Waiver of Written Documentation of Consent/HIPAA

NCT04041375

Using Peer Navigators to Increase Access to VA and Community Resources for Veterans With Diabetes-related Distress

10/15/2018

You are invited to take part in a research study conducted by the Michael E. DeBakey VAMC. Participation in this study is strictly voluntary.

Background

Patients with diabetes are often challenged by the routine of managing their diabetes, and may experience both stress and medical problems. Diabetes-related medical problems and stress often happen together and affect peoples' ability to live a full, happy and healthy life. Because of this, programs that help you with your medical problems and stress by teaching you to better manage diabetes and stress may improve your life.

Many excellent programs are available in the VA and in the community that help persons with diabetes better manage their medical problems and stress, but often times Veterans have trouble finding these programs.

Purpose

The purpose of the study is to see if a telephone-based coaching program compared to a directory of community and VA resources improves the physical and emotional health of Veterans with diabetes by helping them connect to care in the VA and/or community. The Veterans who receive the directory of community and VA resources will be given this at the beginning of the study and will access resources as they see fit. Those in the coaching program will be coached by a Veteran with knowledge of diabetes, mental health and community resources. Examples of resources available in the VA and community include mental health care and programs to help with diet, exercise and learning about how to better manage diabetes. And that is what the Veteran Support and Resources for Diabetes (iNSPiRED)) study is about. iNSPiRED compares use of a directory of resources to use of "Veteran peer coaches" to help patients better manage their physical and emotional health by connecting Veterans to programs in the VA and/or the community that are important/of interest to the Veteran (e.g., you), and to information on skills that the Veteran can use at home.

Your participation in the study will help us to improve our care of Veterans with diabetes by better using programs available either in the community or in the VA.

Procedures

We hope to include 218 Veterans with diabetes in this study. There is no cost for participating in the study. If you are eligible and would like to participate, you will be in the study for about 6 months. There are two study groups, and you will be assigned to one of them. The group you are assigned to will be chosen by chance. In other words, it will be chosen in a way that is like flipping a coin. One group will be

assigned a Veteran peer coach. The other group will receive a directory of community and VA resources in the mail and no peer coaching.

If you are in the peer coaching group, you will meet with your coach in-person for the first visit, which includes an introduction and initial assessment of your needs, priorities, preferences, and barriers, followed by a suggestion of 2 to 3 community or VA programs and a discussion for next steps. Follow-up calls by phone will occur every 1-3 weeks based on your needs and preference. Information and education on diabetes self-management and psychological well-being may be provided verbally or through mail and will be tailored to your needs and preferences. You will work with your peer coach for three months or less if you choose to terminate sooner.

Whichever group you are in, you will be asked to complete several questionnaires about your health and well-being by telephone. This will occur at the beginning of the study and three and six months later. The questionnaires will take about an hour to complete each time. At six months, you may also be asked questions to help improve the program in the future.

With your permission, we will send you appointment reminders and links to information and resources by text message.

This program is not meant to replace your doctor or interfere with your current treatment. You will continue any treatment or care with your doctor that you're doing now. It's meant to help support the treatments and medications you're already taking.

Who is eligible (and not eligible) to be in this study?

We are looking for Veterans with type 2 diabetes who are having stress that often comes with managing diabetes. Individuals must also have reliable access to a telephone.

Individuals with severe hearing impairment or memory problems that make it impossible to use the telephone are not eligible for this project. Individuals currently participating in another diabetes-related counseling or self-management program are also not eligible.

Potential Risks and Discomforts

This study has minimal risks and discomforts. However, it is important to recognize that talking about physical and mental health problems while answering questionnaires or participating in the coaching sessions can be uncomfortable for some people (which is completely understandable). There is also a

small risk of breach of confidentiality. Study staff will do everything possible to keep others from learning about your participation. The risks, however, are considered low.

Potential Benefits

This intervention will potentially provide you with help in finding care in the VA and in the community that relate to addressing your stress and diabetes. Just as importantly, you will have an opportunity to teach us about how we can better help the veteran population at large and understand what is important to them as far as their health goals are concerned. However, this will always be unique to the person, and it is possible that you may not receive any benefit from your participation in this study. You should know that your participation will help the researchers of this study learn more about how effective this program is, and how well patients accept it.

Alternatives

You may choose to not participate in this study. Participation is always voluntary.

Subject Costs and Payments

There is no cost to participate in this study.

Depending on the number of steps that you complete including today's interview, you may receive up to $175. You will receive $50 after you complete the first set of telephone questionnaires (today), $50 after you complete the second set of telephone questionnaires (3-month), and $75 after you complete the final set of telephone questionnaires (6-month). This money is to compensate you for your time and any cell phone minutes used while completing the questionnaires.

Subject's Rights

Your verbal consent means that you have received the information about this study and that you agree to volunteer to participate in the study. You are not giving up any of your rights by participating in this project. Even after you have chosen to participate, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the study, or if you decide to stop taking part later, your benefits and services will stay the same as before we discussed the study with you. You will not lose any benefits, services, or rights.

Your Health Information

We may be collecting your health information (protected health information). This protected health information might have your name, age, race/ethnicity, address, or something else that identifies you on it. This information is important for the purposes of this study and that alone. Federal law wants us to get your permission to use your protected health information for this study. We may also share your protected health information with other researchers. However, any information we share will be de-identified. This means that all links to your identity will be removed before we share it. Your verbal consent means that you give us permission to use your protected health information for this research study and to share your de-identified information with other researchers.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the study may be published. However, you will not be identified at any point.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed above, representatives of the sponsor, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records specifically related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed. But you should know that our entire team works very hard to ensure that your information remains private.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. This is totally in your right. If you want to remove your protected health information just contact the study staff to tell them about this, and they will give you an address to inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigators, MARK KUNIK and NATALIE HUNDT, and/or someone they appoint will try to answer any and all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff during the day: MARK KUNIK and NATALIE HUNDT at 713-794-8601.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. They ensure that

we abide by treating all people that participants in this program in an ethical manner. Should you have questions feel free to call the IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person not associated with the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.