Evaluation of a Patient Portal Intervention for Diabetes: A Pilot Randomized Controlled Trial

NCT03947333

Informed Consent Document

February 25, 2020

Informed Consent Document

Institutional Review Board
Informed Consent Document for Research

Principal Investigator: William Martinez, MD, MS
Revision Date: 2/16/2020
Study Title: Evaluation of a Patient Portal Intervention for Patients with Diabetes: A Randomized Controlled Trial
Institution/Hospital: Vanderbilt University Medical Center

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?

The purpose of the study is to determine satisfaction with two versions of My Health at Vanderbilt (i.e., the Vanderbilt patient portal) among patients with diabetes. One version will be the currently available version of My Health at Vanderbilt. The second version of My Health at Vanderbilt will contain a new feature.

You are being asked to participate in a research study because you receive care at Vanderbilt University Medical Center (VUMC) and have type 2 diabetes.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Side effects and risks that you can expect if you take part in this study:

The time it takes to participate may be inconvenient for some patients. Some patients may feel discouraged or upset to learn that some measures of their health (like A1C, blood pressure, or cholesterol) are worse than they would like them to be. There is a risk of loss of confidentiality. All efforts, within reason, will be made to keep your personal information in your research record confidential. Some people might feel uncomfortable giving their opinions and providing feedback. You do not have to answer any question you do not want to answer.

Risks that are not known:

Because this version of My Health at Vanderbilt containing a new feature is investigational, there may be risks that we do not know about at this time.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study.
The potential benefits from your participation may be helping the study investigators create tools to improve the health of patients with diabetes.

b) The benefits you might get from being in this study.
Features of My Health at Vanderbilt may improve your understanding of your health and of how to manage your health conditions.

Procedures to be followed:

Because we do not know which version of My Health at Vanderbilt is better, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group.

Participants in one group will be given access to the version of My Health at Vanderbilt that contains the new feature while participants in the other group have access to the current version of My Health at Vanderbilt. We will then compare which of the two has the best results.

At the start of the study, we will ask you to complete a study questionnaire about your background and your knowledge, attitudes, and experiences with diabetes. This questionnaire will take about 25 minutes to complete. After the completed questionnaire is received, you will be notified of your assigned group. You will be assigned to your group for six months at which point your participation in the study will end.

After three months and again at six months (end of the study), you will be asked to complete a questionnaire about your satisfaction with My Health at Vanderbilt and your knowledge, attitudes, and experiences with diabetes. The questionnaire will take about 20 minutes to complete each time.

Authorized study personnel will retrieve the following information about you from your VUMC medical record: a list of your current and past medical problems, list of medications you have been prescribed, your vaccination history, and the date and value of your three most recent diabetes related lab tests such as your blood sugar, blood pressure, kidney function, and cholesterol and your most recent diabetes-related eye exam. This is information will be collected so that we can describe the health status and medical history of the people in the study.

Payments for your time spent taking part in this study or expenses:

Participants can receive $40 for completing the enrollment questionnaire at the start of the study and $35 each for

completing the three-month and six-month follow-up questionnaires. After each questionnaire, you will be asked to fill out a Request for Payment to Volunteer Subjects form and a prepaid credit card will be mailed to your home address.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study. However, you will need access to a desktop computer with internet access. You will NOT receive compensation for costs associated with computer use or internet access.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or possibly injury, please feel free to contact William Martinez, MD, MS at 615-933-3645 or email the study team at mhavstudy@VUMC.org.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

You may be withdrawn from the study if you do not complete the enrollment questionnaire or follow-up questionnaires, or do not use My Health at Vanderbilt at all during the study period. If you are withdrawn from the study for any reason, you will be notified and a reason will be provided.

What will happen if you decide to stop being in this study?

If you withdraw from the study, we will stop getting any more data about you. However, the health data we stored before you withdrew your consent may still be used for reporting and research quality. Withdrawing from the study will not affect your medical care at Vanderbilt.

Clinical Trials Registry:

A description of this clinical trial will be available on 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 Web site at any time.

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We will have a record of your name on this form. We will not record your name on the study questionnaire transcripts of the interviews, health data we retrieve from your medical record, or diabetes dashboard usage data we collect for your My Health at Vanderbilt account. Instead, we will identify each participant with a number (e.g., participant 1, participant 2). A document linking the participant number to a name will be stored separately on a password-protected computed and accessible only to the principal investigator and study coordinator. Any audio files will be deleted from recording devices after transcription is complete. Audio files and transcripts will be uploaded and stored on password protected, computer servers Vanderbilt University Medical Center. When we report the results of this work, we may include quotations from participants. We will never give the name or any other identifying information of the person we are quoting.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked questionnaire and interview responses, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, and National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts within reason will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. William Martinez (Principal Investigator) and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. William Martinez in writing and let him know that you withdraw your consent. His mailing address is Vanderbilt University Medical Center, Division of General Internal Medicine, 2525 West End Avenue, Suite 450, Nashville TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Study Results:

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team, it may no longer be protected by confidentiality laws.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Please note that in order to enroll in the study, you will need to complete the items below AND certify your answers on the next screen.

I have read and understood the consent document. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

◯ Yes
◯ No

Please sign below to indicate that you read and understood the consent document, and that you voluntarily accept to participate in this study.

_____

Please print your FIRST name:

_____

Please print your LAST name:

_____

Please provide your date of birth:

_____

Please provide us with your phone number so we can contact you:

_____

Please provide us with your email address so that we can contact you:

_____

Thank you for your interest in this research study.

Please download or print a copy of your consent form on the next screen and keep it for your records. Please note you must certify your information on the next page and click 'Submit' in order to be enrolled in the study.

We will contact you within one week to complete the study enrollment questionnaire and provide further instructions.

Thank you for your consideration. You will not be enrolled in the study.
Please close your web browser and do not continue to the next page.
Thank you for your time.