Improving Cardiac Rehabilitation Outcomes Through Mobile Case Management (iCARE)

NCT04938661

9/27/2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **September 27, 2024**
Not to be used after: **September 26, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Improving cardiac rehabilitation outcomes through mobile case management (iCARE)

IRB#: 20-002258

Principal Investigator: Dr. Thomas Olson and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to find out if doing cardiac rehab at home, or a mix of cardiac rehab at home and in the clinic, is as effective as coming in to the clinic for cardiac rehab. You are being asked to take part in this research study because you are taking part in cardiac rehab at Mayo Clinic, Rochester.
What's Involved	Study participation involves a baseline, 3 month, and 1 year visit to Mayo Clinic for cardiac rehab assessments. The baseline and 3 month visits are standard for any patient in cardiac rehab; the 1 year visit is done just for research. The 1 year visit will be identical to your baseline and 3 month visits.
Key Information	This study may not make your health better. However, your participation may help other patients in cardiac rehab in the future. The risks associated with this study are similar to standard cardiac rehab visits.

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Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. Thomas Olson **Phone:** (507) 284-4441 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

A description of this research study will be available on http://www.mayo.edu/research/clinical-trials. This website will not include information that can identify you. You can search these websites at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are taking part in cardiac rehab at Mayo Clinic.

The plan is to have about 333 people take part in this study at Mayo Clinic, Rochester.

Why is this research study being done?

We are doing this research study to find out if doing cardiac rehab at home, or a mix of cardiac rehab at home and in the clinic, is as effective as coming in to the clinic for cardiac rehab.

Information you should know

Who is Funding the Study?
The National Institute of Nursing Research and Mayo Clinic are funding the study. The National Institute of Nursing Research and Mayo Clinic will pay the institution to cover costs related to running the study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for 1 year.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

We will assign you by chance (like a coin toss) to one of three groups, listed below. You and the Principal Investigator can't choose your study group. You will have a 1 in 3 chance of being assigned to each group.

The three groups are as follows:
Arm 1: This arm consists of patients who will do traditional cardiac rehab at our Mayo Clinic facility over the course of 36 sessions. This includes supervised exercise sessions, cooking demonstrations, lectures, video presentations, group support, and quality of life questionnaires.

Arm 2: This arm consists of patients who will do traditional cardiac rehab at our Mayo Clinic facility over the course of 36 sessions, with the addition of the mHealth platform.

The mHealth platform provides access to e-Learning modules with factsheets, videos, and quality of life questionnaires. A Social Network Module will allow patients to communicate via a secure network with other patients. The Social Network Module also allows for secure two-way interaction with healthcare providers. Participants in Arm 2 will also receive a blood pressure cuff and weight scale for use in their homes. You can either receive these devices during your onsite baseline visit or have them shipped directly to your personal address. If the devices are shipped directly to your personal address, a member of the study staff will assist you with device setup via a video visit. You will be asked to use these devices and upload the appropriate data into the mHealth app.

Arm 3: This arm consists of patients who will participate in cardiac rehab from home using the mHealth platform for 36 sessions. You will be provided paper copies of educational content when you leave the hospital. You will be encouraged to exercise three days per week and fill out quality of life questionnaires in the mHealth platform. Once a week (up to 12 of the 36 sessions of cardiac rehab) you will have a virtual visit (either video or telephone visit) with Mayo Clinic Cardiac Rehab staff.

The mHealth platform provides access to e-Learning modules with factsheets, videos, and quality of life questionnaires. A Social Network Module will allow patients to communicate via a secure network with other patients. The Social Network Module also allows for secure two-way interaction with healthcare providers. Participants in Arm 3 will also receive a blood pressure cuff and weight scale for use in their homes. You can either receive these devices

during one of your onsite baseline visit or have them shipped directly to your personal address. If the devices are shipped directly to your personal address, a member of the study staff will assist you with device setup via a video visit. You will be asked to use these devices and upload the appropriate data into the mHealth app.

Each group will participate in a baseline visit, 3 month visit, and 1 year visit. These visits will take about 3 hours. The baseline and 3 month visits are standard for any patient in cardiac rehab; the 1 year visit is done just for research. The 1 year visit will be identical to your baseline and 3 month visits. At these visits we will:

- Check your vital signs
- Ask you about your medical history
- Draw a blood sample (9mL or about 2 teaspoons)
  - Including a pregnancy test for women of child bearing potential
- Assess your body composition by:
  - Measuring your body mass index (BMI)
  - Measuring your waist to hip ratio
  - Perform a DEXA scan
- Give you some quality of life questionnaires to fill out
- Assess your exercise capacity by:
  - Performing a 6 minute walk test
  - Performing a 12-lead ECG monitored cardiopulmonary exercise test (CPET)

If you have undergone surgery for cardiac rehabilitation (coronary artery bypass, heart valve repair/replacement, or heart transplant), you will only take part in a 6 minute walk test to assess your exercise capacity, not a CPET.

If you are in a group that uses the mHealth platform your name and email address will be shared with Moving Analytics, the company that runs the mHealth platform, so they can send you a link to download the platform on either your smart phone or your desktop computer.

eCARE sub-study (optional)
If you decide to participate in this study, regardless of which study arm you are in, you also have the choice to participate in a sub-study called eCARE. In this sub-study participants will participate in the main study, described above, and also be asked to wear a Fitbit activity tracker to collect data on physical activity while in the Cardiac Rehab program. You will receive your Fitbit at your baseline visit and can keep it upon completion of study participation. The study team will assist you with setting up your FitBit. Any information entered in to the Fitbit app will be shared with Fitbit Inc., including name and email.

The Fitbit is a smartwatch which will be worn on the wrist like a regular watch would be worn. The Fitbit is water resistant up to 50 meters (150 feet). It can be worn while swimming, showering, and any other activities of daily living that may result in the device getting wet. The Fitbit should be worn 24/7 unless being charged or cleaned. The Fitbit can be cleaned at any time by rinsing with fresh water. Do not use soap or any other household cleaning products.
I agree to participate in the optional eCARE sub-study:

☐ Yes ☐ No Please initial here: _____Date: _____

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

Blood Draw Risk:
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Dual Energy X-Ray Absorptiometry (DEXA) Risks:
A DEXA scan uses x-rays to measure body composition or bone density

Radiation Risks:
You will be exposed to radiation from the DEXA scan. The amount of radiation has a low risk of harmful effects.

Cardiopulmonary Exercise Testing (CPET) Risks:
While exercise testing is generally safe, there is a chance of heart attack, stroke, or dangerous arrhythmias occurring during this testing. We take precautions to prevent these risks during the test. This test uses small sticky pads that are placed on your chest to measure the electrical activity of your heart. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads.

Six Minute Walk Test Risk:
Complications associated with the 6MWT are the same as walking in a parking lot or grocery store since you self-select your walking speed and can stop and rest at any time. The test will be stopped if you experience excessive chest pain or lightheadedness. In that event, vital signs will be monitored as appropriate.

Fitbit Device
No risks or discomforts are expected from the wrist band you are being asked to wear for the study. The device is similar to wearing a watch around your wrist. If skin reddening or inflammation appears, or it becomes uncomfortable, please inform the study team or your primary care clinician.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

This study may not make your health better. However, your participation may help other patients in cardiac rehab in the future.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study.

These tests and procedures are:

- The Fitbit device, if you choose to participate in the sub-study
- Virtual visits (if participating in the Arm 3 group)
- The following tests during the 1 year visit
    - *Office visit*
    - *Blood sample*
    - *DEXA scan*
    - *6 minute walk test*
    - *CPET*
    - *Pregnancy test*

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care.
These tests and procedures are:

- The following tests during the baseline and 3 month visit
    - *Office visit*
    - *Blood sample*
    - *DEXA scan*
    - *6 minute walk test*
    - *CPET*
    - *Pregnancy test*

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive $50 for the baseline, 3 month, and 1 year visit for a total of up to $150. There is no additional compensation for participating in the Fitbit sub-study.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

If you are enrolled in the study, you will be identified by a study number. Only the study staff will have access to the link between your study number and your identifying information. All study related information will be stored on password protected computers and in locked file cabinets.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. 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 sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature