Myocardial Infarction, COmbined-device, Recovery Enhancement Study

NCT03760796

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Informed Consent (MICORE Study)
ID: IRB00099938
Martin, Seth (PI)
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**1. Welcome:** Welcome and thank you for considering being part of this research study.

**Learn more about the study first:** This research study investigates how this app could be used to help patients recover from a heart attack in a safer and more effective way. We will examine what happens when patients are given an app with necessary information and resources early in the heart attack recovery process. The study will determine if it is feasible to help patients navigate the hospital discharge process using our digital health solution to educate themselves about their heart disease, new medications, follow-up, and how recovery is going after a heart attack. Data acquired will be analyzed to help make the app easier to use and more helpful for patients recovering from a heart attack in the future. Participation in this study will last for up to 1 year following your discharge from the hospital.

We will ask you to answer survey questions at the time of enrollment as well as at one, six and twelve months following discharge, daily logging of medication taking and vital signs, logging at least two follow-up appointments prior to discharge, entering two contacts into the app prior to discharge, and completing all the short educational articles within one week following discharge.

It is possible that this app will help you increase your knowledge and better manage your health. In addition, the data that you contribute as a research participant could help others in the future. Participation in this study is voluntary and you will continue to receive standard of care regardless of whether or not you choose to participate.

If you are participating in the "iShare" iPhone loaner program, you agree to allow the study team to use remote management features on your loaner phone which allows us to provide you with software updates, receive status updates from your loaner phone including network IP address, and remotely deactivate or track the location of the loaner phone should it be lost or stolen. You are responsible for contacting the study team as soon as possible should your phone or watch become lost, stolen, or damaged.

**2. Privacy:** Your data will be encrypted (transformed into a form unreadable by anyone without a secret encryption key to prevent unauthorized access) and stored securely in our database.

**Learn more about how your privacy and identity are protected.** In the case that your information will need to be shared with people outside of Johns Hopkins like Food and Drug Administration, we will ensure that the information will not include

any of your personal information. You may choose to allow your friends and family to gain access to the app alongside you and to access your personal health information. To do so, you will need to specify their full name and email through our app and take into consideration that adding friends and family increases risk of loss of confidentiality.

**3. Data Use:** Only qualified people working on this study will have access to your information.

**Learn more about data use:** There are sensors in your phone, and Apple Watch, that can assess physical activity and we will collect such data with your permission. We will not access your personal contacts or other applications. We may ask for access to your photos and camera so that you can store your insurance card and other medical information, as well as the ability to send email updates to your selected healthcare providers. We also will collect comprehensive set of information from your electronic medical records, such as your age, sex, medications, cardiac risk factors, and other characteristics. You will also receive an iHealth blood pressure monitor so it can be paired with your phone and can track your blood pressure and record it in mobile application. If the app is downloaded on your personal iPhone you can continue to access it after study completion. If you access the app following study completion your data will continue to be sent to our backend server, and we will use this data for app development purposes. If you do not wish to keep using the app or do not want your data to be sent to our servers, then please delete the app from your phone following study completion.

**4. Data Gathering.** The study will gather digital health data (such as pulse rate, physical activity, and blood pressure) with your permission. You will be given an Apple Watch and iHealth blood pressure cuff to monitor these vitals. The Apple Watch should be returned 30 days following discharge but the iHealth blood pressure cuff does not need to be returned to the study team.

**Learn more about data gathering:** The research team will be studying your feedback, what information you enter in the app, and how much you use the app. We do our best to ensure that only people who need to use your information for the study have access to it and keep it confidential - but, we cannot guarantee this.

**5. Study Survey.** The study involves survey questions about the app and your hospitalization. You will be emailed surveys at 3 days, 1 month, 6 months, and 12 months following your discharge from the hospital.

**Learn more about the study survey:** We will ask you survey questions about your experience using the app and being hospitalized for a heart attack. If you do not respond to the 3 day and 1-month online surveys within a week of the email being sent one of our study team members will follow up with you so you can provide your responses by phone interview. In recognition of your effort and time, you will be compensated with a $10 electronic gift card upon successful completion of survey questions emailed to you 3 and 30 days following your discharge from the hospital. If you note being readmitted to a hospital outside the Hopkins healthcare system you will be emailed a form asking for permission to obtain access to your hospital records so we can better understand why you were readmitted. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any questions you do not want to answer.

6. **Disclosure**: A researcher and Johns Hopkins have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Erin Spaulding (603-724-0604). This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

**7. Withdrawing.** You have the option to stop participating at any time.

**Learn more about withdrawing:** We will continue to collect information about you until the end of the study unless you tell us you have changed your mind. If you change your mind and don't want your information used for the study anymore, you can call The Johns Hopkins Institutional Review Board at 410-955-3008. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

**8. Review**: [Full electronic copy of all sections of the informed consent above are provided with instructions "Review the form below, and tap Agree if you're ready to continue." The patient has the option for a paper-based copy or PDF to be emailed. An agreement/disclaimer is also provided to the patient, "This digital health tool

empowers you to take control of your health, but does not replace your care team. Questions or concerns about your medical care should be directed to your existing care providers."]

**9. Consent Page:** [Patient is asked to type in their First Name and Last Name to agree that they have reviewed the consent.]

**10. Signature Page:** [Patient is asked to use their finger to sign the informed consent.]