Research Protocol:

Perceived Social Support, Heart Rate Variability, and Hopelessness in Patients with Ischemic Heart Disease

(Hope Beats Study)

NCT:

NCT05003791

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LIST OF ABBREVIATIONS

HF	High frequency
HIPAA	Health Insurance Portability and Accountability Act
HRV	Heart rate variability
IHD	Ischemic heart disease
PHI	Protected health information
PSS	Perceived social support
QA	Quality assurance
RMSSD	Square root of the mean of the sum of the squares of differences between adjacent RR intervals
RR	The interval between normal successive heartbeats
USPS	United States Postal Service

1.0 Project Summary/Abstract

Cardiovascular disease is the leading cause of death worldwide, with ischemic heart disease (IHD) the leading cause of cardiovascular mortality. Persons with IHD suffering from psychological distress, including hopelessness, are more likely to die from IHD. Following a stressful event, the vagus nerve enables activation of either a sympathetic (fight/flight) or parasympathetic (rest/digest) response. Heart rate variability (HRV), the beat-to-beat variability between normal successive heart beats, is a biomarker of both adaptive and maladaptive reactions to stress. Decreased HRV predicts greater risk for morbidity and mortality and is associated with poor mental health outcomes in persons with IHD. As stated by polyvagal theory, HRV may be influenced by social support. Decreased perceived social support (PSS), a social determinant of cardiovascular risk, is predictive of increased morbidity and mortality in persons with IHD. Decreased PSS has been associated with hopelessness in patients with cancer, but this relationship has not been studied in IHD beyond the applicant's small pilot study of patients with hopelessness. Hopelessness, a negative outlook and sense of helplessness about the future, is present in 27-52% of patients with IHD. This is of grave concern, because hopelessness is associated with a 3.4 times increased risk of mortality and nonfatal myocardial infarction in patients with IHD, independent of depression. This research focuses on understanding the biological (HRV) and social (PSS) aspects of hopelessness, with the long-term goal of developing and testing novel interventions to reduce the adverse effects of hopelessness and improve health outcomes in patients with IHD. Participants for this cross-sectional study will be recruited while hospitalized for an IHD event. Participants will include patients who report moderate to severe hopelessness from Dr. Dunn's NIH-funded study (R01NR017649, *n* = 225); additional patients with minimal to no hopelessness will be recruited and enrolled by the applicant (*n* = 45). Data collection will take place remotely two weeks after hospital discharge. Specific aims include: Aim 1) Evaluate the relationship between HRV and hopelessness in patients with IHD; Aim 2) Determine the relationship between PSS and hopelessness in patients with IHD; and Aim 3) Explore the possible mediating effect of HRV on the relationship between PSS and hopelessness in patients with IHD. The outcomes of this proposed study and the training plan will prepare the PhD student to launch a program of research focused on the biological and social dynamics of symptoms experienced in patients with IHD, with a long-term goal of promoting personalized health treatments for persons with IHD.

2.0 Objectives/Aims

Specific Aims are to:

Aim 1: Evaluate the relationship between HRV and hopelessness in patients with IHD.

Hypothesis: Higher levels of HF HRV will be associated with lower levels of hopelessness.

Aim 2: Determine the relationship between PSS and hopelessness.

Hypothesis: Higher levels of PSS will be associated with lower levels of hopelessness.

Aim 3: Explore the possible mediating effect of HRV on the relationship between PSS and hopelessness.

Hypothesis: HF HRV will mediate the relationship between PSS and hopelessness.

* As an extension of Dr. Dunn's NIH-funded study (https://clinicaltrials.gov/ct2/show/NCT03907891), data collected from patients with IHD who report moderate to severe hopelessness will be analyzed to examine the aims. The PI of this study (Hope Beats) will also collect and analyze data from patients with minimal to no hopelessness. The data collected from patients reporting minimal to no hopelessness are presented in this clinical trial registration.

3.0 Eligibility

3.1 Inclusion Criteria

- Eligibility criteria for hopelessness screening include: Adults ≥ 18 years old; diagnosed with myocardial infarction, unstable angina, or who undergoing percutaneous coronary intervention or coronary artery bypass graft surgery; speak and read English; and can complete the screening instrument.

3.2 Exclusion Criteria

- The following exclusion criteria are in place because they alter heart rate variability: having a pacemaker or implanted cardioverter-defibrillator, chronic arrhythmia, history or current valvular disease, history of organ transplant, current use of immunosuppressive medications, or diabetic autonomic insufficiency. Although research conducted in 2016 identified HRV diminishing with age when controlling for disease and medication use, more recent research has identified no relationship between HRV and age. A study of healthy individuals, controlling for other health conditions, did not find any relationship between resting HRV and age in adults older than 40. Another study of healthy participants identified no significant difference in resting HRV between persons in the age group 40-49 compared to 50-59. Because the median age for a male with IHD is 65 years and for females is 70 years, the age range of 40-80 years was chosen to be representative of the IHD population and to mitigate the confounding effect of age on HRV.

3.3 Excluded or Vulnerable Populations

- Only English-speaking patients are eligible to enroll in the study, because not all instruments are readily available in languages other than English.

4.0 Subject Enrollment

The PI will screen potentially eligible patients over the phone or in person. Screening will include asking patients if they meet any of the exclusion criteria described above. Patients who are eligible for enrollment after screening will be asked by the PI to participate in the proposed research. The PI will read through a script to describe the study. If a patient agrees to enrollment in the study, written consent will be obtained. If the participant is enrolled after hospital discharge, they will be sent a link via email or text message, which will take them to the REDCap e-consent page, where they will provide an electronic signature. After the electronic signature is accepted and confirmed, a copy of the signed e-consent will be sent to the patient by email and/or postal mail and a copy will be saved in the REDCap database.

5.0 Study Design and Procedures

Human Subjects Involvement, Characteristics, and Design

The proposed study uses a cross-sectional design. Patients enrolled in Dr. Dunn's study (until March 3/6/2023) with moderate to severe hopelessness and the additional 45 patients recruited who screen to have minimal to no hopelessness by the PhD student will be included in the analysis of Aim 2. Aims 1 and 3 will include patients from Dr. Dunn's study who meet the stated inclusion and exclusion criteria for the proposed study, in addition to the 45 patients who report minimal to no hopelessness. Both groups of patients (moderate to severe hopelessness and minimal to no hopelessness) will complete the same hopelessness screening in the hospital and the Week 2 data collection measures.

Data Collection Procedures. Study participants will receive a study package by USPS mail two weeks after hospital discharge plus or minus two days and will also receive an instructional phone visit at Week 2. Study package materials will include a Polar H7 heart rate monitor, ActiGraph wGT3X-BT (to link to the Polar monitor for HRV data collection), written instructions for HRV measurement, hard copies of questionnaires (to read along with during the data collection phone call), instructions to return the monitors, and a prepaid return envelope. Participants will also be sent a secure link via text or email to an instructional video depicting verbal and visual demonstration of proper placement for the Polar H7 heart rate monitor and ActiGraph wGT3X-BT. The PI will call the participant once a mail delivery notice has been received. During the call, the PI will confirm proper placement of the two monitors used to measure HRV and answer any questions. All data collection will occur at Week 2. Study measures and their characteristics can be found in Table 1.

Heart Rate Variability Procedures. At Week 2, participants will be instructed to place the Polar H7 heart rate monitor around the center of their chest, in contact with the skin, and the ActiGraph wGT3X-BT around their waist, according to directions outlined in the written instructions provided and as demonstrated in the instructional video and practiced with the applicant over the phone. Participants will be informed that the monitors are used to gather data about their body at rest. The Polar H7 heart rate monitor connects to the ActiGraph with Bluetooth® wireless technology so that the interval between normal heart beats (RR data) can be transferred to csv files for analysis. The HRV protocol will take place during a 10-minute time period on two consecutive days, to ensure at least one 10-minute time frame of usable data. Participants will be instructed to place the monitors first thing in the morning after they wake up and empty their bladder. Once the monitors are placed, participants will be instructed to lay supine quietly for 10 minutes and avoid moving or using any devices or watching tv. The standardized HRV protocol improves reliability of the HRV measurement because control of extraneous variables is maintained. Respirations will not be controlled because this can artificially increase HF HRV. The gold standard amount of time for a short-term HRV recording is 5 minutes. The 5 minutes of the recording with the least amount of artifact will be used for analysis. After 10 minutes of recording are completed, the heart rate monitor and ActiGraph will be removed. After the participant completes the 10-minute HRV measurements on two consecutive days, they will be asked to return the monitors in a prepaid envelope that will be

picked up from their mailbox by USPS and returned to the PI, mitigating any exposure to COVID-19.

Phone Visit to Complete Questionnaires. After completion of the HRV measurement instructional phone visit, participants will receive their Week 2 data collection visit. Participants in the PI's study will receive their phone visit from the PI. The PI will follow a script for data collection. Data collection interviews will take on average 20 minutes. During the phone visit, the data collector/PhD student will first ask how HRV measurement went that morning and remind participants to complete the measurement the following morning. Participants will then be asked to complete the four questionnaires indicated at the Week 2 timepoint in Table 1 (demographic questionnaire, State-Trait Hopelessness Scale, ENRICHD Social Support Inventory, and Patient Health Questionnaire-9). Demographic data are being collected to describe the sample and determine if these variables are confounders. Depressive symptoms are being measured as a potential covariate because of the known association between hopelessness and depression.[16] Upon completion of data collection, participants will be compensated $20 for their time and commitment to the study. This is the same amount that patients enrolled in Dr. Dunn's study receive after their Week 2 visit. All questionnaire and electronic medical record data will be logged directly into REDCap using a secure electronic tablet. Data from medical records will be collected within 2 weeks of the participant's hospital discharge.

Measures. Characteristics of study measures appear in Table 1.

Table 1. Study Measures, Concepts, Variables, & Psychometric Properties

Measure	Concept	Time-point	# Items	Range	Description	Reliability/ Validity
Polar H7 Heart Rate Monitor	Heart rate variability	Week 2	NA	Varies by domain	• Monitor is worn across patient's chest to provide heart rate data •Monitor has Bluetooth capabilities with ActiGraph WGT3X-BT so RR data can be transferred to csv files for analysis	Strong correlation with ECG for measuring short-term HRV (r=0.99)
Demographic Questionnaire	Demographics	Week 2	17	NA	•Age, sex, race, smoking status, ability to participate in physical activity, history of depression, marital status, education level, insurance status, employment status	NA
State-Trait Hopelessness Scale (STHS)	State and trait hopelessness	Week 2	23	1-4	•4-point Likert-type scale: 1 = strongly disagree, 4 = strongly agree •Differentiates state and trait hopelessness •Adding the item scores and dividing by the number of items provides a total score for each subscale	•Reliability: state α = 0.87, trait α = 0.87 •Concurrent and predictive validity with IHD patients
ENRICHD Social Support Inventory (ESSI)	Perceived social support	Week 2	5	5-25	•5-point Likert-type scale: 1 = none of the time, 5 = all of the time • Items summed for score: higher scores indicate greater perceived social support	Found valid and reliable in patients with IHD
Patient Health Questionnaire -9 (PHQ-9)	Depressive symptoms	Week 2	9	0-27	•Measures depressive symptom severity •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	Internal reliability and criterion and construct validity previously established
Medical Records Abstraction Form	Clinical characteristics	Hospital	5	NA	•Two purposes: 1) To confirm eligibility and 2) To collect diagnoses, cardiovascular procedures, and admission height and weight	NA

6.0 Expected Risks/Benefits

Potential Risks. There is minimal likelihood or seriousness of potential risks to participants. There are no identified physical, legal, or financial risks. Participants may become fatigued during completion of the study questionnaires and HRV monitoring and may feel apprehensive or distressed sharing information, but there is low probability of this and a low level of seriousness. There is potential for loss of confidentiality; however, procedures to protect against this risk will be put in place, as described below. Patients will continue to seek and receive standard medical care for their IHD diagnosis; therefore, any health care problems that may arise will be referred to their health care provider.

Protections Against Risk: The PI who will conduct remote data collection (by phone) 2 weeks after patients' hospital discharge, has been trained to assess for potential fatigue or apprehension of participants. If participants exhibit apprehension, they will be given the option to discuss this, to complete the questionnaires at another time, to be referred to their physician for further counseling follow-up, or to discontinue the study. These are all expected to be effective approaches. Patients will additionally be informed that they can withdraw from the study at any time, without loss of benefits they would otherwise be entitled to and without penalty to their health care. There is no risk for incidental findings.

7.0 Data Collection and Management Procedures

The Polar H7 heart rate monitor connects to the ActiGraph with *Bluetooth*® wireless technology so that the interval between normal heart beats (RR data) can be transferred to comma-separated value files for HRV analysis. The RR data will be exported from ActiLife and uploaded and analyzed in Kubios HRV Software (a secure HRV analysis software for scientific research) to generate the time, frequency, and nonlinear domain measures of HRV. Patient numeric codes will be used when analyzing the data; no patient identifiers will be used. All questionnaire and electronic medical record data will be logged directly into the REDCap database via Web interface. The web server synchronizes uploaded files to an alternate location and is backed up daily. De-identified data sets for analyses will be created by importing data from REDCap into the statistical programs R and SPSS.

8.0 Data Analysis

Data Analysis for Each Aim. Confirmation of the internal reliability of scales will be assessed using Cronbach's alpha. The following analyses will be used for each aim.

Aim 1: Kubios HRV software will be used to generate the HRV data for time, frequency, and nonlinear domain analyses. Kubios uses a threshold-based artifact correction algorithm that compares RR beats against a local average interval. The lowest level threshold that accurately detects artifact without overcorrecting normal beats will be used for each recording. Recordings with >5% artifact will not be used in analysis because even a small number of corrected ectopic or missing beats can have a great influence on short-term HRV results. To prevent the issue of not having useable data for a participant, participants are instructed to obtain the measurement at two separate timepoints. The recording with the least artifact will be used. The primary analysis for Aim 1 involves regressing hopelessness levels on HRV, after controlling for relevant demographic (e.g., age, sex) and other covariates (e.g., time of day, deviation from protocol,

etc.), using a multiple regression framework. All covariates as well as hopelessness and HRV levels will be normalized using transformations as needed; to ensure model robustness to variable distributions we will also apply rank-based approaches and bootstrapping of standard errors. As part of a sensitivity analysis, we will fit these same models within the two subgroups: those with moderate to severe hopelessness versus minimal to no hopelessness. Additional subgroup analyses will be completed to evaluate potential differences between sexes and type of IHD event and will include adding interaction terms to the models between sex or type of IHD event and HRV.

Aim 2: The STHS and ESSI scores for all patients in Dr. Dunn's study enrolled until 3/6/23 and the 45 patients that will be recruited for the proposed application will be pooled to assess the relationship between hopelessness and PSS. Again, we will analyze the relationship using a multiple regression framework regressing STHS on ESSI and controlling for relevant demographics (see previous paragraph). A secondary analysis will add depression to the model to ensure that any relationship between STHS and ESSI is not better explained by depression. Additional secondary analyses will follow as noted above with subgroup analyses by level of hopelessness and interactions for sex and type of IHD event with ESSI.

Aim 3: Finally, we will follow the approach of Shrout and Bolger to evaluate the potential for HRV to be acting as a mediator of the PSS and hopelessness relationship. As suggested by Shrout and Bolger, bootstrapping will be used to determine the significance of the mediation effect.

Missing Data. Previous analyses using several of the same instruments in similar populations have yielded low missing data rates (< 1-2%). These individuals are typically not included in the analysis. For scales such as the STHS and PHQ-9, a regression-based imputation procedure to predict single or multiple missing items will be used, assuming data are missing completely at random.

9.0 Quality Control and Quality Assurance

The PI is responsible for collecting and analyzing the data for the proposed study. HRV data will be analyzed as soon as monitors are returned to ensure proper data capture. Participants that do not have an appropriate HRV recording will be asked to wear again. The PI will ensure all data is entered accurately during each visit.

10.0 Data and Safety Monitoring

Institutional Review Board (IRB) approval was received from both the sponsoring institution and recruitment site hospital before the study began.

11.0 Regulatory Requirements

11.1 Informed Consent

The recruiting hospital is responsible for recruiting, consenting and screening eligible patients (i.e., those who are screened as hopeless) for Dr. Dunn's study. Interested patients will provide verbal consent for the hopelessness screening, including a HIPAA waiver. The screening consent includes permission for review of the patient's medical records to collect patient

characteristics and comorbidities. Those patients who do not qualify for Dr. Dunn's study will be referred to the PI for assessment of eligibility for the PI's study.

Patients who do not meet the hopelessness criteria for Dr. Dunn's study (they have minimal or no hopelessness) will be approached by the PI to discuss possible enrollment in the proposed study. The PI will screen patients over the phone or in person to ensure they do not meet any of the study exclusion criteria. If a patient is eligible and agrees to enrollment in the study, written consent will be obtained. The consent will explain the study, risks, benefits, voluntary nature of participation, and the patient's right to discontinue participation at any time without consequences. If the participant is enrolled after hospital discharge, they will be sent a link via email or text message, which will take them to the REDCap e-consent page, where they will provide an electronic signature. After the electronic signature is accepted and confirmed, a copy of the signed e-consent will be sent to the patient by email and/or postal mail and a copy will be saved in the REDCap database.

11.2 Subject Confidentiality

Confidentiality: The confidentiality of participants and their data will be protected in the following ways: 1) no identifying information will be used as sources of identification for participants; 2) at time of enrollment, the REDCap system will assign each patient a four-digit numerical code, which will become the identifier of records for all patients; 3) consent forms will be kept double-locked separate from research data; 4) contact information needed for USPS shipments and phone visits will be entered and stored on a secure dedicated server with appropriate firewalls using the REDCap system; 5) all electronic tablets used to collect and send data will be double-password-protected; 6) electronic copies of completed questionnaires will be stored on a secure dedicated server with appropriate firewalls using the REDCap system; 7) dissemination of research data will be done in aggregate form only; and 8) hospital name and city will be omitted in all reports and presentations.

11.3 Unanticipated Problems

Participants will be queried about potential adverse events and unanticipated problems as defined below:

Adverse event. An adverse event will be defined in this research as any untoward or unfavorable medical occurrence in a study participant, including any abnormal symptom (including psychological), sign (including physical), or disease temporally associated with the participant's involvement in the research, whether or not considered related to participation in the research. Adverse events in this study will include, but not be limited to, death, cardiac restenosis (myocardial infarction, revascularization with coronary artery bypass surgery or percutaneous coronary intervention), or suicidal ideation.

Unanticipated problem. An unanticipated problem will be defined in this research as any incident, experience, or outcome that meets all of the following criteria: 1) unexpected (nature, severity, or frequency) given the research procedures that are described in the research protocol and informed consent, and given the characteristics of the study population; 2) related

or possibly related (reasonable possibility that the problem may have been caused by study procedures) to participation in the research; and 3) suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Unanticipated problems in this study will include, but not be limited to, a breach of confidentiality.

Adverse events and unanticipated problems will be monitored in several ways during the implementation of the study protocol. First, adverse events and unanticipated problems will be monitored by the PI during data collection. The PI will document any adverse events and unanticipated problems reported to them by participants and report these immediately to their advisor. Second, all patients will be provided a toll-free phone number to contact the PI directly if they have any issues or concerns to report

All adverse events and unanticipated problems will be reported to the PI's advisor within 24 hours. If the advisor evaluates the adverse events and unanticipated problems to be moderate or serious, she will notify the PI and convene the SMC. All unanticipated problems or serious adverse events that may be related to the study protocol will be reported by the PI to the university IRB and hospital IRB within 48 hours of the committee meeting. The PI will immediately respond and closely monitor any reported adverse events and unanticipated problems. The PI will enter all adverse events and unanticipated problems into the study database. Regardless of whether an adverse event or unanticipated problem is related to the study protocol, the participant's primary care provider will be notified of an event if it affects the patient's clinical status.

APPENDICES

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Appendix A
Screening, Recruitment, and Enrollment

A1: Eligibility Screening for Hopelessness

Indicate yes or no whether the following inclusion criteria are met for the study:

Inclusion Criteria	Yes	No
≥18 years old		
Diagnosed with MI, unstable angina, who underwent percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) surgery		
Speaks and reads English		
Can complete the screening instrument		

If "yes" to all the above criteria, patient is eligible to be screened for hopelessness (see state scale of State-Trait Hopelessness Scale on next page)

State Hopelessness: Screening and Scoring

Today (Right now)…

1. Today, it is difficult for me to imagine my future.	Strongly disagree 1	Disagree 2	Agree 3	Strongly agree 4
2. Today, I believe I cannot make a difference.	Strongly disagree 1	Disagree 2	Agree 3	Strongly agree 4
3. Today, I believe that things will improve.	**Strongly disagree 4**	**Disagree 3**	**Agree 2**	**Strongly agree 1**
4. Today, I believe I am powerless to change my future.	Strongly disagree 1	Disagree 2	Agree 3	Strongly agree 4
5. Today, I see my future as gloomy.	Strongly disagree 1	Disagree 2	Agree 3	Strongly agree 4
6. Today, I believe I will accomplish what I set out to do.	**Strongly disagree 4**	**Disagree 3**	**Agree 2**	**Strongly agree 1**
7. Today, I believe I can help improve things.	**Strongly disagree 4**	**Disagree 3**	**Agree 2**	**Strongly agree 1**
8. Today, I feel giving up would be easier.	Strongly disagree 1	Disagree 2	Agree 3	Strongly agree 4
9. Today, I believe I can overcome obstacles.	**Strongly disagree 4**	**Disagree 3**	**Agree 2**	**Strongly agree 1**
10. Today, things will not work out as I would like.	Strongly disagree 1	Disagree 2	Agree 3	Strongly agree 4

Steps to score:

1) Add 10 item scores, to get a total (NOTE that reverse-scored items have different values in bold above). TOTAL SCORE = _____ Divide total by 10 to get a final score. FINAL SCORE = _____
3) Repeat steps 1 and 2 to confirm final score
4) If FINAL SCORE is 1.8 or greater, patient is eligible for the Dr. Dunn's study. If FINAL SCORE is less than 1.8, patient is eligible for the student's study

A2: Exclusion Criteria for Enrollment in PI's Study

Indicate yes or no whether the following exclusion criteria are met for the study:

Exclusion Criteria	Yes	No
Younger than 40 or older than 80 years of age		
Has a pacemaker or implanted cardioverter-defibrillator		
Has a chronic arrhythmia		
History of or current valvular disease		
History of organ transplant		
Current use of immunosuppressive medications		
Diagnosed with diabetic autonomic insufficiency		

If "no" to all the above criteria, patient is eligible to enroll in the PI's study

Appendix B
Data Collection Script

B1: Week 2 Data Collection Script

Hello Mr./Ms./Mrs. _____,

My name is _____ and I am an investigator for the research project that you enrolled in during your hospital stay. How are you doing today?

During this call, I will instruct you on how to wear the two monitors that were shipped to you and I will have you complete some questionnaires with me. This visit typically takes 15-20 minutes.

When our team talked with you in the hospital, they asked your permission to audio record my session with you today. It will be used to give me feedback on how I do. Is that OK?

If Yes: Thank you. To ensure your confidentiality, I will no longer be using your name.
If No: Proceed as usual

Heart Rate Variability

To start, I will assist you in placing the two monitors that were recently shipped to you. I will need you to place these monitors first thing in the morning and wear them for 10 minutes on two consecutive days. The black monitor links to the red monitor to give us information about your body at rest.

We ask that after you wake up, use the restroom, and then place the monitors and wear them for 10 minutes. In the bag you will find the two monitors. The monitor labeled Polar will need to be worn around your chest and in contact with your skin. Please open the ultrasound gel in the bag and place some gel on the inside part of the Polar monitor. This helps it connect better with your skin. Next, place the monitor around your chest and make sure it is tight enough so that it does not move. The piece that has Polar written on it should be in the front center of your chest. Next, place the red monitor around your waist with the red monitor centered over your right thigh. A blue light should flash on the red activity monitor when both monitors are on correctly. If a blue light is not flashing, use your hands to warm the monitor around your chest until the blue light flashes.

Once the monitor is flashing blue, I will need you to lay flat on your back for 10 minutes. During this time, I ask that you remain silent and still. The monitors should be placed first thing in the morning, after you use the restroom, for two days in a row.

Questionnaires

We will now complete the questionnaires together. Please find the hard copy of the questionnaires that were shipped to you so that you can read along. To complete the questionnaires, I will read each question to you and have you state your answer. I will chart your answers in our computer system. Do you have any questions before we begin?

Demographics and Characteristics

The first questionnaire will have you answer questions about yourself. (Ask patient the questions in questionnaire and chart answers in REDCap)

Self-Assessment Questionnaire (Hopelessness)

For the next questionnaire, please note that the first set of questions asks how you feel “today (right now)”, and the second set of questions asks how you feel “typically (over time). Also note that some of the questions are worded in a positive manner, and others are worded in a negative manner”. (Ask patient the questions in questionnaire and chart answers in REDCap)

Suicidal Ideation Screening

To be completed only if participant scores 1.8 or higher on the self-assessment questionnaire

The next few questions I ask will be used to assess your safety. (Complete suicide ideation questions with patient and following instructions in the virtual suicide protocol based on patient risk level).

Patient Health Questionnaire (PHQ-9)

We will move on to the next questionnaire. Over the last 2 weeks, how often have you been bothered by any of the following problems? (Ask patient the questions in questionnaire and chart answers in REDCap)

Enriched Social Support Instrument

The next set of questions assesses how you view your social support. The scale ranges from none of the time to all of the time. (Ask patient the questions in questionnaire and chart answers in REDCap)

Serious Adverse Events and Adverse Events

At the end of every visit, I like to check in and make sure you have not experienced any of the following since the research staff talked with you in the hospital or after your discharge home. (Complete questions).

Return Monitors and Compensation

Thank you so much for your time today! Please remember to place the two monitors in the prepaid return envelope. You can place the envelope in your mailbox and the postal service will pick it up. Once I receive the returned monitors, I will send you $20 to thank you for participating in the study.

Do you have any questions about how to return the monitors or any other questions about the study?

Thank you for participation in the study!

Appendix C
Participant Documents

C1: Written Instructions to Complete Heart Rate Variability Measurement

Placement of Two Monitors

Thank you for your participation in our research study. When you receive this package, please give me a call and I will instruct you on how to wear the monitors for the study. The instructions below describe the same process I will guide you through over the phone.

Please complete your wearing of the two monitors the first time on the morning after you receive the package. We ask that after you wake up, use the restroom, and then place the monitors and wear them for 10 minutes. In the bag you will find the two monitors. The monitor labeled Polar will need to be worn around your chest and in contact with your skin. Please open the ultrasound gel in the bag and place some on the inside part of the Polar monitor. This helps it connect better with your skin. Next, place the monitor around your chest and make sure it is tight enough so that it does not move. The piece that has Polar written on it should be in the front center of your chest. Next, place the red monitor around your waist. The two monitors should be worn as shown in the image below. A blue light should flash on the red activity monitor when both monitors are on correctly. If a blue light is not flashing, use your hands to warm the monitor around your chest until the blue light flashes.

Once both monitors are on correctly, please find a spot in your house where you feel comfortable lying flat on your back for 10 minutes, such as your bed or a couch. While lying down, please remain silent and try not to move for the 10 minutes. Once the 10 minutes is done, you can remove both monitors.

Complete this same process again the next morning. After you have worn the two monitors two times for 10 minutes, you can remove them a final time and place them in the prepaid return envelope.

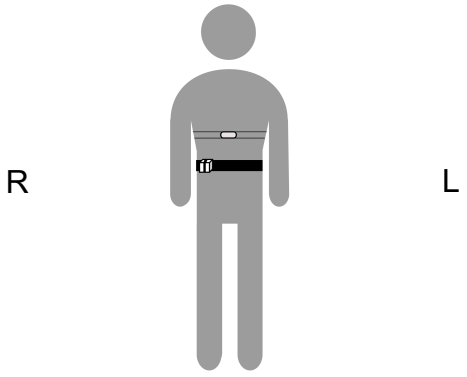

Figure showing proper monitor placement.

Thank you!

C2: Directions to Return Monitors after Heart Rate Variability Measurement

Directions to Return 2 Monitors to Research Staff

After you have worn the 2 monitors for 10 minutes on two consecutive days and completed your phone visit with a data collector, please place the monitors in the return envelope. Shipping has been prepaid and the US Postal Service will pick up the envelope from your mailbox**.**

After you complete your phone visit with a data collector and research staff receive the returned monitors, you will be sent $20 for completing the study.

Please do not hesitate to call with any questions.

Thank you for your participation in the study!

Appendix D
Data Collection Instruments

D1: State-Trait Hopelessness Scale

Self-assessment (State-Trait Hopelessness) Scale
Part 1 of 2

DIRECTIONS: A number of statements, which people may use to describe their thoughts, are given below. Read each statement and then circle the response to the right of the statement that best describes how you are thinking **today (right now)**. There are no right or wrong answers. All of your information will be kept confidential.

Today (Right now)…

1. Today, it is difficult for me to imagine my future.	Strongly disagree	Disagree	Agree	Strongly agree
2. Today, I believe I cannot make a difference.	Strongly disagree	Disagree	Agree	Strongly agree
3. Today, I believe that things will improve.	Strongly disagree	Disagree	Agree	Strongly agree
4. Today, I believe I am powerless to change my future.	Strongly disagree	Disagree	Agree	Strongly agree
5. Today, I see my future as gloomy.	Strongly disagree	Disagree	Agree	Strongly agree
6. Today, I believe I will accomplish what I set out to do.	Strongly disagree	Disagree	Agree	Strongly agree
7. Today, I believe I can help improve things.	Strongly disagree	Disagree	Agree	Strongly agree
8. Today, I feel giving up would be easier.	Strongly disagree	Disagree	Agree	Strongly agree
9. Today, I believe I can overcome obstacles.	Strongly disagree	Disagree	Agree	Strongly agree
10. Today, things will not work out as I would like.	Strongly disagree	Disagree	Agree	Strongly agree

Self-assessment (State-Trait Hopelessness) Scale

Part 2 of 2

DIRECTIONS: A number of statements, which people may use to describe their thoughts, are given below. Read each statement and then circle the response to the right of the statement that best describes how you **typically** think—or how you have thought **over the years.** There are no right or wrong answers. All of your information will be kept confidential.

Typically (Over the years)…

1. Typically, things do not work out as I would like.	Strongly disagree	Disagree	Agree	Strongly agree
2. Typically, I believe I can overcome obstacles.	Strongly disagree	Disagree	Agree	Strongly agree
3. Typically, I see myself as fortunate.	Strongly disagree	Disagree	Agree	Strongly agree
4. Typically, I see my future as gloomy.	Strongly disagree	Disagree	Agree	Strongly agree
5. Typically, negative things seem to happen to me.	Strongly disagree	Disagree	Agree	Strongly agree
6. Typically, it is difficult for me to imagine my future.	Strongly disagree	Disagree	Agree	Strongly agree
7. Typically, I believe I can help improve things.	Strongly disagree	Disagree	Agree	Strongly agree
8. Typically, I feel giving up would be easier.	Strongly disagree	Disagree	Agree	Strongly agree
9. Typically, I believe I will accomplish what I set out to do.	Strongly disagree	Disagree	Agree	Strongly agree
10. Typically, I believe that things will improve.	Strongly disagree	Disagree	Agree	Strongly agree
11. Typically, I believe I cannot make a difference.	Strongly disagree	Disagree	Agree	Strongly agree
12. Typically, I doubt that anything is worthwhile.	Strongly disagree	Disagree	Agree	Strongly agree
13. Typically, I believe I am powerless to change my future.	Strongly disagree	Disagree	Agree	Strongly agree

D2: ENRICHD Social Support Instrument

5-item ENRICHD Social Support Instrument

1	Is there someone available to whom you can count on to listen to you when you need to talk?	none of the time	a little of the time	some of the time	most of the time	all of the time
2	Is there someone available to you to give you good advice about a problem?	none of the time	a little of the time	some of the time	most of the time	all of the time
3	Is there someone available to you who shows you love and affection?	none of the time	a little of the time	some of the time	most of the time	all of the time
4	Can you count on anyone to provide you with emotional support (talking over problems or helping you make a difficult decision)	none of the time	a little of the time	some of the time	most of the time	all of the time
5	Do you have as much contact as you would like with someone you feel close to, someone in whom you can trust and confide in?	none of the time	a little of the time	some of the time	most of the time	all of the time

D3: Demographic Instrument

Demographics

1. What is your age in years?

2. What is your sex?

(1) Female
(2) Male

3. Are you of Hispanic or Latino origin?

(1) Yes
(2) No

4. What is your race?

(1) White
(2) Black/African American
(3) American Indian or Alaska Native
(4) Native Hawaiian or other Pacific Islander Asian
(5) Other _____

5. What is your marital status?

(1) Married
(2) Separated
(3) Divorced
(4) Widowed
(5) Never been married

6. Have you ever been diagnosed or treated for depression?

(1) Yes
(2) No

7. What is the highest grade of school or year of college you completed?

(1) Eighth grade or less
(2) Some high school
(3) High school graduate
(4) Some college
(5) College graduate (bachelors)

(6) Some post-graduate college work (masters, doctoral)
(7) Graduate with masters- or doctoral-level degree

8. What is your current job status?

(1) Employed full-time
(2) Employed part-time
(3) Retired
(4) Disabled or unable to work
(5) Student
(6) Other (please list) _____

9. What type of health insurance do you have?

(1) Medicare
(2) Medicaid
(3) Government VA
(4) Employer provided
(5) Privately purchased
(6) No health insurance

D4: Patient Health Questionnaire

Patient Health Questionnaire (PHQ-9)

1. Little interest or pleasure in doing things	not at all	several days	more than half the days	nearly every day
2. Feeling down, depressed or hopeless	not at all	several days	more than half the days	nearly every day
3. Trouble falling or staying asleep, or sleeping too much	not at all	several days	more than half the days	nearly every day
4. Feeling tired or having little energy	not at all	several days	more than half the days	nearly every day
5. Poor appetite or overeating	not at all	several days	more than half the days	nearly every day
6. Feeling bad about yourself, or that you are a failure or have let yourself or your family down	not at all	several days	more than half the days	nearly every day
7. Trouble concentrating on things, such as reading the newspaper or watching television	not at all	several days	more than half the days	nearly every day
8. Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual.	not at all	several days	more than half the days	nearly every day
9. Thoughts that you would be better off dead or of hurting yourself in some way	not at all	several days	more than half the days	nearly every day
10. If you checked off <u>any</u> problems, how <u>difficult</u> have these problems made it for you to do your work, take care of things at home, or get along with other people?	not difficult at all	somewhat difficult	very difficult	extremely difficult