A Mobile Relational Agent to Enhance Atrial Fibrillation Self-Care

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University of Pittsburgh
School of Medicine
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Consent to Be a Research Subject

Title: A Mobile Relational Agent to Enhance Atrial Fibrillation Self-care

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Key Information

- You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.
- Summary of the Research ○ Purpose of the research: The overall purpose of this study is to see if we can improve how people live with A fib.
  - There are 4 study visits in total. These are at the start and then 4, 8 and 12 months later.
  - People in this study get a smartphone that they use every day for 4 months.
  - You are asked questions at each of the visits about how you are doing.
- There are no risks to your health from using a smartphone.
- You may benefit by being in this study as you can learn more about A fib. You may also feel like you have more control of your health. You will receive $150 for participating.
- If you decide not to participate, your other choices may include ○ Getting treatment or care for A fib without being in a study. ○ Taking part in another study. ○ Not getting any treatment.

Introduction

You are being asked to be in a research study. We want to tell you some things before you decide to be part of the study. This process is called informed consent. It is a chance to learn about the study and ask questions. Before making your decision:

- Please read this form or have it read to you
- Please ask questions about anything that is not clear

You will receive a copy of this paper to keep. Feel free to take your time thinking about whether you would like to participate.

By signing this form, you don't give up any legal rights. You can decide at any point to be in the study or not. You can also change your mind later and decide not to be in this study. How you decide now or later won't affect your care at UPMC.

Study Overview

You are being asked to be part of this study because you have atrial fibrillation, also known as "A fib" or AF.

A fib is a heartbeat that is not regular. It can cause many problems, like a stroke. Many people take blood thinners to help stop a stroke when they have A fib. They might also have symptoms from their A fib. The overall purpose of this study is to see if we can improve how people live with A fib.

People who join this study will have 4 separate visits with the research team. The first visit will be at the start. The visits will then be every 4 months. People will have visit at the start and then at 4, 8 and 12 months after the start. Everyone in this study will receive a mobile phone with a screen on it. This kind of phone is called a smartphone. If you have a smartphone, you can decide to use that phone as part of this study.

People who participate will be in 1 of 2 groups. The investigators do not decide who goes to which group. They let a computer decide who goes to which group instead, so that it is random (like flipping a coin). Everyone in this study will receive a mobile phone with a screen on it. This kind of phone is called a smartphone. If you have a smartphone, you can decide to use that phone as part of this study.

The first group will have a session on A fib and get a brochure that talks about A fib and how to stop a stroke. This group will receive a phone and instructions on how to use it. There will be a program called WebMD on the phone. WebMD can record when you take your medicines and help you look up information. The study team will ask you to use WebMD every day.

The other group will have a different program on their phone for managing A Fib. This group will also use a device to check their heartbeat for 30 seconds at a time. The information from the phone is being stored by our partners at Northeastern University in Boston, MA, who will not know who you are. Everyone in the study will be asked to use their phone and its applications at least once each day.

If there is something that could affect your health, like a fast heartbeat that could be dangerous for you, the study team will tell your doctors. That way, your doctors can respond to important findings or information. Your doctors might not have known this information if you were not part of this study, and by our telling them they can then respond. You should know that when the

study team talks to your doctors, however, that communication can become part of your medical record as a result. This is similar to how calling your doctor becomes part of your medical record.

You need to keep in mind that the phone program does not take the place of your regular medical care. If you think you are having an emergency, call 911. You need to seek care and help for medical problems if you have an emergency, just as you would if you were not part of this study.

Everyone will have an interview and then follow up at 4, 8, and 12 months later. Here is what will happen:

- The research person will ask you questions about A fib, your medical history, and your background.
- You will receive periodic check-in calls from study staff during the first 4 months.
- At 4 months, you will come back for the second visit. The research person will again ask you some questions. You will give back the phone at this visit. If you can't attend the visit at 4 months, we will provide you with a package to send us back the phone.
- At 8 and 12 months, you will have visits by phone. The person calling you will be from the study and will not know what group of the study you are in.
- The research team will look at your medical record and what happens to you over the 12 months.
- The research team will ask for your signed permission to get information about your medications from your pharmacy over the 12 months.

In the event that we are unable to contact you during the study period, we would like your permission to contact your caregiver and/or emergency contact.

Risks and Discomforts

The big risk in being part of this study is that other people might learn that you are taking part in a research study. We will do everything we can to protect your privacy and to keep your records private and confidential. To protect your privacy, we will keep all information in a secure location. All paper records will be stored in cabinets behind two locked doors. Records on computers will have special passwords so that only the study team can see them. Also, you will never be identified in any way in any presentation or report of this research study.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. We also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government

agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

We may release information about you when you say it is okay. For example, you may give us permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Use of Medical Record Information

We are asking for your permission to review your medical records over the course of the study. We will look at your diagnosis, age, past medical history, procedures, and results of medical tests. We will also ask you to sign a copy of an "*Authorization for Release of Protected Health Information"* in case you have a clinic or hospital visit at a non-UPMC center/hospital during the study period. Your medical information and information obtained during this study may be shared with other groups, like the University of Pittsburgh Research Conduct and Compliance Office for study monitoring.

We will also ask you to sign two copies of an "*Authorization to Use and Disclose (Release) Health Information*" form so that we can contact your pharmacy to get information about medicines that you take.

Putting our study on the web site ClinicalTrials.gov

A description of this clinical trial will be available on a website for clinical trials, http://www.ClinicalTrials.gov, as required by U.S. law. 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.

Protecting your confidentiality

We will make every attempt to protect your privacy and the confidentiality of your records, but we cannot guarantee confidentiality if your personal information is disclosed to others outside UPMC or the University.

This identifiable medical record information will be made available to members of the research team for an indefinite period of time. We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

Benefits

People in this study may benefit from participating. People in both groups may learn more about A fib and how to care for themselves with this condition. In addition to the payments explained below, you might benefit from having your A fib more closely monitored than you would if you weren't in the study.

Costs and Payments

You or your insurance provider won't be charged for the costs of this research study. You will be charged for standard medical care that you receive even if you did not participate in this study.

People in this study will be paid $25 for the first visit, $50 for the second visit at 4 months. We will provide the second payment when we get back the phone. You will be paid $25 for the visit at 8 months and then $50 for the final visit at 12 months. This will total $150.

Also, you can use the phone for 4 months. You need to know that the phone is not set up with an account to pay for extra things and that we will ask you to return it after 4 months.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered.

I understand that I am encouraged to ask questions about any aspect of this research study. I may have questions in the future and those will also be answered.

I understand that my questions, concerns, or complaints will be addressed by the people who are doing this study.

I understand that I can contact the University of Pittsburgh's Human Research Protection Office to discuss problems, concerns, and questions, obtain information, offer input, or discuss situations.

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

A copy of this consent form will be given to me.

_____ _____ _____

Participant's Printed Name Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered. We will always be available to address future questions, concerns, or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Signature of Person Obtaining Consent

_____ _____

Role in Research Study Date