Official Title:	Rehabilitation at Home Using Mobile Health In Older Adults After Hospitalization for Ischemic Heart Disease
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NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	RESILIENT: REhabilitation at home uSIng mobiLe health In oldEr adults after hospitalizatioN for ischemic hearT disease s18-02017
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

Some of the people who may be able to take part in this study will be asked to take the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) to assess for decisional capacity due to their medical condition.

2. What is the purpose of this study?

The goal of this research study is to understand whether a personalized care plan for home exercise, coupled with the use of mobile health technology following a hospital admission for a heart attack or a cardiovascular procedure (percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG]), can prevent decline and improve physical activity, health, and independence in activities of daily living. The researchers would also like to evaluate whether this reduces any possible hospital readmissions.

You have been asked to take part in this study because you are 65 years of age or older and have been admitted to NYULMC or NYULMC-affiliated hospitals with a heart attack, or had elective PCI or CABG.

Participation in this study will in no way affect your standard of care at NYULMC or NYULMC-affiliated hospitals, as determined clinically appropriate by your doctor and healthcare team.

3. How long will I be in the study? How many other people will be in the study?

This study will last about 12 months. You will be asked to actively participate for 3 months, which will involve about 2 visits and at most 13 weekly phone calls. At the 6-month and 12-month time points, the study team will review your medical records for additional data.

About 400 people ages 65 and older are to be entered into this study across all sites. The entire study will take approximately 5 years.

This study will be both an in-patient and an out-patient study. This means some of the study will happen while you are in the hospital. Other study visits will be at NYU Langone outpatient settings (e.g. clinics).

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the treatment groups and receive either the study intervention or the usual care. There are no special requirements or criteria to be in either group. You will have a 3 out of 4 (75%) chance of receiving mobile health cardiac rehabilitation (mHealth-CR) and a 1 out of 4 (25%) chance of receiving standard medical care.

4.1 Baseline Visit (Intervention Group and Usual Care Group)

a. After signing the consent form, the research coordinator will spend about 1 hour with you. At this visit the research coordinator will:

- Interview you to collect general information such as contact information and demographics (age, race, gender, education, etc.), and information about your health, symptoms, daily functioning, and lifestyle.
- Conduct a brief physical assessment, which will include the following:
  - Squeeze a handheld device to measure your grip strength
  - A 6-minute timed walking test in which you will be asked to walk at a self-selected pace for 6 minutes (conducted by a research nurse)
- Conduct questionnaires about your health, symptoms, daily functioning, lifestyle, and health goals
- Schedule you to participate in a 15-minute phone call with the research coordinator to conduct an “Activities of Daily Living” questionnaire once every 2 weeks during the first month, and monthly during your second and third months’ duration in the study.

b. Intervention (Intervention Group Only)

- You will receive a 1-hour educational visit with an NYULMC licensed physical therapist that will include information on cardiac risk factor management, postoperative recovery, and a program of home

exercise that will be tailored to your abilities and limitations. In the event that an in-person intake visit cannot be conducted with the exercise therapist, a video visit will take place instead. We may use the Zoom Videoconferencing software to conduct the intake with the physical therapist through a password protected video phone call. The licensed physical therapist will also provide you with resistance bands to be used for your prescribed exercise regimen. As a part of your exercise therapy, certain aerobic prescriptions like outdoor walking could be made by your exercise therapist. In instances where you cannot participate in outdoor exercise due to reasons relating to the COVID-19 pandemic and winter weather, your physical therapist will provide you with aerobic activity videos that can be done indoors in order to facilitate your adherence to the exercise program.

As part of the intervention group, you will be asked to take the following study devices home for the duration of the study period: FitBit wearable activity monitor (and charger), tablet computer (and charger), and blood pressure cuff monitor. Details regarding these study devices are detailed below.

- You will be provided by the study team with a FitBit wearable activity monitor. The research team will explain how and when to wear the monitor, and will answer any questions.

  You will be asked to wear the FitBit activity monitor over the next 3 months, until your follow-up visit with the Research Coordinator or member of the study team. You will be asked to wear the device at all hours, aside from those spent sleeping and bathing, until the Research Coordinator, or other member of the study team collects it at follow-up (3 months post-hospital discharge).

  Information regarding your physical activity will be recorded. This information will include measures such as number of steps, calories burned, and amount of time spent being active and inactive. **Your physical activity data will not be monitored in real time and therefore this information will not be used as part of your clinical care. If at any point you believe that you are experiencing symptoms related to your heart, please call 911.**

- You will be provided a tablet computer to collect activity and health information. **This information will not be used as part of your clinical care. If at any point you believe that you are experiencing symptoms related to your heart, please call 911.** You will be using an application, “Moving Analytics”, throughout the study period (more details below). The Research Coordinator or study team member will work with you to explain the tablet and application.

- The Research Coordinator or study team member will introduce you to the mobile health technology software that you will be using for the study period, Moving Analytics. This application will help to reinforce the care plan given to you by your physical therapist through daily reminders and easily accessible visual activity plans. You will also be able to communicate with the physical therapist through this application, throughout the study period. The tablet that you receive will be pre-installed with both Moving Analytics and FitBit.

- You will be asked to participate in a 15-minute phone call with the research coordinator to conduct an “Activities of Daily Living” questionnaire once every 2 weeks during Month 1, and monthly during Month 2 and 3. You will also be asked to participate in a weekly phone call with the physical therapists during which the care plan may be modified and any questions you may have about the tablet computer or applications will be answered. Weekly phone calls will last around 20 minutes. The Research Coordinator will work with your schedule to set up a date for the phone call communications. You may still be referred to facility-based cardiac rehabilitation by your treating physician.

c. Follow-Up Visit 3-months after hospital discharge (Intervention Group and Usual Care Group)

The Research Coordinator or other member of the study team will schedule you for a visit at three months post-hospital discharge to perform a follow-up assessment, that will include many of the questions and physical assessments from your initial baseline visit. This visit will occur either in-hospital or at a research-

designated facility affiliated with NYU Langone Health. The research coordinator will spend around 1 hour with you. The questions will be regarding your health, symptoms, lifestyle, and any possible readmissions to the hospital since your cardiac event and/or procedure.

The research coordinator and research nurse will then conduct a second brief physical assessment, which will include the following:

- Squeeze a handheld device to measure your grip strength
- A 6-minute timed walking test in which you will be asked to walk at a self-selected pace for 6 minutes (conducted by a research nurse)

For intervention participants only: The Research Coordinator or other member of the study team will also collect the tablet computer, FitBit wearable activity monitor, and blood pressure cuff during this visit.

d. Review of Hospital Medical Records

We will review your medical record for your initial hospitalization and for any other hospitalizations that occur over the next 3 months, up until 12 months after your hospitalization. We will use this information to understand your medical history, diagnosis, and the details of possible readmissions.

Any identifiable private health information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

There is a small possibility that your information could be viewed by someone who is not authorized to do so. All electronic records are accessible only to the NYULMC research staff who undergo thorough training in data management and security. Any data collected on paper copy will be stored in a locked cabinet on a secure floor that requires an NYULMC ID for entry. Any relevant medical records will only be viewed by authorized research staff. Data input from the applications on the tablet will be transferred to the NYU study team and stored in a secure HIPAA-compliant internet-based platform that is only accessible by authorized research staff. Data obtained through the applications will be given a random study number that is de-identified from all personal identification indicators, therefore ensuring patient confidentiality from the devices.

Baseline assessment (for both intervention and control participants):

There is a small chance that you may trip during the 6-minute walking test (6MWT). You will not be asked to do anything outside of your normal level of activity. If you appear unsteady, or the research nurse has concerns about your safety, the research nurse will not perform this test or may stop the test early. You may also choose to stop the walking test at any time. Additional theoretical risks during the walking test include a drop in blood pressure, dizziness, angina, arrhythmia, dyspnea, leg cramps, and falls. Several studies have shown that these risks are rare, even in hospitalized patients.

For intervention participants only:

The tablet computers are meant to be used for study purposes only. We ask that you use the tablet strictly for the Moving Analytics and FitBit applications. **Downloading other applications and/or using your personal email on the tablet computer may expose you and your personal information to a security risk.**

The FitBit has been FDA approved. There is a chance that this activity monitor could cause some slight skin irritation. If this occurs, please let the research coordinator know.

There is a small chance that with home-based exercises, you may become fatigued, and feel unable to complete them. If at any point you feel that you cannot complete the exercises, we ask that you stop. The physical therapist can work with you to tailor the care plan to your individual needs and abilities.

There may also be risks we're not currently aware of.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

There is no definitive direct benefit to participants from study treatment or other study procedures during the course of the study. If you are assigned to the intervention group, there is a chance you may benefit beyond standard medical care. We hope the information from this study will help future patients with your condition.

8. What other choices do I have if I do not participate?

Declining to participate in the present research study will in no way affect your standard care for your hospitalization or heart disease.

9. Will I be paid for being in this study?

You will be paid per completed visit. After you are enrolled and complete the baseline interview and assessments, the research coordinator will give you a $25 compensation through a ClinCard. After you complete all 13 weekly phone calls, the follow-up interview, and the follow-up assessment, the research coordinator will give you a $90 compensation through the ClinCard. This compensation is inclusive of travel costs.

If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed visit. If you complete all the study visits, you will receive the indicated total of $115 for being in this study.

In order for you to receive a payment check, you need to give the study staff either your Social Security number or your Alien Registration number. If you do not have either of these numbers, you may be in the study but will not receive any payment.

If you are interested in participating in this study, but are having difficulties finding transportation to and from the baseline and/or follow-up study visit at the NYU Medical Center, the study team will assist you with arranging transportation for your attendance of the research visit(s) at no cost.

10. Will I have to pay for anything?

There are no anticipated costs to you for participating in the research study. If you are assigned to the intervention group, there will be no costs associated with these procedures.

The tablet computer, FitBit monitor, and blood pressure cuff monitor will be provided to participants at no cost, but must be returned to the study team at the end of the study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. Although you may report symptoms within the Moving Analytics application, these symptoms will not be monitored in real time and will not result in medical care being provided to you.

If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician or the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health carebenefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing **t**o be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institutes of Health/National Institutes of Aging
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Financial Disclosure

NYU School of Medicine maintains a financial disclosure process, by which people who conduct research must disclose any financial investments (for example, stock shares or patent holdings), or payments (for example, for consulting or speaking engagements) that are related to the research.

No conflicts of interest have been identified by the personnel involved in this study.

16. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at anytime.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

_____
Subject Initials

☐ Checking this box indicates my permission to be contacted by this study team after my completion of the study about taking part in future research.

_____
Subject Initials

17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date