My Diabetes Care: A Pragmatic, Parallel-design, Randomized Controlled Trial

NCT05451914

Informed Consent Document

7/26/2024

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Institutional Review Board
Informed Consent Document for Research
Study Title: My Diabetes Care: A Pragmatic Randomized Controlled Trial
Version Date: 6/11/2024

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:
Vanderbilt University Medical Center (VUMC) in Nashville and Brigham and Women's Hospital (BWH) in Boston have similar patient portals. The patient portal at Vanderbilt is called My Health at Vanderbilt. The patient portal at BWH is called Patient Gateway.

The purpose of the study is to determine satisfaction with two versions of the patient portal. In addition, we will determine their effect on blood sugar control and knowledge and experience about diabetes. One version will be the currently available version of the patient portal at each site. The second version will be the currently available version of the patient portal at each site with an new feature added.

The new feature is called My Diabetes Care. My Diabetes Care displays patients' diabetes health data using graphics and easy to understand description. In addition, MDC provides diabetes self-care resources and supports diabetes self-care.

Since we do not know which version of the patient portal 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 patient portal at their site. Participants in the other group will be given access to a version of their patient portal with My Diabetes Care added.

The study will involve using the patient portal (My Health at Vanderbilt at VUMC or Patient Gateway at BWH), completing study questionnaires, and using mail-in home hemoglobin A1c test kits. To participate in the study, you must be willing to complete the hemoglobin A1c test kits at 4 timepoints throughout the study.

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 answering survey questiona and giving thier opinions. 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. Though all reasonable efforts will be made to ensure accurate data transmission and entry, there is a slight risk of incorrect home a1c test kit data being entered into your research record. 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. Mail-in home A1c test kits involve a finger stick to get four drops of blood for the test. Complications from finger sticks are rare but can include bruising or infection. You will be provided with detailed instructions to do this properly.

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 the patient portal, with or without My Diabetes Care, may improve your understanding of your diabetes health data and/or how you care for your diabetes.

Procedures to be followed and approximate duration of the study:
The study will last approximately 12 months. There are four parts to this study: enrollment/randomization, 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
Prior to being assigned to one of the two study groups (current patient portal or current patient portal plus My Diabetes Care), we will ask you to complete a baseline survey. The baseline survey will ask you about your background. It will also ask you about your knowledge, attitudes, and experiences with diabetes. This survey will be emailed to you and takes about 20 minutes to complete. You will also be sent a mail-in home A1c test kit and instructions. You will be asked to use the kit and mail it back in a postage paid envelope. It takes about 5 minutes to use the kit. In order to detect any improvement in A1 over time, only patients with an A1C value of 7.5 or above will be able to participate further.

Randomization
After we receive your completed baseline survey and A1c test kit result, you will be randomly assigned to one of the two study groups (current patient portal or current patient portal plus My Diabetes Care). You will receive an email with information about your assigned group.

3-Month, 6-Month, and 12-Month Follow-Up
At 3 months, 6 months, and 12 months after being ssigned to one of the two study groups, you will be asked to complete a survey and a mail-in home A1c test kit. You will be asked to use the kit and mail it back in a postage paid envelope. The surveys will be emailed to you at the right time. The surveys will ask you about your knowledge, attitudes, and experiences with diabetes and take about 20 minutes to complete.

We will track how you use the patient portal and My Diabetes Care over the study period. We will get information from your medical record about your health problems, medicines, and lab tests. We will use this information to make sure you are eligible to be in the study and to describe the medical history of the people in the study.

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 baseline questionnaire or baseline mail-in home A1c test kit. You may also be withdrawn from the study if your baseline A1c is below 7.5. 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.