UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title:

Title: Association of Health Belief Variables, Religiosity, and Spirituality with Anticoagulation Use in Older Adults with Atrial Fibrillation

Protocol Number: H00019104

Sponsor: /National Institute of Health

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Daytime Phone Number: 508-441-3562 ext. 5

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.

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You are being invited to participate in a research study because our records indicate you are 65 years or older, have a diagnosis of atrial fibrillation or atrial flutter, and have a combination of factors (including your age and health conditions) where your stroke risk is sufficiently high that you would typically be eligible for stroke prevention using an oral anticoagulant (or blood thinner) or a procedure to close your left atrial appendage (using a Watchman device or other method) .

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 factors that may influence the use of anticoagulation (blood thinner medication) for stroke prevention among older adults with atrial fibrillation or flutter. We will be examining factors such as trust in physicians, risk perception, religious/spiritual beliefs and practices that may affect the use of anticoagulation. **If you join this research,** you will participate in virtual/remove interview on telephone or web conferencing software and will be asked to complete a survey.

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 for older adults with atrial fibrillation

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 about important factors that play a role in deciding to use anticoagulation for stroke prevention.

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

Why is this research being done?

The purpose of this research is to understand the factors influencing anticoagulation use for stroke prevention among older adults with atrial fibrillation or flutter. We aim to examine the role of trust in physicians, risk perception, and religious or spiritual beliefs in shaping medication decisions to improve anticoagulation use and health outcomes in a diverse population of older adults.

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How many people will take part in this research?

About 100 people will take part at UMass Chan Medical School. About another 100 people will take part from the University of Florida. A total of about 200 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.

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 is not secure, but we can still use them if you prefer to be reached that way.

In the this study, you will be asked to complete a 21-item questionnaire 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. This questionnaire will gather information about your understanding of stroke risk, your trust in healthcare providers, and your beliefs about the effectiveness of anticoagulation medication for stroke prevention. Additionally, you will be asked about your religious and spiritual beliefs, including the role of religion and spirituality in your life and their influence on your health-related decisions. This interview will last about 30 minutes.

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. 5**, or emailing **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
Questionnaire	• You will be asked to complete a questionnaire about your understanding of the risk of having a stroke, your trust in doctors, and your belief in the effectiveness of anticoagulation.	30	To be conducted within a month of study enrollment

Will you be collecting any specimens from me?

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

Will being in this research help me in any way?

There may be no direct benefits to the participant. The potential benefits to subjects from study participation include increases knowledge of atrial fibrillation and anticoagulation.

Could being in this research hurt me?

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There are no known risks to your physical health from participating in this study. Discussing your experience as a clinician and difficult situations you encounter could potentially raise difficult emotions regarding your overall wellbeing as a person and as a healthcare provider. Additionally, the exit interview will take some time to schedule and complete and may be uncomfortable if talking about your experience with stroke prevention and the difficulties you experience as a healthcare provider 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 this study, after completing the one-on-one interview, you will be paid $25.

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.

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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.

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

It is unlikley that you will have any injury by taking part in this 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 answer questions about your health, religious, and spiritual beliefs and practices.

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

Participation in this research study is completely voluntary. You have the right to decline or withdraw at any time without any impact on the quality of care you receive.

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 that requires treatment
- The study doctor decides it is in the best interest of your health and welfare to discontinue

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The research is canceled by UMass and its study doctors

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

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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.

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.