Promoting Benzodiazepine Cessation Through an Electronically-delivered Patient Self-management Intervention

NCT04572750

9/1/2022

Participant Name: _____ **Date:** _____

Title of Study Promoting Benzodiazepine Cessation via Electronically Delivered Patient Self-Management Intervention Study

Principal Investigator: Michael A. Cucciare, PhD

VAMC: Central Arkansas Veterans Healthcare System, 598 Version # 2, Date 08July2022

SUMMARY

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a research participant at any time before, during, or after the study, please contact the Institutional Review Board (IRB) at (501) 257-6521 for help. If you have questions about this study, you may contact the Principal Investigator, Michael Cucciare at (501) 526-8179.

The research is being conducted to learn more about a new educational website designed to help Veterans taking benzodiazepine medications, like Klonopin or Ativan, learn more about how they can manage their medications.

If you agree to join the study, your active participation will last around 6 months. You will be asked to complete two study calls, one at baseline and another call 6 months later. Each call will last about 30-45 minutes. During these calls we will ask you questions about how you are feeling, your physical health and your use of benzodiazepines. Half of the Veterans who take part in the study will be randomly selected and given access to the study website. At the end of the study, the other half (who were not given access to the website) will be given access if they would like.

The most common risks of participation may include discomfort in answering questions about your lifestyle and how you are feeling both physically and emotionally. You may skip any questions that you do not want to answer or stop study participation at any time.

You may not benefit directly from being in this study; however, your participation may help others in the future by helping us to learn more about how this educational website can help Veterans manage their medications.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you.

INTRODUCTION

You are being invited to take part in a research study that is being carried out at the Central Arkansas Veterans Healthcare System. 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. The study is being funded by the VA and will be conducted at the Central Arkansas Veterans Healthcare System (CAVHS.)

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received

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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.

BACKGROUND AND PURPOSE

The purpose of the study is to learn whether a new website, EMPOWER for Veterans, helps Veterans learn more about managing their benzodiazepine medications. After learning more about their medications, some Veterans may choose to change their medication use; however, you are not required to do so as part of this study. Veterans who have been seen in the primary care clinic at CAVHS or an affiliated VA site within the past year are eligible to participate. Up to 170 Veterans will take part in this research study.

DURATION OF THE RESEARCH

This research study is expected to take approximately 2 years to complete; however, your participation will last 6 months.

STUDY PROCEDURES

If you decide to join the study, you will be randomly assigned (like flipping a coin) to get access to the EMPOWER website now or at a later date. All participants will be given access to the EMPOWER website upon study completion or 12 months after completion of the baseline telephone interview.

You will be asked to complete a baseline telephone interview at the start of the study and a follow-up telephone interview 6 months later. Each time we will collect information on your medications, how often you use them, how much alcohol you drink, how well you are sleeping, and how you are feeling physically and emotionally.

Prior to the 6-month telephone call, you will receive a call from our study team to schedule your final 6-month telephone interview. If we are unable to reach you by telephone to schedule a 6-month telephone interview, we will continue trying to contact you by phone for up to 3 months following your 6-month follow-up date.

If we are unable to reach you by phone, we will send the follow-up assessment to you by mail with detailed instructions on how to complete and return it to the study team.
All assessments should take approximately 30-45 minutes. You are free to skip any questions that you prefer not to answer during the telephone interviews or on the paper forms.

During the study and for about 1 year after your baseline interview, we will review your medical record to gather information about your medication use.

POSSIBLE RISKS OR DISCOMFORTS

The potential risks associated with study participation may include discomfort in talking about how you are feeling emotionally or physically, or how well you are sleeping. You can skip any questions you do

not want to answer or withdraw from the study at any time without penalty or loss of benefits to which you were otherwise entitled.

Risks of the usual care you receive are not risks of the research. 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. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

CONFIDENTIALITY

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. We protect your privacy and the confidentiality of your data in the following ways: Your study information will be stored in locked filing cabinets in locked offices that only study team members can access. Electronic information will be stored on an encrypted password protected VA server.

It is important for other health care providers taking care of you to know you are taking part in this study. We will note in your medical record that you are taking part in this study. A copy of your signed and dated consent and HIPAA forms will be placed in your VHA medical record. There are times when we might have to show your records to other people. Only the study team, Blue Ridge Technologies (the contractor working on the EMPOWER for Veterans website), DocuSign (a VA contracted company that allows us to capture electronic signatures) and other authorized persons like officials from the Government Accounting Agency (GAO), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the Research Administration staff of CAVHS will have access to your study information. By signing this document, you consent to such inspection.

You may withdraw from the study at any time by talking to a member of the study team. After you withdraw, we will not collect any new information about you, but we may still use data about you collected before you withdrew.

RESULTS

Study results will not be shared until after the study has ended. If you would like to receive the results of this study, you may request them from Dr. Cucciare at 501-526-8179 or Lakiesha Kemp at 501-352-5591. Study results published in papers or presentation will identify combined group data not individual participant data. Any talks or papers about this study will not identify you. Your information collected as part of this research, even if identifiers are removed, will not be used for use in future research studies.

POTENTIAL BENEFITS

You may not benefit directly from being in this study; however, your participation may benefit others in the future by helping us to better understand how Veterans learn about their medications and how they can affect their health.

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COSTS TO PARTICIPANTS

Neither you or your insurance will be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and services, you will still pay these co-payments for VA care and services that are not part of this study.

PAYMENT OFFERED FOR PARTICIPATION

To compensate you for your time, checks for $30 will be mailed to you 4-6 weeks after you complete the baseline and 6-month assessments. Participants who complete both the baseline and 6-month assessments will receive a total of $60.00.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility. This does not apply to treatment for injuries that result from non-compliance by you with study procedures. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form. Emergency and ongoing medical treatment will be provided as needed

Should you have a medical concern, get hurt or sick because of taking part in this study, you may call

Ms. Kathy Marchant, RN at (501) 231 - 9457
OR
Dr. Richard Owen at (501) 249 - 3650

During and after business hours.

PARTICIPATION IS VOLUNTARY

Study participation is voluntary, and you may withdraw at any time and without loss of any benefits to which you are entitled. Your decision not to take part will not affect the relationship you have with your doctors or other staff, and it will not affect the usual care that you receive as a patient. If you do decide to stop participating, Dr. Cucciare will not collect any more information about you but will continue to have access to the information about you that was collected while you were still a participant.

ADDITIONAL CONTACT INFORMATION

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint or offer your input with a person who part of the study team is not, you can contact the IRB Administrator at (501) 257-6521, the Research Compliance Officer at (501) 257-6980, or the Research and Development Coordinator at (501) 257-4816. If you have any questions about your rights as a study participant or would like to ask about a study-related harm or injury, you may contact the Principal Investigator, Dr. Michael Cucciare at (501) 526-8179 or study representative, Lakiesha Kemp at (501) 352-5591.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study team 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. You also confirm that you have read this consent, or it has been read to you. A copy of this signed consent will also be put in your medical record.

_____ / /

Signature of Participant Date

_____ / /

Signature of Person Obtaining Consent Date