Characterization of sleep with trauma nightmares using ambulatory sleep measurement

NCT03974503

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Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: ***11/04/2024***

Participant Name: _____ Date:_____

Title of Study: Characterization of sleep with trauma nightmares using ambulatory sleep measurement

Principal Investigator: Katherine Miller, PhD VA Facility: Minneapolis VA Health Care System

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by VA Clinical Science Research and Development. 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?

We want to understand what is happening with Veterans' sleep when they have nightmares. We will do this by measuring sleep in Veterans' homes using two tools while they are in the study and by giving a non-medication treatment for sleep and nightmares.

By doing this study, we hope to learn more about what is happening during Veterans' sleep from night-to-night. This information can help us know more about how the treatment works or if we should change our treatment options. Your participation will last about 5 months

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

You might learn more about your sleep and you might experience improvements in your sleep and nightmares during treatment. For a complete description of benefits, refer to the Detailed Information section of this form.

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

You may feel uncomfortable while talking about your trauma symptoms and nightmares. Study staff will travel to your home to put a sleep monitoring device on your mattress that will stay there during your study participation, you may feel uncomfortable having research staff in your home. You will complete an at-home sleep study and you may experience discomfort from wearing body sensors overnight. You also may learn that you have a medical condition called sleep apnea that may require treatment outside of the study.

If you are interested in receiving treatment for your nightmares and not participate in this study, you could seek treatment through the Sleep Center or a mental health provider through a standard physician referral. For a complete description of risks, and alternative treatment/procedures, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to participate, 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 Katherine Miller, PhD, of the Minneapolis VA Health Care System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 612-467-3894

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to help us learn more about your sleep over many nights. With this research we hope to learn what your sleep looks like when you have a nightmare and when you do not. We will do this by measuring your sleep in your home with two sleep study devices. We also want to see how a non-medication treatment changes parts of your sleep that may be linked to nightmares. You are being invited to participate because you have nightmares related to a stressful life experience. This information can help us know more about how our treatments may work or if we should change our treatment options.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in this study will take about 5 months. The length of time in the study may be shorter if we learn that you do not qualify for the study. If you complete all parts of the study, there will be 8 study visits. These visits may occur in-person at the Minneapolis VA, or they may be held virtually.

- Three visits will be about 1 – 2 hours, and 5 visits will be about 1 hour each.
- We will also plan at least 2 visits to your home (30 minutes to 1 hour each). These visits are to set-up or remove the sleep monitoring devices.
- There is a chance that we will need to make other trips to your home, if the devices stop working.

We plan to enroll 57 Veterans from the Minneapolis VA Health Care System.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

All study procedures will be completed at the Minneapolis VA Health Care System either in-person, virtually to your home, or in-person at your home. No experimental procedures are part of this research study. If the sessions are conducted virtually, you will be required to use an email address to receive a link and your phone or computer to access the telehealth visit. If you agree to participate in this study, there are three stages:

The first stage:

At the first visit, we will ask you interview-style questions about your mood, responses to the upsetting event, and your nightmares. You will also complete questions on paper, or

computer. These questions ask about your emotions, sleep, and nightmares. The questions and interview will help us know if you are a good fit for this study.

- We will ask your permission to audio-record the interview part of the assessment to make sure the research staff are following the protocol. If you do not want to be audio recorded, you can still participate in the study.
- There may be a possibility that there will be two research staff present during the assessments for training purposes. We will only do this with your verbal permission.

The second stage:

- If you are eligible, we will schedule a visit to your home.
- If you have someone sleep in the bed with you most nights of the week, we will need to make sure that he or she is okay having the sleep monitoring device on the bed. We will provide you an information sheet that you can share with your partner about the study, so they understand what we are going to do. With your written permission, we can talk with your partner and answer any questions they might have before the visit to your home. **If your partner is not okay with having the device on your bed, you will not be able to participate in the study**.
- We will also request that we be able to text you, if you have text capabilities on your phone, so that we can arrange the home visits and update you quickly if anything changes.
- If all agree, members of our research team will schedule a visit to your home and set-up a system on your mattress. It is like a topper that lays on top of your normal mattress, under your fitted sheet, where you sleep. The device is hooked up to a computer. It collects dates, time, body movement, heart rate, and breathing. We set it up, so it automatically collects the information, so you do not have to do anything. We use this system, so you barely feel it. This topper will stay on your bed for about 7 weeks.
- On that same day we set up the mattress, we will also set you up for a polysomnography. This sleep study will be for one night and it will record your brain waves, oxygen levels, breathing, and eye and leg movements. This involves wearing a sensor near your nose, a belt around your chest and your waist, a sensor on your wrist/finger, as well as electrodes attached to the scalp, face, chest, and legs. This study will help us learn more about your brain and body while you are sleeping, and learn if you have a condition called sleep apnea. We will pick up the polysomnography equipment the next morning.
  - If we learn that you have sleep apnea, you will be able to continue to participate but we will want you to get the treatment that is clinically needed. We will consult with a physician at the sleep center and place a referral to discuss follow-up and treatment options with you.
- We will request that you sign an equipment loan agreement, which indicates that you take responsibility for the equipment while it is in your home and will make sure it is

available when we arrange to pick it up. If you do not feel comfortable or do not feel capable of taking responsibility of the equipment, then you will not be able to participate in the study.

- Before each visit to your home, all members of your household and study staff will be asked a series of health-related questions in accordance with hospital protocols. There may be additional steps that are necessary to ensure the safety of you and the research staff.

The third stage:

- You will continue in the study and sleep each night on the mattress system during the treatment part of the study.
- You will also be randomized to receive one of two non-medication treatment sessions for nightmares. This means you will be assigned to one of the treatments by chance, like a coin toss. Both treatments are designed to improve your sleeping and nightmare problems and have been shown in other research studies to help. Each session lasts about 1 – 1.5 hours, and you will have one session each week for 5 weeks either in person at the Minneapolis VA or through a virtual videoconferencing platform. The possible treatment you would be randomly assigned to are:
  - Exposure, Relaxation, and Rescripting Therapy (ERRT). This therapy is given to Veterans or military personnel with trauma-related nightmares and sleep disturbances. As part of the therapy, you will need to discuss what your nightmares are about and your reactions to the trauma that is giving you nightmares.
  - Sleep and Nightmare Management for Service Members & Veterans. This therapy is also given to Veterans or military personnel with trauma-related nightmares and sleep disturbances. As part of this therapy, you will not discuss what your nightmares are about.
- At each of these treatment sessions we will ask your permission to audio-record the treatment visits. We would like to audio-record these sessions, so we can make sure the research staff are following the protocols. If you do not want to be audio recorded, you can still participate in this study.
  - There may be a possibility that there will be two research staff present during the sessions for training purposes. We will only do this with your verbal permission.
- If we have virtual therapy sessions, it is important to maintain a setting that is as like being in the office together as possible. To maximize the benefit of nightmare therapy sessions, we ask that you please observe the following:
  - Make sure that you are somewhere where you can have reasonable privacy during your session.

- The therapist may use clinical judgment to determine if it is ok to proceed with a session and may not begin therapy if you are in a public place or significantly distracted (e.g., by childcare).
- Therapy will not be conducted while you are driving.

- You will fill out study-related questionnaires before and after the session to track your symptoms over time. These will be done by paper or computer systems.
- While these treatment sessions are similar to treatment you could get outside of this study, they are considered a research procedure because you are being randomly assigned to one of the two treatments.
- A week after treatment is done, we will invite you to another appointment either in-person or virtually to ask you the same questions that we did before treatment. We will ask you **not** to tell the interviewer what treatment you were in because we do not want them to know. We will also visit your home to remove the mattress system.
- 3-months after treatment is done, we will give you a call on the phone or video to ask you those same questions.

During your participation in the study, we will collect data from your medical record. You will not be provided access to your research data. Visits involving clinical assessment and treatment sessions will be minimally documented in your medical chart but will include information about suicide risk, if applicable.

For participating in this study, you will receive:

- $30 for completion of the screening visit
- $100 for the first week of sleeping on the mattress
- $75 for doing the polysomnography sleep study at your home
- $50 for sleeping on the mattress during treatment
- $50 for the visit after treatment finishes
- $25 for the follow-up visit
- Total participation equals up to $330. The amount you receive will be based on the study activities that you complete.

You will receive payment for the parts of the study you complete. You will receive a debit express debit MasterCard utilized by the VAHCS Agent Cashier. There is also an option to receive payment through direct deposit to your bank account. For both methods, we will provide you with the necessary forms to receive payments.

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

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Complete your diaries as instructed.
    - Complete your questionnaires as instructed.
    - Ask questions as you think of them.
- Participate in the treatment sessions and try your best to do the practice assignments discussed in those sessions.
- Keep study equipment in your home. If you have a problem with the equipment, please let the study staff know right away.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible burden from extra appointments or interactions of therapies. 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.

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

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- Throughout the study and during some treatment sessions, you will be asked to answer questions about the upsetting event you experienced and about your nightmares. It is possible that some of these questions may make you feel uncomfortable. The questions we use are like those asked during standard interviews before mental health treatment. You can choose not to answer any questions at any time. We will also stop if you become upset and you can decide if you want to continue. If you indicate certain thoughts, we may need to refer you to the Emergency room for evaluation. We also will never put your name on any of the data.
- Since the type of nightmare-treatment you are getting is selected by a flip of the coin, there is a chance that the treatment may not be best suited for you.
- You will be asked to have research staff come to your home and set-up and remove a sleep monitoring device during the study. This may feel burdensome and uncomfortable. We chose the mattress system because it does not require you to do anything and has been used with over 900 Veterans without a problem. For cleanliness, the mattress has a non- absorbent cloth topper. This topper is waterproof

and allows us to completely clean the mattress topper between uses. While rare, it is possible that the foam inside the mattress system may have a detectable odor, which could transfer to your bedding. If you are particularly sensitive to smells, this system may not be suited for you. In the rare chance that bed bugs are detected during a prior use, we will follow hospital procedures for removal and cleaning of equipment. You also can stop using the mattress system at any time. If you choose to have the mattress system removed, your participation in the study would end and we can help facilitate a referral for sleep care outside of the study.

- It is possible that your bed partner may not want the equipment in the home. In this case, we would not be able to include you in the study.
- You may also experience some discomfort from wearing body sensors overnight during the polysomnography sleep study. The sensors are unlikely to cause an allergic reaction, but we cannot completely rule this out. We chose these procedures to be only one night, so it is as brief as possible.
- It is possible that results from the sleep study will tell us that you have sleep apnea, and that may be upsetting to learn since it is a concerning medical condition. If this happens, we will provide referrals to the Sleep Center, so you can get the right treatment.
- You may need to travel to the Minneapolis VA for treatment sessions and two assessments, which may cause an inconvenience. Or, we may hold these appointments virtually. In this situation, you will need to use your phone or computer to access appointments. These appointments will also require you to have access to reliable Wi-Fi or cellular data.
    - Because the virtual visits require an electronic link to be sent to you via email or phone number, if you choose to not be contacted in this way, you will need to attend appointments in person at the Minneapolis VA or your participation in the study would end.
    - Virtual visits can present different risks than in-person visits. A VA-approved system will be used that is secure. For safety and emergency purposes, researchers will follow hospital protocol for conducting virtual visits which includes obtaining your verbal consent to participate before every visit. In accordance with the safety plan, the researcher will also confirm your address, phone number, and an emergency phone number. The virtual “room” will be locked for duration of the visit.
- Another possible risk is that you may get upset while in therapy. Treatment may help you have less stress and you can learn new skills to deal with it. Previous studies of the treatments show that participants report less nightmares and better sleep. We do not know for sure how you will respond to the treatment. If during these sessions you express certain thoughts, we may need to refer you to Emergency services for evaluation.
- Breach of confidentiality is a potential risk. To reduce this risk, only study staff will have access to your data. All data will be stored in locked filing cabinets behind a locked door. Electronic data are maintained on the VA’s secure server and will not be transmitted

outside the facility.

- If you were to become injured while you are in this study, please tell the study doctor and also your primary care physician that you are in a research study.
- There may also be risks that we currently do not know about.
- You may stop participating in this study at any time.

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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

- You may not benefit from participating in this research study.
- You may experience improvement with your sleep, less stress, and fewer nightmares.
- The monitoring of your sleep may help you learn about the factors impacting your sleep and nightmares.
- If you are found to have sleep apnea, this finding would benefit you because you will be referred for treatment.
- In the future, the results of the study may benefit Veterans in helping with sleep problems and nightmares.

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

- You have the choice not to participate in this research study. Participation is voluntary, and you do not have to participate if you do not want to.
- If you are interested in receiving treatment for your nightmares, you could seek treatment at the Sleep Center through a standard physician referral and not participate in this study.
- You may also discuss alternatives with your VA or non-VA Primary Care Physician.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

During this study, we will collect personal information such as:

- your name,

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- the last four digits of your social security number/medical record number,
- dates,
- your telephone number,
- email address
- your home address, and
- information for an emergency contact

We will also ask questions about your emotions, sleep, the upsetting event you experienced, and nightmares. Sleep data collected may be entered into your medical record if a referral to the sleep center is recommended. This information can be viewed by medical staff at Minneapolis VA Health Care System who are not on this study.

Your name and social security/medical record number will be used only as necessary within the Minneapolis VA Health Care System. Summary data collected during this study that does not directly identify you may be disclosed to the study sponsor, VA Clinical Sciences Research and Development, and their data monitoring committee.

If you have an accident or reaction during the study, your entire medical record may be used and disclosed as clinically necessary.

There may be a small possibility that we would have to contact authorities if safety (either your own or the research staff's) becomes at risk while you are in the study. In this case your record may be used as clinically necessary.

Internal monitors from the Minneapolis VA Health Care System Institutional Review Board (IRB), our local Research and Development committee, or someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, and the Food and Drug Administration may inspect study records for quality assurance.

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.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

There is a possibility that your identifiers might be removed from the identifiable private

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information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

All hard copies of research records will be stored in locked filing cabinets in a locked office at the Minneapolis VA Health Care System. Electronic data will be stored in a secure VA server.

The PI may consult with an expert in the treatment of nightmares. This consultation will never include identifying information but may include a discussion of your sleep and nightmares. This consultation is to make sure you are getting quality care.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

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, email address, telephone number, 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, which may include the VA Clinical Science Research and Development Data Monitoring Committee, the VA Institutional Review Board, 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.

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This 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.

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. Miller and her 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?

You 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, you will still pay these co-payments for VA care and medications that are not part of this study.

Every reasonable safety measure will be used to protect your well-being. The Minneapolis VA Health Care System will provide necessary medical care and treatment for any injury that is a result of participation in this study for Veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

There will be no cost to you for participation in this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged, nor your insurance billed for research-related interventions or procedures that are required by the protocol.

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 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.

It is important that you tell Dr. Katherine Miller if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call her at 612-467-3894. Emergency and ongoing medical treatment will be provided as needed.

You are also encouraged to tell Dr. Miller and your VA or non-VA Primary Care Physician if you experience any injury or medical problem while you are in the study.

DO I HAVE TO TAKE PART IN THE STUDY?

You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you withdraw, we may call you to complete a final assessment and arrange a time to pick up any study equipment at your house. You should withdraw in writing using the Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration Research form. Even if you withdraw, we can continue to use information about you that has been collected up to that point. No information will be collected after you formally withdraw in writing.

This study is expected to end after all participants have completed all visits, and all information has been collected. Your participation in this study may also be stopped at any time without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You tell the research staff that you are pregnant while participating in the study.
- You verbally or physically threaten the safety of the research team.
- You do not follow study procedures.
- The study is cancelled by the sponsor.

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

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In case there are medical problems, research related injuries or questions, you have been told that you should call Dr. Miller at 612-467-3894 during the day. If it is an emergency, you should call 911 or the Veteran's Crisis Line at 988 and press 1.

If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subject or you want to check the validity of the study and its personnel within the VA, you should contact the Patient Representative at 612-467-2106 from 8:00 AM to 4:30 PM Monday through Friday.

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 Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call 612-629-7387 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?

The research team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

FUTURE USE OF DATA AND RE-CONTACT

While this study is open, we may want to contact you to see if you would be interested in participating in additional assessments or for another research study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Miller or a member of her research team has explained the 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 for this study. You also confirm that you have read this consent document, or it has been read to you, and you have been given the opportunity to ask questions and have those answered. You will receive a physical or electronic copy of this consent after you sign it.

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Participant Name: _____ Date:_____

Title of Study: Characterization of sleep with trauma nightmares using ambulatory sleep measurement

Principal Investigator: Katherine Miller, PhD VA Facility: Minneapolis VA Health Care System

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

Bed Partner Contact:

☐ I agree to allow study staff to talk with my bed partner to provide information about the study and the mattress topper on the bed, if my partner has questions or concerns.

☐ I do **NOT** have a bed partner. _____(please initial)

Audio Recording:

☐ I understand that I will be asked at the time of the interviews and my therapy sessions if it can be audio recorded, and I can agree or decline at that time. _____(please initial)

Voluntary Contact:

☐ I agree to be contacted by email and/or MyHealtheVet secure messaging.

☐ I do **NOT** agree to be contacted by email and/or MyHealtheVet secure messaging.

_____(please initial)

☐ I agree to receive text messages.

☐ I do **NOT** agree to receive text messages.

_____(please initial)

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