A positive psychology intervention to promote health behaviors in heart failure: a randomized controlled pilot trial

NCT03220204

3/2/2018

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 was adapted to this specific population. Next, we performed a single-arm, proof-of-concept trial (N=11, IRB#2016P001443) to examine the feasibility of the intervention and our outcome measures, as well as to gain preliminary feedback from participants. Based on this information, we have created an optimized, 12-week, telephone-delivered, PP-based health behavior intervention and aim to examine its feasibility, acceptability, and preliminary impact in a group of patients with mild to moderate HF in a randomized, controlled pilot trial.

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 was 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. More recently, Dr. Celano was the Principal Investigator of a study to develop a telephone-based PP intervention for psychiatric inpatients with bipolar depression, and he 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 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. Results from this study suggest that higher levels of optimism are prospectively associated with greater physical activity and reduced cardiac readmissions 6 months later [43]. 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.[44] 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 examine the feasibility and potential utility of a PP- based intervention to improve health behavior adherence in patients with New York Heart Association (NYHA) class I, II, or III HF (IRB# 2016P001443). After successfully completing qualitative interviews in 32 HF patients, Dr. Celano developed a 10-week PP-based health behavior intervention for this population, and tested it in a proof-of-concept trial. Though follow up for this trial is still ongoing, preliminary analyses involving the first five participants revealed that the intervention was feasible (with 100% of exercises completed), easy to complete, and subjectively helpful. Furthermore, the intervention led to numerical improvements in both positive affect and daily moderate to vigorous physical activity. Now, Dr. Celano is using the information from the first two phases of this trial to inform his proposed randomized-controlled trial of this PP-based health behavior intervention for HF patients. Dr. Celano's involvement in these studies has provided him with information about the links between positive states and outcomes in cardiac patients, experience with developing and delivering a PP-based health behavior intervention, and experience with the outcome measures and accelerometers 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**

Intervention to increase positive emotions and promote health behaviors in cardiac patients. There is clear evidence linking positive emotions with superior cardiac outcomes.[21,25,45] 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,[46,47] 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).[48]

To address this gap in knowledge, we have created and optimized a novel PP-based health behavior intervention 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.[49] In the first phase of treatment development (IRB # 2015P000069), we 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, which we tested during phase two of this project (IRB # 2016P001443). Though follow-up is ongoing, preliminary analyses after 5 participants revealed that the intervention was feasible, subjectively helpful, and associated with significant immediate improvements in happiness and numerical improvements in positive affect and moderate to vigorous physical activity. Using feedback from participants and the data from this proof-of-concept trial, we have created an optimized version of the intervention. We now wish to test the feasibility and efficacy of the optimized intervention in a three-arm, randomized pilot trial.

In this project, we hope to do the following:

1. Test a 12-week, telephone-delivered health behavior intervention utilizing PP exercises and systematic goal-setting in a three-arm, randomized, controlled pilot trial in patients with mild to moderate HF (N=75).
2. Determine whether this optimized intervention is feasible in a small cohort of HF patients.
3. Explore potential benefits of the intervention on outcomes of interest (e.g., psychological health, functioning, and health behavior adherence) compared to a motivational interviewing- (MI) based education condition and treatment as usual (TAU).

II. SPECIFIC AIMS

Specific Aim #1 (Feasibility [primary outcome], acceptability, immediate impact): To assess the feasibility, acceptability, and immediate impact of the PP-based health behavior intervention

on optimism and happiness in a three-arm (N=75), randomized, controlled pilot trial.

Hypothesis: The PP intervention will be feasible (the majority of participants will complete at least 7 of 12 sessions/exercises) and 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 positive affect and optimism (post-exercise ratings of positive affect and optimism will be higher than pre-exercise ratings (measured by pre- and post- measurements on a Likert scale).

Specific Aim #2 (overall impact on psychological health): to examine the intervention's overall impact on both positive (positive affect, optimism) and negative (depression, anxiety) psychological health, compared to TAU and an MI-based educational control condition.

Hypothesis: The intervention will lead to significant pre-post increases in positive affect and optimism and significant reductions in depression and anxiety. Compared to the control conditions, the PP-based intervention will lead to greater numerical improvements in all psychological outcomes.

Specific Aim #3 (adherence and functional outcomes): To examine the impact of the intervention on physical activity (steps, as measured by accelerometer; primary health behavior outcome), medication adherence, sodium intake, HF-related QoL, and generic HRQoL, compared to TAU and an MI-based educational control condition.

Hypothesis: The intervention will lead to significant pre-post improvements in adherence and functional outcomes at follow-up and will lead to greater numerical improvements in these outcomes compared to the treatment as usual and the MI-based control condition.

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 or MGH-affiliated primary care clinic.[50] 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)[51] items regarding diet/exercise/medications. The MOS has been used in multiple prior studies assessing adherence in cardiac patients, including our own studies in this population.[40,52,53] This threshold score on the MOS 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.[54]
- 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 common[1] and has been associated with poor functioning[2-5] 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, QoL, 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 and health behavior 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 QoL.[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 or one of MGH's primary care clinics.

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.

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 Partners Healthcare RPDR. 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.[55]

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 in the MGH Heart Center or primary care physician located in an MGH primary care clinic.
2.) Study staff then will obtain permission for initial contact from each potentially eligible patient's cardiologist or PCP 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 physician (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 or PCP 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.) For patients who were contacted for the previous phase of the study and agreed to be contacted in the future, study staff will send an opt-out letter from Dr. Celano describing this new phase, the procedure to opt out of further contact, and whom to call for further information.

5.) Should study staff receive no reply within 10 days, 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 send them an opt-out letter and call 10 days later to inform them about the study. 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. In this phase, we will be contacting potential participants who were approached for the previous phases of REACH for Health, and who were interested in being contacted 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 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 the 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.

Participants also will be informed that they will receive a check for $40 after completing the week 12 follow-up assessment in addition to wearing and returning the step counter. Participants will receive an additional check for $60 after completing the week 24 follow-up assessment and returning a second worn step counter. Participants must return the step counter in good condition and with at least 5 days of usable data in order for remuneration to be appropriated. For tax reasons, a social security number is required in order to issue the full $100. However, if a participant is uncomfortable giving that information, they can be compensated with a $50 check after the completion of both follow-up assessments. 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 a 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

Participants will be randomized to receive one of three conditions: (1) the PP-based intervention, (2) an MI-based educational control condition, or (3) TAU. They will be randomized by a random-number generator and will be assigned a condition after Actigraph data is checked and has been found to be adequate at in-hospital Visit #2. The research assistant (RA)/blinded assessor who will conduct the follow-up assessments will be blind to the study condition. The interventionist and subjects will not be blind to the study condition.

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 (for those recruited inpatient), in an office on the MGH main campus (for those recruited via opt-out letter), or over the phone (if a participant prefers to not come to the hospital for an in-person visit). Height and weight will be recorded (measured in person or taken from the medical record if inpatient). Participants then will meet with a member of the study staff (the study "trainer") and complete self-report questionnaires. These questionnaires assess state optimism (State Optimism Measure; SOM), general optimism (Life Orientation Test-Revised; LOT-R),[56] anxiety/depression (Hospital Anxiety and Depression Scale; HADS),[57] positive emotions (Positive and Negative Affect Schedule; PANAS),[65] HRQoL (Medical Outcomes Study; MOS, Short Form-12; SF-12),[58] cardiac symptoms and heart failure-related QoL (Kansas City Cardiomyopathy Questionnaire; KCCQ),[59,60] medication adherence (Self-Reported Medication Adherence [adapted from the Heart and Soul Study]; SRMA),[61] and sodium intake (Scored Sodium Questionnaire; SSQ).[62] Participants will also answer questions about their alcohol (using the AUDIT-C)[63] and cigarette use. In sum, these scales should take approximately 30 minutes to complete.

After completing the baseline questionnaires, 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 12 and 24-week assessments (we will send participants the ActiGraph in the mail at the appropriate time). In contrast to the pedometer, which is used by 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 a time for the participant to come in for the second in person visit one week after the initial visit. In total this initial visit will take approximately 45 minutes.

Second Visit (Week 2; in person).

At the second in person visit, which will take place one week after the initial visit, we will collect the Actigraph from participants, and check to ensure participants had at least 5 valid days of data. At this point, participants will be randomized to one of the three conditions noted above. Patients in the TAU group will receive no further intervention and will be scheduled for a follow-up appointment in 12 weeks. Participants in the PP and goal-setting or MI-only conditions will be provided with a manual corresponding to their treatment condition, as well as a copy of *Learning to Live with Heart Failure*,[65] a practical guide which is provided by MGH to all HF patients admitted to a cardiology unit at MGH.

PP and goal-setting intervention: 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.

MI-based educational intervention: Participants in the MI-only control group will similarly have the rationale of the MI-based health behavior program explained to them, and will be assigned the first exercise. They also will be given a pedometer for their personal use. We estimate that this portion of the visit will take approximately 20 minutes.

PP-based Health Behavior Intervention:

Weekly phone sessions (Weeks 1-12). All participants will be asked to complete 12 weekly PP exercises and will be asked to speak with a study trainer weekly. In addition, in the final week, 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 45 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 goal-setting portions of the program 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 four-week modules focusing on a different psychological state:

Module 1: Gratitude-based activities

Session 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.

Session 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.

Session 3: Capitalizing on positive events. [66,67]
Participants identify three good events 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.

Session 4: Integrating gratitude-based activities into daily life.
Participants work to integrate one or more of the gratitude-based skills into their daily lives over the course of the week.

Module 2: Strength-based activities

Session 5: 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.

Session 6: Using personal strengths, part 1.[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.

Session 7: Using personal strengths, part 2.[33]
Participants choose a second personal strength that is important to them and then find a new way to use that strength over the following week.

Session 8: 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

Session 9: Enjoyable and meaningful activities.[68]
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.

Session 10: Performing acts of kindness.
Participants complete three acts of kindness. 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 acts made them feel.

Session 11: The "Good Life". [69]
Participants write about their ideal life over the next year in one or more life domains.

Session 12: Integrating meaning-based activities into daily life.
Participants work to perform enjoyable and meaningful acts for themselves and others in daily life.

Wrap-up session: 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 four-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: Increasing physical activity

Session 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.

Session 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.

Session 3: Barriers and problem-solving related to physical activity.
Participants will discuss ways to problem solve around barriers to physical activity.

Session 4: Reviewing and reflecting on physical activity.
Participants will reflect on their physical activity in the past few weeks and their progress to their overall physical activity goal. Based on their experience, they will revise their overall physical activity goal, if needed. Finally, participants will be mailed a graph of their weekly step counts to date.

Module 2: Maintaining gains related to physical activity

Session 5: Finding new routes.
Participants will explore their neighborhood and brainstorm new places to walk

Session 6: Using resources and making small changes.
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.

Participants also will think of ways to introduce small amounts of physical activity into their daily schedules.

Session 7: Continuing progress and managing slips.
Participants will learn about managing 'slips' or times when they get off track from their goals.

Session 8: Reviewing and reflecting on physical activity.
Participants will reflect on their physical activity in the past few weeks and their progress to their overall physical activity goal. Based on their experience, they will revise their overall physical activity goal, if needed. Finally, participants will be mailed a graph of their weekly step counts to date.

Module 3: Other important healthy behaviors

Session 9: 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.

Session 10: 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.

Session 11: 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.

Session 12: Medication adherence and resources.
The trainer will review with participants the importance of medication adherence, as well as participants' current medication adherence. 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

Session 13: 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. Finally, participants will be mailed a graph of their weekly step counts to date.

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,[65] 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 7 PP exercises / goal-setting sessions. In other words, if a participant completes at least 7 sessions, missed sessions will not be considered a deviation from the protocol.

MI-based educational control condition:
The MI-based educational intervention was selected as the active control condition for several reasons. The inclusion of MI and education regarding key cardiac health behaviors aims to increase the retention of participants included in this condition. However, the focus of this intervention on multiple health behaviors and the lack of specific goal-setting make it less likely that this control intervention will significantly impact physical activity (our primary health behavior outcome) and our other health behaviors of interest. Finally, as an attentional control, it has a parallel structure to the experimental arm with a treatment manual, weekly exercises, and weekly calls to review exercises.

Each week, participants will learn about a different health behavior topic related to cardiac health. They will also be introduced to motivational interviewing topics in concert with the health behavior education topics. The intervention is divided into five sections, focusing on five different important cardiac health-related topics:

<u>Part One: A Healthy Heart</u>

Understanding Heart Disease and Its Risks *(Session 1)*
Participants will review information about heart disease, including HF, as well as information about heart disease and its associated risk factors.

How to Take Care of Your Heart *(Session 2)*
Participants will review information about the importance of health behaviors to reduce the risk of heart disease.

<u>Part Two: Staying Active</u>

The Importance of Staying Active *(Session 3)*
Participants will review the cardiovascular benefits of physical activity, questions to ask their physician prior to starting physical activity, and ways to set goals related to physical activity.

How You Can Stay Active *(Session 4)*
Participants will identify one way in which they wish to change their physical activity. They will discuss the importance of making the change and their confidence about being able to do so. Finally, they will create a list of pros and cons for behavior change.

Barriers to and Resources for Activity *(Session 5)*

Participants will identify barriers to physical activity in their life and brainstorm ways to problem-solve around those barriers. Furthermore, they will identify social, community-based, and equipment resources available to help them with physical activity.

Part Three: Heart-healthy Diet

Benefits of a Heart-Healthy Diet *(Session 6)*

Participants will learn about the cardiovascular benefits of a heart-healthy diet. They will be encouraged to track their food intake over the next week to learn more about their diet.

Reducing Sodium *(Session 7)*

Participants will learn about the importance of reducing sodium in their diet. Next, they will identify one way in which they wish to change their diet. They will discuss the importance of making the change and their confidence about being able to do so. Finally, they will create a list of pros and cons for behavior change.

Barriers to and Resources for a Heart-healthy Diet *(Session 8)*

Participants will review how to properly read a food label and learn techniques to make healthy decisions while food shopping. They also will identify barriers to a healthy diet, problem-solve those barriers, and identify resources that can help to improve their diet.

Part Four: Taking Medications

Taking Medications Regularly *(Session 9)*

Participants will review the importance of medication adherence and learn about medications typically prescribed for HF. Participants will be encouraged to create a list of their current medications, as well as any questions they have for their physicians about their medications.

Barriers to and Resources for Taking Medications Regularly *(Session 10)*

Participants will identify barriers to taking medications, problem-solve those barriers, and identify resources to help them maintain adherence to medications.

Part Five: Stress Reduction

How Relaxation Can Help Your Heart *(Session 11)*

Participants will learn about the risks of acute and chronic stress. They will learn to recognize their reactions to stress and will be introduced to methods for relieving stress.

How to Practice Relaxation Regularly *(Session 12)*

Participants will learn about relaxation response exercises and ways to incorporate these exercises into daily life.

Planning for the Future *(Session 13)*

Participants will review the information learned over the course of the program and think of ways to remain healthy after the end of the program.

Treatment as Usual (TAU):

Participants in the TAU group will not receive any interventions between the baseline visit and follow-up visits. The inclusion of this group will allow us to examine the overall impact of the PP-based intervention compared to TAU, as well as its impact compared to an active comparator.

Follow Ups:

Follow-up phone calls (Week 12 and Week 24 [post randomization]). At Weeks 12 and 24, a member of the study staff will call participants to repeat the self-report questionnaires that were administered at baseline. These questionnaires assess state optimism (State Optimism Measure; SOM), general optimism (LOT-R), positive affect (PANAS), overall health behavior adherence (MOS), anxiety/depression (HADS), HRQoL (SF-12), cardiac symptoms and HF-related QoL (KCCQ), medication adherence (SRMA), and sodium intake (SSQ). Participants will also be asked about cardiac-related hospital readmissions and cardiac rehabilitation, and to rate their overall satisfaction with the treatment they received for their cardiac condition over the course of the study 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) has 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,[33,66,68,70,71] 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 will engage in several training exercises prior to study initiation. He will review the treatment manual and our team's prior training manuals related to these exercises. He will then complete all exercises to gain experience performing and reviewing each exercise.

Dr. Celano also has 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. This study utilizes a nearly identical MI-based control condition, with which Dr. Celano has experience. Both the goal-setting portion of the PP-based intervention and MI-based control condition aim to improve health behaviors that studies have shown to be critical for cardiac health in patients with HF.[6-12] Similar to his training related to the PP exercises, Dr. Celano will review the treatment manuals for this project and complete each exercise 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	Initial Visit	Second in Person Visit	Phone Sessions (12 weeks)	Follow-up Phone Call (Week 12)	Follow-up Phone Call (Week 24)
Cognitive screen	X					

Chart review to confirm eligibility	X					
Assessment of inclusion criteria (MOS, NYHA class)	X					
Chart review for baseline characteristics		X				
Randomization to PP or Control Condition			X			
Weekly intervention exercises*			X	X		
Exercise ratings			X	X		
Self-report measures (SSQ, SRMA, MOS, LOT-R, PANAS, HADS, KCCQ, SF-12, SOM)		X			X	X
Objective adherence data (ActiGraph step counter)		X			X	X
Satisfaction with Care					X	X
Hospital Readmissions					X	X

*Type of exercise assigned will depend on whether participant is in PP-MI or control condition

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, SSQ, SOM, 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 visit and prior to in-person visit #2 to measure their baseline physical activity.

Baseline information about enrolled participants will also be obtained from the participants, care providers, and electronic medical record as required for characterization of our population. This information will include data regarding medical history (history of coronary artery disease, acute coronary syndrome, coronary artery bypass graft, hypertension, diabetes mellitus, hyperlipidemia, body mass index, height, weight, 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, education). 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 7 of 12 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[72,73] 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.[74,75] 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.[76,77] In this trial, participants will wear the accelerometer (for 1 week at baseline and 1 week at each follow-up time point) to assess the feasibility of doing so, ensure adequate capture of physical activity, and examine the impact of the intervention on this health behavior. We will measure the number of steps taken daily and the amount of time spent in moderate to vigorous physical activity (MVPA) to examine the impact of the intervention on these important outcomes. 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.[61]

(c) Dietary adherence. We will assess sodium intake over the past month using the Scored Sodium Questionnaire (SSQ).[62] 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.[62] 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 12 and 24-week follow ups.

(d) Self-reported adherence. We will assess self-reported adherence using the MOS[51] 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 has been used in multiple prior studies assessing adherence in cardiac patients, including our own studies in this population.[40,52,53]

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) Optimism will be measured using the Life Orientation Test-Revised (LOT-R), a well-validated 6-item instrument, and the State Optimism Measure (SOM). Dispositional optimism is the positive psychological state most linked to cardiac outcomes,[23,78,79] and the LOT-R has been used to measure optimism in many studies of cardiac patients.[80-82] Though dispositional optimism theoretically would be stable over time, research suggests that LOT-R scores can change quickly in response to psychological interventions.[38,83,84] We also will be using a short scale developed by our team (SOM) to measure state optimism.

(b) Positive affect (primary psychological outcome measure) will be measured using the positive affect items on the Positive and Negative Affect Schedule (PANAS),[85] a well-validated scale used in other intervention trials and in patients with HF.[86,87]

(c) Anxiety and depression will be measured using the anxiety and depression subscales of the Hospital Anxiety and Depression Scale (HADS).[88] This well-validated scale has been used in many studies of patients with heart disease (including our group's studies),[38,40,88-90] 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.[59] 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[59,60] and is strongly correlated with NYHA class.[60] 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),[58] an instrument which has been used in multiple cardiac studies in the past, including our work.[38,40,83,91-96] The SF-12 also is a reliable marker of QoL in HF[97] and has been associated with mortality in this high-risk cohort.[98]

VI. BIOSTATISTICAL ANALYSIS

A and B. Specific data variables and study endpoints

Aim #1 (*Feasibility [primary outcome]*, acceptability, and immediate impact): To assess whether PP exercises administered over the phone are feasible, acceptable, and lead to improvements in positive affect and optimism in patients with NYHA class I-III HF.

Measures:

- Rates of completion of exercises (recorded by study trainer).
- Successful use of ActiGraph accelerometer.
- Patient rating of immediate outcomes on 10-point Likert scale: Ease of completion, overall utility, change in positive affect and optimism from pre- to post-exercise.

The intervention will be considered feasible if ≥7 of the 12 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 one of the follow-up time points. 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 positive affect and optimism significantly higher post-exercise than pre-exercises across exercises (via mixed linear models).

Aim #2 (*overall impact on psychological health*): To examine the intervention's impact on both positive (positive affect, optimism) and negative (depression, anxiety) psychological health, compared to TAU and a MI-based educational control condition.

Measures:

- Optimism: LOT-R; SOM
- Positive affect: PANAS (primary outcome measure for this aim)
- Anxiety/depression: HADS

We will examine between-group differences (PP-based condition vs. MI-informed educational control and PP-based condition vs. TAU) on changes in each of these psychological outcomes to assess the impact of the intervention compared to both an active control and TAU. The primary study endpoint will be 12 weeks, though we will secondarily assess the impact of the intervention on outcomes at 24 weeks as well.

Aim #3 (*Impact on functional outcomes and health behaviors*): To examine the impact of the intervention on physical activity (steps, as measured by accelerometer; primary health behavior outcome), medication adherence, sodium intake, HF-related QoL, and generic HRQoL, compared to treatment as usual and an MI-based health behavior education intervention.

Measures:

- HF-related QoL: KCCQ
- HF symptoms: KCCQ subscale
- Health related quality of life: SF-12
- Self-reported adherence: MOS
- Physical activity: ActiGraph accelerometer
- Medication adherence: SRMA
- Sodium intake: SSQ

We will examine between-group differences (PP-based condition vs. MI-informed educational control and PP-based condition vs. TAU) on changes in functional outcomes and health behaviors to assess the impact of the intervention compared to both an active control and TAU.

C. Statistical methods

Data will be downloaded from REDCap into the Stata statistical package. For Aim 1 (feasibility, acceptability), descriptive statistics will be used to report proportion of exercise completion and mean scores on exercise ratings of ease and utility. To examine the immediate impact of the intervention on positive affect and optimism, we will use linear mixed models (to account for within-person correlations) to examine the improvement in these scores from pre- to post-exercise.

For our secondary aims, we will initially compare physical activity (# of steps/day) at 12 and 24 weeks between groups using a Wilcoxon rank sum test, given that the distribution of the number of steps will likely be skewed. In addition, we will compare between-group differences in change over time in all self-report measures (including psychological, functional, and health behavior outcomes) at the 12 and 24-week time points using random effects regression models with a random intercept for each patient. All statistical tests will be two-tailed, with $p<.05$ considered significant.

D. Power analysis

We have performed power analyses assuming 20 participants in each group. To account for potential drop outs between enrollment and randomization, we will enroll 75 participants with a goal of randomizing 60. This pilot trial is not designed to detect significant between-group differences in 12- or 24-week health behavior outcomes, but is powered to meet our primary aims of feasibility and immediate impact. For feasibility, 75-80% of subjects have completed the majority of PP exercises in our prior work, and 90% completed the majority of PP exercises in our proof-of-concept trial in patients with HF. With 20 PP participants, we will have at least 80% power to detect a difference between our expected proportion of participants completing at least 5 out of 8 PP exercises (80%) and the null hypothesis (true proportion of 50% or less) at the

two sided 0.05 level using a binomial proportion test. In a prior study, we found that PP interventions led to a moderate (*d*=.52) improvement in optimism immediately post-exercise.[99] If we assume completion of ~140 exercises from 20 subjects and a within-person correlation of 0.5 for change in pre-/post- ratings across exercises, our proposed study is powered at over 80% to detect a similar effect size improvement of optimism immediately post-exercise at the two-sided 0.05 level.

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. We are using an accelerometer and step-counter 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 Omron pedometer which we will provide participants to use in self-monitoring similarly poses minimal risk, given that it has no sharp edges, no shock risk, and no other known risks.

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 or other study staff member) will liaise with participants regarding any battery problems or technical advice on the Actigraph accelerometer, step counter, and related equipment. 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 or Omron technical support to resolve any device issues. A log of all technical difficulties will be maintained.

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, co-investigators delivering the intervention, 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 a research team office.

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.

Partners Healthcare has an electronic system that lets study doctors know if participants are admitted to a Partners Hospital, or if a participant visits a Partners Hospital Emergency Department. This allows study doctors to know about any possible problems or side effects a participant experiences while taking part in the study.

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. As with any program which promotes an increase in physical activity, there is an inherent potential physical risk imposed (e.g., falls, worsening cardiac symptoms). For those who enroll in the program and give us permission to communicate with their clinician, we will inform the clinician of their patient's participation and offer to speak to them if they have any concerns or recommendations about setting goals related to physical activity or other health behaviors. 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

Though it is possible that participants will not receive benefit from participation, they also may benefit significantly. Participants in the PP-based intervention 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. Furthermore, participants in the PP-based health behavior intervention will be provided with information regarding health behaviors and will be encouraged to set goals related to physical activity, dietary adherence, and medication adherence. These participants may make significant health behavior changes, which could help them feel better physically and reduce their risk for complications related to their heart disease.

Participants receiving the MI-based health behavior education intervention also may benefit from the educational information provided to them and the MI-based intervention. Like those individuals in the PP-based intervention, participants receiving MI may improve their health behaviors, which could lead to significant improvements in physical health and function.

Finally, participants in the TAU group also may receive some benefits. Contact with study trainers and the systematic follow-up assessments may also provide support and social connection for participants with significant medical illness. This may be an improvement over no such contact or systematic evaluation, as is current standard practice.

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, journal clubs are held with the study team regularly; 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., ensuring study databases have no personal identifying information, using 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 pilot trial to determine if all aspects of the protocol are feasible, acceptable, and effective. After 12 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 60 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.

IX. REFERENCES

1. Lloyd-Jones D, Adams RJ, Brown TM, et al. Heart disease and stroke statistics--2010 update: a report from the American Heart Association. Circulation 2010;121:e46-e215.
2. Celano CM, Huffman JC. Depression and cardiac disease: a review. Cardiology in Review 2011;19:130-42.
3. Chen J, Normand SL, Wang Y, Krumholz HM. National and regional trends in heart failure hospitalization and mortality rates for Medicare beneficiaries, 1998-2008. JAMA 2011;306:1669-78.
4. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2011 update: a report from the American Heart Association. Circulation 2011;123:e18-e209.
5. Coelho R, Ramos S, Prata J, Bettencourt P, Ferreira A, Cerqueira-Gomes M. Heart failure and health related quality of life. Clin Pract Epidemiol Ment Health 2005;1:19.
6. O'Connor CM, Whellan DJ, Lee KL, et al. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA 2009;301:1439-50.
7. Wright SP, Walsh H, Ingley KM, et al. Uptake of self-management strategies in a heart failure management programme. Eur J Heart Fail 2003;5:371-80.
8. Belardinelli R, Georgiou D, Cianci G, Purcaro A. Randomized, controlled trial of long-term moderate exercise training in chronic heart failure: effects on functional capacity, quality of life, and clinical outcome. Circulation 1999;99:1173-82.
9. Wu JR, Moser DK, Lennie TA, Burkhart PV. Medication adherence in patients who have heart failure: a review of the literature. Nurs Clin North Am 2008;43:133-53; vii-viii.
10. Pina IL, Apstein CS, Balady GJ, et al. Exercise and heart failure: A statement from the American Heart Association Committee on exercise, rehabilitation, and prevention. Circulation 2003;107:1210-25.
11. Arcand J, Ivanov J, Sasson A, et al. A high-sodium diet is associated with acute decompensated heart failure in ambulatory heart failure patients: a prospective follow-up study. Am J Clin Nutr 2011;93:332-7.
12. Lennie TA, Song EK, Wu JR, et al. Three gram sodium intake is associated with longer event-free survival only in patients with advanced heart failure. J Card Fail 2011;17:325-30.
13. Corotto PS, McCarey MM, Adams S, Khazanie P, Whellan DJ. Heart failure patient adherence: epidemiology, cause, and treatment. Heart Fail Clin 2013;9:49-58.
14. Lemon SC, Olendzki B, Magner R, et al. The dietary quality of persons with heart failure in NHANES 1999-2006. J Gen Intern Med 2010;25:135-40.
15. Ni H, Nauman D, Burgess D, Wise K, Crispell K, Hershberger RE. Factors influencing knowledge of and adherence to self-care among patients with heart failure. Arch Intern Med 1999;159:1613-9.

16. Carlson B, Riegel B, Moser DK. Self-care abilities of patients with heart failure. Heart Lung 2001;30:351-9.
17. Ditewig JB, Blok H, Havers J, van Veenendaal H. Effectiveness of self-management interventions on mortality, hospital readmissions, chronic heart failure hospitalization rate and quality of life in patients with chronic heart failure: a systematic review. Patient Educ Couns 2010;78:297-315.
18. Grady KL. Self-care and quality of life outcomes in heart failure patients. J Cardiovasc Nurs 2008;23:285-92.
19. Phillips CO, Singa RM, Rubin HR, Jaarsma T. Complexity of program and clinical outcomes of heart failure disease management incorporating specialist nurse-led heart failure clinics. A meta-regression analysis. Eur J Heart Fail 2005;7:333-41.
20. Grady KL, de Leon CF, Kozak AT, et al. Does self-management counseling in patients with heart failure improve quality of life? Findings from the Heart Failure Adherence and Retention Trial (HART). Qual Life Res 2013;23:31-8.
21. Chida Y, Steptoe A. Positive psychological well-being and mortality: a quantitative review of prospective observational studies. Psychosom Med 2008;70:741-56.
22. Rasmussen HN, Scheier MF, Greenhouse JB. Optimism and physical health: a meta-analytic review. Ann Behav Med 2009;37:239-56.
23. Tindle HA, Chang YF, Kuller LH, et al. Optimism, cynical hostility, and incident coronary heart disease and mortality in the Women's Health Initiative. Circulation 2009;120:656-62.
24. Giltay EJ, Geleijnse JM, Zitman FG, Hoekstra T, Schouten EG. Dispositional optimism and all-cause and cardiovascular mortality in a prospective cohort of elderly Dutch men and women. Arch Gen Psychiatry 2004;61:1126-35.
25. Kubzansky LD, Thurston RC. Emotional vitality and incident coronary heart disease: benefits of healthy psychological functioning. Archives of General Psychiatry 2007;64:1393-401.
26. Giltay EJ, Geleijnse JM, Zitman FG, Buijsse B, Kromhout D. Lifestyle and dietary correlates of dispositional optimism in men: The Zutphen Elderly Study. J Psychosom Res 2007;63:483-90.
27. Kelloniemi H, Ek E, Laitinen J. Optimism, dietary habits, body mass index and smoking among young Finnish adults. Appetite 2005;45:169-76.
28. Tinker LF, Rosal MC, Young AF, et al. Predictors of dietary change and maintenance in the Women's Health Initiative Dietary Modification Trial. J Am Diet Assoc 2007;107:1155-66.
29. Browning C, Sims J, Kendig H, Teshuva K. Predictors of physical activity behavior in older community-dwelling adults. Journal of Allied Health 2009;38:8-17.
30. Steptoe A, Wright C, Kunz-Ebrecht SR, Iliffe S. Dispositional optimism and health behaviour in community-dwelling older people: associations with healthy ageing. British Journal of Health Psychology 2006;11:71-84.
31. Leedham B, Meyerowitz BE, Muirhead J, Frist WH. Positive expectations predict health after heart transplantation. Health Psychol 1995;14:74-9.
32. Seligman ME, Rashid T, Parks AC. Positive psychotherapy. American Psychologist 2006;61:774-88.
33. Seligman ME, Steen TA, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. American Psychologist 2005;60:410-21.

34. Bolier L, Haverman M, Westerhof GJ, Riper H, Smit F, Bohlmeijer E. Positive psychology interventions: a meta-analysis of randomized controlled studies. BioMed Central Public Health 2013;13:119.
35. Sin NL, Lyubomirsky S. Enhancing well-being and alleviating depressive symptoms with positive psychology interventions: a practice-friendly meta-analysis. Journal of Clinical Psychology 2009;65:467-87.
36. Ogedegbe GO, Boutin-Foster C, Wells MT, et al. A randomized controlled trial of positive-affect intervention and medication adherence in hypertensive African Americans. Arch Intern Med 2012;172:322-6.
37. Peterson JC, Charlson ME, Hoffman Z, et al. A randomized controlled trial of positive-affect induction to promote physical activity after percutaneous coronary intervention. Arch Intern Med 2012;172:329-36.
38. Huffman JC, Mastromauro CA, Boehm JK, et al. Development of a positive psychology intervention for patients with acute cardiovascular disease. Heart International 2011;6:e14.
39. Huffman JC, Millstein RA, Mastromauro CA, et al. A positive psychology intervention for patients with an acute coronary syndrome: treatment development and proof-of-concept trial. J Happiness Stud 2015:1-22.
40. Huffman JC, Mastromauro CA, Sowden GL, Fricchione GL, Healy BC, Januzzi JL. Impact of a depression care management program for hospitalized cardiac patients. Circ Cardiovasc Qual Outcomes 2011;4:198-205.
41. Huffman JC, Mastromauro CA, Sowden GL, Wittmann C, Rodman R, Januzzi JL. A collaborative care depression management program for cardiac inpatients: depression characteristics and in-hospital outcomes. Psychosomatics 2011;52:26-33.
42. Celano CM, Suarez L, Mastromauro C, Januzzi JL, Huffman JC. Feasibility and utility of screening for depression and anxiety disorders in patients with cardiovascular disease. Circulation: Cardiovascular Quality and Outcomes 2013;6:498-504.
43. Huffman JC, Beale EE, Celano CM, et al. Effects of Optimism and Gratitude on Physical Activity, Biomarkers, and Readmissions After an Acute Coronary Syndrome. The Gratitude Research in Acute Coronary Events Study 2016;9:55-63.
44. Huffman JC, DuBois CM, Mastromauro CA, Moore SV, Suarez L, Park ER. Positive psychological states and health behaviors in acute coronary syndrome patients: a qualitative study. J Health Psychol 2014;21:1026-36.
45. Rasmussen HN, Scheier MF, Greenhouse JB. Optimism and physical health: a meta-analytic review. Ann Behav Med 2009;37:239-56.
46. Tacon AM, McComb J, Caldera Y, Randolph P. Mindfulness meditation, anxiety reduction, and heart disease: a pilot study. Fam Community Health 2003;26:25-33.
47. Dusek JA, Hibberd PL, Buczynski B, et al. Stress management versus lifestyle modification on systolic hypertension and medication elimination: a randomized trial. Journal of Alternative and Complementary Medicine 2008;14:129-38.
48. Charlson ME, Boutin-Foster C, Mancuso CA, et al. Randomized controlled trials of positive affect and self-affirmation to facilitate healthy behaviors in patients with cardiopulmonary diseases: rationale, trial design, and methods. Contemp Clin Trials 2007;28:748-62.
49. Fredrickson BL. The role of positive emotions in positive psychology. The broaden-and-build theory of positive emotions. Am Psychol 2001;56:218-26.

50. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. Boston: Little, Brown & Co; 1994.
51. DiMatteo MR, Hays RD, Sherbourne CD. Adherence to cancer regimens: implications for treating the older patient. Oncology 1992;6:50-7.
52. Ziegelstein RC, Fauerbach JA, Stevens SS, Romanelli J, Richter DP, Bush DE. Patients with depression are less likely to follow recommendations to reduce cardiac risk during recovery from a myocardial infarction. Arch Intern Med 2000;160:1818-23.
53. Bauer LK, Caro MA, Beach SR, et al. Effects of depression and anxiety improvement on adherence to medication and health behaviors in recently hospitalized cardiac patients. Am J Cardiol 2012;109:1266-71.
54. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. Medical Care 2002;40:771-81.
55. Research Information Services & Computing: Research Patient Data Registry. (Accessed June 3, 2016, 2016, at https://rpdrssl.partners.org/partners/rpdrinfo/home/overview.htm.)
56. Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the Life Orientation Test. J Pers Soc Psychol 1994;67:1063-78.
57. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-70.
58. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Medical Care 1996;34:220-33.
59. Green CP, Porter CB, Bresnahan DR, Spertus JA. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. J Am Coll Cardiol 2000;35:1245-55.
60. Garin O, Herdman M, Vilagut G, et al. Assessing health-related quality of life in patients with heart failure: a systematic, standardized comparison of available measures. Heart failure reviews 2014;19:359-67.
61. Gehi AK, Ali S, Na B, Whooley MA. Self-reported medication adherence and cardiovascular events in patients with stable coronary heart disease: the heart and soul study. Arch Intern Med 2007;167:1798-803.
62. Mason B, Ross L, Gill E, Healy H, Juffs P, Kark A. Development and validation of a dietary screening tool for high sodium consumption in Australian renal patients. J Ren Nutr 2014;24:123-34 e1-3.
63. Bradley KA, DeBenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR. AUDIT-C as a brief screen for alcohol misuse in primary care. Alcohol Clin Exp Res 2007;31:1208-17.
64. Kelly LA, McMillan DG, Anderson A, Fippinger M, Fillerup G, Rider J. Validity of actigraphs uniaxial and triaxial accelerometers for assessment of physical activity in adults in laboratory conditions. BMC Med Phys 2013;13:5.
65. Learning to Live with Heart Failure. Chapel Hill, NC: University of North Carolina; 2016.
66. Moskowitz JT, Hult JR, Duncan LG, et al. A positive affect intervention for people experiencing health-related stress: development and non-randomized pilot test. J Health Psychol 2012;17:676-92.
67. Langston CA. Capitalizing on and coping with daily-life events: Expressive responses to positive events. J Pers Soc Psychol 1994;67:1112.

68. Krumholz HM, Peterson ED, Ayanian JZ, et al. Report of the National Heart, Lung, and Blood Institute working group on outcomes research in cardiovascular disease. Circulation 2005;111:3158-66.
69. Schueller SM, Parks AC. Disseminating self-help: positive psychology exercises in an online trial. J Med Internet Res 2012;14:e63.
70. Gander F, Proyer RT, Ruch W, Wyss T. Strength-based positive interventions: Further evidence for their potential in enhancing well-being and alleviating depression. J Happiness Stud 2013;14:1241-59.
71. Emmons RA, McCullough ME. Counting blessings versus burdens: an experimental investigation of gratitude and subjective well-being in daily life. J Pers Soc Psychol 2003;84:377-89.
72. O'Connor CM, Whellan DJ, Wojdyla D, et al. Factors related to morbidity and mortality in patients with chronic heart failure with systolic dysfunction: the HF-ACTION predictive risk score model. Circ Heart Fail 2012;5:63-71.
73. Passantino A, Lagioia R, Mastropasqua F, Scrutinio D. Short-term change in distance walked in 6 min is an indicator of outcome in patients with chronic heart failure in clinical practice. J Am Coll Cardiol 2006;48:99-105.
74. Westerterp KR. Assessment of physical activity level in relation to obesity: current evidence and research issues. Med Sci Sports Exerc 1999;31:S522-5.
75. Westerterp KR. Assessment of physical activity: a critical appraisal. European Journal of Applied Physiology 2009;105:823-8.
76. Welk G. Physical Activity Assessments for Health-related Research. Champaign, IL: Human Kinetics; 2002.
77. Copeland JL, Esliger DW. Accelerometer assessment of physical activity in active, healthy older adults. Journal of Aging and Physical Activity 2009;17:17-30.
78. Tindle H, Davis E, Kuller L. Attitudes and cardiovascular disease. Maturitas 2010;67:108-13.
79. Tindle H, Belnap BH, Houck PR, et al. Optimism, response to treatment of depression, and rehospitalization after coronary artery bypass graft surgery. Psychosomatic Medicine 2012;74:200-7.
80. Trivedi RB, Blumenthal JA, O'Connor C, et al. Coping styles in heart failure patients with depressive symptoms. J Psychosom Res 2009;67:339-46.
81. Carroll SL, Arthur HM. A comparative study of uncertainty, optimism and anxiety in patients receiving their first implantable defibrillator for primary or secondary prevention of sudden cardiac death. Int J Nurs Stud 2010;47:836-45.
82. Scheier MF, Matthews KA, Owens JF, et al. Optimism and rehospitalization after coronary artery bypass graft surgery. Archives of Internal Medicine 1999;159:829-35.
83. Huffman JC, DuBois CM, Mastromauro CA, et al. Positive psychological interventions in medical psychiatry patients. Academy of Psychosomatic Medicine Annual Meeting. Atlanta, GA2012.
84. Meevissen YM, Peters ML, Alberts HJ. Become more optimistic by imagining a best possible self: effects of a two week intervention. Journal of Behavior Therapy and Experimental Psychiatry 2011;42:371-8.
85. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol 1988;54:1063-70.

86. McClure JB, Ludman E, Grothaus L, Pabiniak C, Richards J, Mohelnitzky A. Immediate and short-term impact of a brief motivational smoking intervention using a biomedical risk assessment: the Get PHIT trial. Nicotine & Tobacco Research 2009;11:394-403.
87. Brouwers C, Mommersteeg PM, Nyklicek I, et al. Positive affect dimensions and their association with inflammatory biomarkers in patients with chronic heart failure. Biol Psychol 2013;92:220-6.
88. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the hospital anxiety and depression scale. An updated literature review. Journal of psychosomatic research 2002;52:69-77.
89. Frasure-Smith N, Lesperance F. Depression and anxiety as predictors of 2-year cardiac events in patients with stable coronary artery disease. Archives of General Psychiatry 2008;65:62-71.
90. Turner A, Phillips L, Hambridge JA, Baker AL, Bowman J, Colyvas K. Clinical outcomes associated with depression, anxiety and social support among cardiac rehabilitation attendees. Aust N Z J Psychiatry 2010;44:658-66.
91. Lim LL, Fisher JD. Use of the 12-item short-form (SF-12) Health Survey in an Australian heart and stroke population. Quality of Life Research 1999;8:1-8.
92. Maurer MS, Cuddihy P, Weisenberg J, et al. The prevalence and impact of anergia (lack of energy) in subjects with heart failure and its associations with actigraphy. J Card Fail 2009;15:145-51.
93. Muller-Nordhorn J, Roll S, Willich SN. Comparison of the short form (SF)-12 health status instrument with the SF-36 in patients with coronary heart disease. Heart 2004;90:523-7.
94. Ni H, Toy W, Burgess D, et al. Comparative responsiveness of Short-Form 12 and Minnesota Living With Heart Failure Questionnaire in patients with heart failure. J Card Fail 2000;6:83-91.
95. Thombs BD, Ziegelstein RC, Stewart DE, Abbey SE, Parakh K, Grace SL. Usefulness of persistent symptoms of depression to predict physical health status 12 months after an acute coronary syndrome. American Journal of Cardiology 2008;101:15-9.
96. Wootton R, Gramotnev H, Hailey D. A randomized controlled trial of telephone-supported care coordination in patients with congestive heart failure. J Telemed Telecare 2009;15:182-6.
97. Bennett SJ, Oldridge NB, Eckert GJ, et al. Comparison of quality of life measures in heart failure. Nurs Res 2003;52:207-16.
98. Chamberlain AM, McNallan SM, Dunlay SM, et al. Physical health status measures predict all-cause mortality in patients with heart failure. Circ Heart Fail 2013;6:669-75.
99. Huffman JC, Dubois CM, Healy BC, et al. Feasibility and utility of positive psychology exercises for suicidal inpatients. General Hospital Psychiatry 2014;36:88-94.