Written Consent to Participate in a Research Study

Project Title: Reducing COVID-19 Related Disability in Rural Community-Dwelling Older Adults Using Smart Technology
Principal Investigator Name: Rachel Proffitt
Sponsor: National Institute on Aging (National Institutes of Health)
IRB Assigned Project Number: 2043542

Key Information About the Study

You are being asked to participate in a clinical trial. The purpose of the clinical trial is to compare the effects of a self-management intervention to standard health education in combination with new technology. You are being asked to have a sensor system installed in your home and participate in telehealth treatment sessions for a year. Possible benefits include reduced disability and improved health-related quality of life. Some possible risks may include a loss of privacy.

Please read this form carefully and take your time. You can discuss this study with your family, friends, or doctor if you want. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

The National Institutes of Health, specifically National Institute on Aging, is providing the funding for this study. One of the study investigators, Dr. Marjorie Skubic, has a financial interest in the company that makes the sensors (Foresite Healthcare) used in this study. The University of Missouri and/or the investigators may develop intellectual property related to the project.

Purpose of the Research

You are being asked to participate in this clinical trial because you are over the age of 65 and have difficulty with one or more activities of daily living. You also live in a rural area of the state of Missouri. The purpose of the clinical trial is to compare the effects of a self-management intervention to standard health education. Additionally, this clinical trial will investigate a new technology: a sensor system to inform treatment decisions. All study participants will have a sensor system installed in their home.

What will happen during the study?

If you take part in this study, you will have the following tests and procedures:

Because we don't know which of the interventions is best, we will "randomize" you into one of the two study groups. "Randomize" means putting you into a group by chance. It is like flipping a coin or pulling a number from a hat. You will have an equal chance of being placed in either

group. A computer program chooses which group you go in. You and the study staff cannot choose which group you go into.

Sensor System

The sensor system will be installed in your home. The sensor system consists of two depth sensors (Figure 1), motion sensors, and a bed sensor (Figure 2). We will install all sensors in unobtrusive locations in your home. All wires and cords will be covered or out of the way. We will also provide you with a small tablet. This device will be placed on a flat surface of your choosing (most people prefer a kitchen countertop or a living room end table).

Figure 1. The Foresite Healthcare integrated depth sensor embedded system mounted in a kitchen area of an apartment (circled).

Figure 2. The hydraulic bed sensor positioned under the mattress

Study Arm 1- Self-Management Intervention

The self-management intervention will be delivered over the course of a year. You will receive a minimum of four intervention sessions with each healthcare profession: occupational therapy (OT), nursing (RN), and social work (SW). Working with the team of healthcare professionals, you will set SMART goals and identify areas of concern. You will receive a total of 15 intervention sessions over the course of a year. All intervention sessions will occur via telehealth. You will be provided with a tablet computer for the telehealth sessions. We will train you on how to use the tablet computer and provide troubleshooting instructions.

The sensor system described above sends data to our secure server. Special health assessment algorithms analyze the data and look at trends. The algorithms are able to detect changes in trends and provide alerts. For example, the algorithm may detect from the bed sensor that you have been more restless at night for the past 3 nights. The system will then send out an alert to the healthcare providers providing the intervention. You will also be able to view your data and alerts by logging into the Health Assistant Dashboard on the tablet. You can designate other individuals to be able to view your data, such as a family member. We will train you on how to use the tablet and provide troubleshooting instructions.

At 3 months, 6 months, and 9 months you will participate in a quarterly interview. During the quarterly interview, we will ask you about any doctor visits and other healthcare usage, including new medications or procedures. We will also ask you about how you interact with the Health Assistant. We will complete the Goal Attainment Scaling measure during each interview.

Study Arm 2- Standard Health Education Intervention
Standard health education will be delivered over the course of a year. You will receive a total of five intervention sessions. We will provide information about any medication conditions you have and answer questions. All intervention sessions will occur via telehealth. You will be provided with a tablet computer for the telehealth sessions. We will train you on how to use the tablet computer and provide troubleshooting instructions.

The sensor system described above sends data to our secure server. Special health assessment algorithms analyze the data and look at trends. The algorithms are able to detect changes in trends and provide alerts. For example, the algorithm may detect from the bed sensor that you have been more restless at night for the past 3 nights. You will also be able to view your data and alerts by logging into the Health Assistant Dashboard on the tablet. You can designate other individuals to be able to view your data, such as a family member. We will train you on how to use the tablet and provide troubleshooting instructions.

At 3 months, 6 months, and 9 months you will participate in a quarterly interview. During the quarterly interview, we will ask you about any doctor visits and other healthcare usage, including new medications or procedures. We will also ask you about how you interact with the Health Assistant.

There will be about 64 people participating in this study.

Will you share with me any results or health problems/issues that you learn about me while in the study?

If we find any clinically relevant research results as a result of the study intervention or the sensor system data that include results about you, we will inform you as soon as possible. If the investigators identify potential health problems or issues as part of the research, you will be provided with this information and, with your permission, the investigators will share this information with your primary care physician or other healthcare provider of your choice. It is possible that you may need testing or treatment for a new or existing health condition. You and/or your health plan/insurance are responsible for the costs of this testing or treatment.

How long will I be in the study?

Your participation is expected to last about 14 months.

Are there benefits to taking part in the study?

You may or may not benefit because of your participation in the study. You may experience a reduction of disability and improvement in health-related quality of life. Family members and caregivers may experience a reduction in burden of care and may experience an improvement in

mental health. You may gain a better understanding of your abilities. You may learn more about how technology can play a role in monitoring your functional performance and health status. Information learned from the study may help other people in the future.

What are the possible risks of participating in this study?

There are risks expected when taking part in this study. There are some that we know about and some may not know about yet. Some risks include questions making you feel uncomfortable. There is a potential risk of loss of confidentiality. There is a risk that you may experience a decline in function or health over the course of the year.

You will be put into a group by chance. The intervention you receive may turn out to be less effective or have more side effects than that in the other group. It may also be less effective and have more side effects than other interventions available for older adults with disabilities.

To help lower these possible risks, you do not have to answer any questions that make you feel uncomfortable. To address privacy and confidentiality, we use a secure server that we have used for over a decade with no loss of privacy. In the event that you experience a decline in health or function, the sensor system will send an alert to study staff. Falls will also trigger an alert to study staff, interveners, and any trusted contacts you designate at the beginning of the study.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

What other choices do I have if I don't want to be in this study?

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study. The research team can share other options that may be available to you.

Will I receive compensation for taking part in this study?

You will be compensated for taking part in this study. For your time and effort, you will receive a total of $250. You will receive $50 at the baseline/sensor installation visit, $50 at 3, 6, and 9 months each, and $50 at the final assessment visit. Compensation will be provided via check.

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

Are there any costs for participating in this study?

You should not expect any additional costs by participating in this study.

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Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential, including health information. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location.

We might collect information from you that indicate the possibility of neglect/elder abuse. One or more of the study staff are mandated reporters. This means that they are required by law to report any of these findings to the appropriate state agencies. These agencies include the Missouri Department of Social Services and the Missouri Department of Health and Senior Services.

You must give us permission to publish the images, audio recordings, and video recordings we take of you during the study. You will be able to look at, listen to, or watch them before you give your permission for us to use them. Images, audio recordings, and video recordings will not contain anything that might identify you.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

We may share what we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.

Permission to Use your Protected Health Information:

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.

You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

Some identifiers about you will be obtained from your health records and are necessary for this research. The identifiers will include your name, address, dates related to you, phone numbers, email addresses, web address, IP address, photos, and other characteristics that could identify you.

We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.

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- Study monitors and auditors who make sure that the study is being done properly.
- National Institutes of Health who is sponsoring the study, and their contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.

The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your permission for us to use and/or release your information will not expire unless you cancel your permission in writing.

You can cancel your permission at any time by writing to:
Investigator's Name: Rachel Proffitt, OTD, OTR/L
Institution: University of Missouri
Department: Occupational Therapy
Address: 812 Clark Hall, 703 S. 5th St., Columbia, MO 65211

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You will not be allowed to access your protected health information that is obtained or created during this research project until the end of the study.

Where can I get more information about this clinical trial?

A description of this clinical trial will be available on 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.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher at 573-884-2418 or proffittrm@health.missouri.edu.

If you have questions about your rights as a research participant, or have problems or complaints, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

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If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email muresearchrpa@missouri.edu.

Do I get a copy of this consent?

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

Consent to Participate - Signatures

Optional Items

My initials state my choice about allowing my information to be stored and used for future research:

Yes_____ No_____

Subject's Signature	**Date**

Investigator Authorized to Obtain Consent	**Date**

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