My Diabetes Care: A Scalability and Usability Study

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Informed Consent Document

9/21/2022

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Institutional Review Board
Informed Consent Document for Research
Study Title: My Diabetes Care: A Scalability and Usability Study
Version Date: 9/21/2022

Part 1 of 2: Master Consent

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key information about this study:
The purpose of the study is to find out what patients think about a potential new feature of the patient portal (Patient Gateway or My Health at Vanderbilt). The potential new feature is called My Diabetes Care. My Diabetes Care displays patients' diabetes health data and information about how to care for diabetes. The study will involve completing study questionnaires There are no right or wrong answers. We simply want to know what you think and why you think it. We are interested in all feedback and opinions. This information will be used by the study investigators to improve My Diabetes Care and make it more useful to patients.

You are being asked to participate in this research study because you receive care at Vanderbilt University Medical Center (VUMC) or Brigham Women's Hospital (BWH) and have type 2 diabetes. The National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health has given VUMC a grant to improve the care of patients with diabetes. The project is led by Dr. William Martinez at VUMC, and Dr. Lipika Samal at BWH.

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 you can expect if you take part in this study:
The time it takes to participate may be inconvenient for some patients. 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. 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.

Good effects that might result from this study:
o The benefits to science and humankind that might result from this study.
The potential benefits from your participation will be helping the study investigators create tools to improve the health status of patients with diabetes.
o The benefits you might get from being in this study.
Using My Diabetes Care might improve your understanding of your diabetes health data and/or how to care for your diabetes.

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 patient portal, we will ask you to complete a study enrollment questionnaire. The enrollment questionnaire will ask you about your background. It 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 patient portal mobile app (Patient Gateway app or My Health at Vanderbilt 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'd like during the month. We will track how often you view MDC and what features you use.

At the end of 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 and take

about 20 minutes to complete.

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

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 happens if you choose to withdraw from study participation?
You can withdraw from the study at any time by contacting the study team listed on the consent form. 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 or Brigham and Women's Hospital.

Clinical Trials Registry:
A description of this clinical trial will be made 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 website at any time.

Privacy:
Any 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 research done on your deidentified information. This research may help us or other scientists learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
The study results will be made available at www.clinicaltrials.gov.