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RESEARCH ARTICLE

# Heart up! RCT protocol to increase physical activity in cardiac patients who report hopelessness: Amended for the COVID-19 pandemic

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## Abstract

Hopelessness is associated with decreased physical activity (PA) and increased adverse events and death in patients with ischemic heart disease (IHD). Rates of PA in patients with IHD continue to be low in both hospital-based cardiac rehabilitation and home settings. While researchers have investigated strategies to increase PA among patients with IHD, interventions to promote PA specifically in IHD patients who report hopelessness are lacking. We describe the protocol for a NIH-funded randomized controlled trial designed to establish the effectiveness of a 6-week intervention (*Heart Up!*) to promote increased PA in IHD patients who report hopelessness. Participants (*n* = 225) are randomized to one of three groups: (1) motivational social support (MSS) from a nurse, (2) MSS from a nurse plus significant other support (SOS), or (3) attention control. Aims are to: (1) test the effectiveness of 6 weeks of MSS and MSS with SOS on increasing mean minutes per day of moderate to vigorous PA; (2) determine the effects of change in moderate to vigorous PA on hopelessness; and (3) determine if perceived social support and motivation (exercise self-regulation) mediate the effects of the intervention on PA. A total of 69 participants have been enrolled to date. The protocol has been consistently and accurately used by research personnel. We address the protocol challenges presented by the COVID-19 pandemic and steps taken to maintain fidelity to the intervention. Findings from this study could transform care for IHD patients who report hopelessness by promoting self-management of important PA goals that can contribute to better health outcomes.

**KEYWORDS**
cardiac, COVID-19, hopelessness, physical activity, research protocol

## 1 | INTRODUCTION

Hopelessness is associated with a 3.4 times increased risk of mortality or nonfatal myocardial infarction in patients with ischemic heart disease (IHD), independent of depression (Pedersen et al., 2007). Hopelessness, a negative outlook and sense of helplessness toward the future, (Abramson et al., 1989), has been identified in 27%–52% of patients with IHD (Dunn et al., 2006; Dunn et al., 2017; Kangelaris et al., 2010) and persists for up to 12 months (Dunn et al., 2009; Dunn et al., 2017). Hopelessness is associated with decreased physical functioning (Dunn et al., 2009) and decreased physical activity (PA) in both home (Dunn et al., 2017) and hospital-based cardiac

rehabilitation (CR) settings (Dunn et al., 2009), independent of depression. The future is challenging for patients with IHD as they commonly face a new cardiac diagnosis and a number of recommended lifestyle changes. Therefore, hopelessness may represent a state in response to these new events or a trait reflecting a patient's habitual outlook toward life. The differentiation between state and trait hopelessness is important. State hopelessness may be more responsive to short-term interventions in an outpatient setting, whereas trait hopelessness may require long-term cognitive therapy (Abramson et al., 1989).

Evidence is overwhelming that physical inactivity independently contributes to increased adverse events and death in the general population and those with IHD (Whooley et al., 2008; Win et al., 2011; Ye et al., 2013), and ample evidence indicates that exercise reduces morbidity and mortality for patients with IHD (Anderson et al., 2016; Goel et al., 2011; Smith et al., 2011). Even with known benefits and established PA guidelines (Smith et al., 2011), PA adherence is low. Participation in CR programs is less than 20%, particularly in females, older adults, and socioeconomically disadvantaged groups (Gaalema et al., 2014; Karmali et al., 2014); and adherence to home-based exercise guidelines is less than 50% (Dunn et al., 2017). Compared to patients with IHD who do not report hopelessness, those with hopelessness have significantly lower attendance in CR (Dunn et al., 2009) and lower daily PA in home settings (Dunn et al., 2017), independent of depression.

We are the only research team conducting studies to promote self-management of IHD through PA specifically in patients who report hopelessness. Interventions are needed because individuals experiencing hopelessness feel incapable of helping themselves (Abramson et al., 1989), putting them at high risk for poor PA adherence. Our previously conducted pilot study confirmed feasibility of a 6 weeks, novel intervention (*Heart Up!*; Dunn et al., 2019) to increase PA and reduce hopelessness in patients with IHD. This paper's purpose is to describe the study protocol for our current randomized controlled trial (RCT) to test the effectiveness of *Heart Up!*.

## 2 | METHODS

### 2.1 | Theoretical framework

The study design was based on Self-Determination Theory (SDT; Deci & Ryan, 2008; Ryan & Deci, 2000; Ryan & Edward, 2002) and Cohen's Stress and Coping Social Support Theory (Cohen et al., 2001; Figure 1). According to SDT, self-determined motivation originates from a person's tendency to take an active role in directing one's own behavior; and self-determined behavior is associated with greater success in long-term behavioral change and maintenance (Deci & Ryan, 2008). SDT focuses on intrinsic motivation, which involves an individual seeking life challenges that allow for growth (Ryan & Deci, 2000). When competence, autonomy, and relatedness are perceived, intrinsic motivation increases and leads to desired behavior change (Deci & Ryan, 2008).

The *Heart Up!* intervention includes motivational interviewing and text messaging components. Motivational interviewing provides a supportive environment to further enhance competence, autonomy, and relatedness (Marklund et al., 2005). The provision of additional social support through text messages is intended to enhance the supportive environment. Social support can include instrumental (material aid), informational (instruction), or emotional (encouragement) resources (Cohen et al., 2001). The intervention's text messages were developed to focus on encouragement.
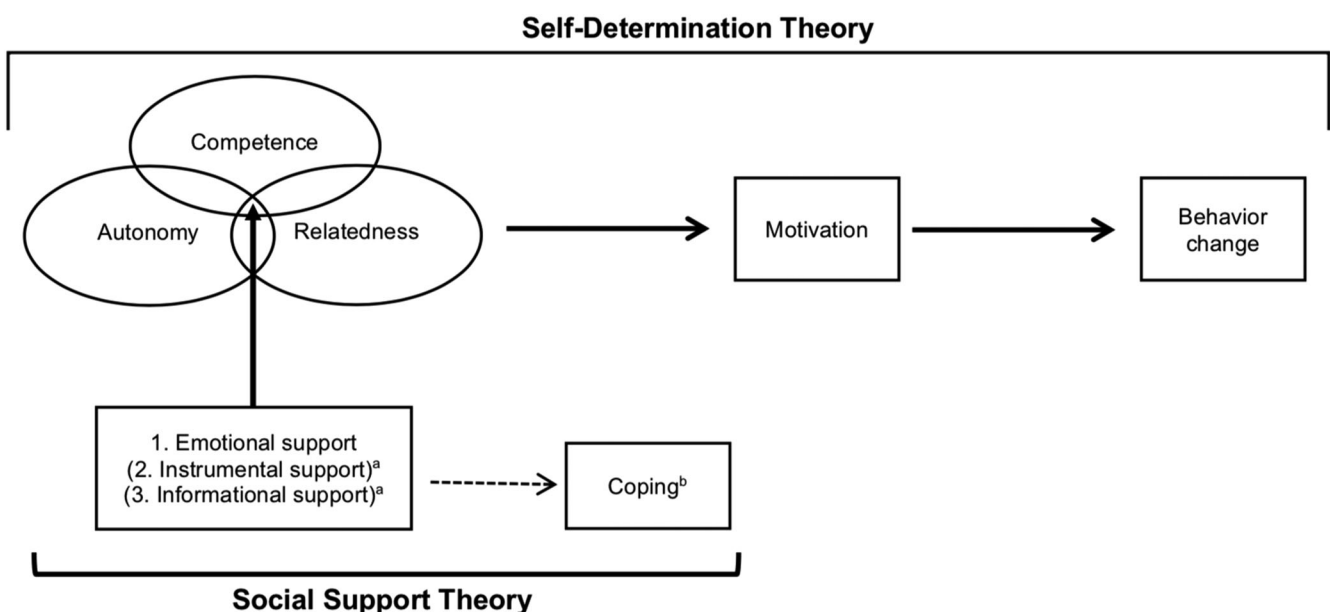


**FIGURE 1** Theoretical Framework Based on Self-Determination Theory and Cohen's Social Support Theory. (a) Instrumental support and informational support are not a focus of this study; (b). The relationship between emotional support and coping is not a focus of this study

## 2.2 | Study design

In the current RCT, we are employing the same parallel three group design used in our previous pilot study (Dunn et al., 2019): (1) motivational social support (MSS) from a nurse alone, (2) MSS from a nurse with additional significant other support (SOS), and (3) attention control (AC). Data are collected following hospital discharge in the participant's home at three time points over 6 months. The two groups of participants randomized to MSS, with or without SOS, meet in person with a nurse trained in motivational interviewing and then receive 6 weeks of daily text messages from the nurse. Participants in the MSS with SOS group identify a significant other, who also sends daily text messages (developed by the researchers) over the same time period. The AC group receives American Heart Association (AHA) educational videos to match the other groups' motivational interviewing session time.

The scientific premise for the two treatment conditions (nurse-provided motivational social support and nurse plus significant other support) is based on known associations among these two variables. Increased social support (Aliabad et al., 2014; Moore et al., 2003) and increased motivation (Russell & Bray, 2010) are predictive of increased PA in the IHD population. An intervention within an individual's existing social network (e.g., significant other support in this RCT) can be effective in building strong and long-lasting social support (Shapiro et al., 2012). No research has examined social support and motivation together specifically in IHD patients who report hopelessness.

## 2.3 | Specific aims and hypotheses

The RCT measurement model is shown in Figure 2. Our short-term goal is to increase PA and decrease state hopelessness in patients with IHD. The long-term goal is to sustain PA gains and improve associated health outcomes (e.g., IHD risk factors, morbidity, and mortality).

Aim 1: Test the effectiveness of 6 weeks of MSS and MSS with SOS on increasing mean minutes/day of moderate to vigorous PA, measured by an accelerometer.

Hypothesis 1: *The MSS with SOS group will have the greatest increase in mean minutes/day of moderate to vigorous PA compared to the MSS only or AC groups, while the MSS only group will have a larger increase compared to AC.*

Aim 2: Determine the effects of change in minutes/day of moderate to vigorous PA on state hopelessness, measured by the State-Trait Hopelessness Scale (STHS).

Hypothesis 2: *Increased minutes/day of moderate to vigorous PA per day will be associated with decreased state hopelessness for experimental groups.*

Aim 3: Determine if perceived social support (measured by the ENRICHD Social Support Inventory) and motivation (exercise self-regulation; measured by the Exercise Self-Regulation Questionnaire) mediate effects of the intervention on PA.

Hypothesis 3: *Increased perceived social support and increased motivation (exercise self-regulation) will mediate the effects of Heart Up! resulting in a greater increase in moderate to vigorous PA at 8 and 24 weeks.*

## 2.4 | Setting

The sample is being recruited and enrolled from inpatient care units at one cardiovascular hospital in the Midwest. Enrollment began in August 2019.

## 2.5 | Sample

The target population is adults with IHD who report moderate to severe levels of hopelessness. Hopelessness screening is conducted with hospitalized patients who meet eligibility criteria, including:
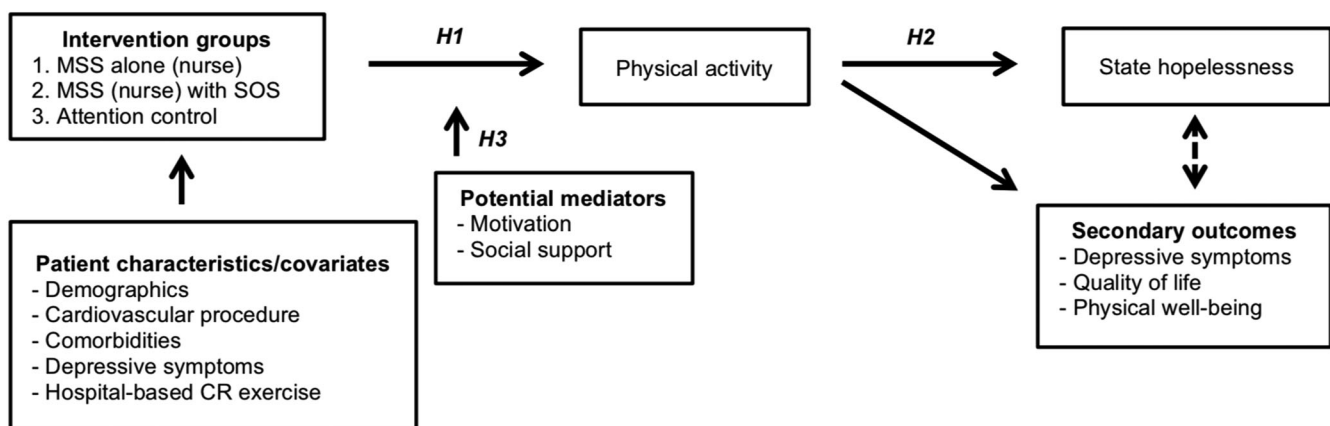


**FIGURE 2** Conceptual model of measures. CR, cardiac rehabilitation; H, Hypotheses 1, 2, or 3; MSS, motivational social support; SOS, significant other support

adults ≥18 years old; diagnosed with myocardial infarction or unstable angina, who undergo percutaneous coronary intervention or coronary artery bypass graft surgery; use a cell phone with text messaging capability; receive a provider recommendation to engage in PA; have a planned discharge home; can identify a significant other who can text message them; live within 100 miles of the hospital; speak and read English; and can complete the screening instrument. Patients who meet the hopelessness criteria are invited to participate in the RCT. The significant other must be ≥18 years old, use a cell phone with text messaging capability, speak and read English, be able to complete the consent form, may or may not be living with the patient, and is selected by the patient as their significant other to serve in a supportive role.

Our team has experience working with IHD patients who report hopelessness. Our recent pilot study enrolled 69.8% of eligible patients with hopelessness and retained 67% of these patients until study completion (Dunn et al., 2019).

### 2.5.1 | Sample size justification and power

To account for potential 33% attrition, we plan to over-sample up to 225 participants (75 per group). Our goal is 50 subjects per group. We are using an intention-to-treat analysis by including all randomized participants in our analyses. A sample size of 150 provides at least 80% power for all aims to detect medium effect sizes. Sample size for the study was based primarily on ensuring our ability to detect a clinically meaningful effect for the primary outcome of PA (Aim 1).

For Aim 1, we will have 84.6% power to detect medium effect sizes (effect size of 0.5: a change of 2.5 min/day in PA for pooled $SD$ of 5 min/day) with 50 individuals in each of the three groups. Estimates of the covariance of PA over time (1.2) and effect size (medium) were determined from the pilot study (Dunn et al., 2019). Based on the U.S. Department of Health and Human Services 2018 PA Guidelines Advisory Committee Scientific Report, any increase in PA contributes to the health benefits associated with the accumulated volume of PA. The report provides evidence that for many chronic conditions (including IHD), individuals who become more physically active at any level and duration, relative to their peers with the same condition, have reduced risks of disease progression, development of other chronic diseases, and mortality in addition to improved physical functioning and quality of life (U.S. Department of Health and Human Services, 2018).

For Aim 2 this sample size (50 per group) yields 80% power to detect a correlation of 0.126 between change in PA and change in hopelessness levels. Thus, the estimated correlation of 0.19 from the pilot study will have sufficient power to be detected in the RCT.

For Aim 3, effect sizes of at least 0.5 (as observed in the pilot study) will be detected with at least 84.6% power for the direct impact of treatment groups on social support or motivation after adjustment for mediating variables. Partial correlations of at least 0.126 between social support or motivation and change in PA, after

controlling for treatment group, will have at least 80% power. Thus, Aim 3 will have sufficient power to detect moderate to weak mediating effects of social support or motivation on PA.

All power calculations assume a significance level of 0.05 and two-sided tests.

## 2.6 | Procedures

### 2.6.1 | Recruitment

Recruiters, who are employed by the hospital's research department and do not provide direct patient care, determine patient eligibility for hopelessness screening by reviewing the patient's medical record. The recruiters approach eligible patients and invite them to be screened for potential consideration for the study (Table 1). Recruiters use a script to introduce the hopelessness screening, explaining that eligibility for the RCT will depend on screening results. Interested patients provide written consent for the screening, including a HIPAA waiver. Patients are screened for hopelessness using the 10-item state subscale of the 23-item STHS (Dunn et al., 2014). Based on cut-point criteria in previous research (Dunn et al., 2017; Dunn et al., 2019), a criterion of ≥1.8 is used for classification of moderate to severe hopelessness. Patients who do not meet the hopelessness criteria are ineligible and thanked for their time.

For patients who meet hopelessness screening criteria and wish to participate, the recruiters read through a script describing the RCT (Table 1). Patients are informed that, if they are randomized to the MSS with SOS group, they will be asked to identify a significant other to provide support. If the patient agrees to enrollment, written consent is obtained. For participants randomized to the MSS with SOS group, the recruiter meets with the participant's significant other in the hospital or by phone to explain the study and their potential role in sending text messages to the participant. The significant other provides verbal consent and an information sheet is provided.

### 2.6.2 | Randomization

After providing consent, the participant is randomized using a randomization scheme loaded into the university's Research Electronic Data Capture (REDCap) system. The randomization strategy used by REDCap is stratified (by gender and race/ethnicity) block random assignment. Study investigators, data analysts, and data collectors are blinded to group allocation.

### 2.6.3 | Group conditions

Group 1: MSS. Participants receive a 60-min session of motivational interviewing in their home from a trained nurse. The nurse applies

**TABLE 1** Procedures chart

| Timing (location) | Design | | |
|---|---|---|---|
| Preintervention (in hospital) | Patients consented and screened for state hopelessness<br>Consent of eligible patients for RCT<br>Randomization to groups<br>Consent of significant other **(MSS with SOS group)** | | |
| Baseline Week 1 (home) | Accelerometer placement (for 1 week): **3 groups** | | |
| Baseline Week 2 (home) | Data collection: Accelerometer removal and data collection interview (hopelessness, motivation, social support, cardiac rehabilitation exercise participation, physical well-being, quality of life): 3 groups | | |
| | Group 1: MSS | Group 2: MSS with SOS | Group 3: AC |
| Intervention Week 2 (home) | Motivational interviewing | Motivational interviewing | Educational videos |
| Intervention Weeks 2–8 (electronic) | Text messages nurse | • Text messages nurse<br>• Text messages significant other | |
| Postintervention/Week 8 (mail) | Accelerometer placement (for 1 week): **3 groups** | | |
| Postintervention/Week 9 (home) | Accelerometer removal, data collection (same as Week 2): 3 groups | | |
| Postintervention/Week 24 (mail) | Accelerometer placement (for 1 week): **3 groups** | | |
| Postintervention/Week 25 (home) | Accelerometer removal, data collection (same as Week 9): 3 groups | | |

Abbreviations: AC, attention control; MSS, motivational social support; RCT, randomized controlled trial; SOS, significant other support.

motivational interviewing techniques to explore the participant's thoughts about changing behavior to attain adequate PA (Gillham & Endacott, 2010). The session includes the participant's thoughts about PA and types of PA available. Barriers to PA are assessed and discussed. Benefits of PA and setting PA goals are identified (Miller & Rollnick, 2013). Six motivational interviewing tools are used to further identify and examine factors related to PA in a concrete manner: (a) Values Card, (b) Importance of PA Ruler, (c) Confidence with PA Ruler, (d) Positive Attributes Card, (e) Barriers to PA Card, and (f) Next Steps Card (Miller & Rollnick, 2013). The nurse provides and reviews a written copy of the hospital's guidelines for CR home exercise, which includes warm-up guidelines, progressive levels of aerobic exercise, a Rate of Perceived Exertion scale, and instructions on what to do if symptoms develop (e.g., when to call provider or 911). The nurse also assesses the participants' ability to take a radial pulse and provides written instructions on the correct manner to take a pulse. Participants are encouraged to share their resting pulse and pulse increase after exercise with their provider. Participants are provided with *Heart Up!* magnets to be used for displaying the tools provided.

After completing the motivational interviewing, the nurse explains that the participant will begin receiving daily text messages from the nurse the following day, continuing for 6 weeks. The text messages are sent via REDCap, with each text being "signed" by the nurse. The order of texts is randomized so that the order is unique to each participant, allowing the team to determine if the text messages are effective in general versus dependent on the order messages are given. Based on participant preference in our prior work, texts are randomized to arrive between 10:00 a.m. to 12:00 noon. REDCap confirms that texts were sent.

Group 2: MSS with SOS. In addition to receiving the motivational interviewing and text messages from the nurse, participants receive daily text messages from their significant other (developed by the researchers) for the 6-week period. It is hypothesized that the intervention's integration of social support within the participant's existing social network (their self-identified significant other) will be a critical component and provide the greatest impact in increasing PA. The nurse provides a list of the text messages to the significant other by email and/or postal mail. A daily text message reminder is sent by REDCap to the significant other and includes the text message to be sent to the participant. The order of significant other text messages is randomized so that their general effectiveness can be determined. The significant other is asked to respond to the daily REDCap reminder to verify that their message was sent to the participant. Significant others are asked to send messages between 1:00 p.m. and 3:00 p.m. and to vary the times sent from day to day.

Group 3: AC. Participants in the AC group receive a 60-min session with a nurse focused on the viewing of AHA YouTube

educational videos (atherosclerosis and associated risk factors). The nurse provides AHA educational flyers on the same topics. To control for the effects of providing written copies of the hospital's exercise guidelines and pulse-taking instructions, the nurse provides these to AC participants as well.

### 2.6.4 | Intervention fidelity

Treatment fidelity is assured through established methods outlined by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium (Bellg et al., 2004). A treatment fidelity plan, overseen by the project manager, incorporates the NIH workgroup's five recommended components: study design, training, treatment delivery, treatment receipt, and treatment enactment (Bellg et al., 2004; Table 2). A minimum of 25% of the audiotaped motivational interviewing sessions are randomly selected for quality assurance (QA) review by an external motivational interviewing trainer and 25% or more of audiotaped AC sessions are reviewed by the project manager. Motivational interviewing instruments completed by participants (e.g., Rulers) undergo QA review for completeness and accuracy. The delivery and receipt of text messages are tracked in REDCap. If text messages are not being sent by a significant other, the project manager contacts the significant other to discuss and problem-solve. If a significant other is unable or unwilling to send the text messages, the participant is asked to select a different significant other for study participation.

### 2.7 | Data collection

Data collection for all groups occurs in the participant's home at three time points over 24 weeks and includes accelerometer monitoring for 1 week before each data collection visit (Table 1). There is one accelerometer placement visit in the home at baseline (1 week after hospital discharge). At the home accelerometer visit, the data collector instructs the participant on the use of the accelerometer and a PA log and places the activated monitor on the participant. The participant is asked to wear the accelerometer and complete the log for 1 week. The data collector returns after the week to retrieve the accelerometer and to conduct baseline data collection. At Weeks 7 and 23, the accelerometer is shipped to the participant with instructions to wear it again for 1 week. At Weeks 8 and 24, data collectors return to the participant's home to retrieve the accelerometer and conduct data collection. Data collection interviews take on average 30 min. If a participant becomes fatigued during any home visit, the participant is allowed to rest, or study staff reschedule the visit. Medical record data are collected after the participant's hospital discharge (Table 1).

### 2.7.1 | Measures

Variables for the study's aims/hypotheses and potential mediators, covariates and secondary outcomes are shown in Figure 2.

Characteristics of the measures and measurement time points appear in Table 3.

#### Primary outcomes

The pre-specified primary outcomes are PA and state hopelessness. Mean minutes/day of moderate to vigorous PA is measured by an ActiGraph GT9X Link Accelerometer (ActiGraph LLC, 2020). State hopelessness is measured by the STHS (Dunn et al., 2014).

#### Secondary outcomes

The prespecified secondary outcomes (depressive symptoms, physical well-being, and quality of life) warrant examination due to their known associations with PA. Increased PA has been associated with decreased depressive symptoms (Hughes et al., 2010; McGrady et al., 2009; Pinto et al., 2013), increased physical functioning (a component of physical well-being; Anderson et al., 2016; Dalal et al., 2010; Smith et al., 2011), and increased quality of life (De Smedt et al., 2013; Marchionni et al., 2003) in IHD patients. Depressive symptoms are measured using the Patient Health Quetionnaire-9 (Kroenke & Spitzer, 2002; Kroenke et al., 2001). Physical well-being is measured using the PROMIS-29 (Cella et al., 2010). Quality of life is measured using the EuroQol (EQ-5d-5L; EuroQol Research Foundation, 2019; Herdman et al., 2011; Janssen et al., 2013).

#### Mediators

There are two prespecified mediators in the RCT. Motivation (exercise self-regulation) is measured by the Exercise Self-Regulation Questionnaire (Russell & Bray, 2010). Perceived social support is measured by the ENRICHD Social Support Inventory (Gottlieb & Bergen, 2010; Vaglio et al., 2004).

#### Covariates

Potential covariates include patient demographic characteristics and clinical history, comorbidities, depressive symptoms and participation in a CR exercise program. In addition to the known association between decreased depressive symptoms and increased PA (described above), a moderate positive correlation has been identified between depressive symptoms and state hopelessness ($r = .36$, $p < .001$) in patients with IHD (Dunn et al., 2017). Increased participation in a CR program has been associated with increased PA in patients with IHD (Dunn et al., 2017) and a 0.24-point lower state hopelessness score in IHD patients who report hopelessness (Dunn et al., 2017).

### 2.7.2 | Suicide risk management (SRM) protocol

A SRM protocol was developed for use in the RCT. The SRM protocol identifies suicidal ideation and measures ideation severity through use of the Columbia-Suicide Severity Rating Scale (Posner et al., 2011) and its affiliated Clinical Triage Guidelines (The Columbia Lighthouse Project, 2016). The SRM protocol guides research staff through a plan of

**TABLE 2** Treatment fidelity plan summary

| Component | Description |
|---|---|
| Study design | The research team has established protocols and scripts for the motivational interviewing session, attention control session, and text messages |
| | The project manager, in collaboration with the principal investigator, instructs study personnel on protocols |
| | The project manager leads bi-weekly meetings of recruiters, data collectors, motivational interview nurses, and attention control nurses to review protocol adherence |
| Training | All staff are trained in Good Clinical Practices using a certified program |
| | Recruiters are trained regarding: |
| | • recruitment |
| | • screening |
| | • consenting |
| | • enrollment protocol |
| | • enter data into the Research Electronic Data Capture (REDCap) system |
| | • data collection via medical record abstraction |
| | Data collectors are trained: |
| | • to interview the participants |
| | • on the use of the accelerometer equipment |
| | Motivational interviewer nurses are trained online and in-person by a motivational interviewing trainer to: |
| | • interview the participants |
| | • deliver the intervention |
| | Attention control nurses are trained to: |
| | • interview the participants |
| | • deliver the intervention |
| | Training for recruiters, data collectors and nurses include: |
| | • didactic information |
| | • a script |
| | • role-playing |
| | • case studies |
| | • return-demonstration |
| | Ongoing motivational interviewing training during booster training sessions with a motivational interviewing trainer |
| | Separate training manuals have been developed for: |
| | • screening and enrollment |
| | • data collection |
| | • motivational interviewing |
| | • attention control |
| | • accelerometer placement |
| Treatment delivery | Delivery of the motivational interviewing intervention is supported through the use of a Motivational Interviewing Roadmap, which includes: |
| | • detailed lists for pre-meeting preparation |
| | • greetings and introductions |
| | • setting an agenda |
| | • asking permission to audiotape |
| | • motivational interviewing strategies |
| | • physical activity topics |
| | • setting goals |
| | • affirmation |
| | • review of the text messaging intervention component |
| | • closing of the session |
| | Reviews of the audiotaped sessions by the motivational interviewing trainer include: |
| | • examination of adherence to the intervention protocol |
| | • constructive comments and concerns are shared as part of the audiotape review |
| | • booster training sessions are provided by the trainer to address any concerns |
| | • additional audiotaped sessions as needed |
| | Delivery of the attention control intervention is supported by: |
| | • a script, which includes detailed lists for pre-meeting preparation |
| | • greetings and introductions |

**TABLE 2** (Continued)

| Component | Description |
| --- | --- |
| | • setting an agenda<br>• asking permission to audiotape<br>• use of several American Heart Association videos and literature<br>• closing of the session<br>Reviews of audiotaped sessions by the attention control nurses by the project manager include:<br>• examination of adherence to the intervention protocol<br>• constructive comments and concerns are shared as part of the audiotape review<br>• booster training sessions are provided by the project manager to address any concerns<br>• additional audiotaped sessions as needed<br>Delivery of the nurse and significant other text messages is completed by the automated REDCap system and is tracked by the project manager on a weekly basis |
| Treatment receipt | The intervention protocol, Motivational Interviewing Roadmap, and scripts include confirmation that patients receive and understand the intervention and can perform the behaviors asked of them<br>Treatment receipt is evaluated by review of audiotapes for evidence that patients received and understood<br>Any indication that this evidence is absent results in a booster training session<br>Receipt of the first text messages from both the nurse and significant other are confirmed by phone by the project manager |
| Treatment enactment | The performance of physical activity behaviors in a real-life setting will be evaluated by the project manager, in collaboration with the PI, through a review of accelerometer data and the patient physical activity logs<br>Any indication that this evidence is absent will result in an immediate review of protocol and training sessions |

action based on risk level over the course of the study, from hospital enrollment to home-based visits. A detailed description of the SRM protocol is available elsewhere (Dunn et al., 2020).

## 2.8 | Analytic methods

Data are stored on a secure dedicated server with appropriate firewalls using the university's REDCap system. Data are entered into the REDCap database via Web interface. Deidentified datasets are created by importing data from REDCap into the statistical program R (Version 4.0.0). QA reports are reviewed bi-annually by a Safety Monitoring Committee.

Data analysis and hypothesis testing will proceed in several steps: (a) description of the sample overall and across the three groups, as well as participants lost to attrition; (b) confirmation of internal reliability of scales; and (c) bivariate and multivariate analysis of the interrelationships between treatment groups for PA and state hopelessness.

### 2.8.1 | Analysis plan for Aims

Initial bivariate analyses for Aims 1 (test the effectiveness of 6 weeks of MSS and MSS with SOS on increasing mean minutes/day of moderate to vigorous PA) and 2 (determine the effects of change in minutes/day of moderate to vigorous PA on state hopelessness) will be conducted using analysis of variance or simple linear models using R, testing for changes in minutes of moderate to vigorous PA (Aim 1) or association between change in PA and changes in state hopelessness (Aim 2) between baseline and Week 8 or baseline and Week 24 by treatment

group. We will also use linear mixed effects models (lme4 function in R) to incorporate multiple waves of data from each participant, covariates, and mediators into the analysis (Aims 1, 2, and 3), following the approach we have used before (Dunn et al., 2017). We will simultaneously model data across the two postbaseline time points and account for within- and between-subject effects and time-independent and time-dependent predictors. For Aim 1, we will predict minutes of moderate to vigorous PA by treatment group, adjusting for covariates and baseline PA level. Aim 2 follows an approach similar to Aim 1, and predicts state hopelessness levels by changes in PA, adjusting for covariates and baseline state hopelessness levels.

For Aim 3 (determine if social support and motivation mediate effects of the *Heart Up!* intervention on PA), models for Aims 1 and 2 will be expanded by also including one or more mediating variables, including prior measurements of state hopelessness and moderate to vigorous PA. In particular, we will directly estimate and test indirect effects using a path model, with bootstrapped estimation of the indirect effects confidence intervals. Models will include covariates as in Aims 1 and 2 and include multiple waves of data. We will use a modified Bonferroni approach (Holm, 1979) to control for Type I errors when testing multiple mediators simultaneously.

### 2.8.2 | Subgroup analyses and sex as a biological variable

Subgroup analyses (e.g., sex) will be conducted by estimating main effects of treatment groups or mediating variables on the response within each subgroup, and testing for potential differential effects between subgroups by incorporating relevant interaction terms into the models.

**TABLE 3** Characteristics of measures

| Measure | Concept | Variable type | Time points | #items | Range | Description | Reliability/validity |
|---|---|---|---|---|---|---|---|
| ActiGraph GT9X Link Accelerometer activity | Physical activity: Mean minutes/day moderate to vigorous physical | Primary outcome | Weeks 1, 8, 24 | NA | Moderate = 1952–5724 CPM Vigorous = 5725–9498 CPM (Freedson et al., 1998) | • 3-axis accelerometer, worn on waist<br>• Measures duration and intensity of acceleration<br>• Used with IHD patients in both home and hospital-based CR settings (Jones et al., 2007; Oliveira et al., 2008)<br>• Provides 13 cut-points for PA levels (measure = CPM)<br>• Cut-points derived from research (ActiGraph Research Database, 2017) | Used for over 10 years in academic and government research involving PA, including validation testing (ActiGraph LLC, 2020) |
| State-Trait Hopelessness Scale (STHS) | State and trait hopelessness | Primary outcome | Weeks 2, 9, 25 | 23 | 1–4 | • 4-point Likert-type scale: 1 = strongly disagree, 4 = strongly agree<br>• Adding the item scores and dividing by the number of items provides a total score for each subscale (Dunn et al., 2014) | • Reliability:<br>• State α = .87, trait α = .87 (Dunn et al., 2014)<br>• Concurrent and predictive validity with IHD patients (Dunn et al., 2014) |
| Exercise Self-Regulation Questionnaire (ESRQ) | Motivation (exercise self-regulation) | Mediator (common data element) | Weeks 2, 9, 25 | 16 | 1–7 | • 7-point Likert-type scale: 1 = not at all true, 7 = very true<br>• Average of summed scores provides a total score for each subscale (Russell & Bray, 2010)<br>• Subscales: External regulation, introjected regulation, identified regulation, intrinsic motivation | Confirmed reliability and validity with patients in a CR program (Russell & Bray, 2010) |
| ENRICHD Social Support Inventory (ESSI) | Perceived social support (emotional support) | Mediator | Weeks 2, 9, 25 | 7 | 1–30 | • 5-point Likert-type scale (6 items): 1 = none of the time, 5 = all of the time<br>• Items summed for score: Higher scores indicate greater social support<br>• Score ≤2 on at least two items (excluding item 4) or ≤3 on two or more items, (excluding items 4 and 7) or a total score of ≤18 on items 1, 2, 3, 5 and 6 = low social support (Gottlieb & Bergen, 2010; Vaglio et al., 2004) | Found valid and reliable in patients with IHD (Gottlieb & Bergen, 2010; Vaglio et al., 2004) |

(Continues)

**TABLE 3** (Continued)

| Measure | Concept | Variable type | Time points | #Items | Range | Description | Reliability/validity |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Demographic Questionnaire | Demographics | Covariate | Week 1, 2, 9, 25 | 17 | NA | • Age, sex, race, marital status, education level, insurance status, employment status and information about exercise history | NA |
| Medical Records Abstraction Form | Clinical characteristics | Covariate | Week 1 | 5 | NA | • Two purposes: (a) confirm eligibility and (b) collect cardiac diagnoses, noncardiac diagnoses, cardiovascular procedures, ejection fraction, height and weight, and length of stay in days | NA |
| Charlson Comorbidity Index | Comorbidities | Covariate | Week 1 | 19 | 0–100 | • A prognostic index of comorbidity (Charlson et al., 1987; Núñez et al., 2004) • Composite score calculated as a weighted sum of the 19 conditions • 1-year mortality based on illness severity (mild, moderate, severe), reason for admission and weighted comorbidity score | Reliable and valid prognostic indicator for hospital and 1-year outcomes in IHD patients (Núñez et al., 2004; Radovanovic et al., 2014) |
| Cardiac Rehabilitation Exercise Participation Tool (CREPT) | Hospital-based CR exercise | Covariate | Weeks 2, 9, 25 | 20 | NA | • Assesses a patient's referral and exercise participation using categorical style questions. | Established reliability and validity with IHD patients (Dunn et al., 2017; Dunn et al., 2009) |
| Patient Health Questionnaire-9 (PHQ-9) | Depressive symptoms | Covariate & secondary outcome | Weeks 2, 9, 25 | 9 | 0–27 | • Measures depressive symptom severity (De Jonge et al., 2007; Smolderen et al., 2009) • Items scored on a Likert-type scale from 0 (not at all) to 3 (nearly every day) and summed for a total score • Separate cognitive and somatic depressive symptoms dimensions have been validated in patients with IHD (De Jonge et al., 2007; Smolderen et al., 2009) | Internal reliability and reliability of 2 dimensions (somatic: $\alpha = .70$; cognitive: $\alpha = .82$); criterion, construct validity (Kronenke & Spitzer, 2002; Kroenke et al., 2001) |

**TABLE 3** (Continued)

| Measure | Concept | Variable type | Time points | #items | Range | Description | Reliability/validity |
|---|---|---|---|---|---|---|---|
| PROMIS-29 | Physical well-being | Secondary outcome (common data element) | Weeks 2, 9, 25 | 29 | 4–20 (raw scores) | • Likert-type scale: 1 (low) to 5 (high) <br> • Scores for 8 subscales, including physical function (well-being); <br> • Raw scores converted to t scores (Cella et al., 2010) | Well-established reliability and validity (Cella et al., 2010) |
| EuroQol (EQ-5d-5L) | Quality of life (QOL) | Secondary outcome | Weeks 2, 9, 25 | 26 | 1–5 | • Assesses 5 dimensions: Mobility, self-care, usual activities, pain/discomfort and anxiety/depression <br> • Likert-type scale from 1 (low) to 5 (high) <br> • Values for 5 dimensions can be combined for a value describing health state/QOL (Herdman et al., 2011; Janssen et al., 2015) | Reliable and valid in diverse populations, 8 chronic conditions, including IHD (EuroQol Research Foundation, 2019) |

Abbreviations: CPM, counts per minute; CR, cardiac rehabilitation; IHD, ischemic heart disease; NA, not applicable; PA, physical activity.

Females are less likely to receive a referral to CR (Dunn et al., 2017), participate in a CR program (Gaalema et al., 2014; Karmali et al., 2014), and to exercise independently (Clark et al., 2013; Midence et al., 2016). Subgroup analyses will be performed for potential differential responses to treatments and/or mediating effects by sex. Power for detecting large effect size differences between the three groups, or large effect size correlations, will be 80% for sex subgroup analyses.

### 2.8.3 | Handling of missing data

Previous analyses using several of the same instruments in similar populations (Dunn et al., 2017; Meijer et al., 2011; Surtees et al., 2008) have yielded low missing data rates (<1%–2%). Thus, these individuals are typically ignored in the analysis. For scales, such as the STHS and PHQ-9, we have used a regression-based imputation procedure to predict single or multiple missing items and assumed that data are missing completely at random (Dunn et al., 2014; Dunn et al., 2017; Dunn et al., 2019). These same approaches will be used for the RCT. A regression-based imputation procedure will be used to predict missing accelerometer data.

## 2.9 | Human subjects protection

Institutional review board approval was obtained by the principal investigator's university and the participating hospital.

### 2.9.1 | Security procedures

All tablets and computers used to collect and send data are double password protected and have appropriate security and firewalls. Paper consent forms are uploaded from the hospital's research department into REDCap and the original signed consent is kept double-locked in the hospital's research department.

### 2.9.2 | Safety monitoring committee

This study is monitored by a Safety Monitoring Committee, defined by the Policy of the NINR for Data and Safety Monitoring of Extramural Clinical Trials (National Institute of Nursing Research, 2014) as a small group of experts (two or more) who are independent of the protocol who review data from a particular study. The committee for this study consists of a clinical trial expert and a biostatistician. The members are independent of the RCT and represent the interest of the enrolled participants.

### 2.9.3 | Identification of adverse events

Adverse events are monitored by study enrollers, data collectors and nurses. All adverse events are reported to the project manager and PI

within 24 h via an automated REDCap email. If the project manager and PI evaluate an adverse event to be moderate or serious, they convene the Safety and Monitoring Committee within 48 h. All events deemed to be serious by the committee are reported to the university IRB and NIH program officer.

## 2.10 | The COVID-19 pandemic and associated protocol changes

Enrollment began in August 2019. Enrollment was temporarily suspended in March 2020 due to the COVID-19 pandemic. At the time of suspension, 43 participants had been enrolled.

Adults with IHD are at higher risk for serious illness and death from COVID-19 (Centers for Disease Control and Prevention, 2020; Chow et al., 2020). COVID-19's stay-at-home and social distancing measures are additionally expected to result in decreased PA levels, leading to adverse effects on mental health and increased incidence of cardiovascular disease (Mattioli et al., 2020). Because our RCT is collecting multiple mental, social and behavioral health variables that may be positively impacted by the *Heart Up!* intervention during the pandemic, transitioning the RCT so that it would be COVID-19 compatible was a priority.

### 2.10.1 | Amendment 1

In March 2020, we transformed the intervention components and data collection activities from in-person to remote format for the 43 enrolled participants. The motivational interviewing and AC educational activities were changed from in-person to videoconferencing using a secure Zoom technology platform provided by the university for research use. Data collection at all time points was changed from in-person to phone calls. Delivery and instruction of the accelerometer equipment at baseline was changed from in-person to mail shipment, followed by a phone instruction visit and access to a video instruction link.

### 2.10.2 | Amendment 2

In May 2020, the RCT restarted participant enrollment. The protocol was amended to state that patients would continue to be recruited, consented and screened for hopelessness in the hospital setting, but that this would be completed by recruiters placing a phone call to the patient's hospital room. When patients are identified as meeting the moderate to severe hopelessness criteria, recruiters then meet with the patient in-person in the hospital room, with assurance that physical distancing measures will be followed.

## 3 | DISCUSSION

We have described our innovative RCT, which is the first known to test an intervention to promote PA and reduce hopelessness in adults with IHD who report hopelessness. Since the 13 months of active recruitment, 69 patients of the 225 targeted have been enrolled. We have faced several challenges, including the COVID-19 pandemic, and amended our protocol to meet them.

## 3.1 | Overcoming challenges

Given the nature of hopelessness (a negative and helpless outlook), recruiting and retaining patients who report hopelessness can be challenging (Davis et al., 2013). However, attrition rates for the RCT have been lower than expected. Before COVID-19, 11 of the enrolled 43 participants withdrew from the study (26%). Since re-activation of enrollment in May 2020, 23 of 69 participants withdrew (33.3%). We attribute the positive retention numbers to our team's experience working with adults with IHD who report hopelessness. Positive therapeutic communication skills are stressed during staff training. Research staff emphasize to participants the importance of completing the intervention, wearing the accelerometer, and completing data collection sessions. Participants are scheduled for their first home visits before hospital discharge and provided a study brochure with photos and the first names of study staff. They receive reminder phone calls for all appointments. Participants are provided adequate time at all visits to share their feelings and have their questions answered. To compensate participants for their time, we provide a total of $100. At study completion, participants receive a thank you letter and those in the AC group receive the *Heart Up!* magnets (given previously to participants in the MSS groups). These strategies have been effective.

Our team has a history of successfully enrolling IHD patients in the hospital setting (Dunn et al., 2017; Dunn et al., 2019). However, increasingly shortened lengths of hospital stays for patients with IHD have posed a challenge for recruitment in this RCT. Recruiters have developed strategies to overcome this problem by screening for eligible patients on a daily basis and approaching patients at a time of the day when less activity is occurring on hospital units (early morning). These approaches have been effective in screening the majority of patients for eligibility before hospital discharge.

An unexpected recruitment challenge arose at the enrollment hospital with an increased trend of discharging patients with coronary artery bypass surgery to a sub-acute rehabilitation facility for a short period of time, rather than keeping these patients in the hospital until home discharge. Because the original RCT inclusion criteria included a planned discharge home, a protocol change was made to account for patients going to subacute rehabilitation. We now enroll patients who have either a planned discharge home or discharge to a sub-acute rehabilitation facility with an expected stay of 7 days or less before discharge home.

Research staff have found the scheduling of home visits to be challenging with some study participants. Some participants are difficult to reach by phone. Others have missed their scheduled home visits, leading to lengthy and unproductive drive times for research staff. Staff have developed strategies to overcome this problem, including an appointment reminder letter upon participant enrollment and reminder phone calls and text messages to

participants and their significant others as needed. These strategies have been effective for most participants. It is noteworthy that this challenge has been reduced since changing the home visits from in-person to remote in response to COVID-19. Study participants have been generally more willing to schedule their visits by teleconference (intervention component) and phone (data collection) as compared to in-person visits.

## 3.2 | COVID-19: Overcoming unanticipated challenges

The COVID-19 pandemic has presented the greatest challenge to our study. The pandemic has disrupted many components of people's lives, creating mandated stay-at-home and physical distancing measures, economic challenges, and emotional suffering. We were uncertain of the pandemic's effect on attrition rates of participants already enrolled in the RCT; but to date, attrition rates remain within our target goal. Since restarting recruitment in May 2020, the rate of enrollment has remained stable. Steady enrollment and attrition amidst the pandemic may be related to characteristics of our study population. Participants with IHD who are suffering from hopelessness may find benefits to meeting with research staff at a time of restricted socialization.

At the onset of COVID-19's shelter-in-place/physical distancing measures, rather than pause the RCT protocol for the participants already enrolled, we modified the delivery of the in-person data collection and intervention components to data collection by phone and the motivational interviewing and AC interventions by video conferencing. Participants have been receptive to data collection by phone and the quality of data has not been adversely affected. Similarly, participants have been receptive to motivational interviewing or AC activity by teleconference. Ongoing fidelity assessments have confirmed the maintenance of treatment fidelity since the change to teleconference format.

The COVID-19 pandemic provides a unique opportunity to evaluate the use of various telehealth strategies. Motivational interviewing has been effective in increasing PA in patients with IHD (Beckie & Beckstead, 2010; Janssen et al., 2013; Murphy et al., 2013); however, there is no known literature describing its use during a pandemic. Text messages from health professionals as reminders, information, or for motivational purposes have been successful in increasing PA in patients with IHD (Burke et al., 2015; Chow et al., 2015); however, there is limited research examining the use of therapeutic text messages during a pandemic. One descriptive study in Italy during the COVID-19 pandemic reports the use of text messages with patients with cancer, identifying text messages as useful for patients to share needs and fears (Gebbia et al., 2020). Although feasibility and preliminary efficacy of the *Heart Up!* intervention in a fully remote format (teleconference and phone) has not been previously tested, participants who have received the remote intervention since COVID-19 began (*n* = 5), report satisfaction with the intervention.

## 4 | CONCLUSION

The *Heart Up!* intervention is focused on the physical and mental health of a high-risk population of individuals with IHD who are hopeless. This research will provide the evidence needed to advance the science by helping individuals with IHD, who have a negative and helpless outlook, better manage a key risk factor (inactivity). The *Heart Up!* intervention is practical and efficient with excellent potential for translation into practice. The transition of the *Heart Up!* intervention to a remote format (teleconference and phone) may serve as a model for self-management of PA and hopelessness in other cardiovascular or chronic conditions, and may be found effective during the current and future pandemics.

## CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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