My Diabetes Care Mobile: A Usability Study

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Informed Consent Document

May 22, 2021

Informed Consent Document

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:

My Diabetes Care Mobile Usability Study

Version Date:

5/22/2021

PI:

William Martinez, MD, MS

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:

The purpose of the study is to find out what patients with diabetes think about a potential new feature within the My Health At Vanderbilt mobile app. We also want to see how patients use the new feature. The new feature is called My Diabetes Care.

My Diabetes Care (MDC):

Displays your diabetes health data (A1C, blood pressure, cholesterol, and flu shot status)Compares your diabetes health data to the goal rangeCompares your diabetes health data to similar groups of patients (patients in the same age group, same gender, and taking similar medicines)Provides information about diabetes and things you can do to improve how you take care of your diabetesLets you prepare for upcoming doctor's appointments where you plan to talk about diabetes with your doctorDetailed Information:

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

You are being asked to participate in this 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.

Procedures to be followed and approximate duration of the study:

The study will last approximately 1 month.

Prior to receiving access to My Diabetes Care (MDC) within the My Health At Vanderbilt mobile app, we will ask you to complete a study questionnaire. The questionnaire will ask you about your background. The questionnaire will also ask you about your knowledge, attitudes, and experiences with diabetes. This questionnaire will take about 20

minutes to complete.

After completing the questionnaire, you will be given access to MDC within the My Health At Vanderbilt mobile app. You will have access for 1 month. You will be asked to use MDC for at least 10 minutes during the month. However, you can view and use MDC whenever you want for as long as you want during the month. We will track how often you view MDC and what features you use.

At the end of the 1 month, you will be asked to complete a final questionnaire about your experience using MDC. The final questionnaire will also ask you again about your knowledge, attitudes, and experiences with diabetes. This final questionnaire will take about 25 minutes to complete.

Finally, some participants will be invited to complete an interview with a member of the study staff. The interview will let us understand in detail patients' experiences using MDC. The interview will last about 30-45 minutes. The interview will be audio recorded and can either be done over the phone or via Zoom video conferencing. We will transcribe the recordings and study them to learn how we can improve MDC.

Authorized study staff 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 most recent diabetes related lab tests such as your blood sugar, blood pressure, and cholesterol. We will collect this information so that we can describe the health status and medical history of the people who participated in the study.

Expected costs:

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

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:

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.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.

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.

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

Participants can receive $40 for completing the questionnaire at the start of the study, $5 for using the mobile app for at least 10 minutes during the study period (1 month), and $35 for completing the questionnaire at the end of the study. Participants who complete the interview will receive an additional $40. 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. The Request for Payment to Volunteer Subjects form has a field to enter your Social Security Number as VUMC is required to ask for your Social Security Number by the Internal Revenue Service (IRS).

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. 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?

You can withdraw from the study at any time by contacting the study team listed on the consent form. Withdrawing from the study will not affect the medical care you receive at Vanderbilt. 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.

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 MDCmobilestudy@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.

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.

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 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 computer server 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: Date of IRB Approval: 06/08/2021

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:
William Martinez, MD, MS
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.

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.

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.

If I participate in a study interview, I agree to have the interview be audio-recorded?

◯ Yes
◯ No

I have read and understood the consent document, and I voluntarily accept to participate 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 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.