Impact of a Corrie Cardiac Rehabilitation Program

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STUDY PROTOCOL

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

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1. Abstract

Cardiovascular disease (CVD) is the leading cause of mortality in the United States, affecting approximately 1 in 2 American adults.[1] Evidence supports the initiation of secondary prevention measures for individuals with CVD soon after a CVD event.[2, 3] This increases the chance of patient adherence to lifestyle modification and new therapies and is known as Phase I or inpatient cardiac rehabilitation (CR).[2, 4] However, Phase I, inpatient CR is not widely implemented in practice.[5] After hospital discharge, patients should be referred to Phase II or early outpatient CR, which is a comprehensive program including supervised exercise therapy, patient counseling, cholesterol control, blood pressure control and other key elements for secondary prevention of CVD.[4, 6] However, there is a gap of time, usually weeks between Phase I CR and initiation of Phase II CR, presenting an opportunity for continued patient engagement via digital health technology ("Phase 1.5" CR). Following completion of Phase II CR, patients enter a Phase III of CR wherein physical activity/exercise is performed with less supervision and then to Phase IV, which is an indefinite phase of ongoing self-management wherein patients ideally continue with heart healthy habits. Patients who participate in CR have a lower mortality rate, are less likely to be readmitted to the hospital, experience fewer subsequent cardiac events, and have improved functional status.[7-9] Despite overwhelming evidence for improved CVD outcomes with secondary prevention by means of CR, its implementation has historically been low, most notably among vulnerable populations.[10] Racial/ethnic minorities, women, veterans, older adults, and individuals with lower socioeconomic status have the lowest CR participation rates among eligible patients.[11, 12]

To address these critical gaps in the recovery process, participation in CR, and improve secondary prevention for patients with CVD, we developed a multilevel intervention that is based on a digital health strategy using the established Corrie Health platform, with funding from the American Heart Association. Corrie Health is a digital health intervention (DHI) that was originally developed at Johns Hopkins to support acute myocardial infarction recovery.[13] The Corrie CV multilevel secondary prevention program is designed to deliver Phase I through IV CR. It includes a customized smartphone application (app) with real-time data analytics, supervised exercise, patient education, medication adherence reminders/tracking, LDL cholesterol and hemoglobin A1c level tracking, smartwatch integration (Apple Watch or Fitbit) for physical activity / exercise and heart rate tracking, wireless blood pressure monitor integration, app enabled reminders,

health coach guided action plans to promote behavior change and clinician level intervention. Corrie Health delivers an accessible, early intervention from hospital to home, thereby mitigating the conventional barriers to secondary prevention traditionally delivered in-person, e.g., cost, scheduling, and transportation access.[14] While smartphone ownership is increasing in White, Hispanic and Black individuals in the US, smartphone app use is even higher among Black individuals, facilitating access to lifesaving interventions for individuals who have been historically disadvantaged with respect to access to care.[15, 16]

Overall, we aim to evaluate efficacy and safety of the multi-level Corrie digital health intervention (DHI) in a parallel arm randomized controlled trial (RCT), while ensuring the study protocol promotes evaluation of the DHI secondary prevention program in diverse groups of patients. The DHI will complement usual care, which includes in-person center-based CR, and will be compared to usual care alone. The primary outcome measure of the study is the difference in distance participants walked (i.e. functional capacity) using the 6 minute walk test (6MWT) at final study follow-up (12 weeks post-randomization)between the intervention and usual care groups. The 6MWT is a rigorously validated clinical assessment of functional performance in individuals with cardiovascular disease).[17, 18]

2. **Objectives**

Primary Outcome

- Difference in distance participants walked (i.e. functional capacity) between the intervention and usual care groups, as measured by the 6MWT at final study (12 weeks post-randomization) follow-up

Key Secondary Outcomes (measured at 12 weeks post-randomization**):**

- Composite score of secondary cardiovascular prevention metric (see Table 1)
- LDL cholesterol level
- CR engagement measure: The total number of CR sessions attended, whether 12 sessions of CR sessions attended within 90 days of a CVD event (Healthcare Effectiveness Data and Information Set (HEDIS) measure for patient engagement in cardiac rehabilitation)[19]
- Quality of Life – PROMIS Global Health Scale v1.2 [20, 21]

In addition to the secondary outcomes outlined above, we will measure factors that may be relevant to heterogeneity of treatment effects and intervention's mechanism of action, as follows.

Health factors:

- Systolic blood pressure and diastolic blood pressure
- Waist circumference
- Hip circumference
- Body mass index (BMI)

- Glycosylated hemoglobin (HbA1c)
- Total cholesterol level, triglyceride level, high density lipoprotein cholesterol level, non-HDL- cholesterol
- Tobacco use status, quitting attempts – self-report/questionnaire
- Diet – Rate Your Plate [22] [23]
- Physical Activity - The Rapid Assessment of Physical Activity (RAPA)
- eHealth Literacy – eHealth Literacy Scale (eHEALS)[26, 27]

Psychosocial factors:

- Depressive symptoms – Patient Health Questionnaire 8 (PHQ – 8)[28]
- Anxiety – Generalized Anxiety Disorder 7 (GAD 7)
- Perceived stress – Perceived Stress Scale (PSS-10) [29]
- Patient activation – Patient Activation Measure 10 [30]

Engagement in Center-Based CR Sessions:

- Number of individuals completing 2, 12, 24 and 36 in person CR sessions (HEDIS measures)
- Number of CR sessions attended per individual

Safety Outcomes:

- Hospitalization, emergency room visits, myocardial infarction, acute coronary syndrome, transient ischemic attack, stroke, or cardiac procedures - as reported in the EHR or via patient/caregiver report, verified by health records.
- Death – as reported in EHR or via caregiver report, verified by death certificates or health records.

Cost of care:

- As assessed by a Markov Model of cost-effectiveness[31] – the hospital costs (in US dollars) for emergency department (ED) visits and hospital readmissions will be compared between the intervention and usual care groups.

For the intervention arm only, we will measure intervention user satisfaction and engagement:

- User Engagement – Total number of interactions in the smartphone app and interactions with specific features of the smartphone app per participant, collected via the Corrie Health Platform User Analytics
- User Satisfaction – System Usability Scale modified for Corrie[32]

Table 1. Composite score components of secondary cardiovascular prevention metric

Cardiovascular Secondary Prevention Metric Components	
Ideal	Diagnosis of diabetes: HbA1c <7% No diagnosis of diabetes: HbA1c <5.7%

Intermediate	Diagnosis of diabetes: HbA1c 7-7.9% No diagnosis of diabetes: HbA1c 5.7-6.4%
Poor	Diagnosis of diabetes HbA1c ≥8% No diagnosis of diabetes: HbA1c ≥6.5%
Ideal	SBP <130 and DBP <80 mmHg
Intermediate	SBP 130-139 and DBP <90 or SBP <130 and DBP 80-89 mmHg
Poor	SBP ≥140 or DBP ≥90 mmHg
Ideal	LDL-C cholesterol <70 mg/dL
Intermediate	LDL-C cholesterol 70 - 99 mg/dL
Poor	LDL-C cholesterol ≥100mg/dL
Ideal	BMI <25 kg/m^2
Intermediate	BMI 25-29 kg/m^2
Poor	BMI ≥30 kg/m^2
Ideal	≥150 min/wk moderate or ≥75 min/wk vigorous or ≥150 min/wk moderate and vigorous physical activities
Intermediate	1-149 min/wk moderate or 1-74 min/wk vigorous or 1-149 min/wk moderate and vigorous physical activities
Poor	None
Ideal	Never smoker (<100 cigarettes in lifetime)
Intermediate	Former smoker
Poor	Current smoker
Ideal Diet	Rate Your Plate 64 - 81
Intermediate Diet	Rate Your Plate 46 - 63
Poor Diet	Rate Your Plate 27 - 45
For each component ideal profile is consistent with a score of 2, intermediate profile is consistent with a score of 1 and poor profile with a score of 0. Subsequently a total score ranging from zero (worst CV Health) to 14 points (best CV health) is calculated.	

3. Background

The Corrie DHI program consists of a patient-facing smartphone app which provides education; recommendations for lifestyle modifications; medication, vitals, and exercise monitoring; appointment scheduling and tracking; care team directory; electronic wallet for health and stent cards; the ability to send PDF summary reports to clinicians; and follow-up reminders to optimize cardiac recovery and secondary prevention. The original version of the Corrie Health digital platform was tested in acute MI patients at 4 clinical sites including Johns Hopkins Hospital, Johns Hopkins Bayview, Reading Hospital and Massachusetts General Hospital (MiCORE IRB00099938).[13] Patient-monitored data flows into secure servers on the backend, providing a source of rich, granular data over time for heart rate, steps, weight, blood pressure, and medication adherence. Corrie is built on Apple and Android platforms.

For the present trial, the original Corrie Health digital platform was adapted to include extensive exercise tracking with pre-and post- exercise data capture along with weekly

evaluations and goal setting by a trained "Corrie Coach" to promote behavior change and mental health support. Exercise can be performed anywhere a patient feels comfortable with, including neighborhood gyms or outdoors. Furthermore, patients will be provided with motivational messaging and feedback on progress with their goals. The Corrie Message Bank (attached as supplemental document) has been developed by combining validated messages from the mActive trial,[33-35] American Heart Association's Care Pathway messages, and patient generated messages. The Corrie Clinical Dashboard allows for intuitive data visualization by the clinician of key cardiovascular health metrics including blood pressure, heart rate, steps, medication adherence, exercise, and education completion. The clinician then uses this data to generate actionable insights and provide comprehensive feedback to the patient. The trial intervention has been optimized with input from demographically diverse patients, caregivers and clinicians (IRB00266731). A preliminary version of the intervention is being evaluated in our IRB approved quality improvement project (IRB00248849). Preliminary data from the quality improvement project supports that it is feasible to evaluate the intervention in a RCT.

CR is a multi-component intervention with core components including physical activity, nutritional counseling, lipid management, weight management, blood pressure management, diabetes management, tobacco cessation, and psychological management, as outlined in American Heart Association's and American Association of Cardiovascular and Pulmonary Rehabilitation Scientific Statement (Figure 1).[36] It consists of four phases. Phase I includes early secondary prevention interventions, which starts immediately after cardiac event/surgery/intervention in the hospital setting. Phase II CR is an outpatient program with goals to help individuals modify their CVD risk factors and transition to independent physical activity, which is further intensified with less supervision during Phase III CR. Phase IV CR refers to ongoing self-management.[4] Our study intervention has the advantage of being deployed as soon as a patient experiences a CVD event or undergoes cardiac surgery/procedure, thus empowering patients in a timely manner with knowledge regarding their new diagnosis and equipping them early with self-management tools.

Furthermore, a home-based program can reach patients who were previously unable to participate in CR and promote health equity by eliminating barriers to access including transportation, parking, and limited working hours of CR centers. We have taken a number of measures in the study protocol to promote equitable participation in the trial. First, we optimized the intervention using inclusive, Human Centered Design Methodology where input from diverse groups of patients, clinicians and caregivers guided the design process. Second, we collaborated with the Johns Hopkins Center for Health Equity Community advisory board, consisting of community advocates, community leaders, community-based organization representatives and patients, to incorporate feedback on the study protocol and procedures. Third, we will cover transportation and/or parking fees for in-person CR assessment sessions in the intervention group. Fourth, we will provide devices, using our established "iShare" program,[13] to participants who do not own either a smartphone or smartwatch. Fifth, we will offer personalized onboarding and technology assistance for patients to ensure equitable technology onboarding. Our study will generate evidence regarding the efficacy and safety of

the DHI (Table 2), which could promote digitally-enabled hybrid CR uptake at scale and reduce the gap in lifesaving CR access and utilization.

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Table 2. Components of DHI: The Corrie Hybrid Cardiac Rehabilitation Program

Patient Level - Corrie App, Smartwatch, Blood pressure monitor, exercise resistance bands, Corrie "Coach" (attached in supplemental documents) and contextual motivational messages (attached in supplemental documents)
Clinician Level – Reminder for CR referral, Reminder for ordering repeat lipid panel upon discharge (as recommended by professional society guidelines), In person assessment and two monitored and supervised sessions for personalization of home exercise, improving confidence and self-efficacy for home exercise, and assessment of safety of home exercise

Figure 1. Core components of Cardiac Rehabilitation/Secondary Prevention Programs as per American Heart Association and American Association of Cardiovascular and Pulmonary Rehabilitation Statement.[36]

4. Study Procedures

General Overview:

We will conduct a multi-site, parallel arm randomized clinical trial to evaluate the efficacy of the intervention plus usual care compared to usual care alone (1:1 allocation ratio) in individuals who present to study hospitals with the following diagnosis or interventions: ST elevation myocardial infarction (STEMI), Type 1 non ST elevation myocardial infarction (NSTEMI), Atherosclerotic Cardiovascular Disease (ASCVD) requiring coronary revascularization via percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG), and valvular heart disease interventions including valvular heart surgery and transcatheter aortic valve replacement (TAVR). We will evaluate the primary outcome and secondary outcomes at 12 weeks post-randomization. Study sites include Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County Hospital, and Suburban Hospital.

Enrollment, Randomization and Measurements:

1. The list of patients admitted to Johns Hopkins Hospital (JHH), Johns Hopkins Bayview Medical Center (JHBMC), Howard County General Hospital (HCGH), and Suburban Hospital will be reviewed daily. We will query an electronic medical record (EHR) system to alert study investigators about patients admitted with any of the qualifying diagnoses to help with screening process. We will also query the list of the cardiac surgery operating room and cardiac catheterization lab to identify qualifying patients undergoing cardiac surgery or PCI procedure on an ambulatory basis. Furthermore, IRB approved flyers will be placed in clinician work rooms allowing clinicians to refer patients to the study. Patients who meet the inclusion criteria (see below in section 5) will be entered in the REDCap (Research Electronic Data Capture) database.
2. Study team members will subsequently screen patient charts for exclusion criteria. Before approaching eligible patients for consent, study team members will ask the attending physician of the patient to obtain permission from patients for the study team to approach them.
3. Patients will be approached in the hospital anytime during their index hospital admission or presentation for procedure.
4. Once patients are approached, further questions will be asked to screen for exclusion criteria including visual, motor, and/or auditory impairment limiting digital health technology use.
5. Written consent will be obtained at the bedside in the clinical units at participating sites. For patients who are not consent at bedside (e.g. patients undergoing same-day PCI procedure who have received sedation within preceding 24 hours), study team will follow up with a telephone call within 1 week after discharge to gauge interest in

participation. For interested patients, informed consent will be obtained remotely via Docusign.

6. Patients will be given detailed information and consent form to review during bedside or remote enrollment.
7. Sufficient time will be provided to the patient to read and understand the consent form with a repeat of information if necessary.
8. Patients will be given the opportunity to ask any questions to the research team while considering to participate in the study.
9. Patients with hearing, motor, and visual impairment will not be included (precludes meaningful use of intervention technology).
10. The study team member will share with the patient that they can take as much time as necessary to understand the consent form. Study team members will then ask questions to the patient to clarify whether they understand the information provided in the consent form.
11. Once informed consent is obtained, an Epic documentation (Research note) and research flag will be placed in the EHR.
12. If the patient is non-English speaking, study participation will not be available, given the need for extensive communication needed during CR, especially hybrid CR.
13. After consent is obtained by the research team member and prior to randomization, baseline data (e.g. demographic information, relevant medical history, blood pressure, heart rate)) will be obtained.
14. Following hospital discharge, consented patients will be followed up with a telephone call during a 4-week run-in period to assess their continued interest in study participation, as well as to verify their insurance approval for in-center CR. Those who qualify will then be randomized at a 1:1 ratio to the intervention plus usual care (intervention group) or usual care alone (control group). Usual care is defined as care according to patient care team's standard practice. Randomization will be based on a dynamic randomization strategy that minimizes the difference in age, sex, and treatment modality (cardiac surgery, cardiac catheter-based procedure, or medical therapy alone).
15. If the order for CR referral is not done automatically, we will encourage the primary team to place the order for CR in the EHR and/or place the CR order on behalf of the primary team following attending physician approval, to ensure 100% CR referral rate for all study participants.
16. We will use a random number generator for generation of random number sequences and adopt open source software for dynamic randomization implementation. We will minimize bias by concealed allocation at time of enrollment.
17. Once randomization arm is determined, a study team member will inform each patient of their allocation.
18. Individuals who are randomized to the intervention who do not own a smartphone or smartwatch will be provided with devices. This program, called iShare, was previously established and successfully implemented by our study team in the MiCORE trial.[13] Participants will be allowed to keep the devices even after the study ends, if desired, to facilitate subsequent phases of CR and potential long-term studies in the future. If

patients decide to leave the program during the study or within 6 months of study completion, they will be expected to return the devices to the study team.

19. Individuals randomized to the intervention will receive personalized technology onboarding from a study team member. Depending on their level of technological literacy, patients will receive tailored video- and in-person guidance on how to download the app onto the phone, use the smartwatch [Apple Watch (FDA cleared) or Fitbit (FDA cleared)] and blood pressure monitor [Omron Blood pressure cuff (FDA cleared)] which will be paired with the smartphone via Bluetooth. The research team will have access to data on onboarding details as well as data collected via these devices, which will be reviewed during business hours on a daily basis. The participants will also be given a StartKit document which will include information on how to use the app to reference following discharge (Uploaded as supplementary document). Furthermore, patients will be provided with an email address and phone number to allow them to contact study investigators in case they have questions about technology use. They will also be able to submit feedback or questions regarding app use directly via the app. The patients will be encouraged to start using the app immediately but will be told to avoid unmonitored exercise until they have attended an in-person CR center for at least two visits, where risk stratification is performed based on AACVPR criteria (uploaded in Section 20.2). These two in-person sessions will serve as a basis for personalization of the home exercise plan, improving self-efficacy and confidence for home exercise, and assessment of safety for home exercise. If patients have any high risk features precluding home exercise, they will not be allowed to do home exercise as part of study intervention but they will be able to receive coaching calls, education and track medication intake via the app as well as work on modification of other cardiovascular risk factors. Additionally, they will be encouraged to continue attending in-person CR sessions for safe, monitored exercise, and will be advised to perform lower levels of usual physical activity (e.g., walking, range of motion exercises) as advised by the CR staff.
20. The initial phase of study participation in the hospital will be limited to study description and informed consent. All interventions will start following the 4-week run-in period, for those randomized to the intervention group.
21. To promote privacy of health information, a login will be required to access the app (created upon onboarding). Additionally, the iPhone or Android phone will be set to password protected mode / face ID activated.
22. After obtaining consent, app permissions to the Corrie smartphone app will be provided by the study team. In order for an app to access any data on an iOS/Android smartphone, the app must ask the user for permission and if and only if that permission is granted, the app can access that data. This is inherently enforced on all apps by the operating system. In our case, we only will ask for permissions to access:
    - Relevant digital health data from iOS and Android HealthKits, in particular: physical activity, blood pressure and heart rate.
    - Photos to store an insurance card or other cards like a stent card. Even if the access-permission is granted, it is limited to the images specified by the user.

- Display notifications, such as an alert to take medications.
- Send email function to allow users to send a PDF of their consent form or a PDF of relevant health info (e.g., medication list, progress report) to their care providers. No app is allowed to read any data from the mail app.

Participants will be given the option to take a photo in which they are identifiable using the app and can specify authorization for internal or external use via the standard media consent form.

23. For individuals randomized to the intervention, a study team member will help patients locate a nearby in-person CR center, ideally a Johns Hopkins CR center. If a non-Hopkins center is required due to patient location, then the study team will help patients identify a CR center by using the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) website database of CR programs, provide a number to call, and assist in making the call if needed.
24. Individuals randomized to the intervention will receive a notification on their phones to remind them to go to a local laboratory to have a repeat Lipid panel at 4 weeks after discharge from the hospital. An order for a repeat lipid panel will be placed by their clinical team prior to hospital discharge as it is a guideline recommendation to have a lipid panel rechecked to ensure adequate cholesterol control.[36, 37] This component is part of the multi-level intervention offered to the intervention group. Patients will receive education on optimal lipid levels and encouragement to follow up with their clinician (physician or advanced care provider) to adjust their cholesterol management regimen if their LDL-C values are above the goal. Johns Hopkins patients will also have access to the Johns Hopkins Lipid clinic number through the app and if other sites are involved, local cardiology clinic numbers will be included.
25. All study participants randomized to the intervention arm, prior to initiating unmonitored exercise at home, will attend at least two in-person CR sessions. These sessions will serve as a basis for personalization of the home exercise plan, improving self-efficacy and confidence for home exercise, and assessment of safety for home exercise. These two in-person sessions are part of the proposed standard of care for hybrid CR models for tailored approach to home-based exercise. Patients who are deemed high risk for exercise per AACVPR criteria[4] will be encouraged to engage in the education, medication tracking, and behavior change components of the intervention, but not home exercises. They will be encouraged to continue attending in-person CR sessions for safe, monitored exercise, and will be advised to perform lower levels of usual physical activity (e.g., walking, range of motion upper body movements) as advised by the CR staff. Such patients will be maintained in the study for intention-to-treat analysis.
26. All patients will be encouraged to continue attending in-person CR sessions. Participants will be encouraged to attend Johns Hopkins CR centers for at least the first two sessions for safety evaluation, which will be assessed through electronic medical records. If a study participant chooses to attend an external CR center, safety assessment will occur by contacting the external CR staff for their assessment of how the study participant performed during the first two in-person CR sessions. For the intervention group only, to

overcome the barriers of access, we will cover transportation and/or parking fees for participants to attend the two required in-person CR sessions using research funds.

Patients will receive prescriptions for exercise from a center-based exercise physiologist during the in-person CR sessions. Even participants who have been randomized to the intervention arm will be encouraged to attend in-person CR sessions, especially at 30-day and 60-days (beyond the first two required in-person CR sessions) to allow for appropriate exercise modifications to their Individualized Treatment Plans by the exercise physiologist. For patients who elect to not continue to attend in person CR sessions beyond the first two sessions, once cleared for home exercise, updated exercise prescriptions will be provided by the study exercise physiologist as per AACVPR guidelines.

27. All patients randomized to the intervention will receive weekly virtual check-ins consisting of a video call (unless patient opts out of the video component for only audio call) from a trained exercise physiologist health coach, starting within 1 week from randomization. These virtual check-ins will be used to guide patients with individualized risk factor modification, stress reduction and on adapting their exercise prescription (for those cleared for home exercise), where the latter will be performed by a study exercise physiologist. If during the virtual check-in the patient reports high risk symptoms (e.g. chest pain), the health coach will follow Cardiac Rehabilitation Standard Operating Procedure scenarios (attached in supplementary documents) to handle the different emergencies, and they will be asked to pause the exercise component of the intervention until safety of returning to exercise is determined by their caring clinician. The Corrie Dashboard will be monitored once a day and any red flags will be handled similarly as per the Standard Operating Procedure. Patients will be informed that the study team cannot replace their care teams and patients should contact their clinicians, call 911 or go to emergency room when experiencing severe symptoms or abnormal vital signs. Virtual, synchronous, audiovisual group-based education sessions will be offered weekly by the exercise physiologist health coach. These sessions will supplement the weekly virtual check-ins for patients randomized to the intervention. These educational, patient-support/social networking forums aim to enhance the social experience of this virtual model. Social media platforms (such as Facebook group), moderated by the study team, may be used to facilitate voluntary communication and interaction among study participants for community-building purposes.
28. At 12 weeks post-randomization follow up, all study participants will receive a survey via REDCap to report any adverse events, including a heart attack, repeat cardiac procedure, stroke, transient ischemic attack, emergency room visit, or hospital readmission. If a patient is readmitted to a Hopkins affiliated hospital or other site's hospital, their EHR will be searched for confirmation and cause of readmission. If the person is readmitted to an outside hospital, we will email them an Authorization for Release of Health Information form asking for permission to obtain their EHR of readmission. If patients cannot be reached, we will contact their emergency contact to

identify whether the patient is alive and also search the EHR. If death is reported, it will be verified by death certificates or through the EHR.

29. At 12 weeks post-randomization follow up, all participants will attend an in-person study visit at Johns Hopkins Bayview Institute for Clinical and Translational Research (ICTR; Clinical Research Unit) site where all measurements outlined in Table 3 will be conducted, including vital signs, blood work for HbA1c and Lipid panel (non-fasting), body measurements, and 6MWT. If a participant cannot attend the final visit at Johns Hopkins Bayview ICTR site due to medical conditions, exceptions can be made to accommodate the participant at another study site. The 6MWT will be performed by ICTR staff blinded to study arm assignment to avoid bias in measurement (compared to the pre-discharge 6MWT for hospital-enrolled patients, which will be obtained by a trained study team member). Participants will be given an option to complete online surveys while attending the in-person study visit. If at either of these time points (baseline and 12 weeks post-randomization), participants do not respond to the online surveys within 7 days, a member of the study team will attempt to obtain their responses to the surveys via a phone interview. In order to accommodate flexible scheduling, we will aim to allow up to 24 weeks for the final study visit. For the ICTR study visit, parking and transportation fees will be covered by the research study budget for all patients.
30. If the study engages additional sites in the future, local participant recruitment will be conducted by local research team members. Site specific research team members will undergo training prior to site activation and thus recruitment and onboarding to the DHI will be conducted in consistent manner. Decisions regarding patient management will be made by the patient care team.
31. For study participants in both the intervention and control groups, sociodemographic data as well as clinical data will be extracted from EHR (REDCap variable list is uploaded in section for supplementary documents).

Table 3. Study Visits and Measurements

Visit 1. Baseline visit (Data obtained by chart review, at the bedside and online surveys delivered via email through REDCap)	**Visit 2. Virtual visit at 4 weeks (for Intervention Arm only)**	**Visit 3. 12-weeks post-randomization follow up visit (Data obtained at in-person visit and online surveys delivered via email through REDCap)**
In-person Measurements		**In-person Measurements**
Weight		Weight
Height		Height
Blood pressure		Blood pressure
Heart rate		Heart rate
Waist & Hip circumference		Waist & Hip circumference
		6 min walk test
Electronic Medical Record Review		**Laboratory values and chart review**
Lipid panel within 30 days of enrollment*	Lipid panel	Lipid panel*

HbA1c within 3 months of enrollment*		HbA1c*
Baseline clinical characteristics**		Interval clinical events**
Surveys delivered via email through REDCap #		**Surveys delivered via email through REDCap #**
e-Health Literacy scale		e-Health Literacy scale
The Rapid Assessment of Physical Activity		The Rapid Assessment of Physical Activity
Rate Your Plate		Rate Your Plate
Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Scale v1.2		Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Scale v1.2
Patient Activation Measure 10 [30]		Patient Activation Measure 10 [30]
Patient Health Questionnaire (PHQ-8) ##		Patient Health Questionnaire (PHQ-8)
Generalized Anxiety Disorder 7 (GAD 7)		Generalized Anxiety Disorder (GAD 7)
Perceived Stress Score		Perceived Stress Score
Sociodemographic survey (education level, income level)		Sociodemographic survey (education level, income level)
Smoking status, quitting attempts		Smoking status, quitting attempts
		Electronic Medical Records and Corrie Health Platform User Analytics
		Number of in-person and off – site (asynchronous) exercise sessions
		Surveys delivered via email through REDCap
		Adverse Outcome Questionnaire (myocardial infarction, stroke, Emergency room visit, hospitalization or death)
		For individuals randomized to intervention arm
		User Engagement - Total number of interactions in the smartphone app and feature specific interactions using the smartphone app per participant, collected via the Corrie Health Platform User Analytics
		User Satisfaction – System Usability Scale
		Cost Data
		The hospital costs (in US dollars) for emergency department (ED) visit, hospital readmission, and acute myocardial infarction (MI) will be compared between intervention and usual care groups.
*If these laboratory values are not available patient's care team will be reminded to place an order in EPIC as these values should be		*Bloodwork during the follow – up visit will be obtained during the study visit and costs will be charged from the study budget.

monitored as per cardiology society guideline recommendations. ** Baseline clinical characteristics will record relevant details related to cardiovascular risk, such as demographics, laboratory, and imaging (e.g. ECG, echocardiography, cardiac catheterization) data. # Patients will also receive an email via REDCap to complete the following surveys: Patients will be advised to complete those surveys within 48 hours of enrollment. The standard email greeting is included as a Supplemental Study Document. Survey responses will be recorded electronically via REDCap. All surveys are uploaded in supplementary data material section. ## If PHQ-8 score is ≥10 (moderate or more severe depression) and patient is randomized to the intervention arm, the study coordinator will ask the patient to obtain permission from the patient's primary care clinician or mental health clinician for home exercise (similar to practice for in-person CR) prior to engaging in the exercise portion of the intervention.		** Interval clinical events, such as adverse cardiovascular events, will be recorded from review of electronic medical records, in addition to the survey. # Patients will also receive an email via REDCap to complete the following surveys in English. Patients will be advised to complete those surveys within 48 hours of study. The standard email greeting is included as a Supplemental Study Document. Survey responses will be recorded electronically via REDCap. All surveys are uploaded in supplementary data material section. Patients will be given an option to complete all surveys during the study visit.

Study duration and number of study visits required of research participants

Each participant will be enrolled in the study from the time of enrollment during or shortly following hospitalization or cath lab encounter to 12 weeks post-randomization after discharge. Study visits will occur at baseline (at patient bedside or via follow up call) and 12 weeks post-randomization post-discharge (at Bayview Clinical Research Unit, up to maximum 18 weeks post- (to account for delays related to clearance of procedure-related precautions (e.g. sternal precautions following CABG surgery) or insurance approval for starting in-person CR sessions), whichever occurs earlier). Patients in the intervention arm will also be encouraged to have a lipid panel rechecked (ordered by the primary team at discharge) at their local laboratory 4 weeks post-discharge. Patients in the control group will receive reminders from the study team to participate in the final study visit.

Blinding

Although blinding participants or study team members enrolling patients is not possible, outcome assessors will be blinded to intervention allocation. We will instruct study participants not to discuss allocation with study personnel prior to both the initial and follow-up assessments.

Definition of treatment failure or participant removal criteria

For participants in the intervention group: If the participant stops using the Corrie DHI for >30 days or does not respond to phone calls after failing to complete the study surveys after 7 days, the participant will be considered lost to follow up.
For participants in the Control group: If the participant does not respond to phone calls after failing to complete the study surveys after 7 days, the participant will be considered lost to follow up.

Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely

When the study ends or a participant's participation in the study ends prematurely, participants in the intervention group may keep their app (in which case their use will continue to be tracked). Any other devices that were provided during the study will be expected to be returned.
Participants may be given the option to participate in future research studies.

5. Inclusion/Exclusion Criteria

Inclusion Criteria

- Adult aged 18 years or older
- Individuals presenting to the hospital for the following conditions or interventions: Acute myocardial infarction (STEMI or NSTEMI type 1), Coronary artery bypass grafting (CABG), coronary artery angioplasty/stenting (PCI), heart valve surgery, transcatheter aortic valve replacement (TAVR).

Exclusion Criteria

- Does not speak English
- Physical disability that would preclude safe and adequate exercise performance
- High risk for falls (Score >13 on Johns Hopkins Fall Risk Assessment Tool – see Supplemental documents)
- Visual or hearing impairment which precludes the use of the intervention
- Mental or behavioral impairment leading to inability to cooperate with study procedures
- Clinically significant depression (uncontrolled) or history of psychosis
- Pregnancy
- Left ventricular ejection fraction <40%

- Unaddressed severe valvular heart disease (e.g. severe: aortic stenosis, aortic regurgitation, mitral stenosis, mitral regurgitation)
- Hypertrophic obstructive cardiomyopathy with peak resting left ventricular outflow gradient of >25 mmHg
- Atrial fibrillation with uncontrolled ventricular rate (Heart rate >110 at rest) at baseline assessment
- Untreated high degree atrioventricular block (ie. Mobitz II or complete heart block without permanent pacemaker)
- History of cardiac arrest or sudden death
- Presence of cardiac defibrillator
- Uncontrolled resting arterial hypertension (Systolic blood pressure >200 mmHg or diastolic BP >110mmHg) at baseline assessment
- Unrepaired aortic dissection
- Incomplete/failed coronary revascularization procedure of culprit artery
- Significant complications from myocardial infarction, cardiac surgery, or cardiac procedure including: congestive heart failure (LVEF <40%), cardiogenic shock, signs/symptoms of persistent post-procedure ischemia, and unaddressed post-procedural arrhythmia or conduction complications (e.g. new left bundle branch block post-TAVR without pacemaker)

If an eligible patient is deemed clinically unstable and unable to participate at the time of initial assessment, the research team member may return at a later date for reassessment.

6. Drugs/ Substances/ Devices

1. The Corrie app is available on both iPhone and Android platforms. In discussion with an FDA-consultant, because the functionality of the app is as an organizational and navigational tool for patients, it does not require pre-approval from the FDA before use with patients. It falls within the category of mobile apps for which the FDA is exercising enforcement discretion.
2. The Apple Watch, Fitbit, and Omron blood pressure cuff all have received FDA clearance and are safe for patient use (see supplementary documents).

7. Statistical Analysis

The primary outcome measure of the study is the difference in distance participants walked (i.e. functional capacity) between the intervention and usual care groups, as measured by the 6MWT at final study follow-up at 12 weeks post-randomization. Based on the estimates from a prior RCT [41] in patients with acute coronary syndrome in a smartphone-based, cardiac rehabilitation program, but also accounting for a significant anticipated proportion of cardiac surgery and TAVR patients in our trial population, we assume a pooled standard deviation of 107 meters for follow-up 6MWT distance. and a minimally clinically important difference of 30 meters in 6MWT distance.[42]

For the trial to demonstrate noninferiority with 80% power, assuming a pooled standard deviation of 107 meters for the follow-up 6MWT and a true 6MWT difference in favor of the Corrie HCR program of 30 m, 160 patients will be required (80 per group) to exclude a difference of >12.5 m in favor of the usual care group. The noninferiority margin of 12.5 m was chosen to represent about 40% of the minimum important difference of 30 m in 6MWT as identified in previous studies. Accounting for an attrition rate of 20% during follow-up after randomization, a total of 200 (100 per group) participants will be randomized in a 1:1 ratio to the 2 treatment arms. In order to accrue 200 patients for randomization, we expect to recruit up to 300 patients, until target randomization number has been met. We will compare the mean level of 6MWT at 12 weeks post-randomization between the intervention and control groups using a generalized linear regression model. The sample size calculation was performed using the TWOSAMPLEMEANS statement in SAS version 9.4 procedure PROC POWER (SAS Institute Inc., Cary, NC), in which the null value option was specified to represent the noninferiority margin.

If a participant has an adverse event that results in them being discontinued from the study or does not engage with the intervention, that participant will be included in the intention-to-treat analysis, which is the primary form of analysis for our study.

In addition to the primary intention-to-treat analysis, a pre-specified, per-protocol analysis will be conducted 1) inclusive of intervention group participants who remain active in the study and engage with the intervention, and separately 2) among those participants (in both control and intervention arms) who have completed at least two in-person CR sessions, in order to assess the efficacy of the intervention.
In addition, pre-specified subgroup analyses will be performed, stratified by: age, sex, treatment modality (cardiac surgery, catheter-based intervention, or medical therapy), and LDL-C level (threshold LDL-C ≥55mg/dL).

8. Risks

Risks include adverse events during off site/CR exercise. To minimize this risk, we have the following measures in place: (1) We will only enroll participants in the study who do not have high risk clinical characteristics for exercise based on AACVPR criteria. (2) We will ask patients to refrain from unmonitored exercise until they undergo further assessment for high risk exercise features during two in-person CR sessions and are determined to be low to moderate risk for exercise. If individuals are deemed high risk, they will be encouraged to continue attending in-person CR sessions for safe, monitored exercise, and will be advised to perform lower levels of usual physical activity (e.g., walking and range of motion exercises) as advised by the CR staff. (3) We will provide weekly check-ins with patients to guide them accordingly if their vitals are not within normal range or report concerning symptoms. The guide for these check-ins has been compiled based on the Johns Hopkins in-person CR protocols and is attached in supplementary document section. (4) Dashboard will

be monitored once a day (during business hours). Any symptoms or red flag vitals will be managed as per standardized operating procedure.

The 6MWT is a low-risk medical test that is performed under supervision of a trained exercise physiologist. Potential risks include chest pain, shortness of breath, leg cramps, losing balance, excessive sweating, and falling.

Another risk is breach of confidentiality. The Corrie Health digital platform uses a high level of personal security password protection and encryption to meet privacy standards. The study team will disclose to the participant and IRB if a breach of confidentiality occurs.

Financial risk is minimized by covering costs for transportation and parking for in-person visits for the intervention group using study research funds.

9. Benefits

Participants in the intervention group will be given access to the Corrie DHI. Through this intervention they may benefit from greater knowledge about their diagnosis, risk factors, how to modify their risk factors and develop self-efficacy to continue risk factor modification after completion of the program. Furthermore, they may benefit from off-site/home based physical activity (after it is determined to be safe by in-person CR assessment) and develop skills that help them manage their medications as well as follow-up appointments with their primary care provider, cardiologist, and in-person CR. Patients enrolled in usual care may not derive significant direct benefit, aside from knowledge gained during the consent process and health information gained through measurements taken at the final study visit. Moreover, the data that they contribute as a research participant could help others in the future.

10. Payment and Remuneration

For participants in the intervention arm, the Corrie App, Smartphone and/or smartwatch, Blood pressure monitor, and exercise resistance bands will be provided to participants (if they do not own one) at no cost to them. If a participant stops engaging with the intervention for at least 1 week during the study or within 6 months of study completion, we will ask devices to be returned to study team so that they can be recycled for use for other participants or future studies. All participants will be compensated via $50 e-gift cards at the completion of the study, after the final study visit, for which transportation and parking fees will be covered by the study research funds. For the intervention arm, transportation and parking costs associated with the two in-person CR visits will also be covered by the study research funds.

11. Costs

Costs associated with smartphone and smartwatch application development, costs for iShare smartphone devices, blood pressure monitors, resistance bands and $50 gift cards have been paid through American Heart Association's Strategically Focused Research Network Grant (Grant number 134503). Apple Watches for iShare program have been provided by Apple Inc.

12. Johns Hopkins Serving as a Coordinating Center

Johns Hopkins Medicine is serving as the single IRB for this study. It is the preference of Johns Hopkins Medicine IRB to use the SMART IRB reliance agreement as the basis of reliance. The SMART IRB master reliance agreement was created in 2016 to harmonize and streamline the IRB review process for multisite studies. It enables reliance on a study-by-study basis, clearly defines roles and responsibilities of relying institutions and reviewing IRBs, and eliminates the need to sign reliance agreements for each study [e.g., a non-SMART IRB agreement]. 900+ institutions have already signed onto this agreement and are actively using it as the basis of reliance for multisite projects. Sites that will rely on JHM IRB are still responsible for conducting a local context review prior to the start of research at their site and for following any local and institutionally required policies as it applies to research at their site [e.g., reporting of unanticipated problems].

The JHM PI has contact information for all sites, each participating center has an active FWA with OHR on file. Each site will collect and manage data as described in the protocol. Sites will notify the coordinating center of adverse event reports and deviations via the RF3 and RF4 forms. Sites will complete a continuing review enrollment form that will be submitted at the time the parent continuing review is submitted. As part of any site conference calls, the coordinating center will inform sites of coordinating centers prompt reporting policy and will ensure they are submitted to JHM IRB per requirements.

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