Subject Name _____ **Date** _____

Title of Study Impact of a Hospital Mobility Program on Function after Discharge

Principal Investigator Cynthia J. Brown, MD, MSPH **VAMC** **Birmingham (521)**

Sponsor

This research is being sponsored by Department of Veteran's Affairs. If you decide to participate you will be asked to undergo examinations, tests and assessments that may not normally be required for the treatment of your condition. These examinations, tests and assessments will be paid for with money provided by the sponsor. Any money remaining at the end of the project will be used by Cynthia J. Brown, M.D., to pay other research expenses.

Introduction and Purpose

You are being asked to participate in a study to determine if a walking program, conducted during your hospital stay, is safe and practical. The purpose of this study is to learn whether a walking program will help persons who are admitted to the hospital for a short-term problem. You have been asked to participate in this study because you are 50 years of age or older and hospitalized. We expect to enroll 230 patients who are 50 years of age or older from the medical wards of the Birmingham VAMC. You will be followed in the hospital until you leave the medical ward, or are discharged from the hospital. After you are discharged, you will be contacted by telephone once a month for 6 months. We will contact you again 9 months after you are discharged, and one final time 12 months after you are discharged. The expected duration of your participation is 13 months. This is a research study.

Procedures

No laboratory tests will be performed for this study. This study involves two groups: a control group and a walking program group. You will be assigned to one of the groups based on your ward assignment. You will be evaluated every day while you are in the hospital, and 8 times after you are discharged. If you are in the walking group, you will receive assistance with walking three times a day while you are in the hospital. If you are in the control group, you will be visited three times a day by a member of the research team to check on how you are doing.

Procedures at Admission

When you first join the study, you will be asked questions about how well you can perform everyday activities such as eating, dressing, bathing, grocery shopping, and house cleaning. We will ask about your home; how you move about your home; how far and how often you move about your neighborhood and your community; and whether you need help walking or driving. We will ask what kind of symptoms are bothering you, like pain or dizziness. We will ask you to walk a short distance (10 feet) and we will measure how fast you walk. You will be asked to do this two times. As with all the research tests you should not feel like you have to do more than you are able to do, and the researcher will help you if you need help. While you are walking, we will ask you how hard it is for you to walk, or how much effort you feel it takes. During these procedures, a researcher will be standing close to you to prevent you from falling. You also will wear a safety belt around your waist. Performing these activities should take about 25 minutes.

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Procedures during Hospitalization

You will be asked to wear a step counting device on your ankle while you are in the hospital. This device records how many steps you take, and when you take these steps. The device will be kept on one of your legs during your entire hospital stay. The researcher will check every day to make sure the monitor is not causing you any discomfort. Each day you are in the hospital the researcher will ask you how often and where you have been moving around, and whether you've needed any help. These questions will take about 5 minutes.

One time during your hospitalization you will be asked some questions about how often you see friends and family, and how comfortable you feel asking them for help. We will also ask whether you have had any recent falls, emergency department visits, or hospitalizations; and we will ask questions about how you feel things are going in your life. These questions should take about 25 minutes.

If you are assigned to a walking group, you will receive assistance to walk three times each day by a member of the research team who has been trained by a physical therapist. The study staff will work with you on transferring from the bed and walking. If you walk, the study staff will ask you how hard it is for you to walk, or how much effort you feel it takes. You will be provided with a rolling walker if you need one. Each session will last 15-20 minutes. If you become tired, you can rest. You can also choose not to walk during any of the study staff visits.

If you are assigned to the control group, you will be visited three times each day by a member of the research team to see how you are doing. Each visit will last 15-20 minutes.

Procedures at Discharge

Just before you leave the hospital, you will be asked questions about how well you can perform everyday activities such as eating and dressing. We will ask what kind of symptoms are bothering you, like pain or dizziness. We will also ask you to walk a short distance (10 feet) and we will measure how fast you walk. You will be asked to do this two times. As with all the research tests you should not feel like you have to do more than you are able to do, and the researcher will help you if you need help.

Procedures after Discharge from the Hospital

You will be called about once a month for six months after you have been discharged from the hospital; once about nine months after discharge; and one final time about twelve months after discharge. If you happen to be hospitalized at BVAMC at time of your scheduled call, we will visit you in your hospital room, if you feel well enough. You will be asked some of the same questions we asked in the hospital, such as how well you can perform everyday activities such as eating, dressing and grocery shopping. We will ask about your home; how you move about your home; how far and how often you move about your neighborhood and your community; and whether you need help walking or driving. You will be asked some questions about how often you see or talk to friends and family, and how comfortable you feel asking them for help. We will also ask whether you have had any recent falls, emergency department visits, or hospitalizations; and we will ask questions about how you feel things are going in your life. Four of these calls will take 20-29 minutes, two of them will take 21-37 minutes, and two of them will take 27-36 minutes.

Some of the calls are a little longer than the others because during these we will ask more questions about your friends and family.

Risks and Discomforts

It is possible that the step counting device and its Velcro band could cause some discomfort or skin irritation; such instances are rare. To avoid this possibility, the researchers will check your skin near the device every day you wear it, and will move the device to your other leg or remove it if there are any problems. The researchers will ask you if the device is causing you any concern or discomfort while you are wearing it.

There is a slight risk of falling during the walking sessions. To avoid this risk, study staff are trained on safe walking techniques. You will wear a safety belt around your waist that allows study staff to hold onto you whenever you are working with members of the study team. If you are weak or a larger person, two people will walk with you.

You may experience some fatigue or shortness of breath during the walking sessions. If you become tired while walking, you can rest. You can also choose not to walk during any of the study staff visits.

You may feel some discomfort with the questions you are asked. You are free to answer to not answer any study questions. There is a minor risk for loss of privacy if for some reason the answers to your questions are not kept confidential.

Benefits

If you are in the walking group, your ability to walk, transfer from the bed to a chair ,and carry out tasks such as bathing and dressing may improve. Both groups may enjoy the visits from members of the research team while they are in the hospital. However, we cannot guarantee benefits for either group.

You may not benefit directly from taking part in this study. However, your participation may provide valuable information to the medical community about how much people move around during their hospital stay, and may lead to ways to increase people's mobility while in the hospital.

Alternative Treatment

There are no alternatives to the experimental walking program in this study. The only alternative is to choose not to participate.

Compensation/Payments

When you complete the hospital portion of this study, you will be paid $20 to compensate you for your time. You will be paid an additional $10 for each completed interview after you leave the hospital. If you complete all components of the study, you will receive a total of $100. Payment will be mailed to you in the form of a check and should be received within 4-6 weeks of completing each segment of the study.

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Cost of Participation

Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Research-Related Injury

You will be participating in a research project approved by the BVAMC Research and Development Committee and conducted under the supervision of one or more VA employees. If you are injured as a result of your participation as a research subject in this study, the VA medical facility will provide you with necessary medical treatment in accordance with Federal regulations. VA will not necessarily be responsible for treatment for injuries that result from noncompliance with study procedures although veterans injured as a result of such participation may be eligible for care from VA under other statutory and regulatory provisions.

Any cost of care will be in accordance with your eligibility for care at VA. Care outside VA may not be free and VA may not pay for that care.

If you have any questions regarding this study or you are injured and become ill as a result of participation in this study, please call **Dr. Cynthia J. Brown at (205) 933-8101 ext. 7064**. Dr. Brown may also be reached after hours by paging her at (205) 934-3411 (beeper 7748). If you are unable to reach the health care provider listed and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at (205) 558-4725 to obtain advice.

Clinical Trials

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.

Confidentiality

The study staff will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. The sponsor company Department of Veterans Affairs, VA personnel, VA Institutional Review Board (IRB) and other federal oversight agencies reserve the right to inspect both the research data and your medical records. All data and identifiable information will be maintained in strict accordance with VA policies regarding the protection and destruction of sensitive information, both during and after the completion of the study.

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Voluntary Participation and Withdrawal

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and discontinue participation at any time. If you decide to withdraw from this study, you are asked to contact Dr. Cynthia J. Brown (205) 933-8101, ext. 7064. Discontinuation will in no way affect or jeopardize the quality of care you receive now or in the future at this institution or your right to participate in other studies. Your doctor may also withdraw you without your consent for medical or other reasons in a study not terminated (e.g. if you become too ill to be involved).

New Findings

Any significant new findings that develop during the course of the research study that in the opinion of the investigator may affect your willingness to continue to participate will be provided to you as soon as possible.

Questions

If you have any questions about the legitimacy of this study, your rights as a research participant, complaints/concerns about this research, or to discuss problems, obtain information and offer input; please contact the Research & Development Office and the staff will direct you to the appropriate person to handle your situation. The phone number for the Research & Development Office is (205) 558-4747.

For questions about the study or research-related injuries, please contact Dr. Cynthia J. Brown at (205) 933-8101, ext. 7064. Dr Brown may also be reached after hours by paging her at (205) 934-3411 (beeper 7748).

VA - IRB

Approved 10-25-17

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You have read or have had read to you all of the above. Dr. Cynthia Brown or another qualified member of the study staff has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you.

You understand that you do not have to take part in this study. Your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

The results of this study may be published, but your records will not be revealed unless required by law.

In case there are medical problems or questions, you have been told you can call Dr. Cynthia Brown at (205) 933-8101, ext. 7300 during the day and the VA Emergency Room at (205) 558-4725 after hours. If any medical problems occur in connection with this study the VA will provide emergency care in accordance with your eligibility.

You understand your rights as a research subject and you voluntarily consent to participation in this study. You understand what the study is about and how and why it is being done. You will receive a signed copy of this consent form. **Please keep this form because it contains important phone numbers and other information.**

By signing and dating this informed consent, you are not waiving any of your legal rights.

		/ /
Participant's Name (printed)	Participant's Signature	Date (MM/DD/YYYY)
		/ /
Name of person conducting consent discussion (printed)	Signature of person conducting informed consent discussion	Date (MM/DD/YYYY)

ONLY WHEN APPLICABLE:

		/ /
*Name of Subject's Representative (printed)	Subject's Representative Signature	Date (MM/DD/YYYY)

*Only required if subject is incompetent

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