## I. Background and significance

### A. Historical background

Every year, over 1.3 million Americans suffer an acute coronary syndrome, or ACS (myocardial infarction or unstable angina).[1] Of these post-ACS patients, approximately 20% will be rehospitalized for ischemic heart disease or suffer mortality within the next year.[2] Adherence to recommended post-ACS health behaviors—especially increasing physical activity—is associated with substantially lower risk of recurrent events and mortality.[3,4] However, the majority of ACS patients have not been able to increase their activity to recommended levels.[1,3,5]

Positive psychological constructs, such as optimism, are associated with greater adherence to evidence-based recommendations for physical activity,[6] as well as lower rates of heart disease and cardiac mortality.[7,8] Exercises that aim to cultivate positive cognitive and emotional experiences, known as positive psychology (PP) interventions, utilize short tasks that focus on gratitude (e.g., counting blessings), altruism (e.g., performing kind acts), use of personal strengths, and related constructs.[9] PP interventions have been extensively studied and found to reduce distress and improve psychological well-being in a total of over 6000 participants.[10]

Given the connections between positive psychological constructs and health behaviors, and an ongoing need for innovative, feasible, and effective methods of improving health behaviors, PP interventions may provide a novel approach to increasing adherence and improving cardiac outcomes in ACS patients. Thus far, there has been limited study to assess whether PP interventions can promote health behaviors,[11,12] and prior to our pilot work in this area,[13] no study had evaluated a PP intervention in post-ACS patients.

In addition, interventions to improve health have increasingly begun to focus on mobile health ("mHealth") interventions to deliver text-based messages containing suggestions, support, education, or other specific content. These ecological momentary interventions (EMIs) can be tailored to the individual and implemented in real time (i.e., daily life).[14] Mobile or electronic devices can be used to provide these interventions in the daily lives of individuals. With a web-based survey, Proudfoot[15] showed that 76% of the general population is interested in using mobile technology for either monitoring or self-management of health. Using EMIs has numerous advantages such as the ability to reach large populations at lower costs,[16,17] especially given that the number of worldwide mobile phone users is immense and continues to expand.[18] A recent meta-analysis found that PP-related EMIs were found to be effective in improving mental health and positive psychological well-being.[19] Furthermore, an EMI intervention focused on providing lifestyle-based one-way text messages (e.g., promoting healthy diet, health screening, and physical activity) led to improvement in cardiac risk factors.[20]

However, no prior intervention has examined the use of text-based messages in the key population of post-ACS patients, In addition, prior work has not examined a combination of messages that promote both positive psychological constructs and education/support around health behavior adherence, such as physical activity or diet. This may be a promising approach given that a combination of psychological and health education interventions may have greater effects on health behavior adherence than either alone.[21]

### B. Preliminary studies

Our team has experience delivering PP interventions, in person and by phone, to numerous patients with depression, multiple sclerosis, diabetes, and most relevant to this IRB proposal, post-ACS patients. We have found that these interventions have been associated with improvements in positive affect, depression, anxiety, and health-related quality of life. We also have experience delivering health education/motivation interventions in over 100 post-ACS patients as part of a combined PP/goal-setting intervention for physical activity.[21] However, we do not yet have experience delivering elements of

these interventions by text messaging, which could serve as an ideal adjunct to promote maintenance of effects after a more intensive initial intervention, or as a promising stand-alone intervention.

**C. Rationale for proposed research and benefits to patients and/or society**

Given: (a) the relationship between psychological well-being and health behavior adherence/superior cardiac outcomes, (b) the potential for combined PP and educational interventions to improve adherence more than either alone, and (c) the acceptability and impact of health-related text messaging on health outcomes in cardiac patients, the use of combined PP-based and health behavior-related text messages in post-ACS patients has the potential to increase physical activity and reduce adverse events in a high-risk, high-yield population of patients. This would have direct benefits to patients and would impact public health, given that >1 million Americans suffer an ACS each year. Given that most post-ACS patients (mean age ~60[22,23]) would likely not be used to receiving healthcare related interventions remotely, key first steps are to determine whether post-ACS patients are willing and able to receive such text messages, whether they find the messages acceptable, and whether they lead to short-term changes in self-reported psychological and behavioral outcomes.

## II. Specific Aims

We will conduct a pilot one-arm project delivering 7 text messages/week containing messages related to PP activities (e.g., recalling positive events), having a heart-healthy diet, or becoming more physically active, for 4 weeks among 80 patients with a prior ACS.

**Specific Aim 1:** To assess the feasibility and acceptability of a pilot text-message-based intervention for post-ACS patients (primary aim).
Hypotheses: Over 50% of eligible patients will enroll in the project and text messages will be successfully delivered to over 90% of enrolled participants. In addition, participants' mean ratings of the intervention's burden (<4/10) will suggest that the intervention is well-accepted.

**Specific aim 2:** To examine the short-term impact of the intervention on relevant self-reported outcomes.
Hypotheses: Participants will have mean pre-post increases in positive affect, optimism, determination, depression, anxiety, self-reported physical activity, self-reported dietary adherence, and self-rated health/function.

**Specific aim 3:** To understand ACS patients' experience, via open-ended interviews, receiving text messages in this project regarding the preferred frequency, duration, timing, and content of the text messages, along with any specific benefits obtained from participation.
Hypotheses: Though qualitative research does not have formal hypotheses, we expect that participants will find that this frequency and duration of messaging was acceptable, and that the positive psychological and physical activity-based messages will be experienced as equally beneficial.

## III. Participant Selection

The convenience sample for this pilot study will be enrolled from two sources: (a) participants prospectively enrolled from inpatient cardiac units at MGH admitted for an ACS, and (b) participants in prior post-ACS studies performed with our team (specifically the observational Gratitude Research in Acute Coronary Events [GRACE] study [PHS IRB 2012P001191], and two linked Positive Emotions in Acute Coronary Events [PEACE] studies [PHS IRB 2013P001961 and 2014P001756]).

### A. Inclusion/exclusion criteria

**Inclusion criteria:** patients eligible for this pilot study must meet the following criteria:

**1. Prior acute coronary syndrome.** To have received a diagnosis of ACS, patients must have met criteria for acute myocardial infarction (MI) or unstable angina (UA). For MI, potential subjects must have met established consensus criteria,[24] specifically elevation of cardiac biomarkers (cardiac troponin T) in addition to: (1) symptoms of ischemia (e.g., acute chest pain), (2) ischemic changes on electrocardiogram (e.g., ST-segment elevation or ST-depression and T-wave inversions), or (3) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. For UA, subjects met formal standardized criteria used in prior cardiac studies:[25,26] (1) crescendo angina, (2) new onset (within 1 month) angina with minimal exertion, or (3) angina with minimal exertion or at rest. When unclear, diagnoses will be clarified with the primary treatment team and adjudicated by the study cardiologist (Dr. James Januzzi [J.J.])

**2. Ability to receive text messages via cellular phone**. Participants must have a cellular phone that: (a) can receive text messages, (b) that they use or check (e.g., checking for voicemail or email messages) at least daily, and (c) that has an unlimited text message plan (to prevent the study text messages causing them to be charged for reception of the messages).

**Exclusion criteria:** patients will be excluded if they had:

1. A periprocedural ACS (ACS occurring in the setting of another medical procedure)
2. A medical condition likely to be terminal within the timeframe of the study
3. An unrelated condition limiting physical activity
4. An inability to communicate in English, or
5. A cognitive disturbance precluding participation or informed consent, as identified using a six-item cognitive screen designed to assess suitability for research participation.[27]

Patients with a periprocedural ACS will be excluded due to concerns that such events may occur in the absence of structural heart disease and likely represent a different pathophysiology, course, and prognosis than those with 'endogenous' ACS. Those unable to complete physical activity due to an unrelated medical condition (e.g., arthritis) will be excluded because the intervention is focused on promoting activity and because this would impede measurement of one study outcome (self-reported physical activity). Furthermore, for all patients, we will only enroll them if they have no contraindications to physical activity per their primary cardiology team. Overall, determination of exclusion criteria will be made in conjunction with the primary medical team (e.g., regarding comorbid or terminal conditions) with consultation and adjudication from the study team cardiologist (J.J.) as needed.

### B. Source of participants and methods of recruitment

Regarding hospitalized patients, recruitment and informed consent procedures for hospitalized cardiac patients will be highly similar to those used for our prior PP studies occurring in ACS patients on cardiac units that occurred on the same units (Partners Healthcare System [PHS] IRB 2013P001961, 2014P001756) and involved very similar inclusion/exclusion criteria. Specifically, two cardiac inpatient

units (Ellison 10 and 11) will serve as the source of subjects for the study. Potential subjects will be those patients who are admitted with a primary diagnosis of ACS. To recruit subjects, study staff will review electronic patient censuses with the study team physician investigators to ensure that the patient indeed appears to have been admitted with an ACS and to identify any specific clear contraindications to participation (e,g., periprocedural ACS noted in record). Study staff will then approach treatment providers on the care unit to inquire about the accuracy of the ACS diagnosis for such patients. If a potentially eligible patient is identified, the study staff member will ask the treatment provider (physician, nurse, or nurse practitioner) to ask the patient whether it would be okay for a study staff member to inform the patient about an optional study on the unit. If the patient is amenable, a study staff member will discuss the study with the patient and assess for inclusion/exclusion criteria.

Regarding recruitment of patients who were in our team's prior studies, we will send them opt-out letters by mail (see letters), signed by the study principal investigator. These letters will explain that we are recruiting potential participants for this study. The letter will describe that if they do not wish to receive a call explaining the study, they can call the study team opt-out line to inform the study team. If the team does not receive an opt-out call after 2 weeks, a study coordinator will call the potential participant (who will have had an ACS, confirmed using the above criteria, based on their qualification for the prior study) and describe the study. The staff member will clarify that this is an optional, separate study from the one in which they previously enrolled.

## IV. Participant enrollment

### A. Methods of enrollment/Procedures for obtaining informed consent

For hospitalized patients, if the patient is interested in the study after the discussion as mentioned above, a study coordinator or physician will approach the patient to further discuss the study. If the patient is willing, the staff member will directly assess for inclusion criteria (especially related to cellular phone availability and use) and exclusion criteria (e.g., comorbid medical illnesses/prognosis and cognitive deficits, as assessed by study staff using the six-item screen). Next, if the patient meets study criteria and is interested in the study, the study staff member 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. To ensure that subjects have the capacity to provide informed consent, we will ask potential subjects to describe their understanding of the study's purpose and their role (e.g., that they understand the timing of text messages and study assessments and their purpose, confidentiality and its limits, and their ability to end participation in the study at any time for any reason). Patients will be given as long as they would like to sign consent (they can complete baseline procedures by phone after discharge if they enroll later). Finally, once subjects sign the consent form, the investigator will perform a focused review of the subject'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 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 inpatient treatment team (and the study cardiologist as needed).

For participants from prior studies, if the patient is potentially interested in the study, the study coordinator will assess the patient for inclusion and exclusion criteria, and if the patient is eligible and willing to participate, we will mail the patient a consent form (and the coordinator will call the patient to ask if there are any questions about the form or the study), and upon receipt of the signed consent form, the participant will be enrolled. We will also ask the participant if they are able to "walk a block or two on level ground," to ensure they are able to safely partake in physical activity. If they answer "no," to this question, we will offer to inquire with their medical provider whether physical activity (such as

walking) is safe, and when needed in such cases, will obtain a release of information to do so.

In all cases, once patients are confirmed subjects in the study, they will complete a series of baseline assessments (see below).

**B. Treatment assignment**

Participants will be enrolled and complete written informed consent as described above. All participants will be assigned to the active/experimental condition (receiving 7 text messages/week for 2 weeks) for the purposes of this pilot/proof-of-concept study.

## V. Study procedures

### A. Study visits

**Baseline assessment and orientation to the intervention**. For patients enrolled during hospitalization, we will contact these participants 2 weeks post-discharge by phone to complete the baseline assessment and the orientation visit to initiate text messaging. This timing will ensure adequate recovery such that participants will be able to complete physical activity upon beginning the intervention (given that the majority of ACS patients are able to engage in basic physical activity such as brisk walking within a week of discharge). For participants from prior studies enrolled via the opt-out letters, the study team will contact them upon receipt of the signed consent form by mail to complete baseline assessments and intervention orientation.

The baseline assessment will consist of gathering of basic demographic information and completion of very brief self-report assessments about psychological, health behavior, and overall health/functional outcome measures (see below for further detail). Upon completion of this assessment, the study coordinator will describe the role of the text messages, specifically describing that participants will receive text messages daily for 4 weeks. The coordinator will reiterate the rationale for the project—that completing exercises to boost mood and optimism may translate into greater well-being, vitality, and energy (and being more active), and that specific reminders and support around becoming more active may more directly promote activity. The coordinator at that contact will also transmit a test text message to confirm successful transmission of such messages.

**2-Week Check-in.** During week 2 of the intervention, the coordinator will contact the patient over the phone to receive any feedback, answer any questions the participants may have, and to reinforce the purpose of the study.

**Follow-up assessment #1.** After completion of the text messaging intervention (week 4), participants will be contacted by phone to repeat the self-report assessments, and to complete quantitative (2 questions) and qualitative (15 minute interview) questions about the intervention.

**Follow-up assessment #2.** Four weeks later (week 8), participants will once more complete the self-report assessments (without interview). This will end their study participation.

### B. Drugs to be used

No drugs will be administered

### C. Devices to be used

No medical devices will be used.

### D. Procedures

A total of 28 intervention text messages (1/day for 4 weeks) will be sent to participants following the baseline assessment.

Messages will be addressed to participants by name (if desired) and sent at a time of their choosing. Immediately following the delivery of the message, participants will receive a second text message asking them to rate the utility of the message on a scale of 0 to 10 (0=not helpful at all and 10=very helpful). A score of 7 or above will be rated "liked" while a score of 6 or below will be rated "disliked." Participants will respond via text message with a rating score, which will be combined with prior feedback and then used to select all subsequent messages. Participants will first receive a set of 14 preselected daily messages that contain a broad range of attributes to allow sufficient participant feedback to clearly identify preferences. Daily adaptation then begins through probabilistic weighting of messages based on prior "liked" attributes. To accomplish this, all messages are annotated for multiple attributes, which include content type (e.g., PP), specific content (e.g., optimism), nature (e.g., information), and whether the message is explicitly prosocial.

The learning algorithm calculates the proportion "liked" (P) of each message type, using messages "liked" and "disliked" of that type and the total number of messages (N) of that attribute with feedback. A weighting multiplier (W) specifies the adaptation rate; a larger W leads to more rapid favoring of messages with "liked" attributes; we chose W=1.5 for a moderate rate of evolution. The values are combined (B = 1 + [W x P x N]) to produce a modifier (B), which changes the probability of selecting future messages of that specific type.

We will deploy the dynamic daily TMI using a database (DynamoDB)[28] to maintain and execute the adaptive algorithm; the database selects messages based on participant responses. Amazon Web Services[29] allows communication between this database and the secure text-messaging program Twilio[30], which securely (HIPAA-compliant) delivers messages to participants

The messages via this server will be sent using the Twilio texting program used by REDCap, which also uses Amazon Web Services (see Twilio security features at https://s3.amazonaws.com/ahoy-assets.twilio.com/Whitepapers/Twilio_Whitepaper_Security-Architecture.pdf). Twilio allows software developers to programmatically make and receive phone calls and send and receive text messages using its web service. Our study team has purchased a Twilio account to allow messages to come from an anonymous phone number rather than the phone of a study staff member.

We have piloted the sending of text messages using these methods within the study team and found them to be feasible and efficient.

The messages will be signed by the Massachusetts General Hospital Cardiac Psychiatry Research Program. Example text messages are listed in Table 1:

| **Daily messages in adaptive TMI with assignment of specific attributes** | | | | |
|---|---|---|---|---|
| **Message** | **Main category** | **Subcategory** | **Education/ Activity** | **Prosocial** |
| Perform 3 kind acts today. | PP | Altruism | Activity | Yes |
| Walking 15 more min/day reduces risk of heart disease. | Physical activity | Walking | Education | No |
| Miss one TV show this evening and take a walk around your block for at least 15-20 minutes. | Physical activity | Walking; TV | Activity | No |
| Eat a piece of fruit today for an afternoon snack. | Diet | Fruit | Activity | No |
| Eating less red meat is associated with lower body weight and lower risk of heart disease. | Diet | Saturated fat/ cholesterol | Education | No |
| **Table 1. Sample messages and assignment of specific attributes.** | | | | |

Participants will be informed that while study staff do not monitor or respond to text messages regularly, participants can opt-out of future messages by texting, "STOP" or calling the study team at any time.

**E. Data to be collected and when data will be collected**

**Baseline Assessment**

Upon enrollment, we will collect basic demographic data (age, gender, race/ethnicity) to characterize our population. Participants will then complete baseline study assessments:

At baseline we will also collect the following self-report measures:

(1) **Measures of psychological states**:

- *Positive psychological states*: Participants will rate their levels of positive affect, optimism, and determination, over the past week, on a 0-10 Likert scale.
- *Negative psychological states*: Participants will also rate levels of depression and anxiety, over the past week, on 0-10 scales.

(2) **Measures of health behaviors and function**:

- *Self-reported physical activity*. Participants will complete a two-item assessment for physical activity that has been validated and used in thousands of patients in the Kaiser Permanente system.[31] We will record completion of moderate activity in number of minutes of activity/week. The items are:
    - In the past 4 weeks, how many days/week did you engage in moderate or greater physical activity (like a brisk walk)?'
    - On those days, how many minutes do you engage in activity at this level?'

These two measures are then multiplied to arrive at the average min/week of moderate or greater physical activity.

- Self-reported dietary adherence: Participants will be asked a single item about self-reported dietary adherence, adapted from the Medical Outcomes Study Specific Adherence Scale[32]: "In the last month, how often have you followed a low-fat, low-salt, or other diet as prescribed by your treatment team?" Choices will include "None of the time," "A little of the time," "Some of the time," "A good bit of the time," "most of the time," and "all of the time."
- *Self-reported health*: Participants will be asked a single item about self-reported health: "In general, how would you rate your health today" with the possible choices being "very good" (1), "good" (2), "moderate" (3), "bad" (4) or "very bad" (5). This scale is a robust predictor of mortality and correlates strongly with other objective health indicators.[33]

*Physical function* will be assessed with the Duke Activity Status Index (DASI).[34] The DASI contains 12 items that inquire about activities of daily living (e.g., bathing), basic physical activity (e.g., walking, climbing stairs), and more strenuous physical function (e.g., vigorous sports) to gauge overall functional capacity. It has been extensively used in cardiac patients,[35,36] and is reliable, valid, and responsive to change. The DASI predicts prognosis in cardiac patients above and beyond the effects of biomarkers,[37] and is prospectively associated with new cardiac events[38] and cardiac mortality.[36]

**Follow-up assessment #1**

After the four-week text message period, participants will then complete a follow-up assessment. The follow-up assessment will consist of the quantitative measures above, in addition to 0-10 overall ratings of the intervention's burden and utility. Finally, they will complete an open-ended (approximately 15 minute) interview:

- Receipt: Did you receive the text messages? How many out of the 28 did you receive?
- Burden/Utility: Were the texts bothersome or annoying? Were they helpful? How?

- Were some more helpful than others? Were the texts about happiness or being active more helpful?
- Impact: Did a text ever specifically lead to an action (e.g., activity, a kind act)?
- Frequency: Were they not frequent enough? Too frequent? Just right?
- Duration: How long would such a program be useful? Would it be useful to have occasional reminders?
- Content: Any thoughts about additional content that could be included in the messages?

We will digitally record and transcribe the qualitative interviews to allow analyses for themes.

**Follow-up assessment #2**

Finally, four weeks later, participants will again repeat by phone the initial self-report quantitative measures.

## VI. Biostatistical Analysis

### A. Specific data variables to be collected for the study

| Assessment | Screening | Enrollment | 4 weeks | 8 weeks |
|---|---|---|---|---|
| Cognitive screen (six-item screen) | X | | | |
| Basic demographic information | | X | | |
| Psychological measures (positive/negative) | | X | X | X |
| Self-reported activity, health, and function (DASI) | | X | X | X |
| Qualitative interview for feedback | | | X | |

### B/C. Study endpoints and statistical methods

*Specific Aim 1: To assess the feasibility and acceptability of a pilot text-message-based intervention for post-ACS patients*.

We will record: (a) % of eligible patients who enroll, (b) % of participants who receive text messages, (c) % of text messages received, and mean ratings of intervention burden.

Data analysis: We will use descriptive statistics (e.g., proportions, means, standard deviations) to assess these outcomes and we will compare them to our hypothesized outcomes: Over 50% of eligible patients will enroll in the project, text messages will be successfully delivered to over 90% of enrolled participants, and participants' mean ratings of the burden of the messages at 4 weeks will be <4/10.

*Specific aim 2: To examine the short-term impact of the intervention on relevant self-reported outcomes*

We will record: pre-post changes in positive affect, optimism, gratitude, determination, depression, anxiety, self-rated physical activity, self-rated health, and physical function, at both 4 and 8 weeks

Data analysis: We will use descriptive statistics to calculate the mean and standard deviation of each variable at each timepoint, along with the change in each variable between baseline and the follow-up

timepoint(s). We will also examine the effect size (Cohen's d) of the pre-post change in each outcome variable at each timepoint (4 and 8 weeks), calculated by dividing the mean change in the variable by the standard deviation of the variable (averaged across timepoints). We will also perform exploratory paired t tests for each outcome variable to assess for significant ($p<.05$, two-tailed) change in these variables, though this pilot project would not be powered to detect pre-post changes. We hypothesize that the text messages will be associated with a small to medium effect size (d=.2-.5) in these outcomes at 4 and 8 weeks.

*Specific aim 3: To understand ACS patients' experience receiving text messages in this project regarding the preferred frequency, duration, timing, and content of the text messages, along with any specific benefits obtained from participation.*

We will record and transcribe responses to the qualitative interviews, and extract themes relevant to the above topics. We will not perform quantitative analyses for this aim, but will use the derived theme(s) to inform future studies utilizing text messaging in this population.

### D. Power analyses

As a proof-of-concept/pilot study, we will not be powered to detect pre-post changes in our main outcome variables with N=80(and estimated 10-15% dropout based on prior studies). However, this study will provide us very useful information on feasibility/acceptability and some useful preliminary data on the potential magnitude of effect of the text messages, along with qualitative feedback from all participants on the logistics, burden, and benefits of such a program.

## VII. RISKS AND DISCOMFORTS

### A. Complications of procedures

Participants may be charged for text messages. We will specifically inquire whether participants have a text messaging plan on their cellular phone; we will be clear that we are unable to provide any funds to cover the costs of text messages and will only enroll those participants who have an unlimited text messaging plan on their device to prevent participants from being charged. Regarding physical activity, the messages recommend walking as the primary physical activity. It is possible that increasing physical activity could have adverse health effects, such as pain, fatigue, or exacerbation of chronic physical symptoms. We will clarify with all participants and when requested, their care providers, that increasing their physical activity by walking is safe.

### B. Drug side effects

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

### C. Device complications/malfunctions

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

### D. Psychosocial risks

Participants may experience discomfort at discussing self-rated psychological experiences and their health at the initial and follow-up assessments and could experience the evaluation as intrusive. Likewise, though the follow-up assessments (including interview at 4 weeks) should be less than 30 minutes, participants may experience this long or inconvenient, and we will check in with them about

this during the assessment. We can break up the assessment into shorter parts (quantitative assessment, qualitative interview) as needed. The text messages (one/day x 4 weeks) may also be experienced as intrusive. We will let patients know at the outset of the interviews that they can ask to stop receiving them at any time via text or phone call.

Participants who do not find the study to provide a benefit to them may find this upsetting as well. Activities to obtain data through the follow-up assessments may be inconvenient for subjects. We will take all measures to ensure patient comfort and will postpone or end interviews at subjects' request. We will also ensure that the PI or other psychiatrist study staff is available to intervene if needed (due to patient discomfort or to answer specific questions about the study), during in-hospital and phone assessments. We have used the briefest methods necessary to assess emotional states and other outcomes to reduce patient discomfort.

As with any study, there is the risk of a breach of confidentiality; these risks will be minimized by using subject 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 and the research assistants doing follow-up assessments; in some cases this may also include the study cardiologist if there is a question of patient safety or accuracy of ACS diagnosis) will have any access to personally identifiable information about subjects, and such access will be limited only to information necessary to complete study tasks. We will repeatedly confirm participants' cellular phone number prior to initiating the text messages and will send a generic text message to participants and receive confirmation of receipt from them in real time before proceeding with any of the study text messages. In addition, the text messages will only contain participants' first names as entered by them. Regarding follow-up assessments and interviews, the digitally audiotaped recordings of the interviews will be identified only with a number (with this number linked to identifying information that is kept in a password-protected database), will be kept in a password-protected database, and will be destroyed once the time period for keeping research-related data has passed. Study staff have been trained in the importance of data confidentiality and proper methods of maintaining privacy and confidentiality.

The main psychosocial safety concern related to patients in this study is regarding depression and suicidal ideation, since we will be asking about depressive symptoms via a 0-10 scale. If patients report a depression score of 8 or higher at either of the follow-up assessments, they will be asked a series of questions about suicidal ideation (see suicidal ideation script). If patients (either enrolled or not enrolled in the study) express suicidal ideation, the study psychiatrist will perform a specific evaluation regarding suicidality and will arrange urgent assessment and management as needed (e.g., arranging for a patient to be seen immediately for a safety assessment in an emergency department). These protections/responses have been used as part of several of our team's projects in the past (e.g., 2010P001414, 2014P001756), and while we expect it to be very unlikely that a participant will have active suicidal ideation, we have successfully activated this protocol and arranged for urgent assessment for projects in the past.

### E. Radiation risks

There will be no radiation exposure in this study.

## VI. POTENTIAL BENEFITS

### A. Potential Benefits to Participating Individuals

Participating individuals may not benefit from participation in this study. Participants receiving the text messages may experience improvements in their psychological well-being, motivation to be active, amount of physical activity, and/or self-rated health. This may be an improvement over no prompts to improve mood and activity, as is current standard practice. Furthermore, the serial evaluations will allow access to emergent care if required.

**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 physical activity and with superior cardiac outcomes. In addition, communications directly promoting physical activity have likewise been linked with greater activity and improvement in cardiac risk factors. Text messaging is being increasingly investigated as a simple, relatively non-intrusive means of providing support, education, and health promotion. This study, by examining the feasibility and preliminary impact of text messages focused on well-being and activity promotion, may serve as the first step in developing a program in ACS patients. Enhancing activity in this population could in turn result in decreased morbidity and mortality. If the text messaging program in this and future studies proves to be feasible, well-accepted, and associated with improvements in physical activity and other key outcomes, it may be well be possible to utilize these easily-delivered messages as part of a clinical care package for ACS 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 subject self-report) will be entered into the REDCap database. At intervals throughout the study, the PI (Dr. Huffman) 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**

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 the text messages (e.g., difficulty sending the messages, participant complaints about intrusiveness of daily messages), we will review our methods and alter the study protocol as needed.

**C. Outcomes monitoring**

For this exploratory study, we will not plan to perform interim analyses. However, given the feasibility and acceptability focus of this study, we will review ratings of intervention ease/utility and pre-post changes in outcomes after 10 and/or 20 participants if our weekly team meeting reviews suggest that there are substantial barriers to acceptability (e.g., reports from participants at follow-ups/interviews, high rates of dropout, requests to stop text messages), in addition to strongly considering changes in the protocol as outlined above in Safety Monitoring, above.

**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.

---

## References


1. 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(4):e18-e209.
2. Yeo KK, Fam JM, Lim ST, et al. Comparison of clinical characteristics, 1-year readmission rates, cost and mortality amongst patients undergoing percutaneous coronary intervention for stable angina, acute coronary syndromes and ST-elevation myocardial infarction. *EuroIntervention.* 2012;8:295.
3. Chow CK, Jolly S, Rao-Melacini P, Fox KA, Anand SS, Yusuf S. Association of diet, exercise, and smoking modification with risk of early cardiovascular events after acute coronary syndromes. *Circulation.* 2010;121(6):750-758.
4. 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. *Archives of Internal Medicine.* 2007;167(16):1798-1803.
5. Sud A, Kline-Rogers EM, Eagle KA, et al. Adherence to medications by patients after acute coronary syndromes. *Annals of Pharmacotherapy.* 2005;39(11):1792-1797.
6. 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(Pt 1):71-84.
7. Rasmussen HN, Scheier MF, Greenhouse JB. Optimism and physical health: a meta-analytic review. *Annals of Behavioral Medicine.* 2009;37:239-256.
8. 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(8):656-662.
9. Seligman M, Steen T, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. *American Psychologist.* 2005;60(5):410-421.
10. 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(5):467-487.
11. Sin NL, Lyubomirsky S. Enhancing well-being and alleviating depressive symptoms with positive psychology interventions: a practice-friendly meta-analysis. *J Clin Psychol.* 2009;65(5):467-487.
12. Charlson M, Boutin-Foster C, Mancuso C, et al. Randomized controlled trials of positive affect and self-affirmation to facilitate healthy behaviors in patients with cardiopulmonary diseases. *Contemp Clin Trials.* 2007;28:748-762.
13. Huffman JC. Development of a positive psychology intervention for patients with acute cardiovascular disease. *Psychosomatic medicine.* 2011;6(2):e14.
14. Mehl R, Conner T. Handbook of research methods for studying daily life. New York: Guilford Press; 2012.

15. Proudfoot J, Parker G, Hadzi Pavlovic D, Manicavasagar V, Adler E, Whitton A. Community attitudes to the appropriation of mobile phones for monitoring and managing depression, anxiety, and stress. *Journal of medical Internet research.* 2010;12(5):e64.
16. Olff M. Mobile mental health: a challenging research agenda. *European journal of psychotraumatology.* 2015;6:27882.
17. Price M, Yuen EK, Goetter EM, et al. mHealth: a mechanism to deliver more accessible, more effective mental health care. *Clinical psychology & psychotherapy.* 2014;21(5):427-436.
18. International Telecommuncation Union. 2005-2015 ICT data for the world bgrablod, http://www.itu.int/en/ITU-D/Statistics/Documents/statistics/2015/ITU_Key_2005-2015_ICT_data.xls U.
19. Versluis A VB, Spinhoven P, van der Ploeg MM, Brosschot JF. Changing mental health and positive psychological well-being using ecological momentary interventions: a systematic review and meta-analysis. J Med Internet Res 2016; 18(6):e152.
20. Chow CK, Redfern J, Hillis GS, et al. Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease: A Randomized Clinical Trial. *JAMA.* 2015;314(12):1255-1263.
21. Huffman JC, Albanese AM, Campbell KA, Beach SR, Millstein RA, Mastromauro CA, Healy BC, Chung WJ, Januzzi JL, Collins LM, Park ER. The Positive Emotions after Acute Coronary Events (PEACE) behavioral health intervention: A factorial design study. Abstract presented at Harvard Psychiatry Day, Boston MA, March 11, 2016 (paper under review as of July 2016).
22. Huffman JC, Mastromauro CA, Sowden GL, Fricchione GL, Healy BC, Januzzi JL. Impact of a depression care management program for hospitalized cardiac patients. *Circulation: Cardiovascular Quality and Outcomes.* 2011;4(2):198-205.
23. Huffman JC, Mastromauro CA, Beach SR, et al. Collaborative care for depression and anxiety disorders in patients with recent cardiac events. *JAMA Internal Medicine.* 2014;174(6):927-935.
24. Thygesen K, Alpert JS, Jaffe AS, et al. Third universal definition of myocardial infarction. *Journal of the American College of Cardiology.* 2012;60(16):1581-1598.
25. Weisz G, Moses JW, Teirstein PS, et al. Safety of sirolimus-eluting stenting and its effect on restenosis in patients with unstable angina pectoris (a SIRIUS substudy). *Am J Cardiol.* 2007;99(8):1044-1050.
26. Huffman JC, Beach SR, Suarez L, et al. Design and baseline data from the Management of Sadness and Anxiety in Cardiology (MOSAIC) randomized controlled trial. *Contemporary Clinical Trials.* 2013;36(2):488-501.
27. 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(9):771-781.
28. Amazon Web Services. Amazon DynamoDB Features. Accessed at: https://aws.amazon.com/dynamodb/features/, September 12, 2018.
29. Amazon Web Services. Cloud computing in healthcare. https://aws.amazon.com/health/. Accessed September 20, 2018.
30. Twilio. Programmable SMS built for developers. Accessed at: https://www.twilio.com/sms, August 21, 2018.
31. Sallis R. Developing healthcare systems to support exercise: exercise as the fifth vital sign. *British journal of sports medicine.* 2011;45(6):473-474.
32. DiMatteo MR, Hays RD, Sherbourne CD. Adherence to cancer regimens: implications for treating the older patient. *Oncology (Williston Park, NY).* 1992;6(2 Suppl):50-57.
33. Idler EL, Benyamini Y. Self-rated health and mortality: a review of twenty-seven community studies. *Journal of health and social behavior.* 1997;38(1):21-37.
34. Alonso J, Permanyer-Miralda G, Cascant P, Brotons C, Prieto L, Soler-Soler J. Measuring functional status of chronic coronary patients. Reliability, validity and responsiveness to clinical change of the reduced version of the Duke Activity Status Index (DASI). *European Heart Journal.* 1997;18(3):414-419.

35. Ellis JJ, Eagle KA, Kline-Rogers EM, Erickson SR. Perceived work performance of patients who experienced an acute coronary syndrome event. *Cardiology.* 2005;104(3):120-126.
36. Grodin JL, Hammadah M, Fan Y, Hazen SL, Tang WH. Prognostic value of estimating functional capacity with the use of the Duke Activity Status Index in stable patients with chronic heart failure. *Journal of cardiac failure.* 2015;21(1):44-50.
37. Tang WH, Topol EJ, Fan Y, et al. Prognostic value of estimated functional capacity incremental to cardiac biomarkers in stable cardiac patients. J Am Heart Assoc. 2014;3(5):e000960.
38. Wessel TR, Arant CB, Olson MB, et al. Relationship of physical fitness vs body mass index with coronary artery disease and cardiovascular events in women. *Journal of the American Medical Association.* 2004;292(10):1179-1187.