suicidal thoughts and/or behaviors that pose a risk to personal safety or others, study procedures will be stopped. Clinicians will provide your family with referrals to higher levels of care to ensure the safety of you and/or your child. Finally, we may suggest that you be withdrawn from the study if you and/or your child are unwilling to participate in the study or the majority of the activities. If you are withdrawn from the study, your data up to that point will be stored with the other confidential data. In published manuscripts, we will acknowledge your withdrawal and will not reveal your identity. We may examine the data if there is any question regarding differences in parents who completed the study and those that did not. However, the data from withdrawn participants will not be included in analyses.

What happens if you choose to withdraw from study participation?
Your participation is voluntary. You may choose to withdraw from the study at any time for any reason. You can also skip any questions that you do not wish to answer. There will be no negative outcomes if you choose not to participate in this study. Your future care at Vanderbilt University will not be affected. If you choose to remove yourself from the study, your data up to that point will be stored with the other confidential data. We will state your withdrawal in published manuscripts, but will not reveal your identity. We may examine the data if there is any question about differences between parents who did or did not complete the study. However, the data from withdrawn participants will not be included in analyses.

Contact Information:

If you should have any questions about this research study or possibly injury, please feel free to contact Jessica Schwartzman, Ph.D. at [redacted] or the Faculty Advisor, Blythe Corbett, Ph.D., [redacted].

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:
Your personal information in your research record will be confidential. However, total confidentiality cannot be guaranteed. Only the study researchers will use your child's information. Drs. Schwartzman and Corbett will protect your child's identity with professional standards. The U.S. Department of Health and Human Services has the right to view our medical records related to this research to verify data. The information from this study may be published in medical journals. However, family identities will not be shared. All records will be kept in a locked filing cabinet. Per state law, we will immediately report any evidence of possible child abuse with information of the suspected offender. We must report to the proper authorities if any information is shared during this study about suicide, homicide, child abuse, or neglect. Study information available to the public will not include your child's identity. Complete confidentiality cannot be guaranteed because research documents are not protected from subpoena.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

If information from the study is published or presented at scientific meetings, your name and other personal information will not be used. The Vanderbilt Institutional Review Board has the authority to review your research and medical records.

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- working with you to contact your doctor,
- contact a trusted family member, or a therapist to discuss your thoughts,
- or work with you on a plan that may include getting you to a hospital for safety

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document. The material in this document has been explained to me verbally. All my questions have been answered. I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Date of IRB Approval: 07/15/2021

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