

Positive psychology for acute coronary syndrome patients: a randomized, controlled pilot trial

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I. Background and significance

A. Historical background

Preventing medical events is a critical public health concern, and health behaviors play a major role in such prevention. A key example of the importance of health behaviors is the secondary prevention of recurrent cardiovascular events in patients suffering an acute coronary syndrome (ACS). Each year, 1.3 million Americans suffer an ACS (myocardial infarction [MI] or unstable angina [UA]).¹ Among post-ACS patients, 20% will be re-hospitalized for ischemic heart disease in the next year,² and approximately the same proportion will die within a year of their initial event.³ ACS patients are a cohort for whom healthy behavior can play a major role in preventing these potentially lethal recurrent events. Indeed, ACS patients who follow recommendations to increase physical activity, follow a low-fat diet, and adhere to evidence-based treatment regimens (e.g., aspirin, beta-blockers) are substantially less likely to suffer recurrent events or mortality.^{4,5}

Despite the clear importance of health behaviors in post-ACS patients, many do not adhere to these medical recommendations. Indeed, studies have found that the majority of ACS patients have non-adherence to at least one drug category in the year following their event,¹ and over 70% are non-adherent to diet and/or exercise recommendations post-ACS.^{4,6}

Psychological factors may play a substantial role in the poor adherence of this population. For example, depressive symptoms have been linked to non-adherence to diet, physical activity, medication, and other key secondary prevention measures in ACS patients,⁷ and milder forms of psychological distress (e.g., stress, mild anxiety) are also associated with limited adherence and/or adverse cardiac outcomes.⁸⁻¹¹ However, interventions that focus solely on the treatment of negative emotional states have not consistently resulted in improved adherence or reduced cardiac events.¹²⁻¹⁴

Conversely, positive psychological states, such as optimism, have been associated with greater adherence to healthy behaviors in persons with and without known heart disease.¹⁵⁻¹⁸ For example, studies in both younger and older adults have found optimists to be more likely to follow a heart-healthy diet than pessimists.^{19,20} Older adults with higher levels of optimism and/or positive health beliefs also have higher rates of physical activity than those with lower levels.^{18,20,21} Furthermore, patients with positive mood prior to cardiac transplant surgery are more likely to be adherent to a post-surgical medication regimen at 6 months.¹⁵

Possibly due to these effects on health behaviors, optimism, 'emotional vitality,' and other positive emotional states have also been prospectively associated with reductions in the incidence of coronary heart disease (CHD), cardiac mortality, and all-cause mortality.²²⁻²⁴ In patients with known heart disease, optimism, vigor, and well-being have been independently associated with fewer hospital readmissions in heart failure patients²⁵ and increased survival following cardiac surgery,²⁶ along with reduced mortality in patients with more broadly-defined CHD.¹⁷ Furthermore, the benefits of positive psychological states on cardiac outcomes appear to be independent of negative affective states, including depressive symptoms,^{27,28} suggesting that it

is not simply an absence of depression or anxiety that confers the cardiovascular benefit associated with positive emotions.

Clearly positive psychological states are important—but can they be cultivated or taught? Although a sizeable portion of happiness is explained by static factors (e.g., intrinsic disposition and external life events), it appears that approximately 40% of happiness is directly under one's own control,²⁹ and specific interventions can increase positive emotions and cognitions. In recent years, there is an emerging focus on *positive psychology (PP)*, a discipline that aims to improve the frequency and intensity of positive emotional experiences.^{30,31} Positive psychology interventions have focused on targeted activities in several domains, including altruism (e.g., performing acts of kindness), gratitude (e.g., systematically recalling positive life events), using one's personal strengths in a deliberate manner, and optimism (e.g., imagining positive future outcomes). Although some 'resiliency programs' in medical patients have included small components of these interventions with good effect,^{32,33} trials of positive psychology interventions in the medically ill have been exceedingly rare.³⁴ This represents a powerful opportunity to create an innovative treatment for post-ACS patients with the potential to improve health behaviors in a vulnerable population.

We postulate that positive psychology interventions have the potential to improve adherence to health behaviors by increasing optimism, motivation, and vitality. However, such interventions have not been attempted in this population prior to our pre-pilot work (see Preliminary Studies). Furthermore, there is still much to learn about the proper composition of positive psychology interventions when attempting to intervene in medically-ill patients and impact health behavior, a complex phenomenon. If we were to develop a feasible intervention that increases physical activity and other health behaviors in 'a high-risk post-ACS population, this could result in reduced cardiac events and mortality, giving it major public health significance.

To accomplish this, we completed 60 qualitative interviews with ACS patients (IRB #2011-P-002729) to better understand the experiences of this population and the connections between positive emotions and health behaviors. These interviews allowed us to develop a PP intervention targeted at improving adherence to health behaviors in patients with ACS, which we then tested in a single-arm, proof-of-concept trial (IRB # 2013P001961). This trial found the intervention to be feasible (74% of participants completed the majority of exercises) and compared to participants in the control condition, PP participants showed greater improvements in positive affect, anxiety, and depression.³⁵

We then set out to optimize our PP intervention for our target population (IRB #2014-P-001756). Using a factorial design, we: (a) assessed the optimal frequency of exercise completion, (b) determined the utility of 'booster sessions' after an initial 8-week intervention, and (c) determined the relative merits of utilizing PP exercises alone versus an intervention combining PP with motivational interviewing (MI).³⁶ Based on the results of this trial and our prior work, we created an optimized, 12-week, telephone-delivered, combined PP-MI intervention to increase physical activity in patients who experienced an ACS.

Our next step, as detailed in this protocol, is to test our optimized intervention in a randomized, controlled pilot trial.

B. Preliminary studies

Pilot trial of PP in patients with heart disease. Our team partnered with a national expert in PP (Sonja Lyubomirsky) to test PP interventions in patients with heart disease (IRB #2009P-002386). We created a treatment manual of established PP exercises related to gratitude, altruism, and optimism. The manual was used in a 3-arm, 8-week pilot study (N=26) in cardiac patients comparing a phone-based PP intervention to active (mindfulness)³⁷ and control (recollection)³⁸ conditions.

Methods. Eligible patients were those admitted to Massachusetts General Hospital (MGH) for an ACS or heart failure. Participants received a manual specific to their treatment arm, and study staff completed an exercise with participants in the hospital. The remainder of the treatment was completed post-discharge: each week, participants completed an exercise and read a section of the manual; exercises were reviewed with staff weekly in a 20 minute call.

Results. Across all groups, 70% of exercises were completed, with 77% completion in the PP group. Over 8 weeks, PP participants had greater improvements in depression, anxiety, and optimism than participants in the other two arms.³⁹

Relevance to proposed study. The methods, intervention, and outcome measures of this study were similar to those that will be used in this project, except that this project will be a two-arm trial in patients with ACS, include a PP plus MI intervention (instead of PP alone), use methods that have been refined and specifically adapted to ACS patients, and utilize expanded methods of health behavior and other outcome measurements.

Qualitative interviews in ACS patients. In this study, (IRB #2011-P-002729) we explored connections between positive psychological states and health behaviors in patients following an ACS.

Methods. We completed 32 in-hospital qualitative interviews and 28 follow-up interviews 3 months post-discharge of patients who were admitted to the hospital with an ACS. In these interviews, we explored barriers to completing health behaviors, the presence and nature of positive psychological states, and content and delivery of PP exercises. We also gathered baseline sociodemographic and medical information, as well as follow-up data regarding patients' self-reported adherence to health behaviors. All interviews were transcribed and analyzed using directed content analysis. Predictors of subsequent non-adherence to health behaviors also were identified.

Results. Post-ACS patients frequently expressed positive emotions. In qualitative interviews, both optimism and positive affect were associated with completion of physical activity and healthy eating in a bidirectional manner. In contrast, gratitude, while common, was infrequently linked to completion of health behaviors. Finally, higher levels of depression and lower levels of optimism and positive affect at baseline were predictive of subsequent nonadherence to health behaviors.⁴⁰

Relevance to proposed study. This study gave our team greater experience in recruiting inpatients following an ACS and successfully completing psychological and medical assessments by phone. Furthermore, it confirmed our hypotheses that positive psychological states and health behaviors are related. Finally, the results of this study helped to guide the development of our intervention (e.g., we shortened the intervention from a planned 12 weeks back to 8 weeks and included an exercise focused on past success).

PP for ACS: Proof-of-concept trial. This study was a one-arm, 8-week trial (IRB# 2013-P-001961) to test the feasibility of a PP intervention for patients recently admitted following ACS. The primary aim was to assess whether the intervention exercises were feasible and linked with immediate boosts in positive affect upon completion. The secondary goal was to assess whether the intervention impacted patients' psychological well-being at 8 weeks.

Methods. Participants completed questionnaires assessing positive psychological states, medical and functional status, and pre-admission health behaviors. Then they completed 8 weekly PP exercises, along with weekly phone calls with study staff to review the exercises. Finally, following the intervention, participants completed a follow-up assessment to assess for the same psychological, behavioral, and medical/functional states measured at baseline. We assessed the frequency of exercise completion and the pre/post exercise rating scales of positive states, as well as pre- and post-intervention psychological states, functional/medical states, and adherence to healthy diet, exercise, and medication behaviors.

Results. The intervention was feasible, as 74% of participants completed at least 5 out of 8 exercises, and the ease ($M = 7.4/10$; $SD = 2.1$) and utility ($M = 8.1/10$, $SD = 1.6$) of the intervention exercises were rated highly by participants.⁴¹ Additionally, compared to participants in a "treatment as usual" control condition, intervention participants showed greater improvements in positive affect, anxiety, and depression ($ds = .47-.71$).⁴¹

Relevance to proposed study. This study confirmed the feasibility of the intervention in terms of completion rates, and also demonstrated the intervention's effectiveness to improve psychological outcomes such as positive affect, anxiety, and depression. Lastly, this study provided the team with greater experience recruiting inpatients with an ACS, successfully completing intervention sessions, and administering psychological and medical assessments by phone.

Trajectory of positive psychological states in patients with ACS: A comparison study. We also completed an observational study (IRB #2014P-000945) to track the natural history of ACS patients' positive psychological states, behavioral adherence, and medical/functional outcomes following discharge. We aimed to evaluate whether the intervention in the proof-of-concept trial described above had effects above and beyond the natural progression of states in this cohort. To do this we enrolled a prospective comparison group of 25 ACS patients who did not receive the PP intervention. Participants completed the same self-report measures of psychological and medical health as in the proof-of-concept trial, at baseline and 8 weeks post-discharge.

Results: As mentioned above, intervention participants showed greater improvements in positive affect, anxiety, and depression ($ds = .47-.71$) compared to participants in this "treatment as usual" condition.⁴¹

Relevance to proposed study. In addition to providing our team greater experience recruiting ACS patients and assessing participants' mood and health status by phone, this study provided our team with knowledge about the natural trajectory of patients' positive emotions, health behaviors, and functioning in the hospital and then 8 weeks post-discharge. It also provided us with experience enrolling post-ACS patients into our studies and administering our outcome measures.

Positive psychology for acute coronary syndrome patients: a factorial design study. Next, we completed a study to optimize our PP intervention prior to testing it in a randomized, controlled trial. Using an 8-arm factorial trial design, we examined: (a) the optimal frequency of

PP exercise completion, (b) the utility of ‘booster sessions’ after an initial 8-week intervention, and (c) the relative merits of utilizing PP exercises alone versus an intervention combining PP with MI (PP/MI). Participants completed a minimum of 8 weekly intervention calls, with up to an additional three “booster” calls held every other week (depending on their condition). In these phone calls, participants were asked to complete PP exercises daily or weekly, and may also have received guidance with setting and achieving goals related to physical activity (MI). At 8 and 16 weeks, participants wore an accelerometer to measure their amount of moderate and vigorous physical activity, and also completed a battery of questionnaires assessing psychological outcomes, behavioral adherence, and medical/functional outcomes.

Progress: We have completed enrollment and the obtainment of follow-up data. Though final data analyses are pending, 65% of participants completed at least half of the exercises, and 64% of all exercises were completed. Excluding participants who dropped out prior to completing any exercises, 82% of individuals completed at least half of the exercises, and 76% of all exercises were completed. Though final analyses are pending, we anticipate that booster sessions will be associated with more sustained improvements in psychological and physical health, and the addition of MI will lead to greater improvements in physical activity.

Relevance to proposed study. This study has allowed us to identify which components of the intervention are associated with the greatest improvements in mental health, functioning, and adherence to health behaviors. It also has given us more experience recruiting participants from the inpatient cardiac units, delivering PP and PP/MI interventions, and obtaining information regarding the outcomes we will be examining in this study.

Other PP intervention studies. We have also completed studies of PP interventions in other populations (e.g., those with psychiatric illness) (PHS IRB #2010P-002826; 2012P-001154; 2012P-002294,). These studies have allowed us to gain further experience in delivering PP interventions in a wide variety of contexts. These additional studies have allowed us to refine the intervention manual for the proposed study by selecting exercises that appear to be most associated with improvements in positive affect, and by adapting the instructions and exercises to make them the most acceptable/relevant to patients’ experiences.

C. Rationale/potential benefits/overview of proposed research

There is clear evidence linking positive emotions with superior cardiac outcomes⁴²⁻⁴⁴ and recent trials have found anhedonia—a lack of interest/positive emotion—to be independently associated with post-ACS mortality^{45,46} Despite this, there has been minimal study of interventions in cardiac patients that specifically focus on the cultivation of positive emotional states. To address this gap in knowledge, we aim to develop a novel PP-based health behavior intervention that is adapted for patients hospitalized for ACS. 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.⁴⁷

In the preliminary work noted above, we created and tested a PP-based health behavior intervention in ACS patients and performed a factorial trial to determine which components of the intervention were most effective at improving health behaviors and mental and physical health. Based on this work, we have created an optimized, PP-MI intervention to promote

physical activity. We now plan to test this optimized intervention in a randomized controlled pilot trial in 48 patients recently hospitalized for an ACS.

II. Specific aims

Aim # 1 (primary aim): To assess the feasibility and acceptability of the refined PP-MI intervention in patients who have experienced an ACS.

Hypothesis: The PP-MI intervention will be feasible and acceptable, with $\geq 70\%$ of all exercises completed, self-report follow-up data obtained from $\geq 85\%$ of participants, and physical activity data gathered from $\geq 80\%$ participants.

Aim #2 : To assess the efficacy of the PP-MI intervention to increase moderate to vigorous physical activity (MVPA) at follow-up, compared to an MI-alone control condition, in patients who recently have experienced an ACS.

Hypothesis: The PP-MI intervention will be associated with greater improvements in MVPA compared to the control group at 12 (primary timepoint) and 24 weeks.

Aim # 3: To examine the efficacy of the PP-MI intervention on psychological health, health-related quality of life, and functional status.

Hypothesis: The PP-MI intervention will be associated with greater improvements in psychological health (optimism, positive affect, depression, anxiety), health-related quality of life, and functional status, compared to MI alone.

III. Participant selection

A. Inclusion/exclusion criteria

- Adult patients admitted to MGH or BWH inpatient units with a primary cardiac diagnosis of ACS (myocardial infarction [MI] or unstable angina [UA]) or who develop an ACS while in the hospital, OR adult patients admitted to a Partners institution who have experienced an ACS in the past 2 weeks and who have a Partners-affiliated primary care physician or cardiologist. To meet criteria for MI, eligible patients must meet at least two of three World Health Organization⁴⁸ criteria for an acute MI: typical chest pain, elevated cardiac enzymes, and electrocardiographic changes consistent with MI. For UA, participants must have new-onset angina within 2 months, exacerbation of previous angina with rest pain or with minimal exercise, or angina within 2 weeks of MI.
- Suboptimal adherence to health behaviors. This will be defined as a total item score of <15 (suboptimal) on three Medical Outcomes Study-Specific Adherence Scale (MOS SAS)^{49,50} items OR a total item score of 15 and a physical activity item score of ≤ 5 .

Exclusion criteria:

- Cognitive deficits, assessed via a 6-item cognitive screen⁵¹ used to assess appropriate participation of medically ill patients in research studies.⁵²⁻⁵⁴
- Medical conditions precluding interviews or likely to lead to death within 6 months, determined in consultation with the primary treatment team and cardiology co-investigator Dr. Januzzi.

- Inability to perform moderate to vigorous physical activity, as defined by an inability to walk without aid of an assistive device such as a walker or cane, OR inability to walk at a steady pace for at least 5 minutes without stopping.
- Inability to communicate in English.
- Inability to participate in physical activity.

Justification and description of inclusion/exclusion criteria

We are recruiting patients with a primary admission diagnosis of ACS, or patients who develop an ACS while in the hospital. ACS diagnosis will be clarified with the inpatient or outpatient care team and, as needed, adjudicated by cardiology co-investigator Dr. Januzzi. We are including patients with suboptimal adherence (as measured by the MOS SAS, which has been used in multiple prior studies assessing adherence in cardiac patients^{7,55}) to ensure that there is room for improvement in health behavior adherence. We chose a cutoff score of 15, which should allow inclusion of the vast majority of patients with an ACS to ensure an intervention that is applicable to most patients. We have used this scale and this cutoff in prior studies with good effect.

We are excluding patients with impaired cognition to ensure that participants are able to meaningfully participate in both the consent process and exercises, and are using the 6-item cognitive screen because this tool has been used in prior studies involving medically-ill patients. We are excluding patients with medical conditions precluding interviews or likely to lead to death within 6 months given that these patients may be unable to meaningfully complete study assessments or are at high risk of dying before study completion. We are excluding those who cannot complete physical activity, particularly MVPA, because this will not allow us to complete meaningful assessments of such activity with the accelerometer.

We chose to include only patients who speak English for the time being, given that essentially all PP interventions in the past (and our own experience) have utilized exercises in English, and this will allow us to hold more variables constant as we pilot test this work (i.e., if we included several languages and it was not effective, we would not know whether it was because the intervention was lacking or whether our language/cultural translations of the exercises were suboptimal). In the future, we plan to develop and include a manual in Spanish.

B. Source of participants and recruitment methods

All participants will be adults with an ACS admitted to an inpatient unit at MGH or BWH (for in-hospital recruitment), or who were admitted to any Partners-affiliated hospital in the past two weeks and who see a primary care physician or cardiologist in a Partners-affiliated clinic (RPDR-based recruitment).

In hospital recruitment. Recruitment and enrollment will follow the methods of our prior PP studies in cardiac patients. We will recruit patients from MGH and BWH inpatient units who are admitted with a primary cardiac diagnosis of ACS or who develop an ACS while in the hospital. We will enroll up to 80 ACS patients, with a goal of randomizing at least 48 patients.

To recruit participants, a physician, licensed social worker, medical student, or international medically-trained research fellow, will review electronic patient censuses and daily reports of the cardiac marker troponin for patients hospitalized at MGH or BWH, to check for

patients possibly diagnosed with ACS. If a patient appears to have a possible ACS based on this review, a member of the study team (physician, psychologist, social work investigator, or trained research assistant) will approach the patient's treatment team, to inquire whether he/she had an ACS. If the patient appears to meet study criteria, a member of the clinical team, who would not be associated with the consent process in any way, will ask the patient whether he or she is willing to hear about an optional research study.

If the patient meets criteria for ACS and is amenable to hearing about the study, a member of the study team (physician, psychologist, social work investigator, medical student, or a trained research assistant) will meet with the patient, confirm that it is okay to describe an optional study, describe the study to them, and answer any questions that they have. When discussing the study, the study clinician will emphasize the study's optional nature and participants' ability to opt out / un-enroll at any time, for any reason.

Interested patients will undergo assessment of adherence status with the MOS SAS, cognitive evaluation (with a six-item screen), and review for exclusion criteria. Only those patients who are interested and eligible for the study will ultimately undergo informed consent with a member of the study team (physician, psychologist, social work investigator, medical student, or a trained research assistant). With the help of a member of the study team, the participant will then schedule a visit to the Translational and Clinical Research Center (TCRC) at MGH within 3 weeks of discharge (goal = 2 weeks post-discharge) to meet their interventionist (the study team member they will be working most closely with), complete baseline questionnaires, receive their first of three step counters, and begin the study intervention.

Any questions about medical exclusion criteria will be clarified/adjudicated by the PI (Dr. Huffman) and our cardiology co-Investigator (Dr. Januzzi). In the rare instance that 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 other study procedures for that participant.

We will also contact patients in the interim period between their consent in-hospital and their visit to the TCRC to remind them of their visit.

Outpatient recruitment via Research Patient Database Registry (RPDR). All participants will be adults who have been hospitalized at a Partners-affiliated hospital within the past 2 weeks for ACS and who also see a primary care physician or cardiologist at a Partners-affiliated clinic. Participants can be referred to the study by an outpatient treatment team member (physician, nurse, or nurse practitioner) or through systematic searches using the RPDR. 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.⁵⁶

To identify potentially eligible patients:

- 1.) An RPDR query will be performed to identify those patients hospitalized within the past 2 weeks with a diagnosis of ACS (MI or UA). Study staff will review the medical record to confirm potential participant eligibility and to identify their linkage to a cardiologist or primary care physician.
- 2.) Study staff then will obtain permission for initial contact from each potentially

eligible patient's cardiologist or primary care physician 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 Jeff Huffman, MD (PI). The letter from the cardiologist or primary care physician informs the patient that he or she is allowing the study to contact patients with an ACS in case they are interested in learning about the trial. Dr. Huffman's letter is an opt-out letter describing the study, the procedure to opt out of further contact, and whom to call for further information. These letters will be sent from a central location at MGH.
- 4.) Should study staff receive no reply within 1 week, 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 a letter study opt-out letter signed by Jeff Huffman, MD (PI) as outlined above. Should the patient not reply within 1 week, staff members will call the patient to describe the study, assess patient interest, and confirm eligibility (pending patient interest). RODY identifies patients who are willing to be contacted about research studies. Patients who have agreed to be contacted are identifiable through the RPDR search; each patient's RODY status is available in the demographics table included in the RPDR output.

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

IV. Participant enrollment

A. Methods of enrollment

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

B. Procedures for obtaining informed consent

In-hospital consent:

If the patient is interested in the study after the discussion of the details of the study and assessment for exclusion criteria, a physician, psychologist, social work investigator, medical student or a trained 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, patients will have at least 24 hours to consider enrollment. To ensure that patients have the capacity to provide informed consent, we will ask potential patients to describe their understanding of the study's purpose and their role (e.g., that they understand the timing of interventions and assessments, 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). If the patient is about to be discharged and would like more time to review the consent form than is available to them in the hospital, they may take the consent form home to review and send back a signed copy if they ultimately choose to participate in the study. The study team member will also complete with the participant a release of information form that will allow us to contact treaters for information about treatment and outcomes at 12 and 24 weeks. With the help of a member of the study team, the participant will then schedule a visit to the MGH to meet their interventionist, complete baseline questionnaires, and receive their first of three step counters. Participants who enroll in the study, as well as potential participants who choose to take a consent form home to review it further, will receive a brochure that provides additional information about the study.

Consent at baseline visit:

For participants identified through RPDR searches and contacted via opt-out letter and phone call, eligibility will be assessed on the phone. Those participants who appear to be eligible for the study will be scheduled to come to the TCRC at MGH for the baseline study visit. Prior to the visit, a copy of the consent form will be mailed (or e-mailed, if the patient prefers) to the participant. At the baseline visit, a study team member will review the consent form with the participant and ultimately will enroll the patient, as noted above.

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 patients sign the consent form, the investigator will perform a focused review of the patient's medical record (including laboratory data) to again confirm that the patient was admitted for ACS, and will consult with the study cardiologist in the event that there is any need for further clarification. If there is question about the patient's medical prognosis (to assess whether the patient has a condition likely to lead to death within 6 months) the study team will consult with the inpatient or outpatient treatment team and the study cardiologist.

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 the intervention or MI-based health behavior education (control) arm. They will be randomized by a random-number generator and will be assigned a condition after receiving baseline questionnaires when they return to MGH after discharge. The research assistant (RA)/blinded assessor who will conduct the follow ups 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 (See Table 1)

Baseline Assessment and Initial visit (Week 0). The initial visit will occur at TCRC at MGH about two weeks after discharge from the hospital. Participants will first have their height and weight measured, then meet with a member of the study staff (the study “trainer”) and complete self-report questionnaires verbally or through a REDCap survey on an encrypted, secured iPad (participant preference). These questionnaires assess positive affect (Positive and Negative Affect Schedule; PANAS),⁵⁷ adherence to physical activity (a modified version of the International Physical Activity Questionnaire; IPAQ),^{58,59} adherence to medication (Self-Reported Medication Adherence; SRMA),⁶⁰ dietary adherence to a low-fat diet (MEDFICTS),⁶¹ cigarette use, and alcohol use (Alcohol Use Disorders Identification Test; AUDIT-C)⁶². Questionnaires will also assess general optimism (Life Orientation Test-Revised; LOT-R),^{63,64} and state optimism (State Optimism Measure; SOM), anxiety/depression (Hospital Anxiety and Depression Scale; HADS),⁶⁵ stress (Perceived Stress Scale-4; PSS-4),⁶⁶ physical functioning (Duke Activity Status Index; DASI)⁶⁷, health-related quality of life (Short Form-12; SF-12),⁶⁸ and cardiac symptoms (list from the Women and Ischemia Syndrome Evaluation study; WISE)⁶⁹. Participants also will report their race and ethnicity, as well as their marital status and whether or not they live alone. These scales should take approximately 30 minutes to complete.

After completing baseline questionnaires and receiving randomization, subjects in both groups will have an initial in-person session, in which the interventionist will provide a treatment manual specific to their condition, review the rationale for the initial exercise, and assign the exercise. If the patient is in the PP-MI condition, the trainer will explain the rationale for both the PP and MI (referred to as “goal setting”) portions of the program. The interventionist will also provide the participant with a copy of the MGH *Caring for Your Heart Handbook*, which all participants (regardless of condition) will receive. 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. This will take 10-15 minutes.

After explaining the program, the trainer will introduce to participants how to use a step counter (ActiGraph), and will ask the participant to wear an Actigraph GT3X+ accelerometer for 7 days to make sure they are comfortable using the device and that useable data can be obtained from the participant. ActiGraph accelerometers are validated as measures of physical activity and have been used in numerous studies of physical activity in patients with medical illness.⁷⁰ The accelerometer is a band with a small 1.5” square attached device that is worn around the lower waist, either on a waistband or clipped to the belt or waistband of clothing. It tracks the number

of steps taken. After explaining how to use the devices, the study trainer will schedule an appointment to call the participant in 1 week to review the first exercise over the phone. Lastly, participants in both conditions will also be given a digital pedometer (Omron) that clips on a belt or other article of clothing, to promote and track physical activity.

Table 1. Schedule of study events.

	Pre-enrollment	Week 0	Weeks 1-12	Week 12	Week 24
Cognitive screen	X				
Self-reported adherence (MOS-SAS)	X		X	X	X
Cigarette Use, Alcohol Use (AUDIT-C), Sociodemographic Data		X			
Chart review for baseline characteristics		X			
Self-report measures (DASI, SF-12, LOT-R, SOM, HADS, IPAQ, MEDFICTS, SRMA, PSS-4, PANAS, WISE)		X		X	X
Physical activity (step counter)		X*		X	X

*not used as a baseline measure, but as a way of getting the participant accustomed to the device

Weekly phone sessions (Weeks 1-12). After discharge from the hospital, participants will complete twelve 30-minute weekly phone sessions with a study trainer. The phone sessions primarily will include a review of the prior week's session content and a discussion of the rationale and assignment of the next week's exercise/assignment. These calls will be recorded so that a percentage of these recordings can be reviewed to ensure that both the intervention and control arms of the study are being delivered as described in the protocol and trainer manual.

Positive psychology plus motivational interviewing (PP-MI) condition (intervention)

For the PP portion of the intervention, the study trainer will (a) review the week's PP exercise (including the participant's ratings of pre- and post-exercise ease and helpfulness of the exercise), (b) discuss the rationale of the next week's PP exercise through a guided review of the PP manual, and (c) assign the next week's PP exercise. For the MI portion, participants will (a) review their physical activity goal from the prior week, (b) discuss techniques for improving physical activity, and (c) set a physical activity goal for the next week. The exercises and content for both PP and MI will be assigned in the same order for all participants receiving them.

Positive Psychology Exercises. The positive psychology exercises used in this study were selected based on their superior performance in our pre-pilot research and others' work, and have been organized into three sections by theme:

Gratitude-Based Activities:

Gratitude for Positive Events³⁰ (Session 1).

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

Gratitude letter/Expressions of Gratitude³⁰(Session 2).

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.

Capitalizing on Positive Events^{71,72} (Session 3).

Participants recall 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.

Using gratitude in daily life (Session 4).

Participants focus on implementing gratitude interventions and skills into daily life.

Strength-Based Activities:

Remembering past success/Remembering daily successes (Session 5).

Participants recall a prior event in which they experienced success. They then write about the event, the positive feelings evoked, the steps taken by the participant to contribute to the success, and the feelings generated by recalling the event.

Using personal strengths, part 1³⁰(Session 6).

Participants choose a personal strength and then use it in a new way over the subsequent week.

Using Personal Strengths, part 2³⁰ (Session 7).

Participants choose an additional personal strength and then use it in a new way over the subsequent week.

Using strengths in daily life (Session 8).

Participants focus on implementing strengths-based interventions and skills into daily life.

Meaning-Based Activities:

Enjoyable and meaningful activities⁷³ (Session 9).

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.

Performing acts of kindness (Session 10).

Participants complete three acts of kindness in one day, then write how the act made them feel.

The “Good Life”⁷⁴ (Session 11).

Participants write about their ideal life over the next year in one or more life domains.

Focusing on Meaning in Life (Session 12)

Participants focus on implementing enjoyment- and values-based interventions and skills into daily life.

Planning for the future (Session 13)

Participants review their favorite exercises and make a plan for continuing to use their PP-based skills in the future.

Motivational Interviewing. Elyse Park (PhD), a certified motivational interviewing trainer, has assisted our team with the development of a program for patients hospitalized with ACS to increase their physical activity and related health behaviors. MI is a goal-oriented, client-centered approach to helping patients resolve their ambivalence to change their health behaviors.

Each session will follow the same structure. Study trainers will: (a) ask participants about their health goals, (b) advise them about current health guidelines and/or refer them to their treatment team, (c) assess readiness to set a goal by identifying how important participants feel the goal is, how confident participants are about making a change, and what the participants' pros and cons are for making a change, (d) assist participants in clarifying their goals and problem-solving barriers to reaching those goals, and (e) arrange for the next session by summarizing the participant's plan and scheduling the next session.

Moving for better health and tracking your activity (Session 1)

Participants will review their level of activity before their hospitalization and identify a specific physical activity goal to accomplish during the program. Then, they will identify how important it is to reach their goal, how confident they are in doing so, and what the pros and cons are for changing their level of activity.

Setting a SMART Physical Activity Goal (Session 2)

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.

Barriers and Problem Solving (Session 3)

Participants will think about their past and anticipated barriers and helpful factors to being more physically active. They will continue to refine set new goals.

Reviewing and Reflecting on Physical Activity (Session 4)

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. Participants will be mailed a graph of their weekly step counts over the past four weeks.

Finding New Routes (Session 5)

Participants will explore their neighborhood and brainstorm new places to walk.

Using Neighborhood and Equipment Resources (Session 6)

Participants will think through what resources they may have in their neighborhood which could help them be more active. Additionally, participants will think through the equipment that they have or need that would make it easier for them to be more active.

Using Social Resources and Making Small Changes(*Session 7*)

Participants will discuss their social resources and how these resources can be used to promote physical activity. Participants also will think of ways to introduce small amounts of physical activity into their daily schedules.

Reviewing and Reflecting on Physical Activity (*Session 8*)

Participants will reflect on their physical activity in the past few weeks and assess how they have been progressing towards their ultimate physical activity goal. If needed, they will revise their overall physical activity goal. Participants will be mailed a graph of their weekly step counts over the past eight weeks.

Continuing progress and managing ‘slips’ (*Session 9*)

Participants will learn about managing ‘slips’ or times when they get off track from their goals.

Reducing Your Sitting Time (*Session 10*)

Participants will assess the amount of time they spend sitting during the day, and will discuss some strategies for reducing their sitting time throughout the day.

Standing Breaks (*Session 11*)

Trainers will discuss the benefits of standing breaks with participants and help brainstorm strategies for incorporating standing breaks into the participants’ days.

Increasing You Strength Through Exercise (*Session 12*)

Participants will learn about the benefits of strength training and discuss ways of increasing the amount of strength training they engage in. Participants will be mailed a graph of their weekly step counts over the past twelve weeks.

Reviewing progress and thinking about the future (*Session 13*)

Trainers will assist participants with reviewing their accomplishments in the program and help them to create a plan for physical activity for the near future.

Participants in the PP-MI group will also receive a journal after completing the 12-week intervention. In their final phone session, they will be advised to use the journal to monitor positive psychological states and/or physical activity.

Motivational interviewing (MI) health behavior education (control condition)

The MI-based health behavior education intervention was selected as the 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 physical activity goal-setting make it less likely that this control intervention will significantly impact physical activity (our primary health behavior outcome). 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:

Part One: A Healthy Heart

Recovering from a Cardiac Event (Session 1)

Participants will review information about recovering from an ACS, as well as information about CAD 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 CAD.

Part Two: Staying Active

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 Fat and Sodium (Session 7)

Participants will learn about the importance of reducing fat, sodium, sugar, and alcohol 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 CAD. 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.

Follow-up phone calls (Week 12 & Week 24). At Weeks 12 and 24, a member of the study staff will call participants to repeat most of the self-report questionnaires that were administered at baseline (Week 0). These questionnaires assess adherence to physical activity (a modified version of the IPAQ), adherence to medication (SRMA), and dietary adherence to a low-fat diet (MEDFICTS). Questionnaires will also assess optimism (LOT-R), state optimism (SOM), positive emotions (PANAS), overall health behavior adherence (MOS-SAS), anxiety/depression (HADS), stress (PSS-4), physical functioning (DASI), health-related quality of life (SF-12), and cardiac symptoms (WISE). Participants will also be asked about cardiac-related hospital readmissions and attendance at cardiac rehabilitation, to rate their overall satisfaction with the treatment they received for their cardiac condition (outside of this study) over the last 12 weeks on a scale of 1 (excellent) to 5 (poor), and some questions about ease of use of the study devices. In sum, these scales should take approximately 30-40 minutes to complete.

We will schedule all phone calls during times that are acceptable to participants to reduce intrusions in their lives. We will remind participants of their upcoming study sessions and follow-up phone calls by phone, letter, or e-mail depending on their preference. If participants would rather complete the follow-up questionnaires in written or e-mail form rather than over the phone, we will send them a paper or electronic packet at the time of the follow-up. Participants who choose to complete the follow-up questions through e-mail will be sent a PDF file that will contain no personal identifiable information including name, social security number, address etc. The PDF file will only be labeled with a secure study ID number, and all e-mail communications

will occur via firewalled Partners e-mail accounts (study members' accounts), rather than through outside e-mail servers to protect patient confidentiality.

Participants will receive a check for \$40 after completing the week 12 follow-up in addition to wearing and returning the 12-week accelerometer. Participants will receive an additional check for \$60 after completing the week 24 follow-up phone call and returning the 24-week accelerometer. Participants must return the step counter in good condition and with at least 5 days of data (at least 8 hours of active wear time per day) in order for remuneration to be appropriated. Participants will be informed of this remuneration in the consent form. 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.

Training. Dr. Huffman (PI) and Carol Mastromauro (LICSW) have substantial experience in explaining and delivering PP exercises from their pilot studies in cardiac and psychiatric patients. The PP exercises for this trial have been identified via published literature,^{30,72,73,75,76} 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. Additional staff members involved in intervention delivery are trained in several stages. They review a provider training manual created specifically for the project; this manual describes the rationale and procedures for each exercise, provides guidance for maintaining the focus of the interaction solely on the PP exercise and MI topic, and contains specific advice to convey to participants to facilitate completion of the given exercise. Staff then complete relevant background reading about PP, observe sessions, and complete all exercises in pairs to gain experience performing and reviewing each exercise.

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

There are no devices used in this study.

D. Procedures/surgical interventions

There are no procedures/surgical interventions in this study.

E. Data to be collected (Table 1)

Baseline data

Baseline information about enrolled participants will also be obtained by study staff from participants, care providers, and the electronic medical record as required for characterization of our population. This information will include data regarding medical history (history of prior

acute coronary syndrome, coronary artery bypass graft, congestive heart failure, hypertension, diabetes mellitus, hyperlipidemia, and current smoking), current medical variables (admission diagnosis, renal function, and left ventricular ejection fraction), medications, length of hospital stay, alcohol use, cigarette use, and sociodemographic data (age, gender, race/ethnicity, living alone). This information will help us to ensure that the population we recruit is a representative population of patients suffering ACS. As with all data, this will be linked in our database only via a participant ID number, and we will only collect that information (above) needed to characterize our population.

Objective adherence data

We will measure physical activity using a multi-axial ActiGraph GT-3X+ accelerometer (Actigraph, Pensacola, FL) that provides second-by-second step counts. The ActiGraph is a square 1.5" device that can be worn over or under clothes at the waist, either on an elastic band around the waist or on a clip appended to the belt or waistband of pants. Activity data is downloaded through a USB port on the step counter. We will use these step counters to assess activity because they are often considered to be the standard for measuring habitual physical activity.^{77,78} We chose to use ActiGraph accelerometers because they are the most widely used monitors for research purposes and adequately discriminate between different levels of activity.^{79,80} We will measure activity (MVPA) during two independent seven day periods beginning during week 12 and week 24 respectively.

Psychological outcomes

At the baseline visit and 12- and 24-week follow-ups, we will use structured scales to obtain information about psychological outcomes and adherence to health behaviors:

- (a) Positive affect will be measured using the positive affect items on the PANAS, a well-validated scale used in other telephone-administered intervention trials.^{81,82}
- (b) Optimism will be measured using the LOT-R, a frequently used 6-item instrument that assesses optimism and pessimism. This scale has been used to measure optimism in cardiac patients,^{83,84} including a study linking optimism to rates of readmission following cardiac surgery.⁸⁵ This instrument measures dispositional (rather than state) optimism, which is thought to be a relatively static construct. However it is dispositional optimism that is most linked to cardiac outcomes,^{24,86} and LOT-R scores were responsive to change even in the very short-term in a recent positive psychology intervention.⁸⁷ We also will be using a short scale developed by our team (SOM) to measure state optimism.
- (c) Anxiety and depression will be measured using the anxiety and depression subscales of the HADS. This well-validated scale has the advantage of having few somatic symptom items that can confound mood/anxiety assessment in medically ill patients. We also have experience with its use.^{14,55} We will assess this outcome to explore how positive and negative affect may improve independently of one another over 24 weeks.
- (d) Stress will be measured with the PSS-4, a shortened version of the widely-used scale. We are interested in the moderating effects of stress on outcomes.

Medical outcomes

At the baseline visit and 12 and 24 week follow-ups, we will use structured questionnaires to obtain information about medical outcomes. These include:

- (a) Physical functioning, assessed by the DASI. This scale has been used in prior studies of illness, including our own, to assess medical outcomes.^{88,89}
- (b) Health related quality of life (HRQoL), measured with the SF-12. We chose the SF-12 because it is brief, it has been used in multiple studies of cardiac patients,⁹⁰⁻⁹⁴ and we have experience with its use in prior studies.
- (c) A cardiac symptom list adapted from the Women and Ischemia Syndrome Evaluation (WISE)⁶⁹ study will be used to assess the presence and intensity of ten cardiac symptoms felt to best capture the range of symptoms experienced by ACS patients.

Self-reported adherence outcomes

- (a) In addition to the objective adherence methods, we will collect self-reported adherence to diet, medications, and activity using the MOS SAS. The MOS SAS assesses key behaviors to cardiac health (diet, exercise, and medication adherence) and was used by Ziegelstein and colleagues⁷ in their study of adherence in post-MI patients.
- (b) Baseline physical activity (prior to hospitalization) will be measured with a modified version of the IPAQ to capture an estimate of the number of minutes spent performing MVPA in the past week (or a typical week, if the past 7 days atypical). The IPAQ has been used and validated in medical cohorts.^{58,59}
- (c) Medication adherence will be measured using the SRMA, a two-item measure of the percentage of time patients report taking their heart medications in the past one and two weeks.
- (d) Dietary adherence to a low-fat diet will be measured with the MEDFICTS scale recommended by National Cholesterol Education Program (NCEP). It is a widely-used and well-validated measure of cholesterol and saturated fat-intake.

Exercise ratings

We will obtain self-report ratings from participants for each completed exercise on two domains (ease of completion, overall utility). Participants will be asked to rate the ease (“how easy was the exercise to complete) and utility (“how helpful was the exercise”) of each exercise on Likert scales of 0-10 (0 = “not easy” or “not helpful,” 10 = “very easy” or “very helpful”).

VI. Biostatistical analyses:

A and B. Specific data variables and study endpoints

Aim 1: (*feasibility, acceptability*; primary aim): To determine whether the PP-MI intervention is feasible and acceptable by participants.

Measures:

- Rates of intervention completion (recorded by study trainer)
- Follow-up completion of self-report and objective adherence measures
- Measures of ease and utility

The intervention will be considered feasible if (1) at least 70% of all exercises are completed, (2) self-report follow-up data is obtained in 85% of participants, and (3) full accelerometer data is obtained in 80% of participants. The intervention will be considered acceptable if participants rate the PP exercises as at least 6/10 on ease and at least 7/10 on utility.

Aim #2 (between-group differences physical activity): To assess which group (intervention or control) is associated with the greatest physical activity at 12 (primary timepoint) and 24 weeks post-enrollment, as measured by self-report International Physical Activity Questionnaire (IPAQ).

Measures:

- Physical activity (IPAQ) (primary health behavior outcome measure)

Aim #3 (psychological, health behavior, and functional outcomes): To examine the impact of the PP-MI intervention on self-reported adherence measures, psychological outcomes, functioning, and health-related quality of life at 12 (primary timepoint) and 24 weeks post-enrollment.

Measures:

- Self-reported adherence (MOS-SAS)
- Cigarette Use
- Physical activity (IPAQ)
- Medication adherence (SRMA)
- Dietary adherence (MEDFICTS)
- Alcohol Use (AUDIT-C)
- Psychological outcomes:
 - Positive emotions (PANAS)
 - Optimism (LOT-R)
 - State Optimism (SOM)
 - Depression/Anxiety (HADS-D and HADS-A)
 - Stress (PSS-4)
- Medical outcomes:
 - Physical functioning (DASI)
 - Health-related quality of life (SF-12)
 - Cardiac Symptoms (WISE)

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 the proportion of exercises completed and proportion of participants who provided follow-up information.

Descriptive statistics also will be used to determine mean ratings of ease and utility for each exercise. Significance will be set at $p < .05$, using two-tailed statistical tests.

For the Aim #2 analyses (between-group differences in MVPA), we will perform random effects regression analyses with a random intercept for each participant. We will include group, time, and group x time interaction variables and will control for baseline physical activity (as measured by IPAQ). This will allow us to include participants with some missing data.

For the Aim # 3 analyses (between-group differences on psychological, health behavior, functional, and quality-of-life outcomes), we will use a random effects regression model with a random intercept for each participant, as in Aim #2.

D. Power analysis

The study will likely not be powered to definitely test for between-group differences on the secondary outcome, but it should be adequate to generate effect sizes for a larger, multisite efficacy trial by the end of the grant period. We hypothesize that the intervention will have a moderate effect size on physical activity (vs. the control condition), based on similar effect sizes for psychological interventions in cardiac patients.⁹⁵⁻⁹⁷

VII. Risks and discomforts

A. Complications of surgical/non-surgical procedures

No surgical or non-surgical procedures are being used in 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 that, although not determined to be a device, can malfunction.

The accelerometer utilized to measure physical activity should pose minimal risk. The accelerometer (ActiGraph) we are using to measure activity is small, secure, and without sharp edges. It has been used in thousands of patients participating in research studies. Immersing it in water for a prolonged period may render it unusable but does not pose a shock risk. The step counter is plugged into a USB port to download data, but participants will not have to do this; they will simply mail the step counter in a certified mail envelope provided to them, and study members will download the data.

We will provide explicit instructions regarding the use of the accelerometer to ensure safety and proper use, and to reduce inconvenience/distress associated with uncertainty about its safety or use. The study scientific team (e.g, research coordinator, project director) will liaise with participants regarding any battery problems or for technical advice on the MEMSCap and related equipment. In the event of device malfunction, a new device will be sent to the participant.

The Omron pedometer which we will provide participants to use in self-monitoring similar poses minimal risk, given that it has no sharp edges, no shock risk, or other known risks.

D. Risks

Confidentiality. The primary risk to participants in this project is that of confidentiality. We will minimize this risk in our proposed trial using methods from our prior work. We will use the methods of two IRB-approved studies by our group that have enrolled participants hospitalized for an ACS and were subsequently interviewed or received PP interventions by phone: one that included interviews about health behaviors and positive emotions during hospitalization and three months later by phone (2011-P-002729), one that assessed the feasibility and impact of positive psychology exercises administered over the phone (2013-P-001961), and a large (n=128) factorial trial to determine which components of a PP intervention were most efficacious (2014-P-001756). Specifically, we will minimize these risks by using participant numbers rather than identifying personal data on all study documents, by storing all documents in locked cabinets/offices, and by using password-protected databases to store personal information.

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 will ask all participants if it is acceptable to leave voice messages on their phones, as well as the appropriate times to call them. We will adhere to any and all patient requests regarding contact. Lastly, we will also inform subjects that sessions will be audiotaped and that random sessions reviewed by study staff for quality assurance; the audiotapes will be marked only with subject identification numbers and will be erased following review. The remaining sessions will be erased following each subject's completion of the study (after follow-up assessments are completed or the patient withdraws from the study).

Informed consent process. With regard to the consent process, we will approach/recruit participants only after patients' clinicians/floor nurses (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, or through the opt-out letter process described above. 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. As mentioned above, for participants identified through RPDR searches and contacted via opt-out letter and phone call, those participants who appear to be eligible for the study will be scheduled to come to MGH for the baseline study visit. Prior to the visit, a copy of the consent form will be mailed (or e-mailed, if the patient prefers) to

the participant. At the baseline visit, a study team member will review the consent form with the participant and ultimately will enroll the patient in the same manner as described above.

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). If participants 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 Dr. Huffman (PI) will be available to consult (and call the participant) as needed. If the participant is having urgent medical symptoms, the study physician(s) will take all needed steps to ensure emergent evaluation, which may include ensuring evaluation in nearest emergency room.

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/participant if there is either an acutely elevated risk of self-harm or if additional information is needed to clarify risk. As with medical issues, if the participant 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.

VIII. Potential benefits

A. Potential benefits to participants

It is possible that participants will not receive benefit from participation. It is also possible that they will receive some benefits. Participants 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.

Participants also may receive education regarding health behaviors and/or motivational interviewing regarding health behaviors. This may prompt participants to engage in more health

behaviors, which may have both psychological (e.g., improved mood) and physical benefits (e.g., more energy). Ultimately, engaging in more health behaviors could potentially lead to fewer hospitalizations, better functioning, and longer survival.

B. Potential benefits to society

A variety of interventions have been utilized to improve health and psychological outcomes in cardiac patients, but these problems remain in a large proportion of patients with cardiac diseases like ACS. This study could provide a critical step in the development of a novel intervention that takes a different approach to health behaviors in patients with ACS, by leveraging positive psychological states as a means to superior outcomes. Such an intervention, if effective, may be a viable option for many patients, given that positive psychology interventions are simple and do not require substantial provider training.

This trial will allow us to explore the feasibility and impact of an innovative, simple, and potentially powerful intervention in a cohort of patients with ACS. The data from this trial will allow us to test the intervention in a larger, randomized, controlled trial in the future.

IX. Monitoring and quality assurances

A. Independent monitoring of source data

Entry of data into REDCap will be reviewed by the PI and study biostatistician at intervals to ensure that data is being correctly captured/entered into this system. They will also review downloading of data from REDCap into Stata to ensure that the data is being accurately transmitted to the study database for study analyses.

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

We will utilize a Data Safety Monitoring Board (DSMB) for this study. The following procedures will be followed to ensure participant safety and the validity and integrity of data:

Functions of the DSMB. The DSMB will review proposed amendments to the study protocol, complete expedited monitoring of all serious adverse events, monitor drop-outs and non-serious adverse events, determine whether study procedures should be changed or the study should be halted for reasons related to the safety of study subjects, and perform periodic review of the completeness and validity of data to be used for analysis of safety and efficacy. The DSMB will also ensure subject privacy and research data confidentiality.

Membership of the DSMB. The DSMB will consist of members with extensive research experience in diabetes, mental health, and biostatistics of clinical trials. Three members will be Dr. Andrew Nierenberg (Psychiatry), Dr. Michelle O'Donoghue (Cardiology), and Dr. Lee Baer (Biostatistics); all have agreed to serve in this role throughout the study. The DSMB Chairperson (Dr. Nierenberg) will communicate by email and phone with the other members, and will coordinate formal, scheduled meetings of all members of the study and the PI.

Monitoring of Safety Data by the DSMB. Safety information for this study will be reported to the DSMB in an unblinded manner. A statistical penalty will not be assessed for the unblinded review of safety by the DSMB. Unblinded data will not be released to investigators

unless necessary for safety reasons.

Range of Safety Reporting to the DSMB. It is considered necessary that the DSMB review not only adverse events (AEs) and serious adverse events (SAEs), but other data that may reflect differences in safety between treatment groups. This includes treatment retention rates and reasons for dropout.

Serious Adverse Events. Expedited review will occur for all events meeting the definition of Serious Adverse Events (SAEs); i.e., any fatal event, immediately life-threatening event, permanently or substantially disabling event, or event requiring or prolonging inpatient hospitalization. This also includes any event that a study investigator or the DSMB judges to impose a significant hazard, contraindication, side effect, or precaution. All relevant information will be reported to the DSMB for each SAE including information about the event and its outcome, study group assignment, medications, the subject's medical history and current conditions, and any relevant laboratory data. Notification by e-mail and FAX transmittal of all related study forms shall be made to the DSMB. Information will be reviewed and a determination made of possible relevance to the study.

Non-Serious Adverse Events. At periodic intervals determined by the DSMB (e.g., quarterly during the study and then again at its completion), the DSMB will be provided with unblinded summaries of the numbers and rates of adverse events by treatment group. These reports will include types of events, severity, and treatment phase. Data on individual non-serious adverse events is not expected to be needed for this review.

Other Safety-Related Reports. At quarterly intervals, the DSMB will also receive unblinded summary reports of treatment retention and reasons for drop-out, by treatment arm and study phase.

Study Stopping Rules. If at any time during the course of the study, the DSMB judges that risk to participants outweighs the potential benefits, the DSMB shall have the discretion and responsibility to recommend that the study be terminated.

Monitoring of Data Quality by the DSMB. At least on a quarterly basis during the course of the study, the DSMB will receive a report on data quality and completeness. Dr. Brian Healy (study biostatistician) will prepare these reports in collaboration with Dr. Huffman. At a minimum, this will include an overview of the progress of patient intake and retention; summary reports describing patient compliance with evaluations as described in the protocol; and a summary of the completeness and quality of key data elements needed to characterize patients, study interventions, and primary and secondary outcomes. These reports will be used by the DSMB to evaluate the capacity of the data capture and processing to support scientifically valid analyses.

Annual DSMB Report to NIH/NHLBI. During the course of the study, the DSMB will prepare annual summary reports (two reports in total) of its findings regarding safety and quality based on data received to that point in the study. If there are more specific concerns about data quality, study safety, or other issues, the DSMB can elect to generate reports more frequently. This report will include a summary of all safety findings, as well as an assessment of protocol compliance and data quality. Any recommendations to improve patient safety, protocol adherence, or data quality will be made in this DSMB report. A copy of this DSMB report will also be sent to the PHS IRB along with the annual renewal report.

In addition to the work of the DSMB, the research team will meet on a weekly basis to review study progress. During these weekly meetings, the principal investigator will review informed consent documents, study forms, and procedures completed that week. The study team

will also discuss any procedural difficulties, recruitment issues, and adverse events at this meeting (and before if needed). If there are consistent issues with the logistics, feasibility, or acceptability of recruitment, enrollment, follow-ups, or the intervention (e.g., participant complaints about length of follow-ups), we will review our methods and alter the study protocol as needed.

C. Outcomes monitoring

Dr. Huffman (PI) will review study outcomes after four participants have completed the trial in order to assess the feasibility and acceptability of exercises and to ensure adequate completion of follow-up measures. If participants' completion or follow-up rates are far below the expected rates, if acceptability scores on the exercises are low, if 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. Further, we will preliminarily assess outcome measures after 20 participants have completed the study to ensure the feasibility and acceptability remains adequate and to monitor potential outcomes. We will then complete the more formal data analysis once all 48 participants have completed the trial.

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. Huffman) will amend the protocol if it is deemed necessary to protect the safety and welfare of the participants.

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