

















## PROTOCOL

# Efficacy and Adherence Rates of a Novel Community-Informed Virtual World-Based Cardiac Rehabilitation Program: Protocol for the *Destination Cardiac Rehab* Randomized Controlled Trial

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**BACKGROUND:** Innovative restructuring of cardiac rehabilitation (CR) delivery remains critical to reduce barriers and improve access to diverse populations. *Destination Cardiac Rehab* is a novel virtual world technology-based CR program delivered through the virtual world platform, Second Life, which previously demonstrated high acceptability as an extension of traditional center-based CR. This study aims to evaluate efficacy and adherence of the virtual world-based CR program compared with center-based CR within a community-informed, implementation science framework.

**METHODS:** Using a noninferiority, hybrid type 1 effectiveness-implementation, randomized controlled trial, 150 patients with an eligible cardiovascular event will be recruited from 6 geographically diverse CR centers across the United States. Participants will be randomized 1:1 to either the 12-week *Destination Cardiac Rehab* or the center-based CR control groups. The primary efficacy outcome is a composite cardiovascular health score based on the American Heart Association Life's Essential 8 at 3 and 6 months. Adherence outcomes include CR session attendance and participation in exercise sessions. A diverse patient/caregiver/stakeholder advisory board was assembled to guide recruitment, implementation, and dissemination plans and to contextualize study findings. The institutional review board-approved randomized controlled trial will enroll and randomize patients to the intervention (or control group) in 3 consecutive waves/year over 3 years. The results will be published at data collection and analyses completion.

**CONCLUSIONS:** The *Destination Cardiac Rehab* randomized controlled trial tests an innovative and potentially scalable model to enhance CR participation and advance health equity. Our findings will inform the use of effective virtual CR programs to expand equitable access to diverse patient populations.

**REGISTRATION:** URL: <https://www.clinicaltrials.gov>; Unique identifier: NCT05897710.

**Key Words:** cardiac rehabilitation ■ cardiovascular health ■ health disparities ■ home-based programs ■ social determinants of health

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## Nonstandard Abbreviations and Acronyms

<b>AHA</b>	American Heart Association
<b>CBCR</b>	center-based cardiac rehabilitation
<b>CR</b>	cardiac rehabilitation
<b>CVH</b>	cardiovascular health
<b>EP</b>	exercise physiologist
<b>FG</b>	focus group
<b>LE8</b>	Life's Essential 8
<b>MACE</b>	major adverse cardiovascular event
<b>NC</b>	nurse coach
<b>PA</b>	physical activity
<b>PCS-AB</b>	patient/caregiver/stakeholder advisory board
<b>RE-AIM Reach</b>	effectiveness, adoption, implementation, and maintenance
<b>REDCap</b>	Research Electronic Data Capture
<b>VW</b>	virtual world
<b>VWCR</b>	virtual world–based cardiac rehabilitation

Despite abundant evidence demonstrating the benefits of cardiac rehabilitation (CR), including improvement in cardiovascular health, survival, functional capacity, health-related quality of life, psychosocial factors, and reduction in major adverse cardiovascular events (MACEs), <25% of eligible patients participate.<sup>1-4</sup> Barriers to participation include scheduling conflicts, distance to CR centers, lack of transportation, and cost.<sup>5-11</sup> These social determinants of health influence access to CR, particularly among women, racial and ethnic minority groups, and patients who are socioeconomically disadvantaged.<sup>12-14</sup> Efforts to develop innovative home-based CR programs ensued in response to a call by the American Heart Association (AHA) Presidential Advisory Board to reengineer the traditional center-based CR (CBCR) model to mitigate these barriers and increase equitable access to an essential component of cardiovascular preventive care.<sup>15-20</sup> These efforts were amplified during the COVID-19 pandemic, which further underscored the value of remote CR programs.<sup>21-27</sup> Unfortunately, the emergence of various novel CR programs over the past 20 years has failed to substantially improve CR participation and adherence.<sup>15,28,29</sup> Consequently, the goal set out by the Million Hearts CR collaborative in 2017 to increase CR participation from 20% to 70% has not been achieved, and ongoing innovation remains essential to broaden CR access.<sup>30</sup>

Incorporating mobile and internet technologies into remote CR programs has shown promise in expanding CR uptake and adherence.<sup>9,15,30-34</sup> In addition, incorporation of nonexercise components (eg, stress management, peer support, and diet modification) has been shown to improve CR completion.<sup>35</sup> Thus, our study team developed a novel comprehensive CR program, *Destination Cardiac Rehab*, which takes place in the virtual world (VW)–based platform Second Life, an immersive computer-based environment that mimics in-person experiences and incorporates an important component lacking in early home-based CR models: engagement in a social network. VW platforms have been successfully used for health education and chronic disease management.<sup>36-39</sup> *Destination Cardiac Rehab* capitalizes on the unique aspects of VWs and was designed to simulate the traditional CR experience while eliminating common barriers to in-person engagement.<sup>40</sup> The details of the intervention and prior pilot studies are outlined below.

We will conduct a hybrid type 1 effectiveness-implementation randomized controlled trial that aims to expand on our prior studies by directly comparing *Destination Cardiac Rehab* with CBCR with a particular focus on recruiting participants from populations with historically lower access to CR (ie, priority populations).<sup>41</sup> The objectives of this study are encompassed into 2 specific aims: (1) to evaluate the efficacy of *Destination Cardiac Rehab* on cardiovascular health (CVH) compared with CBCR and (2) to compare participation and adherence to *Destination Cardiac Rehab* versus CBCR. We hypothesize that *Destination Cardiac Rehab* will demonstrate noninferior efficacy and higher adherence rates compared with those of traditional CR. Study participants, CR staff, and key stakeholders will participate in postintervention focus groups (FGs) to inform future scalability efforts.

## METHODS

The data that will be generated from this study will be available from the corresponding author on reasonable request. Recruitment and enrollment of the first cohort are expected to begin in spring 2024. Data collection is expected to be completed in the first quarter of 2028. We aim to submit an article with the final study results in winter 2029. The study protocol has been registered (NCT05897710), and is IRB-approved (identifier: 22-011357).

### Intervention Design and Conceptual Framework

*Destination Cardiac Rehab* takes place on the VW-based platform, Second Life, where participants create and interact with peers and CR staff via avatars,

designed to mimic an in-person CR program. Group education sessions (detailed below), including lectures, tours of a virtual gym and restaurant, and peer support groups, take place within the VW. The program was designed with sound behavior change theories, including self-determination theory, a framework used in executing successful lifestyle interventions to promote sustainable self-management and healthy lifestyle change.<sup>42</sup> Self-determination theory highlights 3 key experiences, competence, autonomy, and relatedness, that promote motivation and engagement in healthy behaviors within the context of cardiac rehabilitation. Competence involves mastering skills, supported by the *Destination Cardiac Rehab* education curriculum and CR staff. Autonomy entails self-directed learning, enabled by choices in activities and learning methods in *Destination Cardiac Rehab*. Relatedness emphasizes social connections, central to the support groups in *Destination Cardiac Rehab*. In addition, the platform capitalizes on a phenomenon, known as the proteus effect, in which people tend to emulate the behaviors and attitudes of their virtual avatars.<sup>43</sup> On the basis of these behavioral change theories in addition to close emulation of an in-person experience, *Destination Cardiac Rehab* has the potential to have similar efficacy to CBCR.

### Prior Work

The results of 2 prior pilot studies evaluating *Destination Cardiac Rehab* have been published. Using a mixed-methods approach, the first proof-of-concept study demonstrated feasibility and revealed positive participant perceptions of the VW experience. Participant feedback obtained during postintervention FGs was used to refine the program.<sup>44</sup> A follow-up multisite clinical trial demonstrated excellent participant retention and attendance rates as well as high user satisfaction.<sup>45</sup> These positive perspectives and use were also seen among those historically underrepresented in CR (eg, women, racial and ethnic minority groups, and those with a high burden of CR access barriers).<sup>46</sup> Although underpowered to assess CVH outcomes, positive CVH trends in lipids, physical activity (PA), blood pressure (BP), and weight were noted.<sup>45</sup> Comparison of the impact of *Destination Cardiac Rehab* on CVH to that of CBCR is needed to establish our novel virtual world-based CR (VWCR) program as an acceptable alternative to CBCR.

### Community-Oriented Trial Design

We plan to conduct a multiphase, multicenter, 2-arm non-inferiority, hybrid type 1 effectiveness-implementation randomized controlled trial to rigorously test the efficacy of a 12-week VWCR intervention, *Destination Cardiac Rehab* (Figure 1), compared with CBCR. The study will



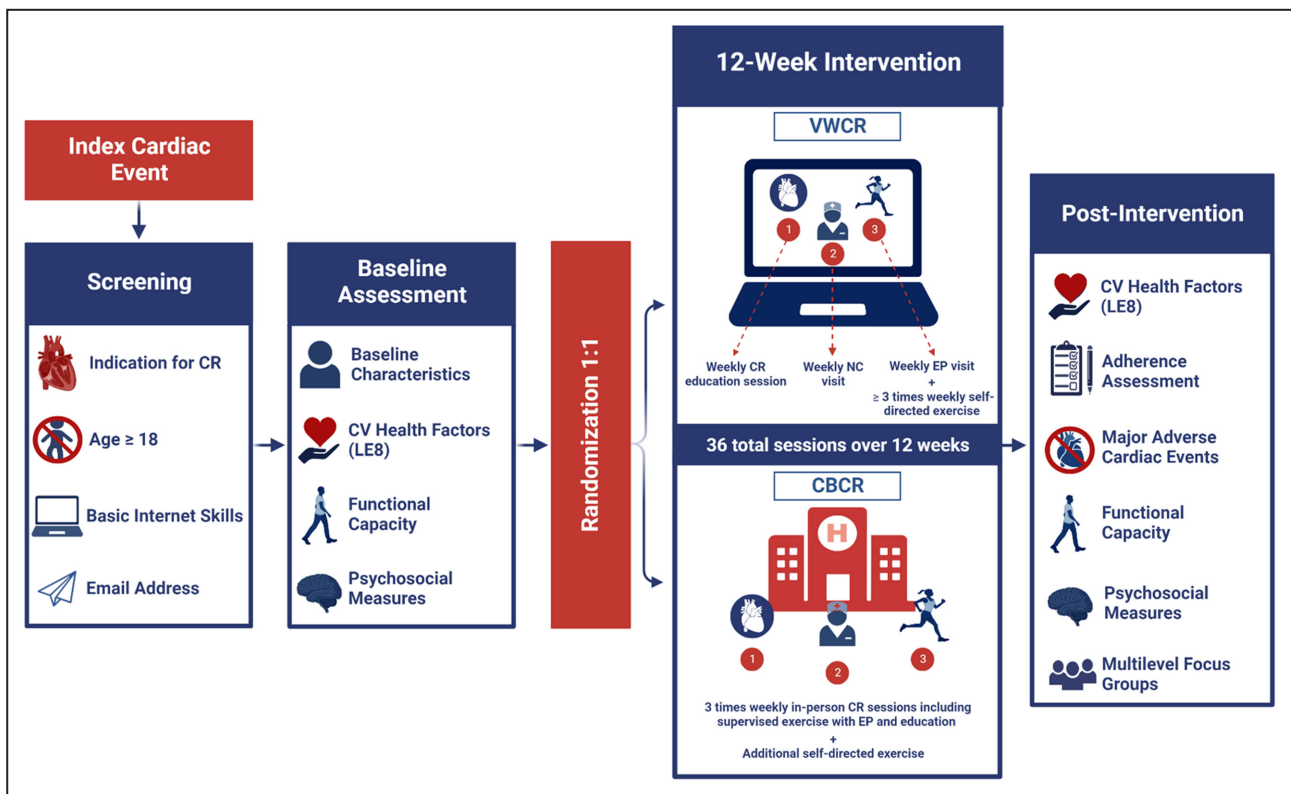
**Figure 1. *Destination Cardiac Rehab* logo.**  
Created with Adobe Illustrator.

be designed in partnership with a patient/community/stakeholder advisory board (PCS-AB). The Consolidated Standards of Reporting Trials checklist was used when preparing the study protocol.<sup>47</sup> See Figure 2 for a summary of the study design and study arms.

### PCS-AB and CR Perspectives Survey

The study team principal investigator (L.C.B.) previously established a PCS-AB from pilot and community-based participatory research studies that informed an equity-focused, patient-centered *Destination Cardiac Rehab* program in pilot studies.<sup>40,44,45,48</sup> To further enhance the community-oriented trial, a study-specific PCS-AB will be reinforced and expanded to include ≈25 diverse members from all 6 study sites (see the Study Setting section), including patients who completed CR, patients who enrolled in but did not complete CR, CR-eligible patients who did not enroll, and caregivers of CR participants or CR-eligible patients, as well as representatives from key stakeholder/advocacy groups (eg, American Association of Cardiology and Pulmonary Rehabilitation, AHA, payers, and information technology). The study team will partner with the PCS-AB during the study planning and implementation phases to ensure its cultural, age, and sex appropriateness, design recruitment materials, contextualize study findings, and develop/execute a dissemination plan.

As a part of our community-engaged process to study design, new members to the PCS-AB will be introduced to the VWCR platform, and all members will undergo a comprehensive orientation. During the trial planning phase, the PCS-AB will meet monthly (up to 6 virtual meetings) to provide input on study materials and feedback for the continued refinement of the VWCR platform. A subset of members will participate in a 1-week Mock Patient Journey trial of the VWCR program and



**Figure 2. Overview of study design and study arms.**

Participants will be screened for eligibility following index cardiac event and randomized 1:1 following baseline assessment. Participants will undergo a 12-week intervention. Postintervention assessments will occur at 3 and 6 months after randomization. CBCR indicates center-based CR; CR, cardiac rehabilitation; CV, cardiovascular; EP, exercise physiologist; LE8, Life's Essential 8; NC, nurse coach; and VWCR, virtual world-based CR. Created with [BioRender.com](https://www.biorender.com).

attend an additional session for program-specific feedback. This input will be used for procedural streamlining/troubleshooting and to further enhance the platform's design, cultural appropriateness, and usability. The PCS-AB will continue to meet throughout the trial implementation phase on a quarterly basis.

The PSC-AB members will receive \$250 for joining the advisory board in addition to \$20 per virtual meeting attended. Members of the Mock Patient Journey will receive an additional \$40.

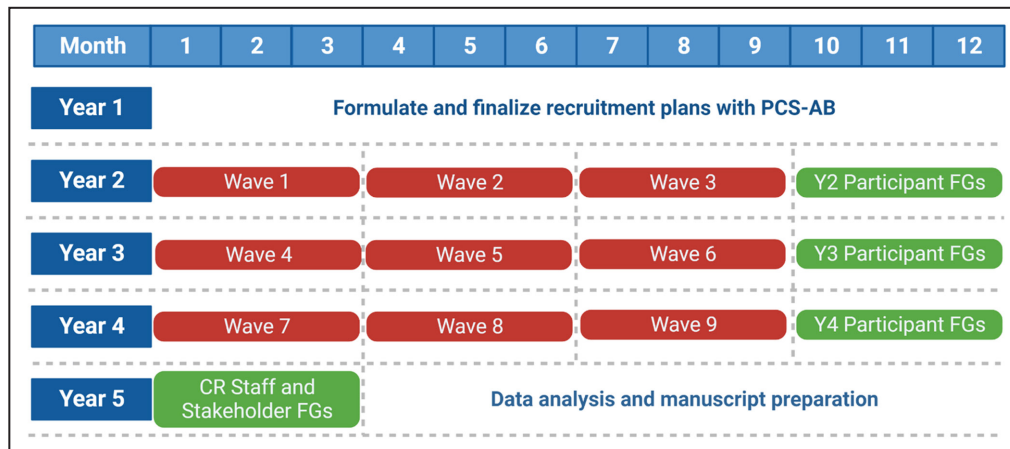
Participants will also be provided with Fitbit PA monitors, Omron Evolv wireless Bluetooth BP monitors, and headsets (for optimal audio communication within the VW platform) as additional incentives. Participants who do not have access to a personal computer will be loaned a laptop for the duration of this study. In addition, patients who are eligible for CR or who have completed CR will be recruited to complete an online survey (CR Perspectives Survey) that aims to identify barriers and facilitators to CR participation and understand features of CR that are most important to patients to further inform the intervention design. The survey will be distributed nationally and across all 6 study sites.

## Study Setting

The study will take place at 6 academic centers with high-quality CBCR programs in diverse geographic regions throughout the United States, including 3 Mayo Clinic sites (Rochester, MN; Scottsdale, AZ; and Jacksonville, FL), Johns Hopkins Hospital (Baltimore, MD), University of California (Irvine, CA), and University of Mississippi Medical Center (Jackson, MS). Each site serves high volumes of diverse cardiac patients by racial and ethnic background, sex and gender, community (rural versus urban), and socioeconomic status to enhance the prospect of recruiting study participants from high-priority populations.

## Study Population/Eligibility Criteria

Eligible participants include adults (aged  $\geq 18$  years) hospitalized for a cardiac event (eg, acute coronary syndrome, stable angina or heart failure, or cardiac surgery) who have basic Internet navigation skills and an active email address. Participants will be excluded if they are high risk by the American Association of Cardiology and Pulmonary Rehabilitation risk stratification (because of safety concerns of unsupervised



**Figure 3. Summary of study timeline.**

The study team will formulate and finalize recruitment plans in year (Y) 1. The intervention will occur in 3 waves per year over Y2 to Y4. Participant focus groups (FGs) will be conducted at the end of Y2 to Y4. Cardiac rehabilitation (CR) staff and stakeholder FGs will occur at the beginning of Y5. Data analysis will be complete by the end of Y5. PCS-AB indicates patient/caregiver/stakeholder advisory board. Created with [BioRender.com](https://www.biorender.com).

exercise), pregnant, or non-English speaking, or have a visual/hearing impairment or mental disability precluding independent use of the VW platform.<sup>49,50</sup>

### Recruitment

Potential participants will be identified from the hospital service census and outpatient CR enrollment lists (those who have not yet completed their first CR session) by the study coordinator at each site. After confirming eligibility, each patient will be approached before dismissal and provided with a study overview and a VW demo video. Participants will provide written informed consent at the time of recruitment or at the baseline visit. Recruitment materials will be culturally and contextually tailored to high-priority populations. We aim to recruit a diverse population that adequately represents the priority population, including ~50% women and participants from diverse racial and ethnic backgrounds. On the basis of patient demographics of the study sites, we anticipate recruiting individuals within the following racial and ethnic distributions: 1.7% American Indian/Alaska Native individuals, 10% Asian individuals, 35% Black individuals, 10% Hispanic or Latino individuals, 3.5% Native Hawaiian or other Pacific Islander individuals, 35% White individuals, and 4.3% individuals of >1 race or ethnicity. Study coordinators will monitor sociodemographics, including age, race, and ethnicity, to provide the study team an opportunity to adjust recruitment strategies to meet the proposed goals.

All participants will receive a PA tracker (Fitbit) to accurately assess free-living PA and heart rates and an Omron Evolv wireless Bluetooth BP monitor. Participants will receive up to \$150 total by cash

card at baseline and follow-up health assessments. Participant transportation and/or parking costs to attend health assessments will be covered as needed with allocated study funding.

### Randomization and Blinding

Patients will be randomly assigned to either the *Destination Cardiac Rehab* arm (intervention) or the CBCR arm (control) in a 1:1 ratio using a computer software-generated list at their baseline visit using Research Electronic Data Capture (REDCap). We will use stratified permuted block randomization with sex and site as strata. Stratified randomization by site ensures balance so that within each site there are similar numbers of participants assigned to each arm. Each site as a unit represents a complex set of characteristics, including race and ethnicity of the population represented by the site, workload of site staff, or underlying practice differences. These characteristics, and hence site more broadly, may be prognostic for outcomes and may influence intervention responsiveness. Thus, stratifying randomization by site may improve statistical power compared with randomization without stratification. To ensure that staff consenting and randomizing patients are unable to predict future randomization sequence, a random sequence of block size (2, 4, and 6) will be used. Because of the nature of the intervention, neither participants nor staff will be blinded to allocation.

### Study Duration/Timeline

Year 1 will encompass hiring/training study staff, obtaining Institutional Review Board (IRB) approval at all clinical sites, and finalizing the recruitment plan with

the PCS-AB. To ensure adequate and valuable interaction with study staff and participants in smaller groups within the VWCR arm, we will deliver the intervention in 3 consecutive waves/year (years 2–4). Quantitative data collection/follow-up for study primary and secondary end points will be completed at 3 and 6 months after randomization per cohort. Participant FGs will occur at year end and will include participants from 3 waves. Staff and stakeholder FGs will occur in the first quarter of year 5. Data analysis will be completed in year 5. See [Figure 3](#) for a summary of the study timeline.

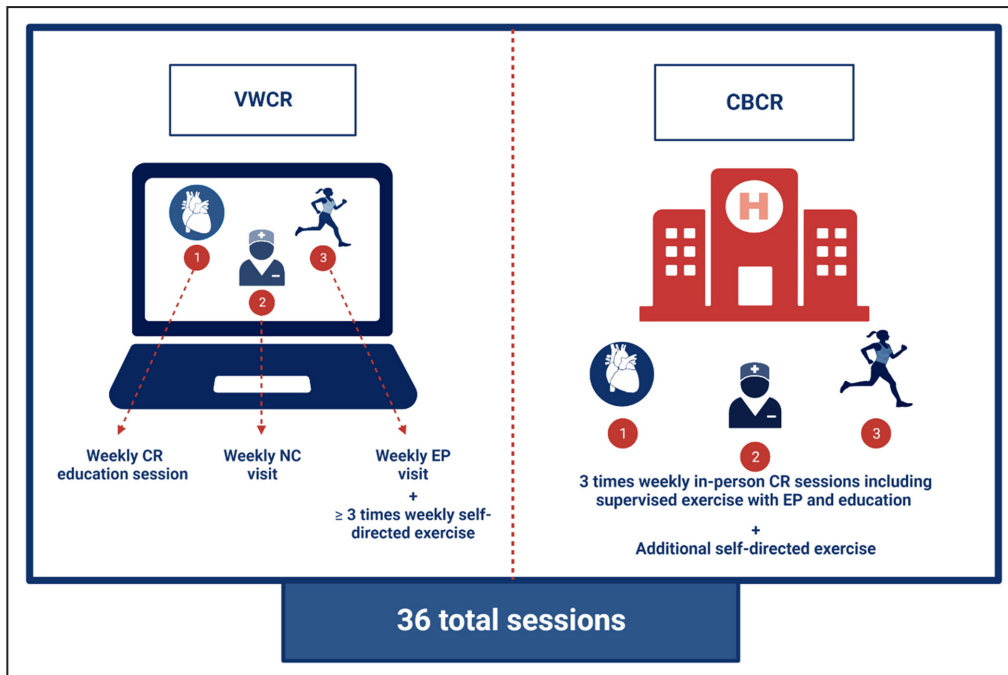
## Intervention

### Destination Cardiac Rehab Arm

Patients randomized to the intervention group will have access to an interactive healthy lifestyle CR community, *Destination Cardiac Rehab*. The intervention is delivered on a secure VW platform via an established Mayo Clinic infrastructure, Linden Lab’s Second Life. To minimize access barriers and maximize equity, participants in the intervention arm will receive a loaner laptop for use during the study installed with VWCR software and/or high-speed fifth-generation wireless modems/service as needed. They will also receive a wireless BP monitor for home BP and heart rate self-monitoring to share with the study team. During the baseline assessment, participants randomized to the

*Destination Cardiac Rehab* arm will receive instructional training with the VW support staff that will provide an overview of Second Life and *Destination Cardiac Rehab*, create an avatar, and review the basic features and navigation of the VW platform. VW support staff will be mindful to customize training to individual digital skills/literacy needs. Technology support staff will be available during all VW sessions.

Participants will undergo an initial assessment and form an individualized treatment plan, which will be updated every 30 days during the intervention. Components of the individualized treatment plan include relevant clinical history, exercise program description, risk factor modification plan, and psychosocial assessment. Participants in the intervention arm will attend 3 synchronous virtual sessions per week over 12 weeks for a total of 36 prescribed sessions and touchpoints with CR staff and will be instructed to engage in  $\geq 3$  asynchronous self-directed, moderate-intensity exercise sessions per week. Participants will be encouraged to wear their PA monitor during self-directed exercise for verification by the study team to avoid recall bias. Group education sessions will occur at a scheduled time each week in VWCR, but will be recorded for those unable to attend live. The exercise physiologist (EP) and nurse coach (NC) visits will be individualized and scheduled to meet participant scheduling needs. Exercise sessions occur asynchronously and can be



**Figure 4. Cardiac rehabilitation program participant requirements by study arm.**

Participants in the intervention arm will participate in 3 virtual sessions per week: a group education session, nurse coach (NC) visit, and exercise physiologist (EP) visit, in addition to  $\geq 3$  self-directed exercise sessions per week. Participants in the control arm will participate in 3 in-person sessions per week and will also be encouraged to exercise outside of cardiac rehabilitation (CR) sessions. CBCR indicates center-based CR; and VWCR, virtual world-based CR. Created with [BioRender.com](#).

completed at the convenience of participants. [Figure 4](#) details the participant requirements by study arm.

### Education Sessions

A series of weekly, 1-hour group sessions covering relevant CVH topics ([Table 1](#)) will occur over 12 weeks within the VWCR platform. These sessions will be led by a cardiovascular disease specialist (principal investigator and site leads) and a cardiovascular nurse educator, both trained in motivational interviewing and the Second Life application. Participants will engage via their avatar in study team–led and self-guided virtual activities, including grocery store, home kitchen, and restaurant tours ([Figure 5](#)) with a registered dietitian, as well as a variety of fitness activities.

### EP Visits

Participants will meet weekly with an EP via private virtual visits on a platform within the electronic medical record, compliant with the Health Insurance Portability and Accountability Act, to discuss and review self-directed exercise patterns (frequency, type, intensity, and duration) and to receive a personalized exercise prescription (including cardioaerobic and resistance training).<sup>50,51</sup> Although no structured supervised exercise will occur during these sessions, participants may review exercise techniques with the EP as needed.

### NC Visits

An NC will be assigned to each patient for personalized, collaborative goal setting for lifestyle change and cardiovascular risk factors. At weekly private virtual visits via the Health Insurance Portability and Accountability Act–compliant platform within the electronic medical

record, the NC will review key concepts from the CR curriculum, cardiovascular symptoms, PA patterns, BPs, and medications, and assist with social determinants of health as identified by the patient (eg, local community resource referrals).

### Peer Support Group Sessions and Discussion Forum

To mimic the social interaction experienced by participants in CBCR, optional weekly live peer social happy hour group sessions will be available within the VWCR platform for participants to virtually meet via their avatars to share their progress in translating healthy lifestyle changes from the VW to the physical world. A peer discussion forum will be available at all times to the participants on the *Destination Cardiac Rehab* platform. The peer support group is adjunctive rather than a core component of the intervention and is designed to simulate the social interactions patients may experience in CBCR.

### CBCR Arm

The control group will enroll in a standard CBCR program, which consists of 36 sessions (typically 3 sessions/week) over 12 weeks at most clinical sites. Analogous to the intervention group, participants will undergo an initial session and individualized treatment plan (which will be updated every 30 days by CR clinicians), and meet with EPs and NCs regularly throughout the program for supervised exercise training with exercise prescriptions, clinical assessments, and risk factor modification ([Figure 1](#)). Participants in the CBCR group may also engage in self-directed exercise outside of in-person sessions and will be encouraged to wear their PA tracker for verification by the study team.

### Safety Assessments and Adverse Event Reporting

Participants in the intervention arm will be instructed to self-monitor for worrisome cardiovascular symptoms (eg, chest pain, excessive dyspnea, and lightheadedness). During each VW session (education sessions, EP visits, and NC visits), the CR staff will ask about any worrisome symptoms. If an adverse event (defined as any new unfavorable symptom/diagnosis that was either absent at baseline or worsens during the intervention) is identified, CR staff will immediately report to the site-specific cardiovascular disease specialist for appropriate triage. Participants will be asked to discontinue self-directed exercise until deemed safe by the cardiovascular disease specialist. Participants in both arms may discontinue CR at will or with the development of an adverse event but, with their permission, will continue interval assessments to ensure adequate

**Table 1. Overview of *Destination Cardiac Rehab* Education Session Curriculum**

Session	Topic
1	Overview of types of heart disease
2	Managing heart disease risk factors
3	Heart medications
4	Benefits of exercise
5	Smoking cessation
6	Practical exercise tips
7	Stress management and heart disease
8	Sexuality and heart disease
9	Heart-healthy nutrition review
10	High blood pressure
11	Fitness concepts and implementation strategies (including fitness center tour with exercise physiologist)
12	Dining out the healthy way (including interactive restaurant and grocery store tour with dietitian)



**Figure 5.** Images of *Destination Cardiac Rehab*.

**A,** Peer support group. **B,** Patient using treadmill in fitness center. **C,** Patient at restaurant. **D,** Patient practicing yoga in fitness center. Created with [BioRender.com](https://www.biorender.com/).

intention-to-treat analysis. Temporary or permanent discontinuation and the reason for discontinuation will be documented by the study team.

## Data Collection and Management

### Health Assessments

Quantitative assessments (summarized in [Table 2](#)) in both study arms will be performed in person with the study team at baseline and 3 and 6 months after randomization. Data will be maintained on a secure site and will be deidentified for analysis.

The baseline assessment will include completion of a survey, anthropometric and laboratory data, and a functional assessment. The survey will include questions on demographics (sex/gender, age, race and ethnicity, marital status, socioeconomic status, and insurance status), cardiovascular disease history, including the indication for CR, other cardiovascular comorbidities, and current use of guideline-based cardiovascular medication therapies (including aspirin, statin, cardioselective  $\beta$ -blocker, angiotensin-converting enzyme inhibitor/angiotensin receptor blocker/angiotensin receptor/neprilysin inhibitor, mineralocorticoid receptor antagonist,

and sodium-glucose cotransporter-2 inhibitor, as indicated), other baseline characteristics (general health, additional medical history, health status, and preventive care), and outcome measures.

Anthropometric data will include height measurement (to nearest centimeter by stadiometer), weight measurement (with calibrated scale in kilograms), and BP (average of 3 sitting readings). Laboratory evaluation will include fasting lipid panel, hemoglobin A1c (percentage), and fasting glucose (mg/dL). Functional capacity will be assessed by measuring 6-minute walk distance (meters). Two follow-up assessments will occur at 3 and 6 months after randomization with similar data collected as those obtained during the baseline visit, excluding questions on demographic information and baseline characteristics.

### Qualitative Assessment

#### Focus Groups

At 3 to 9 months after randomization, study participants will be recruited to participate in optional FGs, which will include a semistructured interview with questions probing CR satisfaction, acceptability, and facilitators/



**Table 2. Summary of Patient Assessments**

Assessment	Screening/enrollment	3 Months after randomization	6 Months after randomization
Individual information			
Demographics (sex/gender, age, race and ethnicity, marital status, SES, and insurance status)	X		
Cardiovascular disease history (indication for CR, other cardiovascular comorbidities, and current use of guideline-based cardiovascular medication therapies)	X		
General health, medical history, health status, and preventive care	X		
Cardiovascular health (LE8) measures			
Diet quality	X	X	X
PA patterns	X	X	X
Nicotine exposure	X	X	X
Sleep quality	X	X	X
Body mass index	X	X	X
Blood lipids (non-HDL)	X	X	X
Blood glucose/hemoglobin A1c	X	X	X
BP	X	X	X
Cardiovascular outcomes			
MACE composite		X	X
Functional capacity			
6-Min walk distance	X	X	X
Psychosocial measures			
Quality of life	X	X	X
Diet/PA self-efficacy	X	X	X
Diet/PA self-regulation	X	X	X
Diet/PA social support	X	X	X

BP indicates blood pressure; CR, cardiac rehabilitation; HDL, high-density lipoprotein; LE8, Life's Essential 8; MACE, major adverse cardiovascular event; PA, physical activity; and SES, socioeconomic status.

barriers to completion. An FG in year 5 will be conducted with the CR staff and key stakeholders (eg, clinicians, payers, and community organizations) to elicit feedback on the intervention and to better understand barriers/facilitators and costs projected to support or hinder sustainment/scalability using the Consolidated Framework for Implementation Research.<sup>52</sup>

Evaluation will follow the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to understand influences on adherence/clinical outcomes as well as cost-effectiveness to inform the potential for future sustainability and scalability of *Destination Cardiac Rehab*.<sup>53,54</sup> In addition, the Clinical Sustainability Assessment tool will be used for sustainability planning.<sup>55</sup> Implementation outcomes or evaluation measures used to assess each RE-AIM domain are summarized in [Table 3](#).

## Primary Outcome Measures

### Cardiovascular Health

The AHA defined 8 essential components of CVH, coined Life's Essential 8 (LE8), that when optimized

are strongly associated with reduced MACEs, cardiovascular disease mortality, and all-cause mortality.<sup>56–59</sup> Positive trends in the AHA's prior iteration of LE8, Life's Simple 7, which included 7 of 8 LE8 components, have been noted in patients attending CR.<sup>56</sup> On the basis of this robust evidence, LE8 was selected as the primary outcome measure as it is a more comprehensive measure of CVH and has a strong correlation with the aforementioned hard end points often used to evaluate CR programs. The components include both health behaviors (diet, PA, nicotine exposure, and sleep health) and health factors (body mass index, blood lipids, blood glucose levels, and BP). The aforementioned survey completed at baseline and follow-up assessments will include validated questionnaires, Mediterranean Eating Patterns for Americans,<sup>60</sup> the International Physical Activity Questionnaire,<sup>61</sup> National Health and Nutrition Examination Survey Smoking-Cigarette Use Questionnaire,<sup>62</sup> and the Pittsburgh Sleep Quality Index<sup>63</sup> to evaluate diet quality, PA patterns, nicotine exposure, and sleep quality, respectively. Body mass index will be calculated by the height and weight measured at the baseline

**Table 3. Evaluation Using RE-AIM Framework**

RE-AIM element	Data source(s)	Evaluation measures
<b>Reach</b>		
Representativeness: participant	Enrollment data	Number/proportions by demographic subgroups
Representativeness: setting	Site characteristics	Size, location, staff, and demographic of patients served
Penetration/refusion reasons	Screening lists	Number/proportions not participating for each reason overall and by subgroups
<b>Effectiveness</b>		
Primary outcome: adherence	Participant follow-up data	Number of sessions attended relative to number prescribed* Goal ≥70% of sessions: VWCR: 25 of 36 virtual sessions (education, EP, and NC sessions); CBCR: 25 of 36 in-person sessions
Secondary outcome: adherence		Number of sessions attended relative to sessions prescribed Number of self-directed moderate-intensity exercise sessions completed per week
Secondary outcome: retention		Percentage of participants completing baseline and 3- and 6-mo and follow-up clinical assessments
Secondary outcome: clinical		3-mo CVH (LE8 score) outcome, MACEs
Secondary outcome: cost-effectiveness		3- and 6-mo estimated per-participant direct and indirect health care costs for both VWCR and CBCR
<b>Adoption</b>		
Acceptability/satisfaction	Focus groups	Participant satisfaction with VWCR intervention or CBCR CR staff (EP, NC) satisfaction with VWCR intervention
Barriers/facilitators to adoption	Focus groups Implementation checklists Study team notes	Site-specific impediments to program execution; catalyzing factors supporting program uptake by implementers
<b>Implementation</b>		
Fidelity	Focus groups Implementation checklists Protocol variations Participant follow-up data VW platform data Study team notes	Fidelity to intervention (VWCR) and control (CBCR) groups will be measured as follows: Curriculum: number of sessions/participant, session type (group/individual), independent use (unscheduled visits), and completion of experiential learning activities (eg, fitness center, restaurant), EP and NC: number of virtual (or in-person) visit sessions/participant, mode of delivery (telephone/video, in-person), session duration, session type (group/individual), what was delivered (eg, exercise, health behavior counseling, or SDOH review), and quality of interventionist delivery (enthusiasm, confidence, and communication style)
<b>Maintenance</b>		
Sustainability and scalability	Stakeholder focus groups	Projected facilitators/barriers to sustainability/scaling from stakeholders (clinicians, payers, and advocacy groups) as follows: review of direct and indirect health care costs, personnel costs (salaries), intervention materials, and facility-level overhead costs

CBCR indicates center-based CR; CR, cardiac rehabilitation; CVH, cardiovascular health; EP, exercise physiologist; LE8, Life's Essential 8; MACE, major adverse cardiovascular event; NC, nurse coach; RE-AIM, Reach, Effectiveness, Adoption, Implementation, and Maintenance; SDOH, social determinants of health; VW, virtual world; and VWCR, VW-based CR.

\*Number of VWCR sessions/participant, session type (group/individual), independent use (unscheduled visits), and areas visited (eg, fitness center, restaurant).

and follow-up visits and reported as kg/m<sup>2</sup>. Additional health factor metrics obtained at baseline and after intervention will include non-high-density lipoprotein cholesterol levels (mg/dL), hemoglobin A1c (percentage), or fasting blood glucose (mg/dL), and an average of 3 sitting BP readings (mm Hg). An overall LE8 score will be generated by calculating an unweighted average score on a scale of 0 to 100 (Table 4). Average LE8 scores will be categorized as low (0–49), moderate (49–78), or high (80–100). The LE8 components will be measured at baseline and 3 and 6 months after randomization.

**Participation and Adherence**

Studies have demonstrated a dose-response association between CR adherence and reduction in MACEs, highlighting the importance of participant attendance and the basis for which we chose to include participation and adherence as a primary outcome measure.<sup>64,65</sup> Optimal adherence will be defined as completion of ≥70% of prescribed weekly virtual or in-person sessions (≥25 of 36 sessions) in the *Destination Cardiac Rehab* and CBCR arms based on the goal set out by the Million Hearts CR Collaborative and empirical evidence from a recent meta-analysis.<sup>30,64</sup> Attendance

**Table 4. LE8 Composite Scoring Guide**

Metric	Score	
Diet quality	Points	Quantiles of adherence
	100	≥95th Percentile
	80	75th–94th Percentile
	50	50th–74th Percentile
	25	25th–49th Percentile
	0	1st–24th Percentile
PA	Points	Min/wk
	100	≥150
	90	120–149
	80	90–119
	60	60–89
	40	30–59
	20	1–29
	0	0
Nicotine exposure	Points	Status
	100	Never smoker
	75	Former smoker, quit ≥5y ago
	50	Former smoker, quit 1–5y ago
	25	Former smoker, quit <1 y ago
0	Current smoker Subtract 20 points for living with active indoor smoker in home	
Sleep health	Points	Hours of sleep/night
	100	7 to <9
	90	9 to <10
	70	6 to <7
	40	5 to <6 or ≥10
	20	4 to <5
0	<4	
BMI	Points	BMI, kg/m <sup>2</sup>
	100	<25
	70	25.0–29.9
	30	30.0–34.9
	15	35.0–39.9
0	≥40.0	
Blood lipids	Points	Non-HDL cholesterol, mg/dL
	100	<130
	60	130–159
	40	160–189
	20	190–219
0	≥220 If on lipid-lowering therapy, subtract 20 points	
Blood glucose	Points	HbA1c, %; or FBG, mg/dL
	100	No history of diabetes and FBG <100 or <5.7
	60	No history of diabetes and FBG 100–125 or 5.7–6.4
	40	Diabetes with HbA1c 6.4–7.0

(Continued)

**Table 4. Continued**

Metric	Score	
	30	Diabetes with HbA1c 7.0–7.9
	20	Diabetes with HbA1c 8.0–8.9
	10	Diabetes with HbA1c 9.0–9.9
	0	Diabetes with HbA1c ≥10.0
BP	Points	BP, mmHg
	100	<120/80 to 120–129/<80
	75	130–139 or 80–89
	50	140–159 or 90–99
	25	≥160 or ≥100
	0	Subtract 20 points if on BP treatment
	LE8 composite score total points/8	

BMI indicates body mass index; BP, blood pressure; FBG, fasting blood glucose; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; LE8, Life’s Essential 8; and PA, physical activity.

to the *Destination Cardiac Rehab* education sessions as well as EP and NC virtual visits will be monitored by the VW web administrator, EPs, and NCs, respectively. Participant adherence in the control group will be measured by number of prescribed in-person sessions attended, as documented by CR staff.

### Secondary Outcome Measures Cardiovascular Outcomes

Cardiovascular outcomes will be measured using a MACE composite end point, including the following: (1) cardiovascular-related hospital readmissions or (2) all-cause or cardiovascular-related mortality at 3 and 6 months after randomization. Data on reasons for hospital admissions will be collected through extraction of clinical documentation in the electronic medical record, and deaths will be determined from the electronic medical record and caregiver report.

### Exercise Sessions

Participants in both arms will report number of self-directed exercise sessions completed per week, which will be confirmed by data from the provided PA tracker (Fitbit) with a goal of adherence to ≥3 self-directed and/or in-person (control group only) moderate-intensity exercise sessions per week in accordance with CR quality measures outlined by the American College of Cardiology/AHA and prior works demonstrating improved outcomes in patients who engage in ≥36 sessions of combined in-person and self-directed exercise over the course of CR.<sup>5,64,65</sup>

### Functional Capacity

The 6-minute walk test is a commonly used metric to assess functional exercise capacity.<sup>66</sup> A prior

meta-analysis revealed that distance walked over 6 minutes improves in patients who have completed CR.<sup>66</sup> The change in 6-minute walk test distance (measured in meters) from baseline to 3 and 6 months after randomization will be compared between the intervention and control arms.

### Psychosocial Measures

Psychosocial measures, including health-related quality of life,<sup>67</sup> healthy diet/regular PA self-efficacy,<sup>68,69</sup> self-regulation,<sup>70,71</sup> and social support,<sup>72</sup> will be measured using validated questionnaires at 3 and 6 months after randomization.

### Power and Sample Size Calculations

To establish noninferiority of the primary efficacy outcome (comparison of LE8 scores at 3 months between arms), we will use a 5-point noninferiority margin based on prior studies suggesting that a 5-point increase in LE8 is associated with an additional 1-year life expectancy free of disease for a 50-year-old individual.<sup>45,57</sup> This noninferiority margin is sufficient to conclude that *Destination Cardiac Rehab* is not meaningfully worse than CBCR. Assuming there is no difference between intervention arms under the alternative hypothesis, a total sample size of 110 participants (55/arm) with complete 3-month follow-up provides 90% power to conclude noninferiority for the LE8 outcome at 3 months based on a noninferiority margin of 5 points, assuming a residual SD of 8 points and 1-sided test with  $\alpha$  level 0.025. Prior population-based studies have observed an SD of up to 12 points, but we anticipate the populations eligible for CR are more homogeneous. Furthermore, the statistical analysis will adjust for prognostic prerandomization variables, including baseline LE8 (ANCOVA model). An SD of 10 in this population would result in a residual SD of 8 if the correlation between baseline LE8 and 3-month LE8 is moderately strong ( $\rho=0.6$ ). Assuming  $\approx 25\%$  dropout, we will enroll and randomize 150 participants. If the residual SD is larger than anticipated, we retain 74% power for a residual SD of 10 and nearly 60% power for a residual SD of 12.

As described previously, a participant is adherent if attending  $\geq 70\%$  of prescribed weekly virtual or in-person sessions. We hypothesize that the rate of adherence (percentage of participants who are adherent) in *Destination Cardiac Rehab* will be noninferior to the rate of adherence in CBCR. A 25% absolute difference in the adherence rate is considered noninferior. On the basis of prior *Destination Cardiac Rehab* adherence data,<sup>40</sup> we anticipate higher adherence than observed in prior studies. Assuming a 50% adherence rate among CBCR, a 2-sample test of proportions among

150 total participants (75 per arm) provides 86% power to conclude noninferiority with 1-sided  $\alpha$  level 0.025. If CBCR adherence percentage is 80%, the design provides 97% power.

## Statistical Analysis

### Quantitative Data Analysis

#### Cardiovascular Health

The primary outcome for aim 1 is comparison of the LE8 score at 3-month follow-up between randomized arms. A noninferiority hypothesis will be tested, with the null hypothesis ( $H_0$ ) stating that  $\delta$  (calculated as  $\mu_{VW} - \mu_{CB}$ )  $\leq -5$  versus the alternative hypothesis ( $H_A$ ) stating that  $\delta > -5$  where  $\mu_{VW}$  and  $\mu_{CB}$  are mean LE8 at 3 months in *Destination Cardiac Rehab* and CBCR groups, respectively.  $\delta$  rejects  $H_0$  in favor of noninferiority of *Destination Cardiac Rehab* if the lower bound of the 2-sided 95% CI on  $\delta$  is above  $-5$  points.  $\delta$  will be estimated from a linear mixed effects model, which will control for baseline LE8, sex, and random effect of site. If noninferiority is established, a superiority hypothesis will be tested using a 2-sided  $\alpha$  level 0.05. We will assess moderators of the treatment effect by assessing interactions between baseline visit data and treatment. As the primary goal is to assess a strategy of assignment to *Destination Cardiac Rehab* or CBCR, the analysis of CVH outcomes will use intention-to-treat principles with participants analyzed according to randomized arm independent of participation and adherence.

#### Participation and Adherence

Adherence to *Destination Cardiac Rehab* (versus CBCR) will be assessed by comparing the proportion of participants in each arm attending  $\geq 70\%$  of sessions prescribed in each group using a Cochran-Mantel-Haenszel test stratified by site, estimating the risk difference (adherence probabilities). Alternatively, continuous percentage of sessions completed will be compared between arms using a Wilcoxon rank-sum test for superiority. Quantitative data will be summarized by descriptive statistics with  $t$  tests and generalized linear models. To inform generalizability to high-priority populations and to evaluate the possibility of bias attributable to attrition, sociodemographic and contextual factors (eg, sex/gender, age, race and ethnicity, socioeconomic status, and geographic location) of adherent/nonadherent will be compared. If there are any discovered differences, corresponding variables will be adjusted for in subsequent analyses. Mediation of intervention effects with respect to each aim 1 end point (LE8 score, MACEs) will be assessed by participant adherence level using multivariable regression and interaction analyses.

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## Secondary Outcomes

The MACE composite outcome will be compared using Kaplan-Meier analysis and shared frailty Cox proportional hazards models, adjusting for sex and site using Firth correction. We will evaluate the 6-minute walk test distance using linear and generalized linear mixed effects models. Superiority hypothesis testing will occur as noninferiority boundaries are not prespecified for these outcomes. Estimates will be reported with 95% CIs and *P* values.

## Qualitative Data Analysis

Using rapid assessment analysis techniques, the FG moderator will provide a summary analysis of the discussion following each FG.<sup>73,74</sup> Sessions will be recorded and transcribed, and transcripts will be independently reviewed by 2 study team members to validate the summary analysis. Data from the semi-structured FG interviews will be organized and aligned with research questions in a matrix framework. The study team will systematically examine and code each cell in the matrix to identify emergent themes within and across sites and by participant characteristics.<sup>75</sup> A third team member will assist with discrepancy resolution to ensure consensus. Content analysis will be facilitated by QSR NVivo software, version 10 (Doncaster, Victoria, Australia). We will use triangulation as cross-verification of our results with comparison across multiple data sources (eg, survey, adherence, and FG data).<sup>50,76,77</sup>

## Missing Data

To account for missing data, sensitivity analyses will be conducted under various mechanisms. First, study coordinators will attempt to ascertain and document participant reasons for dropout. Multiple imputation under missing at random assumptions will impute plausible values based on observed data for participants in which dropout reason is unknown. For participants who provide dropout reason, sensitivity analyses may also be conducted under missing not at random assumptions. In addition, pattern-mixture models will be used to assess sensitivity of results based on location-shift attributable to the not at random mechanism. Missing data for MACE outcomes are expected to be rare as MACEs may be ascertained through review of electronic medical records. Adherence measures will not be missing as dropout reflects nonadherence.

## Ethical Considerations

The protocol, informed consent form(s), and all participant materials will be submitted to the IRB for review and approval at all sites (Mayo Clinic will serve as the IRB of record). Approval of the protocol and consent

form must be obtained before participant enrollment. Any addendum to the protocol will require review and approval by the IRB. All patient visits and data collection will occur at the clinical sites, ensuring participant confidentiality according to Health Insurance Portability and Accountability Act. Data will be collected in REDCap. Study staff will be trained to ensure consistency in data collection. Any data will be identified only by a participant identification number to maintain confidentiality. The principal investigator (L.C.B.) will have full access to all the data in the study and takes responsibility for their integrity and data analysis.

A Data Safety Monitoring Board composed of independent CR experts will be established to oversee and ensure the safety and integrity of data collection. The Data Safety Monitoring Board will operate independently of the research team. The Data Safety Monitoring Board will periodically review and assess the safety data throughout the study, including monitoring adverse events or potential risks to participation. The Data Safety Monitoring Board will also evaluate interim data analyses and provide recommendations to ensure participant safety.

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## DISCUSSION

With the persistent disparity in CR participation, especially among medically underserved populations, ongoing equity-focused innovation in CR delivery models remains critical.<sup>6,9,10,12,29,32,33</sup> To our knowledge, this is the first study to rigorously test the efficacy and participation in a VWCR program compared with CBCR. Our intervention meets all of the CR quality metrics outlined by the AHA and closely matches the traditional CBCR experience that has established efficacy in improving important CVH outcomes.<sup>5,51</sup> Furthermore, the intervention was designed to closely and virtually mimic an in-person experience. Both the intervention and control groups will be prescribed 36 exercise sessions over 12 weeks and engage in 36 touch points with CR staff. As such, we predict that *Destination Cardiac Rehab* will demonstrate comparable effects on CVH outcomes to that of CBCR. The efficacy outcome measures chosen include the clinically relevant quality performance measures outlined by the AHA in addition to many other important outcome measures commonly used to evaluate CR efficacy.<sup>5</sup>

Our community-oriented clinical trial has several strengths and equity-promoting aspects. The integration of a social network fosters a sense of group accountability and equitable inclusion, important elements to behavioral change that are often missing in home-based CR, possibly accounting for its suboptimal engagement.<sup>9,37,78,79</sup> Furthermore, our study team capitalized on the unique features of VW platforms in

addition to the various benefits of home-based CR to create a patient-centric intervention that has previously demonstrated excellent adherence, with 71% of patients attending  $\geq 75\%$  of sessions.<sup>44,45</sup> On the basis of our prior feasibility study, we expect at least comparable, if not superior, participation in the *Destination Cardiac Rehab* group compared with CBCR. We also evaluate both short- and longer-term effects (at 3 and 6 months after randomization) of the intervention on key CR outcomes, CVH (clinical and behavioral factors), MACEs, and functional capacity. In addition, this intervention has the potential to serve as an alternative CR delivery model as it was designed with and will have ongoing input from diverse community members with a goal to reach populations with the most CR barriers. Finally, our rigorous mixed-methods approach and further evaluation of our program using the RE-AIM framework will inform future implementation, dissemination, and scalability to reach all CR-eligible patients.

### Limitations

Our study does have potential limitations that may limit generalizability and scalability of the intervention. Notably, the VWCR platform is not supported by mobile devices (eg, smartphones, tablets), which may limit generalizability. In addition, participants with no access to a home computer and/or Internet will be provided with a laptop and/or high-speed wireless modems/service. Although this provides an advantage in recruiting a diverse patient population, it may limit future implementation to priority populations. However, the cost benefits of provision of relatively inexpensive devices and Internet access outweigh the exuberant costs associated with cardiovascular-related hospitalizations and morbidity faced by patients unable to attend CBCR.<sup>80,81</sup> This highlights the importance of ongoing efforts to address the digital divide.<sup>82,83</sup> Participants will be recruited from academic medical centers, which may limit generalizability to medically underserved populations. In addition, because of constraints of the intervention platform at this time, this study could not accommodate non-English-speaking individuals, a population that is highly underrepresented in CR programs.<sup>84</sup> Scalability plans will include the addition of other languages to serve non-English-speaking patients. Finally, insurance reimbursement continues to hamper implementation of home-based and virtual CR platforms. The US Congress recently chose to terminate Medicare coverage of virtual CR programs beyond the COVID-19 public health emergency, which could significantly restrict implementation of *Destination Cardiac Rehab*.<sup>85</sup> Fortunately, the Sustainable Cardiopulmonary Rehabilitation Services in the Home Act was recently proposed in Congress to address this important issue, emphasizing the importance of building the evidence

base and ongoing advocacy for alternative virtual CR platforms that expand access to a vital component of cardiovascular care.<sup>86</sup>

## CONCLUSIONS

Our study is the first study to evaluate the efficacy of a VWCR program compared with the standard of care. If *Destination Cardiac Rehab* demonstrates noninferior outcomes compared with CBCR, our VWCR program could serve as an alternative method of CR delivery, potentially expanding access to critical populations with high barriers to traditional CR participation.

## ARTICLE INFORMATION

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### Disclosures

None.

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