# Impact of a Corrie Cardiac Rehabilitation Program

# NCT05238103

# 3/27/2023

# RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

**Protocol Title**: Impact of a Mobile Technology Enabled Corrie Cardiac Rehabilitation Program on Functional Status and Cardiovascular Outcomes (mTECH REHAB): A Randomized Controlled Trial

**Application No.:** IRB00308410

**Sponsor/Supporter/Funded By:** American Heart Association and Apple Inc.

**Lead Principal Investigator**: **Lena M. Mathews, MD, MHS**

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**See "Study Site Information" page(s) near the end of this consent form for your local study site contacts.**

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

## 1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

- We are conducting a research study to evaluate two different ways to participate in cardiac rehabilitation. Cardiac rehabilitation is considered a core part of the recovery process from a cardiac event, and includes components such as structured exercise, health education, medication review, and lifestyle changes, in addition to routine clinical care. Traditionally, cardiac rehabilitation takes place as part of a supervised program offered in a cardiac rehabilitation center (Traditional CR), and starts a few weeks after hospital discharge.

- The goal of this study is to evaluate the effects of a hybrid cardiac rehabilitation program (Hybrid CR). The Hybrid CR program has added components in addition to usual care (which includes Traditional CR), and entails a combination of center-based and home-based exercise sessions, as well as a smartphone app, smartwatch, blood pressure monitor, and weekly calls from the study team to track progress at home.
- If you agree to participate, and meet all of the screening requirements for eligibility, you will be randomized to either Traditional CR or Hybrid CR. Randomization means you will be assigned to one of these groups by chance, which is like flipping a coin.
- Participants randomized to the Hybrid CR group will be asked to attend at least two in–person cardiac rehabilitation evaluation sessions at the cardiac rehabilitation center to personalize their home exercise program and to ensure they are safe to exercise at home.
- Participants randomized to the Traditional CR group will continue to receive the care provided by their treatment team, which includes going to the cardiac rehabilitation center for exercise and health education.
- Participation in this study will last for up to 16 weeks following discharge from the hospital.
- During the study, all participants in both groups will have procedures done for research purposes including a health assessment, blood work, and questionnaires at enrollment and a follow-up visit 16 weeks later. We will also collect information about you from your medical records.
- Risks of participation include fall or injury that may result from exercising, bleeding and discomfort from blood draws, feeling uncomfortable when answering questionnaires, and that information about you may become known to people outside this study.
- Although cardiac rehabilitation is almost universally recommended, the benefits you will obtain will largely depend on the extent to which you participate regularly in the offered activities within each group. Therefore, you may or may not benefit from participating in this study.

## 2. Why is this research being done?

This research is being done to investigate whether Hybrid CR is effective in helping patients recover from a heart attack, heart surgery, or heart procedure, compared to Traditional CR. Cardiac rehabilitation is a guideline-recommended program that involves health education, structured exercise, and regular follow up that helps patients recover from a cardiovascular event and reduces the risk of cardiovascular complications and death for patients. However, many eligible patients do not routinely participate in Traditional CR due to barriers related to access. To address this gap, we developed the Hybrid CR program, which is being evaluated in this study.

***Who can join this study?***

Adults who are at least 18 years old recovering from heart attack, heart surgery, or heart procedure may join the study.

## 3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- We will randomize you by chance, like flipping a coin to either Hybrid Cardiac Rehabilitation or to Traditional CR.
- We will collect information from you during enrollment (beginning of the study) while you are still in the hospital, during follow up calls, and at a follow up visit 16 weeks after hospital discharge (end of study).
- All study participants will be asked to undergo a health assessment to measure your blood pressure and heart rate, and complete a 6-minute walk test at enrollment (if enrolled in the hospital) and the 16-week follow-up visit. We will also collect information from your electronic medical records, such as your age, sex, medications you are using, and other medical conditions that you may have.

- **Data gathering through devices:** *If you are randomized to the Hybrid CR group:*
    - You will be asked to engage in the Hybrid CR program throughout the study using a smartphone app, smartwatch and Bluetooth enabled blood pressure monitor. If you do not now own any of the devices, these will be provided to you by the study team.
    - You will also receive weekly calls from the study team to check on your progress with the program. These calls will include a video component, unless you opt out and prefer audio only. You may receive customized motivational messages to help with your recovery process. You will receive resistance bands to assist in exercise and will be trained how to use them.
    - In addition to home-based participation through the digital health technologies and weekly calls, you will be encouraged to continue to participate in center-based, in-person cardiac rehabilitation as much as possible.
    - There are sensors in your phone, and smartwatch, that will collect some 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.
    - 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. If the app is downloaded on your personal phone, you can continue to access it after study completion. If you access the app on your phone and/or smartwatch following study completion, your data will continue to be sent to our backend server, and we will use this data for program development purposes. In this case, you are free to keep the equipment provided by the study team, such as the phone, smartwatch device, blood pressure monitor, and resistance bands. 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 and return the devices to the study team. You may return the devices at the 16-week follow-up visit.
    - If you are provided with a smartphone or smartwatch by the study team, you agree to allow the study team to use remote management features on your phone or smartwatch which allows us to provide you with software updates, receive status updates from your devices including network IP address, and remotely deactivate or track the location of the phone or smartwatch should it be lost or stolen. You are responsible for contacting the study team as soon as possible should your phone or watch are lost, stolen, or damaged. You can keep the devices after the completion of the study as long as you continue to engage in the program activities. If you decide to stop the program during the study or within 6 months of study completion, you will be expected to return the devices to the study team.
- **Study Surveys**. All participants will be asked to complete a survey about your physical, mental health and health behaviors. You will be emailed surveys at enrollment and 16 weeks following your discharge from the hospital. For participants enrolled in the intervention group, we will ask you additional survey questions about your experience using the program/app. If you do not respond to the enrollment and 16-week 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. If you note being admitted to a hospital or having a cardiac procedure outside the site, you will be emailed a form asking for permission to obtain access to your hospital records so we can better understand why you were admitted or the nature of your procedure.
- **6-minute Walk test**: While in the hospital and at 16 weeks we will measure the six-minute walk test to measure your fitness and exercise capacity. During the test you will walk at your normal pace for six minutes.

  - Preparing for your test:
    - Wear clothes and shoes that are comfortable.
    - You may use your usual walking aids such as a cane or walker, if needed.
    - It is okay to eat a light meal prior to your test.
    - Take your usual medications.
    - Do not exercise within two hours of testing.
  - During the test:
    - The tester will measure your blood pressure, pulse and oxygen level usually with a pulse oximeter before you start to walk.
    - You should be given the following instructions: The object of the test is to walk as far as possible for six minutes. You will walk at your normal pace to a chair or cone, and turn around. And you continue to walk back and forth for six minutes.
    - Let the staff know if you are having chest pain or breathing difficulty.
    - It is acceptable to slow down, rest or stop. After every minute interval, you will be given an update.
  - Safety:
    - The tester will watch to see if you have breathing difficulty or chest pain.
    - Oxygen and other supplies will be nearby if you need them
- **Blood Work:** The study involves examining blood work at enrollment and 16 weeks following your discharge from the hospital. At enrollment, we will first see if your care team has already collected blood samples to measure the metrics that our study is interested in. If not, we will ask to collect up to 2 teaspoons of blood during enrollment and at the 16-week follow-up study visit. Results from the blood tests obtained at 16 weeks will be shared with you.
  - If you are randomized to the intervention group, your care team will order a blood test upon discharge to be obtained 4 weeks after hospital stay. This will include collection of up to one teaspoon of blood at a laboratory that is convenient for you. The results from the blood samples collected at 4 weeks will be shared with you to allow medication adjustment if needed.

The biospecimens (such as blood or urine) you provide for this research study will be processed and then immediately discarded. Your samples will be used as part of this research study only and will not be used or distributed for future research.

**Will research test results be shared with you?**

This study involves research tests that may produce information that could be useful for your clinical care. We will share this information with you. This includes results of your blood tests at 16 week follow up (and 4 week follow-up for those in the intervention group). Your care team may suggest adjusting your cardiovascular medications based on results.

**How long will you be in the study?**

You will be in this study for approximately 16 weeks following hospital discharge

## 4. What happens to data that are collected in the study?

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

The researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at this site and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

We will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within the site.

If data are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data sharing could change over time, and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

## 5. What are the risks or discomforts of the study?

There are no anticipated medical, financial, psychological, or emotional risks of joining this study.

**Blood Draw**
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

**Interviews or Questionnaires**
You may get tired or bored when we are asking you questions, or you are completing questionnaires. You do not have to answer any question you do not want to answer.

**Identifiable private information**
There is the risk that information about you may become known to people outside this study.

**6 Minute Walk Test**
This is a low-risk medical test under supervision. However risks include chest pain, shortness of breath, leg cramps, losing balance, excessive sweating, and falling.

**Off-site Exercise Sessions (Applicable to individuals in Hybrid CR arm)**
Home exercise will only be carried out by participants who have obtained clearance to do so after in-person evaluation in cardiac rehabilitation centers. Adverse events may include abnormal heart rhythm, abnormal blood pressure, heart attack or death, the risk for these complications is minimal.

Off-site exercise is usually recommended by clinicians upon discharge in addition to in-person Cardiac Rehabilitation, nonetheless, we are taking several precautions to minimize the risk.

1) We will ask you to refrain from unmonitored exercise at home until you undergo further assessment for high risk exercise features during in-person cardiac rehabilitation and are determined to be low to moderate risk for exercise. If you are deemed high risk, you will be encouraged to continue attending in-person cardiac rehabilitation sessions for safe, monitored exercise, and will be guided to perform lower levels of usual physical activity (e.g., walking, range of motion upper body movements) as advised the exercise physiologist.

2) We will provide weekly check-ins to guide you accordingly if your vital signs are not within normal range or you report concerning symptoms. The guide for these check-ins has been compiled based on the Johns Hopkins in-person cardiac rehabilitation protocols.

3) We will monitor your entries once a day (during business hours). Any symptoms or red flag vitals will be managed as per standardized operating procedure protocol. We do not replace your care team and can only guide you to direct your care to your treating team. Furthermore, if you are experiencing emergency, it is your responsibility to seek immediate care.

## 6. Are there benefits to being in the study?

You may or may not benefit from being in this study. For those that are randomized to the Hybrid CR program, it may help you increase your knowledge and better manage your health, and you may continue using the app, smartwatches and blood pressure cuff monitoring after the study ends.

If you take part in this study, you may help others in the future.

## 7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your usual medical care will not be affected.

## 8. Will it cost you anything to be in this study?

Please see the "Site Specific Consent Information" section for more information about costs specific to your site.

## 9. Will you be paid if you join this study?

- If you are in the Traditional CR group: You will be given a $50 gift card for participation in the study at the 16-week follow up visit.

- If you are in the Hybrid CR group: We will cover transportation and/or parking fees for the first two in-person cardiac rehabilitation visits. You may keep the devices provided to you if you plan to continue using them and agree with continued data collection through these devices. If you decide to stop program during the study or within 6 months of study completion, you will be expected to return the devices to the study team, either at the 16-week follow-up visit or with a return mailer at no cost to you. You will be given a $50 gift card for participation in the study at the 16-week follow up visit.

## 10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, we may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

## 11. Why might we take you out of the study early?

You may be taken out of the study if:

- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, we may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

## 12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

## 13. What does a conflict of interest mean to you as a participant in this study?

A researcher and Johns Hopkins University 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 University. 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 in how the study is conducted, how the results are analyzed, and how participants are protected.

If you have any questions about this financial interest, please talk to **Dr. Lena Mathews at 410-550-0856.** 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 researchers and/or Johns Hopkins.

## 14. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

**What is the Institutional Review Board (IRB) and how does it protect you?**

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

**What should you do if you have questions about the study?**
Call the principal investigator, **Dr. Lena Mathews** at 410-550-0856. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

You may also contact the investigator for your site in the Site Specific Consent Information section at the end of this consent form.

# SITE SPECIFIC CONSENT INFORMATION

**Site Name**: Johns Hopkins Medicine

**Study Title**: Impact of a mobile Technology Enabled Corrie Cardiac Rehabilitation Program on Functional Status and Cardiovascular Outcomes (mTECH REHAB): A Randomized Controlled Trial

**JHM IRB Application Number**: IRB00308410

**Site Principal Investigator**: Lena M. Mathews, MD, MHS

**Site Principal Investigator Contact Information:**

600 North Wolfe Street, Blalock /Room 524D2
Baltimore, Maryland 21287
Phone: 410-550-0856
Fax: 410-550-1183
E-mail: lmathew6@jhmi.edu

**Emergency Contact:** Chang Kim, MD, PhD; ckim148@jhmi.edu
**Other Study Contact(s):** Mansi Nimbalkar, MS-EP; mnimbal1@jhmi.edu

## Introduction:

This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

## Costs to Study Participants:

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet. This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

It may also include the following, if applicable for the study:

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

## Site IRB Contact Information:

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

If you are taking part at Howard County General Hospital or Suburban Hospital and have questions, call Dr. Lena Mathews at 410-550-0856.

## Additional information about your local site:

## How will your privacy be maintained and how will the confidentiality of your data be protected?

### HIPAA Authorization for Disclosure of Protected Health Information

**What information is being collected, used, or shared?**
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

**Who will see, use or share the information?**
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

**Do you have to sign this Authorization?**
You do not have to sign this Authorization, but if you do not, you may not join the study.

**How long will your information be used or shared?**
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

**What if you change your mind?**
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

**How will your information be protected?**

The Corrie Health digital platform uses a high level of personal security password protection and encryption to meet privacy standards.

## What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

## WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

| Signature of Participant | (Print Name) | Date/Time |
|---|---|---|

| Signature of Person Obtaining Consent | (Print Name) | Date/Time |
|---|---|---|

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

JOHNS HOPKINS
MEDICINE

# Insurance and Research Participant Financial Responsibility Information Sheet

**Clinical Research Study Title: Impact of a mobile Technology Enabled Corrie Cardiac Rehabilitation Program on Cardiovascular Outcomes (mTECH REHAB): A Randomized Controlled Trial**

**Principal Investigator: Lena Mathews, MD, MHS**

**eIRB #: IRB00308410**

**PRA CIR00090514 Revision # 2 Review Date: March 31, 2023**

The following procedures, tests, drugs or devices are part of this research and will be supplied free of charge by the study:

- Lipid panel (16 weeks)
- HbA1c (16 weeks)
- Corrie Cardiac Rehabilitation (Software) app
- Apple Smartphone, Smartwatch or FitBit wristband and blood pressure cuff

You and/or your health insurer will be responsible for all other procedures, tests, drugs or devices that are part of this study such as the following:

- Cardiac rehabilitation evaluation sessions: In-person (synchronous) exercise sessions (if done at one of Hopkins sites)

If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

For questions about your bill, including payment plans, financial assistance or information changes, please call:

**1-855-662-3017**