

Title: Engaging Veterans Seeking Service-Connection Payments in Pain Treatment

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Research Study Information Sheet



Title of Project: "Engaging Veterans Seeking Service-Connection Payments in Pain Treatment UH3"

You are being invited to participate in a research study. The study is being paid for by the National Institute of Health. It is led by researchers at the VA Hospital in Connecticut and Yale University and is being conducted by researchers at VA Hospitals in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. Approximately 1,100 Veterans will be enrolled in this study.

Your involvement in the study will last for about 36 weeks. Your participation involves:

- Three telephone interviews with a research staff member (Baseline and two follow-up interviews)
- Mailing samples of your fingernails to the researchers after each interview
- Allowing the researchers to collect information from your medical record

About half of participants will be offered an hour-long counseling session by phone with up to four follow-up calls (lasting approximately 20 minutes each).

Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits.

WHY IS THIS STUDY BEING DONE?

With this research, we hope to determine if extra counseling offered to Veterans applying for service connection is helpful. The counseling focuses on how to obtain pain treatment and advice about how alcohol and drug use may affect the management of your pain.

You are invited to participate in this study because you are seeking service-connection for a problem with your back, neck, knee or shoulder. You should only participate in this study if you are currently experiencing pain.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you decide to take part in this study, this is what will happen:

1. First Interview and sample collection. You will have an initial phone call with a member of the research staff. The phone call will last about 40 minutes. During this first call, you will be asked

about your pain, psychological symptoms you may have, any substances you may have used (alcohol, legal or illegal drugs, etc.), treatments you have received, and a variety of other matters including how COVID-19 has affected you and your access to care.

During this call, you will also be asked to give the names and telephone numbers of three people who will know where you will be over the next 36 weeks. If you miss a research call and cannot be reached within three weeks, the research staff will contact these people to help locate you. We will ask them if they know how to contact you but will not tell them anything about you or your responses to the study.

After the first phone call, you will be sent a kit to provide clippings from your fingernails to be mailed back to the researchers. The United States Drug Testing Labs will analyze the samples you mail in to determine whether it contains chemicals from alcohol or drugs you may have used. After processing, samples will be destroyed following a standard storage period. You will not receive the results of these tests.

3. Counseling. A counselor who is working with the research staff will call you to let you know if you will be offered a counseling session or not. About half of participants will be offered a counseling session. Whether or not you get offered a counseling session is by chance (like the flip of a coin). If you are in the group that gets offered a counseling session, you will be contacted by a counselor. You will not be paid for participating in that phone call. The phone call will focus on helping you access services at the VA to help you cope with your pain. The counselor will also advise you to be careful about using alcohol or drugs, as these might affect your pain. The first will last for about one hour. You will be offered up to four follow-up calls, but you can participate in as much or as little of the counseling as you wish. Phone calls with the counselor will be audio-recorded for quality assessment and training purposes. You can choose not to be audio-recorded and still participate in the study. If you agree to audio-recording, you can choose to stop the recording at any time.

4. Second Interview and sample collection. You will be contacted by the research staff for a second telephone interview about twelve weeks after the first. The second interview will last for about 40 minutes and will cover topics you were asked about in the first phone call. After the second interview, you will be sent another kit to collect your fingernails to be mailed back to the researchers.

6. Third Interview and sample collection. You will be contacted by the research staff for a third telephone interview about 24 weeks after the second interview. The third interview will last for about 40 minutes and will cover topics you were asked about in the first and second phone

calls. After the interview, you will be sent another kit to collect your fingernails to be mailed back to the researchers.

8. Medical Chart Review. The researchers will collect information about you from your VA records. We will collect information about your military service, your use of VA treatments, distance to VA facilities, prescribed medications, and diagnoses. The research staff will also obtain information about your Compensation and Pension claim(s) and how your claims were decided.

A note will be entered into your VA medical record indicating that you participated in this research study. However, no information about the answers you provide as part of this research or the results of your nail tests will be added to your medical record.

ARE THERE ANY RISKS OR DISCOMFORTS?

1. *Answering questions:* You may find the questions to be boring, frustrating, or upsetting. You may skip questions that you find too uncomfortable to answer.

2. *Information from the study being told to your clinicians at the VA or to someone who reviews your disability application:* The results of the assessments will not be placed in your medical record or disclosed to anyone at the VA outside of the study team. The results of the assessments will not go into your medical record. Counselors will note in your medical record any counseling sessions that occurred and any treatments referrals you expressed interest in. This information is unlikely to impact your service-connection application.

However, if something happens when you meet with the research staff that the staff member thinks is an emergency, they will give that information to VA clinicians who are not connected to the study. This will happen so that you can get an emergency evaluation and treatment. If there is an emergency, the VA clinicians will describe the emergency in your medical record. Examples of things that the research staff will tell VA clinicians include:

- if the research staff think you might harm yourself
- if the research staff think you might harm someone else
- if the research staff think you might be involved in a situation that may hurt a child

3. *The three people whose names you provide may find out that you are in a research study:* You should inform them that you provided their names to a research team and that someone from the VA may call them in case you cannot be reached.

ARE THERE ANY BENEFITS?

You may not directly benefit from the study, however if you receive the counseling session, it may help you receive pain treatments that you would not otherwise have realized were

available to you. It may help you be more careful about using alcohol or drugs in the future. If you don't receive the counseling, there is no direct benefit of study participation to you. However, the information we get from this study might help us learn how to better help Veterans who are applying for service-connection.

WHO WILL SEE MY INFORMATION?

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people such as: VA and Yale committees that review research, Yale University and Bank of America to process study payments, government agencies that review how government money is spent, government committees that review accusations of bad behavior by government employees, and individuals and organizations that analyze VA health information.

Audio-recordings of counseling sessions will be stored on VA Network computers behind the VHA firewall and only VA transcribers and research staff will have access to them.

Data collected from this study may be shared with outside investigators or collaborators only after all information that can identify you has been removed. This data may be used for a variety of research purposes. Any future publications or reports generated from this study or its data will not contain any of your identifiable information.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You can receive a total of \$250 for completing all the study procedures.

Payments are as follows:

- First Interview and sample collection (up to \$70):
\$40 after the first phone interview; \$30 after the first nail collection kit is returned
- Second Interview and sample collection (up to \$80):
\$30 after the second phone interview; \$50 after the second nail collection kit is returned
- Third Interview and sample collection (up to \$100):
\$30 after the third phone interview; \$70 after the third nail collection kit is returned

Payments will be made from Yale University and Bank of America (BoA). You will receive payments via a Bank of America pre-paid debit card. Your name, address, and telephone number will be shared with Bank of America for ePayments. After your first interview, you will receive a BoA pre-paid debit card in the mail, which you will need to activate over the phone. Subsequent payments will automatically add additional funds to your card. Yale will also send you an IRS 1099 form reporting the amount of money paid to you. This is required by law and is used for income tax purposes.

WHO CAN I TALK TO ABOUT THE STUDY?

Every reasonable safety measure will be used to protect your well-being. 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.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, or if you have any questions, complaints, or concerns about the research or related matters, you can contact the study directors, Dr. Marc Rosen at 203-932-5711 x2112 or Dr. Steve Martino at 203-932-5711 x7418.

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) toll free at 1-877-254-3130.