COVER PAGE

Protocol title: Disease Management Platform for Heart Failure (DMP-HF)

NCT number: NCT04782973

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Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title: A novel disease management platform delivered via smartphone application for the management of patients with heart failure: pilot study

Principal Investigator: Pradeep Natarajan, MD MMSc

Site Principal Investigator:

Description of Subject Population: English-speaking adults aged 21 or older admitted to inpatient MGH cardiology step-down services with acute or chronic heart failure

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners (now known as Mass General Brigham, or MGB, but referred to as "Partners" for the purposes of the consent form) now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn about the impact of a digital disease management platform called AMAZE™ on the quality of life, outcomes, and treatment of patients admitted with heart failure for 60 days after they have been discharged from inpatient MGH cardiology step-down services.

How long will you take part in this research study?

If you decide to join this research study, you will use the AMAZE™ mobile application for approximately 60 days.

What will happen if you take part in this research study?

If you decide to join this research study, you will use the AMAZE™ application to monitor various aspects of your health for 60 days following discharge. These include symptoms, medication usage, activity, weight and blood pressure. A member of the study staff will call you after 30 and 60 days of being enrolled in the study to follow up about your health and usage of the app. You are not expected to attend any additional in-person appointments for this study.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include taking your medications as recommended, engaging in positive health behaviors like regular exercise, and improving your understanding of heart failure. Others with heart failure may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

The risks of the study are expected to be minimal. This study asks you to share your medical information on an app. There is the risk that someone who is not supposed to access your data will do so. The study staff will take every precaution to keep your information secure and all data will be stored in a password protected database.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?”

What other treatments or procedures are available for your condition?

This study involves adding a mobile health component to your care once you have been discharged following admission for heart failure. If you choose not to participate in the study, you will receive care as usual by your cardiologist.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Pradeep Natarajan, MD MMSc is the person in charge of this research study. You can call him at (617)726-9292 Monday through Friday 9am-5pm or email him at pnatarajan@mgh.harvard.edu.

If you have questions about the study, you can email the study team at preventioncenterstudy@mgh.harvard.edu or call one of the research coordinators listed below:

Sara Haidermota, (617)724-1240
Rachel Bernardo, (617)643-9133
Kim Lannery, (617)726-1256

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

Your rights as a research subject
Your concerns about the research
A complaint about the research
Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

We are doing this research study to assess whether AMAZE™, a smartphone-based application, can help heart failure patients take better care of themselves after they have been discharged from MGH after an inpatient stay for heart failure. AMAZE™ is a disease management platform designed to educate patients about heart failure, help them engage in healthy behaviors, and take their medications as prescribed. Patients will also be able to use the application to communicate with their healthcare team and a Nurse Navigator.

We would like to test whether the AMAZE™ application can improve the quality of life and medical care of patients admitted with heart failure within 60 days of being discharged. We will also explore whether use of the application leads to a reduction in hospital readmissions, emergency department and urgent care presentations, and ambulatory care visits.

This study is being designed and conducted by research staff at Massachusetts General Hospital. This study is being financially supported by AstraZeneca and in sections below, "the sponsor" is referring to AstraZeneca.

Who will take part in this research?

We plan to enroll 70 patients who are 21 years and older with a diagnosis of heart failure admitted to MGH cardiology services. We are asking you to participate in this study because you have been admitted to MGH cardiology step-down services for heart failure and will be following up with a cardiologist at MGH. We hope that this app will help educate you about heart failure and the steps you can take at home to manage your diagnosis.

In order to participate in the study, you must own a smartphone and be willing to enter health information into the AMAZE™ application. You must also have established plans to follow up with either a primary or heart failure cardiologist at MGH.

You will not be eligible to take part in the study if you will be discharged to a transitional or long-term care facility.

What will happen in this research study?

In this study, we are examining the impact of the AMAZE™ app on your health and heart failure. We will bring parts of your health record in Epic into the application, including your medical history, prescribed medications, and your Mass General Brigham/Partners healthcare appointments.

If you choose to participate in this study, a member of the study staff will help you set up an AMAZE™ account. If we are unable to consent and/or onboard you to the study while you are in the hospital, we can schedule a time to do so remotely over Zoom once you have been discharged. A blood pressure cuff and scale will be provided to you along with instructions on how to use them.

For the duration of the study, you will use the application to do the following:

- View healthcare appointments
- Complete a daily log of symptoms, medications, and activity
- Use the provided devices to measure weight, blood pressure, and heart rate to input into the app
- Complete a quality of life questionnaire three different times during the study
- Send and receive messages with your care team as needed (the messaging system is not monitored by clinical staff in real time and is not intended for emergency use.)
- Learn more about heart failure (causes, diagnosis, management)
- Complete a survey about using the app at the end of the study

At 30- and 60-days following discharge, a member of the study staff will call you to follow up with you. We will ask you about:

- Prescribed medications
- Presentations to urgent care clinics or emergency departments
- Hospital admissions

During the study, a Nurse Navigator will contact you weekly via telephone, video call, or the AMAZE™ app. The Nurse Navigator is an MGH staff nurse that will partner with you to set heart healthy goals, provide clinical support and assist with heart failure related education and questions.

While it is acceptable for a family member or relative to help you navigate the app, AMAZE™ is intended for your personal use and for your individual health information. Additionally, the app contains an option to contact the developer for technical support if needed. The study staff will show you how to do this.

With your consent, we will conduct additional interviews to collect information from you about your experience with the app. These optional interviews will focus on your interaction with different features within the app and your overall satisfaction with the platform, and will be conducted at one or both of the following time-points:

After about 30 days of using the app
After about 60 days of using the app

Participation in these interviews is optional and does not affect your participation in the study. If you change your mind, please let the study staff know and we will make sure not to contact you for the purpose of these interviews.

Would you like to be contacted for these optional interviews?

YES NO Initial _____

When creating an account in AMAZE™, you will be asked to review and accept the Patient App Terms of Use and the AMAZE™ Privacy Policy. AstraZeneca UK Limited and BrightInsight, Inc., the owners of AMAZE™, will disclaim the Patient App Terms of Use and the AMAZE™ Privacy Policy, so they will not apply to a user of the app who is enrolled in this research study for purposes of the research.

AstraZeneca UK Limited and BrightInsight, Inc. own the AMAZE™ application. As with most software, you are being given a license to use the AMAZE™ application with certain restrictions.
You will have the right to use the AMAZE™ application only during the study.
You will have the right to use the AMAZE™ application only for the study and for no other purpose.
You agree not to take apart, modify, or make changes to the AMAZE™ application.
You must not do anything else with it other than use it for its intended purpose (which is to collect information from you as part of the study).
AstraZeneca, BrightInsight, and the AMAZE™ application do not provide medical advice or treatment. AstraZeneca UK Limited and BrightInsight, Inc. are not your medical provider.
The AMAZE™ application does not replace the advice of a medical professional.
AstraZeneca and BrightInsight will have access to and use of your information. AstraZeneca and BrightInsight agree to keep identifying information about you confidential and to comply with all applicable laws regarding your privacy.
You agree to get in touch with the study doctor with questions or concerns about your medical care or treatment which is part of the study.
If you have an inquiry regarding the functionality of the AMAZE™ app, you may contact BrightInsight by e-mail at amaze.support@brightinsight.com

Contacting You
You will be asked to provide your contact information (telephone number and email address.) A Nurse Navigator will contact you by telephone or video call as needed for the duration of the study. A member of the study staff will contact you to ask follow-up questions at 30- and 60-days following discharge.

Partners Alert System
Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department.

Study Information Included in Your Electronic Medical Record
A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use this de-identified data in other research. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

At the completion of this research study, we would like to store and be able to use and share your identifiable health information with researchers at Partners for other research related to heart failure. If we share your health information with other researchers outside of Partners, we will label the information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your information. We will keep the code in a password-protected computer.

Because this health information is identifiable, we are asking your permission to store, use and share it for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of your health information for other research.

Do you agree to let us store and use your health information for other research related to heart failure?

YES NO Initial _____

What are the risks and possible discomforts from being in this research study?

The risks of the study are expected to be minimal. There is the risk that someone who is not supposed to access your data will do so. The study team will make every reasonable effort to keep your data safe and protect the confidentiality of your data. This includes storing your data in a secure system. However, total confidentiality cannot be guaranteed. It is possible that there could be unauthorized access to or a breach of the systems where your data is stored.

A discomfort in this study is a loss of privacy, since more people will view your personal health information, including the study team and the company who made the app, BrightInsight, Inc.

What data are being collected in this study?

A company called BrightInsight, Inc. (BI) is making the AMAZE™ app and will have access to all the data within it. The app will contain information that you enter into it and specific data that is added from your medical record.

AstraZeneca will only receive your information attached to a unique Study ID. AstraZeneca will not try to identify you or any individual participating in the study.

The information that is pulled from your medical record into the AMAZE™ app that BI will NOT share with AstraZeneca includes:

- Your name and medical record number
- Your date of birth
- Your contact information (email address and phone number)

The information that is pulled from your medical record into the AMAZE™ app that BI WILL share with AstraZeneca includes:

- Your age and gender
- State and zip code of residence
- Medical history
- Laboratory results
- Details of prescribed medications
- Details of clinical appointments, ER visits, and hospitalizations
- Details about your provider and care team

BI will share the information that you enter into the AMAZE™ app and how much you use the app with AstraZeneca. This data includes:

- Daily symptoms and overall health
- Activity levels
- Medication usage and adherence
- Your weight, heart rate, and blood pressure
- Your responses to the quality of life and app usability questionnaires
- ER and/or urgent care visits, if any
- Your smartphone information, including model, operating system, app version
- How you use the app, including the daily log, educational resources, and in-app messaging with your care team (without sharing the content of the messages with the sponsor)

The MGH study staff will collect information from your medical record at the time of enrollment and directly from you 30 and 60 days after you have been discharged. We will share a summary of this data with AstraZeneca. The information gathered by the study staff may also be included in publications, but you will not be identified in any articles about the study by any protected personal information. This data includes:

- Details of your hospital, ED, urgent care, or physician visits
- Enrollment in a cardiac rehabilitation program
- Your adherence to prescribed medications

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include taking your medications as recommended, engaging in positive health behaviors like regular exercise, and improving your understanding of heart failure. Others with heart failure may benefit in the future from what we learn in this study.

What other treatments or procedures are available for your condition?

This study involves adding a health app to your care once you have been discharged from the hospital after being admitted for heart failure. If you choose not to participate in the study, you will receive care as usual by your cardiologist.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will not be paid to take part in this research study. We may use your information to develop a new product or medical test to be sold. AstraZeneca, the hospital, and researchers may benefit if this happens. There are no plans to pay you if your information is used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

You will not have to pay for the home scales or blood pressure cuff if either or both are provided to you. When using the AMAZE™ application, if you are not connected to Wi-Fi and use data to run the application without having an unlimited data plan, there may be costs associated with this usage. These costs are expected to be minimal, but a member of the study team can show you

how to update your settings so that the application only runs when your smartphone is connected to Wi-Fi.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

Past, present, and future medical records

Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

Partners researchers and staff involved in this study

The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research

Other researchers and medical centers that are part of this study

The Partners ethics board or an ethics board outside Partners that oversees the research

A group that oversees the data (study information) and safety of this study

Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)

People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers

Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records

Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

Other: The app developer, BrightInsight, Inc., will have access to the identifying health information that you enter into the app for business purposes.

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

I have read this consent form.
This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
I have had the opportunity to ask questions.
I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

I have explained the research to the study subject.
I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent Date Time (optional)

Consent Form Version: June 17, 2021