Effect of Medication Management at Home Via Pharmacy Home Televisits

NCT04340570

May 9, 2022

Participant Name: _____ Date:_____

Title of Study: Effect of Medication Management at Home via Pharmacy Home Televisits

Principal Investigator: VA Facility: James J. Peters VAMC Principal Investigators for Multisite Study:

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Health Services Research and Development Service. 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?

By doing this study, we hope to examine the effect of home video visits with a VA pharmacist compared to in-person clinic-based usual care. If you agree to take part in the study, you would be agreeing to complete a brief screening questionnaire, which will last about 15 mins. Results of the questionnaire will determine if you are eligible to continue with the study. If you are eligible, you will next complete a baseline interview, which will last about 45 minutes. Next depending on which Primary care team you are enrolled in; an appointment may be made for a home video visit for a time that is convenient for you.

Your participation in this research will last about three and half (3.5) hours. This time with be split over three or four visits over six months.

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

By participating in this study, you may either have a video one-on-one conversation with a pharmacist about your medications or not. You will be helping the research team understand the effect of home video visits with a VA pharmacist compared to in-person clinic-based usual care and helping improve care for future Veterans. No matter which group you are enrolled in, you will continue to receive your usual clinic-based care.

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

You may not want to allow members of the research team virtually into your home. You may not want to give up three hours of your time.

For a complete description of risks, refer to the Detailed Consent and/or Appendix.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 04/11/22

LSI Approval Date: N/A

LSI Verification Date: 05/09/22

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DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, 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 - at the James J Peters VA Medical Center in the Bronx, NY. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study him contact information is:- .The other person in charge of this study is - at the Bedford VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: -.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to look at the effect of in-home video visits with a pharmacist on medication management compared to in-person clinic-based usual care.

HOW LONG WILL I BE IN THE STUDY?

Your participation in the project will take about 3.5 hours total and will be split over three or four visits over six months. We expect to enroll approximately 400 Veterans from both the Bronx and Bedford VA for this part of the study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

You will first be asked to complete a brief questionnaire, which would ask your age, chronic conditions, the number of prescription drug you use and your memory. This questionnaire would take about 15 minutes to complete. You are free to skip any questions you would prefer not to answer. This portion of the study will also establish your eligibility for the study. Results obtained on the questionnaire will determine if you are eligible to continue with the study. If you do not meet eligibility than your participation will end here.

Once eligible, you will complete a baseline interview, which will last about 45 minutes. The interview will ask questions about your health, your medications, how comfortable you are with technology, and your quality of life. You are free to skip any questions you would prefer not to answer. This will last about 45 minutes.

After the interview, you will be randomly assigned to either received the home video visit or not based on your primary care team. Since you are being randomly assigned, there is a 50/50 chance (like a coin flip) that you will be assigned to have the home video visit. Regardless of which group you are enrolled in; you will continue to receive your usual clinic-based care.

Next, an appointment for a home video visit may be set up for a time that is convenient for you, or you may continue your usual in-person clinic-based care. About 15 minutes before the scheduled home video visit time, you will need to connect to the internet through your computer, tablet or smartphone if you have a device that can connect to the internet. If you do not have a device that can connect to the internet for a video visit or choose not to use your own device, a VA issued tablet will be provided to you and you will use the VA device to connect to the internet.

If you are in the group that will receive a home video visit then at the appointed time, you will connect with the pharmacist. The pharmacist will ask you about what medications you take, whether you have any side effects, and answer questions you may have about the medications. They will ask you about medications prescribed to you and about other pills you may take such as vitamins or herbal remedies. They may ask you to move the camera to show them different parts of your home where you store medications such as in the bathroom or bedside table. We expect the video visit will take up to 1 hour. A summary of any medication recommendations the pharmacist has as a result of your video visit will be shared with your primary care doctor.

If you are in the group that will not receive an in-home video visit, then you will continue regular follow up with your primary care team.

After the home video visit, a study staff member will contact you after your next primary care visit if you have one within 6 months of joining the study and ask you several questions about your visit. This will take approximately 15 minutes and can be done through telephone or through face-to-face visit whichever is convenient for you. At 6 months, regardless of whether you have had a visit with your primary care team or not, a study staff member will contact you for a questionnaire about you and your medication use. This will take approximately 60 minutes and will be in person or through telephone at a time of your preference and convenience.

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

You will be expected to complete a brief questionnaire to see if you are eligible to join the study. If you are eligible then you may receive a home video visit with a pharmacist or not. If you are in the group that will receive a pharmacist visit, you will be expected to be at home at a time convenient to you to carry out the video visit and connect with a pharmacist. If you need to reschedule the video visit, we ask that you call the study team staff to do so. Regardless of whether you receive a video visit with a pharmacist, you will be asked to complete up to two questionnaires within 6 months.

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

Any study has possible risks or discomforts. You may be asked questions that you are unable to answer, and this may make you uncomfortable. You do not have to answer any questions that you don't want to.

You may be unsteady and at risk for falling if you are asked to walk around your home to show the pharmacist different places you keep medications. You can let the study staff or pharmacist know if you feel you cannot safely walk around your home while conducting the video visit and prefer to remain in one place during the video visit.

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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

- Learning more about your medications
- Having a pharmacist make recommendations to your clinical team about possible changes to your medications
- Getting experience with VA Video Connect

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

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your research records will be kept as confidential as possible. A participant code will be used for data to help protect your privacy. The code number will not be based on any information that could be used to identify you. The master list linking names to codes will be kept separately from the research data, in a secure location. Data collected will be destroyed according to VA's Record Control Schedule, which currently is 6 years after research study is complete. Data collected in this part of the study will not be used for future unrelated research.

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, 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. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), 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. 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 o 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. - or Dr.- and their 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.

If you are eligible for the study and complete the questionnaire at 6 months after joining the study, you will be offered $50 (fifty dollars) for your time in the form of a gift card.

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.

If you should have a medical concern or get hurt or sick while taking part in this study, notify the study staff by calling the: (look at choices)

-_____

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DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of rights to which you are otherwise entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Data already collected prior to withdrawal may be included in the research but no further data collection will be undertaken.

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

If you want to contact the primary research investigators, you can call - at the James J Peters VA Medical Center in the Bronx, NY at - or -, at the Bedford VA Medical Center at -. If you have any questions, concerns, or complaints regarding your rights as a research subject at the Bedford VA, you may call the Acting Administrative Officer for Research, - at-. While at the Bronx, you may contact - ACOS/R&D Program by requesting an appointment at - hospital extension -.

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). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at - if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ 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 and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

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

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