Study Title: Preventing Hospital-Acquired Disability: An Intervention to Improve Older Adult Patient Ambulation

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University of Wisconsin-Madison

Research Subject Information and Consent Form

Title of Study: Preventing Hospital-Acquired Disability: An Intervention to Improve Older Adult Patient Ambulation
Study Investigator: Barbara King, PhD, APRN-BC, Linsey Steege, PhD
Version and Date of Consent Form: Version 4.0, 10/24/22

INVITATION AND SUMMARY

Lack of walking during a hospital stay has been shown to cause weakness and walking problems for older adults after hospital discharge. We are interested in testing a new program that will help older adults maintain their walking ability during a hospital stay. You are being asked whether you would like to voluntarily take part in a research study about helping older adult patients walk during their hospital stay. You are invited because you are an adult patient admitted to one of the units selected for this study at [REDACTED SITE 2]. We plan to include 400 patients in this study.

Your participation in this research study is voluntary. If you decide not to participate, any relationship you have with the University of Wisconsin-Madison (UW-Madison) or [REDACTED SITE 2] will not be affected in any way.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to determine if getting patients up to walk, improves their ability to function after their hospital stay and if they have less use of healthcare services such as the Emergency Room, needing to be readmitted or discharge to a nursing home.

WHO IS SPONSORING THIS STUDY?

The sponsor of this study is the Agency for Healthcare and Quality. The sponsor pays for Drs. King and Steege and University Hospital to run the study.

WHAT WILL MY PARTICIPATION INVOLVE?

Your participation is voluntary. If you decide to take part in this study, you will be asked to:

Participate in a brief (10 minute) visit to when you are admitted and when you are ready to leave the hospital:

1) Answer questions about your ability to perform daily life activities, such as bathing, dressing, feeding, and walking when you arrive at the hospital and before you go home.
2) Do a short test of your walking speed when you arrive and before you go home.

3) Allow us to collect information from your medical record including age, gender, race, ethnicity, reason for admission, past medical history of health problems, albumin level, where you lived before you entered the hospital, your ability to complete basic activities of daily living (bathing, dressing, eating, toileting) on admission and at discharge, how often and how far you walked in the hospital, your body size, your use of a walking device, your fall risk score, where you are being discharged to, and number of days in the hospital.
4) Provide your telephone number and address to arrange for 1, 3, and 6 month post-discharge contacts.

Participate on a brief (10 minute) telephone call – at one (1) month and six (6) months after you are discharged:

1) Answer questions about your ability to perform daily life activities, such as bathing, dressing, feeding, and walking (same questions as in the hospital).
2) Answer questions about your movement in different areas of your home and outside your home.
3) Answer questions about whether or not you were readmitted to a hospital.

Participate in an in-person meeting - three (3) months after you are discharged**:**

1) Answer questions about your ability to perform daily life activities, such as bathing, dressing, feeding, and walking.
2) Answer questions about your movement in different areas of your home and outside your home.
3) Do a short test of your walking speed (same one as you did in the hospital)
4) Answer questions about whether or not you were readmitted to a hospital
5) Participate in a recorded interview (30-60 minutes) about your experience with walking during your hospital stay.

You may skip any questions that you do not wish to answer. The information and assessments are being collected for research purposes and have no effect on your medical care. This information will not be shared with your doctor or your nurses, will not be used in planning your care, and will not become part of your medical record.

ARE THERE ANY RISKS?

A breach of confidentiality could result in damage to you or your reputation, but the chances of this happening are very rare. To protect your confidentiality, we will give you a special identification (ID) number that will be used on all data collection forms that we will fill out for this study. Using an ID number reduces the risk that your information could become known to someone who is not involved in conducting this study. Your contact information will be stored in a separate file from your data collection forms. All of your study information, identified by your ID number, will be stored on a password protected server and in a locked file cabinet, located in a locked office in the University of Wisconsin-Madison School of Nursing. Your study records will be kept confidential. Only the research team will have access to your information.

There are four circumstances in which our research team may be required to share specific information about you to someone outside of the research team:

1) If we believe your life is in immediate danger, we will need to call 911 or escort you to an emergency department.

2) If we discover urgent health issues during the interview that could put your life in immediate danger if left unaddressed, we may communicate those specific concerns to your health care provider. We would share your name, contact information, the fact that you are in a research study, and the reason for referral.

3) If we find evidence of child abuse, we are required to report this evidence to Child Protective Services (CPS).

4) If we find evidence of abuse toward an elder or vulnerable adults who cannot make an informed judgment about whether or not to report this abuse (i.e. the person has severe dementia), we are required to report this evidence of abuse to Adult Protective Services (APS). If an elder at risk requests that a research team member report evidence of abuse to APS on his/her behalf, we are required to do so by law whether or not we have witnessed evidence of abuse. Finally, if we find evidence of abuse and the elder makes an informed decision not to report the abuse, we may still be required by state law to report the evidence of abuse to APS if 'other adults are also at risk of serious bodily harm, death, sexual assault, or significant property loss inflicted by the suspected perpetrator.

ARE THERE ANY BENEFITS?
You will not experience any direct benefits from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about how to overcome barriers that limit patients from getting up to walk during their hospital stay.

ARE THERE ANY COSTS?
There will be no costs to you if you take part in this research study.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?
You will be compensated for your participation at each step - up to $100 total. This will be paid as $25 at discharge, $25 for your participation on the 1 month after discharge phone call, $25 for your participation in the in-person visit 3 months after discharge, and $25 for your participation on the 6 month after discharge phone call. You will be provided the compensation in person at discharge, and in person at the 3-month post discharge visit. Your compensation for the 1- and 6-month post discharge call will be mailed to you.

HOW LONG WILL I BE IN THE STUDY?
You will be in the study during your hospital stay and after discharge. Your participation in the study will end when the 6 month after discharge call is completed.

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you no longer meet the eligibility criteria for the study
- the study is stopped by the sponsor or researchers

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND OR CAN I BE WITHDRAWN FROM THE STUDY WITHOUT MY PERMISSION?

Your decision to take part in this study is voluntary. You do not have to sign this form and you may refuse to do so. If you do not sign this consent form, you will not take part in the study. You may completely withdraw from the study at any time.

IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, YOUR CARE AT [REDACTED SITE 2] WILL NOT BE AFFECTED IN ANY WAY.

WILL MY CONFIDENTIALITY BE PROTECTED?

Researchers might use information learned from this study in scientific journal articles or in presentations. Direct quotes are used in qualitative research publications to support the results from the study. However, information or direct quotes will not identify you personally. Your information will be protected by only using a study identification number on all forms and transcripts that contain information you provide to us. All research materials with information you provide will be stored in a locked file cabinet or stored on a password protected server.

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.

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 or authorization 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?

- The U.S. Office for Human Research Protections
- The study sponsor, Agency for Healthcare Research and Quality
- Collaborating researchers outside UW-Madison, including researchers at [REDACTED SITE].

A description of this study 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 Web site will include a summary of the results. You can search this website at any time

Will information from this study go in my medical record?

No information from this study will be entered into your medical record.

What happens if I am injured because of this study?

If you are injured because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.
- Call the Lead Researcher, Barbara King, at 608-263-5319 to report your injury.

WHAT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions about this research, please contact the study investigator, Barbara King, at 608-263-5319 or Dr. Linsey Steege at 608-263-5191. If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team contact [REDACTED SITE 2 representative].

Authorization to participate in the research study:

If you sign the line below, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.

_____ _____

Signature of Subject **Date**

_____ _____

Signature of Person Obtaining Consent **Date**

****You will receive a copy of this form****