Effects of a Patient Portal Intervention to Address Diabetes Care Gaps: A Pragmatic Randomized Controlled Trial

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Informed Consent Document

March 10, 2022

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Institutional Review Board
Informed Consent Document for Research
Principal Investigator: William Martinez, MD, MS
Version Date: January 27, 2022
Study Title: Effects of a Patient Portal Intervention to Address Diabetes Care Gaps: A Pragmatic Randomized Controlled Trial
Institution/Hospital: Vanderbilt University Medical Center

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

What is the purpose of the study?

The purpose of the study is to determine satisfaction with two versions of the My Health at Vanderbilt (MyHealth) mobile app among patients with diabetes. One version will be the currently available version of the MyHealth mobile app. The second version will be the MyHealth mobile app with a new feature added.

Since we do not know which version of the MyHealth mobile app 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, like by flipping a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. Participants in the one group will be given access to the currently available version of the MyHealth mobile app. Participants in the other group will be given access to a version of the MyHealth mobile app with a new feature added.

The new feature alerts you when it is time for certain types of diabetes care. The new MyHealth feature also lets you request the care via the app. This care includes A1C blood tests, urine protein tests, diabetes eye exams, and pneumonia shots. You will receive a confirmation message once your request is processed. The message will let you know what to do next to get the diabetes care you requested. Your primary care doctor will be the authorizing doctor and will receive your results.

Time Commitment:

You will complete four email surveys over the 12 months you are in the study. Each survey takes about 20 minutes to complete.

Potential Benefits:

You might learn when it is time for certain types of diabetes care. You might learn why certain types of diabetes care are important. You might receive diabetes care that can help prevent health problems.

Potential Costs:

You are responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. The diabetes care you request via using the new MyHealth feature is considered usual care. These costs will be billed to you and/or your insurance.

To be in the study, you will need a smartphone or tablet that can run the MyHealth mobile app. You will NOT be paid for costs related to your smartphone or tablet use or internet access.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to be in this study because you receive care at Vanderbilt University Medical Center (VUMC) and have 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. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Procedures to be followed and approximate duration of the study:

The study will last 12 months. You will be asked to complete surveys, use the MyHealth mobile app, and provide feedback. There are four parts to this study: enrollment, three-month follow-up, six-month follow-up, and twelve-month follow-up. Below is a breakdown of activities in each part of the study.

Enrollment:

You will complete your first survey.You will be randomly assigned to one of two groups with access to:The currently available version of the MyHealth mobile app, orA version of the MyHealth mobile app with the new feature added

Three-month Follow-up:

You will complete your three-month follow-up survey.

Six-month Follow-up:

You will complete your six-month follow-up survey.

Twelve -month Follow-up:

You will complete your twelve-month follow-up survey.

We will email you each survey at the appropriate time. Each survey takes about 20 minutes to complete. We will track how you use the MyHealth mobile app. We will get information from your medical record about your health problems, medicines, lab tests, vaccines, and communications with your primary care doctor. We will use this information to make sure you are eligible to be in the study. We will also use this information to describe the medical history of the people in the study and their use of My Health At Vanderbilt.

Expected costs:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

As noted above, you are responsible for paying for the routine care you receive for your health conditions. This includes the diabetes care you request using the new MyHealth feature. These costs will be billed to you and/or your insurance.

To be in the study, you will need a smartphone or tablet that can run the MyHealth mobile app. You will NOT be paid for costs related to your smartphone or tablet use or internet access.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The time it takes to be in the study might be difficult for you. You might not like giving your opinions and giving feedback. You do not have to answer any question you do not want to answer. There is a risk of loss of privacy. All efforts, within reason, will be made to keep the personal information in your study record confidential.

Unforeseeable risks:

Because one group of participants will have access to a version of the MyHealth mobile app with a feature that is new, there may be risks that we do not know about at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study.Your being in the study might help our team make tools that help people with diabetes take care of their health.

The benefits you might get from being in this study. You might learn when it is time for certain types of diabetes care. You might learn why certain types of diabetes care are important. You might receive diabetes care that can help prevent health problems.

Study Results:

A summary of the results will be available on https://clinicaltrials.gov/ at the conclusion of the study.

Clinical Trials Registry:

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.

Compensation for participation:

You may be paid up to $160 total for being in the study.

$40 for finishing your enrollment survey$40 for finishing the three-month follow-up survey$40 for finishing the six-month follow-up survey$40 for finishing the twelve-month follow-up surveyAfter your finish a survey, you will fill out a form and a prepaid debit card or check will be mailed to your home address.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study. However, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Circumstances under which the Principal Investigator may withdraw you from study participation:

Our team finds that you are not eligible orYou do not finish the enrollment survey orYou are not willing or able to use the MyHealth app on a mobile deviceIf you are withdrawn from the study for any reason, we will let you know and give you a reason.

What happens if you choose to withdraw from study participation?

You can withdraw from the study at any time by contacting our study team. The contact information is below. If you withdraw from the study, it will not affect the medical care you get at Vanderbilt. If you withdraw from the study, our study team will stop collecting data about you. However, the data we collected before you withdrew from the study will stay in your study record.

Contact information:

If you should have any questions about this research study or possibly injury, please feel free to contact William Martinez, MD, MS at 615-669-3160 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.

Confidentiality:

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 remove your name and other identifiers from your surveys, medical record information, and information about how you use of the new MyHealth feature. Instead, we will identify you with a number (for example 001). A document linking your number to your name will be kept separately. All study data will be stored on secure, password protected, computer servers.

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 or other identifiers. 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.

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 to others, federal and state confidentiality laws may no longer protect it.

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.

The Principal Investigator's mailing address is:

William Martinez, MD, MS

Vanderbilt University Medical Center

Division of General Internal Medicine

2525 West End Avenue, Suite 450

Nashville TN 37203

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.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read and understood the informed consent document. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ 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 advance to the next page and download or print a copy of your consent form and keep it for your records. Please note you must certify your information on the next page (by clicking on the certify box) and then click 'Submit' in order to be enrolled in the study.

We will contact you within one week to 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.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read and understood the informed consent document. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ 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.

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