Research Consent Form

Minneapolis VA Health Care System

Veteran Participants

Study Title: Teaching Loved Ones to Help Veterans Optimize their PTSD Care and Healing (COACH)	
Principal Investigator: Laura Meis, PhD	
Protocol #: VAM-19-00541	**ICF Version Date: 2/24/2022**

INTRODUCTION

You are being asked to participate in a research study. The box below highlights some key information that you should know about the project, and more detailed information is provided on the following pages. Take your time to decide. If you do decide to take part in this study, your signed consent and HIPAA forms will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. Whether or not you decide to participate, treatment at the VA for which you are eligible will not be affected.
- **Purpose**. There are certain types of treatments that research has found are effective in treating PTSD. However, not everyone attends enough sessions of the treatment to benefit. Also, even when Veterans do fully complete the treatment, some achieve greater symptom relief than others. With this research, we hope to learn if Veterans gain more from PTSD treatment if a loved one is involved in their therapy.
- **Duration.** This research study is expected to take approximately 1 year. Your individual participation in the project will take 4 to 6 months.
- **Procedures and Activities.** If you decide to take part in this study, you will participate in an initial assessment, 12-17 weeks of PTSD treatment, and a follow-up assessment after treatment is completed.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include answering questions about how you are doing and discussion of symptoms or events from your past that can cause emotional discomfort. Also, a breach of confidentiality could occur if your information is required to report child or elder abuse or required to prevent you from hurting yourself or someone else.
- **Benefits**. There may be no direct benefit to you from being in the study. The knowledge gained from this study may benefit others in the future.
- **Alternatives.** If you do not want to participate in the study, you can seek help in the VA outpatient program. The treatments used in the study, as well as other treatments for PTSD, are available from the VA and from private health care providers. You do not need to participate in this study to get access to them.

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Detailed Information about this Research Study

What is research?

One purpose of this informed consent document is to provide clear information about the activities involved with this study. There are important differences between research and treatment plans:

- The goal of *clinical care* is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.
- The goal of *research* is to learn new things that may help groups of people in the future. Research teams learn things by following the same plan with many study participants, so they do not usually make changes to the plan for one person. You may or may not be helped by volunteering for a research study.

BACKGROUND AND PURPOSE

Why are you being asked to participate?

- You are being asked to voluntarily participate because you have symptoms of PTSD and are able to identify a loved one with whom you've been in a relationship with for at least 6 months and are willing to involve them in this study.

How many people are participating?

- Our goal is to enroll up to 30 Veterans and 30 of their loved ones into the COACH treatment at the Minneapolis VA Hospital.

Who will be conducting the study and who is sponsoring it?

- The Principal Investigator for this study is Dr. Laura Meis, a clinical psychologist and researcher at the Minneapolis VA Healthcare System. The study is funded by the VA's Rehabilitation Research & Development Service (RR&D).

STUDY PROCEDURES

If you decide to take part in this study, you will participate in:

An initial assessment

After consenting to the study, you will complete an online questionnaire and an interview about your present and past medical and psychiatric conditions. The questionnaire will take about 60 minutes and will ask about how you and your family are doing. You will have the option to complete the survey

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online using a tablet, computer or smart phone, or you can choose to complete the survey over the telephone with a study staff member. Your significant other will also be asked to a complete a study questionnaire by mail or phone asking similar questions about how each of you are doing. You will be compensated for completion of this survey.The over-the-phone interview will take up to 90 minutes and will ask about your symptoms of PTSD and other mental health symptoms.

If there is a time gap of more than 60 days between completion of your initial assessments and your therapy start date, you will be required to retake them. After two months, many things can change about how you or your family are doing. In order for your therapist to be as helpful as possible, he or she needs accurate information about how you are doing at the time you begin therapy. Also, in order for our research to be able to test this treatment, we need accurate up-to-date information about how you and your family are at the time you started therapy.

It is possible that, based on your interview, you will no longer be eligible and will not continue with the study. If this occurs, study staff will communicate your interview results back to your referring provider so you can be referred to a treatment, outside of the study, that appropriately fits your needs. If you prefer that we keep your results private, you can decline this request. You will still be paid for your time for the questionnaire and phone interview. If needed, we can schedule more than one visit to complete the interview.

Treatment (12-17 visits)

You will participate in a study to test a new couples therapy for trauma-related concerns. The treatment is adapted from existing evidence-based treatments for PTSD and couples therapy. Therapy sessions take place weekly and are 90 minutes each. At these visits, the following will occur:

- You, your significant other, and the counselor will discuss the role of PTSD in disrupting relationships and intimacy.
- You, your significant other, and the counselor will identify situations or locations that you tend to avoid and develop a plan for confronting those situations outside of sessions.
- You will be asked to repeatedly describe your memories of the trauma and reactions to the trauma with the counselor.
- You will be taught breathing exercises to help you manage distress outside of therapy.
- You, your significant other, and the counselor will build an action plan for continued work at home once you have completed treatment.

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- The sessions will be videotaped. This is a routine part of PTSD treatment. The recordings will be used as part of the study for training purposes and to ensure that your counselor is providing your counseling in the correct manner.

You can be seen for therapy in-person or by telemedicine. If your local VA is under-restrictions to in-person visits due to COVID-19, then delivery by telemedicine is the only available format. Telemedicine sessions are held via videoconference. In doing so, you will need access to a computer, smart phone or tablet with access to fast internet, and have a place in your home to speak privately during your therapy sessions. You may decline to participate via telemedicine, and may wait until in-person sessions are available again

During the 17 sessions that you participate in treatment you will be asked to not start work with another counselor or counselor specifically for PTSD. This is done for scientific reasons. We would be unable to decide if changes in your symptoms were due to the study treatment or due to your treatment outside of the study. If you are currently on medication for these symptoms and seeing a psychiatrist, you can continue the medications. If you are currently in treatment with a counselor, you may continue seeing the counselor during the study. You may participate in self-help groups during the study.

Follow-up assessments

After treatment is completed, approximately 17 weeks, you will meet with study staff over-the-phone to answer questions about your current symptoms of PTSD in order to evaluate improvement and will also be asked to fill out an online questionnaire. You will also be asked to fill out an online questionnaire about how you and your family are doing 3 months after treatment completion. Participation in these evaluations is completely separate from your treatment. That is, if you decide to stop treatment at any time, it is still very important to us to hear about how you are doing and what you have to say about your treatment. We will send you questionnaires by email and/or offer to complete them by telephone for convenience.

Audio-recording of study interviews

The interview about your symptoms that you do with a study staff member for your 'initial' and 'posttreatment' assessments will also be audiotaped so we can make sure the interviews are done correctly. You will not receive copies of these recordings. These recordings and your session recordings (discussed above) will be marked only with your study code number and not your name. All recordings will be stored on secure servers at the Minneapolis VAHCS. You will receive a recording of your sessions for your use in completing homework assignments.

Participants' responsibilities

As a participant in this research study, we ask the following from you:

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- Keep your appointments for study evaluations. If you miss an appointment, please contact the research staff to reschedule as soon as you know you will miss the appointment.
- Fill out your questionnaires as instructed.
- Feel free to ask any and all questions you have as you think of them.
- Tell the investigator or staff if you change your mind about staying in the study.
- If you are assigned to attend counseling sessions alone (without your family member or friend), please do not bring a family member or friend to your treatment sessions or ask your family or friends to contact your counselor, unless there is an emergency. This additional contact between your family/friends and your counselor can invalidate the results of this research.
- While participating in this research study, we would greatly appreciate if you would 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 research, as well as that of the other study you are considering.
- This study involves minimal risk, but if anything about the study especially bothers you, please let us know.

RIGHT OF INVESTIGATOR TO TERMINATE

We may have to end your participation in this study for the following reasons:

1. The study is suspended or canceled.
2. You decide not to participate in the study.
3. You are ineligible for the study.

POSSIBLE RISKS OR DISCOMFORTS

Psychological risks

All Veterans will receive Prolonged Exposure, one of the most extensively studied and effective treatments for PTSD. Additionally, asking a loved one to attend treatment sessions is within the scope of routine care for PTSD. Each of these procedures is likely to improve your well-being. At the same time, benefit cannot be guaranteed. Questions about how you are doing and discussion of symptoms or events from your past can cause emotional discomfort. There may be other unknown side effects that could occur. Additionally, you may feel uncomfortable about being videotaped.

Privacy risks

A breach of confidentiality could occur if your information is required to report child or elder abuse or required to prevent you from hurting yourself or someone else.

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While unlikely, a breach could also occur if someone not associated with the study heard one of your tapes or saw your data. In order to minimize that risk, we label all of your data with your study ID number, which can only be linked to your name by a few study staff. The link between your study ID number and your name will be kept in a secure, password protected location behind the VA firewall. Further, all of your data will be kept in a locked filing cabinet within a locked room and will only be accessible to study staff.

Economic risks

Economic risks include potential loss of wages, transportation costs associated with traveling to and participating in the research intervention, and child care, when necessary.

To help with this, you can also attend these sessions by telephone. Participants will also be allowed $12 an hour to help with the cost of childcare payments (e.g., 2 hour session plus 1 hour travel time equates to $36 for childcare per session). Please notify study staff if this applies to you.

POTENTIAL BENEFITS

Participation in the study may or may not benefit your problems with PTSD. All participants will receive counseling (Prolonged Exposure) that may help you reduce PTSD symptoms. This counseling is widely known to be effective. However, the treatments may not improve your symptoms and there may be no direct benefit to you from being in the study. The knowledge gained from this study may benefit others in the future.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You are being asked to volunteer for this study because you indicated that you are suffering from symptoms of PTSD. Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no penalty to you or loss of benefits to which you would be otherwise entitled.

If you do not want to participate in the study, you can seek help in the VA outpatient program. The treatments used in the study, as well as other treatments for PTSD, are available from the VA and from private health care providers. You do not need to participate in this study to get access to them. Upon request, we will provide you with information about other treatment providers. An additional alternative is simply not to participate in any form of treatment at this time.

CONFIDENTIALITY

The information collected for this study will be kept confidential. As psychological treatment by VA providers is part of this research study, we will include information about your study participation in your

medical record and (as mentioned above) a breach of confidentiality could occur if your information is required to report abuse or prevent harm to yourself or others.

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.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. The results of this study may be published or presented, but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accounting Office and other Federal agencies, the VA Office of Research Oversight, Research and Development Committee, and the VA Institutional Review Board (IRB)/Human Studies Subcommittee to review records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed. The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS-10-1).

Use of Identifiable Private Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us permission to use your information, including health information in your medical records that can identify you. Your information that is collected as part of this research will not be used or distributed for future research studies, even if all identifying information has been removed.

Your information will be protected in the following ways:

All data will be stored on the servers of the Center for Chronic Diseases Outcomes Research (CCDOR) at the Minneapolis VAHCS. CCDOR has well-established procedures to protect the privacy of research participants. No identifying information will appear on any study materials. Instead, only unique study identification numbers randomly assigned to each unique record will be used. Only a limited number of study team members will have access to an encrypted crosswalk table linking study identification numbers to identifying information. Identifiers will be destroyed as quickly as possible. Participants will be asked not to use last names or provide identifying information during recorded interviews. Since subject responses will not be linked to identifying information, the risk for loss of confidentiality is small.

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COSTS TO PARTICIPANTS AND PAYMENT

Costs to participants

There is no cost to you for taking part in this study. Veterans who must make a co-payment for their usual medications or treatments will continue to be required to make such a co-payment. There should be no additional medical costs to you for taking part in this study. However, frequent clinic visits may result in transportation costs and possible wages lost due to time missed from work.

Payment offered for participation

Participants will receive $40 for participating in Baseline surveys, $50 for baseline diagnostic interviews (Veterans only), $60 for posttreatment surveys, $60 for posttreatment diagnostic interviews (Veterans only), and $60 for one-time qualitative exit interviews. Both veterans and intimate partners will complete monthly surveys for outcomes and treatment mechanisms. They will receive $25 for each of these surveys. Additionally, participants will receive $70 for 3-month follow-up surveys. A possible total of $415 for veterans and $305 for loved ones.

Veteran participants will receive payment by direct deposit or debit card after completion of their baseline assessment and clinical interview, post treatment assessment, clinical interview, and exit interview, as well as after the 3-month follow up assessment.

COMPENSATION FOR ANY INJURIES

You have not released the VA Medical Center from liability by consenting to this study. This includes but is not limited to: 1) free medical care other than as described in this consent form, 2) payment of lost wages, or 3) compensation for pain and suffering. Compensation for those items from the VA may be available under applicable Federal Law. You should immediately report any injuries resulting from your participation in this study to your counselor at 612-467-2125 or local study investigator, Dr. Laura Meis at 612-467-4516, during the day. On evenings or weekends, please call the VA operator at 612-725-2000 and ask to have the psychiatrist on call paged. Tell the operator you are in a research study. If you do not live in the metropolitan area, you may call the toll-free number: 866-414-5058.In case you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will pay for necessary medical care for any injury or illness directly related to your participation in this research study. If you receive this type of medical care, you must contact the Research Investigator for this study. You can find contact information in the section of this consent titled “Compensation for Any Injuries”.

PARTICIPATION IS VOLUNTARY

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It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

The researcher may continue to review the data already collected from you prior to your decision not to participate anymore. After you decide to withdraw, the research team cannot collect any more information from you, except from public records.

PERSONS TO CONTACT ABOUT THIS STUDY

You can contact the study coordinator, Erin Linden at 612-467-5868 with any questions about the research study. Please contact your counselor during your treatment for questions about your treatment at 612-725-2000. If it is after hours and you need to speak to someone immediately, please call 612-725-2000 and ask to have the psychiatrist on call paged and tell the operator you are in a research study. If you do not live in the metropolitan area, you may call the toll-free number, 866-414-5058. If any medical problems occur in connection with this study, the VA will provide emergency care. You may also contact your local Patient Representative at 612-467-2106 if you are not having a medical emergency and want to talk to someone about the study who is not part of the research team.

You are encouraged to contact the Patient Representative at (612) 725-2106 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

If you wish to verify the validity of the study and its authorized contacts, call the Patient Representative or contact the IRB office at (612) 629-7387.

ALTERNATIVE CONTACT INFORMATION

If we cannot reach you for assessments for the study, please identify an alternative individual or individuals we may contact to reach you. We will only contact these persons in the event that we lose contact with you. By listing these names, you are not obligating these persons to talk to the researchers; you are only giving your permission for us to contact them. We encourage you to let these persons know that you have given us their name, and let us know if they do not wish for us to contact them. We will only ask them how to reach you and will not disclose any information about your treatment. Refusal to provide this information will not exclude you from participating in the study.

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I have reviewed the information provided in this document. My questions have been answered and I voluntarily consent to participate in this study. I understand that I have not given away any of my legal rights by signing this form.

Subject's Signature: _____ Date: _____

Subject last name & Last 4 of SSN: