COVER PAGE

Official Study Title: Neural Connectivity Before and After Each of Three Treatment Phases of Trauma-focused Therapy for Adolescent Posttraumatic Stress

NCT number: NCT05423444

IRB Approval Date: 12/02/2024

Unique Protocol ID: HSC20220498H

Study: 20220498HU
IRB Approved:
12/2/2024

Concise Summary

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This study will measure how the brain changes when adolescents receive standard treatment for posttraumatic stress. We will collect MRI scans before, during, and after the therapy or treatment. This will allow us to assess changes in the brain in response to therapy, so that we can better tailor treatment to future patients.

For more information, please see the ***Why is this Study being Done*** section below.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?
There are 3 parts of the study: (1) Interviews and questionnaires at the beginning of the study and a few during the study; (2) in-person psychotherapy provided in or around the medical center; and (3) MRI scans and computer games. Parents will assist with completion of questionnaires and have limited participation in the therapy sessions.

Other options are to seek treatment without participating in the study, or not to receive treatment.

For more information, please see the ***What will be done if you decide to be in the research*** section below.

3. How much time will I spend on the study?
From start to end, this study takes about 8 months to complete. This includes completion of interviews and questionnaires, weekly therapy sessions for up to 18 weeks, and 4 MRI scans, with one every 6 weeks.

4. Could taking part in the study help me and are there risks?
You will receive therapy for your posttraumatic stress that may help to alleviate some of your symptoms. The treatment you receive is considered standard care, but it could be emotionally upsetting to talk about traumatic events you have experienced. MRI is generally considered safe, is painless, and does not involve radiation, but there is a risk of injury if metal objects such as jewelry are not removed prior to the procedure. Other risks related to the MRI could include claustrophobia, noise sensitivity, or muscle twitch.

For more information, please see ***How could you or others benefit from your taking part in this study*** section below. For details and a list of risks you should know about, please see the What are the risks of participation in the research section below.

5. What else should I consider before I make my decision?
There is no cost to you for participation. All research procedures, including psychotherapy, will be provided free of charge. There is some time commitment required of parents, but parents may benefit by learning new methods to support their adolescent in dealing with post-traumatic stress.

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Consent to be part of a Research Study
conducted at University of Texas Health Science Center at San Antonio

Information about this form

This form will enroll both you and your child

If you are providing consent for yourself and also for someone else, for example your child, or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow the words "you and your child" refers to you and the person you are providing consent for.

You may be eligible to take part in a research study. This form gives you important information about the study. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Brief summary of the study

From start to end, this study takes about 8 months to complete. There are 3 parts of the study: (1) Interviews and questionnaires at the beginning of the study and a few during the study; (2) psychotherapy provided in-person in or around the medical center, with sessions once per week for 18 weeks; and (3) MRI scans and computer games completed every 6 weeks for a total of 4 MRIs.

Please tell the research staff if you are taking part in another research study.

You do not have to participate if you don't want to. If you sign up, you can still quit the study at any time if you change your mind about participating. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this study?"

The Principal Investigator (PI) is the researcher directing this study. The PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Amy Garrett, Ph.D., who is an Associate Professor in the Psychiatry Department at UT Health San Antonio (UTHSA).

Purpose of this study – "Why is this study being done?"

This study will measure how brain function changes when adolescents receive therapy for symptoms of posttraumatic stress. We will provide a widely-used psychotherapy or the standard treatment and we will collect MRI scans before, during, and after the therapy or treatment. This will allow us to measure how the brain is changing during this time, which could help us to improve psychotherapy for other patients in the future. Also, this study will help us to understand how traumatic experiences affect the brain and how the brain recovers when symptoms improve.

Information about Study Participants – "Who is participating in this study?"

You and your child are being asked to participate in this study because your child has been recommended to receive care for symptoms of posttraumatic stress as a result of being exposed to a traumatic experience. We expect that about 180 adolescents and their parents/guardians will be enrolled in this study.

Information about Study Procedures – "What will happen if you decide to be in the study?"

From start to end, this study takes about 8 months to complete. Many of the procedures are described below as "standard care", which means they are regularly used in clinics. Other procedures are considered research procedures. In the description below, we will indicate the procedures that are for "research only". There are 3

parts of the study: (1) An Interviews (2 hours, completed at home over Zoom) and questionnaires ($1_{UT}h_{H}o_{ea}u_{lth}r_{SA}$

Study: 20220498HU
IRB Approved:
12/2/2024

online questionnaires that are completed from home); (2) Treatment sessions (1hour per week for 18 weeks; can be in-person at UTHSA, or virtual by Zoom); and (3) MRI scans and computer games (4 visits at 2 hours per visit; must attend in person at UTHSA approximately once every 6 weeks) . Each part is described below.

Interviews and Questionnaires
Before we begin the study, we must make sure that it is safe for your child to have an MRI scan, so we will ask you a lot of questions about injuries, surgeries, and other possible metal in the body. The questions will take about 10 minutes. If it is determined that the MRI scan is unsafe for your child, your child will not be permitted to continue with the research.

Second, we will ask you and your child to separately complete a questionnaire that takes about 10-15 minutes. This questionnaire asks if your child has experienced a trauma, and whether she or he is experiencing any of the symptoms associated with posttraumatic stress. Your answers will help us to determine if this therapy will be suitable for your child. If the therapy is not a good fit, we will discuss that with you and your child and then refer you to other providers. If it looks like the therapy could be a good fit, then we will continue with the next steps.

The next step is a clinical interview that lasts between 1.5 and 2 hours, and can be done virtually through Zoom or in person at UTHSA. The interviewer will ask you and your child many questions about your thoughts and feelings in order to clearly understand everything that you and your child have been experiencing, any treatments that your child has received previously, and any medical or psychiatric history. This information is important for determining whether the therapy is the best choice for you. Also, if you continue with the study, this information will be shared with your therapist to provide the background information needed to start the therapy program. Finally, we will email you and your child several questionnaires that you can complete online at home during the next few days. The questionnaires take about an hour to complete. If you do not have a computer or do not wish to receive links by email, you can complete these questionnaires on a computer at our clinic, or we can provide paper and pencil questionnaires instead.

Is it ok for us to send you the questionnaire links by email? .
_____ Yes, I agree to receive questionnaire links from the research team.
_____ No, I do not agree to receive questionnaire links from the research team.

We will also ask you and your child to complete a few online questionnaires and a brief interview after treatment is complete. These post-treatment questionnaires will take 30-40 minutes, and the interview will take another 40 minutes. Finally, we will contact you 3 months after the end of the study, to ask you to participate in a final interview that will take about 30-40 minutes. You can do this interview by Zoom, over the phone, or in person.

Treatment Sessions
If it is determined that your child is eligible for the study, you will be assigned to one of two possible treatment groups. Treatment assignment is based on chance (like flipping a coin). Both of the treatments are standard of care and consist of talk therapy once per week for 18 weeks. Each weekly session lasts about one hour. Treatment will be provided by licensed therapists at UTHSA or Clarity Child Guidance Center. All visits will be provided to you at no cost and can be either in-person or virtual, depending on you and your child's preferences and availability. Medication is not a part of the study. You should not participate in the study if you are seeking psychiatric medication for symptoms of PTSD.

Some of the therapy sessions may be videotaped (for research purposes) so that we can confirm that the therapist is performing the therapy exactly as intended. Sessions will be recorded either by video camera or by Zoom. All recorded sessions will be stored on UTHSA servers, and then they will be deleted as soon as the sessions have been confirmed. Checking the therapy sessions is an important part of clinical research, so this part of the study is required.

Before or after some of the therapy sessions, we may ask you and your child to complete one or two questionnaires using either paper, our iPad, or a laptop. These questionnaires take 10 minutes or less, and are collected to let us know how you and your child are doing.

After the study is complete, if you wish to continue therapy, or if the study doctor feels that your child would benefit from additional therapy, we will refer you to therapists outside the study. You will not be allowed to continue therapy with the study therapist, because that would change the design of the research study.

MRI Scans and Computer Games
An MRI scan will be conducted every 6 weeks, for research purposes, for a total of 4 MRI scans. We will schedule MRI scans to accommodate your schedule as much as possible, and all MRI scans will be conducted at UTHSA. Before the scan, we will ask you and your child to complete questionnaires, including screening again for MRI safety, and asking about current symptoms and any recent changes.

In total, the MRI scan visit will take about 1.5 to 2 hours, but your child will be inside the MRI scanner for only about 40 minutes of that time. At the MRI scanner, your child will be asked to lie on a platform that will travel partly into a tube. Your child's must remain still and may be asked to close his/her eyes or to play a computer game during the scan.

If you or your child is unsure about what happens during a scan, and would like to try it out first, she or he can have a practice MRI scan. The practice scanner looks just like a real MRI scanner and has a recording of MRI sounds, so your child can experience the scanner environment. After your child tries the practice scanner and feels comfortable about it, your child can go in the real MRI scanner. If you or your child wants to skip the practice MRI scan and go ahead with the real MRI scan, that is ok too.

During many of the MRI scans, your child will simply lie still and rest. For some of the MRI scans, we will ask your child to play a computer game, such as looking at letters on a screen and pressing a button, or reading words. We will show your child all the computer games before your child goes in the scanner. Inside the scanner, your child will play these games by looking at a computer screen and using a hand-held device for pressing buttons, sort of like a large computer mouse. The MRI operator will talk to your child over a microphone before and after each scan, and your child can talk to us and tell us if he/she needs anything. <u>If your child becomes uncomfortable in the MRI, he/she can squeeze a ball that starts a buzzer to get our attention, and we will end the scan and let him/her out of the MRI machine if requested.</u>

After the MRI scan is completed, your child will complete a few computer games outside the scanner. The games will be played on our Ipad device, and will take about 10-15 minutes. The games include looking at letters or pictures and pressing buttons according to instructions.

The first MRI scan of the study will be conducted before therapy begins. After the first MRI is complete, we will schedule your child's first therapy session with his/her therapist. The remaining three MRI scans will be scheduled during those 18 weeks of therapy: approximately week 6, 12, and 18. We can schedule the MRIs on the same day as your therapy session, if that is convenient for you. Each MRI will take approximately 1.5 - 2 hours and be similar to the first MRI. As described above, we will ask you to complete questionnaires and interviews after the final MRI.

Risks – "What are the risks of participating in the research?"

Risks associated with receiving Treatment
Both treatments being done in this study are standard treatments that are regularly provided in clinics. There is no difference in the risks associated with the two treatments. Also, there are no additional risks for participation in this study compared to receiving standard talk therapy at any clinic.

Risks of the MRI
MRI is a non-invasive procedure that does not involve radiation, injections, or blood draws. MRI is believed to be safe as long as we carefully screen your child for metal in the body, such as pins from an injury or surgery or metal fragments from metal working. If you are not sure whether your child has metal in his/her body, we will ask you to check with your physician before the MRI. If your child could be pregnant, she should not have an MRI. We will ask female participants to take a pregnancy test to confirm that she is not pregnant.

Other risks of having an MRI include:

- Claustrophobia from the confined space of the scanner. If you feel claustrophobic during the scan, please let us know and we can let you out of the scanner.

- Irritation if you are sensitive to the loud noises of the scanner. We will give you earplugs to block the loud noises of the scanner. If the noises still bother you, let us know and we can let you out of the scanner or give you extra earplugs, whichever you prefer.

- It is possible to get a muscle twitch in the scanner under rare circumstances. If that happens to you, let us know. The muscle twitch should stop when the scan ends.

Risks of the questionnaires and interviews
There is a chance that the questions about your child's symptoms and trauma history will be upsetting. We will gently encourage you to discuss sensitive information, when you are ready, because that information will help your therapist to understand and help you. Part of the therapy could be discussing the traumatic event with your therapist, because that has been shown to help patients who have symptoms of posttraumatic stress. Your therapist has a lot of experience working with children and with this therapy, and will be open to hearing about any concerns. It is always ok to let the therapist know if you feel uncomfortable or want to take a break during the therapy session. We want you to know that you don't have to answer questions if you don't want to, and you can stop the interview and/or therapy if you choose. This research study is voluntary and you always have the option to leave the study and receive therapy without participating in this study. If you decide to withdraw from this study before you have finished it, please let us know as soon as possible so that we refer you to another provider.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, or even at different times, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact the P.I., Dr. Amy Garrett. See the section "Contact Information" for phone numbers and additional information. You may also want to tell your child's pediatrician.

If you are injured as a result of the research procedures, your injury will be treated and you will be responsible for any charges. We have no plans to give you money if you are injured. However, if you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefits of your participation in this study is that you will not need to pay for the therapy sessions or the MRI, and that your child's symptoms will improve from receiving therapy. The results from this study may help the researcher gain an understanding of brain mechanisms of PTSD, which may help other

individuals with PTSD in the future. Also, you may enjoy learning about the brain, MRI, and research.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

Not participating in this research is an option. The researcher will discuss all of your options with you.

Payments – Will there be any payments for participation?

You will be compensated up to $500 for your participation in this study, depending on how much of the study you complete. The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of each visit as identified below. Your name, address and date of birth will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

- For the completing the first set of interviews and questionnaires you will be granted $50.00.
- For completing the first MRI scan visit you will be granted $75.00.
- For completing the second MRI scan you will be granted $75.00.
- For completing the third MRI scan you will be granted $75.00.
- For completing the final MRI scan you will be granted $100.00.
- For completing the final set of interviews and questionnaires, you will be granted $100.00.
- For completing the 3-month follow-up interview, you will be granted $25.00.

There may also be funds available to provide you taxi fare to and from your MRI visits, should you be unable to secure your own transportation. Please speak with a member of the study team for further information.

Receiving study information via text message

The research team would like to communicate with you regarding your participation via text message, such as appointment reminders or other information. In order to do this, we will share your name and phone number with TigerConnect, a texting platform that is approved by UTHSA and uses an encrypted method of messaging that is secure. Standard text messaging rates will apply. When the research team sends you a text message via TigerConnect, you will receive a text that says "you have received a secure message from UT Health San Antonio" with a link. When you click on the link it will take you to a secure website where you can read the text and reply.

Are you willing to receive study-related text messages?

____Yes, I agree to receive texts from the research team.
____No, I do not agree to receive texts from the research team.

Costs – Will taking part in this study cost anything?

You will not be charged for therapy sessions or MRI scans or any other part of the study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you or any research participant. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records, which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. For example, if you are at risk of hurting yourself or another person, or if you report a new incidence of child abuse, we are obligated by law to take steps to protect you and other people. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Name
- Date of birth
- Physical address
- Email address
- Information that is created or collected during your participation in the study including psychotherapy treatment
- Information you give us during your participation in the study such as during interviews or from questionnaires
- Demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by asking you or completion of questionnaires and interviews.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Institutional Review Board and the Compliance Office at UTHSA, and other groups that oversee how research studies are carried out.
- Clarity Child Guidance Center
- UTHSA clinics

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information for the purposes of the research. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by email or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside UTHSA or Clarity for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study. After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Amy Garrett
UTHSA Medical School
Psychiatry Department Mail Code: 7792

UT Health SA
Study: 20220498HU
IRB Approved:
12/2/2024

7703 Floyd Curl.
San Antonio, Texas 78229

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem, which may be, related to this study please contact:

Primary contact:
Amy Garrett, PhD., who can be reached at 210-567-8189 during normal office hours.

If primary is not available, contact:
Dr. Tabatha Blount, who can be reached at 210-567-1600 during normal office hours.

The UTHSA committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject (Parent/Guardian)	Signature of Subject	Date	Time

Youth and Surrogate Signature Section

- If you are under 18, you are giving your assent to participate in this study.
- If you are the parent/guardian, you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You also authorize the collection, use and sharing of another person's protected health information as described in this form.

UT Health SA
Study: 20220498HU
IRB Approved:
12/2/2024

Printed Name of Participant (Child/Adolescent)	Signature of **Participant**, indicating Assent *(If incapable of signing, person obtaining consent should initial here)*	Date	Time

Printed Name of Parent/Guardian Giving Consent & Authorization for Subject	Signature of Person Giving Consent & Authorization ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time

Printed Name of Researcher obtaining consent	Signature of Researcher Obtaining Consent & Authorization	Date	Time

UT Health SA
Study: 20220498HU
IRB Approved:
12/2/2024