Using Smart Devices to Implement an Evidence-based eHealth System for Older Adults
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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 Smart System for Managing Chronic Health Conditions

Formal Study Title: Using Smart Devices to Implement an Evidence-based eHealth System for Older Adults

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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 ehealth system to help older adults with Multiple Chronic Health Conditions (MCC) better manage chronic pain and 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, have been treated in your clinic for the last 12 months, and have chronic pain and at least 3 other 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 including chronic pain, and thereby improve quality of life and help better manage their own health care. This research is being done because chronic pain and 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.

This study is being done at the University of Wisconsin-Madison (UW-Madison), in partnership with primary care clinics in Wisconsin. A total of 291 people will participate in this study.

Funding for this study is provided by the Agency for Health Care Research and Quality (AHRQ).

What will I do in this study?
Participation in the study is completely voluntary and will last a total of 8 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 three groups, decided by chance (like the flip of a coin).

Group 1. Laptop Group: you will receive a computer and an internet hotspot, unless you already have a compatible computer and internet and prefer to use your own, and given access to ElderTree.

Group 2. Smart System Group: you will receive a smart system (smart speaker and smart display) and an internet hotspot, unless you already have a compatible smart system and internet and prefer to use your own, and given access to ElderTree.

Group 3. Control Group: you will receive Treatment as Usual from your health care team.

If you choose to participate you will be asked to:
- Give permission for the study team to request health care use information from your medical records.
- 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 4, and 8 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.
- If in one of the two groups with ElderTree, 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 will 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.
- Complete ElderTree learning modules focused on understanding and coping with chronic pain.
- Allow the research team to collect information on how you use ElderTree.

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 or replace it.
- At the end of the study, if you are in a group that receives the computer or smart system, it is yours to keep. However, we can only pay for the internet hotspot for 8 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 will be collected from medical records at UW Health, including information currently in your medical records as well as information added to your medical records during the course of this study. The data we will obtain from your medical records are:
- Chronic conditions
- 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 8 months. You will complete 3 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, 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.
- It is possible you could get upset from a posting in the online discussion group or participating in the live social Meetups. The study team will routinely monitor discussion groups and facilitate social Meetups, and appropriate action will be taken if a questionable post or comment is made online and/or if posts/comments may put an individual at risk. Participation in the social componenets on ElderTree is voluntary.
- You may feel a sense of loss when internet access is stopped.
- Participants will be asked personal questions related to past or current behaviors and experiences that could produce emotional stress or sadness.
- 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)
- The surveys you will complete in this study 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. Information you enter into ElderTree can be viewed by your primary care provider, via the ElderTree application. The information you enter into ElderTree can also be viewed by the UW

research coordinators. The purpose of this information sharing is to guide your health care team in how best to ensure your health and support you. Your primary care physician will see a graph that charts 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 information will not be entered into your medical record.

Will being in this study help me in any way?
Being in this study may help you learn how to better manage your health conditions and better 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 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?
If you are in the group that receives the laptop or smart system, we will pay you $10 for completing each of the 3 surveys, for a total of $30. If you are in the Control group, we will pay you $30 for completing each survey, for a total of $90. 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.

If you are in the group that receives the laptop or smart system, it 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 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

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, AHRQ

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 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.