UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Enhancing the Engagement in Shared Decision Making for Stroke Prevention among Older Adults with Atrial Fibrillation and Multiple Chronic Conditions

Protocol Number: H00019104

Sponsor: UMass Chan CCTS/National Institute of Health

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Consent Version: v1.0_11.15.2024

KEY INFORMATION

You are being invited to take part in a research study. A member of our research team will explain this research to you. This form helps to summarize the explanation.

You are being invited to participate in a research study because you meet one of the following criteria: (1) you have a diagnosis of atrial fibrillation or atrial flutter, which is an

abnormal or rapid heart rate that commonly leads to poor blood flow; and also have 2 or more medical conditions for which you see a clinical provider (2) you may have been recommended to use an anticoagulant (or blood thinner) in the past year but are not currently taking one, or (3) you may have been prescribed an anticoagulant within the past 30 days but did not take an anticoagulant in the 12 months before you started taking an anticoagulant, or (4) you may have been recommended to have a left atrial appendage occlusion device (watchman's device) inserted to prevent you from having a stroke and you currently have the device inserted or do not have the device inserted in your heart.

If you have any questions or do not understand any part of the information provided, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main purpose of this study is to understand the experiences of patients, their primary caregivers, and clinicians in engaging in shared decision making for stroke prevention among older adults with atrial fibrillation or flutter; and how to improve this current process of decision making.

If you join this research, you will participate in virtual/remove interview on zoom and will be asked to complete an anonymous survey.

As part of the study, the research team will continue to collect information from your medical records up to 3 years after enrolling all patients in our study.

You may not want to be in this study if you are uncomfortable with:

- Sharing your private information with researchers
- Talking about your experience with stroke prevention and managing your other chronic medical conditions

Risks: The study team takes many steps to prevent this and protect your personal information. However, there is a possibility that your personal information may be lost or stolen with a risk of breach of confidentiality. There may also be risks that we do not know yet.

Benefits: There may be no direct benefits to the participant. The potential benefits to you from study participation include learning to engage in share decision making for managing your chronic conditions, specifically in regard to stroke prevention, and learning to discuss your priorities and preferences for managing your health.

Alternatives: Your alternative is to not take part in the research.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

Patient Consent Document

Why is this research being done?

The purpose of this research is to improve the process of engaging in shared decision making for stroke prevention among older adults, their primary caregivers, and their clinicians. We would like to learn about the important factors such as your values, preferences, priorities, goals, knowledge, attitude, practices, barriers, and facilitators that may influence engagement in stroke prevention decision making. We hope to adopt an existing approach called the "patients priorities care model", as a means of improving the engagement in the process of shared decision making for stroke prevention for older adults. This model considers your priorities, preferences, goals of care, the complexity of managing your multiple chronic conditions, while also considering the concerns and worries of your primary caregiver.

How many people will take part in this research?

About 20 people (10 patients, 5 caregivers, and 5 clinicians) will take part at UMass Chan Medical School. About another 20 people will take part from the University of Florida (10 patients, 5 caregivers, and 5 clinicians). A total of about 40 people will participate nationwide.

How long will I be in this research?

The time from study enrollment to the end of the study is approximately two years.

The study team may access your medical information up to 3 years after the time of enrollment.

What happens if I say yes, I want to be in this research?

Study staff will obtain consent and authorization to participate. Once you are reached via phone call, we will offer options to you to be contacted via text or e-mail if preferable. Communication by text or email are not secure, but we can still use them if you prefer to be reached that way.

In the first part of this study, you will be asked to attend a virtual/remote interview (through zoom) which can be done at the time of study enrollment or will be scheduled at a time convenient for you within a month of enrolling in the study. The interview will last about 60 minutes. During the interview, you will be asked questions to explore what matters most to you as a person, including their values, preferences, and concerns about your multiple health conditions. We will ask you identify a specific, realistic, and actionable goal related to stroke prevention, clarify symptoms or conditions that interfere with your goal, and discuss trade-offs (e.g., accepting minor bleeding risks from anticoagulation to prevent a stroke) necessary for your prioritized decisions. Also, we will inquire about your knowledge, attitudes, practices, barriers, and facilitators that may impact engagement in the decision-making process, adoption, and long-term use of stroke prevention strategies (including anticoagulation or watchman device if applicable). We will seek your ideas for overcoming challenges to engaging in stroke prevention decision making to inform the development of a patient-centered care intervention. At the end of each interview, you will complete a short survey to gather your sociodemographic information (name, date of birth, sex, race/ethnicity, religion, education level).

The interview will be audio-recorded and transcribed for research purposes only. The audio recording will be transcribed within 48 hours of the interview being conducted. The audio recording will be deleted after the transcript is reviewed for accuracy.

If you are randomly selected to participate in the second part of this study, you will be contacted after about 6 months of enrolling into the study. During this stage, you will be asked to join us in refining and adapting the patient priorities care model to meet the needs of patients, caregivers, and clinicians when engaging in stroke prevention discussion. During the refinement process, we will contact you twice:

- First to provide support by providing educational materials explaining the patient priorities care framework and how it can enhance the decision-making process for stroke prevention with your clinician. We will also have a practice session, via phone or videoconference, to provide strategies for communicating with your clinician based on your identified healthcare priorities, preferences, and goals of care.

- Second, you will be contacted to participate in a focus group session comprising patients, caregivers, and clinicians to enable us to explore your perspectives on the perceived benefits of identifying your priorities as an older adult living and dealing with multiple chronic conditions. We will also assess your motivation to use the "patient priorities care" in managing your health and discussing about stroke prevention, and identify the resources and actions needed to successfully implement this care model for all patients with multiple chronic conditions. We will ensure that you feel comfortable sharing your experiences in a supportive and safe environment.

In the third part of this study, we will conduct a pilot trial to enable us to test the use of the adapted patient priorities care model as a means of improving engagement in shared decision-making for stroke prevention. We will contact patients and their caregivers once for a facilitation encounter using the patient priorities model and preparing them for their regular clinic visit with their provider. We will follow up the patient and their caregiver in three months by phone calls, messages via text and patient portal, and emails to complete follow-up surveys. For up to 3 years following enrollment into the study, a study staff member may review your medical charts for information related to this study.

You may also contact study staff at any time with any technology issues or other concerns with the study by calling [508-441-3562 ext. 6] or sending an email to [DIV.KL2@umassmed.edu].

The table below provides a summary of the activities involved in this study.

Activity	**Description**	**Duration (minutes)**	**When**
Recruitment	• Decide about giving consent and schedule interview	5	First call
First part: Virtual Interview	• Participate in one-on-one interview with a research personnel member through video/zoom	60	To be conducted within a month of study enrollment

Second part A: Practice Session	• If you are randomly selected, you will participate in a practice session through phone or videoconference to provide strategies to communicate with your clinician based on your identified healthcare priorities, preferences, and goals of care	30	Within six months after your initial enrollment
Second part B: Focus group session	• Participate in a focus group session to elaborate on how best to use the patient priorities framework in managing your health	60	Within 12 months of study enrollment
Third part A: Facilitation encounter	• A study member will conduct patient priorities identification assessments with the patient and their primary caregiver. This encounter will take place 1-2 weeks before the patient's clinic visit with their provider to discuss stroke prevention and will be conducted via video conference	20	Within a month of enrolment into pilot phase of the study
Third part B: Regular clinic visit	• Patients and their caregiver will have follow-up visit in clinic with their provider and engage in decision making for stroke prevention using the patient priorities approach	10	Within 2 months of enrollment in the pilot study phase
Third part C: Follow up survey	• Follow up calls will be made after three months of being in the pilot study to assess study outcomes	60	3 months after pilot study enrollment

Will you be collecting any specimens from me?

No, there will be no type of body specimen collection in this study.

Could being in this research hurt me?

There are no known risks to your physical health from participating in this study. Discussing your priorities, values, and health outcome goals could potentially raise difficult emotions regarding your overall wellbeing as a person. Additionally, the exit interview will take some time to schedule and complete and may be uncomfortable if talking about your experience with stroke prevention or identifying your values, healthcare priorities, preferences, and goals brings up

difficult emotions. You may choose not to discuss any topic which may be uncomfortable for you without any penalty, including no loss of stipend.

There are potential risks associated with data collection and information management. These include inadvertent disclosure of research data collected. There is a slight risk that research records (data collection forms, interview notes and electronic data) might be obtained by persons not authorized to do so. There is a slight risk that research data files might be compromised and obtained or viewed by unauthorized persons. Every effort will be made to inform the subject of this potential and minimize the risks. All efforts will be made to minimize risks. Should any breach of confidentiality occur, you will be notified.

As researchers, we have a responsibility to protect participants and others from physical and/or psychological distress. If the researcher believes there is imminent danger to you or someone else, or there is a concern about your safety, they will stop the study interview and contact emergency services and/or an appropriately trained clinician.

In this scenario, the clinician may make your primary care providers aware of the safety issue so that they can follow up with you.

Will it cost me any money to take part in this research?

The virtual/remote video interview will be performed using Zoom. It can be used free of charge when your smartphone, or other device, is connected to Wi-Fi. You are responsible for any costs from your service provider related to video/talk/text/data usage if you choose to use Zoom while not connected to Wi-Fi.

If you choose to interact with the research study team via text message, you are responsible for any costs from your service provider related to talk/text/data usage.

Will I be given any money or other compensation for being in this study?

- If you participate in the first part of this study, after completing the one-on-one interview, you will be paid $50.
- If you are randomly selected to participate in the second part of this study and you complete the focus group session, you will be paid $50.

Those who participate in the pilot phase of this study including the facilitation encounter, attend their clinic visit, and complete the three-month follow-up survey, will be paid $100.

In order to receive a stipend for study participation, you will need to give us private information like your name, address and phone number. We will store this information in a secure place only accessible to study staff. We will share this information only with the business offices and companies that need it to process the payment. No identifying information will be used in publications. You will need to provide your social security number and complete a W-9 (tax form) if you receive:

- $300 or more from a single study within a single calendar year at UMass Chan, or
- $600 or more in a calendar year across multiple research studies at UMass Chan.

The Medical School may report the payment to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial records. The research team will destroy this information within 3 years after collection.

Will being in this research help me in any way?

The benefits of being in this study may include learning more about your heart condition, Atrial Fibrillation in addition to your multimorbidity. Also, you will learn more about your decision making for stroke prevention to ensure you are guided by your own priorities and health goals. Your being in this study will also help caregivers and clinicians information on how to aid in the decision making for patents own care.

What other choices do I have besides taking part in this research?

If you choose to not participate in this study, this will not impact the care you receive. You have the choice of opting out of participation in the study.

What happens if I am injured because I took part in this research?

It is unlikely that you may get injured due to participating in the study. However, if you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The UMass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by verbally agreeing to participate.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- In the first part of the study, attend the video interview via Zoom
- If you are randomly selected to the second part of the study, participate in the practice session and focus group session
- If you are enrolled in the pilot study, attend the facilitation encounter with a research staff, your regular clinic visit with your provider, and the three-month follow up survey
- Follow the directions of the study doctor and research staff.

- Tell your study doctor and staff about all prescriptions, over the counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues.

What happens if I say yes, but I change my mind later?

Your participation is voluntary. You can choose not to participate, or to stop your participation at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled

If you decide to leave this research, contact the research team so that the investigator can document this and remove you from the study. If you decide to stop, we may ask if we can contact you for safety reasons or to learn why you changed your mind.

If you change your mind, your data will be removed from this study, up to and until the point where removing the data would not seriously impair the research or render it impossible. For example, if the findings of this research are already published, it may not be possible to delete the data or remove it from the analyses.

Can I be removed from the research without my approval?

Your participation in the study is voluntary. If you agree to participate, you are still free to withdraw your consent at any time without giving any reason. Additionally, your participation in the study may be stopped for reasons such as:

- You do not follow the study doctor's instructions
- You become pregnant (for female study participants only)
- Something serious happens to you which may require treatment
- The study doctor decides it is in the best interest of your health and welfare to discontinue
- The research is canceled by UMass and its study doctors

What other choices do I have besides taking part in this research?

Participation in this study is voluntary, and you have the right to decline or withdraw at any time. Alternatives to not participating in this research study should be discussed with your primary care physician.

How will my information be stored and when will it be destroyed?

For electronic data, we will remove your name and any other information that could directly identify you. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data. We will keep electronic health information and research data on secure computer networks.

These computer networks have many levels of protection.

We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the master list of identifiers 3 years after the study is completed.

It is possible that we might use the research data in other future research. We may also share data with researchers that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

If applicable, a description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Who has access to my information?

Consenting to join this study means you allow us, the researchers in this study, and others working with us to use and share some protected health information about you for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Hospital/doctor's office records, including test results and dental records
- Any records relating to condition, the intervention received, and response to the intervention
- Related medical information like family medical history, and current and past medications or therapies

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers and people who work with UMass Chan and UMMH on activities related to the research may need the information to make sure you can take part in the study and to conduct the study.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner. This may include:
    - The Institutional Review Board (IRB) that reviewed this research
    - The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, and compliance offices.

- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Analyze the results of the study

A copy of this consent and authorization may be placed in your UMass Memorial medical record. If you do not have a UMass Memorial medical record, one may be created for you.

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy.

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data. These individuals have been trained to protect confidentiality.

Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed in order to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

You will not be asked to sign this authorization, instead we will request your verbal authorization. If you do not verbally agree to the authorization, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Certificate of Confidentiality

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding.

Identifiable sensitive information includes specimens gathered during the research if there is a small risk of being able to identify you from those specimens, if they are combined with other information.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and

Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

What Will Happen With My Information Used in this Study?

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

Who can I talk to?

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness.
- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

Contact study staff with any questions or concerns. Their **telephone number** is printed in the contact section of this form. If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

You want to get information or provide input about this research.