

**Study Protocol:** Optimizing a self-directed mobile coping skills training intervention to improve cardiorespiratory failure survivors' psychological distress.

**Short Title:** Blueprint

**Study Design:** A Pilot, Randomized Trial

**Version 1.1 dated 22 July 2020**

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## Abbreviations and Definitions

- Adverse Event (AE)
  - Any untoward medical occurrence associated with or observed in the context of a study procedure. For this study and patient population, an AE will be considered any suicidal ideation. No other events will be considered AEs as this patient population is ill and it is expected that other untoward medical occurrences will occur.
- Clinical Trial Management System (CTMS)
  - For this study, a CTMS known as OnCore will be utilized to manage the study's administrative responsibilities and subject level documentation.
- Duke Regional Hospital (DRH)
  - Study site in which eligible patients will be enrolled.
- Duke University Hospital (DUH)
  - Study site in which eligible patients will be enrolled.
- Electronic Data Capture (EDC)
  - For this study, the EDC will be supported by Pattern Health in which relevant study data, such as screening, enrollment, and clinical variables will be documented. Additionally, the study team will utilize RedCap, which is a secure, Duke approved EDC platform, in which the study screening and enrollment logs will be maintained.
- Electronic Health Record (EHR)
  - Used interchangeably with EMR; the EHR is the patient-specific medical record located in the secure MaestroCare (aka: EPIC).
- Electronic Medical Record (EMR)
  - Used interchangeably with EHR; the EMR is the patient-specific medical record located in the secure MaestroCare (aka: EPIC).
- Electronic Patient Reported Outcomes (ePRO)
  - ePRO can be used to describe study source, such as the patient-completed questionnaires (e.g., HADS, PHQ-10, PTSS), or can refer to the system that houses patient-derived data. For this study, ePRO may refer to the patient-questionnaires for psychological distress OR it may refer to the system, which houses the patient-derived data, which is the mCST app known as "Blueprint."
- Hospital Anxiety and Depression Scale survey (HADS)
  - Anxiety and depression symptoms
- Intensive Care Unit (ICU)
  - Defined as any medical, surgical, trauma, neurological, cardiac, or cardio-thoracic unit in which a patient is receiving cardiac or respiratory support for survival means.
- Institutional Review Board (IRB)
  - Ethical and regulatory committee who provides approval and oversight of clinical trial at study site.
- Mobile Coping Skills Training app (mCST, also known as 'Blueprint')
  - A native app that uses this downloaded as a self-contained program and is subject to the device operating system. The mCST created for this study known as "Blueprint", was developed, and is maintained by Pattern Health (212 W Main St Suite 213, Durham, NC 27701).
- Patient Health Questionnaire-10 (PHQ-10)
  - Physical symptoms
- Post-Traumatic Stress Scale survey (PTSS)
  - PTSD symptoms

- **Protocol Deviation (PD)**
  - An inadvertent event or event this is out of the control of the study team and/or the subject that occurs outside of the study protocol design and/or procedures.
- **Protocol Violation**
  - An act of intentionality that is committed by the study team and/or the subject that occurs outside of the study protocol design and/or procedures.
- **Serious Adverse Event (SAE)**
  - Defined as an adverse event that is both serious and expected in nature; the event may have a reasonable possibility that it is related to a study. SAEs for this study are defined as a suicide attempt, a hospitalization, or death.
- **Suicide Ideation (SI)**
  - The idea of committing self-harm and/or the intent to act on the idea of committing self-harm.
- **Unanticipated Problem (UP)**
  - Any other event, not meeting the definition of PD, UP, AE or SAE that, in the opinion of the principal investigator, merits documentation as it occurred outside the expected design of the study and/or study procedures. These events, like PDs, UPs, AEs, or SAEs, may be reported to the IRB and/or the study sponsor, as applicable.

## Clinical Protocol Synopsis

### 1. Title

Optimizing a self-directed mobile coping skills training intervention to improve cardiorespiratory failure survivors' psychological distress (aka: Blueprint).

### 2. Background

As survival has improved for the 2 million people with cardiorespiratory failure managed annually in the US, it has become apparent that these patients suffer from severe and persistent post-discharge symptoms of psychological distress including depression, anxiety, and post-traumatic stress disorder (PTSD). However, few targeted interventions exist that are relevant to patients' experiences and that accommodate their many physical, and social barriers to personalized care. To fill this gap, we have developed an innovative, native mobile coping skills training (CST) program that promotes automated care delivery and self-management of symptom-related distress. CST, by improving self-efficacy and adaptive coping, reduces psychological distress symptoms, thereby also improving quality of life.

Previous trials, in which this pilot randomized clinical trial (RCT) is based, have demonstrated that adaptive coping skills training (CST), is an active response for managing stressful events such as the experience of a critical illness. Cardiorespiratory failure survivors have emphasized in their own words the importance of coping to their perceived quality of life. While the use of adaptive coping skills (e.g., relaxation, positive reframing, problem solving) is associated with decreased psychological distress, survivors infrequently apply such strategies.

Therefore, we propose a 2-year project that will pilot CST via a native mobile app known as "Blueprint" in which 2 distinct aims will be operationalized and tested. Aim 1 focuses on usability prior to release for real patient use. For aim 1, 5 to 15 subjects will be recruited and enrolled and provide feedback on app use. Aim 2, which is the main focus of this project, is an RCT in which 60 eligible patients will be randomized to 1 of 3 arms in a 3:3:2 manner (i.e., n=25: n=25: n=10). The pilot RCT is both necessary and sufficient to inform a future definitive RCT designed to test a longer-term, self-directed mobile app version of CST. The pilot will ultimately aid in addressing key gaps identified in previous trials (CSTEP and LIFT RCTs). Both trials previously conducted raised questions about the ideal balance between the uses of a CST therapist versus the use of an app to deliver content. At the conclusion of this pilot study, we hope to have addressed the key questions raised in previous work and use the learned information to inform the conduct of a next-step multi-center RCT.

### 3. Study Design

As mentioned in section 2, this project consists of two distinct aims: aim 1 (usability) and aim 2 (RCT). Aim 1 of this project will be conducted within a population of 5 to 15 healthy volunteers using a single study visit lasting approximately 30 to 60 minutes in which they will be asked to provide feedback on the app and its contents. Individuals enrolled into this aim will be asked to provide feedback via written communication. Feedback will be used to improve the app for Aim 2 (RCT).

Aim 2, which is the main focus of this exploratory pilot randomized clinical trial (RCT) is to be conducted within a population of 60 cardio-respiratory survivors with a 3-month follow-up. Eligible patients will be those individuals who are admitted to the hospital and receive treatment for cardio or respiratory failure. Additional characteristics of the target population are those that exhibit high psychological distress, as defined by their scoring at the time of hospital discharge via the Hospital Anxiety and Depression Scale (HADS) and Post Traumatic Stress Scale (PTSS) surveys. Eligible patients will be identified via daily electronic medical record (EMR) review and approached for consent while still hospitalized. Patients will be

asked to complete app registration and baseline survey completion post-consent, but at the time of hospitalization, if possible. Upon discharge, patients will be asked to complete survey 1, T1, to assess their levels of psychological distress. Should the patient demonstrate high enough levels of psychological distress, they will be randomized to 1 of 3 treatment arms:

- Arm 1: mCST Intervention Group 1 (self-directed coping skills training app with CST therapist intro call)
- Arm 2: mCST Intervention Group 2 (self-directed coping skills training app only)
- Arm 3: usual care (control group; no CST therapist and no coping skills training app)

Each participant, regardless of randomization arm will be asked to complete the following surveys at the listed time points below:

- Baseline (during hospitalization, post consent)
  - Collect sociodemographic data and establish baseline psychological distress.
- T1 (at the time of hospital discharge, within 1 week of returning to home but no more than 1 month (30 days) from discharge)
  - Complete the HADS, PTSS, and PHQ-10, QOL 100-point visual analog scale, IADL/ADLs
- T2 (1 month (30 days) post date of discharge; up to 2 months (60 days) for completion)
  - Complete the HADS, PTSS, and PHQ-10, QOL 100-point visual analog scale, IADL/ADLs
- T3 (3 months (90 days) post date of discharge; up to 4 months (120 days) for completion)
  - Complete the HADS, PTSS, and PHQ-10, QOL 100-point visual analog scale, IADL/ADLs, CSQ-8

Additionally, each participant, regardless of randomization arm, will be asked to complete a weekly HADS survey during the first month (30 days) of study participation, post discharge. The purpose of this survey is to assess overall psychological distress.

For those patients who are assigned to arms 1 or 2, they will be asked to utilize the app for 1 month (28 days). During that 1 month time period, they will be provided with weekly coping skills, as listed below:

- *Week 1: Progressive Muscle Relaxation and Pleasant Imagery*
  - Week 1 includes two coping skills: progressive muscle relaxation and pleasant imagery. Progressive muscle relaxation is the practice of taking time to enjoy the *feeling* of relaxation, whereas the practice of pleasant imagery is using one's imagination to create a pleasant or happy scene, like a pleasant daydream, that they can return to at any moment.
- *Week 2: Pleasant Activities and activity-Rest Cycling*
  - Week 2, like week 1, includes two coping skills: pleasant activities and activity rest cycling. Pleasant activities is intended to help one *plan* to do regular activities by 1) convincing one's self to find time and effort to complete the activity/ies they enjoy, 2) develop a schedule to help them commit to completing the activity/ies, and 3) encourage one to hold themselves and have others help hold them accountable to complete the activity/ies. Activity rest cycling is a practice in which one learns to overcome "over activity", meaning doing too much at one time or over doing a particular activity. There are 3 components to practicing activity rest cycling: 1) identify activities that one may over-do, 2) take note of how one feels after the activity is completed, and 3) set time limitations on how long one will perform the activity.
- *Week 3: Fast Relax and Managing Negative Thoughts*
  - Week 3 includes two coping skills: Fast relax and managing negative thoughts. The purpose of fast relax is to help one keep feelings, such as pain or tension levels, low throughout the day by allowing one's self to be still and breath fully for a few seconds to a minute. Managing negative thoughts encourages individuals to understand that having negative thoughts is okay and normal; the practice encourages one to notice their negative thoughts,

such as worry, anger, stress, and then teaches them to take control of the thought(s) and then change the thought to be more positive.

- **Week 4: Problem Solving and Maintenance**
  - *Week 4 includes one additional coping skill: problem solving. Problem solving is a skill that helps an individual focus on one problem at a time and teaches them to 1) recognize what the problem is, 2) understand why there is a problem, and 3) help them think about what they can do to solve the problem. Additionally, during week 4, individuals are instructed on how to maintain the coping skills learned during the previous 3 weeks and are encouraged to practice the skill(s) that worked best for them.*

At the beginning of each week, a brief introduction video explaining the study will be provided. During each week's exercise, patients will have the opportunity to listen to pre-recorded visual audios of physicians and patients describing their own, personal coping mechanisms related to each week's skill.

The native app will track fidelity and adherence by way of automated prompts and the use of an interactive dashboard for administrative users (i.e., study team) to track individual patient use. Should a patient stop responding to the app (e.g., stop using it for any period of time), the study team may contact the patient to remind him/her of their commitment to the study and the importance of compliance.

For those individuals in arm 3, they will receive neither therapist nor app-directed intervention. The study team will administer the weekly surveys during the first month (30 days) via email and/or phone, and at T1, T2, and T3.

The study will be conducted at Duke University Hospital (DUH) and Durham Regional Hospital (DRH).

#### **4. Study Objectives, Hypotheses, and Outcomes**

The overall objective of the pilot RCT is to determine the feasibility, acceptability and clinical impact of the intervention on patients' 1- and 3-month psychological distress symptoms of a self-directed mobile coping skills training (mCST) intervention, known as "Blueprint" as compared to usual care control.

The primary hypothesis in which this study is based is that the mCST will be feasible and acceptable based on comparison of observed to priori benchmarks.

The second hypothesis is compared to usual care, the mCST use by enrolled subjects will lead to improvement in symptoms of psychological distress via the HADS and PTSS at the 1- and 3-month mark post randomization.

The primary outcome of the pilot RCT is centered on acceptability and feasibility. The Client Satisfaction Questionnaire 8 will measure acceptability with open-ended participant feedback completed at the time of T3, which is considered end of study (EOS). Feasibility will be measured by frequency of randomization, retention, and adherence. Secondary outcomes are HADS and PTSS scores at 1 and 3 months post-randomization.

#### **5. Study Population**

Blueprint is centered around the RCT portion of this pilot study. As such, the primary characteristics of the targeted study population will be those individuals who have been admitted to a hospital environment and are seriously ill due to respiratory failure or insufficiency (i.e., conditions that typically require respiratory support such as pneumonia, acute respiratory distress syndrome [ARDS], influenza, trauma, and post-op complications) or cardiac failure or insufficiency (i.e., conditions that require advanced cardiac support such

as septic shock, myocardial infarction, cardiogenic shock, and congestive heart failure). Additionally, given the world-wide pandemic of 2020, patients who experience a hospital admission due to COVID-19 and require respiratory and/or cardiac support will also be enrolled.

**Eligibility Criteria:** Patients who are deemed eligible for study participation will ultimately be those individuals who experience high levels of psychological distress (i.e., HADS total  $\geq 8$ ).

Specifically, patients enrolled into this pilot, RCT will meet the following criteria:

#### Inclusion Criteria (at the time of hospital admission)

1. Adult patient  $\geq 18$  years of age.
2. Managed in a hospital setting for  $\geq 24$  hours during the time inclusion criterion #3 is met.
3. Presence of acute cardiac or respiratory failure, defined as having  $\geq 1$  of the following:
  - a. Mechanical ventilation via endotracheal tube for  $\geq 4$  hours
  - b. Non-invasive ventilation (CPAP, BiPAP) for  $\geq 4$  hours in a 24-hour period provided for acute respiratory failure (not for obstructive sleep apnea or other stable use)
  - c. New supplemental oxygen requirement  $\geq 2$  liters per minute (or increase in baseline continuous oxygen)
  - d. Use of vasopressors for shock of any etiology (ie. isoproterenol, phenylephrine, norepinephrine, epinephrine, dopamine, and vasopressin)
  - e. Use of inotropes for shock of any etiology (ie. dobutamine and milrinone)
  - f. Use of pulmonary vasodilators (ie. flolan, treprostinil, etc.)
  - g. Use of aortic balloon pump or cardiac assist device for cardiogenic shock
  - h. Use of diuretic intravenous drip (ie. lasix)
4. Cognitive status intact, defined as:
  - a. No history of significant cognitive impairment (e.g., dementia) per electronic medical records
  - b. Absence of current, significant cognitive impairment ( $\geq 3$  errors on the Callahan cognitive status screen)
  - c. Decisional capacity present
5. Absence of severe and/or persistent serious mental illness that could disrupt study participation, as noted in the electronic medical record (EMR) or affirmed by clinical staff at the time of screening and approach for consent.  
Defined as any of the following:
  - a. Treatment for severe or unstable mental illness (e.g., psychosis, bipolar affective disorder, schizoaffective disorder, schizoid personality disorder, schizophrenia [as per medical record], hospitalization for any psychiatric disorder) within the 6 months preceding the current hospital admission
  - b. No endorsement of active suicidality at time of admission or informed consent
  - c. No active substance abuse at a severity that impairs ability to participate
6. English fluency

#### Exclusion Criteria (at the time of hospital admission)

1. Complex medical care expected soon after discharge (e.g., planned surgeries, transplantation evaluation, extensive travel needs for follow up care, disruptive chemotherapy/radiation regimen)
2. Unable to complete study procedures as determined by staff.
3. Lack of access to either reliable smartphone with cellular data plan or Wi-Fi.

### Inclusion Criteria (at the time of hospital discharge; at home)

1. Elevated baseline psychological distress symptoms, defined as HADS total score of  $\geq 8$  at the completion of survey 1 (T1).

### Exclusion Criteria (at the time of hospital discharge; at home)

1. Failure to randomize within 1 month after discharge from the hospital to home.
2. Failure to access app within 1 month after randomization.

## 7. Study Procedures

### Screening, Recruitment and Consent

Screening for eligible patients will occur daily via MaestroCare by delegated study team members for the Aim 2 (RCT). For Aim 1 (usability), the study team will recruit healthy volunteers from the Pulmonary Medicine Healthy Volunteer Data Repository (Pro00102890). The study team will maintain a robust screening log of all individuals reviewed and will document whether or not each individual was eligible for the study. Additionally, they will document if each individual was approached for consent and the outcome of consent. It will be essential, for the future RCT that it is understood why individuals are or are not eligible for approach and/or subsequent consent, therefore the screening log will track reason for ineligibility and reason for non-consent.

For those individuals who are eligible to consent, the study team will recruit the individual in-person or remotely using an approved telephone script. Patients for the RCT will be approached, ideally at the time of their hospital admission, just prior to their discharge to an in home setting, if possible. Should the study team be unable to make contact with the patient during the hospitalization, the study team will contact them once discharged home. However, patients can be approached earlier in their admission, if well enough, or within a week of returning to their home for participation in the study. All patients will be informed at the time of recruitment that research is voluntary and they do not have to participate if they do not want to. Furthermore, they will be informed that participation will not affect their care in any way. If a patient chooses to not participate, he/she will be documented as a 'declined' patient and the date of decline, as well as reason for decline (if available) will be documented. Should a patient be approached while in the hospital and opt to consent, they will be asked to complete the app registration and baseline survey, and then a study team member will contact them, once home, to remind them to login to the app to complete T1 for randomization. Should a patient be approached post-hospital discharge, he/she will be asked to complete app registration, baseline survey and T1 on the same day for study enrollment and randomization purposes. As with screening, the study team will be required to maintain a robust enrollment log that documents the patient's consent status, version of informed consent with reference date of IRB approval, and then ultimate study status with associated visit milestones.

It is important to note that for this study, there are several statuses an individual can have. They are listed below:

- **Screened (in screening or screened):** defined as any individual whose EMR (aim 2 only) or REDCap CRF (aim 1 only) has been reviewed against protocol for eligibility purposes. Individuals who are assigned this status must be noted on the screening log.
- **Consented:** defined as any individual who is approached for consent and voluntarily chooses to consent to the study, the procedures, risks and benefits with the understanding that they may withdraw at any time. A signed/dated informed consent must be on record to account for this individual. Patients, enrolled in the aim 2, who reach this status will be required to complete T1 at the time of hospital discharge within 1 week but no more than 1 month from returning to home. Individuals who are assigned this status must be noted on the enrollment log.

- **Declined:** defined as any individual who was approached for consent, but opted to NOT consent and therefore to NOT participate in the study. Individuals who are assigned this status must be noted on the screening log.
- **Randomized (aim 2 only):** defined as any patient who was consented to the study, is discharged from hospital to home, completes T1 survey, and continues to meet all eligibility criteria (see Eligibility Criteria, section 5). Patients who reach this status will be required to interact with the app on a daily basis for 1 month and then complete T2 and T3. Patients who are assigned this status must be maintained on the enrollment log.
- **Screen Failed (aim 2 only):** defined as any patient who was consented to the study, is discharged from hospital to home, and completes T1 survey, and DOES NOT meet all eligibility criteria (see Eligibility Criteria, section 5). Patients who reach this status have no additional follow-ups or study requirements. Patients who are assigned this status must be maintained on the enrollment log.
- **Withdraw by PI or Self:** defined as any individual who voluntarily consents to participate in the study, but is then withdrawn from the study. The PI may withdraw a participant at any time without their consent if the PI deems it is in their best interest to no longer participate OR the patient demonstrates continuous lack of compliance with study protocol and study procedures. Additionally, if the patient is re-admitted to the hospital during the time of randomization, he/she will be withdrawn from the study by the PI. The study team may re-enroll the patient at the time of discharge following the same screening procedures. The patient may withdraw themselves at any time; the study team will be asked to document the reason for withdraw for study records. Patients who reach this status have no additional follow-ups or study requirements. Patients who are assigned this status must be maintained on the enrollment log.
- **Lost to Follow-Up (LTF):** defined as any individual who voluntarily consents to participate in the study but after non-compliance and at least 3 documented, attempted contacts appropriately spaced 1-5 days apart, the individual will be considered LTF.
  - For aim 2 only:
    - Patients who reach this status have no additional follow-ups or study requirements. Patients who are assigned this status must be maintained on the enrollment log.
    - A patient who returns the study team's contacts within 1 week of last attempted contact may resume study participation.
- **Completed:** defined as any individual who both consented and randomized to the study and completed T1-T3 (aim 2 only) or any individual who completed assigned study visit (aim 1 only). Individuals who reach this status have no additional follow-up or study requirements. Individuals who are assigned this status must be maintained on the enrollment log.

## Study Visits

For aim 1, each participant will be asked to complete a singular study visit that last approximately 30-60 minutes. During this study visit, post consent, the individual will be asked to do the following:

- Find and install the Pattern Health app
- Register to the Blueprint study
- Complete baseline survey
- Randomize to 1 of 3 arms or screen fail purposely
- Provide feedback on app content and usability.

For aim 2, each consented patient will be asked to complete up to four individual study visits.

- **Baseline:** this visit is to occur post-consent (same day, ideally) at the time of hospital admission just prior to discharge. However, this visit may occur at the time of hospital discharge within 1-3 days of returning to home. At this visit, the following will occur:
  - App Registration
  - Baseline Survey Completion
- **T1 (Day 0) (+30 days):** this visit is to occur at the time of hospital discharge to home, ideally within the first week (7 days) of returning to home; however, it can occur up to 1 month (30 days) from the time of hospital discharge to home. At this visit, the patient will complete the T1 survey via the app, which includes the HADS, PTSS, and PHQ-10 surveys. Score dependent, the patient will be randomized to 1 of 3 arms: Group 1 (Blueprint app), Group 2 (Blueprint app + therapist), and Group 3 (control; no Blueprint app and no therapist). If the patient's psychological distress score is too low; he/she will receive an automated alert via the app describing they are not eligible and their study participation is complete.
- **T2 (Day 30) (+60 days):** this visit is to occur post 1 month randomization for those patients who remain eligible to participate in the study. HADS, PTSS, and PHQ-10 surveys will be administered again. If the patient's survey scores indicate high levels of distress, as defined by a triggered SI alert or increased distress score from T1, a delegated study team member will contact the patient for safety precautions.
- **T3 (Day 90) (+30 days):** this visit is to occur post 3 months randomization for those patients who remain eligible to participate in the study. HADS, PTSS, and PHQ-10 surveys will be administered again. If the patient's survey scores indicate high levels of distress, as defined by a triggered SI alert or increased distress score from T1, a delegated study team member will contact the patient for safety precautions. At the completion of this survey and assuming no additional follow-up is required due to high levels of distress, the patient's participation in the study is complete.

Additionally, each patient who is randomized will be asked to complete:

- **Weekly Check-In:** for those patients who are eligible for randomization to either Groups 1, 2 or 3, a weekly check-in will be completed by a delegated study team member and/or via the app (randomization group dependent). This weekly check in (i.e., HADS survey) will be available beginning day 4 of the week until day 7 of the week.

#### Compensation

Compensation for study participation will be provided to each patient via Greenphire. Participants in aim 1 will receive \$20 for study participation and completion of the singular study visit. Participants in aim 2 may receive up to a total of \$60 for study completion, \$20 for each survey (T1, T2 and T3) to be paid after the participant has completed the trial.

#### 8. Enrollment Sites

This study will be conducted at Duke University Health (DUH) and Duke Regional Hospital (DRH).

It is anticipated that between both sites, the study team will enroll approximately 2/3 of their population from DUH (~40 patients) and 1/3 from DRH (~20).

## 9. Statistical Design, Analyses Plan, and Sample Size and Power

### Statistical Design and Analyses Plan

The primary goal of this 3-arm pilot RCT is to explore the feasibility and acceptability of mCST to inform a definitive future clinical trial. To do so, we will test differences between observed and a priori-defined benchmarks among mCST recipients using t-tests for continuous variables and chi-square tests for categorical variables.

The secondary goal is to estimate a reasonable range of clinical effect of mCST in comparison to a usual care control condition. General linear models will be used to estimate mean changes and corresponding 95% confidence intervals (CIs) in psychological distress (i.e., HADS and PTSS scores) for each treatment group over the 3 months of post-randomization follow-up using SAS PROC MIXED (SAS Institute, Cary NC). We will fit the models with an unstructured covariance matrix to better understand and represent the correlation between patients' repeated measures. We will also use similar modeling strategies to explore how the key clinical characteristics (e.g., history of ICU delirium, illness severity, diagnosis grouping), objective physical characteristics (e.g., functional status), sociodemographic factors, and mechanistic elements (e.g. self-efficacy) described in the conceptual model are associated with changes in psychological distress both within and between treatment groups. While for main analyses we will pool all mCST participants in comparisons with usual care control, we will also perform exploratory analyses similar to those described above to compare all three groups as well.

### Sample Size and Power

This exploratory trial is not intended to test mCST's efficacy. While the 60-person sample size reflects the pragmatics of recruitment during a short enrollment period, it is large enough both to inform us about the potential challenges of delivering an app-based intervention in the context of post-discharge care as well as to provide meaningful confidence intervals for our estimates as was true for the similarly sized LIFT RCT (R34 AT00819).

## 10. Subject Participation Duration

Participating subjects in aim 1 will be asked to participate in a singular study visit lasting 30-60 minutes. Participating subjects in aim 2 will be asked to participate for up to a total of 3 months. Participating in this pilot, randomized RCT will require 1 month of daily, active participation in which the patient is practicing mCST daily and completing weekly check-ins. At the end of the 1 month (post T1 completion), the patient will be asked to complete T2 survey. Once the patient has completed the T2 survey, he/she is finished with active study participation for an additional 2 months at which time they will be asked to complete T3 survey. Patients will be given the option, between T2 and T3 completion, to continue to utilize the app and the mCST content; however, no weekly check-ins will be completed at this time.

## 11. Study Duration

For this project, Aim 1 (usability testing) is anticipated to take approximately 1-3 months to complete depending on rate of recruitment, user response to app usability, and required fixes to app based on user response.

As this project is centered around Aim 2 (pilot RCT), it is anticipated that from the initiation of Aim 2, that it will take 15 months to complete data collection (~12 months for cumulative enrollment with 3 months to complete all long-term follow up). From the time period of completing follow-up, it is estimated that it will take an additional 1-3 months for all final analyses to be completed for all Aims.

## 12. Risk-Benefit Assessment

### Potential risks

It is possible that participating patients could experience a breach of confidentiality should their records be accessed unlawfully by an outside party or general, inadvertent error. In addition, participants may experience mild anxiety when answering survey questions, though we have not observed this in similar interventions such as LIFT or CSTEP. However, we believe that involvement in this study will present no significant physical, psychological, financial, legal, or other risks.

### Adequacy of protection against risks:

#### Recruitment and informed consent procedures.

First, the Duke Institutional Review Board (IRB) will review and approve the study protocol before study initiation. Informed consent (e-consent or written) will be required from all participants, including content experts. Second, we will use a standardized screening and enrollment protocol that respects participant privacy and rights. The study team will only approach those patients that are deemed appropriate for the study, which will be determined by EMR review and/or conversations with the clinical team and/or PI. The approach of patients will be aided by a short IRB-approved recruitment video. The study team will then ask the patient to read and sign the study consent form at the time of enrollment. Potential subjects will be given as much time as they need to consider study participation. For Aim 2, we will take great care to present the treatment group assignment possibilities ("like drawing a number out of a hat") tactfully and with clearly stated equipoise in person or via phone utilizing the IRB approved telephone script, as we have done successfully in past clinical trials. A copy of the consent form will be given to participant and the original maintained in a secure location at the study site.

### Protections against risk

#### *General oversight*

There are several ongoing mechanisms for monitoring the occurrence of adverse events. The PI or delegated study team member will perform day-to-day monitoring of the study activities. Careful monitoring of all persons entering the study will minimize attrition and will ensure the clinical safety of these patients. A telephone number for the study team facilitates this monitoring and an email address ([blueprintstudy@duke.edu](mailto:blueprintstudy@duke.edu)) provided to participants upon entry into the study to report concerns related to study participation.

#### *Plans to prevent coercion of patients and to ensure voluntary participation*

We will strive to create an environment free of any coercive practices for patients. We will stress that study involvement is voluntary and that choosing to participate or not participate will not affect their care in anyway. In addition, we will utilize the standardized 2-minute informational video, which has been used successfully in past trials describe treatment groups and ensure a similar approach across sites.

#### *Specific longitudinal participant oversight plans for severe psychological distress (including suicidal ideation)*

Given the difficult situations faced by patients, we recognize that there is a slight risk that some participants may become distressed completing questionnaires or viewing study materials, as mentioned above.

We will take the following measures to prevent any negative reactions as well as effectively manage any serious distress that occurs:

- (1) All of the in-person and telephone-based data collection sessions will be conducted by study team members who are sensitive to the issues that arise.

(2) Study team members will emphasize to participants that any interviews or other study interactions are participant-controlled. Thus, participants will be instructed that they are in control over what they share and generally how long they discuss any topic that is addressed.

(3) Participants will be told that they can discontinue an interview or telephone session at any time and that they are free to reschedule an interview or treatment session at any time within the week.

(4) Overall, we are very sensitive to the common and pervasive nature of psychological distress among cardiorespiratory failure survivors and are experienced in discussing these issues with them. There is also a potential risk for identifying underlying mental health issues through the mCST sessions, telephone calls, and survey responses. For issues such as passive suicidal ideation or symptoms of depression, anxiety, or PTSD, an informational sheet will be provided with contact numbers for additional mental health services.

Additionally, at the beginning of the program, all subjects will be informed that the training program may uncover unresolved and distressing thoughts or feelings; and a list of resources will be provided at that time.

### Suicidality Response Plan

Should a patient indicate to a study team member, thoughts of suicidality or ideation of suicidality, the Suicidality Response Plan could be activated.

If the participant is deemed to be at high risk based on direct interaction plus the C-SSRS item response, the delegated study team member will administer the C-SSRS to assess the participant to determine if they endorse active suicidal ideation. The trained staff will also determine if the participant is currently being treated by a mental health professional.

If the patient is deemed not to be actively suicidal, they will be given a list of local mental health resources as follows:

- Duke: Call Emergency Psychiatry at (919)-681-4410 or (919)-681-1316, available 24 hours a day, 7 days a week.
- The National Suicide Prevention Lifeline - 1-800-273-TALK (8255) is a free, 24-hour hotline available to anyone in suicidal crisis or emotional distress.

If the participant is considered actively *suicidal* then at least one of the following plans will be followed depending on the location of the participant for each of the following situations:

- Situation 1
  - If the participant is with one of the study personnel, the study personnel will notify the site PI one of the other PIs immediately.
  - The study personnel will either physically walk the subject to the emergency department, or call a Psychiatric Emergency services number relevant to the site as described above.
- Situation 2
  - If the participant is on the telephone:
    - The study personnel will notify the site PI one of the other PIs immediately
    - The study personnel will stay on the telephone with the subject participant.
    - The study personnel will immediately contact 911 to initiate an on-site rescue if such action is clinically indicated.

- The study personnel will stay on the telephone with the subject until EMS services have contacted the participant.

If the participant is determined to be actively suicidal and require immediate medical therapy, they will be withdrawn from the study.

As described above, all concerns about participant safety will be discussed immediately with the PI - including concerning severe distress that does not involve suicidality.

For these situations, once an “alert situation” is known, the PI will refer the participant if needed (based on a PI-led phone call) to local psychological resources. The study team will also make urgent and emergency referrals as needed based on information learned.

To date based on some studies that have included over 400 participants, we have found that <5% of participants will require a call from the PI during some point in the study period. Of those, none has required referral to acute psychiatric care after a detailed interview from the PI. After a disposition / solution has been made, both the resolution (and follow up) will be documented in the ‘contact log’ section of the data system for reporting to the DSMB.

#### Patient Death While in Study

Finally, we recognize that we are working with a critically ill population that is at risk for death during follow up due to their underlying illness. Before T2 and T3 data collection, the study team will review the EMR to look for records of death, halting all study procedures if death has occurred and noting the date. On phoning any participant, the study team will initiate a conversation to tactfully ascertain the patient’s vital status should a family member answer first. If the patient has died, the study team will provide brief support and their condolences.

#### Withdraw While in Study

If an individual states that they wish to drop out, the study team will respect that as well. A follow-up question may be asked to ascertain the reason for withdraw; however, this is for documentation purposes only.

#### Vulnerable Populations

This project will not enroll individuals from vulnerable populations (e.g., imprisoned persons, minors).

#### Adverse events (AEs), serious adverse events, (SAEs) and unanticipated problems (UPs).

It is recognized that there is a slight risk that some participants may become distressed when completing self-report measures or participating in interviews. When necessary, participants who experience psychological distress *related to completing questionnaires* will be referred for appropriate psychiatric or psychological care. All participants will have access to the PI’s contact information 24 hours a day (shown in the consent form). If a telephone interview is required, a trained study team member who has been trained to be sensitive to the nature of these issues will conduct it.

It is anticipated, in this study, for AEs to be extremely rare as it is a behavioral study. However, it is possible that participants could become distressed in a hospital setting or post-discharge due to increased illness and/or limitations. As such, participants could exhibit signs of and/or experience suicidal ideations or be admitted for mental health symptoms. Therefore, for this study, only increased levels of distress related to completing the questionnaires or completing the coping skills practice and/or suicidal ideations will be considered AEs.

Like, AEs, it is not anticipated that SAEs will occur. However, for this study, an SAE would be defined as a suicide attempt, a hospitalization (post hospitalization that initiated the patient’s eligibility for study

participation), or death. All serious adverse events will be reported within the standard timelines required to the IRB, study sponsor, and/or DSMB, as appropriate and when applicable.

Given the nature of this study, it is anticipated that most enrolled patients will not complete their study visits within the assigned protocol window. Additionally, it is expected that visits and/or mCST practices will be missed. As such, these will not be considered protocol deviations. Should other protocol deviations or unanticipated problems occur, they will be discussed with the PI, documented, and reported to the IRB, study sponsor, and/or DSMB, as appropriate and when applicable.

#### Period and Frequency for Event Assessment and Follow-Up

Protocol deviations and other unanticipated problems, as well as AEs and SAEs, will be recorded in the data collection system throughout the study and reported, as appropriate, to the IRB, study sponsor, and/or DSMB, when applicable.

The study team will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the study team will inquire by way of verbal or written request and/or EMR review, of the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

#### Characteristics of an Adverse or Serious Adverse Event

#### **Relationship to Study Intervention**

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
  - a. The event is known to occur with the study intervention.
  - b. There is a temporal relationship between the intervention and event onset.
  - c. The event abates when the intervention is discontinued.
  - d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
  - a. There is no temporal relationship between the intervention and event onset.
  - b. An alternate etiology has been established.

#### **Expectedness**

The Study PI will be responsible for determining whether an event is expected or unexpected. An event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

#### **Severity**

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

#### Reporting Procedures

##### *Adverse and Serious Adverse Events*

For symptoms that are either great in total burden (i.e., total score is high), a delegated study team member (e.g., therapist) will call the participant to check in. For specific symptoms such as the suicidal ideation, a delegated study team member will also call the participant and assess the severity of the situation, triaging them as appropriate to psychiatric support.

For other matters, the study team will maintain frequent telephone contact with most participants, and can refer those with concerning symptoms.

All deaths will be reported to NHLBI Program Officer and to the DSMB Chair within 72 hours of study's knowledge of death. For each patient who dies, a brief report containing the following variables will be provided:

- Age
- Principal diagnosis
- Number of comorbidities
- Admission APACHE II score
- Days since enrollment
- Brief description of circumstances surrounding death including expected or unexpected.

Serious (fatal or life-threatening) SAEs that are unanticipated and that are related to the intervention will be reported to the NHLBI Program Officer and to the DSMB Chair within 7 days of study staff's knowledge of the SAE.

The summary of all other SAEs will be reported to NHLBI Program Officer and to the DSMB quarterly, unless otherwise requested by the DSMB.

#### Protocol Deviations and Other Unanticipated Problem Reporting

Incidents or events that meet the reporting criteria, as outlined by the Duke IRB, will be reported to the Duke IRB as needed.

The following will be included, at a minimum:

- A detailed description of the event, incident, experience, or outcome;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

#### Privacy

The study team will closely safeguard participant privacy regarding protected health and personal information. A study ID number will be generated at the time of consent and will be maintained in a secure file (e.g., linker file) which will contain the patient name and medical record number. Further, names, birthdates, telephone numbers, addresses, and medical record numbers will be stored securely as described in the RDSP and only accessible by delegated study team members. The RedCAP system will store all data on a secure Duke University server with a sophisticated dual backup system. Study participants cannot view data via the ePRO system or the electronic data capture (EDC) system, supported by Pattern Health. Patients will only have access to the ePRO system and will access the one-way view ePRO system via secure, PHI-free email or text links sent from the app.

#### Digital security

The study digital infrastructure consists of a mobile (i.e., native) app with a built-in electronic patient reported outcomes (ePRO) function, an electronic data capture (EDC) system, and a separate RedCAP digital study database.

- **mCST app:** The mCST app will be a native app. The programming service providers, Pattern Health, endeavor to build technological solutions that preserve the privacy, confidentiality, and security of protected health information that may be part of health records or research datasets. Protected Health Information (PHI) is handled according to appropriate Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Regulations. All staff who work with sensitive data are required to complete appropriate HIPAA training with periodic updates, complete human subjects and data privacy training, comply with site IT Security Policies, and agree to the provisions of the University Rules of Behavior and Sanction Policy. All sites strive to implement reasonable security controls in its product builds guided by FISMA, HIPAA, and OMB Circular A-130, Appendix III. Pattern Health has implemented and maintains several security protocols and controls for apps as well. Pattern Health has developed a formal information security program, with a named individual responsible for its overall execution. Pattern Health also periodically conducts an information technology (IT) security risk assessment on its projects, maintains formal documented protocols for reporting security breaches, assesses and manages security risks associated with vendors and subcontractors, maintains employee on-boarding and off-boarding policies that protect study data and integrity, and ensures continuing employee awareness of and education on security policies, standards, and procedures. In terms of development approaches to security, Pattern Health evaluates and installs security patches in a timely fashion, protects systems against self-propagating malware, maintains secure coding policies and practices, and utilizes standardized secure build processes to protect Pattern Health hardware that accesses customer networks, protecting confidential data against attack. All storage of confidential participant data on Pattern Health hardware is strictly prohibited, and the use of off-shore service providers and/or data center facilities is prohibited unless approved by client. For our study, the native app application and supporting backend system that Pattern Health develops will be hosted securely per DHTS regulations.
- **EDC:** The EDC has been developed and is supported by programming service providers, Pattern Health. As noted above, Pattern Health maintains all appropriate PHI and HIPAA regulations related to human subject research and data privacy and integrity pertaining to data management and IT security. The EDC will be a central location in which all study related data abstracted from each enrolled patient's EMR will be stored. Data will be exported and analyzed for research purposes.
- **REDCap:** The project will utilize a REDCap database system customized for our data needs. For data validation, a series of project-defined data checks and conditional constraints can be required to ensure the highest quality data collection. All system login procedures and data submissions will be transported and encrypted via the Transport Layer Security (TLS) protocol to the secure central database at Duke University. The study team will use login/password (reset every 6 months) credentialing for authentication of all study staff. User-level permissions will be based on user roles and defined within the project system to limit a user's access to only those records an individual is authorized to see. Duke Health Technology Solutions staff to verify that security measures are operational will review audit logs routinely. The servers are scanned twice weekly for vulnerabilities and are currently maintained at the highest level of vendor and CERT security recommendations. Data will never be shared outside the project unless authorized by the project leader and the Duke IRB. User authentication is based on user passwords as described earlier. Password creation requirements are in place to guarantee "strong passwords" as defined by the CERT security recommendations. The lead systems administrator is GIAC Security Essentials certified through May 2018.

### 13. Data management

Most data entry will be self-completed by participants using the validated ePRO system accessed via the mCST app. The study team will complete electronic case report forms (eCRFs) securely integrated within the EDC by abstracting relevant clinical data from each patient's EMR. RedCap will be utilized to maintain study screening and enrollment logs. The mCST app dashboard, developed by Pattern Health for

administrative use only, will be accessed and used by delegated study team members to create scheduled reports on the trials' conduct (e.g., study milestones) to enhance the study's quality. Through this dashboard, quality and consistency of data, will be monitored. The Project Manager will do routine data cleaning and statistical team using customized group-blinded reports that will identify missing, outlier, or nonsensical data at time points when remedying them is feasible.

## 14. Data & Safety Monitoring Plan

### Plans for Assurance of Compliance regarding Adverse Event Reporting.

The study team will be required to document and report adverse events (including serious adverse events) to the Institutional Review Board (IRB), as appropriate and in line with institutional reporting criteria. In addition, all adverse events are reported as part of NIH Progress Reports in the non-competitive and competitive renewals.

### Plans for Assuring Data Accuracy and Protocol Compliance.

The PI will supervise the study, including data management, data accuracy, and protocol compliance. The study biostatistician and Project Manager will be the chief data managers and will adhere to established federal and institutional patient safety and protection guidelines. To assure data accuracy, the Project Manager will review data system reports on a routine basis. These reports will show enrollment, missing data, and other values that are neither study ID- nor outcome-based. The Project Manager will process detailed reports to search for errors and generate basic reports for dissemination for regular staff meetings.

### Data Safety Monitoring Board (DSMB).

Aim 2's RCT trial will be supervised by a single independent DSMB composed of professionals with significant experience in clinical trials, mind and body interventions, epidemiology, and biostatistics who are not directly involved in the study, its interpretation, or any study institution and have no active research relationship with a study team member.

The main responsibilities of the DSMB will be to (a) assess for the presence of potential harms and unintended consequences of the mCST intervention, (b) ensure the validity and integrity of the data, and (c) make recommendations to the investigators and to the NIH about whether the study should be continued without modification, continued with modification, or terminated.

The initial DSMB meeting will occur before the initiation of subject enrollment for the purpose of updating members on the study, ensuring agreement on the review process, establishing the review methodology and procedures, ensuring all conflicts of interest are disclosed (to be reviewed by NHLBI staff), reviewing the protocol, and codifying a written charter. The NHLBI's Data Safety Monitoring Plan (DSMP) Template will be used to guide the drafting of the charter. This document will specify procedures for protocol amendments, ensuring participant confidentiality and privacy, ensuring database protection, coordinating center responsibilities, creating adverse outcome definitions (adverse events, unanticipated problems, and serious adverse events), protocol for reporting and responding to adverse events while also maintaining subject confidentiality, justifying sample size, assessing accrual and compliance, halting and stopping rules (drafted with the assistance of the DSMB chair and the DSMB lead statistician), approving informed consent documents, and guidelines for quality control and quality assurance. Before enrollment begins, the DSMB charter will be approved by both the DSMB and the NHLBI; additionally, ClinicalTrials.gov registration will be finalized as per the Milestone Plan shown in the Research Strategy document.

The first DSMB data review will occur either after the first 20 participants have been enrolled or enrollment has occurred for 6 months, whichever is observed first. Thereafter, the DSMB will review cleaned data reports (provided by the Project Manager 2 weeks before the DSMB meeting) every 3 months during enrollment and

follow up, and will prepare a report with any recommendations within 2 weeks following their review. The specific study metrics that the DSMB will review at each meeting include enrollment rate, dropout rate, HADS scores, PTSS scores, and Adverse Events. The primary safety measures will be Adverse Events reports and HADS scores.

Other items reviewed by the DSMB at each meeting will include: (a) data quality, completeness, and timeliness; (b) performance of the individual sites; (c) adequacy of compliance with goals for recruitment and retention, including women and minorities; (d) protocol adherence; and (e) presence of factors that could adversely affect study outcome or compromise data confidentiality. Study participants will be recovering from life-threatening illnesses managed in intensive care units, which increase the likelihood of death overtime in comparison to healthy individuals. As such, any patient deaths and their cause during the follow up period will be recorded, discussed, and highly scrutinized.

The study biostatistician will oversee any DSMB statistical requests and interpretations. During the review process, formal statistical tests may be performed under DSMB supervision if requested (e.g., examining the differences in Adverse Event or outcome rates between factor-based groups). Additionally, the DSMB may request a formal statistical assessment if a suspicious increase in HADS score is observed in any factor-based group. If a specific factor group is found to have a statistically significant increase in HADS score, the DSMB scope of action may include recommendation for stopping the trial. For differences in study dropout rates, appropriate changes to the protocol will be made by PI consensus after DSMB member input. Any protocol changes, as well as any adverse events, will also be immediately reported to the relevant site IRB, the Central Institutional Review Board (located at Duke University), as well as to the NHLBI Program Officer.

#### Quality Assurance and Confidentiality

First, the electronic data entry system “forces” responses to key questionnaire items (e.g., primary outcomes surveys) before allowing progression through the particular interview’s template, thereby minimizing missing data. For less critical items, delayed data entry is possible (though these data elements are non-essential to primary aims analyses). However, each time the study team logs into the secure data entry system, prompts appear on the welcome screen that show what data elements remain incomplete (as well as the time frame within which they must be entered) for all site participants.

The study PI will ensure the validity of the data system by examining electronic summary case report forms within the EDC system to ensure adequacy and accuracy of data collection as well as transcription to the database itself after enrollment of the first 5 participants. Agreement will be reviewed and discrepancies will be discussed.

#### Confidentiality

Subjects will not be identified on any study reports. University firewalls, multiple passwords, and encryption programs protect the security of the electronic data entry system, which will be housed on a highly secure Duke University server. All personal computers are located in lockable offices and are accessible only by frequently changed passwords. The server room is accessible only to designated University Systems Administrators.

[15. Privacy, Data Storage & Confidentiality – see Research Data Security Plan.](#)

#### [16. IRB of Record](#)

Duke University Health System (DUHS) IRB will be utilized as the IRB of record for this project pilot randomized, RCT and the future RCT.

A copy of the most recent DUHS IRB Federal Wide Assurance (FWA) statement may be found at:  
<https://irb.duhs.duke.edu/about-us/federal-wide-assurance>

DUHS IRB current and historical rosters may be found at: <https://irb.duhs.duke.edu/irb-review-process/rosters>

DUHS IRB meeting dates may be found at: <https://irb.duhs.duke.edu/irb-review-process/irb-meetings>

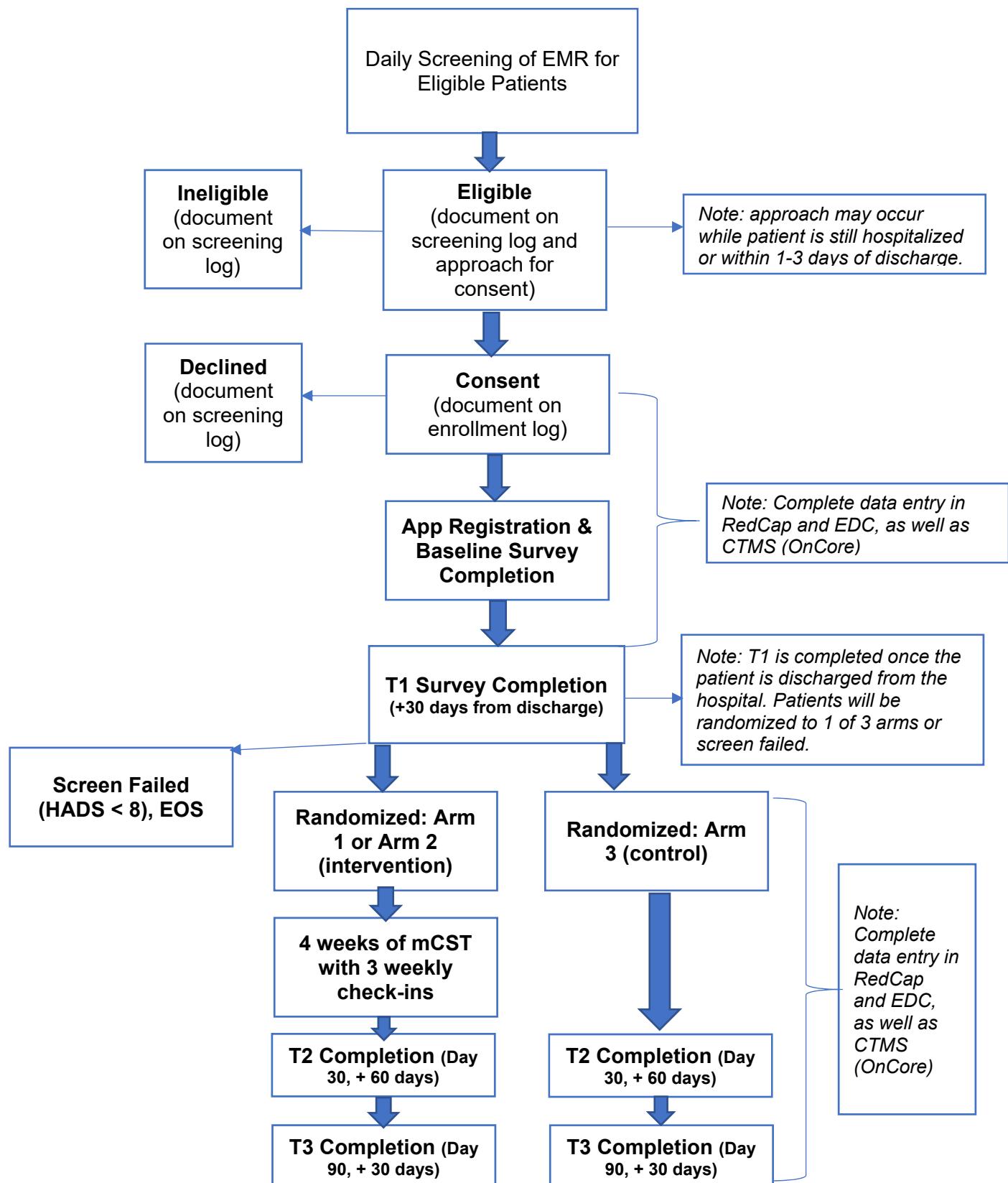
## Appendix 1: Schedule of Events

	Day 0 (In-Hospital, Baseline)	Day 1 , T1 (Discharge) (+30 days)	Week 1	Week 2	Week 3	Week 4 Day 30, T2 (+60 days)	Day 90 (+30 days), T3
<b>Screening*</b>	X						
<b>Consent (a)*</b>	X						
<b>App Registration*</b>	X						
<b>Baseline Survey (b)*</b>	X						
<b>Usability Survey*</b>							
<b>T1 Survey (c)</b>		X					
<b>T2 Survey (c)</b>						X	
<b>T3 Survey (c)</b>							X
<b>Weekly Check-In (d)</b>			X	X	X		
<b>Progressive Muscle Relaxation and Pleasant Imagery (mCST)</b>			X				
<b>Pleasant Activities and Activity Rest Cycling</b>				X			
<b>Fast Relax and Managing Negative Thoughts</b>						X	
<b>Problem Solving and Maintenance</b>							X
<b>Data Entry (e)</b>	X	X				X	X
<b>AE/SAE assessment (f)</b>	X	X				X	X
<b>Survival Status (f)</b>		X				X	X
<b>End of Study (g)</b>							X

- a) Patients may be approached and consented during their admission, if well enough; their hospitalization (e.g., while in step-down), or within 1-3 days of returning to their home for participation in the study
- b) Completion of the baseline survey includes the patient providing self-reported information such as social and demographic information and general health status.
- c) Surveys 1, 2 and 3 will be completed via the app by all study participants, regardless of arm assignments. Patients who are assigned to the control arm will be alerted when it is time to complete their T2 and T3 via app notification.
- d) For those participants assigned to Arm 1 or 2, they will complete a weekly check-in to ascertain overall safety of the patient and usefulness of coping skills practice.
- e) AE/SAE assessment and survival status will be completed via EMR review and/or telephone interview.
- f) Study completion for patients enrolled in the study is considered to occur at the completion of T3. However, participants may undergo EOS if they are withdrawn from the study by the PI or opt to withdraw from the study voluntarily at any time. Should withdraw of a patient occur, the reason for withdraw and date of withdraw will be documented. AE/SAEs and survival status will be noted, as applicable.

\*For aim 1 only.

## Appendix 2: Study Workflow



## Appendix 3: CRFs and Surveys

- A. Hospital Anxiety and Depression Scale (HADS)
- B. Patient Health Questionnaire – 10 (PHQ-10)
- C. Post-Traumatic Stress Scale (PTSS)
- D. QOL-100 Visual Analog Scale
- E. Instrumental Activities of Daily Living/Activities of Daily Living (IADL/ADL)
- F. Baseline Survey

1. Please begin by telling us a little more about yourself.

(This is an information screen that requires no response)

This survey should take approximately 10 minutes to complete. Click Next to continue.

2. Where were you enrolled in the study?

Ask your Clinical Research Coordinator if you are unsure

Response is \*\*one\*\* of:

- Medical ICU
- Surgical ICU
- Cardiac ICU
- Neurological ICU
- Other
- Not Applicable

3. What is your home address?

Street Address City, State and Zip Code

Response is \*\*free-form text\*\*, at least 20 characters.

4. What is your home phone?

(111)111-1111

Response is \*\*free-form text\*\*, at least 10 characters.

5. Is there another phone we could use to contact you?

This question is optional.

(111)111-1111

Response is \*\*free-form text\*\*, at least 10 characters.

6. How do you prefer to be contacted?

Response is \*\*one\*\* of:

- Email
- Text message
- Cell phone call
- Home phone call

7. What is the best time to contact you?

Response is \*\*one\*\* of:

- 6 am - 8 am
- 9 am - 11 am
- 12 pm - 2 pm
- 3 pm - 5 pm
- 6 pm - 8 pm

8. Do you consider yourself Hispanic or Latino?

Response is \*\*one\*\* of:

- Yes
- No
- Don't know or don't want to answer

9. Which racial group do you most identify with?

Select only one.

Response is \*\*one\*\* of:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Other
- I identify with 2 or more groups equally

10. Select all racial groups that you identify with:

Please select all that apply.

Response is \*\*one or more\*\* of:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander

- White
- Other

11. If other, please specify:

Please select all that apply.

Response is \*\*free-form text\*\*.

12. What is your current marital status?

Response is \*\*one\*\* of:

- Married or live with partner
- Separated
- Divorced
- Widowed
- Single

13. Do you have someone who can help to take care of you?

Response is \*\*Yes\*\* or \*\*No\*\*.

14. What is that person's relationship to you?

Response is \*\*one\*\* of:

- Spouse or partner
- Child
- Parent
- Brother or sister
- Other family
- Friend
- Other

15. If other, please specify:

Response is \*\*free-form text\*\*.

16. Do you live with this person?

Response is \*\*Yes\*\* or \*\*No\*\*.

17. Do children 18 or under live at home with you?

Response is \*\*Yes\*\* or \*\*No\*\*.

18. Thinking back to the month or so before hospitalization, what best describes your work situation:

This question is optional.

Response is \*\*one\*\* of:

- Working full time
- Working part time
- Homemaker full time
- Unemployed, looking for work
- Retired
- Disabled
- Student

19. What was the highest grade you completed in school?

This question is optional.

Response is \*\*one\*\* of:

- Less than high school graduate
- High school graduate or equivalent (GED)
- Trade, technical, or vocational school
- Some college but no degree
- College degree
- Postgraduate work or degree

20. How often do you have a drink containing alcohol?

This question is optional.

Response is \*\*one\*\* of:

- Never
- Monthly or less
- 2 to 4 times a month
- 2 to 3 times a week
- 4 or more times a week

21. Do you currently practice meditation or mindfulness?

This question is optional.

Response is \*\*Yes\*\* or \*\*No\*\*.

22. Would you like to be sent a brief overview of the study findings at the conclusion of the study?

This question is optional.

Response is \*\*Yes\*\* or \*\*No\*\*.

23. Please answer these questions by thinking back to the month or so before you were admitted to the hospital.

(This is an information screen that requires no response)

Click Next to continue.

24. I am able to adapt when changes occur.

This question is optional.

Response is \*\*one\*\* of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

25. I can deal with whatever comes my way.

This question is optional.

Response is \*\*one\*\* of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

26. I try to see the humorous side of things when I am faced with problems.

This question is optional.

Response is \*\*one\*\* of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

27. Having to cope with stress can make me stronger.

This question is optional.

Response is \*\*one\*\* of:

- Not true at all

- Rarely true
- Sometimes true
- Often true
- True nearly all the time

28. I tend to bounce back after illness, injury, or other hardships.

This question is optional.

Response is **\*\*one\*\*** of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

29. I believe I can achieve my goals, even if there are obstacles.

This question is optional.

Response is **\*\*one\*\*** of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

30. Under pressure, I stay focused and think clearly.

This question is optional.

Response is **\*\*one\*\*** of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

31. I am not easily discouraged by failure.

This question is optional.

Response is **\*\*one\*\*** of:

- Not true at all
- Rarely true
- Sometimes true

- Often true
- True nearly all the time

32. I think of myself as a strong person when dealing with life's challenges and difficulties.

This question is optional.

Response is \*\*one\*\* of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

33. I am able to handle unpleasant or painful feelings like sadness, fear, and anger.

This question is optional.

Response is \*\*one\*\* of:

- Not true at all
- Rarely true
- Sometimes true
- Often true
- True nearly all the time

34. Click Next to submit your answers.

(This is a score screen that requires no response)

You're almost done!

35. Thank You!

(This is an information screen that requires no response)

Please click Next to exit the survey.

#### G. T1 Survey

# T1

First Survey

1. During the past 3 months, have you been treated for depression, anxiety, PTSD, or any other psychiatric condition?

Response is \*\*Yes\*\* or \*\*No\*\*.

2. In the past 3 months, have you been treated for depression or depressed mood?

Response is \*\*Yes\*\* or \*\*No\*\*.

3. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

4. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

5. In the past 3 months, have you been treated for anxiety?

Response is \*\*Yes\*\* or \*\*No\*\*.

6. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

7. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

8. In the past 3 months, have you been treated for post-traumatic stress disorder (PTSD)?

Response is \*\*Yes\*\* or \*\*No\*\*.

9. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

10. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

11. In the past 3 months, have you been treated for chronic pain?

Response is \*\*Yes\*\* or \*\*No\*\*.

12. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

13. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

14. For the next questions, select the option that best fits your current situation

(This is an information screen that requires no response)

Click Next to continue.

15. I have someone to confide in or talk to about myself and my problems.

Response is \*\*one\*\* of:

- Never
- Rarely
- Sometimes
- Usually
- Always

16. At the end of an average month, what describes how you usually feel when you are paying the bills?

Response is \*\*one\*\* of:

- Short on money and need more to pay bills
- Barely have enough to pay bills and for basic needs
- Have enough for just a few extra things
- Completely comfortable

17. Please select the response that describes how you felt in the past week.

(This is an information screen that requires no response)

Click Next to continue

18. I feel tense or wound up

Response is \*\*one\*\* of:

- Most of the time
- A lot of the time
- Time to time, occasionally
- Not at all

19. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Hardly at all
- Only a little
- Not quite so much
- Definitely as much

20. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Very definitely and quite badly
- Yes, but not too badly
- A little, but it doesn't worry me
- Not at all

21. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- Not at all
- Definitely not so much now
- Not quite so much now
- As much as I always could

22. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- A great deal of the time
- A lot of the time
- From time to time but not too often
- Only occasionally

23. I feel cheerful

Response is \*\*one\*\* of:

- Not at all
- Not often
- Sometimes
- Most of the time

24. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Not at all
- Not often
- Usually
- Definitely

25. I feel as if I am slowed down

Response is \*\*one\*\* of:

- Nearly all of the time
- Very often

- Sometimes
- Not at all

26. I get a sort of frightened feeling like butterflies in the stomach

Response is **\*\*one\*\*** of:

- Very often
- Quite often
- Occasionally
- Not at all

27. I have lost interest in my appearance

Response is **\*\*one\*\*** of:

- Definitely
- I don't take as much care as I should
- I may not take quite as much care
- I take just as much care as ever

28. I feel restless as if I have to be on the move

Response is **\*\*one\*\*** of:

- Very much indeed
- Quite a lot
- Not very much
- Not at all

29. I look forward with enjoyment to things

Response is **\*\*one\*\*** of:

- Hardly at all
- Definitely less than I used to
- A bit less than I used to
- As much as I ever did

30. I get sudden feelings of panic

Response is **\*\*one\*\*** of:

- Very often indeed
- Quite often
- Not very often
- Not at all

31. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Very seldom
- Not often
- Sometimes
- Often

32. Over the last week or so, how often have you been bothered by the following problems?

(This is an information screen that requires no response)

Click Next to continue.

33. Feeling nervous, anxious or on edge

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

34. Not being able to stop or control worrying

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

35. Worrying too much about different things

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

36. Trouble relaxing

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

37. Being so restless that it is hard to sit still

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

38. Becoming easily annoyed or irritable

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

39. Feeling afraid as if something awful might happen

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

40. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No Distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious Distress)

41. In the last week or so, how often have you experienced the following.

(This is an information screen that requires no response)

Click Next to continue.

42. I had sleep problems.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

43. I had nightmares.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

44. I had depression or felt dejected / downtrodden.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

45. I had jumpiness- I am easily frightened by sudden sounds or movements.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

46. I had the need to withdraw from others.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

47. I had irritability - I was easily agitated, annoyed and angered.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

48. I had frequent mood swings.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

49. I had a bad conscience, blamed myself, or had guilty feelings.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

50. I had a fear of places or situations that reminded me of the Intensive Care Unit.

Response is \*\*one position\*\* in this scale:

- 1 (Never)

- 2
- 3
- 4
- 5
- 6
- 7 (Always)

51. I had muscular tension.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

52. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No Distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious Distress)

53. Over the last 2 weeks, how much have you been bothered by any of the following problems?

(This is an information screen that requires no response)

Click Next to continue.

54. Pain

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

55. Difficulty concentrating

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

56. Weakness

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

57. Feeling your heart pound or race

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

58. Shortness of breath (or other breathing problems)

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

59. Stiffness in joints or muscles

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

60. Constipation or diarrhea

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

61. Nausea, gas or indigestion

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

62. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No Distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious Distress)

63. In general, how would you rate your current quality of life?

Response is \*\*one position\*\* in this scale:

- 0 (Worst imaginable quality of life)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Best imaginable quality of life)

78. How much do you agree or disagree with each statement?

(This is an information screen that requires no response)

Click Next to continue.

79. I never give up.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

80. I do everything to get well.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

81. I keep fighting to get better.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

82. I am afraid of pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

83. I can hardly tolerate pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

84. I am tough to myself when in pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

85. I view my illness as a personal learning experience.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

86. I am able to turn my illness into something positive.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

87. I use my illness in a creative way.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

88. I am gloomy about recovery.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

89. I feel the future is bleak.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

90. I do not believe in a happy ending.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

91. I resign myself to my destiny.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

92. I reconcile myself to the inevitable.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

93. I accept whatever will happen.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

94. Please indicate how frequently or infrequently you've been having each experience over the past 3 days, including today.

(This is an information screen that requires no response)

Click Next to continue.

95. I'm finding it difficult to stay focused on what's happening in the present.

Response is **\*\*one\*\*** of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost Never

96. I'm rushing through activities without being really attentive to them.

Response is **\*\*one\*\*** of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

97. I'm doing jobs or tasks automatically, without being aware of what I'm doing.

Response is **\*\*one\*\*** of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

98. I'm finding myself preoccupied with the future or the past.

Response is **\*\*one\*\*** of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

99. I'm finding myself doing things without paying attention.

Response is **\*\*one\*\*** of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

100. Click Next to submit your answers and see your results.

(This is a score screen that requires no response)

101. Thank you.

(This is an information screen that requires no response)

After reviewing your results you were found to have a low needs score, and this is a good thing! You are not required to complete any other surveys or exercises. Your participation has been completed as of today.

**CLICK NEXT TO SAVE YOUR RESULT**

102. Thank you!

(This is an information screen that requires no response)

Congratulations! You are now enrolled in the Blueprint program. You will find new tasks added to your home screen daily.

You can then review your daily tip and complete your coping skills practice.

**CLICK NEXT TO SAVE YOUR RESULT**

#### [H. T2 Survey](#)

# T2

Second Survey

1. In the past month, have you been treated for depression, anxiety, PTSD, or any other psychiatric condition?

Response is \*\*Yes\*\* or \*\*No\*\*.

2. In the past month, have you been treated for depression or depressed mood?

Response is \*\*Yes\*\* or \*\*No\*\*.

3. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

4. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

5. In the past month, have you been treated for anxiety?

Response is \*\*Yes\*\* or \*\*No\*\*.

6. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

7. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

8. In the past month, have you been treated for post-traumatic stress disorder (PTSD)?

Response is \*\*Yes\*\* or \*\*No\*\*.

9. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

10. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

11. In the past month, have you been treated for chronic pain?

Response is \*\*Yes\*\* or \*\*No\*\*.

12. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

13. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

14. Since you were last discharged from the hospital, have you been admitted to the hospital again?

Response is \*\*Yes\*\* or \*\*No\*\*.

15. How many times have you been admitted?

Response is \*\*one\*\* of:

- Once
- 2 times
- 3 or more times

16. For the next questions, select the option that best fits your current situation.

(This is an information screen that requires no response)

Click Next to continue.

17. I have someone to confide in or talk to about myself and my problems.

Response is \*\*one\*\* of:

- Never
- Rarely
- Sometimes
- Usually
- Always

18. At the end of an average month, what describes how you usually feel when you are paying the bills?

Response is \*\*one\*\* of:

- Short on money and need more to pay bills
- Barely have enough to pay bills and for basic needs
- Have enough for just a few extra things
- Completely comfortable

19. Please select the response that describes how you felt in the past week.

(This is an information screen that requires no response)

Click Next to continue

20. I feel tense or wound up

Response is \*\*one\*\* of:

- Not at all
- Time to time, occasionally
- A lot of the time
- Most of the time

21. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

22. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Not at all
- A little, but it doesn't worry me
- Yes, but not too badly
- Very definitely and quite badly

23. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

24. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- Only occasionally
- From time to time but not too often
- A lot of the time
- A great deal of the time

25. I feel cheerful

Response is \*\*one\*\* of:

- Most of the time
- Sometimes
- Not often
- Not at all

26. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Definitely
- Usually
- Not often
- Not at all

27. I feel as if I am slowed down

Response is \*\*one\*\* of:

- Not at all
- Sometimes
- Very often
- Nearly all of the time

28. I get a sort of frightened feeling like butterflies in the stomach

Response is \*\*one\*\* of:

- Not at all
- Occasionally
- Quite often
- Very often

29. I have lost interest in my appearance

Response is \*\*one\*\* of:

- I take just as much care as ever
- I may not take quite as much care
- I don't take as much care as I should
- Definitely

30. I feel restless as if I have to be on the move

Response is \*\*one\*\* of:

- Not at all
- Not very much
- Quite a lot
- Very much indeed

31. I look forward with enjoyment to things

Response is \*\*one\*\* of:

- As much as I ever did
- A bit less than I used to
- Definitely less than I used to
- Hardly at all

32. I get sudden feelings of panic

Response is \*\*one\*\* of:

- Not at all

- Not very often
- Quite often
- Very often indeed

33. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Often
- Sometimes
- Not often
- Very seldom

34. Over the last week or so, how often have you been bothered by the following problems?

(This is an information screen that requires no response)

Click Next to continue.

35. Feeling nervous, anxious or on edge

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

36. Not being able to stop or control worrying

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

37. Worrying too much about different things

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

38. Trouble relaxing

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

39. Being so restless that it is hard to sit still

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

40. Becoming easily annoyed or irritable

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

41. Feeling afraid as if something awful might happen

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

42. The last few questions asked how often you were bothered by the problems. Now, please share show how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious distress)

43. In the last week or so, how often have you experienced the following.

(This is an information screen that requires no response)

Click Next to continue.

44. I had sleep problems.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

45. I had nightmares.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

46. I had depression or felt dejected/downtrodden.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

47. I had jumpiness- I am easily frightened by sudden sounds or movements.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5

- 6
- 7 (Always)

48. I had the need to withdraw from others.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

49. I had irritability - I was easily agitated, annoyed or angered.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

50. I had frequent mood swings.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

51. I had a bad conscience, blamed myself, had guilty feelings.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

52. I had fear of places or situations that remind me of the Intensive Care Unit.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

53. I had muscular tension.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

54. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious distress)

55. Over the last 2 weeks, how much have you been bothered by any of the following problems?

(This is an information screen that requires no response)

Click Next to continue.

56. Pain

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

57. Difficulty concentrating

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

58. Weakness

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

59. Feeling your heart pound or race

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

60. Shortness of breath (or other breathing problems)

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

61. Stiffness in joints or muscles

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

62. Constipation or diarrhea

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

63. Nausea, gas, or indigestion

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

64. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious distress)

65. In general, how would you rate your current quality of life?

Response is \*\*one position\*\* in this scale:

- 0 (Worst imaginable quality of life)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Best imaginable quality of life)

66. Currently I am able to:

(This is an information screen that requires no response)

Click Next to continue.

67. ... bathe myself em>(either a sponge bath, tub bath, or shower)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

68. ... dress myself em>(like putting on a shirt, buttoning and zipping, etc.)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

69. ... feed myselfem> (holding fork, cutting food, drinking from a glass)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

70. ... get from a bed to a chair by myself

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

71. ... control my bladder or bowels

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

72. ... use the toilet by myself

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

73. ... use the telephone em>(including looking up numbers and dialing)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

74. ... get to places beyond walking distance em>(drive own car or travel alone in buses or taxis)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

75. ... go shopping for groceries or clothes

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

76. ... prepare my own meals

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

77. ... do housework em>(wash dishes, clean floors, etc.)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

78. ... take my own medicine

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

79. ... handle my own money em>(write checks, pay bills)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

80. How much do you agree or disagree with each statement?

(This is an information screen that requires no response)

Click Next to continue.

81. I never give up.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

82. I do everything to get well.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

83. I keep fighting to get better.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

84. I am afraid of pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

85. I can hardly tolerate pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

86. I am tough to myself when in pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

87. I view my illness as a personal learning experience.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

88. I am able to turn my illness into something positive.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

89. I use my illness in a creative way.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

90. I am gloomy about recovery.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

91. I feel the future is bleak.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

92. I do not believe in a happy ending.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

93. I resign myself to my destiny.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

94. I reconcile myself to the inevitable.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

95. I accept whatever will happen.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

96. Please indicate how frequently or infrequently you've been having each experience over the past 3 days, including today.

(This is an information screen that requires no response)

Click Next to continue.

97. I'm finding it difficult to stay focused on what's happening in the present.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

98. I'm rushing through activities without being really attentive to them.

Response is \*\*one\*\* of:

- Almost Always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

99. I'm doing jobs or tasks automatically, without being aware of what I'm doing.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

100. I'm finding myself preoccupied with the future or the past.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

101. I'm finding myself doing things without paying attention.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

102. Please help us improve the Blueprint program by answering some questions about it. We are interested in your honest opinion, whether positive or negative.

(This is an information screen that requires no response)

Click Next to continue.

103. How would you rate the quality of the Blueprint program?

Response is \*\*one\*\* of:

- Excellent
- Good
- Fair
- Poor

104. Did you get the kind of program that you wanted?

Response is \*\*one\*\* of:

- Yes, definitely
- Yes, generally
- No, not really
- No, definitely not

105. To what extent has the Blueprint program met your needs?

Response is \*\*one\*\* of:

- Almost all of my needs have been met
- Most of my needs have been met
- Only a few of my needs have been met
- None of my needs have been met

106. If a friend were in need of similar help, would you recommend the Blueprint program to him or her?

Response is \*\*one\*\* of:

- Yes, generally

- Yes, generally
- No, not really
- No, definitely not

107. How satisfied are you with the amount of help you received in the Blueprint program?

Response is **\*\*one\*\*** of:

- Very satisfied
- Mostly satisfied
- Indifferent or mildly dissatisfied
- Quite dissatisfied

108. Has the Blueprint program helped you to deal more effectively with your problems or stresses?

Response is **\*\*one\*\*** of:

- Yes, it helped a great deal
- Yes, it helped somewhat
- No, it really didn't help
- No, it seemed to make things worse

109. In an overall, general sense, how satisfied are you with the Blueprint program?

Response is **\*\*one\*\*** of:

- Very satisfied
- Mostly satisfied
- Indifferent or mildly dissatisfied
- Quite dissatisfied

110. If you were to decide about participating or not in the Blueprint program, would you do it again?

Response is **\*\*one\*\*** of:

- Yes, definitely
- Yes, I think so
- No, I don't think so
- No, definitely not

111. Could you provide any comments about specific ways the Blueprint program helped or didn't help you?

Response is **\*\*free-form text\*\***.

112. Click Next to submit your answers and see your results.

(This is a score screen that requires no response)

113. Thank You!

(This is an information screen that requires no response)

Please click Next to exit the survey.

I. T3 Survey

T3

Third Survey

1. During the past month, have you been treated for depression, anxiety, PTSD, or any other psychiatric condition?

Response is \*\*Yes\*\* or \*\*No\*\*.

2. In the past month, have you been treated for depression or depressed mood?

Response is \*\*Yes\*\* or \*\*No\*\*.

3. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

4. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

5. In the past month, have you been treated for anxiety?

Response is \*\*Yes\*\* or \*\*No\*\*.

6. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

7. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

8. In the past month, have you been treated for post-traumatic stress disorder (PTSD)?

Response is \*\*Yes\*\* or \*\*No\*\*.

9. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

10. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

11. In the past month, have you been treated for chronic pain?

Response is \*\*Yes\*\* or \*\*No\*\*.

12. Were you treated with medication?

Response is \*\*Yes\*\* or \*\*No\*\*.

13. Were you treated by a psychiatrist, psychologist, or counselor?

Response is \*\*Yes\*\* or \*\*No\*\*.

14. Since you were last discharged from the hospital, have you been admitted to the hospital again?

Response is \*\*Yes\*\* or \*\*No\*\*.

15. How many times have you been admitted?

Response is \*\*one\*\* of:

- Once
- 2 times
- 3 or more times

16. For the next questions, select the option that best fits your current situation.

(This is an information screen that requires no response)

Click Next to continue.

17. I have someone to confide in or talk to about myself and my problems.

Response is \*\*one\*\* of:

- Never
- Rarely
- Sometimes
- Usually
- Always

18. At the end of an average month, what describes how you usually feel when you are paying the bills?

Response is \*\*one\*\* of:

- Short on money and need more to pay bills
- Barely have enough to pay bills and for basic needs
- Have enough for just a few extra things

- Completely comfortable

19. Please select the response that describes how you felt in the past week.

(This is an information screen that requires no response)

Click Next to continue

20. I feel tense or wound up

Response is \*\*one\*\* of:

- Not at all
- Time to time, occasionally
- A lot of the time
- Most of the time

21. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

22. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Not at all
- A little, but it doesn't worry me
- Yes, but not too badly
- Very definitely and quite badly

23. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

24. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- Only occasionally
- From time to time but not too often

- A lot of the time
- A great deal of the time

25. I feel cheerful

Response is \*\*one\*\* of:

- Most of the time
- Sometimes
- Not often
- Not at all

26. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Definitely
- Usually
- Not often
- Not at all

27. I feel as if I am slowed down

Response is \*\*one\*\* of:

- Not at all
- Sometimes
- Very often
- Nearly all of the time

28. I get a sort of frightened feeling like butterflies in the stomach

Response is \*\*one\*\* of:

- Not at all
- Occasionally
- Quite often
- Very often

29. I have lost interest in my appearance

Response is \*\*one\*\* of:

- I take just as much care as ever
- I may not take quite as much care
- I don't take as much care as I should
- Definitely

30. I feel restless as if I have to be on the move

Response is \*\*one\*\* of:

- Not at all
- Not very much
- Quite a lot
- Very much indeed

31. I look forward with enjoyment to things

Response is \*\*one\*\* of:

- As much as I ever did
- A bit less than I used to
- Definitely less than I used to
- Hardly at all

32. I get sudden feelings of panic

Response is \*\*one\*\* of:

- Not at all
- Not very often
- Quite often
- Very often indeed

33. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Often
- Sometimes
- Not often
- Very seldom

34. Over the last week or so, how often have you been bothered by the following problems?

(This is an information screen that requires no response)

Click Next to continue.

35. Feeling nervous, anxious or on edge

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

36. Not being able to stop or control worrying

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

37. Worrying too much about different things

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

38. Trouble relaxing

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

39. Being so restless that it is hard to sit still

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

40. Becoming easily annoyed or irritable

Response is \*\*one\*\* of:

- Not at all
- A couple of days
- More than half the days
- Nearly every day

41. Feeling afraid as if something awful might happen

Response is \*\*one\*\* of:

- Not at all
- A couple of days

- More than half the days
- Nearly every day

42. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious distress)

43. In the last week or so, how often have you experienced the following?

(This is an information screen that requires no response)

Click Next to continue.

44. I had sleep problems.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

45. I had nightmares.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

46. I had depression or felt dejected/downtrodden.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

47. I had jumpiness- I am easily frightened by sudden sounds or movements.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

48. I had the need to withdraw from others.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

49. I had irritability - I was easily agitated, annoyed or angered.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

50. I had frequent mood swings.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

51. I had a bad conscience, blamed myself, or had have guilty feelings.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

52. I had a fear of places or situations that remind me of the Intensive Care Unit.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4
- 5
- 6
- 7 (Always)

53. In the past week or so, I had muscular tension.

Response is \*\*one position\*\* in this scale:

- 1 (Never)
- 2
- 3
- 4 [default]
- 5
- 6
- 7 (Always)

54. The last few questions asked how often you were bothered by the problems. Now, please share show how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious distress)

55. Over the last 2 weeks, how much have you been bothered by any of the following problems?

(This is an information screen that requires no response)

Click Next to continue.

56. Pain

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

57. Difficulty concentrating

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

58. Weakness

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

59. Feeling your heart pound or race

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

60. Shortness of breath (or other breathing problems)

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

61. Stiffness in joints or muscles

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

62. Constipation or diarrhea

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

63. Nausea, gas, or indigestion

Response is \*\*one\*\* of:

- Not bothered at all
- Bothered a little
- Bothered a lot

64. The last few questions asked how often you were bothered by the problems. Now, please share how much distress the problem caused you:

Response is \*\*one position\*\* in this scale:

- 0 (No distress)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Serious distress)

65. In general, how would you rate your current quality of life?

Response is **\*\*one position\*\*** in this scale:

- 0 (Worst imaginable quality of life)
- 10
- 20
- 30
- 40
- 50 [default]
- 60
- 70
- 80
- 90
- 100 (Best imaginable quality of life)

66. Currently I am able to:

(This is an information screen that requires no response)

Click Next to continue.

67. ... bathe myself (either a sponge bath, tub bath, or shower)

Response is **\*\*one\*\*** of:

- Need no help
- Need some help or unable to do

68. ... dress myself (like putting on a shirt, buttoning and zipping, etc.)

Response is **\*\*one\*\*** of:

- Need no help
- Need some help or unable to do

69. ... feed myself (holding fork, cutting food, drinking from a glass)

Response is **\*\*one\*\*** of:

- Need no help
- Need some help or unable to do

70. ... get from a bed to a chair by myself

Response is **\*\*one\*\*** of:

- Need no help
- Need some help or unable to do

71. ... control my bladder or bowels

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

72. ... use the toilet by myself

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

73. ... use the telephone (including looking up numbers and dialing)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

74. ... get to places beyond walking distance (drive own car or travel alone in buses or taxis)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

75. ... go shopping for groceries or clothes

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

76. ... prepare my own meals

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

77. ... do housework em>(wash dishes, clean floors, etc.)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

78. ... take my own medicine

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

79. ... handle my own money (write checks, pay bills)

Response is \*\*one\*\* of:

- Need no help
- Need some help or unable to do

80. How much do you agree or disagree with each statement?

(This is an information screen that requires no response)

Click Next to continue.

81. I never give up.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

82. I do everything to get well.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

83. I keep fighting to get better.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

84. I am afraid of pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

85. I can hardly tolerate pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

86. I am tough to myself when in pain.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

87. I view my illness as a personal learning experience.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

88. I am able to turn my illness into something positive.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

89. I use my illness in a creative way.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

90. I am gloomy about recovery.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

91. I feel the future is bleak.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

92. I do not believe in a happy ending.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

93. I resign myself to my destiny.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

94. I reconcile myself to the inevitable.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

95. I accept whatever will happen.

Response is \*\*one\*\* of:

- Totally disagree
- Disagree somewhat
- Neutral
- Agree somewhat
- Totally agree

96. Please indicate how frequently or infrequently you've been having each experience over the past 3 days, including today.

(This is an information screen that requires no response)

Click Next to continue.

97. I'm finding it difficult to stay focused on what's happening in the present.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

98. I'm rushing through activities without being really attentive to them.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

99. I'm doing jobs or tasks automatically, without being aware of what I'm doing.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

100. I'm finding myself preoccupied with the future or the past.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

101. I'm finding myself doing things without paying attention.

Response is \*\*one\*\* of:

- Almost always
- Very frequently
- Somewhat frequently
- Somewhat infrequently
- Very infrequently
- Almost never

102. Click Next to submit your answers and see your results.

(This is a score screen that requires no response)

103. Thank You!

(This is an information screen that requires no response)

Please click Next to exit the survey.

#### J. Weekly Check-Ins

### Week 1 Check In

# Week 1 Check In

## Week 1 Check In

Time for the 1-minute Blueprint weekly mini-survey!

1. Please select the response that describes how you felt in the past week.

(This is an information screen that requires no response)

Click Next to continue

2. I feel tense or wound up

Response is \*\*one\*\* of:

- Not at all
- Time to time, occasionally
- A lot of the time
- Most of the time

3. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

4. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Not at all
- A little, but it doesn't worry me
- Yes, but not too badly
- Very definitely and quite badly

5. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

6. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- Only occasionally
- From time to time but not too often
- A lot of the time
- A great deal of the time

7. I feel cheerful

Response is \*\*one\*\* of:

- Most of the time
- Sometimes
- Not often
- Not at all

8. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Definitely
- Usually
- Not often
- Not at all

9. I feel as if I am slowed down

Response is \*\*one\*\* of:

- Not at all
- Sometimes
- Very often
- Nearly all of the time

10. I get a sort of frightened feeling like butterflies in the stomach

Response is \*\*one\*\* of:

- Not at all
- Occasionally
- Quite often
- Very often

11. I have lost interest in my appearance

Response is \*\*one\*\* of:

- I take just as much care as ever
- I may not take quite as much care
- I don't take as much care as I should
- Definitely

12. I feel restless as if I have to be on the move

Response is \*\*one\*\* of:

- Not at all
- Not very much
- Quite a lot
- Very much indeed

13. I look forward with enjoyment to things

Response is \*\*one\*\* of:

- As much as I ever did
- A bit less than I used to
- Definitely less than I used to
- Hardly at all

14. I get sudden feelings of panic

Response is \*\*one\*\* of:

- Not at all
- Not very often
- Quite often
- Very often indeed

15. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Often
- Sometimes
- Not often
- Very seldom

16. How confident do you feel using progressive muscle relaxation?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70

- 80
- 90
- 100 (Extremely confident)

17. That's okay. It is normal to feel a little unsure at first with progressive muscle relaxation. Most people find that their confidence improves with practice. You can do it!

(This is an information screen that requires no response)

18. You are off to a great start. It is normal to feel this way about progressive muscle relaxation at this point. Remember to practice daily. Great work!

(This is an information screen that requires no response)

19. : Wow, you really have the hang of progressive muscle relaxation. Remember to keep practicing. Great work!

(This is an information screen that requires no response)

20. How helpful is using progressive muscle relaxation

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

21. That's OK. It often takes time to get comfortable with a new skill and see its benefits. Most people find that the more they practice progressive muscle relaxation, the more helpful they find it. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

22. That's great. It sounds like progressive muscle relaxation might be a useful tool for you. Keep practicing—the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

23. Great! It sounds like progressive muscle relaxation is a really useful tool for you. Keep practicing - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

24. How confident do you feel using pleasant imagery

This question includes an image.

Response is **\*\*one position\*\*** in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

25. That's okay. It is normal to feel a little unsure at first with pleasant imagery. Most people find that their confidence improves with practice. You can do it.

(This is an information screen that requires no response)

26. You are off to a great start. It is normal to feel this way about pleasant imagery at this point. Remember to practice daily. Great work!

(This is an information screen that requires no response)

27. Wow, you really have the hang of pleasant imagery. Remember to keep practicing. Great work!

(This is an information screen that requires no response)

28. How helpful is using pleasant imagery?

This question includes an image.

Response is **\*\*one position\*\*** in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80

- 90
- 100 (Extremely helpful)

29. That's OK. It often takes time to get comfortable with a new skill and see its benefits. Most people find that the more they practice pleasant imagery, the more helpful they find it. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

30. That's great. It sounds like pleasant imagery might be a useful tool for you. Keep practicing—the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

31. Great! It sounds like pleasant imagery is a really useful tool for you. Keep practicing - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

32. Thank you!

(This is a score screen that requires no response)

You have completed the assessment. Click Next to submit your responses.

## Week 2 Check In

# Week 1 Check In

Week 1 Check In

Time for the 1-minute Blueprint weekly mini-survey!

1. Please select the response that describes how you felt in the past week.

(This is an information screen that requires no response)

Click Next to continue

2. I feel tense or wound up

Response is \*\*one\*\* of:

- Not at all
- Time to time, occasionally
- A lot of the time
- Most of the time

3. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

4. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Not at all
- A little, but it doesn't worry me
- Yes, but not too badly
- Very definitely and quite badly

5. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

6. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- Only occasionally
- From time to time but not too often
- A lot of the time
- A great deal of the time

7. I feel cheerful

Response is \*\*one\*\* of:

- Most of the time
- Sometimes
- Not often
- Not at all

8. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Definitely
- Usually

- Not often
- Not at all

9. I feel as if I am slowed down

Response is **\*\*one\*\*** of:

- Not at all
- Sometimes
- Very often
- Nearly all of the time

10. I get a sort of frightened feeling like butterflies in the stomach

Response is **\*\*one\*\*** of:

- Not at all
- Occasionally
- Quite often
- Very often

11. I have lost interest in my appearance

Response is **\*\*one\*\*** of:

- I take just as much care as ever
- I may not take quite as much care
- I don't take as much care as I should
- Definitely

12. I feel restless as if I have to be on the move

Response is **\*\*one\*\*** of:

- Not at all
- Not very much
- Quite a lot
- Very much indeed

13. I look forward with enjoyment to things

Response is **\*\*one\*\*** of:

- As much as I ever did
- A bit less than I used to
- Definitely less than I used to
- Hardly at all

14. I get sudden feelings of panic

Response is \*\*one\*\* of:

- Not at all
- Not very often
- Quite often
- Very often indeed

15. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Often
- Sometimes
- Not often
- Very seldom

16. How confident do you feel using progressive muscle relaxation?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

17. That's okay. It is normal to feel a little unsure at first with progressive muscle relaxation. Most people find that their confidence improves with practice. You can do it!

(This is an information screen that requires no response)

18. You are off to a great start. It is normal to feel this way about progressive muscle relaxation at this point. Remember to practice daily. Great work!

(This is an information screen that requires no response)

19. Wow, you really have the hang of progressive muscle relaxation. Remember to keep practicing. Great work!

(This is an information screen that requires no response)

20. How helpful is using progressive muscle relaxation

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

21. That's OK. It often takes time to get comfortable with a new skill and see its benefits. Most people find that the more they practice progressive muscle relaxation, the more helpful they find it. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

22. That's great. It sounds like progressive muscle relaxation might be a useful tool for you. Keep practicing—the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

23. Great! It sounds like progressive muscle relaxation is a really useful tool for you. Keep practicing - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

24. How confident do you feel using pleasant imagery?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

25. That's okay. It is normal to feel a little unsure at first with pleasant imagery. Most people find that their confidence improves with practice. You can do it.

(This is an information screen that requires no response)

26. You are off to a great start. It is normal to feel this way about pleasant imagery at this point. Remember to practice daily. Great work!

(This is an information screen that requires no response)

27. Wow, you really have the hang of pleasant imagery. Remember to keep practicing. Great work!

(This is an information screen that requires no response)

28. How helpful is using pleasant imagery?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

29. That's OK. It often takes time to get comfortable with a new skill and see its benefits. Most people find that the more they practice pleasant imagery, the more helpful they find it. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

30. That's great. It sounds like pleasant imagery might be a useful tool for you. Keep practicing—the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

31. Great! It sounds like pleasant imagery is a really useful tool for you. Keep practicing - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

32. Thank you!

(This is a score screen that requires no response)

You have completed the assessment. Click Next to submit your responses.

## Week 2 Check In

Time for the 1-minute Blueprint weekly mini-survey!

1. Please select the response that describes how you felt in the past week .

(This is an information screen that requires no response)

Click Next to continue

2. I feel tense or wound up

Response is \*\*one\*\* of:

- Not at all
- Time to time, occasionally
- A lot of the time
- Most of the time

3. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

4. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Not at all
- A little, but it doesn't worry me
- Yes, but not too badly
- Very definitely and quite badly

5. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- As much as I always could
- Not quite so much now
- Definitely not so much now

- Not at all

6. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- Only occasionally
- From time to time but not too often
- A lot of the time
- A great deal of the time

7. I feel cheerful

Response is \*\*one\*\* of:

- Most of the time
- Sometimes
- Not often
- Not at all

8. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Definitely
- Usually
- Not often
- Not at all

9. I feel as if I am slowed down

Response is \*\*one\*\* of:

- Not at all
- Sometimes
- Very often
- Nearly all of the time

10. I get a sort of frightened feeling like butterflies in the stomach

Response is \*\*one\*\* of:

- Not at all
- Occasionally
- Quite often
- Very often

11. I have lost interest in my appearance

Response is \*\*one\*\* of:

- I take just as much care as ever
- I may not take quite as much care
- I don't take as much care as I should
- Definitely

12. I feel restless as if I have to be on the move

Response is \*\*one\*\* of:

- Not at all
- Not very much
- Quite a lot
- Very much indeed

13. I look forward with enjoyment to things

Response is \*\*one\*\* of:

- As much as I ever did
- A bit less than I used to
- Definitely less than I used to
- Hardly at all

14. I get sudden feelings of panic

Response is \*\*one\*\* of:

- Not at all
- Not very often
- Quite often
- Very often indeed

15. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Often
- Sometimes
- Not often
- Very seldom

16. Thank you!

(This is a score screen that requires no response)

You have completed the assessment. Click Next to submit your responses.

17. How confident do you feel using pleasant activities ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

18. This feeling is pretty normal at first with pleasant activities . You just have to make a plan--and stick with it! You can do it...

(This is an information screen that requires no response)

19. This is a good start. Remember, it can be tough to find the time for pleasant activities . But you deserve it--and it can help. Hang in there...

(This is an information screen that requires no response)

20. Excellent! You are a pleasant activities expert. Keep it going...great work!

(This is an information screen that requires no response)

21. How helpful is using pleasant activities ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

22. That's OK. Try to keep giving this skill a chance, because the more you take time for pleasant activities , the more you get 'you' time. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

23. Great!. It sounds like pleasant activities are working for you. Keep making the time for these activities, because the more you do the better you could feel.

(This is an information screen that requires no response)

24. Wow! It seems like pleasant activities is a really useful tool for you. Keep taking the time to do these - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

25. How confident do you feel using activity rest cycle ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

26. That's okay because the activity rest cycle can be tough to use at first. Try to focus on one activity at the beginning. This will help your confidence. You can do it!

(This is an information screen that requires no response)

27. You are off to a great start. It is normal not to feel like an activity rest cycle expert at this point. Remember to practice daily. Great work!

(This is an information screen that requires no response)

28. Boom! You really have the hang of the activity rest cycle. Remember to keep practicing. Excellent!

(This is an information screen that requires no response)

29. How helpful is using activity rest cycle ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

30. It can take a little time to work through a new skill and figure out how it might work best. Most people find that the more they practice activity rest cycle , the more helpful they find it. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

31. Really good! It sounds like activity rest cycle is a good addition to the toolbox. Keep practicing—the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

32. Wonderful! It sounds like activity rest cycle is a keeper for you. Keep practicing - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

## Week 3 Check In

Time for the 1-minute Blueprint weekly mini-survey!

1. Please select the response that describes how you felt in the past week .

(This is an information screen that requires no response)

Click Next to continue

2. I feel tense or wound up

Response is \*\*one\*\* of:

- Not at all
- Time to time, occasionally
- A lot of the time
- Most of the time

3. I still enjoy the things I used to enjoy

Response is \*\*one\*\* of:

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

4. I get a frightened feeling like something awful is about to happen

Response is \*\*one\*\* of:

- Not at all
- A little, but it doesn't worry me
- Yes, but not too badly
- Very definitely and quite badly

5. I can laugh and see the funny side of things

Response is \*\*one\*\* of:

- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

6. Worrying thoughts go through my mind

Response is \*\*one\*\* of:

- Only occasionally
- From time to time but not too often
- A lot of the time
- A great deal of the time

7. I feel cheerful

Response is \*\*one\*\* of:

- Most of the time
- Sometimes
- Not often
- Not at all

8. I can sit at ease and feel relaxed

Response is \*\*one\*\* of:

- Definitely

- Usually
- Not often
- Not at all

9. I feel as if I am slowed down

Response is \*\*one\*\* of:

- Not at all
- Sometimes
- Very often
- Nearly all of the time

10. I get a sort of frightened feeling like butterflies in the stomach

Response is \*\*one\*\* of:

- Not at all
- Occasionally
- Quite often
- Very often

11. I have lost interest in my appearance

Response is \*\*one\*\* of:

- I take just as much care as ever
- I may not take quite as much care
- I don't take as much care as I should
- Definitely

12. I feel restless as if I have to be on the move

Response is \*\*one\*\* of:

- Not at all
- Not very much
- Quite a lot
- Very much indeed

13. I look forward with enjoyment to things

Response is \*\*one\*\* of:

- As much as I ever did
- A bit less than I used to
- Definitely less than I used to
- Hardly at all

14. I get sudden feelings of panic

Response is \*\*one\*\* of:

- Not at all
- Not very often
- Quite often
- Very often indeed

15. I can enjoy a good book or radio or TV program

Response is \*\*one\*\* of:

- Often
- Sometimes
- Not often
- Very seldom

16. Thank you!

(This is a score screen that requires no response)

You have completed the assessment. Click Next to submit your responses.

17. How confident do you feel recognizing unhelpful thoughts ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

18. This is totally normal. Try to work on recognizing unhelpful thoughts when you are in certain situations or places. Your confidence will improve as you practice. You can do it!

(This is an information screen that requires no response)

19. OK, really good start! Everybody struggles a bit with recognizing unhelpful thoughts at this point. Remember to practice using positive coping thoughts . Great work!

(This is an information screen that requires no response)

20. Wow, you really have the hang of using coping thoughts to replace negative thoughts. Remember to keep practicing. Great work!

(This is an information screen that requires no response)

21. How helpful is recognizing unhelpful thoughts ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

22. That's OK. But before you give up on using positive coping thoughts , remember that many people start to see the benefits after a couple of weeks or more. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

23. That's great. It seems like you are having success with recognizing unhelpful thoughts . Keep practicing the positive coping thoughts —the more you use them, the more helpful they will be in tough situations.

(This is an information screen that requires no response)

24. Fantastic! It seems like recognizing unhelpful thoughts and replacing them with positive coping thoughts is another keeper for you. Keep practicing - the more you do, the more confident you'll be-- and the more helpful it is likely to be.

(This is an information screen that requires no response)

25. How confident do you feel using fast relax ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10

- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

26. This is OK. Fast relax is a brief skill, but can take some practice. Try using cues during the day (phone rings, you sit down, etc) to remind yourself to use it. You can do it!

(This is an information screen that requires no response)

27. OK, great! The key is just doing fast relax a lot during the day. Use cues to trigger it (phone call, sitting down, etc). Great work!

(This is an information screen that requires no response)

28. You're a fast relax expert now! Remember to keep practicing frequently during the day. Great work!

(This is an information screen that requires no response)

29. How helpful is using fast relax ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all helpful)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely helpful)

30. Try to give it a little more time. Most people find that the more they do fast relax during the day, the more helpful they find it. Give it a try for awhile longer and see what you think.

(This is an information screen that requires no response)

31. OK, good--another keeper for the toolbox! Keep practicing fast relax frequently through the day. Use time or cues to remind yourself. Great!

(This is an information screen that requires no response)

32. This is great. Let's remember that fast relax is a really useful tool for you. Keep practicing - the more you use it, the more helpful it is likely to be.

(This is an information screen that requires no response)

## Week 4 Check In

Time for the 1-minute Blueprint weekly mini-survey!

1. How confident do you feel recognizing unhelpful thoughts ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

2. How helpful is recognizing unhelpful thoughts ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

3. How confident do you feel fast relax ?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

4. How helpful is fast relax?

This question includes an image.

Response is \*\*one position\*\* in this scale:

- 0 (Not at all confident)
- 10
- 20
- 30
- 40
- 50
- 60
- 70
- 80
- 90
- 100 (Extremely confident)

## Appendix 4: Assessment Tools

A. Callahan Cognitive Screen

B. Columbia Suicide Severity Rating Scale (C-SSRS)



## COLUMBIA-SUICIDE SEVERITY RATING SCALE (C-SSRS)

Risk Assessment (Lifeline crisis center version)

NATIONAL SUICIDE PREVENTION LIFELINE



## Columbia-Suicide Severity Rating Scale (C-SSRS)

The Columbia-Suicide Severity Rating Scale (C-SSRS) is a questionnaire used for suicide assessment developed by multiple institutions, including Columbia University, with NIMH support. The scale is evidence-supported and is part of a national and international public health initiative involving the assessment of suicidality. Available in 103 different languages, the scale has been successfully implemented across many settings, including schools, college campuses, military, fire departments, the justice system, primary care and for scientific research.

Several versions of the C-CCRS have been developed for clinical practice. The Risk Assessment version is three pages long, with the initial page focusing on a checklist of all risk and protective factors that may apply. This page is designed to be completed following the client (caller) interview. The next two pages make up the formal assessment. The C-SSRS Risk Assessment is intended to help establish a person's immediate risk of suicide and is used in acute care settings.

In order to make the C-SSRS Risk Assessment available to all Lifeline centers, the Lifeline collaborated with Kelly Posner, Ph.D., Director at the Center for Suicide Risk Assessment at Columbia University/New York State Psychiatric Institute to slightly adjust the first checklist page to meet the Lifeline's Risk Assessment Standards. The following components were added: helplessness, feeling trapped, and engaged with phone worker.

**The approved version of the C-SSRS Risk Assessment follows.** This is one recommended option to consider as a risk assessment tool for your center. If applied, it is intended to be followed exactly according to the instructions and cannot be altered.

Training is available and recommended (though not required for clinical or center practice) before administering the C-SSRS. Training can be administered through a 30-minute interactive slide presentation followed by a question-answer session or using a DVD of the presentation. Those completing the training are then certified to administer the C-SSRS and can receive a certificate, which is valid for two years.

To complete the C-SSRS Training for Clinical Practice, visit <http://c-ssrs.trainingcampus.net/>

For more general information, go to <http://cssrs.columbia.edu/>

Any other related questions, contact Gillian Murphy at [gmurphy@mhaofnyc.org](mailto:gmurphy@mhaofnyc.org).

## COLUMBIA-SUICIDE SEVERITY RATING SCALE (C-SSRS)

Posner, Brent, Lucas, Gould, Stanley, Brown, Fisher, Zelazny, Burke, Oquendo, & Mann  
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### RISK ASSESSMENT VERSION

(\* elements added with permission for Lifeline centers)

<b>Instructions:</b> Check all risk and protective factors that apply. To be completed following the patient interview, review of medical record(s) and/or consultation with family members and/or other professionals.			
<b>Suicidal and Self-Injury Behavior (Past week)</b>		<b>Clinical Status (Recent)</b>	
<input type="checkbox"/>	Actual suicide attempt	<input type="checkbox"/>	Hopelessness
<input type="checkbox"/>	Interrupted attempt	<input type="checkbox"/>	Helplessness*
<input type="checkbox"/>	Aborted attempt	<input type="checkbox"/>	Feeling Trapped*
<input type="checkbox"/>	Other preparatory acts to kill self	<input type="checkbox"/>	Major depressive episode
<input type="checkbox"/>	Self-injury behavior w/o suicide intent	<input type="checkbox"/>	Mixed affective episode
<b>Suicide Ideation (Most Severe in Past Week)</b>		<input type="checkbox"/>	Command hallucinations to hurt self
<input type="checkbox"/>	Wish to be dead	<input type="checkbox"/>	Highly impulsive behavior
<input type="checkbox"/>	Suicidal thoughts	<input type="checkbox"/>	Substance abuse or dependence
<input type="checkbox"/>	Suicidal thoughts with method (but without specific plan or intent to act)	<input type="checkbox"/>	Agitation or severe anxiety
<input type="checkbox"/>	Suicidal intent (without specific plan)	<input type="checkbox"/>	Perceived burden on family or others
<input type="checkbox"/>	Suicidal intent with specific plan	<input type="checkbox"/>	Chronic physical pain or other acute medical problem (AIDS, COPD, cancer, etc.)
<b>Activating Events (Recent)</b>		<input type="checkbox"/>	Homicidal ideation
<input type="checkbox"/>	Recent loss or other significant negative event	<input type="checkbox"/>	Aggressive behavior towards others
Describe:		<input type="checkbox"/>	Method for suicide available (gun, pills, etc.)
		<input type="checkbox"/>	Refuses or feels unable to agree to safety plan
<input type="checkbox"/>	Pending incarceration or homelessness	<input type="checkbox"/>	Sexual abuse (lifetime)
<input type="checkbox"/>	Current or pending isolation or feeling alone	<input type="checkbox"/>	Family history of suicide (lifetime)
<b>Treatment History</b>		<b>Protective Factors (Recent)</b>	
<input type="checkbox"/>	Previous psychiatric diagnoses and treatments	<input type="checkbox"/>	Identifies reasons for living
<input type="checkbox"/>	Hopeless or dissatisfied with treatment	<input type="checkbox"/>	Responsibility to family or others; living with family
<input type="checkbox"/>	Noncompliant with treatment	<input type="checkbox"/>	Supportive social network or family
<input type="checkbox"/>	Not receiving treatment	<input type="checkbox"/>	Fear of death or dying due to pain and suffering
<b>Other Risk Factors</b>		<b>Other Protective Factors</b>	
<input type="checkbox"/>		<input type="checkbox"/>	Belief that suicide is immoral, high spirituality
<input type="checkbox"/>		<input type="checkbox"/>	Engaged in work or school
<input type="checkbox"/>		<input type="checkbox"/>	Engaged with Phone Worker *
<b>Describe any suicidal, self-injury or aggressive behavior (include dates):</b>			

<b>SUICIDAL IDEATION</b>		
Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.	<b>Lifetime: Time He/She Felt Most Suicidal</b>	<b>Past 1 month</b>
<b>1. Wish to be Dead</b> Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up. <i>Have you wished you were dead or wished you could go to sleep and not wake up?</i>  If yes, describe:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>2. Non-Specific Active Suicidal Thoughts</b> General non-specific thoughts of wanting to end one's life/commit suicide (e.g., "I've thought about killing myself") without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period. <i>Have you actually had any thoughts of killing yourself?</i>  If yes, describe:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act</b> Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it...and I would never go through with it." <i>Have you been thinking about how you might do this?</i>  If yes, describe:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan</b> Active suicidal thoughts of killing oneself and subject reports having <u>some intent to act on such thoughts</u> , as opposed to "I have the thoughts but I definitely will not do anything about them." <i>Have you had these thoughts and had some intention of acting on them?</i>  If yes, describe:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>5. Active Suicidal Ideation with Specific Plan and Intent</b> Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. <i>Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</i>  If yes, describe:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>INTENSITY OF IDEATION</b>		
<i>The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe). Ask about time he/she was feeling the most suicidal.</i>		
<b>Lifetime - Most Severe Ideation:</b> _____ <i>Type # (1-5)</i>	<b>Description of Ideation</b>	Most Severe
<b>Recent - Most Severe Ideation:</b> _____ <i>Type # (1-5)</i>	<b>Description of Ideation</b>	Most Severe
<b>Frequency</b> <i>How many times have you had these thoughts?</i> (1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day	—	—
<b>Duration</b> <i>When you have the thoughts how long do they last?</i> (1) Fleeting - few seconds or minutes (4) 4-8 hours/most of day (2) Less than 1 hour/some of the time (5) More than 8 hours/persistent or continuous (3) 1-4 hours/a lot of time	—	—
<b>Controllability</b> <i>Could/can you stop thinking about killing yourself or wanting to die if you want to?</i> (1) Easily able to control thoughts (4) Can control thoughts with a lot of difficulty (2) Can control thoughts with little difficulty (5) Unable to control thoughts (3) Can control thoughts with some difficulty (0) Does not attempt to control thoughts	—	—
<b>Deterrents</b> <i>Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?</i> (1) Deterrents definitely stopped you from attempting suicide (4) Deterrents most likely did not stop you (2) Deterrents probably stopped you (5) Deterrents definitely did not stop you (3) Uncertain that deterrents stopped you (0) Does not apply	—	—
<b>Reasons for Ideation</b> <i>What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?</i> (1) Completely to get attention, revenge or a reaction from others (4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (2) Mostly to get attention, revenge or a reaction from others (5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (3) Equally to get attention, revenge or a reaction from others and to end/stop the pain (0) Does not apply	—	—

<b>SUICIDAL BEHAVIOR</b> (Check all that apply, so long as these are separate events; must ask about all types)				<b>Lifetime</b>	<b>Past 3 months</b>
<b>Actual Attempt:</b> A potentially self-injurious act committed with at least some wish to die, <i>as a result of act</i> . Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is <i>any</i> intent/desire to die associated with the act, then it can be considered an actual suicide attempt. <i>There does not have to be any injury or harm</i> , just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. <b>Have you made a suicide attempt?</b> <b>Have you done anything to harm yourself?</b> <b>Have you done anything dangerous where you could have died?</b> <b>What did you do?</b> <i>Did you _____ as a way to end your life?</i> <i>Did you want to die (even a little) when you _____?</i> <i>Were you trying to end your life when you _____?</i> <i>Or Did you think it was possible you could have died from _____?</i> <i>Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)? (Self-Injurious Behavior without suicidal intent)</i> If yes, describe:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Total # of Attempts _____
<b>Has subject engaged in Non-Suicidal Self-Injurious Behavior?</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Total # of Attempts _____
<b>Interrupted Attempt:</b> When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act ( <i>if not for that, actual attempt would have occurred</i> ). Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. <b>Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?</b> If yes, describe:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Total # of interrupted _____
<b>Interrupted Attempt:</b> When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act ( <i>if not for that, actual attempt would have occurred</i> ). Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. <b>Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?</b> If yes, describe:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Total # of interrupted _____
<b>Aborted or Self-Interrupted Attempt:</b> When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. <b>Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?</b> If yes, describe:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Total # of aborted or self-interrupted _____
<b>Preparatory Acts or Behavior:</b> Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). <b>Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?</b> If yes, describe:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Total # of preparatory acts _____

	Most Recent Attempt Date:	Most Lethal Attempt Date:	Initial/First Attempt Date:
<b>Actual Lethality/Medical Damage:</b> 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; <i>medical</i> hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; <i>medical</i> hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	<i>Enter Code</i> _____	<i>Enter Code</i> _____	<i>Enter Code</i> _____
<b>Potential Lethality: Only Answer if Actual Lethality=0</b> Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over).  0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	<i>Enter Code</i> _____	<i>Enter Code</i> _____	<i>Enter Code</i> _____

## Appendix 5: Study Contact Information

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