INVESTIGATING SOCIAL COMPETENCE IN YOUTH WITH AUTISM: A MULTISITE RCT

PROTOCOL

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- **Pre Intervention:**
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    - **ERP (45 minutes)**
    - **Contextual Assessment of Social Skills – research site offices (30 minutes)**
- **Intervention (10 week theatre program or 10 week Tackling Teenage Training program)**
- **Post Intervention:**
    - **Assessment Visit (1 hour)**
    - **ERP (45 minutes)**
    - **Contextual Assessment of Social Skills (30 minutes)**
- **Follow-up (3 months after post visit)**
    - **Assessment Visit (1 hour)**
    - **ERP (45 minutes)**
    - **Contextual Assessment of Social Skills (30 minutes)**

RECRUITMENT

EVENTS

- Regional autism community outreach groups (i.e. Autism Tennessee Conference)
- State Autism Speaks Walk
- Find other events, possible sources of recruitment using regional support groups and awareness programs (i.e. Tennessee Disability Pathfinder website)

To Bring:
- SENSE Theatre mugs, stress balls, flyers, brochures, t-shirts, DVDs, SENSE banner, containers for giveaway items, pens.

RECRUITMENT RESOURCES

- Research Site Website: Coordinate Links and Information with PI and site information technology department
- Vanderbilt Specific Resources:
    - Research Match
    - Study Finder
    - Autism Speaks
    - University Research Notifications
    - www.sensetheatre.com

MAINTAINING RECRUITMENT

- Maintain ongoing list of interested participants and of peers/counselors.

RECRUITMENT MATERIALS

- Flyers can be found here: Post these in psychiatry, Pediatrics, TRIAD, Developmental Medicine.

- [SENSE Theatre Brochure](#) : Bring to assessments and events.

INCLUSION/EXCLUSION CRITERIA

Inclusion Criteria
This randomized control study will include male and female youth between 10 to 16 years of age. Participants will have a confirmed diagnosis of autism spectrum disorder (ASD) by a clinical psychologist, pediatrician or psychiatrist with expertise in ASD and based on the DSM-V (APA, 2013) and corroborated by the Autism Diagnostic Observation Schedule-Generic (ADOS-G; Lord et al., 1999). Participants whose diagnosis is not confirmed will not be eligible to continue the study. We will recruit participants without confirmed diagnoses but will perform diagnostic testing as described above and if diagnosis is not confirmed participants will not be eligible to continue the study. The ASD group will be high-functioning (intelligence quotient IQ > 70).

In addition to these criteria, 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 examiner 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 study team will consult with Dr. Corbett or the site-PI to determine if the participant should be excluded from the study.

Exclusion Criteria
Youth with ASD and comorbid intellectual impairment will be excluded from the study, as it is unclear if they will comprehend the activities and benefit from the intervention. In order to maintain the safety all participants, youth with current, frequent, and uncontrolled aggression toward other persons or property in the past 6-months will be excluded. This information is obtained during the initial phone screen and during the pre-treatment assessment visit. Participants whose diagnostic testing does not confirm a diagnosis of ASD will not be eligible to continue the study. Additionally, children who are unable to complete significant portions of the research protocol with be excluded. If a participant evidences features of suicidality based on parental report, self-report, or clinical judgement, an immediate referral to Child and Adolescent Psychiatry will be made, and the participant will not be enrolled.

For verbal competence, participants are evaluated for verbal and nonverbal intelligence using the Wechsler Abbreviated Scale of Intelligence (Wechsler, 2nd Edition, 2011). Moreover, the Autism Diagnostic Observation Schedule (ADOS, 2nd Edition; Lord et al., 2012) Module 3 is implemented in the study, which requires participants to have fluent speech. In addition to these criteria, 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 examiner 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 study team will consult with Dr. Corbett or the site-PI to determine if the participant should be excluded from the study.

The Child Depression Inventory (CDI) is a self-report questionnaire consisting of questions related to affective states. Item number 8 explicitly asks, if the child think about or wants to kill him/herself. If a participant endorses this item, it will immediately trigger a response. Specifically, Dr. Corbett or the lead clinician will be contacted immediately to determine the best course of action (see full crisis plan below).

After enrollment in the study, if the participant endorses suicidal ideation (i.e., endorsing suicidality on item #8 on the Child Depression Inventory), Dr. Corbett or another study clinician will be contacted immediately to 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 clinician 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

University of Alabama, Tuscaloosa

University of Alabama Psychology Clinic
Phone: (205-348-5000)
Website: https://psychologyclinic.ua.edu/
Specialist: Dr. Crystal Dillard
Description: Preschool - Senior Adults. Services Provided: Individual Therapy ; (child and adult). Provides the following psychological assessment and testing services: ADD/ADHD/LD learning disabilities, full psychological evaluation, intellectual evaluation, achievement evaluation, IE/PE (gifted program); Does not see children/teens in crisis/suicidal/homicidal.

University of Alabama Child and Adolescent Anxiety Clinic
Phone: (205-348-5000)
Specialist: Dr. Matt Jarrett
Preschool-Senior Adults
Sliding Scale Fee

A specialty within the UA Psychology Clinic that specializes in the assessment and treatment of child and adolescent anxiety disorders including general anxiety disorder, social phobia, separation anxiety disorder, obsessive-compulsive disorder, PTSD, specific phobias and selective mutism.

University of Alabama Autism Spectrum Disorders (ASD) Clinic
(205-348-3130)
https://autism-clinic.ua.edu/
Services Provided: Individual therapy (child and adult), family therapy, social skills groups,   parent training/support groups
Payment: Accepts Insurance (including Medicare and Medicaid)

University of Alabama Speech and Hearing Center
Phone: (205-348-7131)
https://cd.ua.edu/speech-and-hearing-center/our-programs/
Services Provided: Individual and group therapy for children and adults with speech or language disorders / delays
Payment: Varies by Program

Capstone Family Therapy Clinic
Phone: (205-348-8154)
Description: Works with individuals, couples, and families with focus on marriage, family problems.
Also treats eating disorders, substance abuse grief and loss

Stony Brook University
Stony Brook Clinical Autism Program
Child and Adolescent Outpatient Clinic Putnam Hall Stony Brook University   (South Campus), Stony Brook, NY
Specialists:
Judy Crowell, MD
Jennifer Keluskar, PhD
Deborah Reicher, PhD
Website: https://neuro.stonybrookmedicine.edu/clinical_autism_program
Phone: (631) 632-8850 (Option #1 for new patients)

Stony Brook Comprehensive Psychiatric Emergency Program
24-hour psychiatric emergency room
Phone: (631) 444-6050
Website: https://www.stonybrookmedicine.edu/patientcare/psychiatry/cpep

National Resources:
24/7 National Suicide Prevention Lifeline 1-800-273-TALK (8255) En Español: 1-888-628-9454
24/7 Crisis Text Line: Text "HOME" to 741-741
Live Online Chat: Talk to a representative
ASAP Center is part of the National Child Traumatic Stress Network (NCTSN) https://www.asapnctsn.org

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 peer-mediated effects on social cognition, communication, and interaction through either SENSE Theatre or the Tackling Teenage Training (TTT) program. Assignment to the treatments will be randomly assigned.
- 2 visits required before and after treatment, in addition to follow-up survey.
- Autism
- Ages 10-17
- 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
    o   1: Assessment (about 2-3 hrs.)

- - - Diagnostic evaluation (ADOS, ask if completed within last 2 years)
    - Estimated IQ (WASI within last year?)
    - Other tasks measuring social perception
  - 2: CASS (about 30 Minutes)
    - Interaction in study offices
    - 10 min with other children
    - Videotaped to analyze later
  - 3: ERP
    - 45 minutes
    - Watch a social and non-social stimuli and press button in response to stimuli.
    - Wear a mesh hair net type device with tiny sponges.
    - Hair will get slightly damp, but that is the only possible discomfort.
  - 4:Intervention
    - 10 consecutive sessions on for both the SENSE Theatre and TTT interventions.
  - 5: Performance: Friday and Saturday evening (7:00pm) at end of the SENSE Theatre intervention.
  - 6: Post and Follow-up Visits (Assessment, CASS, and ERP).
- Intervention will be free upon completion of all 3 parts (3 visits)
- **Explain randomization:** Your child may be randomly assigned to either the initial study group or an active control group for this study. If your child is assigned to the active control group, you will still complete the study procedures, but will participate in a separate type of intervention program.

VISIT SCHEDULING

General Notes:

- Add each component to Lab Calendar.
- Invite all site's lead investigator and other involved lab members to all scheduled calendar components.
- Give reminder call/email several days before event.

Assessment (2 hours)

- - **Establish Days/Times** for when assessments can be scheduled.
  - **Room Schedule:** Establish a separate calendar for room reservations. If there are any organizations or individuals that site space must be shared with, ensure those individuals are informed and there are no conflicts for space/scheduling.
  - **Reserve Room:** Send email to the research space coordinators with room you are booking, Date, Times, and project for which the assessment room will be needed.
  - **Parking:** Ensure all parking has been reserved for participants upon day and time of their visit.
  - **Site Calendar:** Add Assessment to site Lab Calendar (Inclue Location, subject ID, and who is doing the assessment, in addition to any special notes : first time dx, needs ADOS, does not need ADOS, etc.)

ERP (45 minutes)

- Assessment and ERP are scheduled on the same day for pre-visits.
- Following the assessment, as long as the child meets criteria, give them a 15-30 minute break between assessment and ERP. Time to grab a snack, walk around, etc.
- ERP should be scheduled along the needs and requirements of the site EEG lab performing the ERP task – make sure to have a mutual calendar you can access for the purpose of scheduling appointments.

- o ERP visits can be scheduled for 1 hour blocks in green include:
  - ▪ SENSE Theatre, id number, and age/sex of participant.
- **Immediately confirm with site EEG team of the scheduled date. Reserve parking**
- **SENSE Calendar**: include ERP, subject id, time, parking spaces reserved.

CASS (30 minutes)

- **Before scheduling CASS** visits you must:
  - o (1) Establish with any groups that share research space the times for which you will be using the facilities.
  - o (2) Figure out research helper availability, so you may know which research helpers are available when.
    - ▪ Do these two things BEFORE scheduling participants!
- **Confirm Research Helpers:** After scheduling a participant, contact available research helpers to confirm their availability.
- **Confirm Research Space:** Then email any groups sharing the research to let them know the date and time you will be using the CASS. Email lab members as needed to schedule space for CASS at the beginning of each week while study is active.
- **Reserve parking** for research helpers AND subject.
- Add CASS visit to **site lab calendar**, including subject id, location, time, research helpers, and reserved parking spaces.

SURVEY KIT

Send to parents before their assessment visit/have parents complete during visit:

- Cover Letter: instructions for questionnaire packet and appointment reminder
- Teacher letter: instructions of teacher questionnaires with deadline.
- Consent & Assent
  - o Tell parents to read, but not sign
  - o Come with questions
  - o We will review and sign at visit
- Photo/Video Release.
- Collect information needed for NDAR
- Directions to the site location, including where to meet
- Medications Checklist
- Short Sensory Profile (SSP)
- Social Communication Questionnaire-–Lifetime (SCQ-L)
- ABAS (Parent and Teacher)
- Child Behavior Checklist (CBCL)
- Social Responsiveness Scale-2 (SRS-2,Parent and Teacher)
- Parenting Stress Index Short Form (PSI)
- BRIEF 2
- Conners 3
- MASC-2 Parent Report

- Pubertal Development Scale (PDS)
- Gender Development Survey Parent Report (GDS-Parent)
- Quality of Play Questionnaire (QPQ)

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

Visit 1 (Pre-Test) Only:

****VUMC ONLY**: Due to the unprecedented situation surrounding the global COVID-19 pandemic, we will, via email, ask currently-enrolled families (only at the VUMC site) from Cohort 4 and 5 (and all future subjects) to complete the following three questionnaires, which relate to stress and coping associated with COVID-19, via REDCap online survey or, if they choose, using physical copies of the questionnaires that we would mail to them:

VUMC ONLY: **1) Compas Responses to Stress Questionnaire** (RSQ; Compas, 2020) - **COVID-19 Child Self-Report**: The RSQ can be filled out by children and adolescents regarding their own personal coping and involuntary stress responses in regards to how they respond to stress related to COVID-19.

VUMC ONLY: **2) Compas Responses to Stress Questionnaire** (RSQ; Compas, 2020) - **COVID-19 Adult Self-Report**: The RSQ can be filled out by parents regarding their own personal coping and involuntary stress responses in regards to how they respond to stress related to COVID-19.

VUMC ONLY: **3) Compas Responses to Stress Questionnaire** (RSQ; Compas, 2020) - **COVID-19 Parent Report on Child**: The RSQ can be filled out by parents regarding their child's coping and involuntary stress responses in regards to how their child responds to stress related to COVID-19.

ASSESSMENT VISIT

SETUP & CONSENTING

- Arrive at the assessment facilities 30 minutes prior to family arrival time.
- Gather appropriate testing materials out of cabinets (ADOS, NEPSY, WASI)
- 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)
  - Take the **child's photo** (after parent or guardian has signed Video/Photo Release). Explain that picture will be used during counselor/peer matching.
  - Explain **NDAR** (National Database for Autism Research), and also explain GUID and need for **child's city of birth** in creating unique identifier (see page 14).
- Leave the parent in the family room where they'll wait until the assessment is done with child
  - Retrieve any filled surveys that will be scored later, make sure to check that all files have been answered entirely
- Consenting for Peer Control Group:
  - Peers that are only completing questionnaires and not participating in SENSE Theatre and/or TTT will be provided informed consent forms in person or via email. When conducted by phone, research personnel will review the study process with the parent and then scan or fax the consent form. Once signed/

returned forms are received, the parent and child will be given a link to a REDCap survey to complete questionnaires.

- **Review all questionnaires to confirm they are complete**

TESTING

TASKS

- **The following administration of tests and timelines are normative, but can vary from child to child**
    - ADOS - 45 minutes
    - NEPSY Memory for Faces - 5 minutes
    - WASI Vocab - 12 minutes
    - WASI Matrix Reasoning - 8 minutes
    - WASI Similarities - 5 minutes
    - WASI Block Design - 15 minutes
    - NEPSY Memory for Faces Delayed - 3 minutes
    - NEPSY Affect Recognition - 7 minutes
    - NEPSY Theory of Mind - 7 minutes
    - Cohen's Perceived Stress - 5 minutes
    - MASC-2 Self Report - 10 minutes
    - Gender Development Survey Self Report (GDS-Self) – 5 minutes
    - Social Experiences Questionnaire- Self Report (SEQ-S)-- 5 minutes
    - Brief Fear of Negative Evaluation-2 (BFNE-2)—5 minutes
    - Child Depression Inventory (CDI-2)—5 minutes (If the child endorses item #8 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).

CONTEXTUAL ASSESSMENT OF SOCIAL SKILLS (CASS)

- Protocol is based off Ratto et al. (2011).
    - Requires two opposite-sex peers to act as research helpers; one research helper and the participant are led into an observation room (site specific) and told "thank you both so much for coming in. Right now we'd like for each of you to act as if you had recently joined a new club or social group, and now you're sitting next to each other, waiting for the first meeting of this new club or group to start. You will have 3 minutes to talk to each other, then I will come back in the room."
    - Research Helper 1 will be the friendly social condition, being supportive and interested in the conversation.
    - Allow for 3 minutes to pass. Record the behaviors that take place during this time for future behavioral coding.
    - Once 3 minutes have passed, remove the research helper from the room. Have participant complete a rating scale while the next research helper is prepared.
    - Research Helper 2 will be the indifferent social condition, they will behave as bored by the conversation and lack social support.
    - Once 3 minutes have passed, remove the research helper from the room.

- Following the completion of the CASS, participants will complete the State-Trait Anxiety Inventory for Children (STAIC) and the Conversation Rating Scale

*Results from the diagnostic and standardized measures and questionnaires will be sent to parents in a brief letter within 6 to 8 weeks of the study assessments.

POST-VISITS

POST-ASSESSMENT

Send to parent/have parent complete at assessment:

- ABAS-3
- PDS
- SSP
- CBCL
- BRIEF-2
- GDS-Parent
- PSI
- Conners- 3
- MASC-2 Parent Report
- QPQ

TESTING

TASKS

- NEPSY Memory for Faces - 5 minutes
- MASC-2 Self Report - 10 minutes
- GDS-Self – 5 minutes
- NEPSY Memory for Faces Delayed - 3 minutes
- NEPSY Affect Recognition - 7 minutes
- NEPSY Theory of Mind - 7 minutes
-
- Cohen's Perceived Stress - 5 minutes
- SEQ-S—5 minutes
- BFNE-2—5 minutes
- CDI-2—5 minutes (If the child endorses item #8 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).

POST-ERP

- Protocol for ERP does not change in post-visit.

- ERP may come before Assessment during post-visits.

POST-CASS

- Utilize research helpers unknown to participant (not the same research helpers as pre-CASS)

FOLLOW-UP

FORMS

Send to parent/have parent complete at assessment:

- ABAS-3
- PDS
- SSP
- CBCL
- BRIEF-2
- GDS-Parent
- PSI
- Conner's 3
- MASC-2 Parent Report
- QPQ

Tasks include:

- NEPSY Memory for Faces - 5 minutes
- MASC-2 Self Report - 10 minutes
- Gender Development Survey Self Report – 5 minutes
- NEPSY Memory for Faces Delayed - 3 minutes
- NEPSY Affect Recognition - 7 minutes
- NEPSY Theory of Mind - 7 minutes
- Cohen's Perceived Stress - 5 minutes
- SEQ—5 minutes
- BFNE—5 minutes
- CDI—5 minutes (If the child endorses item #8 suggesting suicidal ideation, the crisis plan implemented in the Inclusion\Exclusion Criteria section).

All forms must be completed by same rater in Pre and Post (i.e. same teachers and same parent/guardian)!
*Follow-Up forms sent to both Experimental and Control groups approximately 8 weeks after post-visits.

FOLLOW- UP ERP

- Protocol for ERP does not change in follow-up visit.
- ERP may come before Assessment during follow-up

FOLLOW- UP CASS

- Utilize research helpers unknown to participant (not the same research helpers as in the pre and post- CASS)

SENSE THEATRE/TACKLING TEENAGE TRAINING INTERVENTION PREPARATION

GROUP ASSIGNMENT

- Once randomization into SENSE Theatre or TTT is complete and participants have been assigned to groups, send letters to families informing them of what group they are assigned.
- Send out RedCap survey which collects information regarding Medication (see if there have been any changes), food allergies, behavioral information, t-shirt size.
- Add participant and research helper contacts to a designated lab cell phone

PEERS/COUNSELORS

- **Application:** Interested peers and counselors will complete an application
- **Decisions:** Lead site investigator, and theatre director will narrow down who is to be interviewed for a peer and counselor position.
- **Background checks:** all adults participating in the intervention (18 years +) must have an existing background check with Vanderbilt or go through the process of getting one.
- **Protection of Minors Training:** Make sure all counselors and peers are compliant with the site's requirements for protections of minors training. Contact site IRB for "Research Involving Minors" for more information pertinent to site requirements.
- **Consent and Video Release Forms:** sent to peers/counselors participating in intervention.
- **Intervention Information:** Send training schedule, location map, and first days schedule (via email), and an email reminder 1 week before training begins.

TRAINING

SPEAKERS

- Site PI will be responsible for contacting and choosing speakers.
- Coordinate who will be presenting when, 6 weeks before intervention begins.
  - Research Assistant/Coordinator—"Introduction to Autism"
  - Confidentiality & Code of Conduct, SENSE Theatre Manual, SENSE Lab & Theatre, Behavioral Strategies.
- Copies of past presentations can be provided to any sites by the SENSE Research Coordinator.

BINDERS

- Binder Materials:
  - Binder Covers (Color)
  - Binder spine labels (color)

- o Divider Tab Labels
- o Presentations (Black and White)
- o Schedule
- o Music/Lyrics (SENSE Theatre Intervention only)
- o Name Tags
- o Pre/Post Test
- o SENSE Theatre Manual (Black and White)
- o Script (Black and White) (SENSE Theatre Intervention only)
- The lead site investigator, theatre director, research assistant/coordinator, and nurse(s) should be provided a sheet that details participant contact information, allergies, and medications, along with a picture for identification purposes.

FOOD

- Create catering order 3-5 days in advance
  - o A light breakfast, coffee and bagels
  - o Lunch based on preference (sandwiches, pizza, salads, etc.)

ROOM

- Reserve Room 2-4 weeks in advance.
- Coordinate room reservations with administration. Classrooms with projectors and whiteboard are best, conference rooms if the group is small.

INTERVENTION

Intervention Packets: before Intervention begins the following should be sent to participants 1 month before it begins.

- o Letter to Parents
- o Schedule with important dates
- o Release Forms
- o First Day Schedule
- o Intervention checklist

DAILY TASKS:

- o **Daily Schedule:** coordinate with lead site investigator and theatre/training director after each day of intervention program to determine schedule for next session.
- o **Daily Email**: Blythe will send first and last email to parents, peers, and counselors.
  - ▪ Each day, you will give a brief review of the day; give any reminders, updates, etc. Also attach schedule for next session.
- o Prepare Snacks/Waters for participants/counselors/peers.
- o Bring extra copies of schedule for Dry Erase Board and any participants that need a hard copy.
- o Check attendance, call families who may be running late, etc.

ONLINE VIDEOS

- Contact site information technology regarding uploading peer modeling videos to a password protected website for families to access at home.

ORDERING

- Snacks
    - Lay's Chips, Gold Fish. Fruit Snacks, Water, Granola Bars
- T-Shirts:
    - Lead site investigator and site graphics design will coordinate on t-shirt design and ordering.
- Binders:
    - 1 ½" for peers/counselors
    - 1/2" for participants
    - Dividers for peer and participant binders
- Any Props/Equipment used for the production
    - Past examples include stress balls, Bradfield Lighting, etc.
    - Costumes
        - Usually provided by theatre team and participants
            - Theatre director will set up a time for costumes to be coordinated
            - Prepare a document that states:
                - What particpant is wearing from site
                - What items they need to bring from home to complete costume.

CONSTANT CONTACT (PERFOMANCE INVITES)

- Blythe and Ed will send this out, but create a .CSV file which follows the following format, including contact information for peers, counselors, participants, and any other new SENSE Theatre staff.
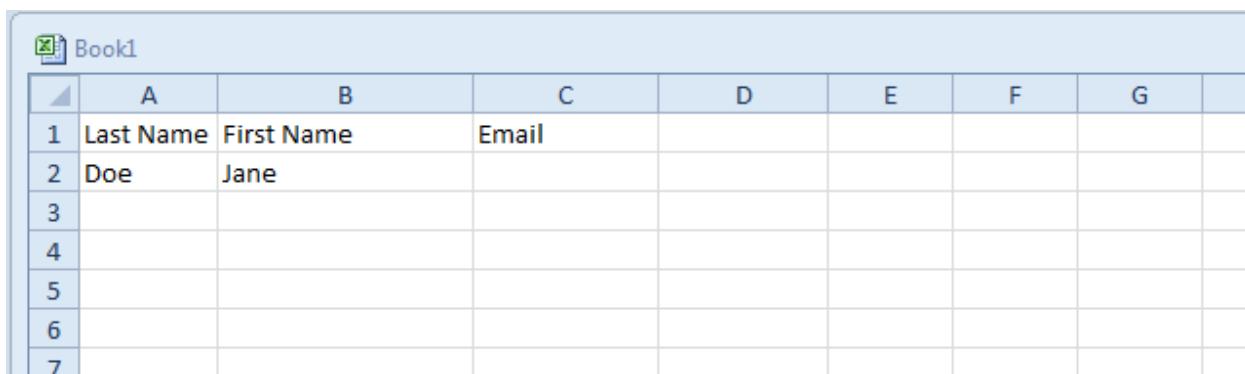

	A	B	C	D	E	F	G
1	Last Name	First Name	Email				
2	Doe	Jane					
3							
4							
5							
6							
7							

PARTICPANT, COUNSELOR, AND PEER CERTIFICATES

- Kylie Beck will create a Certificate of Complete and Certificate of Appreciation Template for you in Word.
- You will be responsible for creating a Mail Merge using the template and saving it as a PDF to be printed.

Directions of Mail Merge: Adapted from this website.

1. Go to *Step by Step Mail Merge Wizard*, under the Mailings Tab in Microsoft Word.
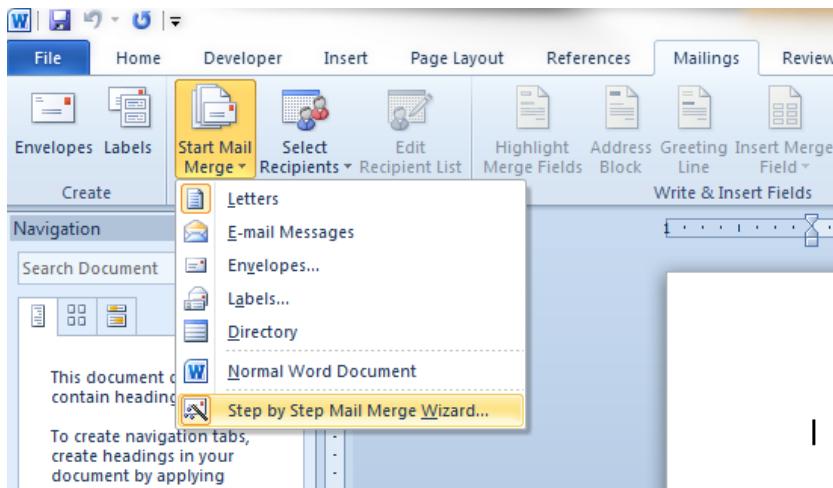
2. Choose *Letters*
3. Use the *Current Document*
4. Use an *Existing List* (Have an already created Document with **Fields: Last Name, First Name**)
5. *Preview* your letters
6. Save Document as a PDF or select *Merge to Adobe* PDF in Mailings tab:

7. Send this Document to Graphics Design or printing service to be printed.

POST-INTERVENTION

Mail DVDs

- For individuals who cannot attend DVD screening, mail DVDs after screening to those individuals in padded envelopes.

SHARING CONTACT INFO

- Many families will want to be able to keep in touch after SENSE Theatre/TTT is over.
- Send out an email asking families/peer/counselors if they are interested in having their contact information shared with SENSE participants/staff.
- Then you may create a list of individuals who are okay with having their contact information shared, this can be emailed then, to these families/individuals.

FIRST STEPS

- Create an NDAR login by completing the account request form.
- Request access to the collection by emailing **NDAR help** (NDARhelp@mail.nih.gov) and including the user ID you created.
- Once you have an NDAR account/login and have access to the collection, you will be able to submit data.

NDAR DATA STRUCTURES/TEMPLATES

- All the Data Structures for SENSE Theatre are currently saved in the Student folder under NDAR student.
- Data Dictionary files are found here, these are useful if we would like to upload these into RedCap or if you have a question about how an item in the data template is defined.
- Data Templates are used to enter data
- If, in the future, a data dictionary/template is needed, you can simply email **NDAR Help** with a scanned version of the measure and they will create a template for you.

NDAR GUIDS

- In order to submit data to NDAR each participant you're submitting data for must have a GUID (Global Unique Identifier)
- To create a GUID, one must have subject Legal Name at Birth, Date of Birth, Sex, and City/Municipality of Birth.
- Create a GUID by first putting in identifying information into GUID template found here.

- GUIDs are created by going to the **GUID Tool** which can be found on the [NDAR home page](#) under **resources**. Instead of submitting the forms for each individual separately use "Get GUIDs for Multiple Subjects" under the "Functions" tab.
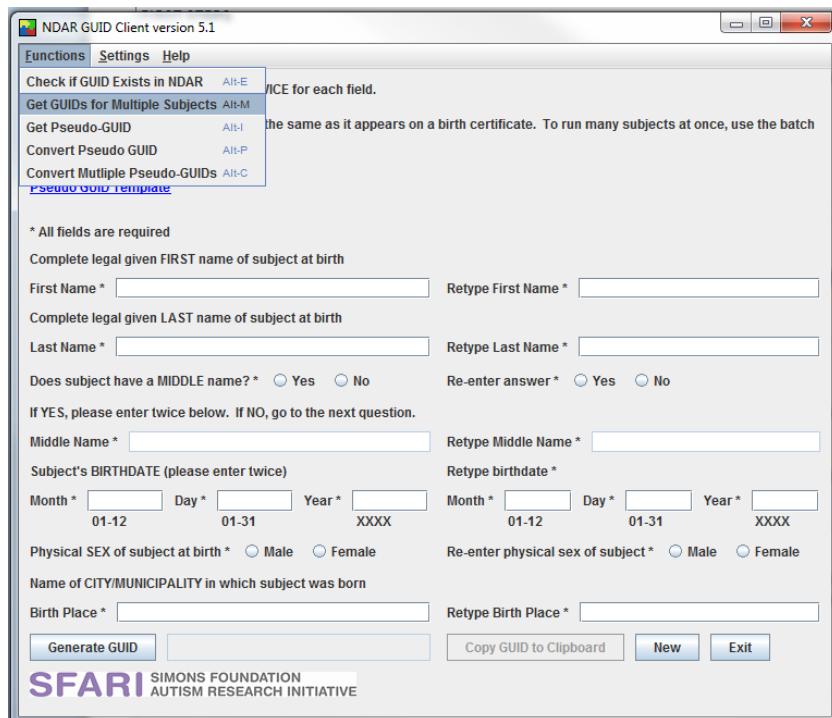
- Then you will upload your GUID .csv file:

ID=Study ID, so for SENSE Theatre it would be the numbers after ST.

Middle name is not required for a GUID, if you have subject middle name, then you would enter "YES" under the column "SUBJECTHASMIDDLENAME"

- Upload your excel .csv file, and then create GUIDs. GUIDs will automatically be saved in the folder in which you saved the GUID .CSV file [here.](#) You can also **copy and paste the output into a spreadsheet.**

SUBMITTING DATA TO NDAR: DATA VALIDATION TOOL

- Data validation tool can be found on NDAR homepage under Resources as well.
- Choose data you wish to upload and validate.
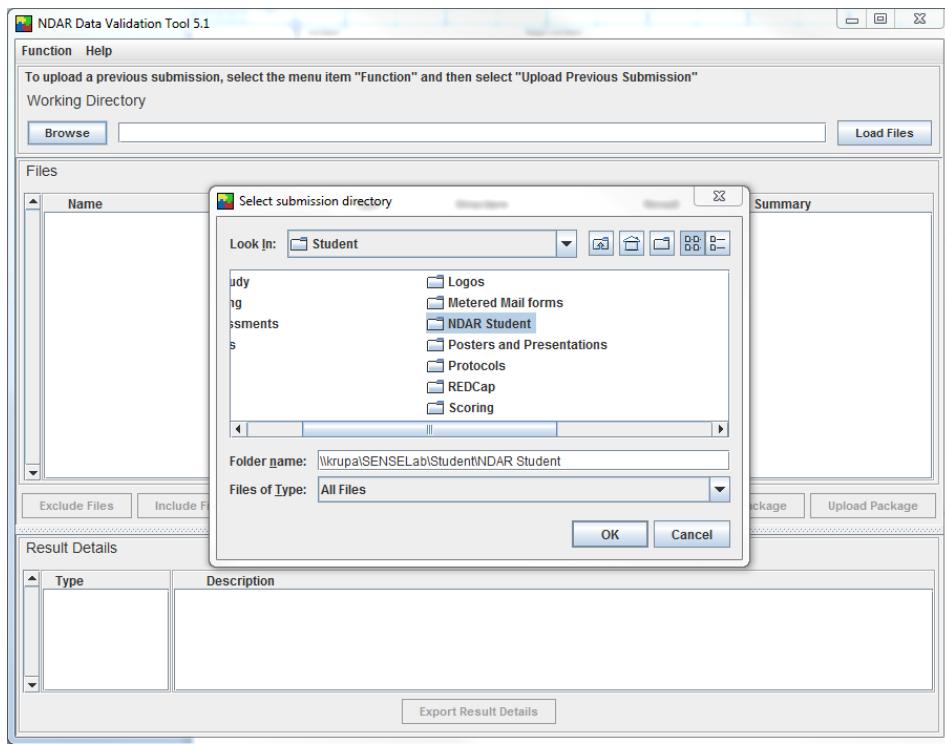
- 1: Load files
- 2: Validate files
- 3: Check Errors/Warnings
- 4: Validate again
- 5: Repeat steps 2-4 if needed.
- Build Submission Package once all files are found to be valid.
- Upload Package
- Check NDAR site for submitted data.

NDAR CONTACTS

Name	Email	Phone
NDAR Help**	ndarhelp@mail.nih.gov	301-443-3265
Lisa Gilotty, PhD	gilottyl@mail.nih.gov	301-443-3825

IMPORTANT NOTES ABOUT NDAR

- For every NDAR submission, NDAR expects the submission to be cumulative, so submit everything you have ever submitted to NDAR for that data set each time you submit.
- Also, even if there is nothing new with your data at the submission date, still submit data.
- Sometimes you will notice during Validation, errors arise that seem to be related to the original template or data dictionary→email or call NDAR help with these issue. Sometimes corrections to templates must be made on their end.
- Private vs. Public: Be sure to check the NDAR collection page.

- o Check "Share" dates for collection.
  - o Demographic-early release date
  - o Dependent measures: released upon publication/completion of grant.
- Useful NDAR information here

MISCELLANEOUS

- VUMC SITE ONLY: iMotions Software Analysis
  - o These analyses use videos of participants' faces and are done using iMotions, a well-established computer program that measures how the face moves and computes deidentified values for various emotional facial expressions. This is accomplished statistically, comparing the actual appearance of the face and the configuration of the features numerically with normative databases provided by facial expression engines. The program only identifies expression of emotion; it does not use facial landmarks or any other means to identify who is in the video nor does it store recordings to improve its internal database and algorithms.
  - o After initial upload to the iMotions program, videos will be deleted from the program, at which point de-identified numerical data will be used for the remainder of analyses.