

I. BACKGROUND & SIGNIFICANCE

A. Historical Background

The scope of the problem: Heart failure (HF) is a common and progressively debilitating illness that affects nearly 6 million Americans.¹ It has been associated with increased medical morbidity, including repeated hospitalizations, poor functioning, and reduced quality of life (QoL).²⁻⁵ Furthermore, it is costly; in 2010, it led to approximately \$39 billion in direct and indirect costs in the United States.¹ Finally, HF is lethal, with studies estimating that 50% of HF patients die within 5 years of diagnosis.⁴

The role of health behaviors in HF outcomes: Health behaviors significantly impact prognosis for patients with HF. Maintenance of a low sodium diet, adherence to medications, and increased physical activity have been associated with improved health, reduced hospital readmissions, and lower rates of mortality in HF patients.⁶⁻¹² Exercise is particularly important, as exercise training programs have been associated with improved exercise capacity, QoL, and survival in randomized, controlled trials.^{6,8} As a result, the American Heart Association (AHA) recommends exercise training for all patients with chronic, stable HF.¹⁰

However, many HF patients struggle with adherence to health behavior recommendations.^{13,14} Fifteen to 33% of patients with HF consume more sodium than is typically recommended.¹⁴ Up to 54% of HF patients have suboptimal adherence to their cardiac medications,⁹ and one-third to one-half of HF patients engage in physical exercise less than once a week.^{15,16} In sum, despite clear evidence that adherence may help to improve outcomes, patients with HF still struggle to complete health behaviors.

Interventions to improve health behaviors in HF: Interventions designed to increase adherence to health behaviors in HF have had mixed success,¹⁷⁻²⁰ with systematic reviews suggesting that only half of interventions lead to improvements in QoL or hospitalizations.^{17,18} Less complex interventions in particular often have failed to impact readmissions or number of days in the hospital.¹⁹ Unfortunately, the intensity of more complex interventions (that require significant provider time) may make them cost-prohibitive.

Impact of psychological states on cardiac outcomes and health behaviors: Positive psychological states such as positive affect or optimism have been linked to improved long-term health outcomes, including reduced mortality, in healthy individuals and in those with cardiovascular disease. Numerous studies have confirmed the prospective association between positive states and mortality, oftentimes independent of negative emotional states and relevant medical factors.²¹⁻²⁴ In one study of over 6,000 patients, greater positive affect was linked to a reduced risk of heart disease, even after controlling for health behaviors and depression.²⁵ Similarly, in a study of over 97,000 women, baseline optimism was prospectively and independently associated with lower rates of incident coronary heart disease and mortality.²³

The impact of positive states on cardiac outcomes may be mediated in part by health behaviors. In a study of 773 elderly men, dispositional optimism was prospectively linked to more physical activity and higher intake of fruits and vegetables.²⁶ Other studies confirm the relationship between positive states and diet,^{27,28} physical activity,^{29,30} and medication adherence.³¹ Given these links, an intervention to boost positive emotional states has the potential to improve health behaviors and medical outcomes in the HF population.

Positive psychology (PP): PP is an area of study that aims to boost positive psychological states (e.g., optimism, gratitude, positive affect) through systematic exercises, such as performing kind acts,

writing a letter of gratitude, or using a strength in a new way.^{32,33} These exercises are easily delivered and completed, require minimal provider training, and can be delivered easily via telephone. In non-cardiac patients, these interventions increase well-being and reduce depression consistently and substantially.^{34,35}

Research suggests that PP interventions may be effective in cardiac populations. Positive affect induction, though not a formal PP exercise, has been associated with increased medication adherence and greater physical activity in hypertensive patients and in post-percutaneous coronary intervention patients, respectively.^{36,37} Furthermore, in a pilot trial by our group, a formal, 4-week PP intervention for cardiac inpatients was feasible, acceptable, and associated with greater numerical improvements in psychological outcomes compared to relaxation response and attentional control groups.³⁸ In a second preliminary study in patients who had suffered an acute coronary syndrome (ACS), a PP intervention led to improvements in depression, anxiety, and positive affect compared to treatment as usual.³⁹

However, aside from our research group's work, no studies have evaluated formal PP interventions to promote health behaviors in cardiac patients in general or HF patients in particular. Such interventions have the potential to leverage positive psychological states to improve health behaviors in this high-risk group of patients. Further study of these interventions is critical to determine how they can be applied to HF patients.

To address this question, we recently completed qualitative interviews with 32 HF patients (IRB # 2015P000069) to better understand their HF symptoms, examine the relationships between positive psychological constructs and health behaviors, and identify barriers and facilitators to completing health behaviors. The information gained from these interviews allowed for the creation of an intervention that is adapted to this specific population and that has the greatest likelihood of providing benefit to these high risk patients. The focus of this study is to examine the feasibility, acceptability, and preliminary impact of our customized PP-based health behavior intervention in a group of patients with mild to moderate HF.

B. Preliminary Studies

Dr. Celano is ideally suited to complete the proposed study given his prior research experience. He has been co-investigator for both observational and intervention studies focusing on positive psychological states in cardiac patients, and he is the principal investigator (PI) of a PP intervention trial in psychiatric inpatients with bipolar depression. The studies below demonstrate his ability to perform the proposed trial.

Preliminary Studies #1: Observational and Intervention Studies in Cardiovascular Disease. As part of the Cardiac Psychiatry Research Program (CPRP) team, Dr. Celano has served as a co-investigator for a number of intervention studies to investigate the use of psychological interventions in hospitalized patients with cardiac disease. This includes a large (N=175) collaborative care depression management trial^{40,41} and a recently completed collaborative care study (N=183) for depression or anxiety disorders in patients with HF and other cardiac diseases.⁴² These two studies have provided experience with the recruitment, enrollment, and retention of participants with heart disease and with many of the outcome measures that will be used in the proposed study.

Preliminary Studies #2: Positive Psychology Interventions. Dr. Celano also has experience with PP interventions in non-cardiac populations. He served as a co-investigator for a study involving the systematic administration of PP exercises to psychiatric inpatients (N=61) with suicidal ideation. In this study, 189/213 (88.7%) assigned exercises were completed, suggesting that the intervention was

feasible and acceptable. Currently, Dr. Celano is the Principal Investigator of a study to develop a telephone-based PP intervention for psychiatric inpatients with bipolar depression and has successfully recruited 45 participants over the first two phases of the study. He also has served as the Project Director for two PP intervention trials—one in depression, the other in diabetes. These studies introduced Dr. Celano to the measurement of positive psychological states using the same tools as those for the proposed study (e.g., LOT-R, PANAS), gave him experience with delivering PP interventions via telephone, and demonstrated our team's ability to retain a high percentage of patients despite their level of risk and psychiatric illness.

Preliminary Studies #3: Positive Psychological States in Cardiovascular Disease. Finally, Dr. Celano's work as a co-investigator in the CPRP has exposed him to the study of positive psychological states in patients with cardiovascular disease. In a pilot study, our team developed and tested an 8-week PP intervention to cultivate gratitude, optimism, and kindness in 30 cardiac inpatients (N=9 in the PP group) and found the PP intervention to be feasible and well-accepted.³⁸ Furthermore, Dr. Celano has played an active role in a prospective, observational study (N=212) to examine the associations between positive psychological states and health behaviors in post-ACS patients. Preliminary results from this study suggest that higher levels of gratitude and optimism are prospectively associated with greater self-reported physical activity, heart-healthy diet, and medication adherence 6 months later. Dr. Celano also serves as the Project Director of a study to examine the use of PP interventions in post-ACS patients. Results from the first stage of this study suggest that in the post-ACS period, patients view positive emotions as promoters of health behaviors.⁴³ In the second phase of this study, an 8-week, telephone-based PP intervention led to greater improvements in depression, anxiety, and positive affect, compared to treatment as usual.³⁹ Finally, Dr. Celano is the PI of an ongoing study to better understand the links between positive psychological states and health behaviors in patients with New York Heart Association (NYHA) class II or III HF. He has reached his enrollment goal 32 participants (follow-up is ongoing), and preliminary results suggest that patients with HF identify bidirectional links between positive psychological states and health behavior performance. Dr. Celano has used the information from these interviews to create an 8-week PP-based health behavior intervention for this population. Dr. Celano's involvement in these ongoing studies has provided him with information about the links between positive states and outcomes in cardiac patients and experience with the outcome measures, accelerometers, and electronic pill bottles to be used in the proposed study.

Relevance of Preliminary Work to the Proposed Project: Dr. Celano now has experience recruiting and retaining patients at Massachusetts General Hospital (MGH) who have HF and other cardiac illnesses, measuring psychological and medical variables effectively, and developing interventions to increase positive psychological states. These experiences make him well-positioned to successfully and efficiently complete the proposed project.

C. Rationale/Potential Benefits/Overview of Proposed Research

Creation of an intervention to increase positive emotions and promote health behaviors in cardiac patients. There is clear evidence linking positive emotions with superior cardiac outcomes.^{21,25,44} Despite this, there has been minimal study of interventions in cardiac patients that specifically focus on the cultivation of positive emotional states. Though some programs have utilized relaxation or mindfulness,^{45,46} PP interventions had never been used in patients with HF until our pre-pilot study, despite their well-documented overall efficacy.³⁵ Indeed, aside from our team's work to

develop a PP-based intervention for post-ACS patients, we are aware of only one other trial that used PP in any cardiac population (outpatients with hypertension or undergoing angioplasty).⁴⁷

To address this gap in knowledge, we aim to test the feasibility and immediate impact of a novel PP-based health behavior intervention that is adapted for patients with HF. A treatment cultivating positive emotions in this vulnerable population could provide broad and significant health benefits, and may have distinct—and more powerful—effects than simply attempting to dampen negative emotions.⁴⁸ In the first phase of treatment development (IRB # 2015P000069), we aimed to adapt our prior PP-based interventions to patients with HF. We successfully performed qualitative research (N=32) to: (a) assess barriers to health behavior completion, (b) identify the causes and extent of positive emotional deficits, (c) examine potential links between positive emotional deficits and impaired health behaviors, and (d) inquire about the utility of potential PP and goal-setting exercises in participants with NYHA class II or III HF. Using this information we developed a customized, PP-based health behavior intervention based on these results and the existing literature.

In the current phase of treatment development (Phase 2: Refining the intervention), we will perform a small (N=11) proof-of-concept trial to ensure our intervention's initial feasibility and to refine the intervention prior to a larger pilot study.

In this project, we hope to do the following:

1. Test a 10-week, telephone-delivered health behavior intervention utilizing PP exercises and systematic goal-setting in a brief, non-randomized, proof-of-concept trial (N=11).
2. Determine whether this initial intervention is feasible in a small cohort of HF patients.
3. Explore potential benefits of the intervention on outcomes of interest (e.g., optimism, positive affect).

II. SPECIFIC AIMS

Specific Aim #1 (Feasibility; primary aim): To assess the feasibility of the PP-based health behavior intervention, adherence methods, and outcome assessments in patients with NYHA class I-III HF.

Hypothesis: The PP exercises and goal-setting sessions will be feasible (i.e., 5 of the 9 exercises/sessions will be completed by a majority of patients). Furthermore, we will obtain complete objective follow-up data in at least 80% of enrolled participants at 10 weeks for both the medication and activity measurement methods.

Specific Aim #2 (Acceptability and immediate impact): To assess whether the intervention is acceptable to participants, as measured by ratings provided before and after each exercise, as well as its immediate impact on optimism.

Hypothesis: The intervention will be acceptable (mean score of at least 6 out of 10 on ratings of ease of completion and subjective helpfulness of the exercises) and will have adequate immediate impact on optimism (post-exercise ratings of optimism will be higher than pre-exercise ratings).

Specific Aim #3 (Intermediate outcomes): To assess whether this preliminary intervention appears to result in improvement of psychological well-being (as measured by dispositional optimism, positive affect, anxiety, and depression).

Hypothesis: The intervention will lead to improvements in optimism and positive affect and reductions in depression and anxiety at 10 weeks compared to baseline.

Exploratory Aim (adherence and functional outcomes): To examine the impact of the intervention on physical activity, medication adherence, sodium intake, HF-related QoL, and generic HRQoL.

Hypothesis: The intervention will lead to improvements in adherence and functional outcomes at follow-up.

III. PARTICIPANT SELECTION

A. Inclusion/Exclusion Criteria

Inclusion criteria:

- Adult patients with NYHA class I, II, or III HF admitted to an MGH inpatient unit or outpatients at the MGH Heart Center.⁴⁹ Patients with NYHA class IV HF have ongoing HF symptoms at rest, making it difficult for them to increase physical activity and other health behaviors; therefore, they will not be included. HF diagnosis will be confirmed via chart review and with the patient's treatment team as needed. NYHA class will be confirmed with the patient and adjudicated by Dr. Januzzi or the patient's treatment team when necessary.
- Suboptimal adherence to health behaviors. This will be defined as a total score of ≤ 15 on three Medical Outcomes Study Specific Adherence Scale (MOS SAS)⁵⁰ items regarding diet/exercise/medications. The MOS SAS has been used in multiple prior studies assessing adherence in cardiac patients, including our own studies in this population.^{40,51,52} This threshold score on the MOS SAS will ensure that all participants will have the potential to improve their health behaviors.

Exclusion criteria:

- Cognitive deficits impeding a participant's ability to provide informed consent or participate, assessed via a 6-item cognitive test that is sensitive and specific for screening for cognitive impairment in research participants.⁵³
- Medical conditions precluding interviews or likely to lead to death within 6 months.
- Inability to speak English, inability to read or write, inability to walk, or lack of a telephone.

Justification for inclusion and exclusion criteria: We will recruit individuals over age 18 that have NYHA class I, II, or III HF and endorse suboptimal adherence to physical activity, diet, and/or medication use. We will study HF because it is extremely common¹ and has been associated with poor functioning²⁻⁵ and high rates of mortality (50% of individuals with HF die within 5 years of diagnosis).⁴ We chose NYHA class I, II, and III HF patients because class II and III patients comprise the majority of participants in studies that identify links between physical activity and improved exercise capacity, quality of life, and survival^{6,8} and because class I patients also likely would benefit from increases in physical activity and health behaviors. We did not include NYHA class IV patients

because they may be too physically impaired to perform some of the PP exercises included in the intervention.

We will focus on adherence to health behaviors in HF for several reasons. First, adherence to health behaviors is associated with better HF outcomes, including lower rates of mortality,⁶⁻¹⁰ but patients with HF often struggle to adhere to these behaviors.^{13,14} Second, existing interventions to improve health behaviors are costly and have had limited impact on medical outcomes and quality of life.¹⁷⁻²⁰ Finally, positive psychological states have been associated with improved adherence to health behaviors in healthy and other medically ill populations,²⁶⁻³¹ suggesting that an intervention to boost these states in HF patients may be an effective way to improve these behaviors and medical outcomes in general. We will enroll only those patients who have at least mild deficiencies in health behaviors.

Exclusion criteria will include cognitive deficits, medical conditions that preclude participation in the intervention or are likely to lead to death within 6 months, inability to walk, inability to speak English, and lack of a telephone. The main purpose of these exclusion criteria is to ensure that all participants are able to fully participate in intervention procedures and provide outcome data. Children under age 18 will be excluded because they often are not directly responsible for their adherence to health behaviors (e.g., medication adherence) and because they will not be able to provide informed consent. Individuals with cognitive deficits may have difficulty recalling their affective states or providing informed consent for the study. Patients who have medical impairments that lead to a high risk of dying within 6 months likely will struggle to complete the intervention and other study procedures. Potential participants without a telephone will be unable to perform the intervention and therefore will be excluded.

As physical activity (as measured by accelerometer) is our primary health behavior outcome measure, those patients who cannot walk will be excluded, as the accelerometers were primarily designed for step-based activities. Finally, individuals who do not speak or read English will be excluded because our current proposed interventional materials are only available in English and because it is unclear whether the intervention and study assessments could be effectively administered over the phone using interpreter services—certainly this would add an additional potential barrier to assessment and might result in inaccurate conclusions about the course of illness when in fact the language barrier/interpreter presence may have been a confounding factor. If our results suggest that the intervention is promising, we will work to expand our study to non-English-speaking populations. All potential participants will be evaluated for exclusion criteria prior to enrollment, in concert with their treatment team.

B. Sources of participants and recruitment methods

All participants will be adults with NYHA class I, II, or III HF admitted to an inpatient unit at MGH or seen as outpatients at the MGH Heart Center.

In hospital recruitment. Potential participants will be identified through daily reviews of the inpatient unit censuses and contact with (and subsequent clearance by) an inpatient team member (physician, nurse, or nurse practitioner). If a potential participant is identified, the study staff member will ask the treatment provider to inquire whether it would be okay for a study staff member to inform the patient about an optional study. If the patient were amenable, a study staff member would meet with the patient, confirm that it is okay to describe an optional study, and then discuss the study with the patient and inquire about inclusion/exclusion criteria. Interested patients will undergo cognitive evaluation (with the six-item screen), discussion of medical history to review for exclusion criteria and

confirm NYHA class, and assessment of adherence status with the MOS SAS.

Sociodemographic and medical data (age, gender, medical and psychiatric diagnoses, NYHA class, ejection fraction, alcohol consumption, and smoking history), and baseline assessments on self-report measures (including health behaviors), will be obtained at enrollment.

Outpatient recruitment via Research Patient Database Registry (RPDR). All participants will be adults with NYHA class I, II, or III HF listed in their electronic medical record. Participants can be referred to the study by an outpatient treatment team member (physician, nurse, or nurse practitioner) or through systematic searches using the RPDR at MGH. The RPDR is a centralized clinical data registry that gathers data from various hospital legacy systems and stores it in one place. Researchers access this data using the RPDR online Query Tool. They may query the RPDR data for aggregate totals and, with proper IRB approval, obtain medical record data. The RPDR ensures the security of patient information by controlling and auditing the distribution of patient data within the guidelines of the IRB and with the use of several built-in, automated security measures.⁵⁴

To identify potentially eligible patients:

- 1.) An RPDR query will be performed to identify those patients with a diagnosis of HF. Study staff will review the medical record to confirm potential participant eligibility and to identify their linkage to a cardiologist.
- 2.) Study staff then will obtain permission for initial contact from each potentially eligible patient's cardiologist via e-mail or by having providers review letters and discard ones that they do not approve.
- 3.) For physician-approved patients, study staff will send a study introduction letter from the patient's cardiologist (with the clinician's name at the bottom) and a study opt-out letter signed by Christopher Celano, MD (PI). The letter from the cardiologist informs the patient that he or she is allowing the study to contact patients with HF in case they are interested in learning about the trial. Dr. Celano's letter is an opt-out letter describing the study, the procedure to opt out of further contact, and whom to call for further information. These letters will be sent from a central location at MGH.
- 4.) Should study staff receive no reply within 2 weeks, staff members will call the patient on the phone to assess interest in the study and to describe the study over the phone. If the patient remains interested, staff will confirm eligibility and assess for exclusion criteria. If the patient remains interested and appears eligible, study staff will set up an appointment time to go through the consent procedures and conduct the initial study visit. We will then mail or e-mail participants a consent form to look over ahead of time, so that they may prepare questions for the first visit. Note: If a participant prefers to perform all study visits by phone, a consent form will be mailed to the participant. This will be reviewed over the phone, and if the patient remains interested, he or she will sign the consent form and mail it back to study staff at MGH. Once the signed consent form is received, study staff will mail study materials to the participant, and the participant will be called for the first study visit.

For potentially eligible patients who are enrolled in the MGH Research Options Direct to You (RODY) Program, we will directly contact them via phone to inform them about the project. RODY identifies patients who are willing to be contacted directly about research studies. Patients who have agreed to be contacted directly are identifiable through the RPDR search; each patient's RODY status is available in the demographics table included in the RPDR output.

Future Studies. For participants approached either inpatient or outpatient, we will inquire at the end of the screen about whether they are interested in being contacted for future studies. This will allow us to create a database for contacting patients regarding any research studies we conduct in the future.

IV. PARTICIPANT ENROLLMENT

A. Methods of Enrollment

We will enroll participants through the recruitment procedures, described above, and the informed consent procedures, described below.

B. Procedures for obtaining informed consent

If the patient is interested in the study after the discussion/assessment for exclusion criteria as mentioned above, a licensed physician, psychologist, social work investigator, medical student, or research assistant will approach the patient, verbally discuss the study in detail and give the patient adequate time to read a written IRB-approved consent form and to ask questions. If they desire, participants will have at least 24 hours to consider enrollment. To ensure that participants have the capacity to provide informed consent, we will ask potential participants to describe their understanding of the study's purpose and their role (e.g., that they understand the timing of intervention and its purpose, audiotaping of phone sessions and the purpose for the audiotaping, confidentiality and its limits, our focused review of medical records, and their ability to end participation in the study at any time for any reason). Patients will be given at least 24 hours if desired to consider participation in the study. In addition, patients will be informed that they will receive \$100 for completing the study (including the 10-week follow up phone call) and returning the ActiGraph GT3X+ device, mailed to them as a check at the end of the study. For tax reasons, we require a social security number in order to issue the full \$100. However, if you are uncomfortable giving that information, we can compensate you with a \$50 check without requiring your social security number. Outpatient participants who come to MGH for an initial in-person visit also will be informed that they will be reimbursed for parking.

It is exceedingly unlikely that a potential participant will be a patient currently in an investigator's clinical practice. However, if an investigator discovers that a potential participant is a member of his/her clinical practice, an alternate investigator will be substituted to provide a description of the study and obtain informed consent.

Finally, once a participant signs the consent form, the investigator will perform a focused review of the participant's medical record (including laboratory data) to again confirm that the patient has HF, and will consult with the study cardiologist in the event that there is any need for further clarification. If there is question about the patient's medical prognosis (to assess whether the patient has a condition likely to lead to death within 6 months) the study team will consult with the patient's inpatient or outpatient team and/or the study cardiologist. Participants will be asked to sign a release form at the time of consent to allow study staff to discuss their diagnosis and aforementioned medical variables during the study.

Partners Healthcare has an electronic system that lets the participants' study doctors know if they are admitted to a Partners Hospital, or if they visit a Partners Hospital Emergency Department. We will

use this system to ensure that the study doctors know about any possible problems or side effects participants experience while taking part in the study.

C. Treatment assignment/randomization

There is no randomization procedure required for this trial.

V. STUDY PROCEDURES

A. Study visits/evaluations (See Table 1)

Initial visit (Week 1; in person). The initial visit will occur in an MGH inpatient unit, in the outpatient cardiac clinic, in a designated private office within the CPRP suite (for those contacted via opt-out letter), or over the phone (if a participant prefers to not come to the hospital for an in-person visit). Participants will meet with a member of the study staff (the study “trainer”) and complete self-report questionnaires. These questionnaires assess optimism (Life Orientation Test-Revised; LOT-R),⁵⁵ anxiety/depression (Hospital Anxiety and Depression Scale; HADS),⁵⁶ positive emotions (Positive and Negative Affect Schedule; PANAS),⁶⁵ health-related quality of life (MOS Short Form-12; SF-12),⁵⁷ cardiac symptoms and heart failure-related quality of life (Kansas City Cardiomyopathy Questionnaire; KCCQ),^{58,59} medication adherence (Self-Reported Medication Adherence [adapted from the Heart and Soul Study]; SRMA),⁶⁰ and sodium intake (Scored Sodium Questionnaire; SSQ).⁶¹ Participants will also answer questions about their alcohol (using the AUDIT-C)⁶² and cigarette use. In sum, these scales should take approximately 30 minutes to complete.

After completion of the questionnaires, participants will be provided with a treatment manual, with weekly PP exercises and information to teach participants about the importance of health behaviors and set goals to improve these behaviors. They also will receive a copy of *Learning to Live with Heart Failure*,⁶³ a practical guide which is provided by MGH to all HF patients admitted to a cardiology unit at MGH.

The trainer then will introduce the participant to the PP and goal-setting portions of the intervention. For the PP portion, participants will be assigned the first exercise (gratitude for positive events) and will be instructed to perform the exercise within the next week. Prior to completing the exercise, participants will be asked to rate their current level of happiness and optimism, using a 10-point Likert scale. Immediately after completing the exercise, participants will rate the ease of exercise completion, overall utility of the exercise, and their current levels of happiness and optimism, all using 10-point Likert scales. For the first goal-setting session, the trainer will discuss the importance of physical activity in HF. Participants will be given a pedometer, which participants will use to monitor the number of steps they take daily over the following week. The trainer will instruct them in its use and set a goal for monitoring their baseline physical activity over the next week. This pedometer will not be used as an outcome measure but simply will be a tool that participants can use to monitor their activity. We anticipate that this portion of the visit will take approximately 20 minutes.

After assigning the first week’s PP and goal-setting exercises, participants will receive an Actigraph GT3X+ accelerometer, and its use will be demonstrated by the trainer. We will measure activity at baseline (for 7 days) and in the 7 days following the 10-week assessment (we will send participants the ActiGraph in the mail at the appropriate time). In contrast to the pedometer, which is used for participants to monitor their activity, the ActiGraph accelerometer provides no information to

participants about their physical activity and will only be used by the study team to measure physical activity as an outcome.

ActiGraph accelerometers are validated as measures of physical activity and have been used in numerous studies of physical activity in patients with medical illness.⁶⁴ The accelerometer is a small 1.5" square device that can be worn on an elastic band (around the lower waist) or clipped onto a belt. It tracks the number of steps taken. After explaining how to use the accelerometer, the study trainer will schedule an appointment to call the participant in 1 week to review the first exercise. In total this initial visit will take approximately 50-60 minutes.

Weekly phone sessions (Weeks 1-10). All participants will be asked to complete 9 weekly PP exercises and will be asked to speak with a study trainer weekly. In addition, in Week 10, there will be a wrap-up phone call that focuses on the progress the participant has made in the program and makes a plan for continuing to use PP skills and engage in healthy activities in the future. Weekly phone sessions will last approximately 30 minutes. These calls will be recorded so that a percentage (10%) of these recordings can be reviewed to ensure that the PP and goal-setting portions of the intervention are being delivered as described in the protocol and trainer manual.

Program Content. All phone sessions will include (a) a review of the week's PP exercise (including the participant's ratings of pre- and post-exercise happiness, ease and helpfulness of the exercise, and optimism related to the future), (b) a discussion of the rationale of the next week's PP exercise through a guided review of the PP manual, and (c) assignment of the next week's PP exercise. Additionally for the goal-setting portion, participants will (a) review their goals and behaviors from the prior week, (b) discuss techniques for improving health behavior adherence (e.g., monitoring physical activity, reading nutrition labels), and (c) set goals for the next week. The exercises and content for both PP and MI will be assigned in the same order for all participants receiving them. During the calls, the trainer and participant will also review the next section of the treatment manual and prepare for the upcoming week's exercise.

Positive Psychology Exercises. The PP exercises used in this study were selected based on their superior performance in our pre-pilot research and others' work. They will be grouped into three-week modules focusing on a different psychological state:

Module 1: Gratitude-based activities

Week 1 (in-person visit): Gratitude for positive events.³³

Participants recall three events, small or large, in the preceding week that were associated with satisfaction, happiness, pride, or other positive states.

Week 2: Expressing gratitude.³³

Participants write a letter of gratitude thanking a person for an act of kindness; participants may, at their discretion, share the letter with the other person.

Week 3: Integrating gratitude-based activities into daily life.

Participants work to be more aware of positive things over the course of the week and then boost the positive feelings gained from them by sharing the events with others, or recording or celebrating the events in some way.

Module 2: Strength-based activities

Week 4: Recalling a past success.³³

Participants recall a prior event in which they experienced success. They write about the event, their contribution to the success, and the positive feelings evoked by recalling it. Finally, they consider how they might use the experience to be successful in the future.

Week 5: Using personal strengths.³³

Participants choose a personal strength that is important to them and then find a new way to use that strength over the following week.

Week 6: Integrating strength-based skills into daily life.

Participants work to be more aware of successes that occur in their daily life and how they can use their strengths on an everyday basis.

Module 3: Meaning-based activities

Week 7: Enjoyable and meaningful activities.⁶⁵

Participants complete a series of self-selected activities that vary between those that bring immediate boosts in mood and those that are more deeply meaningful.

Week 8: Performing acts of kindness.

Participants complete three acts of kindness in one day. The acts can be small or large, planned or spontaneous, but must be expressly completed to be kind to another. Participants then write how doing the act made them feel.

Week 9: Integrating meaning-based activities into daily life.

Participants work to perform enjoyable and meaningful acts for themselves and others in daily life. Trainers help participants create a plan for using these skills on their own in the near future.

Week 10: Planning for the Future.

Participants review the skills they have used in the program and make a plan for using these skills in everyday life moving forward.

Goal-setting. The goal-setting portion of the program aims to provide patients with knowledge about important HF-related health behaviors and assist them with setting goals to become more adherent to these health behaviors. This intervention will focus on three distinct health behaviors: physical activity, low-sodium diet, and medication adherence. These also will be divided into three-session modules, which will be completed in parallel to the PP exercises.

Each session follows the same structure. Study trainers will: (a) ask participants about their health goals, (b) provide education about a health behavior and/or refer them to their treatment team if clarification is needed, and (c) set a health behavior goal for the next week. Health behavior goals will be individualized to the participant, and participants will be encouraged to speak with their treatment team if they have any questions about appropriate goals for diet or physical activity. While all sessions

will involve tracking participants' progress towards their health behavior goals, the educational components will vary from week to week:

Module 1: Physical activity

Week 1 (in-person visit): Introduction to increasing physical activity.

The trainer will review with participants the potential health benefits of physical activity, as well as participants' current physical activity. Participants will receive a pedometer and set a goal of monitoring their physical activity (through steps measured by the pedometer) over the next week.

Week 2: Setting a SMART physical activity goal.

Participants will learn about setting goals that are SMART (specific, measurable, attainable, relevant, and time-based) and will be encouraged to set a small behavioral goal related to physical activity.

Week 3: Physical activity resources.

Participants will be asked to identify resources (community, friends/family, equipment) for engaging in physical activity and how they can use them to work toward their goals. They will also discuss ways to problem solve around barriers to physical activity.

Module 2: Heart-healthy diet

Week 4: Introduction to a heart-healthy diet.

The trainer will review with participants the potential health benefits of a low sodium diet, as well as participants' current dietary habits. Participants will be encouraged to keep track of their salt intake over the next week and contact their physician if they are unsure how much sodium they should be consuming daily.

Week 5: Setting a SMART heart-healthy diet goal.

Participants will be encouraged to set a small behavioral goal related to diet and to continue to monitor their sodium intake.

Week 6: Heart-healthy diet resources.

Participants will be asked to identify resources (community, friends/family, low sodium diet recipes/books) for having a low sodium diet and how they can use them to work toward their goals. They will also discuss ways to problem solve around barriers to a heart-healthy diet.

Module 3: Medication adherence

Week 7: Introduction to medication adherence.

The trainer will review with participants the importance of medication adherence, as well as participants' current medication adherence. Participants will be encouraged to monitor their medication adherence over the next week.

Week 8: Setting a SMART medication goal.

Participants will be encouraged to set a goal related to medication adherence and to continue to monitor their medication adherence.

Week 9: Medication resources.

Trainers and participants will discuss different resources (e.g., medication pill boxes, electronic reminders) that can help participants remember to be adherent to their medications. They will also discuss ways to problem solve around barriers to medication adherence.

Week 10: Planning for the future.

Trainers will assist participants with reviewing their accomplishments and benefits gained from health behavior adherence thus far, and help them to create a plan for physical activity, heart-healthy diet, and medication adherence for the near future

At each session, health behavior goals will be reviewed with the participant, and if there are any concerns about the goals, participants will be encouraged to speak with their outpatient treatment team for clarification. Educational information will be based on the *Learning to Live with Heart Failure* guide,⁶³ which is provided to all patients with HF who are admitted to an MGH cardiology unit. Study staff will confer with the study cardiologist if any other questions arise.

Given the results of our prior PP studies, and given that this is a feasibility study (i.e., we want to assess participants' willingness to complete the exercises), we will expect participants to complete at least 5 PP exercises / goal-setting sessions. In other words, if a participant completes at least 5 sessions, missed sessions will not be considered a deviation from the protocol.

Follow-up phone call (Week 10). At Week 10, a member of the study staff will call participants to repeat the self-report questionnaires that were administered at baseline. These questionnaires assess optimism (LOT-R), positive emotions (PANAS), overall health behavior adherence (MOS SAS), anxiety/depression (HADS), health-related quality of life (SF-12), cardiac symptoms and heart failure-related quality of life (KCCQ), medication adherence (SRMA), and sodium intake (SSQ). Participants will also be asked about alcohol use (AUDIT-C), cigarette smoking, cardiac-related hospital readmissions, and cardiac rehabilitation, and to rate their overall satisfaction with the treatment they received for their cardiac condition over the last 10 weeks on a scale of 0 (not at all satisfied) to 10 (completely satisfied). Finally, patients will be asked about their experience in the study, including any aspects of the intervention or study procedures that could be improved, during follow-up assessment. In sum, these scales should take approximately 30-40 minutes to complete. If participants would rather complete the follow-up questionnaires in written form rather than over the phone, we will send them a paper packet at the time of the follow-up.

Training. Dr. Celano (PI) and Carol Mastromauro (LICSW) have substantial experience in explaining and delivering PP exercises from their studies in cardiac and psychiatric patients. The PP exercises for this trial have been identified via published literature,^{33,65-68} or directly from researchers, and modified appropriately for this population. Additional text outlining the rationale and instructions for each exercise are located in the written packets for each exercise that are provided to participants. Dr. Celano and Ms. Mastromauro will engage in several training exercises prior to study initiation. Together, they will review the treatment manual and our team's prior training manuals related to these exercises. They then will complete all exercises together to gain experience performing and reviewing each exercise.

Dr. Celano and Ms. Mastromauro also have significant experience with providing guidance and motivation towards goal-setting from the ongoing work in cardiac patients. Dr. Celano currently is the Project Director of another study examining the efficacy of PP and goal-setting interventions in patients with ACS, and Ms. Mastromauro serves as an interventionist for that same study. The goal-setting portion of the intervention aims to improve health behaviors that studies have shown to be critical for cardiac health in patients with HF.⁶⁻¹² Similar to their training related to the PP exercises, Dr. Celano and Ms. Mastromauro will review the treatment manual for this project and complete each exercise together to gain experience providing education and setting goals related to physical activity, sodium restriction, and medication adherence.

Table 1. Schedule of study events.

	Pre-enrollment	Baseline and Initial Visit	Phone Sessions (Weeks 2-10)	Follow-up Phone Call (Week 10)
Cognitive screen	X			
Chart review to confirm eligibility	X			
Assessment of inclusion criteria (MOS SAS, NYHA class)	X			
Chart review for baseline characteristics		X		
PP exercise		X	X	
Goal-setting exercise		X	X	
Exercise ratings		X	X	
Self-report measures (SSQ, LOT-R, PANAS, HADS, KCCQ, SRMA, SF-12)		X		X
Objective adherence data (ActiGraph step counter)		X		X

B. Drugs to be used

No specific medications are being studied or administered solely for research purposes in this study.

C. Devices to be used

No specific devices are being studied or administered solely for research purposes in this study.

D. Procedures/ surgical interventions

No procedures or surgical interventions will be performed solely for research purposes in this study.

E. Data to be collected (See Table 1)

Baseline Data: Participants will complete the MOS SAS, SSQ, LOT-R, PANAS, HADS, KCCQ, SRMA, and SF-12 in person and will receive an Actigraph accelerometer. They will be asked

to begin wearing the accelerometer after their initial. Using the accelerometer in this phase of the study will allow us to test its feasibility and identify any potential problems with its use.

Baseline information about enrolled participants will also be obtained from the patients, care providers, and the electronic medical record as required for characterization of our population. This information will include data regarding medical history (history of acute coronary syndrome, coronary artery bypass graft, hypertension, diabetes mellitus, hyperlipidemia, and current smoking), current medical variables (renal function, N-terminal pro-B-type natriuretic peptide, left ventricular ejection fraction, NYHA class), medications, and sociodemographic data (age, gender, race/ethnicity, living alone). This information will help us to ensure that the population we recruit is a representative population of patients suffering from HF so that the health behavior intervention we are testing is applicable to the broadest population of patients.

Feasibility (primary study aim): Feasibility will be measured by the number of PP sessions that were completed by participants. We will consider the intervention feasible if the majority of participants complete at least 5 of 9 exercises/sessions.

Acceptability: Following each PP exercise, participants will be asked to rate the ease of completion and subjective helpfulness of the exercise on a scale of 0 (very difficult/not helpful) to 10 (very easy/very helpful).

Immediate impact: To examine the immediate impact of the PP exercises on positive affect and optimism, participants will be asked to rate these psychological states before and after each exercise on a 10-point Likert scale (0 = not happy/optimistic, 10 = very happy/optimistic).

Measurement of health behaviors. We will assess three main health behaviors in this trial.

(a) Physical activity (primary health behavior outcome measure). We selected physical activity as our main health behavior outcome for several reasons. Physical activity is a key modifiable prognostic factor in HF patients^{69,70} and has been associated with improved exercise capacity, QoL, and survival in this population.^{6,8} Furthermore, there are established links between higher levels of positive emotions (particularly optimism) and increased physical activity,^{26,29,30} suggesting that a PP intervention could impact this behavior. Finally, increasing physical activity is likely to require a relatively broad approach, as compared to other behaviors, which may improve with simple interventions such as electronic reminders.

Physical activity will be measured using the ActiGraph GT3X+ three-axis accelerometer (ActiGraph, LLC, Pensacola, FL). Accelerometers are often considered to be the standard for measuring habitual physical activity.^{71,72} ActiGraph GT3X+ step counters are validated as measures of physical activity and have been used in numerous studies of physical activity in patients with medical illness.⁶⁴ We chose to use ActiGraph GT3X+ accelerometers because they are the most widely used monitors for research purposes and adequately discriminate between different levels of activity.^{73,74} In this trial, participants will wear the accelerometer (for 1 week at baseline and 1 week at follow-up) to assess the feasibility of doing so and to ensure adequate capture of physical activity. We will measure the number of steps taken daily for the last 7 days they wore the device to ensure that this will provide us with adequate information for subsequent trials. We will turn off all notifications on the device prior to the start of the study. We will require at least 480 minutes of wear time to be considered a valid day,

and at least 5 valid days for a participant's data to be considered complete. If a participant does not provide at least this much data, we will ask the participant to re-wear the step counter until information from at least 5 valid days has been captured.

(b) Medication adherence. We will assess medication adherence using a self-report medication adherence (SRMA) measure. Specifically, we will ask participants what percent of the time (in 10% increments) they took all of their medications as prescribed in the past week and in the past 2 weeks. These questions were adapted from the adherence measure used in the Heart and Soul Study.⁶⁰

(c) Dietary adherence. We will assess sodium intake over the past month using the Scored Sodium Questionnaire (SSQ).⁶¹ This scale assesses the frequency with which participants consume a variety of sodium-containing foods, ranging from "Rarely or Never Eaten" to "At Least Once Daily." Total SSQ score has been shown to correlate significantly with 24-hour urinary sodium, and the SSQ has been validated in patients with significant medical illness.⁶¹ If participants are hospitalized, they will be asked to describe their sodium intake prior to admission, given that their diet in the hospital may be significantly different than their typical diet at home. The SSQ will be completed both at baseline and again at the 10-week follow up.

(d) Self-reported adherence. We will assess self-reported adherence using the MOS SAS⁵⁰ items regarding diet/exercise/medications. Participants will be asked to rate how often they completed each health behavior over the last month, with choices rating from "none of the time" to "all of the time." The MOS SAS has been used in multiple prior studies assessing adherence in cardiac patients, including our own studies in this population.^{40,51,52}

Measurement of psychological outcomes. We will measure optimism, positive affect and other psychological constructs that may potentially be impacted by the PP-based health behavior intervention that will be tested in subsequent trials. Doing so in this study will allow us to evaluate the feasibility of using these scales in this specific patient population.

(a) Dispositional optimism (primary psychological outcome measure) will be measured using the Life Orientation Test-Revised (LOT-R), a well-validated 6-item instrument. Dispositional optimism is the positive psychological state most linked to cardiac outcomes,^{23,75,76} and the LOT-R has been used to measure optimism in many studies of cardiac patients.⁷⁷⁻⁷⁹ Though dispositional optimism theoretically would be stable over time, research suggests that LOT-R scores can change quickly in response to psychological interventions.^{38,80,81}

(b) Positive affect will be measured using the positive affect items on the Positive and Negative Affect Schedule (PANAS),⁸² a well-validated scale used in other intervention trials and in patients with HF.^{83,84}

(c) Anxiety and depression will be measured using the anxiety and depression subscales of the Hospital Anxiety and Depression Scale (HADS).⁸⁵ This well-validated scale has been used in many studies of patients with heart disease (including our group's studies),^{38,40,85-87} and has the advantage of having few somatic symptom items that can confound mood/anxiety assessment in medically-ill patients.

Measurement of physical outcomes. We will also assess selected physical outcomes.

(a) Cardiac symptoms and HF-related QoL (primary functional outcome measure) will be

measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ), a well-validated questionnaire of health status in HF.⁵⁸ The full scale will be used to measure HF-specific health-related QoL (HRQoL), and an eight-question subset of the KCCQ will be used as a measure of HF symptoms. The KCCQ is a valid, reliable, and responsive instrument in patients with HF^{58,59} and is strongly correlated with NYHA class.⁵⁹ We chose the KCCQ as our primary functional outcome measure because it likely would be affected by all three of our health behaviors of interest (physical activity, medication adherence, and diet).

(b) Generic HRQoL will be assessed via the Medical Outcomes Study Short Form-12 (SF-12),⁵⁷ an instrument which has been used in multiple cardiac studies in the past, including our work.^{38,40,80,88-93} The SF-12 also is a reliable marker of QoL in HF⁹⁴ and has been associated with mortality in this high-risk cohort.⁹⁵

VI. BIOSTATISTICAL ANALYSIS

A and B. Specific data variables and study endpoints

Aim #1 (Feasibility; primary aim): To assess whether PP exercises administered over the phone are feasible in patients with NYHA class I-III HF.

Measures:

- Rates of completion of exercises (recorded by study trainer).
- Successful use of ActiGraph accelerometer.

The intervention will be considered feasible if 5 of the 9 sessions are completed by a majority of patients. The objective assessment measures will be considered feasible if we obtain adequate physical activity data (at least 5 valid days of accelerometer wear time) in at least 80% of enrolled participants at 10 weeks.

Aim #2 (Acceptability and immediate impact): To assess whether PP exercises administered over the phone are acceptable and lead to improvements in optimism in patients with NYHA class I-III HF.

Measures:

- Patient rating of immediate outcomes on 10-point Likert scale: Ease of completion, overall utility, change in optimism from pre- to post-exercise.

The PP exercises will be considered to be acceptable if participants have mean scores of at least 6/10 on the ratings of ease of completion and subjective helpfulness across exercises. The PP exercises will be considered to have adequate impact if participants rate optimism significantly higher post-exercise than pre-exercises across exercises (via one-sample t test).

Aim #3 and Exploratory Aim (Impact on psychological outcomes, functional outcomes, and health behaviors): To determine whether the PP intervention is linked to improvements in psychological well-being, functioning, and health behavior adherence from baseline to 10 weeks.

Measures:

- Optimism: LOT-R (primary measure for this aim)
- Positive emotions: PANAS
- Anxiety/depression: HADS
- HF-related QoL: KCCQ
- Health related quality of life: SF-12
- Self-reported adherence: MOS SAS
- Physical activity: ActiGraph accelerometer
- Medication adherence: SRMA
- Sodium intake: SSQ

We will consider the PP intervention to show promise for improving psychological well-being if mean scores on all psychological outcome measures are superior at 10 weeks compared to baseline. Given that this small trial is focused primarily on feasibility, we have set a low bar for improvement (i.e., even slight pre-post improvement). If these basic pre-post improvements did not occur, it would be important to reassess the intervention before moving on. We will move to a next-step trial once we have developed an intervention that appears to be feasible, to match hypotheses generated by our qualitative research, and to have some impact on optimism/positive affect based on a very small sample. Similarly, we will consider the intervention to show promise for improving other outcomes if there are pre-post improvements in the medical/functional outcomes.

C. Statistical methods

Data will be downloaded from REDCap into the Stata statistical package. For Aims 1 and 2 (feasibility, acceptability, and immediate impact), descriptive statistics will be used to report proportion of exercise completion and mean scores on exercise ratings. Differences between pre- and post-optimism scores will be compared using paired t tests.

To compare mean scores on outcome variables for Aim 3 and the exploratory aim, paired t tests will be used to explore mean differences between baseline and 10 week values. All statistical tests will be two-tailed and $p < .05$ considered significant, though this study will not be powered to detect statistically significant differences between baseline and follow-up points.

D. Power analysis

This exploratory proof-of-concept study with 11 patients (maximum 15 patients enrolled to obtain 10 completers), as noted, will not be powered to detect statistically significant differences between baseline and follow-up points, and is designed to assess feasibility of methods.

VII. RISKS AND DISCOMFORTS

A. Complications of surgical/non-surgical procedures

No procedures will be conducted as part of this study

B. Drug side effects and toxicities

No specific medications are being studied or administered solely for research purposes in this study.

C. Device complications

No specific devices are being studied or administered solely for research purposes in this study. However, we are using an accelerometer that, although not determined to be a “device,” can malfunction.

The device utilized to measure physical activity should pose minimal risk. The accelerometer (ActiGraph GT3X+) used to measure activity is small, light, and without sharp edges. Immersing the device in water for a prolonged period may render it unusable but does not pose a shock risk. Participants will mail the device back after 7 days in a pre-paid envelope provided by the study team.

The participant will be instructed to contact study staff by phone should a problem develop with the accelerometer during the course of the study. If there is an irresolvable problem, the participant will send the device back to the research assistant, and be provided a new one. Study staff will work directly with Actigraph technical support to resolve any device issues. A log of all technical difficulties will be maintained.

We will provide explicit instructions regarding the use of the accelerometer and step counter to ensure safety and proper use, and to reduce inconvenience/distress associated with uncertainty about their safety or use. We will reduce technological failure by educating study participants and providing a technical help line as noted above. The scientific team (i.e., Dr. Celano, the PI) will liaise with participants regarding any battery problems or technical advice on the Actigraph accelerometer, step counter, and related equipment.

D. Psychosocial risks

Confidentiality. As with any study, there is the risk of a breach of confidentiality; these risks will be minimized by using participant numbers rather than identifying personal data on study documents, and by using locked cabinets/offices and password-protected databases to store personal information. Only study staff (the PI, the research assistant entering data, and the research assistant doing follow-up assessments) will have any access to personally identifiable information about participants, and such access will be limited only to information necessary to complete study tasks.

All data regarding the objective adherence devices will be encoded only with the study participant number that is linked to personal identifying information in the study database. The devices will not be marked with any personal identifiable information, and the database that will be used to monitor accelerometer data will only contain participant numbers. The accelerometers do not record or link participants’ names with their data, and accelerometer data will only be accessed from a locked Partners computer in Warren 1226.

We will ensure that contact with participants is confidential by using only the phone numbers and other contact information that are specifically allowed by the participants and not leaving study-related messages for participants unless expressly allowed by participants. Upon enrollment, we ask all

participants if it is acceptable to leave voice messages on their phones, as well as the appropriate times to call them. We adhere to any and all patient requests regarding contact.

Informed consent process. With regard to the consent process, we will approach/recruit participants in the hospital only after patients' treatment team members (who would not be associated with the consent process in any way) ask patients if they are interested in hearing more about an optional study. In the outpatient setting, we will only contact those participants who express interest in the study or do not opt out after receiving an opt-out letter. If an investigator is clinically caring for a potential participant, an alternate, trained study staff member will approach the patient and complete the informed consent process and all study procedures for that participant. When discussing the study, we will emphasize the study's optional nature and participants' ability to opt out/un-enroll at any time, for any reason.

Medical & psychiatric emergencies. If patients report acute medical symptoms, they will be directed to emergency medical care, and their primary medical physicians may be contacted as needed. If study staff have questions regarding medical symptoms and their urgency, Dr. Januzzi (co-investigator and cardiologist) and the PI will be available to consult (and call patient) as needed. This study utilizes a questionnaire that assesses depressive symptoms (HADS), and thus, participants might disclose information about suicidal thinking or behavior. Due to this possibility, the follow-up call will be performed at a time when a psychiatrist study investigator is available to intervene as needed. If participants report suicidal ideation, study staff will complete specific suicide risk assessment questions to assess immediate risk of self-harm, and the psychiatrist will immediately assess the situation/patient if there is either an acutely elevated risk of self-harm or if additional information is needed to clarify risk. If the patient is at imminent risk, the study psychiatrist will take all needed steps to ensure emergent evaluation, which may include ensuring evaluation in the nearest emergency room. Participants will be informed of all of these measures to ensure confidentiality—and the limits of confidentiality, such as arranging for emergent medical or psychiatric care if safety is at imminent risk—as part of the informed consent process. However given that this is a medical rather than a psychiatric population we anticipate the rate of suicidality in this population will be low.

We will ask participants to report adverse events related to study participation they may have experienced at any time throughout the study. Any adverse events will be reported to the PI and to the IRB according to Partners HRC guidelines.

E. Radiation risks

There will be no radiation exposure in this study.

VI. POTENTIAL BENEFITS

A. Potential Benefits to Participants

It is possible that participants will not receive benefit from participation. Patients will undergo a series of exercises that are designed to increase optimism, improve well-being, and potentially improve cardiac health behaviors. Analyses of PP studies have been that these interventions are associated with improved psychological well-being and decreased depressive symptoms, and optimism

is associated with superior medical outcomes. Therefore, participating individuals may benefit by having improvements in these important and clinically relevant outcomes. Overall, contact with study trainers and the systematic follow-up assessments may also provide support and social connection for participants at a time of recent medical crisis. This may be an improvement over no such contact or systematic evaluation, as is current standard practice.

Patients will be given the opportunity to identify positive emotions and consider ways to enhance their own positive emotions. Description of the PP exercises may enlighten them as to potential means of improving their own emotional states. Furthermore, they will have the opportunity to consider possible barriers to adherence to health-related behaviors.

B. Potential Benefits to Society

Increasing positive psychological states in cardiac patients may have important public health benefits. Optimism and other positive affective states are prospectively associated with increased participation in healthy behaviors and with superior cardiac outcomes. The creation of a PP-based intervention—based on the previous qualitative research phase—targeted at improving positive emotional states in HF patients could lead to a novel approach to enhancing adherence in this population, which in turn might result in decreased morbidity and mortality in this population. Future studies could investigate the feasibility of implementing this intervention in a similar population and examine the impact on cardiac and psychological outcomes. If the PP-based health behavior intervention in this study proves to be feasible, well-accepted, and associated with improvements in physical activity and other key outcomes, it may well be possible to utilize these easily-delivered and completed exercises as part of a clinical care package for HF patients. Thus participation in this study may result in substantial benefit to future patients.

VIII. MONITORING AND QUALITY ASSURANCE

A. Independent Monitoring of Source Data

All source data (e.g., chart review data and participant self-report) will be entered into the REDCap database. The PI (Dr. Celano) will review this data to ensure that it is being entered correctly and will perform ‘test downloads’ of the data to ensure that it can be captured in the statistical package to be used in this study.

B. Safety Monitoring (e.g., DSMB)

Safety monitoring will be performed by Dr. Celano (PI), who will ensure that the study team is adequately identifying, reviewing, and reporting adverse events and unanticipated problems to the Partners Institutional Review Board (IRB). Upon certification of IRB approval of this protocol, Dr. Celano will submit this document to the NHLBI Grants Management Officer prior to beginning any study procedures. Dr. Celano will also submit an annual progress report confirming adherence to the data and safety monitoring plan, including a summary of any data and safety monitoring issues that occurred since the previous reporting period, as well as any changes made to the protocol and any new and continuing IRB approvals since the last filed report. A more detailed description of monitoring mechanisms, intervals, and the information monitored is outlined below.

Monitoring mechanism: Dr. Celano (PI) will take primary responsibility for the data safety monitoring. However, this study will have a formal data safety monitoring board (DSMB), which will be chaired by Dr. Jeff Huffman (psychiatry, primary mentor), and populated by Dr. Elyse Park (psychology, co-mentor), Dr. Hanna Gaggin (cardiology, external to study), and Dr. Bettina Hoeppner (psychology, external to study).

Monitoring intervals: Monitoring of adverse events will occur on an ongoing basis with notification of Dr. Celano with any adverse study-related events. More systematic weekly meetings for review of feasibility/acceptability information and minor IRB deviations will be held between Dr. Celano and study staff, including the lead research coordinator. Dr. Celano will then discuss any potential issues regarding data safety or protocol deviations with Dr. Huffman during weekly supervision meetings. This allows the team to review this information and make adjustments to procedures as required. Furthermore, weekly journal clubs are held with the study team; these include discussions of related projects (e.g., studies of physical activity in cardiac patients, studies of positive psychological interventions) and the general psychiatry and cardiology literature. Finally, the formal DSMB will meet every four months to monitor patient safety outcomes. These ongoing, weekly, and intermittent reviews ensure that the study procedures minimize research-related risk by reviewing specific outcomes linked to the project and by reviewing relevant literature to ensure that interventions are best practice. Dr. Celano (study PI) is responsible for directly reporting serious study-related adverse events to the NIH/NHLBI, and even if there are no such events, a yearly report summarizing adherence to the DSMP, review of study-related enrollment and issues during the study period, and any relevant changes to the protocol, will be sent to NHLBI.

Information to be monitored: Information to be monitored will include: (a) an evaluation of the progress of the research study, including assessments of data quality and timeliness and participant recruitment, accrual and retention consistent with plans for diversity and generalizability, (b) a review of study safety data—adverse event (and minor deviation) information—to determine whether the study should continue as originally designed, be changed, or be stopped, (c) review of procedures to maintain participant confidentiality (e.g., storage of identifiable information in locked cabinets, ensuring study databases have no personal identifying information, use of study participant numbers on communications about the study), and (d) an assessment of external factors or relevant information (e.g., developments in the literature, results of related studies, etc.) that may have an impact on the safety of participants or on the ethics of the research study, such as through the journal club listed above.

C. Outcomes Monitoring

As noted above, this study is a proof-of-concept trial to determine if all aspects of the protocol are feasible, acceptable, and effective. After 5 participants have completed the trial, we will briefly review the study and our outcomes. If participants' acceptability scores in the PP group are low (or optimism scores decrease following the exercises), or we sense more generally that some participants have been dissatisfied with the program, we will likely alter the protocol to address these issues. Similarly, if our rates of session completion are far below expected rates, we will reassess our protocol and likely make substantial changes. We will then complete the more formal data analysis once 10 participants have completed the trial.

On a weekly basis, the research team will meet to review study progress. At that time, the principal investigator will review informed consent documents, study forms, and procedures completed

that week, as well as all chart review forms performed that week for completeness and accuracy. The study team will also discuss any procedural difficulties, recruitment issues, and adverse events at this meeting (and before if needed). Investigators will also review consent documents and address acute issues in real time throughout the week. We will take several measures to ensure the integrity of data collection/entry/analysis and the fidelity of our intervention. Dr. Huffman will periodically review the recordings of weekly phone calls to ensure their fidelity.

D. Adverse event reporting guidelines

We will follow all PHRC guidelines with respect to reporting unanticipated problems, including adverse events. Specifically, when a serious or nonserious adverse event occurs, the PI will review the event to determine if it was possibly or definitely related to participation in the research. For all unanticipated problems and adverse events deemed related or possibly related to the research, we will complete and submit an Other Event report through Insight/eIRB as soon as possible and within 5 working days/7 calendar days (as defined in the March 2014 Reporting Unanticipated Problems Including Adverse Events report). At Continuing Review, we will provide a summary of all unanticipated problems as per PHRC protocol. Finally, if there are unanticipated problems, especially if serious or recurrent, the PI (Dr. Celano) will amend the protocol if it is deemed necessary to protect the safety and welfare of the participants.

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