Manage Emotions to Reduce Aggression - MERA: A Brief Aggression Treatment for Veterans With PTSD Symptoms

NCT04793776

December 5, 2025

Participant Name: _____ Date:_____

Title of Study: Manage Emotions to Reduce Aggression – MERA: A Brief Aggression Treatment for Veterans with PTSD Symptoms

Principal Investigator: Shannon Miles, Ph.D. VA Facility: James A. Haley Veterans' Hospital, Tampa, FL

Principal Investigator for Multisite Study: Shannon Miles, Ph.D.

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Office of Clinical Science Research and Development (CSR&D). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Some Veterans who have Posttraumatic Stress Disorder (PTSD) symptoms also have difficulty managing aggression. They don't want to be aggressive but don't know how to stop. Our research shows that problems dealing with emotions are related to aggression. We made a 3-session treatment with the goal of helping Veterans manage their emotions and reduce their aggression.

The purpose of this study is to see if our treatment, called Manage Emotions to Reduce Aggression (MERA), can reduce aggression when compared to Present Centered Therapy (PCT). MERA teaches you how to manage emotions with skills that you can use in your daily life. PCT provides education about PTSD and helps you problem solve current stressors. Both treatments are done once per week for 90 minutes. Another goal of this study is to see if MERA helps Veterans start PTSD treatments, such as Cognitive Processing Therapy or Prolonged Exposure.

By doing this study, we hope to learn if MERA can help Veterans be less aggressive. Your participation in this research will last about 14 weeks and require 5 study visits.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to take part in the study because it may help you control your aggression. For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to be a part of this study because it will ask you to talk about your emotions and aggressive behavior, which may make you feel uncomfortable. Additionally, if you report abuse of a child, elder, or vulnerable person, the law requires us to report this to the appropriate authorities. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

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If you decide not to participate in this research, there are other choices that this VA offers to help you reduce your aggression, such as therapy with your regular therapist. You can also talk to a prescriber about medications. For a complete description of alternate treatment procedures, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Shannon Miles, Ph.D., Principal Investigator, at the James A. Haley Veterans' Hospital, Tampa, Florida. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact information is (813) 972-2000, Ext. 6728.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

Some Veterans with PTSD symptoms say they have trouble controlling their aggression. Aggression can lead to devastating consequences, such as being arrested, family violence, and friends and family not being supportive of the Veteran. Veterans with PTSD primarily engage in impulsive aggression which is unplanned and a reaction to things that happen to them. They are not trying to be aggressive, but they lose control of themselves. They want to stop being aggressive.

We know that the ability to notice and deal with your emotions is related to fewer aggressive acts. Because of this we developed a brief, 3 session treatment called Manage Emotions to Reduce Aggression (MERA) that teaches Veterans how to cope with their emotions. We tested this treatment in a small study, and Veterans said they liked it. Now we want to compare MERA to a treatment that is often provided to Veterans with PTSD, called Present Centered Therapy (PCT) which helps Veterans manage daily stressors.

By conducting this research, we hope to learn if MERA can help Veterans be less aggressive. We will compare MERA and PCT and see which one is most helpful to Veterans who want to reduce their aggression.

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HOW LONG WILL I BE IN THE STUDY?

About 102 people will take part in this study at James A. Haley Veterans' Hospital. A total of 204 Veterans from 2 VA hospitals will take part.

This research study will take 5 years. Your individual participation in the project will take approximately 14 weeks. You will complete a baseline assessment, 3 treatment sessions, and a post-treatment assessment. We will also monitor your chart for 6 months to see if you start PTSD treatment after this study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

These are the steps in the research study that we will ask you to complete.				
Baseline assessment. 3 weeks before your first therapy session. (2.5 hours) →	1st Therapy Session (90 minutes) →	2nd Therapy Session (90 minutes) →	3rd Therapy Session (90 minutes) →	Posttreatment assessment. 2 months after you finish your treatment (2 hours)

- First, you will do a baseline assessment which will take about 2.5 hours. You will complete questionnaires about how you have been feeling, coping with your emotions, and how many times you have been aggressive. You are free to skip any questions that you prefer not to answer. You will talk with an evaluator about your PTSD symptoms and other mental health disorders you may have. The assessment will be audio recorded to make sure your evaluator asked all the questions.
- If you are a good fit for the study, you will then be assigned to either:

  Manage Emotions to Reduce Aggression (MERA)

  or

  Present Centered Therapy (PCT).

  The treatment you will receive will be by chance, like a flip of a coin. You do not get to pick which treatment you get. The treatment session will be audio recorded to make sure the therapist is covering all the session content.
- You will receive daily text messages from the VA Annie app that will ask you, "How many times did you engage in aggression in the past 24 hours."
- Three weeks after your baseline assessment you will start therapy and complete 1 treatment session per week for 3 weeks.

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- You will wait 2 months, and then the independent evaluator will ask you some of the same questions s/he asked you in the baseline assessment. But this assessment will not take as long.
- Study staff will ask to monitor your chart for 6 months after your final therapy session. This will not require any effort on your part.

Tracking your aggression. Throughout the study we will ask you to track your aggression in 2 ways:

1. We will ask you to fill out a form each time you attend a study visit that asks how many times you acted aggressively.
2. We will send you a text message with the VA Annie app every day and ask how many times you acted aggressively during the past 24 hours. Tracking behavior helps people do less of it, so we hope this will help you be less aggressive. We ask you to respond to the text within 2 hours. You will be enrolled in the Annie app during your baseline visit and will receive messages until the last therapy session. Annie is a VA text messaging program that helps Veterans take an active role in their health. Your responses to our text messages are stored in you secure electronic medical record and not on a personal cell phone.

Independent aggression rater. We ask you to allow an adult, with who you have a personal relationship and in-person interactions most days of the week (called the "independent aggression rater"), fill out two short surveys via the telephone. The survey asks how many times you (the Veteran) engaged in aggressive acts in the past week. Study staff will call the independent aggression rater after session 1 and again after the posttreatment assessment. The phone calls should take about 5 minutes each. You will not get to know if s/he decides to participate or how s/he answers to the questions.

Location of study visits. The 5 study visits (2 assessment and 3 therapy sessions) will be conducted either in person at the James A. Haley Veterans' Hospital or virtually using the VA approved and encrypted Veterans' Virtual Care (VVC) platform. Team members from the Tampa or Houston VA hospitals may conduct the assessments or therapy sessions. During the coronavirus pandemic all psychotherapy visits throughout the Veterans' Health Administration are being conducted on VVC. Once the pandemic is over, you can choose to complete the study visits in person or virtually.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you agree to take part in this study, the following are the responsibilities and expectations for participation:

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- Keep your study appointments. If you miss an appointment, please contact the research staff as soon as possible to reschedule.
- Complete questionnaires as instructed and reply to daily texts through Annie app.
- Ask questions as you think of them.
- Do not ask a provider to change your psychotropic medications unless it is an emergency.
- Report any concerns or mental health issues that you experience participating in the study to the study team members.

While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

If you receive PTSD psychotherapy from a provider outside of the VA during or within 6 months of your last treatment session, we will request a copy of your records. Study staff will help you complete VA Form 10-212, which is needed for each non-VA therapist you see.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any therapy has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed.

Questions / Interviews: There is a chance that some of the questions in the interviews may make you feel uncomfortable. If you feel uncomfortable: you can choose not to answer certain questions; you can take a break and continue again later; you can stop the interview; you can stop participating in the study; you can talk with your primary therapist; or you can seek emergency services. Your well-being is more important than the research study. You can report any problems to any members of the study team.

MERA Therapy: As with all psychological treatments, the procedures may cause a temporary mild increase in worry, anxiety, or other emotions. MERA teaches you more adaptive ways of coping with your emotions which means the therapist will ask you to notice your emotions. Any increases in emotions are expected to be temporary. Feelings of discomfort or embarrassment usually are not serious and will go away when you practice the therapy skills or stop talking about the issue. If you have any of these problems, tell the therapist. In the event that you remain distressed or upset after the therapy visit, you will be encouraged to speak to the study therapist or another mental health care professional.

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PCT: Similar to MERA and all psychological treatments, PCT may cause a temporary mild increase in worry, anxiety, or other emotions. The goal of both treatments is to provide education and help your problem solve your current stressors. Any increases in emotions are expected to be temporary. Feelings of discomfort or embarrassment usually are not serious and will go away when you practice the therapy skills or stop talking about the issue. If you have any of these problems, tell the therapist. In the event that you remain distressed or upset after the therapy visit, you will be encouraged to speak to the study therapist or another mental health care professional.

Reporting of Abuse or Suicidal / Homicidal Intent: If you or your independent aggression rater report abuse of a child, elder, or other vulnerable individual, the study staff must report this abuse to the appropriate authorities (Department of Children and Families, child protective services, or adult protective services). If you are at risk for harming yourself or someone else, study staff will alert a licensed mental health professional and stay with you until you can be "handed off" to appropriate medical staff. If you are an outpatient, this may involve taking you to the Emergency Room for evaluation.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

Potential Loss of Confidentiality: The risk of losing confidentiality is minimal and will be managed by storing personally identifying information (PII) in a locked cabinet, using random participant identification (ID) numbers to identify the patient data in paper and electronic form, and not including PII in databases.

Every effort will be made to maintain the confidentiality of your study records. The data from the study may be published; however, you will not be identified. Your identity will remain confidential unless disclosure is required by law.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or

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copy portions of records that identify you. Destruction of all research records pertaining to this study will be in accordance with the Federal Policy of the Department of Veterans Affairs and will be retained for a minimum of 6 years after the end of the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits include:

- Controlling your aggression.
- Learning how to better manage stress and emotions, which can help you feel better in your daily life.
- Feeling more prepared to start PTSD treatment.
- By volunteering you are helping us learn more about Veterans who have PTSD and struggle to control their aggression.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

It is okay if you decide not to participate in this study. Participation in this research study is entirely voluntary. If you do not want to be part of this study, the rights and health care benefits you are entitled to will not change (i.e., including VA benefits and access to standard medical care). If you choose not to be in the study, you can talk with your doctor about other options to reduce aggression including Present Centered Therapy (PCT) outside of the research study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you, including your medical record, social security number, and answers to questions we ask you. We will protect your data in the following ways:

1) Any identifiable information about you will kept confidential and locked in a file cabinet in a locked office or on a password-protected research server which sits behind the VA firewall.
2) We will give you an ID number which will be put on all your forms instead of your name.
3) Personal health information will be shared among the 2 sites (Tampa VA and Houston VA) when required to facilitate assessments or therapy.
4) Coded data will be uploaded into a VA approved secure REDcap or Qualtrics database.
5) In order to send you some study related material, we will need to provide your name and email address to Qualtrics (secure online data collection platform).

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6) Any presentations or papers about the study will not identify you. Your data will be combined with the data of other people taking part in the study.
7) Audio recordings will be created digitally. These will be shared with the Tampa VA by means of a secure VA-protected online server. Only study personnel will have access to the recordings and the files will not be disclosed outside the VA.

We will not share your personal health information or identity unless we have to by law.

There are no current plans to share data for future research. However, federal funders encourage sharing deidentified datasets. Any future research will require IRB and regulatory approvals prior to receiving data and will not be able to link you back to your individual data. If this happens de-identified information may be used for future research without additional informed consent from you.

We will include information about your study participation in your medical record.

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. You can search this website at any time.

Certificate of Confidentiality

To help further protect your information, the investigators have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes,
- information regarding test results for certain communicable diseases to the Florida Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox,
- if you pose imminent physical harm to yourself or others,
- if you pose immediate mental or emotional injury to yourself,
- if the researchers learn that a child has been, or may be, abused or neglected; or

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- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

At each study visit, there will be a brief note entered into your electronic medical record.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: VA Office of Human Research Protections, VA Office of Research Oversight (ORO), VA Government Accountability Office (GAO), VA Office of Clinical Science Research & Development (CSR&D), the VA Institutional Review Board, CSR&D Data Monitoring Committee, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records. This study will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

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You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Shannon Miles and the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

It will not cost you anything to be a part of the study. You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, these co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

Being in the study will require some extra time and effort on your part because of the assessments. You will be paid for your time during the assessments. You will not be paid for the therapy sessions. Payment will be in the form of an electronic funds transfer or gift cards. You will get $40 after completing the baseline assessment even if you do not meet criteria to be in the study. If you do not meet the study criteria, you will not complete any other assessment and your part in the study will be over. If you do meet criteria to be in the study, we will ask you to complete the posttreatment assessment. We will pay you $40 to complete the posttreatment assessment.

In summary: $40 after completing the baseline assessment
$40 after completing the posttreatment assessment
Total = $80 if both assessments are completed.

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If we pay you by electronic direct deposit payment, you will need to fil out forms in MyHealthe Vet and ID.Me You will have to enter your whole social security number, not just the last 4 digits. After you get approved, the study staff will finish setting up your direct deposit.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you or your insurance unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

You have not released this institution from liability for negligence by signing this form. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the Office of Community Care – Payment Operations Management at this VA Medical Center at 877-881-7618.

If you believe you have a medical concern related to this study or have been hurt or became sick because of something that is done during the study, you should call the person listed below immediately.

DURING THE DAY:
Dr. Shannon Miles, Telephone Number: (813) 972-2000, Ext. 6728

AFTER HOURS:
Emergency Room at James A. Haley Veterans' Hospital, Tampa, Florida
Telephone Number: (813) 972-2000

DO I HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you want to volunteer. If you choose to take part in this study, you will need to sign this consent form. If you choose not to participate in the study, there is no penalty, and you will not lose any benefits that you are entitled to or access to any services. If you are a VA employee or student, refusing to enroll in the study will not influence your employment, ratings, recommendations, or academic progress.

You may decide to stop participating in the study at any time after signing this informed consent document without any penalty or loss of benefits. We will keep you informed of any new developments which might affect your willingness to continue to participate in the study. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

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If you decide to stop participating in the study, the study team can continue to use information about you that was already collected but cannot collect further information, except from public records. If you want to stop the therapy, you can still complete the posttreatment assessment.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your mental health may worsen. Your treatment team will decide what treatment you should receive.
- You are not coming for your study visits when scheduled.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, concerns or complaints about this study you can contact:

- The study Principal Investor at the Tampa VA: Dr. Shannon Miles at (813) 972-2000, Ext 6728.
- The study Project Manager at the Tampa VA: Valerie Larson at (813) 417-3499.
- If you would prefer to talk to someone not directly involved in this study, you may contact the Patient Advocate for the Tampa VA at (813) 972-2000 Ext. 5856 or 5757.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Throughout the study, the researcher may notify you (via telephone or at the scheduled visit) of any new information that may become available, and which might affect your decision to remain in the study. If you decide to withdraw from the study, your research doctor will arrange for your mental health care to continue. Clinically relevant research results will not be disclosed to you.

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Principal Investigator: Shannon Miles, Ph.D. VA Facility: James A. Haley Veterans' Hospital, Tampa, FL

Principal Investigator for Multisite Study: Shannon Miles, Ph.D.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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