Smartphone Delivered In-home Cardiopulmonary Rehabilitation

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ATLANTA VA HEALTH CARE SYSTEM
Consent to be a Research Subject

TITLE: Smartphone Delivered In-home Cardiopulmonary Rehabilitation

PRINCIPAL INVESTIGATOR: [redacted]

SPONSOR'S NAME: VA Center for Innovations

INTRODUCTION/PURPOSE: Remote monitoring and increased communication are becoming very important for the care of patients with chronic diseases such as coronary artery disease (CAD), peripheral arterial disease (PAD), and chronic obstructive pulmonary disease (COPD). Mobile technologies such as smartphones may help patients, providers and caregivers better communicate with each other and coordinate patient care. Unfortunately, we do not yet fully understand how patients, their families and care teams may use these new mobile tools or what their real effects are on patient outcomes.

This study will see if a mobile application (or app) called Movn can be used to help manage a home-based cardiovascular or pulmonary rehabilitation (CR or PR, respectively) program for patients with CAD, PAD or COPD. Rehabilitation is normally an outpatient program that can help patients recover after a cardiac or pulmonary event or hospitalization. It can also improve symptoms and walking ability for patients with PAD. We would like to learn if the Movn app can help improve how we deliver this type of rehabilitation. We would also like to compare this to usual care and traditional forms of cardiovascular and pulmonary rehabilitation.

If you agree to participate in this study, you will allow us to read your medical records for data collection purposes. You will either be offered CR immediately, or after 12 weeks (wait-list control group). If you are already in CR, you will enroll in our study so that we can measure the benefit of this intervention to your health. This technology has not been shown to improve medical care and should not take the place of seeking regular medical care. We plan to enroll 320 people for this study.

Some participants with PAD may gain additional benefit from participating in a specialized form of home-based exercise that is uniquely designed for them. If you have PAD, you may therefore be invited to enroll in a separate study (the Smart MOVE Study) which is evaluating a specialized form of home-exercise for PAD patients. You will have to sign a separate consent form for that study. We will also share de-identified data that we collect about you from this study with the Smart MOVE Study.

PROCEDURES: Please read this consent form. Before you decide to take part, discuss any questions or concerns with the research team. If you agree to take part in this study, you will be asked to sign this consent form and a HIPPA form before starting in the study. We will open and collect information from your past, current, and future medical records.

1. We will perform a baseline enrollment interview and examination to determine your exercise prescription. This includes testing an exercise test, likely on a treadmill. You may also be asked to complete several surveys to assess different aspects of your health including your physical, mental and emotional wellbeing as well as your sleep quality, physical activity, and general quality of life. These procedures will take place in your hospital room at the Atlanta VAHCS if you are

currently admitted or during a study visit in the cardiology office on the 2nd floor if you are an outpatient. The exercise stress test and labs at baseline and end of program are considered standard of care and if you were scheduled for a clinical treadmill test by your provider, then you may be subject to co-pays for that. On the other hand, if you were recruited into the study by the research staff, then you will not be subject to co-pays.

2. If you are not already in CR, the study team will invite you to receive CR with Movn, either immediately or after 12 weeks (if in the wait-list group). As part of the standard of care, everyone will be offered an opportunity to enroll in your hospital's existing CR program (if not already enrolled).

3. If/when you enroll in Movn, you will be oriented to the in-home program and the app. The Movn smartphone app will track your health habits, physical activity and other vital measures of your cardiopulmonary fitness. The app will collect data on several aspects of your health, heart rate and blood pressure. The app also includes educational resources with videos and other custom content, including surveys and questionnaires that you may be asked to complete.

4. We will ask you to perform some behavioral tasks during your orientation visit. These tasks are done on a computer or with paper and pencil and will assess how well you remember words and numbers, generate words and phrases, and perform simple calculations. You will also be asked to perform hand movement tests. These tests provide info on your hand performance, such as dexterity, strength and coordination. You may request rest breaks between each task, and of course, may stop at any time.

5. Following your orientation, the home-based exercise program lasts for 12 weeks. This program is part of our home-based cardiac rehab clinical program, and is considered standard of care. If you enroll, you will either be asked to start the program right away or wait 12 weeks before starting. This will be determined by the study team in advance.

6. During the home-based exercise program, you may be contacted by a study nurse or coordinator every week to check on your progress and to answer any questions you may have. You may also be asked to take part in one or more surveys during these weekly phone calls.

7. After the program is completed, you will be asked to return for a follow-up visit with a member of our study team. This visit will take place at the Atlanta VAHCS. During this visit, you will be asked to repeat an exercise test, hand movement test, and the behavior tasks and surveys that you performed before the 12-week program. The exercise stress test at the end of the study is considered standard of care if the program is prescribed by your doctor.

8. Information that is gathered by, or input into, the Movn app is subject to the Movn app's privacy policy, which can be found at https://www.movinganalytics.com/privacyfull.pdf. Moving Analytics, Inc. may use such information in the manner described in the privacy policy, subject to compliance with applicable law.

9. We will provide any necessary technology for the duration of the study, including a smartphone and data plan, if you do not already have one. Additionally, we may provide other fitness devices, including the Jawbone UP3, Apple Watch, and Alivecor Kardia, to monitor your health and the potential benefits from this study. These devices may help us to understand how exercise may

improve your sleep and heart rhythm. The devices must be returned after the study is completed; for the jawbone and Alivecor Kardia, if you continue to share your data with us, then you may keep these devices up to a year. Certain devices are owned by the Government and a police report will be filed if they are lost or stolen; this includes the Apple Watch and iPhone. Please notify them promptly if any devices are lost or stolen.

10. We may continue to monitor your progress, up to a year. During this time, you may keep any devices that we provide (depending on availability). After the year, we will ask for the device to be returned. Use of these devices is optional, and can be returned at any time if not in use.

    To better understand the benefits of exercise, we may install an application on your phone to monitor your physical activity/movement, social activity, and daily mood. This is optional. None of the data from the application can be linked back to you. In other words, it is completely de-identified.

11. If you have peripheral arterial disease (PAD), you may be offered the opportunity to participate in another study that focuses on PAD-specific exercise programming. This would be optional and would not affect your participation in the current study. If you wish to participate in this separate study (the Smart MOVE Study), you will be asked to sign a separate consent form for that study, and in which case we will also share de-identified data about you that we collect from this study with the Smart MOVE Study.

RISKS:

1. Psychologic testing/questionnaires/surveys/interviews: Being asked questions about the stress in your life may cause you to have unpleasant and/or upsetting feelings. If this happens, then you can take a break from the interviews. You can also slow down and take longer to do the tests. Should you so desire, a counseling session and/or referral for counseling will be made available.

2. Risk of starting a CR program: Rarely, physical activity during rehab causes serious problems. These problems can include injuries to your muscles and bones or heart rhythm problems that can lead to a heart attack or death. Before you start, our team will assess your health and physical fitness to make sure you are healthy enough to begin a cardiac rehab program.

3. The exercise treadmill test: You may have chest pain or get short of breath during the treadmill test, but you will be able to stop at any time. During the treadmill test, people can get a muscle or bone injury (like a sprained ankle) or have a change in their heartbeat. Rarely, people can have a heart attack, stroke or die. For people who recently have had a heart attack (less than 3 weeks before), the chance of having another heart attack or dying during the treadmill test is about 1 in 1,000. For all the other patients, the risk is about 1 in 10,000. A credentialed practitioner will perform the treadmill test. Your heart and blood pressure will be monitored during the test and the doctor will stop the test if your heart beat changes, your blood pressure drops or you have bad leg pain. If your heart beat, blood pressure or leg pain does not get better you will be taken to the emergency room for a checkup.

BENEFITS: Taking part in this research study may benefit you by increasing your cardiopulmonary fitness which can improve how you feel in the short term and other long-term outcomes including a

lower risk of hospitalization or worsening of any cardiac or pulmonary conditions. You also may not benefit personally from this study, but we the researchers may learn new things that will help other patients.

ALTERNATIVES: You do not have to be in this study to receive treatment for your condition. Your study doctor can discuss with you the alternative treatments.

CONFIDENTIALITY: We will keep information about you, including any research records we create, strictly confidential to the extent required by law. We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files (this consent and HIPAA Authorization form) locked in a file cabinet in a private office. We will use a study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. People other than those doing this research may have access to your study records including:

- Sponsor, companies or agencies paying for the study (Moving Analytics, Inc., VA Center for Innovations)
- The Office for Human Research Protections (OHRP)
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- The Emory University Institutional Review Board and other offices in Emory University that help run and/or oversee studies
- The Atlanta VAHCS Research Compliance Officer
- VA research staff within the VA Hospital or at Emory University
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will NOT be created if you have any services or procedures done by an Emory provider or facility for this study.

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP), and we will ask you to sign a form saying that you have received this notice.

If you are in an FDA sponsored clinical trial: 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.

COMPENSATION: You will not be compensated for participating in this study unless you are in the wait-list control group; in this case, you will be offered a $30 gift card for your first visit to compensate you for your time.

You will get emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not follow study procedures. If you believe you have been injured by this research, you should contact [redacted]

CONFLICT OF INTEREST: None

COSTS: Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study. If you were prescribed to participate in an exercise program by your clinical provider, then the exercise testing and labs are considered standard of care and subject to your normal co-pays. However, if you were directly recruited into this study and not referred by your provider, then you will not be subject to co-pays.

CONTACT PERSONS: If you have any questions, concerns, or complaints about this study you can call a member of the study staff:

[redacted]

If you have been harmed from being in this study call: [redacted]
If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Emory University Institutional Review Board (404) 712-0720 or toll free at 1-877-503-9797

Or

The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Director at (404) 321-6111 ext. 206933

If you have any questions about your rights as a participant in this recruitment process, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.

NEW FINDINGS: We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

VOLUNTARY PARTICIPATION AND WITHDRAWAL: The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.

Your participation is voluntary and you have the right to refuse to be in this study. You can stop at anytime after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instruction".
We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name

_____ _____ _____
Research Participant's Signature Date Time

(to be entered by participant)

_____
Name of Approved Individual Obtaining Consent

_____ _____ _____
Signature of Approved Individual Obtaining Consent Date Time
(to be entered by Approved Individual)

An Approved individual is one who has completed HRPP training and is officially approved to consent subjects for this specific study. The signature and date of this individual certifies that this is the most current approved consent document for this study.

OPTIONAL DATA REPOSITORY:

In the future, we would like to contact you, either to update our records or to offer you the opportunity to participate in future studies. This contact would be made by one of the investigators, coordinators, or recruiters of this study, and will be made by telephone or by sending you a letter in the mail. The letter may include a questionnaire for you to fill out and return. If you do not want to participate, you will simply be asked to return a card in the mail or call us. If we do not hear from you within 2 weeks of the letter, our coordinator may call you.

Storage of data for future research: Your research data and health information will be stored and made available to other researchers for future studies. The information will be available for any research question, such as research to understand what causes certain disease or to develop new scientific methods.

Because we will keep your data, there is a small chance that your protected health information (PHI) may be lost. We take important steps to prevent this from happening by storing all your data on secure VA research computers and keeping all physical files in a locked cabinet in a locked office.

You can request at any time that [redacted] and colleagues remove your data from this repository, and that they will make all reasonable attempts to honor your request. To make this request you can contact [redacted] in writing and then mail your request to:

[redacted]
Atlanta VA Health Care System
[redacted]

Check one below:

I agree to be contacted for future research studies:

☐ Yes ☐ No Initials_____

I agree to let my research data and health information be stored for future research:

☐ Yes ☐ No Initials_____