INFORMED CONSENT

PROTOCOL TITLE: PHYSICAL TELEREHABILITATION IN VETERANS WITH MULTIPLE SCLEROSIS

NCT02346734

APPROVAL DATE: 7/27/15

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: Physical Telerehabilitation in Veterans with Multiple Sclerosis

Study No.: HP-00040344

Principal Investigator: Walter Royal III, MD (410-605-7000 ext 6623, 1-888-530-0480)

This is a research study. Participation is voluntary and you may ask questions at any time. If you are consenting for someone unable to provide consent for themselves then the word "you" means that person.

PURPOSE OF STUDY

The purpose of this study is to evaluate new ways of helping MS patients to follow a personalized exercise program at home, which will be prescribed by their physicians/therapist. Since you have multiple sclerosis, you qualify for this study and we would like you to consider participating. Please read the following information before making your decision.

The study will involve two steps and you can participate in both of them. The first step will include having several meetings with patients with multiple sclerosis (focus groups) to discuss how it is possible to help people with MS to exercise properly. These meetings will be tape-recorded. Based on the responses from the members of the focus group we will modify the computer program that we are going to use during the second step. The second step is a research study of our computer program called Multiple Sclerosis Home Automated Telemanagement (MS HAT). We want to see if MS HAT system can help you with your exercising and overall health. Overall the research study includes 3 visits (baseline, 3-month, and 6-month).

You will be one of approximately 210 subjects to be asked to participate in this study.

PROCEDURES

The focus groups will consist of 8-10 participants who will meet for approximately two hours to discuss issues related to MS care, physical activity, and technology. The meetings will be audio-taped to assure accuracy. A member of the research team will listen to the audiotapes, write down the important information, and then destroy the tapes.

The study will last six months. During this time you will continue to receive the care usually provided by your healthcare professional. You will still see your own doctors according to your usual schedule. After the initial study evaluation, you will receive an exercise program that is made just for you. The exercise program will include some combination of strength, balance, and stretching exercises. It will be recommended to you by your physiotherapist depending on your

health status. Your physical therapy evaluation and outcome measures will be completed at the Baltimore VA ANNEX. Also, we will randomly select half of the study participants to use the "MS HAT website" at home which will assist them in following the exercise plan approved by their doctor/therapist. The link to the website, user ID and password will be provided. During the baseline visit, the research staff will provide you with a training session on how to access MS HAT website from your computer. If you don't have a computer, a laptop computer with the internet connection will be provided for the duration of the study. You will need to return the computer at the end of study. The other half of the participants will not use the MS HAT system and will be followed by their doctor/therapist in the usual way.

The MS HAT system includes monitoring, analysis and educational parts. You are guided by the system through each internet session. During the session you will perform the following tasks (1) get information about your exercise performance based on your personal exercise plan, (2) receive education on how to improve your multiple sclerosis symptoms. The monitoring component works with you by collecting the data that you will enter. You will be asked about your health and symptoms of your disease. The analysis component will evaluate if your health gets worse and how you follow your exercise plan. The analysis component identifies which part of your treatment plan you should follow and which items are of special concern for you.

During each visit, you will be asked to complete questionnaires that will determine your current condition, your well-being, and your attitudes towards your disease, how you follow your exercise plan, and your level of multiple sclerosis knowledge. There are no costs to you as a consequence of your participation in this research study.

POTENTIAL RISKS/DISCOMFORTS:

There will be no risks associated with the intervention since it does not introduce any new treatments. For all activities performed at the Annex, a clinical provider is on call and can be reached by phone for consult in case of any problems. If there is a medical emergency, an AED is available on site and the 911 emergency medical system would be activated by the research team. If 911 is activated, you would be taken to the nearest available hospital for care. In addition to regular care, the protocol includes only procedures that will help you to follow the treatment plan prescribed by your doctor. The risk of falls is also present. However, this risk will not be any higher than your usual chances of falling during exercise. You should stop participating in this research study if you feel uncomfortable at any time. Your medical care at UMMS and/or VAMC will not be affected in any way if you choose not to participate or decide to withdraw from this research study. Participation in the study is associated with the risk of loss of confidentiality. Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected.

POTENTIAL BENEFITS
You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. However by working with the MS system you may be able to manage your disease more efficiently.

ALTERNATIVES TO PARTICIPATION
This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
It will not cost you anything to take part in this study.

PAYMENT TO PARTICIPANTS
There is no payment given for participating in this study

CONFIDENTIALITY AND ACCESS TO RECORDS
In this study, the participant's confidential information will be collected. Only PI and research team members will have the access to the information. There are three levels of internet/data security to protect participants' confidentiality. The patient information is transmitted with only an assigned patient ID numbers. The patient information is encrypted and will be further protected by University of Maryland Hospital and VA firewall. Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. IRB may inspect and copy your information.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law. There is no anticipated use and/or disclosure of the data for future research.

CONSENT FOR FUTURE RESEARCH
Please check the box below as to whether or not you agree to have contact information stored in the registry and will allow us to contact you for participation in future research studies. Even if you agree to be recontacted now, you may still change your mind about providing this information in the future.

____ Yes, my information may be stored in the registry and I may be re-contacted for information
____ No, my information may not be stored in the registry and I may not be re-contacted for information

Subject Initials _____ Date_____

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Walter Royal II at 410-605-7000 extension 6623 or at 1-888-530-0480.

There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data. You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include, for example: failure to follow instructions of the research staff, or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland Baltimore. The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
BioPark I
800 W. Baltimore Street, Suite 100
Baltimore, MD 21201
410-706-5037

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____	_____
Participant's Signature	Legally Authorized Representative *(When applicable)* Relationship:_____
Date:_____	Date:_____
_____	_____
Investigator or Designee Obtaining Consent Signature	Witness* *(When applicable:* ***only if required by the IRB)***
Date:_____	Date:_____