Atrial Fibrillation Health Literacy and Information Technology Trial in Rural PA
NCT04076020
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Consent to Be a Research Subject

Title: Mobile Health Intervention for Rural Atrial Fibrillation

Principal Investigator: **Jared Magnani, MD, MSc**
3609 Forbes Avenue
Pittsburgh, PA 15213
Tel: (412) 383-0611

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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 either 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 also 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 heart beat for 30 seconds at a time. Sometimes it might be important to let your doctors know about a problem that you report to the program. 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.

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.

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.

If, at any point in the study, you wish to withdraw we will remind you that you can also withdraw your consent for the study team to access your medical records by asking the following: As a reminder, our study intends to follow your medical and pharmacy records from the date of your enrollment, to exactly 12-months later. With your withdrawal from our study, would you also like to withdraw the consent you previously gave us to access those medical and pharmacy records? Or do you still consent to us accessing them up until the 12-month date?

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 authorization will never expire. You need to know that you can always stop giving permission to let us review your records. You just need to send a note that you write. If you do that, you will no longer be able to participate in this study. The research team will use information up to that point only.

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

Date