Consent to Participate in Research

Basic Study Information

Title of the Project: Estimating Recovery in Real-Time for Cardiac Rehabilitation
Principal Investigator: Dr. Thomas Kurian, Associate Professor University of Texas at Austin, Ascension Texas Cardiovascular
Study Sponsor: National Institute of Health

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- This study wants to determine if commercially available devices can be used to track recovery in cardiac rehabilitation.
- These smartwatches and smart rings collect data on exercise motion, sleep, and heart rate data.
- In order to participate, you must be eligible for cardiac rehabilitation. You should be a native English speaker. You need to have a smartphone with an appropriate data plan.
- You should be willing and able to wear one or more smartwatch and smart ring throughout the study. You should remember to charge the devices and use the applications on the phone daily.
- You must be willing to answer daily questions about your sleep quality, levels of daily activity, and severity of symptoms.
- If you choose to participate, you will be asked to wear sensor systems and use the phone to provide survey data on how you are feeling during cardiac rehabilitation.
- You will participate in standard of care cardiac rehabilitation. This is expected to take about 12 weeks (or 36 sessions).
- Risks or discomforts from this research include irritation from wearing multiple sensor devices.
- There is no direct benefit to participating in this study.
- Taking part in this research study is voluntary. You do not have to participate, and you can withdraw at any time.

More detailed information will be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of this study is to determine if data from commercial wearable sensors can be used to track recovery during cardiac rehabilitation. These sensors collect data during cardiac rehabilitation and also at home and during sleep. We seek to use data to estimate improvements in a 6-minute walk test that would come from participating in cardiac

rehabilitation.

Cardiac rehabilitation is known to improve health and reduce risk of death. However, participation in these programs has been limited, are often far and hard to get to, often lack diversity, and are often time-consuming. Therefore, good home monitoring is needed. To achieve this, we need better understanding of data that needs to be captured at home. This study seeks to use commercially available wearable devices to find if data will find good estimates of recovery. We want to create a system to help cardiac rehabilitation at home, using commercial wearable smartwatches and/or smartrings. This will help future health care providers to engage with participants who do not come to center-based programs.

This research is experimental, and the devices are not approved by the Food and Drug Administration for treatment or mitigation of disease.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to take part in routine standard of care cardiac rehabilitation care. You will be asked to wear smartwatch and/or a smartring for this research. An example of the data we collect from smartwatches and smartrings include your movement, heart rate, respiratory rate, and other data that is captured when you are moving and when you are asleep. You will be asked to do the following:

Enrollment Visit – Pre-assessment: You will learn how to use and sync wearable devices and how to use your smartphone to complete daily survey. You will complete a 6 minute walk test facilitated by a clinical research coordinator, who will observe you and record distance walked. This 6 minute walk test will involve wearing an Empatica smartwatch and walking from a chair towards a marker (cone or chair), then turning around and walking back, repeating this for up to 6 minutes or until you need to stop if you are tired or if you are having any difficulty breathing. (2 hours).

Daily data upload and Survey: You will be asked to wear daily a wearable smartwatch and/or smartring. Each morning you will use your smartphone application to complete morning survey of sleep quality. The survey will ask questions about your sleep, your exercise pattern, and if your condition or medication affected your sleep. (5 – 10 Minutes).

Weekly: 3 Cardiac rehabilitation sessions. During the cardiac rehabilitation sessions, you will be asked to wear an Empatica watch, and then complete your standard of care cardiac rehabilitation visit. (2 hours each session, 6 hours total, a total of 36 cardiac rehabilitation sessions)

Post assessment visit: After your final cardiac rehabilitation visit, you will complete another 6-minute walk test. You also be asked to return the smartwatch and/or smartring that you are using at home. devices (2 Hour)

How long will you be in this study and how many people will be in the study?

Participation in this study will last 14 weeks. Two weeks of baseline data collection and 12 weeks of cardiac rehabilitation. We will seek to enroll 50 participants.

What risks and discomforts might you experience from being in this study?

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There are some risks you might experience from being in this study. You may experience discomfort from wearing the sensors, particularly while sleeping. You may also experience a Rash from skin irritation when wearing devices. You may experience boredom while completing some parts of this study. Other risks include falls during the 6-minute walk test. We will mitigate this risk by clearing hazards and monitoring your stability.

There is risk of loss of confidentiality. We will use participant codes to protect privacy and confidentiality. We will keep participant information and code in a secure location. The smartphone applications will use codes. The smartphone applications use secure practice for privacy.

The researchers will let you know about any significant new findings. These findings might be additional risks or discomforts that might make you change your mind about participating in this study.

How could you benefit from this study?

You will not directly benefit from being in this study. Data from this study may help improve cardiac rehabilitation programs in the future.

What will happen to the samples and/or data we collect from you?

As part of this study, we will collect information from you about your condition. We will collect sensor data during your exercise. We will collect sensor data while you are resting. This data includes motion, heart rate and breathing rate data.

We will de-identify this data. This data will be used in calculating estimates of recovery in future clinical use. The de-identified data will be made available for future use, possibly with other researchers. You will not be contacted about future use of your data. The future use of your data will not inform clinical decision making. The future use of your data will not require a new trial.

The commercial devices have standard privacy policies meant to keep your data confidential. They use standard privacy and security. We will share their privacy policies with you. We will generate accounts for you. Therefore, the commercial companies will not have any of your private information. They will store and maintain data captured by the devices.

How will we protect your information?

We will protect your information by creating a participant ID that codes your information. Your information and participant ID are the only direct link to you. This will be stored separately from data. These identifiers will be destroyed 3 years after the study has been completed. The data collected by sensors in this study will only have your code.

Information about you may be given to the following organizations:

- The study sponsor and/or representative of the sponsor
- Ascension Seton Researchers
- Representatives of UT Austin and the UT Austin Institutional Review Board
- Other collaborating organizations: Texas A&M University (only de-identified data)
- Officials of the Department of Health and Human Services.

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 website will include a summary of the results. You can search this website at any time.

To help us protect your privacy we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below. The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen to the information we collect about you after the study is over?

After the research has completed, we will keep your research data to use for at least 3 years and made available for future research.

Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

What if we learn something about your health that you did not know?

As part of this study, we may learn medically relevant information about you. If we learn something that you and your doctor did not know, we will provide this information to you and your cardiologist.

How will we compensate you for being part of the study?

You will receive $50 for enrollment, $25 after completing the first 12 cardiac rehab sessions, $25 for completing another 12 cardiac rehab sessions, $25 for completing the final 12 cardiac rehab sessions, and $50 for returning device.

You will receive a total of $175 for your participation in this study if you complete all activities. Because you are being paid to take part in the study, we are required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay you. It will not be kept as part of your study chart. You will need to complete a Federal W-9 form including your Social Security number for this income tax reporting. This form will be given to the business office. If you do

not provide your social security number and complete an IRS Form W-9, you may still be in the study, but you will not receive any payments for your participation. If you are paid $600 or more in a calendar year by Ascension, you will be sent a Form 1099 to use when preparing your tax forms.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin or Ascension.

You are not waiving any of your legal rights by participating in this study.

What should you know if you are hurt during a study taking place at Ascension Seton?

If there is an emergency, call 911 right away or go to the emergency room and contact your study doctor as soon as you can. If you are hurt or get sick while you are in this research study, you must tell your study doctor right away. Treatment will be available.

Treatment may be billed to you or your insurer. If your insurance is billed, you may be required to pay deductibles and copayments that apply. You should check with your insurance company about any such payments. Ascension does not offer financial compensation or payment if you are hurt or get sick as a result of participating in this research.

What are the costs to you to be part of the study?

To participate in the research, you will not be required to pay for any study related procedures (cost is not applicable). You will only pay costs associated with standard of care. There is no cost to you if the device becomes damaged or lost. You will receive $50 in compensation for returning the device.

What other choices do you have if you do not take part in this study?

If you do not take part in this study, you will still be treated by your healthcare provider per usual practices.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin or Ascension. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, you will be required to provide a formal written notification of the withdrawal (email or letter at the address listed at the end of this form).

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if it is determined by the research team that it is unsafe for you to continue. If any of the following issues come up, we will have to ask you to stop participating:

- Compliance issues, including but not limited to:
  - Completing less than 75% of scheduled cardiac rehabilitation sessions
  - Completing less than 75% of the daily surveys
  - Wearing devices less than 75% of the time
- Issues regarding cardiac rehab participation
  - If your cardiologist or cardiac rehab staff believe it is unsafe for you to continue normal cardiac rehab sessions (due to mobility issues, vital sign instability, unstable medical conditions, etc.)

Your partially collected data will be used in research if you are asked to stop participation. You may request this data be removed.

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Thomas Kurian, MD
Phone: 512-324-3434
Emergency 24-hour Phone: 512-458-1121

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

RESEARCH PARTICIPANT BILL OF RIGHTS

I have been asked to participate in a research study. Before I make a decision on whether or not I want to participate in this study, I have the right:

1. To be told the reason why this study is being done.
2. To be told how the study will be done and what kind of medication or device will be used
3. To know the different types of side effects to expect from my participation in the study.
4. To know what benefits, I will receive from my participation in this study.
5. To be told what other treatment is available for me, including the risks and benefits.
6. To be told what other treatments are available to me after the study has been completed.
7. To be given an opportunity to ask any questions concerning the medical experiment or the procedures involved.
8. To stop the study at any time and know I will continue to receive good care.
9. To receive a copy of the patient rights and the signed and dated informed consent form.
10. To make up my mind about being part of the study without feeling forced to participate.