ElderTree via a Voice Activated Device for Managing Chronic Health Conditions

4/15/2022

NCT05240534

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: ElderTree via a Voice Activated Device for Managing Chronic Health Conditions

Formal Study Title: Using Smart Displays to Implement an Evidence-based eHealth System for Older Adults with Multiple Chronic Conditions

Lead Researcher: David H Gustafson, Ph.D.
Phone: 608-263-4882; Email: dhgustaf@wisc.edu

Where Lead Researcher works: Center for Health Enhancement Systems Studies (CHESS), College of Engineering, University of Wisconsin-Madison

Invitation
We invite you to take part in a research study for ElderTree, an online information and support system designed to help older adults living with multiple chronic health conditions better manage their own health outcomes. ElderTree is designed to increase self-management, health tracking, and communication with others with similar health issues and with your primary care physician. You will have access to ElderTree via a computer or a smart system (voice activated technology). We are inviting you because you are 60 years or older and have at least 5 chronic health conditions.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are we doing this study?
The purpose of this study is to test whether using a voice-activated “smart” technology will increase and sustain the use of ElderTree among patients with multiple chronic health conditions, and thereby improve quality of life and help better manage their own health care. This research is being done because multiple chronic health conditions are common among people aged 60 and older. Multiple chronic conditions can lower quality of life, make health treatment and management complicated and expensive, and can contribute to feelings of isolation and loneliness.

IRB Approval Date: 4/15/2022
University of Wisconsin – Madison

This study is being done at the University of Wisconsin-Madison (UW-Madison), in partnership with primary care clinics in Wisconsin. A total of 356 people will participate in this study.

Funding for this study is provided by the National Heart, Lung, and Blood Institute.

What will I do in this study?
Participation in the study is completely voluntary and will last a total of 18 months. All activities will take place in your home or in a place of your choosing.

After you join the study, you will be randomly put in one of two groups, decided by chance (like the flip of a coin).

Group 1. Laptop Group: you will receive a computer and an internet hotspot, if you don't already have one, and given access to ElderTree.

Group 2. Smart System Group: you will receive a smart display and an internet hotspot, if you don't already have one, and given access to ElderTree.

If you choose to participate you will be asked to:

- Complete a survey at the beginning of the study. The survey will take 20-30 minutes and will ask about your demographics, quality of life, symptom management, pain, medication adherence, and health care utilization.
- Complete surveys at 6, 12 and 18 months. The surveys will be mailed to you to complete and return to us in a self-addressed stamped envelope. You may skip any question on the survey that you do not wish to answer. The surveys will take 20-30 minutes each and will ask about your quality of life, symptom management, pain, medication, and health care utilization. If we do not receive the completed survey in the mail, we may call to remind you to complete it.
- Complete weekly check-ins that will ask you how you are doing, specifically your mood, sleep, eating, and level of social interactions. These questions will be sent to you on the ElderTree system and will take about 2-4 minutes to complete. All questions are voluntary. You are free to refuse to answer any questions you are uncomfortable with. The information you share on ElderTree may be shared with your health care provider and will also be sent to you to share with other health care providers so they can provide you support where it is most needed.
- Explore ElderTree regularly – daily or several times a week – and utilize the various features offered.
- Allow the research team to collect information on how you use the ElderTree site.

Important things to note:

- There is no financial cost to you to participate in this study. The only cost to you is your time spent using the technology and completing surveys.

- If anything happens to the equipment we provide to you (if it is stolen or broken for example), you are not responsible. However, we will not be able to repair/replace it.
- At the end of the study the computer or smart system is yours to keep, however we can only pay for the internet hotspot for 12 months.

How we will use your protected health information (PHI)
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. For this study, we will use the following kinds of PHI:

- Name, address, and phone number
- Things you tell the research team about your health
- Information collected from medical records at UW Health (UW Health patients only) including: # of chronic conditions and health care utilization: hospitalizations (admission and discharge), number of ER visits, urgent care visits, PC visits, specialty care visits, long-term care visits, and rehab visits.

How long will I be in this study?

You will be part of the study and have internet access for 12 months. You will complete 4 surveys during this time; each survey is expected to take 20-30 minutes.

How is being in this study different from my regular health care?
This study is separate from your regular health care. If you decide to participate in the study, it will not change your regular health care in any way.

People with multiple chronic conditions have regular visits with their primary care physician that involve lab tests and medication monitoring. If you participate in this study, you will continue to have these visits as you normally would. For the study, we will ask you to answer surveys about how your conditions affects your behavior and quality of life. You may skip any questions you do not wish to answer.

Do I have to be in the study? What if I say "yes" now and change my mind later?
You do not have to be in this study. Taking part in this research is voluntary. This means that you decide if you want to be in the study. If you decide to participate, you can change your mind and leave the study at any time by letting the researchers know you no longer want to participate.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment or relationship you have with your healthcare provider, or any services you receive from them. No matter what decision you make,

IRB Approval Date: 4/15/2022
University of Wisconsin – Madison

and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your permission for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your permission for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your permission, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your permission, you will not be able to take part in the research study, therefore your access to the ElderTree application and internet access will be ended.

To take back your permission, you will need to tell the researchers by writing to the study coordinator Klaren Pe-Romashko at CHESS, 4155A Mechanical Engineering, 1513 University Avenue, 53706 or emailing kspe@wisc.edu or calling 608-263-3322.

What are the risks?

- There is a risk that your information could become known to someone not involved in this study, which might make you uncomfortable. We take many steps to protect your confidentiality and prevent this from happening.
- ElderTree could give you wrong information. However, a panel of experts reviews the information before it is added to ElderTree.
- You could get wrong information from the Internet. However, we will provide you with simple tips to help you identify more trustworthy sites.
- The surveys you will complete in this study ask personal questions related to past or current behaviors and experiences that could produce emotional stress or sadness. Surveys also ask about symptoms of emotional distress such as depression or anxiety. We are using the survey only for research, not to diagnose mental health issues. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.
- It is possible you could get upset from a posting in the online discussion group or participating in live social meet-ups. The study team will routinely monitor discussion groups and facilitate social meet-ups, and appropriate action will be taken if a questionable post or comment is made and/or if posts/comments may put an individual at risk. Participation in the social components on ElderTree is voluntary.
- There is a risk that you could fall when doing exercises at home and you could develop muscle soreness from doing exercises. You will be instructed on how to do

IRB Approval Date: 4/15/2022
University of Wisconsin – Madison

them safely. You will need to watch a safety video before you can start any of the exercises on ElderTree.

- When you do the balance and strengthening exercises at home, there is a small chance of falling. However, the exercise videos will instruct you about what stable surfaces to use at home to increase your safety. When you do the strength exercises there is a minor risk of muscle or joint pain. The exercise videos will instruct you about how to self-monitor for safety.
- We will be collecting information on how ElderTree is used and may discover behavior that raises concern about harm to yourself or others. If we see anything that suggests imminent and urgent risk of harm, we will contact appropriate others to intervene (e.g. community mental health center and/or police)
- You may feel a sense of loss when internet access is stopped.

Will being in this study help me in any way?
Being in this study may help you better manage your health conditions and communicate with your physician. However, we cannot promise this will happen. Even if the study does not help you directly, your participation in this study may help other people in the future as it will help us learn more about supporting older adults living with several chronic health conditions.

Will being in this study cost me anything?
There will be no cost to you for the activities that are part of this research study.

Will I be paid or receive anything for being in this study?
We will pay you $10 for completing each of the 4 surveys, for a total of $40. Payment will be mailed to you when we receive your completed survey. If you choose to leave the study early, you will receive payment for the surveys completed, but not for future surveys.

The laptop or smart system will be yours to keep at the end of the study if you have completed all of the surveys.

How will researchers keep my research information confidential? We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We will publish and present what we learn from this study, but none of this information will identify you directly.

The study team has a Certificate of Confidentiality from the National Institutes of Health for this study. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and study sponsor responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

With appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- UW Health patients only: Information you enter into ElderTree may be viewed by your primary care provider, via a one-page summary that graphs your weekly scores related to the quality of your sleeping, nutrition, physical activity, memory, falls, moods, balance, pain, medication adherence and quality time spent with others. This summary will be sent to your clinic prior to a scheduled appointment. The purpose of this information sharing is to help your health care team support you. This information will not be entered into your medical record.

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, National Heart, Lung, and Blood Institute

Will information from this study go in my medical record?

None of the information we collect for this study will be put in your medical record.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.

What if I have questions?

If you have questions about this research, please contact the study coordinator, Klaren Pe-Romashko at CHESS, 4155A Mechanical Engineering, 1513 University Avenue, 53706, call 608-263-3322, or email kspe@wisc.edu.

If you choose to email, please note that email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by

email and the research team will do the same. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Klaren Pe-Romashko at 608-263-3322.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.