Official Title: Pragmatic Trial of the Impact of the Electronic Frailty Integrated With Social Needs (eFRIEND) on High Cost, High Burden Healthcare Use of Older Adults
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Informed Consent

Atrium Health Wake Forest Baptist, Center for Healthcare Innovation

eFRIEND: ELECTRONIC FRAILTY INTEGRATED WITH SOCIAL NEEDS

Informed Consent Form to Participate in Research

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SUMMARY

You are invited to participate in a research study. The purpose of this research is to assess whether a program led by Community Health Workers (CHW) helps older adults by connecting them with community resources, improving quality of life and loneliness, and helping them avoid extra hospitalizations. Community Health Workers are frontline public health workers who are trusted members of and have a close understanding of the community they serve. This trusting relationship enables Community Health Workers to serve as a link between health/social services and the community to facilitate access to services and improve the quality of service delivery. You are invited to be in this study because you are an adult aged over 65 years receiving primary care through Atrium Health Wake Forest Baptist, and there may be some resources that could benefit you that you are not aware of or may need help applying for.

Your participation in this research study will involve conversations or visits with a community health worker that could span over a 3 to 12-month period. These may include in person visits that could take place at your home, as well as possible telephone or video visits. These visits will include conversations about your social and health related concerns, and survey questions. We will repeat survey questions 6 months after and 12 months after your initial visit.

This research study has low/minimum risk. That risk is primarily around keeping information safe. While all research studies involve some risks, we will do our best to keep your health information private.

While we cannot promise that you will personally benefit from this study, it is possible you will be connected to additional resources to help with your social or day-to-day activity needs. We hope that this study will help other older adults in the future.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the

study. The people in charge of this study are Drs. Kathryn E. Callahan and Deepak Palakshappa. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, their contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been identified as potentially needing additional health care navigation and social resources services. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to identify and connect resources to the older adult population who may have social or day to day functional needs.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We plan to enroll up to 200 participants in the community health worker intervention. In order to identify the 200 people needed, we may need to screen as many as 1050 subjects because some people will not qualify to be included in the study. All subjects will live within Forsyth County, NC.

WHAT IS INVOLVED IN THE STUDY?

Participants in eFRIEND will receive regularly scheduled in-person and telephone or telehealth contacts with a CHW. The frequency and amount of time of each point of contact will be at the discretion of the CHW. The initial three months will focus on relationship building between the participant and the CHW. At the initial visit, the CHW will assess any needs we may be able to help with. The CHW will then assist with connecting you with any services (such as applying for Meals-on-Wheels). You will then complete follow up surveys after 6 and 12 months in the study.

Do you request that we send important medical findings to your personal physician?

[ ] Yes [ ] No _____Recruiter Initials

How Long Will I Be in the Study?

You will be in the study for about 3-12 months. The length of in person or telehealth visits will be up to the community health worker's discretion. After the visits are completed, there will be surveys to complete up to 6 months after your time with the community health worker.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves minimal risk to you. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. With any research study, there is a slight risk of a breach of confidentiality. We will do our best to protect the confidentiality of protected health information that you share with us. All information that we receive from you by phone and visit will be strictly confidential and will be kept on password-protected computers. Efforts will be made to keep your information safe, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records.

There also may be other risks that we cannot predict. You should tell the research staff and/or community health workers about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.
As part of this study, you will be asked questions about home safety and social supports. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

You do not have to be in this study to continue receiving medical care with your health care provider's office. You should talk to your doctor about all the choices you have.

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility even if recommended by the study team.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card to thank you for your time after completing questionnaires at your baseline, 6-month, and 12-month time points for a total of up to $75.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** age, gender, location, your problem list, and healthcare visits.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as

the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Kathryn Callahan that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Kathryn Callahan, MD, MS
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. I have had a chance to ask

questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Kathryn Callahan at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

Subject Name (Printed):_____

Person Obtaining Consent (Printed):_____

Date: _____Time:_____ am pm