# Empowering Veterans to Actively Communicate and Engage in Shared Decision Making in Medical Visits, A randomized controlled trial

NCT05169359

June 30, 2025

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| **Participant Name:** | **Date:** |
| **Title of Study:** | **Empowering Veterans to Actively Communicate and Engage in Shared Decision Making in Medical Visits, A randomized controlled trial** |
| **Principal Investigator:** | **Howard S Gordon, MD** |

KEY SUMMARY INFORMATION ABOUT THIS STUDY

## WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the Department of Veterans Affairs about helping Veterans prepare for and speak up in medical visits. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. 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 learn whether a pre-visit video can help improve communication and healthcare in Veterans with Type 2 Diabetes Mellitus. Your participation in this research will between 6 months to 3 years.

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

Volunteering will help the VA evaluate if the Speak Up! Video is effective at improving outcomes in Veterans with Diabetes.

*For a complete description of benefits, refer to the Detailed Information section.*

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

You need to have time to participate in up to three 60-minute telephone interviews to complete questionnaires and come to the VA for a blood test.

There is a risk of pain, infection, and bleeding from the blood test. There is a risk of loss of privacy and confidentiality and discomforts from answering survey questions. The alternative is to not participate.

*For a complete description of risks, refer to the Detailed Information section.*

## 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 (Principal Investigator, PI) of the Jesse Brown VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: .

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## DETAILED INFORMATION ABOUT THE STUDY

### WHAT IS THE PURPOSE OF THIS STUDY?

With this research we will evaluate the effectiveness of the educational “Speak Up” video to improve communication and healthcare outcomes in Veterans with Diabetes. The research will also evaluate what it takes for VA clinics to put the video into practice.

### HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 257 people will participate in this research study at Jesse Brown VAMC and affiliated Community Based Outpatient Clinics (CBOCs). Additionally, about 255 people will participate at Hines VA Hospital and CBOCs.

### HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years. Your individual participation in the project will include 3 telephone interviews, one visit to your primary care clinic, another visit for a blood test 3 months after your clinic visit. These will be spread out over time with the length of time ranging from 6 months to 3 years.

### WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you agree to participate you will have 3 interviews by phone to answer survey questionnaires. You will be asked to be approximately 30 minutes early for an upcoming appointment with your primary care provider so you can watch the Speak Up! Video before the appointment, and you will return to the VA for a blood test 3 months after the visit when you watched the video.

### WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

There are four steps in this study that will happen over 3 to 6 months:

1. The first telephone interview will include reviewing this information sheet with you, confirming your agreement to participate and then you will complete several survey questionnaires about demographics, perceptions and beliefs about healthcare, diabetes, physical and mental health. The length of the phone call will be approximately 60 minutes.
2. The second telephone interview will be several weeks before an upcoming visit to your primary care provider. This phone call will involve responding to several survey questionnaires about healthcare, diabetes, and medications you take. The length of the call will be approximately 30 to 60 minutes.
3. After the second phone interview, you will be asked to come in early for a primary care appointment and watch the Speak Up! Video prior to the visit.
4. The third telephone interview will be approximately 1 week after that visit. You will be called to complete several additional survey questionnaires about healthcare, diabetes, medications, physical and mental health, and your visit with the doctor. The length of the phone call will be approximately 60 minutes.

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5. During the third telephone interview we will invite up to five participants per clinic to a fourth phone call for an in-depth interview. You may be one of those participants invited to participate in an in-depth qualitative interview to ask questions about your experiences watching the video in clinic, including your opinion about the video and preference for repeat viewing. The length of the in-depth interview is approximately 30-45 minutes.
6. Three months after your primary care visit return to the VA for a blood test.

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

Blood draw – This study includes a blood test for hemoglobin A1c which requires a blood draw. There may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood.

Questionnaires – This study includes answering questionnaires. Some people become uncomfortable at being asked questions about their feelings, beliefs, and preferences. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

Audio recording – If you are invited to participate in the in-depth interview, we will request your permission to audio record the interview to ensure we accurately capture the content of the interview. The in-depth interview is an optional part of this study. By agreeing to participate in an in-depth interview you voluntarily and without separate compensation authorize voice recording to be made of you by the study team while you are participating in the in-depth interview part of this study. The recording will not be disclosed outside of the research team. The study team has also explained that you will not receive any royalty, fee or other compensation for the study teams use of the voice recording. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded, and may rescind your consent for up to a reasonable time before the voice recording is used.

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 or side effect.

There is also a risk of loss of confidentiality. We will make every effort to protect your identity as a participant in this study. Steps that are taken to protect your identity are outlined in the section titled, “How will my private information be protected?”.

Risks of the usual care you receive are not risks of this study. 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.

## 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 improvement in your communication with your healthcare provider.

## HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

The research team on the study includes researchers at Jesse Brown VA, Hines VA, and Texas A&M University. The research team working on the study will collect information about you. Your individually identifiable health information is information about you that contains your health

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information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. This includes things learned from the procedures described in this consent form such as from questionnaires and interviews. They will also collect other information including your name, address, date of birth, and information from your medical records such as diagnoses, progress notes, medications, laboratory, pathology, and radiology results.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections (OHRP), the Government Accountability Office (GAO), the VA Office of Research Oversight (ORO), the VA Office of Inspector General OIG), the VA Office of General Counsel, the VA Institutional Review Board (IRB) and our local Research and Development Committee (R&DC), our local Human Research Protections Program (HRPP), and other study monitors may look at or copy portions of records that identify you.

All data will be safeguarded to minimize the risk of loss of confidentiality. Data will be stored in locked file cabinets in locked offices or will be stored on password protected VA computer network for paper or electronic data, as appropriate. Names and contact information will not be included in datasets used for analysis. In the data used for analysis you will be identified by study ID code only. The research team at Jesse Brown VA, Hines VA, and Texas A&M will have access to data with the study ID code for analysis and interpretation.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Telephone interviews will be recorded using a VA approved method and stored on password protected VA server. Recordings will be directly saved to VA network storage. Audio-recordings will be transcribed without names or other identifiers. A study ID code will be used to identify each participant on transcriptions and other data collection forms. The link from the code to you will only be accessible to the research assistants and the research investigators, and oversight organizations such as IRB and R&D committee if required. The coded transcripts (without identifiers) will be reviewed and analyzed by research team members from Jesse Brown VA, Hines VA, and Texas A&M.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. The clinical trial registration number for this study is NCT05169359.

## WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You or your insurance 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.

## PAYMENT FOR PARTICIPATION

There is no payment for watching the video at your scheduled appointment because the video is a brief 12-minute video that is integrated into the usual care of the clinic. You will be reimbursed in the

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amount of $35 for completing each of the three telephone interviews: interviews 1, 2, and 3. You will be reimbursed $35 for completing the 3-month post-visit blood draw. You may be eligible for a total participation incentive of $140 if you complete all steps. Payment will be with a CVS gift card. If you participate in the optional in-depth telephone interview you will be reimbursed an additional $25.

**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 or your insurance 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.

Additional compensation, beyond paying for treatment, has not been set aside. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA District Counsel at (708) 202-2216. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact:

DURING THE DAY:

AFTER HOURS:

Emergency and ongoing medical treatment will be provided as needed.

**DO I HAVE TO TAKE PART IN THE STUDY?**

Participation is voluntary and refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If at any time you choose to discontinue participation, you may do so with no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study and still receive the same standard of care that you would otherwise have received.

For data already collected prior to your choice to discontinue, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

**RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION**

If at any time the local site PI feels the study is inappropriate for a participant or due to medical reasons, the PI reserves the right to discontinue/withdrawal the subject from the study.

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

You may contact with any concerns or complaints as to this research study.

If you want to talk to someone who is not involved in this research about your rights as a JBVAMC patient you should contact the Patient Advocate Office at the Jesse Brown VA Medical Center.

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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 Jesse Brown VAMC 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 Jesse Brown VAMC IRB if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.