ADAPTED COGNITIVE BEHAVIORAL THERAPY FOR DEPRESSION IN YOUTH WITH AUTISM

PROTOCOL

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CONTENTS

RESEARCH COMPONENTS

- **Baseline/Intake Visit**
  - Informed consent and assent
  - Baseline Assessments – research site offices (2-3 hours)
    - SRS-2 completed by parent
    - C-SSRS administered by clinician
    - ADOS-2 (if not administered in previous 24 months)
    - WASI-II (if not administered in previous 24 months)
- **Midpoint**
- **Post-treatment Visit**
- **Follow-up (12 weeks after post-treatment)**

RECRUITMENT

RECRUITMENT RESOURCES

- Vanderbilt University Medical Center, Department of Psychiatry and Behavioral Sciences, Outpatient Clinic
    - Flyers distributed to clinic groups at the Department of Psychiatry and Behavioral Sciences
    - Interested families will contact the PI (Schwartzman) by email or phone to express interest in study.

MAINTAINING RECRUITMENT

- Maintain ongoing list of interested participants.

RECRUITMENT MATERIALS

- Study Flyers: Shared with adolescents and their parents upon enrolling in clinical groups at the Department of Psychiatry and Behavioral Sciences.

INCLUSION/EXCLUSION CRITERIA

Parent Inclusion Criteria
To be eligible to participate in this study, one must be at least 18 years of age and a parent or legal guardian of the adolescent participant with ASD. The parent must be able to provide current and historical observations of the functioning of the participant with ASD based on parent report. No data will be recorded from the medical record. The parent must live in close proximity to and have frequent contact with the participant with ASD. Additionally, the parent must complete several questionnaires about themselves (e.g., parenting stress, anxiety).

Parent Exclusion Criteria
Parents of adolescents with ASD who do not have frequent contact with the participant with ASD and/or unable to provide current and historical observations of the functioning of the participant with ASD may be excluded from the study.

Adolescent Inclusion Criteria
Clinical groups include male and female adolescents who are between 11-17 years of age at the time of study entry and who have been diagnosed with autism spectrum disorder (ASD). As part of the clinical service, this diagnosis will be confirmed by a clinical psychologist, pediatrician or psychiatrist with expertise in ASD and based on the DSM-V criteria (APA, 2013). Diagnosis may also be confirmed by elevated scores (T>59) on the parent-rated Social Responsiveness Scale, Second Edition (SRS-2; Constantino, 2012) or the ADOS-2 (if not administered in previous 24 months). Adolescents will have average to above-average intellectual functioning in order to keep pace with the clinical groups, which will be assessed through clinician interview as part of the clinical process and/or may confirmed by administration of the WASI-II (FSIQ > 69; if not administered in previous 24 months). Adolescents must be willing to attend study visits which include semi-structured interviews with the PI and questionnaires. No data will be recorded from the medical record.

Adolescent participants who assented to study participation when they were 17 years old will be asked to complete a study consent if they turn 18 years old during the course of the study.

Adolescent Exclusion Criteria

The following exclusion criteria only apply to participant's involvement in the research study. Meeting inclusion/exclusion criteria will not alter, preclude, nor interfere with the adolescent's participation in the clinical groups – this is a separate process.

- Youth with ASD and comorbid intellectual impairment will be excluded from the study, as the study protocol, assessments, and intervention are not designed for this population.
- Adolescents with severe medical conditions (e.g., uncontrolled seizures) and/or genetic disorders (e.g., Fragile X syndrome) will be excluded from the study.
- Participants whose diagnostic screening (i.e., SRS-2 total T-score > 59) does not confirm a diagnosis of ASD will not be eligible to continue the study.
- In order to maintain the safety all participants, youth with aggression toward others, self, or property in the past 6-months will be excluded from participation in the study. This information will be obtained during the initial phone screen with the parent and baseline visit.
- Adolescents who are unable to complete significant portions of the research protocol with be excluded.
- A participant must communicate using complete sentences and have fluent speech. If it appears that the participant does not understand some of the verbal or written information, the PI will use follow-up questions using simple language to ensure the participant understands the purpose and task demands of the study. After clarification, if the participant is unable to demonstrate understanding, respond to questions or willing to complete the questionnaires or protocols, the PI will determine if the participant should be excluded from the study.

If a participant evidences features of severe suicidality based on parental report (e.g., RCADS), self-report (e.g., RCADS), and/or clinical judgement (e.g., C-SSRS), it will immediately trigger a response. Specifically, the PI (Dr. Schwartzman) will determine the best course of action (see full crisis plan below).

After enrollment in the study, if the participant endorses severe suicidal ideation (i.e., endorsing suicidality on the Revised Children's Anxiety and Depression Scale or severe suicidal ideation on the C-SSRS), the PI (Dr. Schwartzman) will determine the best course of action. Options for addressing the concern may include contacting the participant's outpatient mental health care provider, prompt consultation with pediatric providers within the Department of Psychiatry and Behavioral Sciences, or referral for urgent psychiatric evaluation and treatment. If the threat is determined to not be imminent, the participant may stay enrolled within the study under careful observation. If determined necessary, the parent will be provided with local mental health resources. The PI will also inform the participant and parent of the importance of going to the Emergency Room should thoughts and feelings intensify. Finally, the participant will be notified that the Principal Investigator may withdraw the participant from the study due to suicidality in order for them to prioritize and receive the necessary care.

List of Mental Health Resources:

Vanderbilt University Medical Center (VUMC)
Vanderbilt Inpatient Hospitalization Program
Phone: 615-327-7000
Website: https://www.vanderbilthealth.com/psychiatrichospital/45262
Brief Description: We encourage families to join in the treatment process, because family members can have a positive impact on the patient's success. We also provide an aftercare plan to help continue progress after leaving the hospital.

Vanderbilt Adolescent Partial Hospitalization Program
Director: Jessica Lavender
Phone: 615-9363680
Website: https://www.vanderbilthealth.com/psychiatrichospital/26600

Brief Description: This program is designed to care for children, ages 13 to 17, who are dealing with emotional, behavioral and social problems. We offer therapy and medication evaluation services weekdays from 8:00 a.m. to 2:00 p.m. Your child can relax in our warm, therapeutic rooms, and children do not have to stay overnight. We work with parents to provide individualized care for your child, and we see you as an important part of our team.

Vanderbilt Child and Adolescent Outpatient Psychiatry (CAPOC)
Director: Cheryl Cobb
Phone: 615-343-5555
Website: https://www.childrenshospitalvanderbilt.org/service-line/child-and-adolescent-psychiatry
Brief Description: Our mental health specialists care for children ages 4-12 and adolescents ages 13-17 with many different emotional or behavior problems, including depression, anxiety, post-traumatic stress disorder (PTSD), bipolar disorder and attention deficit/hyperactivity disorder. We are Middle Tennessee's only provider of inpatient mental health services for children.

Low-Cost Outpatient Clinics
Centerstone Child and Family Services
Website: https://centerstone.org/child-and-family-services/
Phone: (888) 291-4357
Brief Description: Recognizing the importance of keeping families together, many of our programs include family counseling and parenting skills development - all aimed at creating an environment where our young clients not only improve, but also thrive. Our services are specifically designed to help children experiencing depression, anger, trauma, abuse and other issues. Services include outpatient, school-based, community-based, and intensive at-home services.

Mental Health Cooperative
Website: https://www.mhc-tn.org/proven-approach/our-services/children-and-youth/
Phone: 615-743-1555
Brief Description: School based-therapy, community-based care management, transitional care management, and intensive care management.

Nashville Child & Family Wellness
Website: https://www.nashvillefamilywellness.com/
Phone: 615-238-9100
iBrief Description: The team of providers at NCFWC includes psychiatrists, nurse practitioner, psychologists, therapists, speech-language pathologists, registered dietitians, and other allied professionals. All providers are all dedicated to using evidence-based modalities and to continually educating themselves on the latest research.

TN Department of Mental Health Youth Suicide Prevention and Mental Health Programs
Website: https://www.tn.gov/behavioral-health/need-help/crisis-services/suicide-prevention/youth-and-young-adult-suicide-prevention-and-mental-health-awareness.html
Phone: 800-560-5767
Brief Description: The Youth and Young Adult Suicide Prevention and Mental Health Awareness program is funded by the state of Tennessee to prevent suicide and promote better mental health among Tennesseans up to 25 years of age. The program expands outcomes based suicide prevention activities, including conducting outreach, providing mental health awareness, and suicide prevention training to Institutions of Higher Education; and assisting Middle Tennessee

Pediatric Offices in establishing processes for providing suicide risk screening and referrals , as indicated to treatment and services.

Outpatient Clinicians
Laura Corona, Ph.D. (Vanderbilt)
Specialties: Autism, developmental delay, Pediatric Developmental Medicine
Website: https://www.childrenshospitalvanderbilt.org/doctors/corona-laura
Phone: 615-936-0249

Liliana Wagner, Ph.D. (Vanderbilt)
Specialties: General child and adolescent mental health.
Website: https://www.childrenshospitalvanderbilt.org/doctors/wagner-liliana
Phone: 615-936-0249

Dan Goldstein, Ph.D. (Nashville Psych)
Specialties: Diagnoses and treats individuals, couples and families with a wide range of concerns, including normal life transitions, depression, anxiety, ADHD and other developmental disorders, bipolar disorder, relationships, grief/loss, divorce, and/or learning disorders.
Website: https://www.nashvillepsych.com/about/daniel-goldstein-phd/
Phone: 615-582-2882

Michelle McAtee, Ph.D. (Autism Tennessee)
Specialties: As a psychologist and behavior analyst, she has worked for over twenty years with children and adults with autism and other developmental disabilities in a variety of settings (including home, early intervention, school, residential, and vocational programs). She has also conducted a number of workshops around the country for families and professionals.
Website: https://autismtennessee.wildapricot.org/Our-Consultants
Phone: 615-385-2077

Outpatient Psychiatrists
Cheryl Cobb, M.D. (Vanderbilt)
Specialties: ADHD, Bipolar, Mood Disorders
Website: https://www.childrenshospitalvanderbilt.org/doctors/cobb-cheryl
iPhone: 615-343-5555

Bradley Freeman, M.D. (Vanderbilt)
Specialties: Anxiety, Mood Disorders, Depression, Eating Disorders
Website: https://www.childrenshospitalvanderbilt.org/doctors/freeman-bradley
Phone: 615-343-5555

24/7 Crisis Lines
Nashville - Centerstone Community Clinic: (800) 681-7444
Mental Health Cooperative Community Clinic: 615-726-0125
National: 1-800-273-8255

Additional information about the screening procedures

The following questions will be asked of participants who endorse suicidal ideation. They are derived from the National Institute of Mental Health (NIMH) Ask Suicide Screening Questions.
https://www.nimh.nih.gov/research/research-conducted-at-nimh/asq-toolkit-materials/asq-tool/asq-screening-tool.shtml

1. In the past few weeks, have you wished you were dead? Yes No
2. In the past few weeks, have you felt that you or your family would be better off if you were dead? Yes No
3. In the past week, have you been having thoughts about killing yourself? Yes No
4. Have you ever tried to kill yourself? Yes No

If yes, how?
When?

If the patient answers yes to any of the above, ask the following question:

5. Are you having thoughts of killing yourself right now? Yes No

- If yes, please describe:
- Next steps: If patient answers "No" to all questions 1 through 4, screening is complete (not necessary to ask question #5). No intervention is necessary (*Note: Clinical judgment can always override a negative screen).
- If patient answers "Yes" to any of questions 1 through 4, or refuses to answer, they are considered a positive screen. Ask question #5 to assess acuity:
    - "Yes" to question #5 = acute positive screen (imminent risk identified)
        - Patient requires a STAT safety/full mental health evaluation. Patient cannot leave until evaluated for safety.
        - Keep patient in sight. Remove all dangerous objects from room. Alert physician or clinician responsible for patient's care.
    - "No" to question #5 = non-acute positive screen (potential risk identified)
    - Patient requires a brief suicide safety assessment to determine if a full mental health evaluation is needed. Patient cannot leave until evaluated for safety.
    - Alert physician or clinician responsible for patient's care.

SCHEDULING PARTICIPANTS

IMPORTANT POINTS TO MAKE

- Studying the effects of an adapted Cognitive Behavioral Therapy (CBT) for adolescents with autism and depressive symptoms. Participants are recruited from ongoing clinical group treatments at the Department of Psychiatry and Behavioral Sciences.
- 4 assessment periods: baseline, midpoint, post-treatment, and follow-up (12 weeks after post-treatment).
- Autism
- Ages 11-17
- Does your child use complete sentences to communicate? How are your child's language skills—must have fluent speech/speak in complete sentences.

- Visit breakdown
    - **Intake/Baseline** (up to 2 hours with breaks)
        - Diagnostic confirmation (ADOS, ask if completed within last 2 years)
        - General cognitive abilities (ask if diagnosis of intellectual disability and WASI-II, ask if completed within last 2 years)
        - Parents and adolescents together will complete a brief, semi-structured interview with a clinician
        - Adolescents will complete questionnaires.
        - Parents will complete questionnaires that ask about their adolescent, and several questionnaires that ask about their own experiences as parents.
    - **Midpoint** (6 weeks into groups): Youth and parent questionnaires and clinical interview (up to 1 hour).
    - **Post-treatment** (after 12 weeks of clinical groups; up to 2 hours with breaks)
        - Parents and adolescents together will complete the same semi-structured interview with a clinician.
        - Adolescents will complete the same questionnaires.
        - Parents will complete the same questionnaires that ask about their adolescent, and several questionnaires that ask about their own experiences as parents.
    - **Follow-up** (12 weeks after post-treatment; up to 2 hours with breaks)
        - Parents and adolescents together will complete the same semi-structured interview with a clinician.
        - Adolescents will complete the same questionnaires.
        - Parents will complete the same questionnaires that ask about their adolescent, and several questionnaires that ask about their own experiences as parents.

Study Timeline: Phonescreen…if eligible… → Baseline Visit → Participation in clinical groups for 12 weeks (Midpoint week 6) → Post-treatment Visit → Follow-up Visit (12 weeks after post-treatment)

VISIT SCHEDULING

General Notes:

- Add each component to Lab Calendar.
- Invite Dr. Schwartzman and all other involved lab members to all scheduled calendar components.
- Give reminder call/email to family several days before event.

Assessments

- **Establish Days/Times** for when assessments can be scheduled.
- **Confirmation Email:** Send a confirmation email to the parent to confirm assessments.
- **Site Calendar:** Add Assessment to site Lab Calendar (Include subject ID, and who is doing the assessment)

BASELINE VISIT

BEFORE VISIT: SURVEY KIT

Send to parents before the baseline visit/have parents complete during visit:

- Cover Letter: instructions for questionnaire packet and appointment reminder
- Consent & Assent

    - Tell parents to read, but not sign
    - Come with questions
    - We will review and sign at visit
- Parent-rated questionnaires about adolescent
    - SRS-2
    - RCADS – Parent version
    - QPQ – Parent version
    - EDI
    - ABAS-3
    - Demographic questionnaire
    - Service systems questionnaire
    - Medication questionnaire
    - Vanderbilt ADHD
    - DII
    - SPI Inventory
- Parent-rated questionnaires about self
    - PHQ-9/REMIT-5
    - GAD-7
    - Cohen Perceived Stress Scale
    - CD-RISC-10
    - PROMIS Global
    - PSI-4

(Parent Surveys: remind parents **not** to fill in child's name, DOB, and other identifying information)

SETUP & CONSENTING

- Arrive at the assessment facilities 30 minutes prior to family arrival time.
- Gather appropriate testing materials out of cabinets (C-SSRS, Depression Causes Inventory)
- When the family arrives bring them into a private family room and begin consenting. (15 minutes)
    - Ensure that 2 consent & 2 assent forms are signed by the family and research staff (1 copy for research team & 1 for family).
    - For any participants who are 17 years old, inform the parent and participant that the participant will have to repeat the consent process once they are 18 years old (i.e., transition to adult).
- After consenting and assenting, parent and child meet together with the study clinician to complete the semi-structured interview (C-SSRS; 15-20 minutes).
- After the interview…
    - Escort the parent to the family room where they'll wait until the assessment is done with child. Collect completed questionnaires from parent.
    - Leave the adolescent with the study clinician to complete assessments and questionnaires.
        - ADOS-2 may be administered (if not done in previous 24 months)
        - WASI-II may be administered (if not done in previous 24 months)
- **Review all questionnaires to confirm they are complete**
- At the end of visit, PI or study clinician will meet with both parent and adolescent to discuss study eligibility.

- If family is eligible, make note of this in research folder and general dates/times that family is available for remaining visits.
- If family is not eligible, make note of this in research folder; no subsequent research visits scheduled.

BASELINE TESTING

TASKS

- **The following administration of tests and timelines are normative, but can vary from child to child**
  - Columbia Suicide Severity Rating Scale – 15-20 minutes
  - RCADS Self-Report —5-7 minutes (If the child endorses item #35 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).
  - QPQ Self Report – 5 minutes
  - Cohen's Perceived Stress - 5 minutes
  - Rosenberg – 3 minutes
  - LEAP – 3 minutes
  - ADOS-2 – 30-45 minutes (if not administered in previous 24 months)
  - WASI-II – 30-45 minutes (if not administered in previous 24 months)
  - CATI – 10-11 minutes
  - DII – 4-5 minutes
  - BFNE – 2-3 minutes
  - SCS-SF – 6-7 minutes
  - PROMIS Global – 2-3 minutes

MIDPOINT

TASKS

- **Youth questionnaires**
  - Columbia Suicide Severity Rating Scale – 15-20 minutes
  - RCADS Self-Report —5 minutes (If the child endorses item #35 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).
  - QPQ Self Report – 5 minutes
- **Parent questionnaires**
  - RCADS – Parent version
  - QPQ – Parent version
  - EDI

POST-TREATMENT

BEFORE VISIT: SURVEY KIT

- Parent-rated questionnaires about adolescent
  - SRS-2
  - RCADS – Parent version

- QPQ – Parent version
- EDI
- Treatment Satisfaction Survey, Parent Version
- DII

- Parent-rated questionnaires about self
  - PHQ-9/REMIT-5
  - GAD-7
  - Cohen Perceived Stress Scale
  - CD-RISC-10
  - PROMIS Global
  - PSI-4

(Parent Surveys: remind parents **not** to fill in child's name, DOB, and other identifying information)

TASKS

- **The following administration of tests and timelines are normative, but can vary from child to child**
  - Columbia Suicide Severity Rating Scale – 15-20 minutes
  - RCADS Self-Report —5 minutes (If the child endorses item #35 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).
  - QPQ Self Report – 5 minutes
  - Cohen's Perceived Stress - 5 minutes
  - Rosenberg – 3 minutes
  - LEAP – 3 minutes
  - Treatment Satisfaction Survey, Teen Version – 3 minutes
  - CATI – 10-11 minutes
  - DII – 4-5 minutes
  - BFNE – 2-3 minutes
  - SCS-SF – 6-7 minutes
  - PROMIS Global – 2-3 minutes

FOLLOW-UP VISIT

BEFORE VISIT: SURVEY KIT

- Parent-rated questionnaires about adolescent
  - SRS-2
  - RCADS – Parent version
  - QPQ – Parent version
  - EDI
  - DII
- Parent-rated questionnaires about self
  - PHQ-9/REMIT-5
  - GAD-7
  - Cohen Perceived Stress Scale

- CD-RISC-10
- PROMIS Global
- PSI-4

(Parent Surveys: remind parents **not** to fill in child's name, DOB, and other identifying information)

FOLLOW-UP TESTING

TASKS

- **The following administration of tests and timelines are normative, but can vary from child to child**
  - Columbia Suicide Severity Rating Scale – 15-20 minutes
  - RCADS Self-Report - 5 minutes (If the child endorses item #35 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).
  - QPQ Self Report – 5 minutes
  - Cohen's Perceived Stress - 5 minutes
  - Rosenberg – 3 minutes
  - LEAP – 3 minutes
  - CATI – 10-11 minutes
  - DII – 4-5 minutes
  - BFNE – 2-3 minutes
  - SCS-SF – 6-7 minutes
  - PROMIS Global – 2-3 minutes

All forms must be completed by same rater in assessments (i.e. same parent/guardian)!
***Follow-Up forms sent to families about 10 weeks after post-treatment.**