# Investigating Social Competence in Youth with Autism: A Multisite RCT

## Informed Consent Document

NCT03368001

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Vanderbilt University Institutional Review Board
Proposal for Research Using Human Participants
**Consent Document for Research Study**

**PI: Blythe Corbett, Ph.D.**
**Title of Study: Investigating Social Competence in Youth with Autism: A Multisite RCT** **Version Date: 3/12/2020**
**Institution/Hospital: Vanderbilt University**

This consent document applies to **the parents/guardians of children ages 10-17 with an autism spectrum disorder.**

Name of participant_____ Age_____

Participant's City of Birth_____

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

Your participation in this research study is voluntary. You may choose not to participate and receive alternative treatments without affecting your healthcare/services or other rights. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study. Your child must be between the ages of 10 and 17. In order to participate in this study, it will be necessary to give your written consent.

Your child will be randomly assigned to one of two treatment conditions that focus on the development of important social skills. Your child will be put into a theatre-based intervention (SENSE Theatre) or a teen development intervention (Tackling Teenage Training) group. Both treatments will consist of 10 sessions. If you would like your son or daughter to receive the condition to which they were not randomized, we request that they attend the majority (i.e. 9 of 10) of the sessions in the condition to which they were randomized.

**1. Purpose of the study:** Your child is being asked to participate in a research study because he or she has an autism spectrum disorder. We hope to learn about the effects of behavior therapy and theatre techniques and to determine if they are helpful in improving social and emotional behavior and reducing stress in children with and without autism.

**2. Procedures to be followed and approximate duration of the study:** The SENSE Theatre and Tackling Teenage Training treatment are part of a research study. In order to be in the treatment you must participate in the research. It will require a commitment of enrollment to attend a majority of the 10 sessions (about 3 hours each).The SENSE Theatre program also includes up to two performances for the participants. Due to the considerable amount of material covered in each session, full participation is important. Thus, we request all participants to come to the majority of the sessions (i.e., 9 out of 10), regardless of whether or not they wish to continue. If something exceptional happens with the family, it will be addressed on an individual basis. The study will include psychological assessments, two ERP tasks, and a social interaction session conducted before and after the SENSE Theatre program. All intervention sessions will involve working with a psychologist and trained typically developed peers. We anticipate that approximately 240 children will participate in the study across the three study sites (Vanderbilt University, Stony Brook University and Virginia Tech) with an estimated 80 participates from each site. Your child will also be asked to complete questionnaires about his or her mood and perception of the study tasks.

The tacking teenage treatment involves teaching adolescents about social development including psychosexual, pubertal development, and topics of sexual behavior and awareness. Parents of children between 10-12 will be able to choose

whether to have their children participate in the full training that includes sexual education material or a modified version that excludes the sexual education material.

No medication or pharmaceutical agent is administered at any time during the course of the study.

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

Assessment: At the first visit, your child will complete some diagnostic and neuropsychological tests to see how he or she understands and expresses emotions, recognizes and remembers faces, and understands other people's point of view. We will also ask you to complete some questionnaires about your child's current behavior, social skills, stress and anxiety. This visit takes about 2-3 hours.

Social Interaction Session: Your child will participate in a social interaction session. He/she will interact with another child for a total of 10 minutes. Your child will be videotaped during the social interaction session. The videotape will be used for coding behavioral responses. This videotape will be destroyed upon completion of the study.

EEG Tasks: Your child will participate in a measurement of brain responses. Testing will involve recording your child's brain waves using soft sensors placed on your child's head. These sensors are arranged like a shower cap. Your child's head will be measured to find the right size net. Before putting on the net, it will be soaked in warm salt water. Before the EEG, your child may be asked to remove any large pieces of jewelry, hair clips, or glasses to enable proper net fitting. Once the EEG net is placed, your child will be able to put the glasses back on. Jewelry and hair clips may be put back on after the EEG. In this study, the EEG is collected for research purposes only. We will not be able to inform you of any diagnostic information, but if we see something unusual, you will be told, and asked to consult your doctor. Once the net is in place, your child will look at pictures on a computer screen.

The Social Interaction, physiological data collection and EEG tasks are completed in one session that will last approximately 1-2 hours.

SENSE Theatre Intervention: Your child will also participate in therapy sessions and theatre rehearsals. These sessions will include learning how to better understand and express emotions, imitate peers, practice scenes from a play and engage in various theatre games to learn how to communicate with words, actions and singing. Your child will be a part of the show, and will perform the play with music up to 2 times for families of participants and the public. Additional cast members will participate in the rehearsals and performance of the musical.

Tackling Teenage Training (TTT) Intervention: The TT intervention is approximately equivalent to SENSE in most of the 'non-specific' and common treatment factors using the Tackling Teenage Training program. The sessions will be similar to the theatre treatment, occurring once per week, providing peer contact and socialization with typically developed peers, as well as clinical attention during group supervision.

Sessions will include topics that focus on social development. Specifically, appearances, first impressions, making friends, maintaining interpersonal relationships, setting boundaries, respecting other's boundaries, and safe internet use. These sessions may include knowledge regarding pubertal and sexual development.

Post-Intervention: Your child will repeat the assessments, social interactions (with new peers), and an ERP visit. We will have you complete some of the same questionnaires from the beginning of the study.

Follow-Up: In order to measure the longevity of changes your child may make, approximately 3 months after the end of the intervention, your child will repeat the assessments, social interactions (with new peers), and an ERP visit. We will have you complete some of the same questionnaires from the beginning of the study.

Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. During and after the study, we will send information about you or your child's health and behavior to NDAR. However, before we send it to NDAR, we will remove information such as name, address, and phone number, and replace that information with a code number. If you decide now or later that you do not want to share you and your child's information using NDAR, let us know, and we will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind.

**4. Expected Costs:** there will be NO COST to participate in the 10-week research intervention.

**5. 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 child's participation in this study. Everyone taking part in the study will be watched carefully for any side effects. At times the session may be tiresome or cause mild frustration or anxiety, but we will give your child breaks whenever needed. As noted, the study is evaluating the effects of social interaction and stress. Therefore, we anticipate that your child will experience some stress in response to exposure to a new environment and novel social experiences. Refusal to enter the theatre, aggression toward other children, threatening behavior toward research personnel, yelling, crying, or any other kind of verbal protest indicating that he/she does not want to continue in the intervention and study are signs that your child does not want to continue in the program. If your child's anxiety becomes excessive or intolerable, the study procedures will be stopped at your request or at the request of your child. The procedure should be no more stressful than coming to a new clinic for routine medical procedures. Therefore, although there are potential risks, the likelihood of any lasting effects from such a testing situation would be minimal.

The physical risks associated with the EEG are minimal and comparable to every-day activities. The following steps are taken to minimize such risks: (1) The EGI system used to record the brain responses is electrically isolated from the participant, eliminating the risk of any current flowing to the participant. (2) The electrodes used for this study do not require skin abrasion for proper contact and therefore minimize infection risk. Risk of infection is further reduced through specific electrode care procedures that include rinsing all electrodes with water immediately after testing and then soaking the electrode net in a cold sterilizing solution (Control III) to eliminate any contaminants that otherwise might pass from participant to participant. Following soaking, the electrodes are again rinsed and then air dried.

**6. Compensation in case of study related injury:**
If it is determined by Vanderbilt and the Investigator with NIMH input that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt or NIMH to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or NIMH to give you money for the injury.

**7. 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 respond to social and emotional information, and the extent to which theatre and peers can improve these areas of functioning. The efficacy of the SENSE Theatre intervention will be evaluated across groups of participants and compared to another treatment aimed at imporving social and developmental understanding.

**b) The benefits you might get from being in this study.**

It is possible that you will not benefit directly by participating in this study. It is also possible that your child may learn from the behavioral and theatrical techniques that will result in improvement in social behavior and expanded understanding and expression of emotion. He or she may also experience less stress and enhanced comfort in social situations as a result of this experience.

**8. Compensation for participation:** There is no financial compensation for participating in this study.

**9. Circumstances under which the Principal Investigator may withdraw you from studyparticipation:** If your child becomes very upset or uncomfortable with the study procedures or experience, the Principal Investigator may withdraw your child from the study. Additionally, if your child is unwilling to participate in the study or the majority of the activities we may suggest that he or she be withdrawn from the study. Finally, if your child is aggressive toward other children, for the protection of all participants, we may withdraw him/her from the study. If your child is withdrawn from study activities, his/her data up to that point will be stored alongside all of the other confidential data. In published manuscripts, we will acknowledge their withdrawal, without revealing their identity in any way. We will maintain the data to be evaluated if there is any question regarding differences in children who completed the study and those that did not. In general, however, the data from withdrawn participants will not be included in analyses.

**10. 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. If you and your child choose not to take part in this study, no negative consequences will occur. Your child's future care at Vanderbilt University will not be affected. If you choose to remove your child from the study, his/her data up to that point will be stored alongside all of the other confidential data. In published manuscripts, we will acknowledge their withdrawal, without revealing their identity in any way. We will maintain the data to be evaluated if there is any question regarding differences in children who completed the study and those that did not. In general, however, the data from withdrawn participants will not be included in analyses.

**11. Contact information:** If you should have any questions about this research study or possible injury, please feel free to contact the Principal Investigator, Blythe Corbett, Ph.D. at (615) 936-0280.

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 Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**12. Clinical Trials Registry:** A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**13. Confidentiality:** All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All records associated with this study will be kept confidential. The information obtained about your child will only be used by the researchers involved with this study. Dr. Corbett will treat your child's identity with professional standards of confidentiality. The U.S. Department of Health and Human Services has the right to inspect all of our medical records related to this research for the purpose of verifying data. The information obtained for this study may be published in medical journals but your identity or your child's identity will not be revealed. All records will be kept in a locked filing cabinet. We are required by state law to immediately report any evidence of possible child abuse with identification of the alleged offender. If any information is revealed during this study concerning suicide, homicide, child abuse, or neglect, it is required by law that this be reported to the proper authorities. By signing this document you allow us to make your records or those of your child's

available to the sponsor of the study. Any information obtained in connection with this study will be used in a manner that does not publicly disclose your child's identity and will be kept confidential. Absolute confidentiality cannot be guaranteed, since research documents are not protected from subpoena.

This study may have some support from the National Institutes of Health (NIH). If so, your child's study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your child's 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 child's information if we learn of possible harm to your child or others, or if your child needs medical help.

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

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

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.

**14. Privacy:** All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare.
This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Corbett and her study team may share the results of your study and/or non- study linked information as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, or the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. Corbett and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least ten years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Corbett in writing and let her know that you withdraw your consent. Her mailing address is: Vanderbilt Kennedy Center, PMB 40, 230 Appleton Place, Nashville, TN 37203. At that time, we will stop gathering any more data

about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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**STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY**

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

| | |
|---|---|
| Date | Signature of Parent/Guardian |

Consent Obtained by:

| | |
|---|---|
| Date | Signature |
| | Printed Name and Title |

**For parents/guardians of participants age 10-12 years old**: A portion of the Tackling Teenage lessons will include sexual education material for children ages 13 – 17 years. This material may be considered sensitive for 10-12 year old children. Therefore, materials for children 10-12 years old have been modified to exclude the sexual education material. Please indicate by checking the box and signing which session you would like for your child to receive.

- ☐ I would like for my child to receive the modified Tackling Teenage Lessons, which **exclude** sexual education material.

  Parent/Guardian signature: _____

- ☐ I would like for my child to receive the original Tackling Teenage Lessons, which **include** sexual education material.

  Parent/Guardian signature: _____

Date of IRB Approval: 05/05/2020
Date of Expiration: 05/04/2021

Institutional Review Board

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**PERMISSION FOR USE OF PHOTOGRAPHS, VIDEO & SOUND**

I give permission for my child, _____, to be photographed and videotaped for use in presentations or print or electronic publications about the mission and activities of the SENSE Lab and its research projects. Photos, videos and sound captured during this research may be used in presentations to the scientific community, publications in scientific journals, description of research on fliers, websites, and other media. The audience for presentations and print and electronic publications includes families affected by disability, researchers, educators, service providers, health care professionals, and the general public.

_____
Name of Participant

_____
Signature of Parent/Guardian Date

_____
Address

_____
City/State/Zip Code

_____
Phone Number

Special Notes:

Date of IRB Approval: 05/05/2020
Date of Expiration: 05/04/2021

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