Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAU2028
Principal Investigator: Meghan Turchioe (mr3554)
IRB Protocol Title: Data-driven shared decision-making to reduce symptom burden in atrial fibrillation

General Information

Consent Number: CF-AACX4300
Participation Duration: 3 months
Anticipated Number of Subjects: 75

Research Purpose: The purpose of this study is to test whether viewing a decision aid helps you decide whether or not having a catheter ablation to treat atrial fibrillation is right for you. A decision aid is a tool, such as a website, that explains information about treatment options, pros and cons of each option, and things to consider while you are making the decision.

Contacts

Contact	Title	Contact Information
Meghan Turchioe	Principal Investigator	Phone: 212-305-1557 Cell: 862-268-5168 Email: mr3554@cumc.columbia.edu
David Slotwiner	Other Engaged Personnel	Email: djs2001@med.cornell.edu

Information on Research

Introduction

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;

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- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The principal investigator (the lead researcher for this project) or a research assistant will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

The purpose of this research is described below in the 'What is Involved in This Study?' section of this consent form.

Why is this study being done?

Study purpose

We are doing this research study to find out whether viewing a decision aid helps you decide whether or not having a catheter ablation to treat atrial fibrillation is right for you. A decision aid is a tool, such as a website, that explains information about treatment options, pros and cons of each option, and things to consider while you are making the decision.

You are being asked to take part in this study because you are scheduled to have a visit with a doctor to discuss whether or not to have a catheter ablation. About 75 people are expected to be enrolled in this study across all sites. This include New York-Presbyterian Columbia University Irving Medical Center and New York-Presbyterian- Queens sites.

What will I be asked to do if I choose to be in this study?

This study will last three months.

We will send you the hyperlink to a website where you can view the atrial fibrillation decision aid. We will ask you to view the decision aid at least once. We will also ask you to complete surveys at four different times over a three-month period of time. You may be asked to complete 3-5 surveys each time. You will be able to complete the surveys online in a time and place that is convenient for you. We will email you a link to the surveys when it is time to complete them. We will follow up by email or telephone if you do not complete surveys within one week of receiving the email to remind you to complete them and help you if you are having technical difficulties.

At the end of the study (after three months), we will also follow up by email or telephone to schedule a brief interview with you to learn about your experiences using the decision aid and whether you think it helped you. We will make an audio recording of the interview. The interview is not expected to last more than 30 minutes.

As part of your participation in this study we will review your medical records and may extract information about your care from them.

Use of Data

We would like to store the data that you agreed to provide as part of this study and possibly use them for future

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research. They will be stored at CUMC either with the researchers on this study or in a central storage facility called a repository.

With your permission, your data will be stored at CUMC indefinitely in identifiable form. Your data will be labeled with a code number that the researchers on this study or the people managing the repository will be able to link to you.

Also with your permission, your data may be used by other Columbia researchers or researchers at other institutions, including commercial companies, for research on your medical condition or other conditions. If they are given to researchers who are not researchers on this study, they will only be given in deidentified form. This means that your name and other identifying information have been permanently removed from your data.

Any future testing or research using your data may lead to the development and use of information, products, tests and treatments having commercial value. You will not receive any compensation that may result from these tests or treatments.

You can change your mind regarding storage and future use of your samples at any time. Please see the Contact section of the consent form for further information.

Benefits

Are there benefits to taking part in this study?

You may or may not receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this study include having a better understanding of atrial fibrillation, and feeling more satisfied with your decision about whether to have a catheter ablation or not. In addition, the information collected from this research may help others in the future.

Compensation

Will I get compensated?

You will receive $50 when you enroll in the study. You will receive another $50 when you complete the study, including the follow-up surveys and exit interview.

Risks

Are there any risks?

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We do not think that there are any significant risks to taking part in this study.

Loss of confidentiality
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Privacy section of this consent form.

Confidentiality

What about confidentiality?

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your questionnaire and interview responses will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in an encrypted data file and only the investigator and study staff will have access to the file.

The following individuals and/or agencies will be able to look at and copy your research records:
- The investigator, Columbia University Medical Center study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University, including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP')
- If this study is sponsored (money or supplies are being provided), the sponsor of this study, the National Institute of Nursing Research ('NINR') of the National Institutes of Health ('NIH'), including persons or organizations working with or owned by the sponsor
- Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.

Additional Costs

What are the costs?

There are no costs to you for taking part in this study.

Alternative Procedures

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What other options are there?

You may choose not to take part in this research study. You are still able to consult with a doctor and other healthcare professionals about whether or not to have a catheter ablation regardless of whether you decide to take part in this study.

Voluntary Participation

Do I have to be in the study?

Voluntary participation

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and NewYork-Presbyterian Hospital.

Statement of Consent

Statement of consent and HIPAA Authorization

I have read the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.

Signatures

Participant Signature Lines

Study Participant

Print Name _____ Signature _____

Date _____

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Research Signature Lines

Person Obtaining Consent

Print Name _____ Signature _____

Date _____

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