Implementation of collaborative care for depression in VA HIV clinics: Translating Initiatives for Depression into Effective Solutions (HITIDES)

NCT05901272

August 29, 2022

Participant Name: _____ **Date:** _____

Study Team Member Conducting Consent:_____

Title of Study: Implementation of collaborative care for depression in VA HIV clinics: Translating Initiatives for Depression into Effective Solutions (HITIDES)

Principal Investigator: Jacob Painter, PharmD, MBA, PhD & Eva Woodward, PhD

VAMC: Central Arkansas Veterans Healthcare System, 598 Version 1, January 6, 2023

VA PROVIDER VERBAL CONSENT

SUMMARY

You are being invited to participate in a research study called "Implementation of collaborative care for depression in VA HIV clinics." 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, Dr. Eva Woodward, email eva.woodward@va.gov.

The research is being conducted to understand your thoughts on engaging Veterans in HITIDES implementation and quality improvement. We want to know what tactics or strategies were used, how easy/hard they were, and suggestions for improvement. We also want to know how this experience with Consumer Voice tools was for you, why you considered it or reasons you decided not to do this (if so), and suggestions for improvement. We anticipate enrolling up to 45 VA employees for this project.

If you agree to join the study, you will be asked to complete the following research procedures:

- An online survey (10-20 minutes) *and*
- Telephone or video call interview with research staff (30-45 minutes)

This research study is expected to take approximately 4 years. Your participation will last for approximately up to 1.5 hours total. Federal employees cannot be compensated for research participation during their tour of duty.

You are being asked to participate in this project because:

- You have expressed interest in HIV Translating Initiatives for Depression into Effective Solutions (HITIDES).
- You are associated with the VA HIV or infectious disease clinic where Veterans Living with HIV (VLWH) are served.

We will protect your privacy by keeping your personal information in electronic folders on secure, password-protected computers only seen by the research team. We will not identify you by name or description in any writings or discussions outside of our research team (e.g., reports). Groups that oversee the study (like the Institutional Review Board) might access the research and see this information.

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Participant Name: _____ **Date:** _____

Study Team Member Conducting Verbal Consent:_____

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Principal Investigator: Jacob Painter, PharmD, MBA, PhD & Eva Woodward, PhD

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The most common benefit of participation are feeling good about sharing your experience to improve VA care for Veterans or other staff trying to engage Veterans. A risk might be frustration if your thoughts are not listened to or do not result in changes.

Alternatives to participating are: You do not have to participate in the study. Also, you are free to stop participating at any time during or after the consenting process. Your decision not to take part in the research study will not affect the relationship you have with your colleagues in VA.

Please note that there are other factors to consider before agreeing to participate, such as use of your personal information, phone 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. You are free to not participate or stop participating at any time during or after the consenting process.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. The information will be protected in the following ways:

- All electronic records will be kept on well-maintained, encrypted VA servers housed on the Central Arkansas Veterans Healthcare System campus.
- Research Investigator files will be destroyed in accordance with Records Schedule DAA-0015-2015-0004. The ISO/PO will be notified within one hour if data loss or misuse is discovered.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting Agency (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of CAVHS. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all Veteran and non-Veteran research participants. By signing this document, you consent to such inspection.

Identifiers will be removed from the identifiable private 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 to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Participant Name: _____ **Date:** _____

Study Team Member Conducting Verbal Consent:_____

Title of Study: Implementation of collaborative care for depression in VA HIV clinics: Translating Initiatives for Depression into Effective Solutions (HITIDES)

Principal Investigator: Jacob Painter, PharmD, MBA, PhD & Eva Woodward, PhD

VAMC: Central Arkansas Veterans Healthcare System, 598 Version 1, January 6, 2023

The research study has been explained to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told this research is voluntary. You have been given the chance to ask questions and obtain answers. Do you have any additional questions?

Do you consent to be a participate in this research study? ☐ Yes ☐ No

Do you consent to your interview being audio recorded and transcribed? ☐Yes ☐No

If you do not wish to be audio recorded, you will still be eligible to participate in this study.

After the interview is complete, additional questions may arise later. We may want to reach out to you again for additional information. Do you consent or decline to be potentially recontacted for any other aspect such as another phone interview or any further needs of this study?

☐ Consent, I agree to be recontacted for future activities for this research study.
☐ Decline, I do not wish to be recontacted for future activities for this research study.

If you decline to be recontacted for future research study activities for this project, you are still eligible to participate in the study.

Participant Name: _____ **Date:** _____

Study Team Member Conducting Verbal Consent:_____

Title of Study: Implementation of collaborative care for depression in VA HIV clinics: Translating Initiatives for Depression into Effective Solutions (HITIDES)

Principal Investigator: Jacob Painter, PharmD, MBA, PhD & Eva Woodward, PhD

VAMC: Central Arkansas Veterans Healthcare System, 598 Version 2, February 22, 2024

VETERAN VERBAL CONSENT

SUMMARY

You are being invited to participate in a research study called "Implementation of collaborative care for depression in VA HIV clinics." 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 Co-Principal Investigator, Eva Woodward, PhD e-mail: eva.woodward2@va.gov.

The research is being done to understand your thoughts about involving Veterans in creating and setting-up new services in VA clinics. We want to know how this experience was for you, why you considered it or reasons you decided not to do this (if so). We also want suggestions for improvement.

If you agree to join the study, you will be asked to complete the following research procedure:

- Telephone or video call interview with research staff (up to 45 minutes total)

Your participation will be completing a telephone or video interview (up to 45 minutes total).

A common risk of participation is discomfort from being asked what did not go well. Another common risk is feeling frustrated. You may feel frustrated if your thoughts are not listened to or they do not result in changes. You may benefit from this study by knowing that sharing your experience could improve VA care for other Veterans. You may get no direct benefit from taking part in the study.

Please note that there are other factors to consider before agreeing to participate, such as 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. You are free to not participate or stop participating at any time during or after the consenting process.

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.

Please listen to the following information closely and discuss it with family and friends if you wish. If anything is not clear or if you would like more details, please let me know. Take your time to decide

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about participation. If you do decide to take part in this study, we will ask for your verbal consent that I shared information with you, and that you were able to discuss any questions and concerns you have with myself or a member of the study team.

BACKGROUND AND PURPOSE

- With this research we hope to support a broad implementation of HIV Translating Initiatives for Depression into Effective Solutions (HITIDES), which adapts the primary care collaborative care model for depression treatment to HIV clinics.
- The PIs of this study are Dr. Jacob Painter and Dr. Eva Woodward. It is sponsored by the VA Health Services Research & Development.
- We want to talk with Veterans who were invited to take part in HITIDES activities using Consumer Voice tools. We want to talk with both of those who did take part and those who declined or dropped out of these activities.
- We will have up to 160 Veteran participants.

DURATION OF THE RESEARCH

This research study is expected to take approximately 4 years. Your individual participation in the project will take approximately 45 minutes.

STUDY PROCEDURES

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

- You will be asked to complete a telephone or video call interview.
- While participating in the interview, you are free to skip any questions you would not like to answer.
- If you agree to participate, we ask that you:
    - Keep your scheduled interview.
    - Ask questions as you think of them.
    - Tell the investigator or research staff if you change your mind about staying in the study.
- Your interview will be audio-recorded so that the study team can transcribe your interview. This will allow the study team the opportunity to accurately collect information. This information will not be disclosed outside of the VA.

POSSIBLE RISKS OR DISCOMFORTS

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.

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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

Taking part in this study will involve collecting private information about you. The information will be protected in the following ways:

- All electronic records will be kept on well-maintained, encrypted VA servers housed on the Central Arkansas Veterans Healthcare System campus.
- Research Investigator files will be destroyed in accordance with Records Schedule DAA-0015-2015-0004. The ISO/PO will be notified within one hour if data loss or misuse is discovered.

We will collect your social security number. This is required to compensate you for your participation in the project. If you do not wish to share your social security number, you will still be able to participate in the project; however, we will be unable to compensate you for your participation.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting Agency (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of CAVHS. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all Veteran and non-Veteran research participants. By signing this document, you consent to such inspection.

Identifiers will be removed from the identifiable private 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 to you.

POTENTIAL BENEFITS

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us treat future patients.

COSTS TO PARTICIPANTS AND PAYMENT

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Costs to Participants*:* You will be asked to bear any costs associated with time away from work for participation in this study.

Payment Offered for Participation:

- You will receive $30 for being interviewed by research staff either by telephone or video call. After completion of your participation, you will be compensated by a check being mailed to you or via electronic funds transfers (EFT).
- Checks and direct deposit are sent out by the Austin Financial Services Center and will generate an Internal Revenue Service Form 1099. Your social security number will be needed to generate the payment.

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.

If you should have a medical concern or get hurt or sick because of taking part in this study, call:

DURING THE DAY: Dr. Eva Woodward, Eva.Woodward2@va.gov

AFTER HOURS: VA Crisis Communications Line at 988, then Press 1.

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

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 doctors or other staff, and it will not affect the usual care that you receive as a patient.

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The study team will continue to use any data collected from you prior to your withdrawal and will not collect further information. Information provided prior to your withdrawal from the study cannot be withdrawn.

FUTURE USE OF DATA AND RE-CONTACT

The information you provide for the study team will be retained for future research. Your data will be stored at the Central Arkansas Veterans Healthcare System in a locked filing cabinet (behind locked office doors) and in secured, encrypted, and password protected electronic files. Only the study team will have access to the data you provide.

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 is not part of the study team, you can contact the IRB Administrator at (501) 257-6521 or the Research Compliance Officer at (501) 257-6980.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The research study has been explained to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told this research is voluntary. You have been given the chance to ask questions and obtain answers. Do you have any additional questions?

Do you consent to be a participate in this research study? ☐ Yes ☐ No

Do you consent to your interview being audio recorded and transcribed? ☐Yes ☐No
If you do not wish to be audio recorded, you will still be eligible to participate in this study.

After the interview is complete, additional questions may arise later. We may want to reach out to you again for additional information. Do you consent or decline to be potentially recontacted for any other aspect such as another phone interview or any further needs of this study?

☐ Consent, I agree to be recontacted for future activities for this research study.

☐ Decline, I do not wish to be recontacted for future activities for this research study.

If you decline to be recontacted for future research study activities for this project, you are still eligible to participate in the study.