

Improving Veteran Access to Integrated Management of Back Pain

NCT04411420

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VA Patient Screener & Informed Consent Telephone Script

Hello, this is [Study staff name]. I am calling from the VA Medical Center in Durham, North Carolina. May I please speak with Mr./Ms. [Patient's last name]?

If No: Thank you, I will call back at another time.

If Yes, continue

PURPOSE

I am calling to tell you more about a research study for Veterans with low back pain. At a recent VA medical appointment, you agreed to be contacted about this study. We want to learn more about Veterans who receive treatment at the VA for their low back pain. May I tell you more about the study?

If No: Thank you for your time.

If Yes: The purpose of this study, titled "Improving Veteran Access to Integrated Management of Back Pain", is to learn more about the characteristics of Veterans receiving treatment at the VA for low back pain. We would like to collect some information about you, your health, and your low back-pain treatment experience at the VA. This would all be done over the phone, so you would not need to come into the VA to participate. If you are eligible, you would answer questions over the phone now, and receive 3 more calls over the next 12 months. Also, to better understand the types and amount of low back-pain care you receive, we will be looking at your VA health records. We hope this study will provide valuable information to the VA about how to better manage care for Veterans with low back-pain.

May I ask you a few questions to see if you are eligible?

If No: Thank you for your time today.

If Yes, continue

SCREENING

(1) The study requires speaking with the research team on the telephone. Will you have access to a telephone and be able to speak with us for the next 12 months?

If No: I'm sorry, but based on your answer, you are not eligible for this study. Thank you for your time.

If Yes, continue

(2) The study also requires that you are not in hospice care or in a nursing home. Are you currently receiving hospice care or living in a nursing home?

If Yes: I'm sorry, but based on your answer, you are not eligible for this study. Thank you for your time.

If No, continue

If Eligible: You are eligible for this study. Next, I am going to read you the consent form. This should only take a few minutes. Please stop me if you have any questions or concerns.

PROCEDURES

About 850 Veterans will take part in this study. If you decide to participate, you will be involved for about 12 months, and you will only be contacted by phone and mail. If you agree to participate, I'll ask you some questions today about your health and your health care at the VA.

This will take about XX minutes. Then we will call you in about 3 months, 6 months, and 12 months and ask you questions similar to today. Each of these calls will last about XX minutes. There will be no cost to you for participating in this study, but you can earn up to \$100 dollars total for participating in this study, or \$25 for each phone call.

We are also asking your permission to contact you at a later date about other studies related to low back-pain care and treatment at the VA. Consenting to future contact is optional.

Do you give permission for the investigator to contact you about future studies related to understanding low back-pain care and treatment at the VA?

Yes No

DISCOMFORTS AND RISKS

We do not anticipate there to be any physical risks associated with this study. There is a potential risk for loss of confidentiality. We will make every effort to keep your information confidential; however, this cannot be guaranteed. Some questions asked as part of this study may make you feel uncomfortable. Any discomfort is usually temporary and well tolerated. You can refuse to answer any question and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

OTHER TREATMENT AVAILABLE

If you choose not to take part in this study, you will continue to receive care from your VA health care team.

SPECIAL INFORMATION

1. You are not required to take part in this study: your participation is entirely voluntary. You can refuse to participate now, or you can withdraw from the study at any time, and this will not affect your health care or eligibility for benefits at the VA.
2. You may not be personally helped by taking part in this study, but your participation may lead to knowledge that will help others.
3. Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. If required, we may also provide your research records to federal agencies, such as the Office for Human Research Protections, the VA Office of the Inspector General, and the Office of Research Oversight.
4. Your data may be stored and used for future studies without additional consent from you if identifiable private information, such as your name or medical record number, are removed.
5. The VA will provide medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAHCS or arrangements may be made for contacted care at another facility. In case of research related injury resulting from this study, you should contact the study team.
6. If you have questions about your rights as a research subject, would like to obtain information, or have other concerns or complaints, you may contact the administrative officer of the research service at 919-286-0411, extension 17-7632.
7. If you would like to check that this study is approved by the Durham VA's Institutional Review Board, please call the research office at 919-286-0411, extension 17-6926.
8. If you have questions about this research study, or need to talk with the study team, you can call the study coordinator or the principal investigator, Dr. Nicki Hastings, toll-free at 888-878-6890 extension 17-7103.

AFFIRMATION FROM SUBJECT

Do you have any questions?

Are you willing to voluntarily consent to participate in this study that I have just described?

Yes No

If No: Thank you for your time today.

If Yes: Thank you! *Proceed to Baseline survey.*