Title: Evaluation of Clinical Effectiveness, Cost, and Implementation Factors to Optimize Scalability of Treatment for Co-occurring SUD and PTSD Among Teens

NCT number: NCT05384223

Document date: 07.25.2025

Principal Investigator: Dr. Paula Riggs
COMIRB No: 21-3736
Version Date: 07.10.2024

Study Title: Evaluation of Clinical Effectiveness, Cost, and Implementation Factors to Optimize Scalability of Treatment for Co-Occurring SUD and PTSD Among Teens

You and your teen are being asked to participate in a research study. This form provides you with important information about the study. A member of the research team will describe this study to you and answer all of your questions prior to obtaining your consent to participate. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study is being done to evaluate the effectiveness of a treatment called Risk Reduction through Family Therapy (RRFT). This integrative treatment is designed for adolescents with a history of potentially traumatic events, and addresses both substance use problems (SUP) and symptoms of Post-Traumatic Stress Disorder (PTSD). This treatment will be compared to Treatment As Usual (TAU). In this study, TAU will be Encompass Treatment, an integrated treatment for co-occurring SUP and psychiatric disorders. Both treatments focus on your teen's substance use, trauma, and other mental health problems. Both treatments are safe and evidence-based.

You and your teen are being asked to participate in this research study because you and your teen meet certain criteria. To be included in this study, all adolescent participants must be between the ages of 13-19, have experienced a traumatic event in their lifetime, have five or more symptoms of PTSD, have a current substance use disorder, have used alcohol or drugs in the past 28 days, and (optionally) be willing to include a caregiver to participate.

Other people in this study

Up to 710 people from your area will participate in the study.

What happens if I join this study?

If you and your teen both agree to join this study, your teen will be randomly assigned to either RRFT or TAU (Encompass). RRFT includes a mix of individual and family sessions (when possible), and incorporates exposure-based strategies, which involve a direct discussion of the thoughts, feelings, and memories associated with specific traumatic events your teen may have experienced. Encompass includes primarily individual therapy sessions with your teen and may include up to one or two family sessions. Encompass also addresses the thoughts, feelings, and memories associated with traumatic events related to your teen's substance use.

As part of the study, you and your teen will be expected to complete up to 20 treatment sessions as well as 4 research visits over the next year. Treatment sessions will be audio-recorded and transcribed. Your therapist will provide information about your therapy attendance to the research team but will not disclose any other details about your treatment. At each research visit, you and your teen will complete assessments consisting of interviews and questionnaires. In addition to treatment sessions and research assessments, your teen will also undergo confidential urine drug screens. Each research visit will take approximately two hours

and all assessments will be administered by a trained research staff member. Research visits will occur in person, over the phone, and/or via videoconference according to your preference. Treatment sessions occur weekly and each research visit will occur three months apart; total study duration is estimated to be about 12 months.

What are the possible discomforts or risks?

Discomforts you may experience while participating in this study include:

1. Breaches of confidentiality are a concern with any study. There is a risk that people outside the research team will see your information. We have outlined several steps to maintain confidentiality, including only using a study identification (ID) number to store and track your data. Nevertheless, if our protocol for maintaining confidentiality were broken, there is a risk of a potential loss to your confidentiality. You should understand that communications via text message over the internet are not secure and that, although unlikely, there is a possibility that information included in a text message can be intercepted and read by other parties beside the person to whom it is addressed.
2. Any new (i.e., previously unreported) disclosures of abuse may be reported to the appropriate authorities if it meets the standard for mandatory reporting. If your teen discloses self-harm, we may need to inform you and other authorities. If you or your teen report self-harm, you will be provided referral to appropriate services.
3. There is a potential that the assessments of your experiences or problems may produce small to moderate amounts of anxiety, sadness, or embarrassment. Assessments used in this study are identical or similar to the ones already used as standard of care at this and other similar community health centers. Often, the anxiety or sadness effects of such treatments are rare and temporary.
4. You/your teen will be randomly assigned to either RRFT (Risk Reduction through Family Therapy) or TAU (Encompass treatment). The study treatment you/your teen receive may prove to be less effective, or have more side effects, than the other study treatment or other available treatments.

The study may include risks that are unknown at this time.

Which treatment will your teen receive?

This study will have two different groups of research subjects. Each group will receive a different treatment; either RRFT or TAU (Encompass). To decide which group your teen will be in, we will use a method of chance. This method is like flipping a coin or rolling dice.

What are the possible benefits of the study?

This study is designed to help us learn more about the effectiveness of RRFT. The potential benefits to your teen receiving RRFT is that the treatment your teen receives may decrease substance use problems and trauma-related symptoms. The potential benefits to your teen receiving Treatment As Usual (Encompass) is that the treatment your teen receives may decrease substance use and other mental health problems. These benefits cannot be guaranteed. Therefore, there is a possibility of no direct benefit from participation in this study. The results from this study may help future individuals with similar needs as your teen.

Are there alternative treatments?

There may be other ways of treating substance use problems and PTSD. These other ways include other forms of therapy. You could also choose to receive no treatment at all.

You should talk to your doctor or counselor about your choices. It is important that you understand all of your choices before you decide to take part in this study. If you leave this study, you will still have these other choices available to you.

Who is paying for this study?

This research is being sponsored by the National Institute on Drug Abuse (NIDA).

The sponsor will only pay for procedures not considered standard of care, as detailed below.

Will I have to pay for anything?

There may be costs associated with taking part in this study depending on the kind of insurance or behavioral health benefits your family has. If you and your teen participate in this study, we will bill Medicaid or other insurance for the treatment your teen receives as part of the study the same way we would bill for treatment your teen receives if you do not participate in the study. Any out-of-pocket treatment expenses, such as insurance co-pays, would be the same for treatment your teen receives as part of the study as it would be for treatment your teen receives if you do not participate in the study.

Will I be paid for being in the study?

Your family will be compensated via Amazon gift card for the research assessments you complete outside of the study treatments. Your family will be paid $75 ($37.50 each for both the adolescent and caregiver participant) for the baseline research visit, $100 ($50 per participant) for the second research visit, $125 ($62.50 per participant) for the third visit, and $150 ($75 per participant) for the final visit. If you complete all four research visits, you will be paid an additional $50 ($25 per participant) at the end of the study. This will add up to a total of $500 if both participants complete all of the study visits. If either the adolescent or caregiver doesn't participate in a visit, if you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.
It is important to know that payments for participation in a study is taxable income, and therefore submission of a W9 Form for each participant is required.

Is my participation voluntary?
Taking part in this study is voluntary. You and your teen have the right to choose not to take part in this study. If you choose to take part, you have the right to stop and withdraw your participation at any time. If you refuse now or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, your teen will still receive normal medical care. The only medical care that your teen will lose is the treatment your teen is receiving as part of this study. You still may be able to get that same kind of care outside of the study. Ask your doctor or counselor for more information.

If new information is found during the study that may affect your care or decision to participate in this study, you will be informed as soon as possible.

Can I be removed from this study?

The research team may decide to stop your participation in this study without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

Also, the sponsor may stop the study at any time.

Both the treatment your teen receives as part of the study and the research assessments are voluntary. Please note, even if your teen chooses to stop treatment, you and your teen will still be part of the research study and we will ask you to complete all scheduled study visits.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Paula Riggs. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Riggs at 303-724-2235. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Riggs with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call COMRIB at 303-724-1055.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results once the study has concluded. You can search this website at any time.

Who will see my research information?

The research team will share clinically relevant information obtained via research assessments with your teen's study clinician/therapist.

Your teen's answers to the study questionnaires as well as the results of their urine drug screen will not be given or shown to you. Your answers to the study questionnaires will not be given or shown to your teen.

The University of Colorado Denver | Anschutz Medical Campus and its affiliated health systems have rules to protect information about you and your child. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protects your privacy. This part of the consent form tells you what information about you and your teen may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Medical University of South Carolina

We cannot do this study without you and your teen's permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not participate in this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado and it affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission of the use and disclose your information at any time by writing to the study's Principal Investigator

(PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Paula Riggs
University of Colorado Anschutz Medical Campus
1890 N Revere Court, Mail Stop F570
Aurora CO, 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board (IRB) that is responsible for overseeing this research.
- The study doctor and the rest of the research team.
- National Institute on Drug Abuse (NIDA), who is the sponsor paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals or share data that does not identify you with qualified investigators or as a supplement as required by some journals. But we will always keep the names and any other identifying information of research subjects, like you and your teen, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed. We may share de-identified data with other investigators who go through a formal request process.

The investigator (or staff acting on behalf of the investigator) will use you and your teen's information for the research outlined in this consent form. Information about you and your teen will not be disclosed to anyone outside of the research team, except institutional or federal officials as listed above.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

- Medical University of South Carolina
- Indiana University
- Oregon Social Learning Center

Information about you that will be seen, collected, and used in this study:

- Name and demographic information (age, date of birth, sex, ethnicity, address, phone number, email, etc.)
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study

- Research visit and research test records
- Psychological and mental health tests
- Alcoholism, alcohol or drug abuse
- Audio-recordings of you or your teen's voice
- Billing or financial information

What happens to the data that is collected in this study?

Scientists at the University of Colorado Denver | Anschutz Medical Campus and the hospitals involved in this study work to find the causes and cures of disease and disorders. The data collected from you and your teen during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belongs to you.
- Both the investigators and any sponsor of this research may study the data collected from you.
- If the data is in a form that identifies you, researchers involved in this study may use this data for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

What will happen to my recorded information?

Any study records containing you or your teen's personal or health information will be kept on password-protected, secure computers or devices that are only accessed by approved research staff. Any paper records containing you or your teen's information will be kept in locked cabinets within locked research offices.

In this study we will be audio-recording treatment sessions. These audio-recordings may also be transcribed. We will keep this information secure and private. We will store this information for 5 years after the end of this study. At the end of that time, we will destroy it.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research.
- If required by Federal, State, or Local laws.

- If necessary for your medical treatment, with your consent.
- For other scientific research conducted in compliance with Federal regulations.
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting.
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Things that must be reported to the authorities

We respect your right to privacy, but some things we cannot keep private. If you give us any information about child abuse or neglect, we have to report that to Colorado Social Services or other agency. If you tell us you are going to physically hurt yourself or someone else, we have to report that to the Colorado state police or other agency. Also, if we receive a court order to turn over your study records, we will have to do that.

Optional consent for data for future research

Please read the statement below and think about your choice. After reading the statement, check "yes" or "no." If you have questions, please talk to your doctor or counselor. Remember, no matter what you decide to do about the storage and future use of your data, you may still take part in the study.

I give my permission for the research team to contact me in the future to ask me to take part in more research.

_____ YES _____ NO _____/_____ /_____ Caregiver, Legal Guardian, and Adolescent Initials

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

Caregiver, Legal Guardian, and Adolescent Initials:

_____/_____/_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____/_____/_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

If the caregiver participating in the study is not the adolescent's legal guardian (and the adolescent is younger than 18 years old), the adolescent's legal guardian will sign below for the

adolescent's participation in the study. If the caregiver is also the adolescent's legal guardian, they will sign as both the caregiver and legal guardian.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use, and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Caregiver Signature:_____ Date: _____

Print Caregiver Name: _____

Adolescent Signature: _____ Date: _____

Print Adolescent Name: _____

Legal Guardian Signature: _____ Date:_____

Print Legal Guardian Name: _____

----------Research Team Use Only----------

Explained by Signature:_____ Date:_____

Print Name:_____

----------Witness(es) Only----------

Is a witness required: _____ YES_____ NO

Witness Signature:_____ Date:_____

Print Name:_____