Transitioning Emotionally and Academically to Middle School Successfully (TEAMSS)

NCT: NCT05145387

11/20/2023

Minor Assent Form for Students
TEAMSS RCT

Project Title: Transitioning Emotionally and Academically to Middle School Successfully: Development of a Brief Intervention to Reduce Student Anxiety (TEAMSS)

Principal Investigator: Golda Ginsburg, Ph.D.

Co-Principal Investigator: Jamie LoCurto, Ph.D.

We are doing a research study to see if a program delivered by school clinicians (school clinicians are the counselors, social workers or psychologists in your middle school) can help students when they feel nervous or worried—this kind of feeling is also called anxiety. A research study is a way to learn more about people. This program is called TEAMSS, and it is a group intervention for reducing anxiety symptoms among students transitioning from elementary to middle school. We want to compare TEAMSS to Enhanced Usual Care (EUC) which includes the usual services provided by middle school clinicians.

If you decide that you want to be part of this study, we will ask you, your parent(s), teacher, and school clinician questions about your feelings, behaviors, family, friends, and how you do in school. The reason for asking these questions is to better understand the things that might make you feel nervous or scared so that the school clinician can help you with these worries.

If you decide to join the study, here is what you will be asked to do:

1. Before the program starts, answer some questions on a computer, on paper, and/or during an interview (it takes about 2 hours).
2. If the study is right for you, then you will start the TEAMSS program. You will receive some tips on middle school, visit your middle school and meet the middle school clinician.
3. If you are assigned to the TEAMSS group, at the start of middle school, you and approximately 20-25 other students in the program at different schools will meet in groups of 3-4 with your school clinician at school for about 7-8 meetings, and each meeting will be about 35-40 minutes. Your parents will meet in a group with the parents of other students and the school clinician three times and the school clinician will talk to your teachers.
4. If you are assigned to the Enhanced Usual Care (EUC) group, you will meet with your middle school clinician as needed. Plus, you and your parent or caregiver will receive written materials by the study team that include: 1) a list of clinicians who can help with anxiety (if needed); 2) a list of websites and books on anxiety that have helpful tips; and 3) tip sheets on successful transitions to Middle School. The websites and books describe ways to reduce anxiety such as tools to help relax, confront difficult situations, change worried thoughts into coping thoughts, and identify ways to manage problems that may come up in the future.
5. You and your parent will answer the same questions and complete the same interviews as you did at the beginning of the study two more times (about 10 weeks and 8 months after the program starts) to see how you are doing. Your teacher and school clinician will also

answer questions about you two more times (about 10 weeks and 8 months after the program starts).

6. All interviews and meetings will be audio or video-taped to make sure that everything is being done correctly by the school clinician and study staff.

Some of the questions and topics discussed during the meetings may make you feel uncomfortable or embarrassed because some of the questions are a little personal. The school clinician and research staff will make every effort to help you feel comfortable. They will do this by showing respect, giving you the time you need, talking, and listening to you. They will not judge you and will try to be as helpful as they can. You may choose not to answer any questions that you do not feel comfortable answering.

You may feel uncomfortable having the interviews and sessions recorded. Your name will not be on the recordings. Audio and video recordings will be stored on a type of separate computer (called an external drive) and locked in a cabinet that only study staff can open. Your full name will not be on the recording, but your school clinician may call you by your first name. If you are uncomfortable with your face being in any recordings, cameras can be turned off so that only your voice is recorded. Voice recordings are required in order to participate in the study so that we can be sure the clinician is teaching the correct program.

Your conversations with the school clinician will be kept "confidential," meaning that it will be kept private. While there is a chance that someone who is not part of the study could find out some information about you, the school clinicians and our study team have a lot of experience keeping information private. The school clinicians and our study team will do several things to protect your personal information, such as not putting your name on any forms or recordings, locking your surveys in file cabinets so that no one except the researchers can look at them, using computer programs and files that no one but the researchers can see, and not talking to anyone outside of the study about your participation.

Each time you are done answering questions when you meet with study staff (before you start meeting with your school clinician, right before 6th grade starts, and after you finish all of those meetings) you will be given an e-gift card to a store like Amazon or Target. You will earn $20 ($10 for the interview and $10 for completing the online measures) after the first meeting with the study team, $40 ($20 for the interview and $20 for completing the online measures) after second, and $50 ($25 for the interview and $25 for completing the online measures) after the third meeting with the study team for a total of up to $110. Your parent will earn the same amount.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. However, it is possible that after you finish the program, you may feel less anxious and worried and feel more comfortable in school and in other activities. We hope that the study will help you to be more successful in school.

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after you begin, that's okay too, you can just tell the researchers, your clinician, or your parents you want to stop. If you do not want to be in this research study, we will tell you what other kinds of help there are for you.

I, _____, want to be in this research study.
(Print your name here)

_____ _____
(Sign your name here) (Date)

Informed Consent Form for Parents
TEAMSS RCT

Principal Investigator (PI): Golda Ginsburg, Ph.D.
UCONN Health
65 Kane St.
West Hartford, CT 06119

PI Phone Number: (860) 523-3788

Co-Investigator(s): Jamie LoCurto, PhD

Title of Research Study: Transitioning Emotionally and Academically to Middle School Successfully: Development of a Brief Intervention to Reduce Student Anxiety (TEAMSS)

Expected Duration of Subject's Participation: Your child may be in this study for approximately 1-2 years

IRB Number: 22-114OS-1

External Sponsor/Funding Entity: Department of Education, Institute of Education Sciences (R305A200195)

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes, you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

This research is being done to compare the preliminary impact of TEAMSS, a multi-component group intervention for reducing anxiety symptoms among students transitioning from elementary to middle school to Enhanced Usual Care (EUC; which includes the usual services provided by middle school clinicians plus written materials provided by the study team for parents and children that include: 1) a specialty mental health referral list if needed; 2) a list of websites and books on child anxiety; and 3) tip sheets on successful transitions to Middle School (MS).

If eligible, your child will be asked to visit (either virtually or in person based on state and university regulations during the COVID-19 pandemic) their future middle school, touring the building and meeting with the middle school clinician. Afterward, you and your child will receive written materials, including tip sheets on how to prepare for the transition to middle school.

You and your child will be randomly assigned (like flipping a coin) to one of two groups—TEAMSS or EUC.

If your child is assigned to TEAMS, in the beginning of middle school, your child will attend 7-8 group sessions, delivered by the school clinician. Each session will last approximately 35-40

minutes (based on duration of class period) during the school day. In addition, there will be 2-3 approximately 60-minute parent groups, delivered by the middle school clinician either virtually or at the school.

If your child is assigned to EUC, they will meet with the middle school clinician as needed plus you and your child will receive written material from the study team with information on child anxiety.

Regardless of group assignment, participation will involve completing a total of three evaluations (usually done virtually) over the course of a year; each evaluation will take approximately 2-3 hours each, for a total of about 6 hours of your time over the next 12 months. Your child's participation will involve approximately 4-6 hours. In addition to the interviews, you and your child will be asked to complete questionnaires to report on feelings and behaviors before the intervention and after the intervention.

The primary risk of participating in the study is that discussing fears and worries in interviews and with a school clinician may make you or your child feel somewhat uncomfortable or embarrassed.

There is no guarantee that your child will benefit directly from participating in this study. However, your child may benefit by learning new strategies to better cope with anxiety.

Before making a decision about whether to participate in this research, you should know that there are other options available to you. There are resources, including referrals to other therapists, as well as books and online materials, which may help your child deal with anxiety. We can provide a list of these alternatives upon request.

A more detailed description of this research follows.

What Is The Purpose Of This Research Study?

This research is being done to compare the preliminary impact of TEAMSS, a multi-component group intervention to Enhanced Usual Care for students with elevated anxiety symptoms who are transitioning to middle school.

Why Am I Invited To Participate?

You and your child are being asked to join this study because your child is transitioning to middle school next year and may be having related symptoms of anxiety/worry. The school's principal has reviewed this study and has given us permission to conduct the study in your child's school.

How Many Other People Do You Think Will Participate?

We expect approximately 42 students to participate in this study.

Is Participation Voluntary?

Participation in this study is voluntary. Before deciding about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members or a friend before deciding.

You can choose not to participate. If you choose to participate in the study, you can change your

mind later and stop participating. If you decide not to participate or you withdraw from the study after starting participation, your decision will not affect your present or future relationship with the school or UConn Health and there will be no penalty or loss of benefits to which you are otherwise entitled.

How Long Will My Participation In This Study Last?

Your child may be in this study for approximately 1-2 years.

What Are The Costs To Me For Participating In This Study?

There are no costs to you or your child for participating in this study.

What Will I Be Asked to Do?

All study procedures described below can be done virtually or in-person as needed.

If you and your child agree to be in this study, we will ask you and your child to do the following things:

1. You and your child will complete a virtual evaluation with study staff to gain more information regarding whether the study is right for your child. This evaluation will take approximately 2-3 hours. You will be asked to fill out some questionnaires and complete an interview about your child's feelings, behaviors, family, friends, and school performance. The reason for asking these questions is to see if the study is right for your child and to better understand the things that might make your child feel nervous or scared so that the school clinician can help with these worries. You will be asked to disclose mental health treatment and medications given outside of school in a Service use form.
2. If the study is right for your child, your child will meet with the middle school clinician for a school tour and meeting and will receive written material to foster the successful transition to middle school.
3. If the study is right for your child, they will be randomly assigned (like flipping a coin) to one of two groups. The goal of both groups is to help your child feel less anxious. Each of these groups are described in more detail below.
4. If assigned to the TEAMSS group, your child will receive a group intervention which includes approximately 7-8, 35-40-minute sessions at school with the school clinician. The intervention is comprised of evidenced-based strategies to reduce anxiety such as tools to help relax, confront difficult situations, change worried thoughts into coping thoughts, and identify ways to manage problems that may come up in the future. There are also approximately 2-3 parent meetings and approximately 2-3 consultation meetings with the students' teachers to review these skills. The parent meetings will be held in a group format (virtually or in person depending on school clinician and parent preferences) with other parents whose child is also participating in the student groups. It should be noted that the study team cannot guarantee that your child's clinician will complete all intervention sessions (e.g., due to time constraints or competing demands). Though we make every reasonable effort to ensure that clinicians deliver the complete intervention, In the event the complete intervention is not delivered, you will be informed of this and provided referrals (if appropriate).
5. If your child is assigned to the Enhanced Usual Care (EUC) group, your child will meet

with their middle school clinician as needed. Plus, you and your child will receive written materials by the study team that include: 1) a specialty mental health referral list (if needed); 2) a list of websites and books on child anxiety; and 3) tip sheets on successful transitions to MS. The websites and books describe evidenced-based strategies to reduce anxiety such as tools to help relax, confront difficult situations, change worried thoughts into coping thoughts, and identify ways to manage problems that may come up in the future.

6. Approximately ten weeks after the groups begin (i.e., in December) and again toward the end of the school year, you and your child will complete evaluations (just like the first one) with study staff. For all evaluations, parents and students will be interviewed individually. When meeting with study staff for these evaluations, an email will be sent to you that contains a link to the virtual meetings or questionnaires. Electronic gift cards will be sent to your email to compensate you for your time. Virtual platforms we use will include those that are approved by the University of Connecticut and are HIPAA compliant to protect confidentiality (e.g., WebEx). If you do not have access to the internet, we will mail paper copies to your home or conduct in-person visits using social distancing measures in accordance with state and university regulations.

Other things to know:
All the assessment interviews with the study staff will be audio and/or video-recorded to assure that the interviewer is asking the right questions, in addition to serving for training purposes for future staff. All the sessions with the school clinician will also be recorded. This will be done to be sure that the clinician is teaching the right information. Video recordings of interviews with study staff will contain images of you and your child; if you or your child are uncomfortable with the image being recorded, cameras can be turned off or away from you and your child so that only the audio is recorded. However, participation in the study does require audio recordings of you and your child.

Audio and video recordings, as well as all study forms, will be uploaded to a secure website at UConn Health Center called ShareFile. For sessions conducted virtually, clinicians will receive training on how to use recording features in videoconferencing platforms used by their school district, including how to upload recordings to a secure website (e.g., file share) for study staff. These files will then be immediately downloaded to a password protected external drive and stored in a locked cabinet that is only accessible to study staff. The recordings will be heard/viewed only by members of our study team and no names will be written on the recordings. Tapes will only be labeled with fully anonymized participant ID numbers and held until data analyses are completed. Nobody in the school will see or hear the recordings.

What Are the Risks Of Participating In This Study?
Some of the questions and topics discussed during the interviews and meetings with the school clinician may make your child feel uncomfortable or embarrassed because some of the questions are a bit personal. Completing the study instruments could also make you feel discomfort or distress. Being recorded may also make your child feel uncomfortable. The school clinician and research staff will make every effort to help your child feel comfortable. They will do this by showing respect, giving your child the time they need, and listening to your child. They will not judge your child and will try to be as helpful as they can. You and your child may also choose

not to respond to questions.

The other risk to participating is that it is possible that someone may see or hear the interviews or clinician sessions without permission. To minimize risk, all study personnel and clinicians will conduct all video sessions from a private space. You and your child should also conduct video interviews and sessions from a private place.

What Are the Benefits Of Participating In this Study?

We do not know if your child will benefit from being in this study, and there may be no direct benefit to your child. By being in this study, however, your child may learn new ways to cope with life's stressors and feel less scared and worried.

Will I Be Compensated For Participating In This Study?

You and your child will be compensated for your time. Specifically, you and your child will each receive up to $20 in gift cards ($10 for the interview and $10 for completing online measures) after the first (baseline) and up to $40 in gift cards ($20 for the interview and $20 for completing online measures) for the second (post evaluation) evaluations and up to $50 in gift cards ($25 for the interview and $25 for completing online measures) for the final evaluation.

You may be asked to complete a W9 form with your name, address, and social security number which will have to be sent to Accounts Payable at UConn Health. If you receive over $600 from participating in research studies over the course of a calendar year, that money must be reported to the IRS as income.

Please select one of the following options:

__ I DO wish to be compensated for my participation in this study.
__ I DO NOT wish to be compensated for my participation in this study.

What Alternative Procedures or Treatments Are Available To Me?

You do not have to allow your child to participate in this research study. If you decide not to allow your child to join this study, you can still receive the standard services available at the school. You can ask the school clinician about other services available at school or in the community that may be of help to your child.

If your child does not join this study, your child's care at school will not be affected.

How Will My Personal Information Be Protected?

We will protect the confidentiality of your data to the best of our ability but cannot guarantee 100% protection.

While there is a chance that someone who is not part of the program could find out some information about you, the study team (principal investigator, research coordinator, co-investigator, etc.) will:

- Keep all study records locked in a secure location.

- Ensure records will be labeled with a number (no names are on any forms) and all contents of the research record will be labeled only with that number. No unique identifying numbers (like social security number, date of birth, etc.) will be used.
- Protect all electronic files (e.g., databases, spreadsheets, etc.) containing any identifying information with password protection. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Additionally, data stored electronically will have passwords to prevent unauthorized access.
- More specifically, your name and other identifiable information (e.g., name, phone number, and email address) will be linked to a study identification number (ID) through a master list spreadsheet; this spreadsheet will be password-protected, stored on a secure server, and will be accessible only to essential study staff.

Note that all study sessions with you and your child will be conducted in a private place. Depending on how your child's school is operating and local guidance, your child can receive the intervention in-person or virtually. For in-person meetings, the school clinician will secure a private place where no one else can see or hear the child. For virtual meetings, you can select a private place for you and your child to complete the sessions. Additional privacy measures will be taken, such as securely storing and sending recordings of study sessions. Because some of the questionnaires are copyrighted you will not be given copies of your child's interviews or surveys.

Generally, only people on the research team will know you and your child's identity and that you and your child are participating in this research study. However, sometimes other people at UConn Health may need to see your information. These include people who review research studies, their staff, or other staff. The sponsor, Institute of Education Sciences, UConn Health's Institutional Review Board and the Human Subjects Protection Office may inspect records to ensure that the study is being done correctly.

Also, study staff are required by law to report suspected or known sexual or physical abuse or neglect or if an individual threatens to harm him or herself or others.

At the conclusion of this study, the researchers intend to publish an article on their findings. Information will be presented in summary format, using aggregate data, and you and your child will not be identified in any publications or presentations.

This study involves the collection of identifiable private information (IPI). Identifiers will be removed from this IPI, and after such removal, the information could be used for future research studies or distributed to another investigator without additional informed consent.

What If I Decide To Stop Participating In The Study?

You and/or your child can agree to his/her participation in the study now and either of you can change your mind later.

If you and/or your child wish to stop being in the study, please tell the study staff right away. Leaving this study early will not stop your child from getting regular care.

If you decide to withdraw, we ask that you let us know by calling Dr. Golda Ginsburg at (860) 523-3788 or by sending written notice to Dr. Golda Ginsburg, UConn Health Partners, 65 Kane St., West Hartford, CT 06119. If you and/or your child withdraw from the study, data that have already been collected will still be used for the study; no further data will be collected from you and/or your child after study withdrawal.

Should significant new findings emerge throughout the course of this study that may relate to your willingness to continue participating, these findings will be provided to you.

Can Someone Else Make Me Stop Participating In This Study?

Your child may be taken out of the study if:

- staying in the study would be harmful or unsafe
- the study is cancelled or has ended
- the school clinician withdraws participation in the study
- there may be some other reason that we do not know at this time to take your child out of the study

Adverse Events

All research involves a chance that something bad might happen to you. This may include personal injury. If you have a problem, you should contact the PI, Golda Ginsburg, immediately. You may contact Dr. Ginsburg at (860) 523-3788 or the UConn Health Institutional Review Board at (860) 679-4849.

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process, contact a representative of the UConn Health Institutional Review Board (860) 679-8729 or (860) 679-4849.

UConn Health does not offer free care. However, treatment for a research-related injury can be obtained at UConn Health for the usual fee.

What if I Have Questions?

The Principal Investigator is willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints, or concerns about the research, you should call the Principal Investigator at (860) 523-3788.

If you have questions about your rights as a research subject, you may contact a coordinator at the Institutional Review Board at (860) 679-8729 or (860) 679-4849.

You may also call a coordinator at the Institutional Review Board if you want to pass along any suggestions, complaints, concerns, or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the Institutional Review Board number for medical-related issues or to schedule

or cancel an appointment.

Contact Over The Internet

Although contact over the Internet (e.g., information sent by e-mail or communication through programs such as WebEx or texting to your preferred cell phone) is not secure and may not remain confidential, many of our participants prefer communicating with us over the Internet. In order to communicate with you via a communication program such as email, we need your permission and this permission is necessary for participation.

____ - YES, I give staff permission to contact me over the Internet (including via text)
____ - NO, I DO NOT give staff permission to contact me over the Internet

Consent To Participation:

By signing this form, you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form, the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, **signed and dated by both the person giving consent and the person obtaining consent**, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	Printed Name	Signature	Date
Subject			
Person obtaining consent, Title			

There may be studies conducted in the future for which you may be an eligible participant. Please initial your preference.

____ - YES I **give** permission to Golda Ginsburg, Ph.D. or her designated staff to add my name and address to a mailing list to receive information about other studies they may conduct.
____ - NO, I **do not give** permission to be contacted about future studies for which I may be an eligible participant.

Informed Consent Form for School Clinicians
TEAMSS RCT

Principal Investigator (PI): Golda Ginsburg, Ph.D.
UCONN Health
65 Kane St.
West Hartford, CT 06119

PI Phone Number: (860) 523-3788

Co-Investigator(s): Jamie LoCurto, Ph.D.

Title of Research Study: Transitioning Emotionally and Academically to Middle School Successfully: Development of a Brief Intervention to Reduce Student Anxiety (TEAMSS)

Expected Duration of Subject's Participation: Approximately 1- 2 years

IRB Number: 22-114OS-1

External Sponsor/Funding Entity: Department of Education, Institute of Education Sciences (R305A200195)

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes, you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

This research is being done to compare the preliminary impact of TEAMSS, a multi-component group intervention for reducing anxiety symptoms among students transitioning from elementary to middle school to enhanced usual care (EUC; school counseling as usual plus written materials provided by the study team to parents and their children that include: 1) a specialty mental health referral list (if appropriate); and 2) a list of websites and books on child anxiety). Eligible students will be randomly assigned and all students will get a tour of the middle school, meet with their middle school clinician, and receive tip sheets on making a successful transition to middle school.

Your participation will involve approximately 6-8 hours of training in the first year of your study participation, plus approximately 15-20 hours over the course of the year delivering the TEAMSS intervention to randomized students, their parents and teachers, receiving coaching from study staff, and completing study questionnaires.

More specifically, if you volunteer, you will be asked to complete questionnaires about yourself and attend a training about how to identify and manage student anxiety using the TEAMSS intervention (described below). You will then be asked to provide the intervention (to students randomized to TEAMSS only). In addition, you will be asked to complete a brief set of forms after

each meeting with the student as well as study forms about all students enrolled in the study before and after the interventions.

The risks of participating are that it may feel uncomfortable initially to make audio and/or video recordings of yourself administering the intervention.

There is no guarantee that you will benefit directly from participating in this study. However, you may benefit by learning new strategies to help students better cope with anxiety.

Before deciding about whether to participate in this research, you should know that there are other options available to you. You might take advantage of other professional resources to learn how best to support students in coping with anxiety.

A more detailed description of this research follows.

What Is The Purpose Of This Research Study?
This research is being done to compare the preliminary impact of TEAMSS, a multi-component group intervention to enhanced usual care (EUC; which includes school counseling as usual plus written materials provided by the study team to parents and their children that include: 1) a specialty mental health referral list (if appropriate); 2) a list of websites and books on child anxiety) for students with elevated anxiety symptoms; and 3) tip sheets on successful transitions to MS.

Why Am I Invited To Participate?
You are being asked to join because you are a school clinician in a middle school. Your principal has reviewed the study and has given us permission to conduct the study in your school.

How Many Other People Do You Think Will Participate?
We expect approximately 20 school clinicians to participate in this Randomized Clinical Trial.

Is Participation Voluntary?
Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members or a friend before making a decision. If you do not join this study, your employment will not be affected. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Additionally, you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

How Long Will My Participation In This Study Last?
You may be in this study up to 3 years.

What Are The Costs To Me For Participating In This Study?
There are no costs to you for participating in this study.

What Will I Be Asked to Do?
All study procedures described below may be done virtually as needed (e.g., attending trainings,

completing questionnaires). These tasks will be done by way of an email sent to you that contains a link to the virtual trainings or questionnaires. Electronic gift cards will be sent to your email to compensate you for your time. Virtual platforms we use will include those that are approved by the University of Connecticut and are HIPAA compliant to protect confidentiality (e.g., Webex). If you do not have access to the internet, we will mail paper copies to your home or conduct in-person visits using social distancing measures in accordance with state and university regulations.

If you agree to be in this study and have the approval of your school principal, we will ask you to complete:

1. Questionnaires about yourself (e.g., your degree, training).
2. A training (approximately 6 hours) led by the study team, which will cover the study procedures, information about child anxiety, and training in each intervention module using a variety of strategies, including direct instruction, observation, role play, video examples, and review of the intervention manual and handouts.
3. Questionnaires regarding your experience with the training process and intervention. These questions should take no longer than 15 minutes to complete.
4. Administer the intervention in the beginning of middle school to students randomized to TEAMSS (versus EUC). The intervention will be manualized, delivered over 7-8 student group sessions. The intervention focuses on teaching a variety of cognitive behavioral coping skills and includes a parent and teacher component as well. More specifically, the intervention is comprised of evidenced-based strategies to reduce anxiety such as tools to help relax, confront difficult situations, change worried thoughts into coping thoughts, and identify ways to manage problems that may come up in the future. There are also 2-3 parent and 2-3 teacher meetings, approximately 60 minutes and 35-40 minutes respectively that you will deliver as part of TEAMSS.
5. Student Data. For each participating student in TEAMSS, you will be asked to complete brief forms after each meeting. For students in both TEAMSS and EUC you will be asked to complete brief surveys before and after the intervention and at a follow-up (toward the end of the school year).
6. Audiotape/Videotape Sessions. All TEAMSS intervention sessions will be audiotaped and/or videotaped and reviewed by study staff for fidelity/adherence. Video recordings of intervention sessions may contain images of you; if you are uncomfortable with your image being recorded, cameras can be turned off or away from you so that only audio is recorded. Participation in the study requires audio recording of you to ensure you are teaching the correct information from the intervention manual(s).

Audio and video recordings, as well as weekly forms, will be uploaded to a secure website. For sessions conducted virtually, clinicians will receive training on how to use recording features in videoconferencing platforms used by their school district, including how to upload recordings to a secure website (e.g., file share) for study staff. These files will then be immediately downloaded to a password protected external drive and stored in a locked cabinet that is only accessible to study staff. The recordings will be heard/viewed only by members of our study team and no names will be written on the recordings. Tapes will only be labeled with fully anonymized participant ID numbers. Nobody in the school will see or hear the recordings.

What Are the Risks Of Participating In This Study?
School clinicians may feel uncomfortable being audio and/or videotaped. However, this information is critical to assess adherence to the interventions, will only be accessible by study staff, and will be stored securely on a hard drive in a locked cabinet. Additionally, you have the right to refuse to answer any question that makes you feel uncomfortable.

What Are the Benefits Of Participating In this Study?
There is no guarantee of direct benefit to you from being in the study. However, you may learn new skills for helping students with anxiety.

Will I Be Compensated For Participating In This Study?
Your time will be reimbursed for completing the training and you will receive a $200 gift card (or e-gift card to Target or Amazon) at the completion of training (which includes completion of evaluation measures). You will also be reimbursed for completing coaching meetings with study staff at $20 per coaching meeting for up to 12 meetings.

You may be asked to complete a W9 form with your name, address, and social security number which will be sent to UConn Health Accounts Payable. If you receive over $600 from participating in research studies over the course of the calendar year, that money must be reported to the IRS as income.

Please select one of the following options:

__ I DO wish to be compensated for my participation in this study.
__ I DO NOT wish to be compensated for my participation in this study.

What Alternative Procedures or Treatments Are Available To Me?
You have the option not to participate in this study. We can provide you with professional resources for how to access training in anxiety reduction.

How Will My Personal Information Be Protected?
We will protect the confidentiality of your data to the best of our ability but cannot guarantee 100% protection.

While there is a chance that someone who is not part of the program could find out some information about you, the study team (principal investigator, research coordinator, co-investigator, etc.) will:

- Keep all study records locked in a secure location.
- Ensure records will be labeled with a number (no names are on any forms) and all contents of the research record will be labeled only with that number. No unique identifying numbers (like social security number, date of birth, etc.) will be used.
- Protect all electronic files (e.g., databases, spreadsheets, etc.) containing any identifying information with password protection. Any computer hosting such files will also have password protection to prevent access by unauthorized users.

Additionally, data stored electronically will have passwords to prevent unauthorized access.

- More specifically, your name and other identifiable information (e.g., name, phone number, and email address) will be linked to a study identification number (ID) through a master list spreadsheet; this spreadsheet will be password-protected, stored on a secure server, and will be accessible only to essential study staff.

Note that all study group meetings with students should be conducted in a private place where no one else can see or hear the child. Depending on how your school is operating and local guidance, you can deliver the intervention in-person or virtually. For in-person meetings, you should secure a private place where no one else can see or hear the child. For virtual meetings, you should help the family select a private place to complete the sessions. Additional privacy measures will be taken, such as securely storing and sending recordings of study sessions.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at UConn Health may need to see your information. These include people who review research studies, their staff, or other staff. The sponsor, Institute of Education Sciences, UConn Health's Institutional Review Board and the Human Subjects Protection Office may inspect records to ensure that the study is being done correctly.

Also, study staff are required by law to report suspected or known sexual or physical abuse or neglect or if an individual threatens to harm him or herself or others.

At the conclusion of this study, the researchers intend to publish an article on their findings. Information will be presented in summary format, using aggregate data, and you will not be identified in any publications or presentations.

This study involves the collection of identifiable private information (IPI). Identifiers will be removed from this IPI, and after such removal, the information could be used for future research studies or distributed to another investigator without additional informed consent.

What If I Decide To Stop Participating In The Study?

You can decide to stop participating in this study at any time. Your decision to stop participating in this study will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you decide to stop taking part in the study, your relationship with your school and UConn Health will not be affected. If you decide to withdraw, we ask that you let us know by calling Dr. Golda Ginsburg at (860) 523-3788 or by sending a written notice to Dr. Golda Ginsburg, UConn Health Partners, 65 Kane St., West Hartford, CT 06119. If you withdraw from the study, data that have already been collected will still be used for the study; no further data will be collected from you after study withdrawal.

Should significant new findings emerge throughout the course of this study that may relate to your willingness to continue participating, these findings will be provided to you.

Can Someone Else Make Me Stop Participating In This Study?

The researcher may prevent you from continuing in this study. You may be taken out of the study if:

- The study is cancelled or has ended.
- There may be other reasons that we do not know at this time to take you out of the study.

Adverse Events

All research involves a chance that something bad might happen to you. This may include personal injury. If you have a problem, you should contact the PI, Golda Ginsburg, immediately. You may contact Dr. Ginsburg at (860) 523-3788 or the UConn Health Institutional Review Board at (860) 679-4849.

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process, contact a representative of the UConn Health Institutional Review Board (860) 679-8729 or (860) 679-4849.

UConn Health does not offer free care. However, treatment for a research-related injury can be obtained at UConn Health for the usual fee.

What if I Have Questions?

The Principal Investigator is willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints, or concerns about the research, you should call the Principal Investigator at (860) 523-3788.

If you have questions about your rights as a research subject, you may contact a coordinator at the Institutional Review Board at (860) 679-8729 or (860) 679-4849.

You may also call a coordinator at the Institutional Review Board if you want to pass along any suggestions, complaints, concerns, or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the Institutional Review Board number for medical-related issues or to schedule or cancel an appointment.

Contact Over The Internet

Although contact over the Internet (e.g., information sent by e-mail or communication through programs such as WebEx or texting to your preferred phone) is not secure and may not remain confidential, many of our participants prefer communicating with us over the Internet. In order to communicate with you via a communication program such as email, we need your permission. Contact over the internet or via texting is usually voluntary; however, all study procedures will be done virtually where possible. Therefore, this permission is necessary for participation.

____ - YES, I give staff permission to contact me over the Internet/Phone

____ - NO, I DO NOT give staff permission to contact me over the Internet

Consent To Participation:

By signing this form, you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form, the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, **signed and dated by both the person giving consent and the person obtaining consent**, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	Printed Name	Signature	Date
Subject			
Person obtaining consent, Title			

There may be studies conducted in the future for which you may be an eligible participant. Please initial your preference.

____ - YES, I **give** permission to Golda Ginsburg, Ph.D. or her designated staff to add my name and address to a mailing list to receive information about other studies they may conduct.
_____ - NO, I **do not give** permission to be contacted about future studies for which I may be an eligible participant.