Protocol and Statistical Analysis Plan for Proposed Pilot Study: Implementing Telehealth-enhanced Hybrid Cardiac Rehabilitation (THCR) among Acute Coronary Syndrome Survivors: A Pilot Randomized Controlled Trial

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1. Study Purpose and Rationale

Over 1.3 million patients are hospitalized annually in the United States for an acute coronary syndrome (ACS; i.e., "heart attack"/myocardial infarction or unstable angina).[1] Within 1-year of an ACS event, 21% of survivors will be re-hospitalized, and ~1 in 5 will die.[2] These adverse outcomes highlight the need to optimize secondary prevention strategies to reduce recurrent events and increase survival in this vulnerable population.

Cardiac rehabilitation (CR)—which involves exercise training, patient education and health behavior modification in clinic- and/or home-based settings—is a secondary prevention program that significantly reduces reinfarction and mortality rates in ACS survivors.[3] Accordingly, CR is recognized as a Class I, Level A recommendation (i.e., highest recommendation and level of evidence classification) for secondary prevention. Yet, fewer than 30% of eligible cardiac patients participate in and adhere to CR programs in the United States.[4,5] Given the unprecedented impact of COVID-19 on our healthcare system, including reduced staff capacity and patient fears related to attending clinic-based programs, CR utilization has declined even further.[6-8] This study addresses the need for innovative strategies to support the uptake of CR among ACS patients in the post-COVID-19 era.[9]

One promising avenue for increasing CR participation and adherence is a telehealth-enhanced hybrid CR (THCR) model that combines telehealth, clinic- and home-based CR.[8] Several expert groups have strongly endorsed hybrid CR models that integrate telehealth (i.e., mobile apps, remote monitoring devices) because of their ability to offer the "best of both worlds" (i.e., in-clinic supervision/safety and at-home convenience) while also promoting real-time patient-provider communication and reimbursement as a telemedicine service.[10,11] Despite its potential, the degree to which and optimal design by which THCR improves stakeholder experiences (i.e., program usability, feasibility, acceptability), adherence (e.g., # of completed sessions), and clinical outcomes (e.g., functional capacity) requires additional investigation.[12] Moreover, few studies have examined how best to address patient, provider, and organizational barriers to implementing a THCR model in ACS patients, a population that is extremely sedentary, largely fails to meet physical activity guidelines, and has much to gain from CR participation. [13-15]

As part of my NHLBI-funded diversity supplement (3R01HL141609-03S1; PI: Moise), I co-designed a THCR model at New-York Presbyterian (NYP) with CR clinicians, health system leaders, and research scientists. For the current study, I will conduct a single center, two-arm, 1:1 parallel group randomized pilot study comparing THCR with traditional CR among ACS patients (N=40) to evaluate the feasibility (e.g., recruitment, adherence) of conducting an adequately powered randomized controlled trial (RCT). I will simultaneously identify acceptability, usability and determinants of THCR implementation using implementation-science methods via exit interviews and/or focus groups,[16] which will then be used to develop theory-informed, multilevel implementation strategies (e.g., telehealth training) in a future hybrid type II effectiveness-implementation trial.

Aim 1. Evaluate the feasibility of conducting a RCT of THCR compared with traditional CR in ACS survivors.
Hypothesis 1. We will demonstrate feasibility on the following study design elements: recruitment, program initiation, outcome assessment, adherence, and fidelity for THCR and, separately, traditional CR participants.

Aim 2. Assess multi—level factors that influence the implementation of THCR among post-ACS patients.
Hypothesis 2. Key constructs will include relative priority, compatibility, external policy and incentives (organizational level); beliefs about capabilities, knowledge, emotion (patient and provider level).

Cardiac Rehabilitation – Standard of Care: Cardiac rehabilitation (CR) is a standard of care, outpatient program that includes exercise training, patient education, and risk factor management (lipids, blood pressure, weight, diabetes mellitus, and smoking) led by a team of CR clinicians (e.g., physical therapist, nurse, exercise physiologist). CR is recognized as a Class I, Level A recommendation (i.e., highest recommendation and level of evidence classification) for secondary prevention by expert groups, including the American Heart Association (AHA) and American College of Cardiology (ACC). Accordingly, as standard of care, treating physicians are recommended to provide patients with a qualifying cardiac event, which includes ACS, with a referral to an outpatient CR program within the first 12 months after the patient's index event. If the patient is interested and willing to participate in an outpatient CR program, the treating physician works with the patient to identify an outpatient CR program that is suitable for the patient's needs (e.g., proximity to patient's home, insurance, etc.). Once a patient referral is received by the outpatient CR program, patients are screened for eligibility by the CR clinicians and then scheduled for their first clinic-based evaluation session (part of usual care). At the clinic-based evaluation session, patients will undergo submaximal exercise tests (six-minute walk test, sit and stand

test, and modified Balke Treadmill test) with a CR physical therapist to determine functional capacity and American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) risk stratification (e.g., low-, moderate-, high-risk). Patients are then scheduled to return to the clinic (1-2 weeks after the clinic-based evaluation session) to begin their official CR program sessions. Patients that have not yet started their official CR program sessions and were stratified as low-to-moderate risk for adverse cardiovascular events will be considered eligible for the current study.

2. Study Design

PHASE I: The purpose of Phase I is to evaluate the feasibility of conducting a RCT of THCR compared with traditional CR among post-ACS patients (Aim 1) and assess factors that influenced implementation among those that participated in the study (Aim 2).

We will recruit **40** participants who recently survived an ACS event and who are enrolled in cardiac rehabilitation (CR) at the NewYork-Presbyterian (NYP) Vanderbilt CardioPulmonary Clinic; an existing, standard of care, secondary prevention program offered at NYP.

Eligibility Criteria: Patients will be **included** if they meet the following criteria:

(1) over the age of 18,
(2) can speak and read English or Spanish,
(3) confirmed ACS based on ICD-10 codes (I20.9, I21.3, I21.4, Z95.1, Z98.61),
(4) had their index event within the past 12 months.

ACS events will be defined according to American Heart Association/American College of Cardiology criteria as either acute myocardial infarction (with or without ST elevation) or unstable angina.[15]

Patients will be **excluded** if they have any of the following:

(1) severe disabling chronic medical and/or psychiatric comorbidities determined on a case-by-case basis that prevent safe or adequate participation;
(2) high-risk for adverse exercise-related cardiovascular events according to the AACVPR risk stratification criteria,
(3) participated in >1 CR program session;
(4) deemed unable to comply with the protocol (either self-selected or indicated during screening that s/he could not complete all requested tasks). This includes, but is not limited to, patients with a level of cognitive impairment indicative of dementia, patients with current alcohol or substance abuse, patients with a significant movement or balance disorder that interferes with walking, patients with impaired circulation or poor perfusion that may impede pulse oximeter readings, and patients with severe mental illness (e.g., schizophrenia);
(5) home-based environment deemed incompatible with the protocol and/or that prevent safe or adequate participation (either self-selected or indicated during screening/onboarding process); and
(6) unavailable for follow-up for reasons such as terminal illness and imminent plans to leave the United States (as we have migrant or mobile patients due to their citizenship and work issues).

These inclusion and exclusion criteria were selected based on AACVPR/ACC/AHA guidelines[17] and previously published protocols.[18]

Overview of Study Design: Patients who meet all eligibility criteria and provide consent will be enrolled into the study and randomized (1:1) to THCR (n=20) or traditional clinic-based CR (n=20). After randomization, each group will initiate the program to which they are allocated, wherein the first intervention visit for each group will be a clinic-based CR session. Each program will include 24 CR sessions over the course of 3-months. As part of standard of care, all patients will complete a six-minute walk test [6MWT], modified Balke Treadmill test, sit-to-stand test, PHQ-9, and Duke Health Profile (DUKE) questionnaire upon program completion (3-month follow up visit).

Sample Size and Power Estimates: Although some have used pilot studies to estimate effect sizes for primary outcomes, I agree with leaders in our field who argue that effect size estimates from small pilot studies are too imprecise to meaningfully inform effect size assumptions of power analyses for larger, later stage

studies.[4-6] Therefore, I do not provide power calculations for the effects of our intervention on adherence and behavioral health outcomes. I will, however, use estimates from these studies (e.g., standard deviations, attrition rates) to help determine an appropriate sample size for a subsequent study that is adequately powered to detect meaningful improvements in measures of adherence, functional capacity, and health-related quality of life.

As this is a pilot study, our sample size was guided by the need to enroll enough participants who recently survived an ACS to examine the feasibility of conducting a larger stage II or III randomized clinical trial of our THCR intervention in this patient population. In particular, I will determine whether we are capable of recruiting, retaining, and assessing participants as well as implementing the desired intervention with high fidelity. If the observed proportion of eligible participants who agree to participate in the trial is 50%, 55%, or 60%, and I therefore have to approach 80, 73, or 67 patients, respectively, in order to enroll 40 patients in this pilot, then I will be able to report with 95% confidence (based on the negative binomial distribution), that the expected proportion of eligible participants in a future trial who will enroll is at least 39%, 43%, or 47%, respectively. This number is entirely feasible based on enrollment numbers (n=478) from our large observational trial of ACS patients with eligibility criteria that largely overlap with this pilot study.

Since one of the main goals of this study is to demonstrate feasibility as it pertains to assessment and adherence, whether study-driven surveys are completed within the allotted timeframe will be noted in the research records and used for analysis.

3. Study Procedures

Recruitment and Screening/Enrollment.
For the purpose of this study, we will recruit patients that are referred and enrolled in CR at the NYP Vanderbilt Cardiopulmonary Rehabilitation (NYP-VCR) Clinic located within the Fauth Center for Cardiopulmonary Rehabilitation (168th Street). Healthcare providers (e.g., physicians, physician assistants) and staff that are part of the patient's clinical care team will be provided with study flyers (see supplementary material) to provide to patients at their professional discretion.
Phase 1. Patients referred to the NYP-VCR Clinic will be evaluated by a CR clinician and enrolled into the clinic's existing CR program as part of standard of care. CR Clinicians who have legitimate (non-research) access to patient data and who are involved in the standard of care treatment of potential participants will review medical records to identify patients who are at low-to-moderate risk for adverse cardiovascular events according to AACVPR risk stratification guidelines and deemed safe to participate and comply with this research protocol. These patients will be considered *preliminarily* eligible for the study.
The treating CR clinician will approach his/her own *preliminary* eligible patients to introduce the study and may provide a study flyer (see supplemental materials). The patient will be asked if they have interest in learning more and if so, the patient will be asked to provide permission (to the clinician) to have the study team approach them about possible participation in research. Next, the CR team will provide the study PI (Dr. Duran) with the first and last name, MRN, ICD-10 diagnosis code(s), and language of *preliminarily* eligible patients (who agreed to be contacted) via an encrypted email or via secure EPIC message direct to research staff. (Note: This message will also confirm the patient contact information and [if scheduled] day and time of the patient's upcoming standard of care evaluation visit.) A member of the research team will then identify the *preliminarily* eligible patients in the electronic health record (EHR) to confirm contact information, ICD-10 diagnosis code, preferred language, and the day and time of their standard of care evaluation visit. If the evaluation visit has not yet been scheduled, the research team will follow up with the CR clinician accordingly.
Research staff will then contact the patient (via phone call, text, email, or in-person) to conduct verbal consent for screening, and for those who agree, complete screening questions by phone, Zoom or in-person based on participant preference and availability. For the Zoom encounters, a member of the research team will send a secure link via email or text. For the in-person encounters, a member of the research team will approach the patient in-person either immediately before or at the conclusion of their standard of care CR evaluation visit. Screening questions will include topics such as comfort level with using electronic devices, home-based environment and resources, and cardiac rehabilitation participation. Sociodemographic factors will include age, gender, race, ethnicity, marital status, education, work history, social support, and home/mailing address. If the

participant has an adequate/safe space to conduct home-based exercise, feels comfortable conducting home-based sessions and being remotely monitored during home-based sessions, and has <1 CR session completed, then the participant will be deemed ***preliminarily*** eligible for the study. If the participant is screened by phone or Zoom prior to the CR evaluation visit and ***preliminary*** eligibility is confirmed, research personnel will send the participant an email with a copy of the full-study consent (to review at their own leisure) and inform the patient that their ***final*** eligibility will be confirmed at their standard of care evaluation visit, as well as verify the date and time of this visit [if scheduled[. To ensure ample time to consider the study and aid understanding, participants will also be offered the opportunity to review the full-study consent with a research team member by phone or via Zoom prior to their evaluation visit. If the participant does not meet preliminary eligibility criteria, the participant will be thanked for their time and will not continue with study activity.

If during the standard of care visit the treating CR clinician determines that the patient continues to demonstrate they are at low-to-moderate risk and has adequate pulse-oximeter readings, a member from the CR team will message a member of the research team (waiting "on standby") via Epic message, email, or telephone. This message will indicate that the patient *continues* to be eligible for the study and thus may be approached for written/signed consent and possible randomization. If the participant does not meet eligibility criteria, the participant will be informed and thanked for their time and will not continue with study activity.

Phase 2. A member of the research team will then approach the patient after their standard of care CR evaluation visit to review the study in more detail and explain participation. If the verbal consent for screening and screening questions have yet to be conducted, it will take place at this time, followed by the written/signed consent process for participation in the overall study. The consent process will begin with a concise and focused presentation of the key information about the research study and will present information in sufficient detail, including details about randomization. Potential subjects will have adequate time to review the documents in a private setting as well as an opportunity to discuss the information provided. If the patient prefers to set up a separate phone call or Zoom videoconference before or after the CR evaluation visit to discuss the study's informed consent document, we will accommodate accordingly. If the consent discussion for participation in the overall study takes place via Zoom, the research team member who conducts the informed consent process will remotely witness the patient signing the consent. The participant will then be asked to mail back the partially executed consent form in a prepaid envelope. Upon receipt of the partially executed consent document, the research team member will countersign the form and document the details of the consent process. In turn, the participant will be provided with a copy of the fully executed consent document.

Baseline Questionnaires and Randomization: Upon obtaining signed consent, research personnel will administer baseline questionnaires and then open an envelope with information about which group the participant has been allocated to via randomization.

Baseline Questionnaires (10 mins): Participants will be asked to complete a set of questionnaires to collect physical activity and exercise sensitivity measures immediately after the written/signed consent process (this is the preferred option). However, if the participant has scheduling conflicts and/or time constraints at the conclusion of their standard of care CR evaluation visit, the research team will provide hard copies of the questionnaires to the participant and give them the option to complete the questionnaires later but prior to their first clinic-based CR Session (Session 1). Research personnel will follow-up by phone and/or email/text and depending upon participant preference, the baseline questionnaires may be completed verbally with a member of the research team or via a secure Qualtrics link. Completion reminder attempts initiated by the research team will be documented.

Randomization: A member of the research team will open an envelope with information about which group the participant has been allocated to via randomization. Computer generated random allocation in SAS will be used to allocate patients to hybrid CR or traditional CR in 1:1 ratio; this process will take place prior to study initiation. Patients randomized to the traditional CR program will complete 24 clinic-based sessions according to NYPH's existing protocols. Patients randomized to the THCR program will complete 5 clinic-based and 19 home-based sessions according to protocols and intervention components (details provided below). If the patient is allocated to the hybrid CR model, research personnel will confirm the participant's home address and preferred days and times of shipment and assembly service for the home-based exercise equipment, as well as onboarding session part 2 (details provided below). In cases where the participant owns and specifically requests to use a comparable home-based exercise bike (e.g., Peloton Bike), the participant will be given the option to use their own equipment after being found acceptable by the research/CR team. (Note: this is what would be done according to standard of care if the participant was not enrolled in the study.) They will also be asked to stay 15-

30 minutes after their first CR session to complete an onboarding session with research personnel (details provided below). If the patient is allocated to the traditional CR model, they will be instructed to complete all clinic-based CR sessions according to existing clinic-based CR protocols, as well as weekly educational videos, weekly surveys, mid- and post-intervention questionnaires and an exit interview. Both arms will receive weekly emails or text messages (based on patient preference) with visit reminders, links to weekly educational videos, and weekly surveys.

Overview of the Hybrid CR Study Design: The Hybrid CR program will include a total of 24 visits over a 12-week period (up to a 6-month period). Clinic-based sessions (described below) will occur at the NYP-VCR clinic at the beginning of the program (Session 1 & 2) and at the end of each month (Session 8, 16, and 24). Home-based sessions will take place remotely, at the participant's home, once or twice per week via telehealth, depending on the week of the program. Patients will be provided with RPM devices and onboarding materials (onboarding session part 1) at the end of their first clinic-based CR session (Session 1), and home-based exercise equipment (stationary bike and weights) will be shipped to their home prior to their first home-based CR session (Session 3). To ensure proper setup of RPM devices and home-based exercise equipment, we will conduct a home-based onboarding session (onboarding session part 2) with the participant. In addition to scheduled sessions, patients will be asked to complete educational videos provided by the Henry Ford Health System, American Heart Association, and University of Ottawa Heart Institute, as well as document their physical activity, dietary intake, medication management and homework sessions via surveys administered on the Samsung Tablet. Patients will be encouraged (but not required) to achieve ≥30 minutes of moderate aerobic activity, such as brisk walking, on ≥5 days per week.

Clinic-based CR Sessions (Session 1 & 2, 8, 16; 60 mins): All patients enrolled in the study, irrespective of program allocation, will complete an initial clinic-based CR session at the NYP-VCR Clinic. The clinic-based CR session will adhere to existing standard of care protocols and will be administered by CR clinicians who have legitimate (non-research) access to patient data and who are involved in the standard of care treatment of participants. Briefly, patients will have their resting heart rate and blood pressure taken, followed by a directly supervised exercise session, wherein exercise heart rate, blood pressure, and rating of perceived exertion (RPE) will be recorded. The exercise session includes aerobic exercise on a treadmill (30 mins), strength training using light weights (1-10 pounds; 20 mins), and stretching (2-5 mins). Participants will then receive positive reinforcement and education about exercise (5 mins). This format will be consistent for all clinic-based CR sessions included in the traditional CR program (Session 1-23) and hybrid CR program (Session 1-2, 8, 16). Participants will receive a PayCard in the mail or in-person following the first clinic-based CR session (Session 1) onto which compensation will be loaded for this and future visits.

Hybrid CR Onboarding Process: Only those allocated to the hybrid CR program (active arm) will complete the onboarding process. A member of the research team will meet with the participant on two separate occasions (onboarding session part 1 and part 2) to onboard participants allocated to the hybrid CR program. *Onboarding Session Part 1 (15-30 mins)* will take place in-person, at the NYP Vanderbilt Clinic, immediately after the participant's first clinic-based CR session has been completed. During this session, research personnel will provide participants with a Hybrid CR binder, RPM devices (pulse oximeter, blood pressure monitor & cuff, Samsung tablet) needed to conduct the home-based CR sessions, as well as provide an access code (4 digit PIN) and instructions on how to use the RPM devices. Research personnel will spend adequate time reviewing how to use the devices and ensure all participant questions are answered. They will also spend time reviewing the home-based exercise equipment (stationary bike and weights), the Borg Rating of Perceived Exertion (RPE) scale, and re-confirm the participant's home address, day, and time of shipment and assembly service. They will also review the Safety Protocol and confirm the day and time of the participant's next clinic-based CR session (Session 2). An overview of the RPM devices and home-based exercise equipment are provided below.

Remote Patient Monitoring (RPM) Devices: To optimize feasibility, cost, and scalability, we leveraged NYPH's investment in Philips Healthcare's remote patient monitoring (RPM) platform. Key components of this platform include: 1) Home pulse oximeter device and blood pressure (BP) device that wirelessly transmits oxygen saturation, heart rate (HR) and BP data to a web-based tracking database (eCareCoordinator [eCC]) during CR sessions/exercise; 2) Samsung Tablet that provides telemonitoring-enabled CR-support via 2-way video calls,

surveys, education, and measurements; and 3) Embedded cellular or Wi-Fi to expand access. Details of the RPM devices are included in the supplemental material.

Home-based Exercise Equipment: To ensure patients receive optimal home-based exercise that is safe and comparable to standard of care, we will provide a stationary bike (a full list of potential bikes is included as Attachment A) for aerobic exercise and set of weights for strength training exercises. To reduce participant burden, the stationary bike will be assembled by a pre-paid team of professionals. Individuals who deliver and assemble the bike will be required to wear a mask and maintain social distancing. The delivery company does not require these individuals to be Covid tested and/or vaccinated. Available tracking information to monitor when equipment will arrive, as well as assembly team information (e.g., name of personnel completing the service) will be shared with participants who wish to receive. Details of the home-based exercise equipment are included in the supplemental material. Briefly, the stationary bike has an adjustable seat and handlebar to ensure proper form, adjustable resistance to ensure adequate exercise intensity, and a tablet holder to support the Samsung Tablet and ensure adequate supervision during video calls. Weights include two ankle/wrist wraps that can hold up to 10 lbs each. Each wrap has slots to securely hold weight packets, and can easily be adjusted based on the participant's needs (note: the manufacturer/brand may vary depending upon availability). In cases where the study-specific provided weights are not available to the participant at the time of the home-based CR session, equivalent weight may be used after being found acceptable by the research/CR team. (Note: this is what would be done according to standard of care if the participant was not enrolled in the study.)

Onboarding Session Part 2 (60 mins) will be scheduled after the participant receives all home-based exercise equipment, and the stationary bike has been assembled. Prior to onboarding session part 2, participants will receive a series of phone calls, emails and/or texts to confirm the following: 1) bike arrival, 2) bike assembly date/time, and 3) onboarding session part 2 date and time. This session will take place from the patient's home-environment using the "video call" feature on the Samsung Tablet. Research personnel will confirm that all RPM devices are properly syncing with the Samsung Tablet and that blood pressure, heart rate, oxygen saturation, and survey responses are properly integrating into the eCC platform in real-time. After RPM device setup is complete, research personnel will confirm proper setup of the cycle ergometer (e.g. seat height, pedals, tablet holder) and ensure that the participant knows how to navigate the display monitor (e.g., time, speed, etc.) and adjustable resistance on the device. Once the device is properly setup, research personnel will review proper RPM device setup to allow remote monitoring during the home-based exercise (aerobic and strength training). After each component of onboarding session part 2 is complete, participants will complete an onboarding feedback questionnaire (via phone or via an emailed/texted link to an online version, depending upon participant preference) and research personnel will schedule the first two Home-based CR Sessions (Session 3 and 4). If maintenance support related to the RPM devices is needed, it will be provided in the same manner as standard of care. If support related to the study-provided home-based exercise equipment is needed, research personnel will be available to provide and facilitate assistance (including arranging for repair and/or replacement in cases where equipment is defected or malfunctions).

Home-based CR Sessions (Session 3-7, 9-15, 17-23; 60 mins): Only those allocated to the hybrid CR program (active arm) will complete home-based CR sessions. All home-based CR sessions will be administered by Research Personnel on a secure Philips Healthcare's eCC Video Visit Platform and will align with what the CR clinician/team would do as standard of care. In the case technical issues occur with the eCC Video Visit Platform, Zoom will be used as the virtual platform to support the 2-way video visit. In the case technical issues occur with the pulse oximeter or blood pressure cuff/monitor, standard of care procedures will be used (e.g., use alternative device, manually determine pulse). The first two home-based CR sessions (Session 3 & 4) will be supervised via a 2-way video visit for the full duration of the session (50-60 mins), while subsequent home-based sessions (Session 5-7, 9-15, 17-23) will be partially supervised (20-30 mins) during the aerobic exercise component. During the first week of home-based CR sessions, the participant's physical home address (e.g.. 1234 Main Street Apt. A, Small Town 10001) as well as the name and phone number of an emergency contact will be confirmed should the participant require any emergency assistance during the CR sessions. Prior to beginning of each home-based session, participants will gather the following equipment: pulse oximeter (attached to a

lanyard), blood pressure cuff, blood pressure monitor, Samsung Tablet, adjustable ankle weights, a chair, and water. Details of the home-based CR sessions are outlined below.

Home-based CR Activity	Measurements	Equipment	Duration
Pre-Exercise Surveys	Exercise Location survey Hybrid CR Pre-Exercise Check In survey	Samsung Tablet	2-3 mins
Resting Vitals	Blood Pressure Heart Rate Oxygen Saturation	Samsung Tablet Blood Pressure Monitor Pulse Oximeter Chair	5 mins
Warm-up	-	-	3-5 mins
Aerobic Exercise	Heart Rate Oxygen Saturation RPE	Samsung Tablet Stationary Bike Pulse Oximeter Borg RPE scale	30 mins
Strength Training	Heart Rate Oxygen Saturation	Adjustable Ankle Weights Chair Pulse Oximeter	15-20 mins
Cool-down	-	-	2-3 mins
Post-exercise surveys	Strength Training survey Satisfaction survey	Samsung Tablet	2-3 mins
Recovery Vitals	Blood Pressure Heart Rate Oxygen Saturation	Samsung Tablet Blood Pressure Monitor Pulse Oximeter Chair	2-3 mins

Homework: Patients in both the hybrid and traditional CR program will be asked to complete weekly, self-administered educational videos on heart healthy living (e.g., nutrition, risk factor management, mental/emotional health) provided by the Henry Ford Health System, American Heart Association, and University of Ottawa Heart Institute (outlined below); record their physical activity, dietary intake, medication management, mental health and homework sessions via weekly Qualtrics surveys (attached materials); and will be encouraged (but not required) to achieve ≥30 minutes of moderate aerobic activity, such as brisk walking, on ≥5 days per week. Participants will be given up to 1 week from the time the surveys are sent/made available to complete them. In cases where a CR session is rescheduled, participants will be given up to 1 weeks from when they resume sessions to complete the homework/surveys. Completion reminder attempts initiated by the research team will be documented.

Time	Education
Week 1	1. How to Monitor your Blood Pressure at Home 2. Anatomy 1: Coronary Artery Disease 3. Getting Fit 1: Physical Activity 4. Getting Fit 2: Exercise 5. Getting Fit 3: Strength and Balance
Week 2	1. Anatomy 1: Angina and Heart Attack 2. Anatomy 1: Medical Tests and Treatment of CAD 3. Anatomy 1: Medications 4. Getting Fit 4: Resistance Bands for Strength
Week 3	1. Risk Factors for Heart Disease: Stress 2. Risk Factors for Heart Disease: Weight 3. Getting Fit 5: Avoiding Injury
Week 4	1. Risk Factors for Heart Disease: Nutrition 2. Eating Smart: Building a Healthy Plate 3. Smart Shopping: Understanding the Label

Week 5	1. Eating Smart: Making Smart Food Choices 2. Eating Out: Portion Size Dining Out 3. Risk Factors of Heart Disease: Smoking 4. Risk Factors of Heart Disease: Cholesterol
Week 6	1. Eating Smart: Making Calories Count 2. Eating Smart: Understanding Fats and Sodium
Week 7	1. Smart Shopping: Produce, Meat, Seafood, Deli
Week 8	1. Smart Shopping: Dairy, Fats and Oils
Week 9	1. Smart Shopping: Bread, Cereal, Frozen Entrees
Week 10	1. Eating Out: Fast Food, Buffets
Week 11	-
Week 12	-

Clinic-based CR Evaluation (Session 24; 60 mins): All patients enrolled in the study, irrespective of program allocation, will complete a final clinic-based CR evaluation session at the NYP-VCR Clinic. The clinic-based CR evaluation session will adhere to existing standard of care protocols and will be administered by CR clinicians who have legitimate (non-research) access to patient data and who are involved in the standard of care treatment of participants. Participants enrolled in the hybrid CR program will receive a reminder phone call and/or email and be instructed to bring all RPM devices with them to their clinic-based CR evaluation session. RPM devices will then be disinfected according to Philip's Healthcare protocols.

Post-Intervention: After completing the last CR session (Session 24), participants will be asked to complete post-intervention questionnaires and an exit interview. To accommodate participant preference, participants will be given the option to complete the questionnaires and exit interview in-person, at the NYP-VCR clinic immediately following the last CR session or at a separate day and time via telephone. The post-intervention sessions must be completed within 1-week after CR session 24. Exceptions to the 1-week turnaround expectation will be considered on a case-by-case basis by the study PI (i.e. the participant is sick or has a planned vacation). Completion reminder attempts initiated by the research team will be documented.

Post-Intervention Questionnaires (20 mins): Participants will complete valid, reliable, and pragmatic 4-item surveys on the acceptability, appropriateness, and feasibility of the intervention: (1) Acceptability of Intervention Measure (AIM), (2) Intervention Appropriateness Measure (IAM), (3) and the Feasibility of Intervention Measure (FIM).[22] They will also complete the same series of baseline questionnaires, implementation determinants questions, satisfaction questions and questions about their experience (e.g., bored, sleepy) while doing the CR sessions. The same battery of questionnaires will be administered half way into the intervention (CR Visit 12) to obtain a mid-intervention assessment.

Exit Interview (30-45 mins): After each participant completes the post-intervention questionnaires, they will participate in a 30-minute exit interview. The exit interview will take place in-person or via telephone. The goal is to assess participant-level barriers and facilitators to participating in and implementing the pilot study, as well as elicit feedback on the hybrid CR intervention design. The interview will be digitally audiotaped using Zoom and transcribed using Microsoft Stream.

After all intervention sessions are complete, participants enrolled in the hybrid CR program will have the option to keep their home-based exercise equipment. If the participant forgot to bring all RPM to their last CR session (Session 24), they will receive a pre-paid package to mail back the RPM devices, which will then be disinfected according to Philip's Healthcare protocols.

Feasibility Measures (Aim 1). To determine feasibility, I will examine the endpoints outlined in **Table 1**.

Table 1. Aim 1 Outcome Measures

Measure Type	Measure	Measure Description
Primary	# of participants enrolled/month	# of participants who completed recruitment activities and successfully consented and enrolled into the pilot study per month

Primary	Mean % of CR sessions completed by THCR participants	% of CR sessions completed by participants allocated to the THCR intervention, which includes 19 home-based and 5 clinic-based sessions.
Secondary	% of participants who attend ≥1 CR session after randomization in each arm	Participants who attend ≥1 CR session will be tallied. Numerator= total # of participants randomized into each arm who attend ≥1 CR session. Denominator= total # of participants randomized into each arm.
Secondary	Mean % of CR sessions completed by traditional CR participants	% of CR sessions completed by participants allocated to the traditional CR intervention, which includes 24 clinic-based sessions.
Secondary	% of participants who report adequate feasibility of the THCR intervention	% of participants who report an average score ≥4 (agree or completely agree) for their rating of the patient-perceived THCR intervention's feasibility on the four-item Feasibility of Intervention Measure (FIM). All four items of the FIM are rated on a Likert response scale ranging from 1 to 5 with higher scores indicating greater feasibility. Each Likert response scale rating will be summed (minimum: 4, maximum: 20) and averaged (minimum: 1, maximum: 5) across all four items.
Tertiary	% of participants who complete outcome assessments upon program completion in each arm	Participants who complete outcome assessments upon program completion will be tallied. Numerator= total # of participants randomized into each arm who complete outcome assessments upon program completion. Denominator= total # of participants randomized into each arm.
Tertiary	Mean % of CR sessions administered as intended in each arm	% of CR sessions (out of all 24 sessions) administered as intended to participants allocated to the THCR intervention and, separately, the traditional CR intervention
Tertiary	# of eligible patients referred to CR/month	# of patients who are referred to CR and eligible for the pilot study per month
Tertiary	% of participants who report adequate acceptability of the THCR intervention	% of participants who report an average score ≥4 (agree or completely agree) for their rating of the patient-perceived THCR intervention's feasibility on the four-item Acceptability of Intervention Measure (AIM). All four items of the AIM are rated on a Likert response scale ranging from 1 to 5 with higher scores indicating greater acceptability. Each Likert response scale rating will be summed (minimum: 4, maximum: 20) and averaged (minimum: 1, maximum: 5) across all four items.
Tertiary	% of participants who report adequate appropriateness of the THCR intervention	% of participants who report an average score ≥4 (agree or completely agree) for their rating of the patient-perceived THCR intervention's feasibility on the four-item Intervention Appropriateness Measure (IAM). All four items of the FIM are rated on a Likert response scale ranging from 1 to 5 with higher scores indicating greater appropriateness. Each Likert response scale rating will be summed (minimum: 4, maximum: 20) and averaged (minimum: 1, maximum: 5) across all four items.
Exploratory	Change in total distance traveled in 6MWT	This is to measure pre-to-post program change in functional capacity (using the six-minute walk test [6MWT]) among THCR and, separately, traditional CR participants. The 6MWT is a sub-maximal exercise test used to assess aerobic capacity and endurance. The total distance (meters) traveled over a time period of six minutes is used as the outcome by which to compare changes in performance capacity.
Exploratory	Change in health-related quality of life score	This is to measure pre-to-post program change in health-related quality of life (Duke health profile questionnaire [DUKE; physical, mental, social, and general health composite scores]) among THCR and, separately, traditional CR participants. The DUKE is a 17-item self-report questionnaire for measuring generic health-related quality of life over a 1-week time period. Responses are scored to calculate physical health, mental health, and social health scores, which are then summed and divided by 3 to obtain a general health score. The general health score ranges from 0 - 100, with high scores indicating better health-related quality of life.

I will use EHR and eCC data to assess feasibility metrics relevant to recruitment, retention, outcome assessments (described below), adherence, and fidelity to both the hybrid CR and traditional CR intervention. Survey data from the FIM, AIM, and IAM will be used to assess patient-perceived intervention feasibility, acceptability, and appropriateness, respectively. Data will be extracted from these sources via Trac requests, patient notes, patient chart review, and data export. Quality of administration will be assessed using direct observations throughout the trial, wherein research personnel will observe CR sessions (including onboarding sessions) and fill out a pragmatic checklist to assess fidelity. ***Feasibility Criteria.*** Feasibility will be achieved if the following criteria are met: (1) ≥3 eligible ACS patients are enrolled/month (recruitment); (2) ≥70% of THCR, and separately, traditional CR participants attend ≥1 CR sessions after randomization (program initiation); (3) ≥70% of THCR, and separately, traditional CR participants complete outcome assessments at 3 month follow up; (4)

≥50% of CR sessions (≥12 of 24) are completed by those allocated to each arm (adherence); (5) ≥80% of CR sessions (≥20 of 24) are administered as intended for each arm (fidelity).

Outcome assessments: Functional Capacity. We will measure the total distance (meters) traveled during the 6MWT. Cardiorespiratory Fitness. We will measure the exercise heart rate (HR), rate of perceived exertion (RPE), maximal speed (mph), incline (% grade), and duration (mins) achieved during the modified Balke treadmill test, a symptom-limited graded exercise test on a treadmill. This information will be used to assess the participant's maximal metabolic equivalents (METs; unitless).[23,24] METs, which quantify the energy cost of activities (1 MET=3.5ml O_2/kg/min), are routinely utilized to indirectly characterize cardiorespiratory fitness.[25] We will also measure exercise heart rate (HR) and exercise rate of perceived exertion (RPE). Health-related Quality of Life. We will administer the validated Duke Health Profile (DUKE) questionnaire to asses health-relate quality of life (physical health, mental health, social health, and general health composite scores)[28], which has been an outcome of interest in clinic-, home-, and hybrid-based trials.[12] Each of these outcome assessments are 1) measured at baseline (e.g., clinic-based screening session) and upon program completion; 2) part of CR standard of care; and 3) will not add additional burden to the participant, CR clinicians, or research staff. All measures will be recorded in the EHR by CR clinicians and extracted by research personnel via Trac requests, patient notes, patient chart review, and/or data export.

Aim 1 Analysis. For recruitment, the estimate will be calculated based on the number of eligible ACS patients enrolled per month over the 2-year period of the pilot trial. For THCR adherence, the estimate will be calculated based on the mean proportion of CR sessions completed (out of all 24 sessions) by THCR participants. For each proportion, I will compute the 1-tailed, 95% lower confidence limit (LCL) to estimate an empirically based lower-limit of the "true" proportion for each feasibility criteria. Evaluation of these endpoints and feasibility criteria (i.e., minimum acceptable values) will inform the decision of whether to move forward with a full-blown, adequately powered RCT. For pre- to post-program changes in the 6MWT and DUKE, I will calculate the mean change scores (post-program minus baseline), standard errors, and between-group differences for each outcome.

Aim 2 Analysis. Data from interviews will be transcribed using Microsoft Stream and I will employ thematic analysis and code for themes using a 6-phase process and NVIVO software, and adhering to the qualitative COREQ research checklists.[29,30] Transcripts will be coded for barriers and facilitators to hybrid CR using the Consolidated Framework for Implementation Research (CFIR; 39 constructs within five domains [e.g., inner setting, outer setting])[31,32] and Theoretical Domains Framework (TDF; 84 theoretical constructs within 14 domains [e.g., knowledge, skills, social/professional role]).[33-35] While there is considerable overlap in these theoretical frameworks, I will leverage the ways in which CFIR addresses system-level determinants and TDF addresses individual-level determinants. Two raters will review the audio and visual data for each participant. Content analysis will be used to identify patterns in the stakeholder's responses to questions about acceptability, barriers, and facilitators to THCR. I will further assess whether CR barriers and acceptability differed among those with high vs. low fidelity to THCR and among those in the THCR vs. traditional arms of the study.

Compensation: Participants will receive a PayCard in-person or in the mail after successfully completing the first two clinic-based CR session (CR Session 1 & 2). Once they confirm receiving the PayCard with study personnel, $50 will be uploaded to the card as compensation for the initial clinic-based visits (payment #1). Following successful completion of CR session 12 and mid-intervention assessments, they will be compensated an additional $50 on the PayCard (payment #2). Following successful completion of CR session 24 and post-intervention assessments, they will be compensated an additional $50 on the PayCard (payment #3). Therefore, the total possible compensation for completing the study is $150. All compensation is loaded onto one PayCard registered specifically to the participant.

In addition, participants enrolled in the hybrid CR program will be permitted to keep the study-provided stationary bike and adjustable ankle/wrist weights upon completion of the study, which has an estimated value of $350.00 - $425.00 when purchased as new.

If upon completing the study a subject indicates that they do not want to keep the study-provided equipment, the research team will offer to arrange for the bike to be picked up and donated to a charitable foundation.

Risks: There are minimal risks associated with participation in moderate-intensity bouts of physical activity including injury or medical complications. Evidence-based secondary prevention guidelines strongly recommend that post-ACS patients (including those who are at low-to-moderate risk for cardiac events) achieve ≥30 minutes of moderate aerobic activity, such as brisk walking, on ≥5 days per week within 2 weeks of hospital discharge as part of standard-of-care practice.[36] Moreover, the American College of Cardiology/American Heart Association guidelines for the management of ACS patients recommend that *all* ACS patients participate in cardiac rehabilitation, which includes moderate-intensity exercise, as well as regular moderate-intensity physical activity (supervised and unsupervised). The most common injuries include muscle strains, joint sprains, and bone injuries. During moderate-intensity physical activity, heart rate and blood pressure may increase. In rare cases (risk approximately equal to one event in 60-80,000 hours of supervised patient exercise: ACSM, 2007), this can lead to a serious cardiac event. Only patients who completed their first initial clinic-based screening/evaluation visit and are deemed medically appropriate for participation will be enrolled in the study. To minimize risk, participants with high-risk features at rest and during exercise will be excluded from study participation. We will further exclude those at high-risk for adverse exercise-related cardiovascular events according to the AACVPR risk stratification criteria. Moreover, all exercise testing, prescription, and progression will be based on evidence-based guidelines that are routinely used to ensure safety in cardiac rehabilitation, and will mirror standard of care.

At the beginning of each Video Visit, we will ask the patient to provide or confirm their current physical address (e.g.. 1234 Main Street Apt. A, Small Town 10001), as well as the name and phone number of an emergency contact should they require any emergency assistance during the visit. In the case of an emergency or adverse event, we will send emergency medical services (EMS) to the physical address and contact the emergency contact. Accordingly, we will have an internal medicine physician (Dr. Nathalie Moise or Dr. Ian Kronish) on-call during video visits to provide study personnel with assistance if participants experience an emergency or adverse event. In the case the participant does not answer the video call at the time of their scheduled session, a member of the research team will initiate the following steps: 1) video call through the eCC platform, and 2) phone call to the participant's preferred number. If the participant does not respond to either of these contact attempts, a member of the research team will mark the session as incomplete. In the case measurements captured by the remote devices do not populate into the eCC during partially supervised session, a member of the research team will initiate the following steps: 1) video call through the eCC platform, and 2) phone call to the participant's preferred number. If the participant does not respond to either of these contact attempts, a member of the research team will call the emergency contact. If the emergency contact cannot be contacted, a member of the research team will call 9-1-1 and send emergency medical services (EMS) to the participant's physical address.

Psychological Distress: The questionnaires pose modest risk of psychological discomfort. Patients may experience a range of sensations during cardiac rehab (e.g., muscle tightness, increased heart rate, shortness of breath). These symptoms are <u>temporary</u>, and while there is risk for experiencing these sensations, engagement in exposure techniques and physical activity is the treatment for anxiety and exercise is also critical for heart health. Thus, while intervention techniques can initially elicit possible anxiety/physical discomfort, repeated practice and engagement will actually serve to decrease anxiety and increase tolerance for exercise.

Loss of Confidentiality: A potential risk from this study is the violation of the participant's privacy, since patient medical information will be used as a source of data. We have measures in place to protect participant privacy and confidentiality.

A NYP-VCR clinical CR supervisor and physical therapist (Mrs. Kimberly Stavrolakes), exercise physiology scientist (Dr. Andrea Duran), and internal medicine physician (Dr. Nathalie Moise) will be on-call during video visits to provide study personnel with assistance if participants experience any adverse responses to exercise during their participation in this pilot study.

Benefits: There is no direct benefit to subjects who participate in this study.

Alternatives: The alternative is not to participate. Additionally, the Principal Investigator may withdraw participants from the study after enrollment upon further examination of eligibility criteria and/or at her

professional discretion. Participants will be informed that they have the option to skip study-based questions and/or not complete all surveys. In turn, the number of skipped questions and/or incomplete surveys will become part of study analysis.

Data and Safety Monitoring: Data and safety monitoring will be conducted by the study staff as directed and overseen by the principal investigator. Investigators and research assistants will meet weekly to discuss any issues or concerns with the study, in particular, whether there were any unexpected complaints about the study procedures or questionnaires, or whether there were any breaches in data confidentiality (which will be reported to the IRB as required by policy). If unexpected complaints about the procedures or questionnaires are generated, then the study may be stopped or altered prior to recruiting the full sample.

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