Targeted Health Coaching Intervention to Improve Physical Activity Maintenance and Mobility Post- Structured Cardiac Rehabilitation Programming Among Older Adults: A Pilot Study (Target-CR)

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Duke University Health System

Consent to Participate in a Research Study

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SUMMARY

The purpose of this study is to identify factors that influence physical activity participation after completion of a structured cardiac rehabilitation program. This study will also examine whether a health coaching intervention is feasible and effective for improving or maintaining physical activity participation following cardiac rehabilitation compared to standard care.

Participants in this intervention study will have two in-person study visits, one at the start of the intervention and one at the end of the intervention. Study visits will include the following:

- Interview on physical activity participation
- Height and weight measurements
- Study questionnaires
- Functional fitness tests

In addition, participants will complete a qualitative interview at the initial study visit to assess factors and triggers that influence current physical activity participation. This interview will be recorded as an audio file to serve as a reference to the study staff conducting the intervention. Individuals that do not wish to be recorded can still participate in the study with staff collecting written notes of the interview.

Participants will be randomly assigned to either a health coaching intervention or a standard care intervention for a 3-month period. The health coaching group will receive six health coaching sessions, each lasting 30-60 minutes, during the 3-month intervention period. The standard care group will complete one 30-minute education session at the beginning of the 3-month intervention period. Both groups will complete a physical activity questionnaire each month during the intervention and wear a physical activity monitor to measure daily step count.

The greatest risk of this study includes the possibility of injury from continued physical activity participation.

You are being asked to take part in this research study because you are an adult 60 years or older who recently completed a cardiac rehabilitation program. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

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Dr. William E. Kraus, MD is the Principal Investigator conducting the study. A grant from the National Institutes of Health (NIH) will sponsor this study as a part of the Duke Roybal Center. Funding for the study will pay for a portion of Dr. Kraus' salary and for that of the research team members.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. William E. Kraus, MD will be your doctor for the study and will be in contact with your regular healthcare provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to identify factors and triggers that influence physical activity participation among older adults after completion of structured cardiac rehabilitation (CR) in a center-based CR program, and compare the effects of a health coaching intervention versus standard care on physical activity maintenance and functional fitness immediately following structured CR.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 26 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form before any research activities take place.

Participants in this study will be asked to complete two in-person study visits and a consent visit that will take place either remotely via ZOOM or in-person. Participants will also complete a 3-month intervention period that will include either a single personalized education session or six personalized health coaching sessions. These sessions can be completed virtually or in-person.

Schedule of Visits

Consent/Screening (~1.5 hours): This visit will be completed virtually or in-person. Study staff will discuss the details of the study and you will be asked to sign the consent form if you choose to participate in the study. You will then complete the following to confirm you are eligible for the study:

- Medical history
- Mental health screening questionnaire

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Baseline Testing (~2.5 hours): This visit will take place at the Duke Center for Living Campus. During this visit, you will undergo the following:

- An interview to assess factors and triggers that influence your physical activity participation
- Height and weight measurement
- Physical activity questionnaire
- Medication review
- Senior fitness test – this functional fitness assessment will include a chair stand test, arm curl test, chair sit and reach test, back scratch test, 8-foot up and go test, and step-in-place test

Randomization (~30 min): Once your baseline testing is complete, you will be randomly assigned (like the flip of a coin) to receive either Health Coaching or Standard Care. A study staff member will contact you to discuss your group assignment, review your personal physical activity prescription and schedule your next session.

Intervention Period (~3 months): Once you are assigned to a group, you will receive one of the following:

- ***Health Coaching Group*** – In this group, you will receive an exercise prescription (daily step goal) based on your last cardiac rehabilitation session exercise prescription. You will be provided an activity monitor to track your step count each day. Additionally, you will be asked to complete 6 virtual or in-person health coaching sessions, each lasting approximately 30-60 minutes. These sessions will take place approximately every other week during the 3-month intervention period.

- ***Education Group*** – In this group, you will receive an exercise prescription (daily step goal) based on your last cardiac rehabilitation session exercise prescription. You will be provided an activity monitor to track your step count each day. Additionally, you will be asked to complete a single virtual or in-person education session, lasting approximately 30 minutes, at the beginning of the 3-month intervention period.

During the intervention period, all participants will be asked to complete a questionnaire assessing ongoing factors and triggers that influence how often you participate in physical activity. You will be asked to complete this questionnaire at weeks 4, 8, and 12 of the intervention period. The questionnaire will be available in paper form or online and will take approximately 10 to 15 minutes each time it is completed.

Exit Testing (~1-2 hours): This visit will take place at the Duke Center for Living Campus. During this visit, you will undergo the following:

- Weight measurement
- Physical activity questionnaire

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- Senior fitness test – this functional fitness assessment will include a chair stand test, arm curl test, chair sit and reach test, back scratch test, 8-foot up and go test, and step-in-place test

HOW LONG WILL I BE IN THIS STUDY?
The total duration of the study will be approximately 5 months depending on your availability to schedule testing and intervention sessions. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to Dr. Kraus or study staff first.

WHAT ARE THE RISKS OF THE STUDY?

- ***Functional Fitness Testing:*** The risks of the functional fitness testing include: dizziness, fainting, abnormal blood pressure, muscle soreness, muscle strain. There may also be risks that are unknown at this time. To decrease risk, functional testing will be supervised by trained staff.

- ***Physical Activity Participation:*** The study intervention will include a daily physical activity goal. Risks of physical activity include: minor discomfort and/or shortness of breath, dizziness, muscle, joint strains and soreness, abnormal blood pressure, irregular heartbeats, and falls. In rare instances, heart attack, stroke, asthma, muscle injury and broken bones, and death may occur. To minimize risks, your exercise program will be based on your fitness level during your cardiac rehabilitation program and your physical activity prescription will be determined by qualified personnel.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
We cannot guarantee that you will receive any benefit from taking part in this study. If you agree to take part in this study, you may benefit from the personalized health coaching or single education session in how to maintain your physical activity level after graduation from a structured cardiac rehabilitation program. Participants in both study groups will receive a physical activity prescription and activity monitor to measure daily step count. Physical activity is well-recognized as a contributor to overall health.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

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Information collected about you for this research study will be kept in a research study record separate from your medical record. You will not have access to this research information until the end of the study. Any significant findings developed during the course of this research, which may bear upon your condition or willingness to continue participation in the study, will be provided to you.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System Institutional Review Board, NIH, and the Duke Clinical Quality Management Program (CQMP). If representatives of the Duke University Health System Institutional Review Board review your research record, they may also need to review your entire medical record.

As a part of this study, the study team will record the qualitative interview conducted at the baseline testing visit. This digital audio file will be stored within your research study record and retained for at least six years after the study is completed.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

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This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Data Privacy/Security Risks of Mobile Apps:

The data collected via the Garmin wristband activity monitor will be stored on your personal device and uploaded to the server of the app. Garmin activity data will be transferred to the Labfront platform to allow the study team to access it. Data will also be stored on the Garmin activity monitor itself. The study team will create a unique study-specific Duke email and an assigned unique default password for each participant. Passwords will be assigned in accordance with applicable Duke Health password security policy requirements. This email address and password will be used solely for account creation and will not be used for communication. No personal information will be used in the study-specific email or password. You will access the mobile application used in this study using the unique email address and password issued to you by the study team. We will provide you the study account information and log-in information so you can activate the app on your phone. During the study, the study team will have access to your study-specific email and password as well as the information maintained in the Garmin Connect account in order to monitor your data collected. For security purposes, this information, including the unique default password, should not be used for any other account. At the end of your participation in the study, we will stop collecting your activity data and you will be provided instructions on how to log out of all study accounts.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the Garmin Connect and Labfront Terms of Use and End User License Agreement prior to using the mobile applications. By logging into your study account, you are agreeing to abide by these guidelines. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. During the study, you are

encouraged to limit personal identifiers you enter into these mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to that information that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. For the purposes of this study, the data managed in the Garmin Connect platform is transmitted to an external vendor's secure platform (Labfront) for use and analysis by the Duke study team.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device.

We are not asking you to make any health decisions based on the use of the mobile app. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait to use the device until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Because e-mail and text does not provide a completely secure and confidential means of communication, please do not use email or text if you wish to keep your communication private. Instead, call the study staff member to speak with them directly.

WHAT ARE THE COSTS TO YOU?

There will be no additional costs to you as a result of being in this study. However, routine medical care (care you would have received whether or not you were in the study) and any other necessary therapies, tests, or lab work that is not study related will not be paid for by the study and will be charged to you or your insurance company.

WHAT ABOUT COMPENSATION?

You will be reimbursed $75 for completion of the baseline study visit and $75 for completion of the exit visit, for a maximum of $150. You will also be allowed to keep the wearable activity monitor provided to you at the baseline study visit.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by

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Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected will remain part of your research record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Kraus in writing and let him know that you are withdrawing from the study. His mailing address is:

William E. Kraus, M.D.
Box 102903
Duke University Medical Center
Durham, NC 27710

Your study doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kraus at (919) 660-6613 during regular business hours and at (919) 970-7682 after hours and on weekends and holidays.

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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time

_____
Printed Name of Subject

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time