Mental Health Among Patients, Providers, and Staff (MHAPPS): Investigating the Mental Health Impact of COVID-19 and Comparing the Effectiveness of Two Caring Contact Interventions

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Confidentiality Statement

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator.

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List of Acronyms

AE	Adverse Event
AIMS	Advancing Integrated Mental Health Solutions
CFR	Code of Federal Regulations
C-SSRS	Columbia Suicide Severity Rating Scale
DSMB	Data & Safety Monitoring Board
ED	Emergency Department
GAD-7	Generalized Anxiety Disorder-7
HIPAA	Health Insurance Portability and Accountability Act of 1996
Hotline	Idaho Suicide Prevention Hotline
ICH GCP	International Council on Harmonisation Good Clinical Practice
INL	Idaho National Laboratory
INQ	Interpersonal Needs Questionnaire
IRB	Institutional Review Board
ITHS	Institute of Translational Health Sciences
MHAPPS	Mental Health Among Patients, Providers, and Staff (short title of trial)
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
OHRP	Office of Human Research Protections
PCORI	Patient Centered Outcomes Research Institute
PHI	Protected Health Information
PHQ-9	Patient Health Questionnaire-9
PHQ-A	Patient Health Questionnaire for Adolescents

PI	Principal Investigator
PLES	People with Lived Experience with Suicide
SAE	Serious Adverse Event
SLHS	St. Luke's Health System
SPARC	Safety Planning Among Recipients of Care
UAP	Unanticipated Problem
US	United States
USPS Task Force	United States Preventive Services Task Force
VA	Veterans Administration
UW	University of Washington

Statement of Compliance

The trial will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), and the Patient Centered Outcomes Research Institute (PCORI) Terms and Conditions of Award. The Principal Investigators will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the St. Luke's Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form, recruitment materials, and all participant-facing materials will be submitted to the St. Luke's IRB for review and approval. Approval of the protocol and all relevant documents must be obtained before any participant is consented and enrolled in the study. In addition to St. Luke's Health System (SLHS) IRB approval, St. Luke's Research Final Authorization will be in place before study activities begin. Any amendment to the protocol or supporting documents will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent forms will be IRB approved. Depending on the extent of changes, the research team and/or the IRB will determine whether participants who provided consent using a previously approved consent form need to be reconsented using the revised consent form.

Statement of Attribution for Protocol Template

Significant portions of the outline and content for this protocol were adapted based on or directly copied from sample text provided in the National Institutes of Health Behavioral and Social Intervention Clinical Trial Protocol Template (v3.0 – 20180827). Because this publicly available resource was used extensively in developing this protocol, we are including this statement of attribution in lieu of individual citations for this reference. Other references used are cited accordingly and listed in the *References* section of this protocol.

Funding for the MHAPPS Trial

The research described in this protocol is funded through a COVID-19 Enhancement award from the Patient-Centered Outcomes Research Institute® (PCORI®), Award HIS-2018C3-14695.

Investigator's Signature

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

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1. Protocol Summary

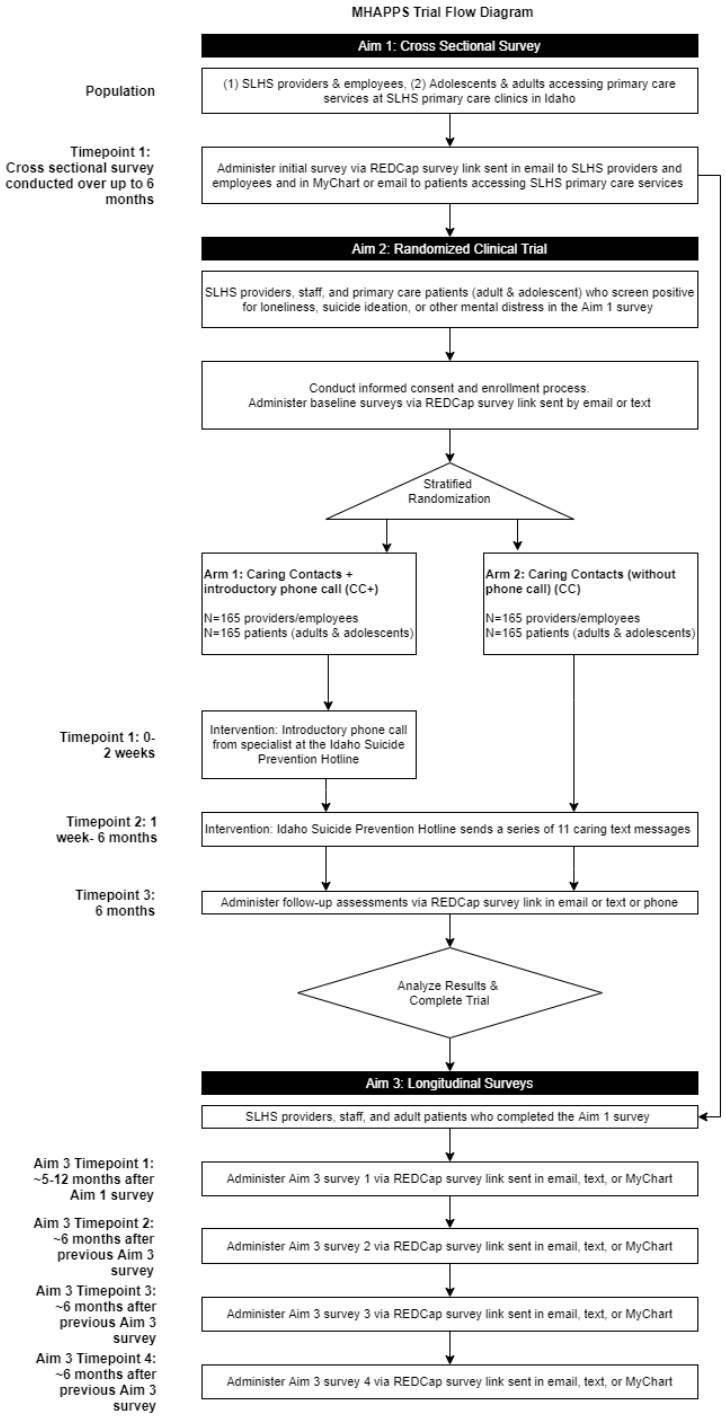
1.1 Synopsis

Title	**Mental Health Among Patients, Providers, and Staff (MHAPPS)**: Investigating the Mental Health Impact of COVID-19 and Comparing the Effectiveness of Two Caring Contact Interventions
Contract Number:	PCORI HIS-2018C3-14695
Study Description	Cross sectional survey (Aim 1) and longitudinal surveys (Aim 3) of mental distress in a cohort of healthcare providers, staff, and patients in the COVID-19 era; and randomized controlled trial (Aim 2) comparing the effectiveness of two versions of a Caring Contacts intervention to reduce loneliness and mental distress.
Specific Aims	**Aim 1:** Measure the prevalence of mental distress including loneliness, anxiety, depression, substance use, suicide ideation and other suicide-related risk factors in providers, employees, and patients served by SLHS. Describe differences associated with age, sex, race, ethnicity, urban or rural residence, living situation, occupation, local COVID-19 prevalence, perceived risk related to COVID-19, and masking and social distancing practices. **Aim 2:** Compare the effectiveness of two versions of the Caring Contacts intervention ((1) introductory phone or video call followed by text messages (CC+), versus (2) text messages alone (CC)) to reduce loneliness and improve mental health outcomes among SLHS patients, providers, and staff experiencing mental distress during the COVID-19 era. **Aim 3:** Survey a cohort of healthcare providers, staff, and patients in Idaho for approximately two additional years to assess how mental distress including loneliness, anxiety, depression, suicide ideation and other suicide-related risk factors changes during the progression of the Covid-19 pandemic and recovery period.
Outcomes	Aim 2 primary outcome: loneliness (NIH Toolbox Social Relationship Scales). [1-3] Aim 2 secondary outcomes: suicide ideation (C-SSRS) [4-13]; presence of risk factors for suicide including those theoretically related: defeat, entrapment, perceived burdensomeness, and thwarted belongingness (INQ) [14,15]; background risk factors including stress (NIH Toolbox), [1-3,16] alcohol and illicit drug use, depression (PHQ-9), [17-19] and anxiety (GAD-7); [20,21] and attendance at mental healthcare appointments. All outcomes measured at 6 months following study enrollment.
Study Population	(1) SLHS providers and employees, and (2) adolescent and adult patients accessing primary care services from SLHS primary care clinics in Idaho. The study will enroll approximately 4,000 participants in the initial survey (Aim 1). The comparative

	effectiveness trial will be comprised of a subset of 660 participants who report elevated loneliness, suicide ideation, or other mental distress in the Aim 1 survey. Enrollment will be stratified by population (providers and employees; patients) with 165 per intervention arm in each stratum.
Description of Study Sites	. (1) SLHS employs over 14,000 providers and staff across the system. (2) SLHS includes over 50 primary care clinics across the state of Idaho
Study Duration	Depending on the Aim that a participant is enrolled in, participation can last for up to 3 years. The Aim 2 clinical trial will last for approximately 12 months, with 6 months for recruitment and 6 months for intervention/outcome assessment. The Aim 3 cohort will be surveyed for approximately 2 years.
Participant Duration	Aim 1 is cross sectional (one timepoint). Aim 2 includes a 6-month long intervention period. Participants will complete a baseline assessment and an outcomes assessment at 6 months (end of intervention). Aim 3 is longitudinal. Participants will be surveyed approximately every 6 months for approximately 2 years.

1.2 Schema / Study Flow Diagram

Figure 1: MHAPPS Trial Flow Diagram



2. Research Question & Specific Aims

Research Question: How can health systems support mental health among providers, employees, and patients during the COVID-19 era while minimizing the burden on the health system?

Specific Aims.

- **Aim 1:** Measure the prevalence of mental distress including loneliness, anxiety, depression, substance use, suicide ideation and other suicide-related risk factors in providers, staff, and patients served by SLHS. Describe differences associated with age, sex, race, ethnicity, urban or rural residence, living situation, occupation, local COVID-19 prevalence, perceived risk related to COVID-19, and masking and social distancing practices.

- **Aim 2:** Compare the effectiveness of two versions of the Caring Contacts intervention ((1) introductory phone or video call (phone call) followed by text messages (CC+), versus (2) text messages alone (CC)) to reduce loneliness and improve mental health outcomes among SLHS patients, providers, and staff experiencing mental distress during the COVID-19 era.
    - **Aim 2 Hypothesis:** We hypothesize that including an introductory phone call with the Caring Contacts intervention will yield better mental health outcomes among providers, staff, and patients experiencing mental distress than a Caring Contacts intervention with no introductory phone call.

- **Aim 3:** Survey a cohort of healthcare providers, staff, and patients in Idaho for up to three years to assess how mental distress (including burnout, suicidal ideation, loneliness, anxiety, depression, post-traumatic stress, resilience, and other measures) changes during the progression of the Covid-19 pandemic and recovery period.

    - **Aim 3 Hypothesis**: We hypothesize that the prevalence and acuity of burnout, suicidal ideation, and other measures of mental distress among healthcare providers and staff will be positively associated with 14-day average COVID-19-positive hospitalizations at SLHS in Idaho, with the association most pronounced among patient-facing providers and staff. We hypothesize that this association will be weaker or non-existent for patients.

3. Introduction

3.1 Background

The COVID-19 pandemic is occurring amid a high prevalence of mental health conditions [22] **and increasing suicide rates** [23] **in the United States.** Individuals are experiencing anxiety, financial hardship, disruption to school and work schedules, and repeated exposure to information and misinformation in

mainstream and social media [24] as a result of the pandemic. This may increase their risk of suicide either directly or through proximal risk factors and can lead to or exacerbate other mental health conditions.[25-36]

Mental health conditions are common in the United States, and in 2017 nearly 1 in 5 adults ages 18 and older reported a mental illness in the last 12 months. [22] In adolescents ages 13-18 years, diagnostic interview data showed nearly 1 in 2 reporting lifetime prevalence of any mental disorder with anxiety disorders being the most common (31.9%). [37] **An increase in social isolation and loneliness are likely to be significant adverse consequences of the pandemic** [25]**, particularly in elderly individuals** [38] **and adolescents.** [39] Both social isolation and loneliness are associated with anxiety, depression, self-harm, and lifetime suicide attempts. [40,41] Additionally, a number of the anticipated consequences of quarantine and social and physical distancing measures introduced to prevent community spread of the disease are themselves risk factors for mental health issues [25] including self-harm, alcohol and substance misuse, domestic and child abuse and psychosocial risks (i.e. social disconnection, loss of income, and feeling a burden). [25,42] Nearly 41% of 5,470 US adults who completed a web-based survey in late June 2020 reported adverse mental or behavioral health conditions with essential workers, young adults, unpaid caregivers, and racial/ethnic minorities being disproportionately affected. [43] **The prevalence of anxiety disorder symptoms was 3x higher than reported in 2019 and depression was 4x higher.** [43]

Suicide is a leading cause of death in the United States and one of only three leading causes of death that is on the rise. [23] Suicide rates have risen by over 30% in more than half of US states since 1999, with Mid-Western and Intermountain West States in particular exhibiting alarmingly high increases in suicide rates. [23] Idaho's suicide rate is the sixth highest in the US, 50% above the national average. [23] In 2016, nearly 45,000 individuals in the U.S. died by suicide, [23] roughly equivalent to one suicide every 12 minutes. In the COVID-19 era, approximately 11% of adults reported seriously considering suicide in the past 30 days, and the percentage was significantly higher among 18-24-year-old respondents (25.5%). [43] **Half of suicide decedents seek healthcare – often in EDs or primary care settings – within a month of their death.** [44]

Healthcare providers and staff face additional stress due to their increased exposure to infected patients [45,46] and the burden of bearing witness to the devastating effects of this disease. Healthcare workers who are younger, female, parents to dependent children, or report pre-existing psychological or physical ill health are more vulnerable to mental distress when caring for patients during a viral outbreak. [45,46] Interventions that support frontline staff's mental well-being are needed to mitigate the added psychological distress during a pandemic. Health systems have an obligation to address mental distress and risk factors for suicidal ideation and behavior in the patient populations they serve and in clinicians and staff they employ.

Experts worldwide and at St. Luke's Health System (SLHS) have called for research to (1) better understand the mental health impact of COVID-19 on the general population, and key populations including healthcare providers and staff, older adults, and adolescents, [25,28] **and (2) to determine the best evidence-based mental health interventions that can be delivered virtually at scale with minimal resources during the COVID-19-era.** [25,27,28] Additionally, the Patient-Centered Outcomes Research Institute (PCORI) has called for research using a comparative effectiveness framework that can provide timely answers to COVID-19-related challenges facing health systems, patients, caregivers, and clinicians.[47] as well as research related to suicide prevention in adult and adolescent patients. [48]

Caring Contacts is an evidence-based suicide prevention intervention and one of the only brief suicide prevention interventions that has demonstrated effectiveness in reducing suicidal ideation and behavior in randomized clinical trials. [49-51] Caring Contacts has been recommended as part of standard care for suicide prevention by the Joint Commission, [52] the US Department of Veterans Affairs (VA), [53] the US Department of Defense, [53] and the National Action Alliance for Suicide Prevention. [44] A recent high-quality trial demonstrated a 44% reduction in the odds of suicidal ideation and a 48% reduction in the odds suicidal behavior among veterans receiving Caring Contacts compared to a control group. [51]

Caring Contacts aim to make individuals feel supported and cared for, typically consisting of brief messages sent via letters [49,50] and postcards, [54,55] emails [56] or text messages [51,57] from a provider to a patient. Caring messages are non-demanding expressions of care for a person's well-being and a reminder that help is available. [50,51,56,58] This study will use a text messaging platform to deliver Caring Contacts which will be cost-effective and low burden to participants and staff, sending 11 pre-scripted messages scheduled over a 6-month timeframe. Trained follow-up specialists at the Idaho Suicide Prevention Hotline (Hotline) will correspond with individuals who choose to respond to the text messages, although it is never required or expected of the participants to respond. Mobile technology-based health interventions can be useful to help alleviate unmet mental health service needs in low-resource settings and marginalized populations such as minorities and people with limited income.[59-61]

The proposed study will address several key gaps in the scientific literature. While the effect of Caring Contacts on suicidal ideation and behavior is well documented, **its effect on other types of mental distress including depression, anxiety and psychological stress has not been rigorously studied,** particularly in civilian populations post-crisis or who have not been discharged with a recent suicide attempt.

The theoretical basis for Caring Contacts and its hypothesized causal mechanism are both related to loneliness or a lack of social connection.[62] The Caring Contacts intervention provides recipients with messages meant to reinforce the idea that someone cares about them, is thinking of them, and expects nothing in return. The messages facilitate a feeling of caring but also serve as a gentle reminder that support and resources are available. A recent meta-analysis of causal mechanisms for brief contact

interventions such as Caring Contacts affirms that social support is the most commonly reported mechanism through which these interventions affect suicidal ideation and behavior. [63]**Loneliness is a well-established risk factor for suicide,** [15,62] **depression,**[36,64-66] **psychological stress,** [66,67] **and anxiety.** [36,64,66] We therefore hypothesize that by reducing loneliness, Caring Contacts may also reduce depressive symptoms, stress, and anxiety, in addition to reducing suicidal ideation and behavior.

The cross-sectional survey (Aim 1) will provide timely data on the prevalence of mental distress among patients, providers, and staff in the COVID-19 era in a largely rural state. The comparative effectiveness trial (Aim 2) will contribute to filling the literature gap regarding whether non-demanding brief contact interventions such as Caring Contacts are effective in supporting individuals struggling with non-suicidal mental distress. The longitudinal survey (Aim 3) following patients, providers, and staff over a period of approximately 2 years to see how mental distress changes over time and assess the association between mental health and (a) time, and (b) 14-day average Covid-19 hospitalizations at St. Luke's Health System in Idaho.

3.2 Significance

The COVID-19 pandemic has dramatically impacted individuals and communities, with implications for both mental and physical health. [25-28,68] **There is an urgent call for research to collect data on mental health effects of the COVID-19 pandemic across vulnerable groups and the population as a whole** [25] **and how mental health consequences can be mitigated under pandemic conditions.** [25] Additionally, providers need actionable research to determine the best evidence-based mental health interventions that can be delivered virtually at scale with minimal resources during the COVID-19 era. [25,27,28] St. Luke's Health System leadership is supportive of this research and has encouraged the inclusion of providers and employees in key study populations.

The proposed research fills key gaps in evidence and is aligned with PCORI research priorities. This study will describe the extent and character of mental distress and risk factors for suicide on key populations in the COVID-19 era. Study participants will include healthcare clinicians/staff and patients, both adult and adolescent, from a private non-profit health system. This would be the first published data comparing the effectiveness of two versions of the Caring Contacts intervention (one with an introductory phone call followed by text messages (CC+) and without an introductory phone call (CC)) with individuals who report loneliness or other mental distress including anxiety, depression, stress, emotional dysregulation, and low health-related quality of life.

This study will provide high-quality data collected with scientific rigor to determine whether CC+ or CC more effectively improves mental health outcomes and suicide risk factors among health care providers and staff, and adolescents and adults in primary care settings. **Additionally, this will be the first randomized controlled trial to study the effects of the Caring Contacts model to support individuals with non-suicidal mental distress.** The study population will include both urban and rural residents in a

state with a high prevalence of suicide, [23] including a rural county with one of the highest infection rates of COVID-19 in the U.S. [69]

This pragmatic study is designed to optimize dissemination and implementation potential and scalability. The intervention design capitalizes on technology and will be delivered in partnership with an established community resource (Idaho Suicide Prevention Hotline) that will reach urban and rural populations. This approach will allow the health system to consistently deliver an effective brief social supportive intervention without requiring any human resources from health system providers and staff responding to COVID-19 demands. **This models a health system-community based partnership that could be realistically replicated and brought to scale by other clinics and health systems faced with similar strains on resource and workforce capacity, including those serving rural populations.** We will partner with the Idaho Suicide Prevention Hotline to disseminate results of this study via the national network of Suicide Prevention Hotlines, which regularly liaise with health systems nationwide.

This study will have immediate and enduring public health impact, allowing health systems and community partners in Idaho and nationally to select the best brief, virtual, evidence-based intervention to provide mental health support. The interventions being compared are feasible to implement at scale even while quarantine and/or social and physical distancing measures are in effect from the pandemic, including in low-resource settings with limited access to behavioral health services.

4. Research Methods

4.1 Study Design

4.1.1. Aim 1: Cross Sectional Survey

Aim 1 is a cross sectional survey of patients, providers, and staff to measure the prevalence of various measures of mental distress and their association with attitudes, beliefs, and practices related to COVID-19.

4.1.2 Aim 2: Comparative Effectiveness Trial

Aim 2 (primary analysis) is a randomized controlled trial comparing the effectiveness of CC+ vs. CC. The study objectives, outcomes, and interventions all pertain to the individual level.

4.1.3 Aim 3: Longitudinal Cohort Surveys

Aim 3 includes a series of 4 surveys sent out approximately every 6 months for a cohort of individuals that completed Aim 1 and consent to participate in Aim 3.

4.2 Randomization

Randomization will occur at the individual level. A list of potentially eligible participants will be generated based on responses to the survey conducted through Aim 1. Survey respondents reporting elevated mental distress will be part of the potentially eligible study population for Aim 2. Statistical software will be used to randomly assign Aim 2 participants to an intervention arm during the informed consent process.

4.3 Masking

This trial will be single masked, with most members of the study team including the lead biostatistician masked to the comparator group (treatment condition) randomly assigned to each participant. Due to the nature of the intervention, masking interventionists or study participants to the comparator received is not feasible. The PI and research coordination team will conduct fidelity monitoring activities that may reveal the treatment assignment of individual participants.

5. Study Population

The study population for this research is adult (Aim 3) and adolescent (Aim 1 & 2) patients, and healthcare providers and staff from St. Luke's Health System in Idaho. Aim 1 will include up to approximately 2,000 patients and 2,000 providers and staff. Aim 2 will include a subset of 660 Aim 1 participants who report elevated levels of mental distress (330 patients, and 330 providers or staff). Aim 3 will include up to 3,146 adults who participated in Aim 1, agreed to be contacted about future research, and consent to participate in Aim 3. SLHS employs over 14,000 people and serves nearly half of the population of Idaho; a recent CDC report indicated that over 40% of adults reported elevated levels of mental distress during the COVID-19 pandemic. The source population is adequately large to meet this study's recruitment goals.

5.1 Inclusion & Exclusion Criteria

Inclusion criteria are intentionally broad, to facilitate recruitment of a study sample that is maximally representative of the population of SLHS patients, providers, and staff.

5.1.1 Inclusion & Exclusion Criteria: Aim 1

Provider & Employee Inclusion Criteria

- Provider or Employee at St. Luke's Health System
- Adults ≥ 18 years of age
- Proficient in spoken and written English language

Provider & Employee Exclusion Criteria

- Individuals who are unable or unwilling to provide informed consent to participate

- Individuals who are study staff for this study or the SPARC Trial

Patient Inclusion Criteria

- Patient at a SLHS primary care site
- Current MyChart account user
- Adults ≥18 years of age
- Minors 12-17 years of age
- Proficient in spoken and written English language

Patient Exclusion Criteria

- Individuals who are unable or unwilling to provide informed consent to participate.
- Individuals who are participants in the SPARC Trial
- Individuals who have not had a primary care visit in the past 12 months

5.1.2 Inclusion & Exclusion Criteria: Aim 2

Provider & Employee Inclusion Criteria

- Moderate or high score for loneliness, suicide ideation, psychological stress, anxiety, or depression:
    - NIH Toolkit Loneliness raw score of 13 or greater or
    - C-SSRS score of 3 or greater; or
    - NIH Toolkit Perceived Stress raw score of 31 or greater for adults; or
    - GAD7 score of 11 or greater; or
    - PHQ9 score of 10 or greater
- Access to a phone for the duration of the study with the ability to receive text messages and phone calls

Provider & Employee Exclusion Criteria

- Individuals who are unable or unwilling to provide informed consent to participate
- Individuals who are in acute crisis as determined by the person conducting the consent process
- Individuals who are study staff for this study or the SPARC Trial
- Individuals who are enrolled as participants in the SPARC comparative effectiveness clinical trial (SPARC Aim 1). Providers or employees who received training related to SPARC and/or who completed the SPARC provider satisfaction survey are not excluded from participating in MHAPPS

Patient Inclusion Criteria

- Moderate or high score for loneliness, suicide ideation, psychological stress, anxiety, or depression:
    - NIH Toolkit Loneliness raw score of 13 or greater for adults or 16 or greater for adolescents; or
    - C-SSRS score of 3 or greater; or
    - GAD7 score of 11 or greater; or
    - PHQ9 score of 10 or greater; or
    - NIH Toolkit Stress raw score of 31 or greater for adults or 33 or greater for adolescents
        - *Note: validated youth versions of the NIH Toolkit assessments (loneliness and perceived stress), and PHQ-A tools will be used for adolescents ; the C-SSRS and GAD7 tools are validated for use with both adults and adolescents.*
- Access to a phone for the duration of the study with the ability to receive text messages and phone calls

Patient Exclusion Criteria

- Patients who are unable or unwilling to provide informed consent/assent to participate (or whose legally authorized representative is unable to provide consent in the case of adolescents). Examples may include but are not limited to patients who present with cognitive impairment, as determined by the person conducting the consent process, that would preclude their ability to consent (i.e. acute psychosis, intoxication, or intellectual disability).
- Individuals who are in acute crisis as determined by the person conducting the consent process

5.1.3 Inclusion & Exclusion Criteria: Aim 3 Surveys

- *Inclusion Criteria*
    - Adults ≥18 years of age
    - Patients and/or providers/staff who completed the Aim 1 baseline survey and indicated interest in being contacted for additional research.
- *Exclusion Criteria*
    - Minors (<18 years of age).
    - Individuals who are unable or unwilling to provide informed consent to participate The Principal Investigator may exclude potential participants if there are any concerns for the safety or wellbeing of study staff or the potential participant.

5.2 Recruitment Strategy

A random selection of MyChart users who have attended a primary care visit at SLHS within the past 12 months will be recruited for the Aim 1 survey through a message including a REDCap survey link sent to

their MyChart account or email. A comprehensive list of providers and employees and their email addresses will be obtained from a contact in the SLHS Human Resources Department, Digital and Analytics, or another appropriate department and a random sample of providers and employees will be selected using appropriate software. Those randomly selected will be recruited for the Aim 1 survey through an email message including a REDCap survey link. The Aim 1 survey will include an option to opt out of being contacted by study staff for participation in a follow-up study if they are potentially eligible.

Participants who indicate interest in the follow-up study who also report elevated mental distress will be the source population for Aim 2. Recruitment for Aim 2 will involve study staff contacting potential participants to describe the Aim 2 clinical trial, conduct informed consent, and enroll interested patients into the trial. Recruitment-related emails will be either automatically sent via REDCap, sent from the mhapps@slhs.org email address, sent from the PI, delegated study staff, or sent via MyChart. In the event that there are more eligible and interested potential participants than available space in the trial, potential participants will be invited to participate in the order in which they completed the Aim 1 Survey.

Aim 3 survey recruitment will involve inviting Aim 1 survey participants to complete additional online surveys in REDCap. Generally, an invitation with up to four reminders will be sent via text, MyChart, or email over up to six weeks. Invitations will be sent in waves to ensure that the Hotline is able to manage the volume of safety checks that come in at one time. Clinical trial (Aim 2) participants will be invited to participate in Aim 3 after they have completed trial participation. This is intended to minimize the impact of implementing Aim 3 to the integrity of the Aim 2 clinical trial.

For Aim 1 and Aim 3, informed consent and study enrollment will be completed by the participant electronically through REDCap, with study staff available by phone or email to answer any questions. For Aim 2, informed consent and study enrollment will be conducted by trained study staff, typically a Research Coordinator over the phone or via video chat. All staff conducting informed consent and study enrollment will be trained in human subjects' protection and study procedures and will be delegated to do so by the study PI.

5.3 Retention

A variety of methods will be used to improve retention of research participants in the clinical trial. A contact sheet will be provided at enrollment allowing patients to share additional contact information (including alternative phone numbers, email addresses, or social media contact information) that may be used to contact participants for retention purposes. A primary cell phone number and an email address are required; providing additional sources of contact on the contact sheet is optional for study participants. Email, text messages, phone calls, or other forms of contact may be used for retention purposes or to assist with scheduling and completing six-month follow-up surveys. Retention methods

are further described in protocol section *10.2 Lost to Follow-Up*.

5.4 Populations for Analyses

Analyses will be completed using the following populations:

1. **Intention to Treat (ITT) Analytic Population**: Data for all participants that complete study enrollment will be included in this dataset.
2. **Safety Analysis Population**: The dataset shared with the Data & Safety Monitoring Board for safety analysis will include data for all participants who completed study enrollment (e.g., the ITT Analytic Population Dataset).
3. **Per-Protocol Analysis Population**: Data for a subset of participants who were retained for the full study, were sent all 11 caring text messages, and received a phone call if randomized to the CC+ intervention (as outlined in protocol section 9) will be included in this dataset.
4. **Additional populations**: Additional datasets may be developed to complete sensitivity analyses, for example, where missing data have been imputed using different techniques.

6. Study Procedures

Aim 1: Cross Sectional Survey (Email REDCap survey link for providers and staff; send REDCap survey link via MyChart, or email for patients)

- Aim 1 study enrollment and informed consent
- Aim 1 Survey
  - Demographics questions
  - C-SSRS (suicide risk)
  - NIH Toolbox Social Relationship Scales (loneliness, stress)
  - INQ (defeat, entrapment, perceived burdensomeness, and thwarted belongingness)
  - PHQ-9 (depression)
  - GAD-7 (anxiety)
  - COVID-19 beliefs and practices survey (brief)

Aim 2: Baseline / Enrollment (Subset of Aim 1 participants; see below)

- Aim 2 study enrollment and informed consent (phone call with Research Coordinator or study staff to complete via REDCap)
- Aim 2 Baseline assessments (Email or text REDCap survey link)
  - Baseline survey (Socio-economic status, gender identity, sexuality, religion, and alcohol and illicit drug use)
  - Expanded COVID-19 beliefs and practices survey (additional questions related to impact of COVID-19 on the individual, and his/her/their family, friends, and community)

- Contact Sheet to collect alternative forms of contact for study participant

Aim 2: Caring Contacts Interventions (see description of interventions in section 9)

- **CC+**: 1 call, within 2 weeks of enrollment, and 11 caring text messages, sent from Hotline follow-up specialists according to a standardized schedule over a 6-month period
- **CC:** 11 personalized caring text messages sent from Hotline follow-up specialists according to a standardized schedule over a 6-month period

6 Month Outcome Assessment (± 4 weeks variance window) (REDCap survey link sent via email or text)

- Aim 2 6-Month Outcome Assessments:
  - C-SSRS (suicide risk)
  - NIH Toolbox Social Relationship Scales (loneliness, stress)
  - INQ (defeat, entrapment, perceived burdensomeness, and thwarted belongingness)
  - PHQ-9 (depression)
  - GAD-7 (anxiety)
  - COVID-19 beliefs and practices survey (brief)

Aim 3 Surveys, approximately every 6 months (± 4 weeks variance window) (REDCap survey link sent via email, MyChart, or text)

- Aim 3 study enrollment and informed consent (included with the first Aim 3 survey only)
- Aim 3 Survey (sent approximately every 6 months, 4 times)
  - C-SSRS (suicide risk)
  - NIH Toolbox Social Relationship Scales (loneliness, stress)
  - INQ (defeat, entrapment, perceived burdensomeness, and thwarted belongingness)
  - PHQ-9 (depression)
  - GAD-7 (anxiety)
  - Copenhagen Burnout Scale (burnout)
  - Non-proprietary single-item burnout measure (burnout) (SLHS providers/staff only)
  - COVID-19-Exposure Scale
  - PC-PTSD-5 (post-traumatic stress disorder)
  - COVID-19 beliefs and practices; impact on daily life survey (brief)
  - Brief Resilience Survey (resilience)

6.1 Schedule of Activities

Table 1: Schedule of MHAPPS Trial Activities

	Aim 1: Timepoint 0	Aim 2: Time Point 1: 0 weeks	Aim 2: Time Point 2: 0-2 weeks	Aim 2: Time Point 3: 1 week – 6 months	Aim 2: Time Point 4: 6 months	Aim 3: Timepoint 5: ~6-12 months – 2.5-3 years
	Timepoints are relative to each study participant.					
Aim 1 Informed Consent/Assent and Survey	X					
Aim 2 Informed Consent/Assent and Enrollment		X				
Aim 2 Baseline Survey & Contact Sheet		X				
Randomization		X				
Phone call with Idaho Suicide Prevention Hotline (Hotline)			CC+ arm only			
Caring text messages (11 total) sent from Hotline				X		
Aim 2 Outcome Survey					X	
Aim 3 Informed Consent and Surveys						X
Safety Outcomes Reporting			X	X	X	X

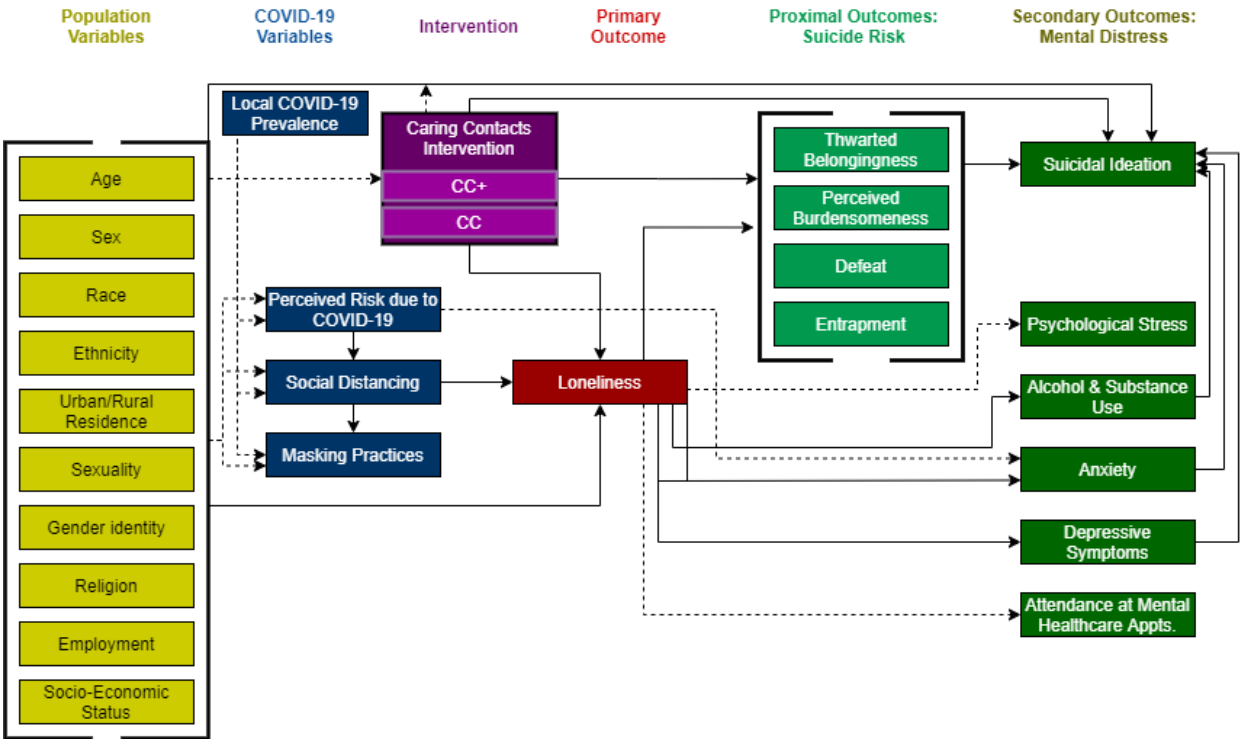
6.2 Safety Procedures for Participants at Risk for Suicide

Participants who screen at high risk for suicide (C-SSRS score of 4-6) during the Aim 1 survey, the Aim 2 Outcome Survey, or any of the Aim 3 surveys will be contacted by the Hotline whenever possible within 12 hours (maximum 24 hours) to assess their safety and provide appropriate support. The Hotline will follow standard Hotline procedures to contact the participant by phone and/or text message. Parents of minor participants who screen at moderate or high risk for suicide may be contacted by a provider from SLHS to inform them of their child's risk. Standard operating procedures (SOPs) for participant safety will be utilized. These SOPs may also be utilized for participants whose responses to caring text messages indicate they may be at acute risk for suicide.

7. Causal Framework

The logic model below depicts the hypothesized and known associations for variables included in this study. All variables included in the causal framework will be measured. The associations depicted with solid arrows are assumed to be true based on empirical evidence (described in protocol *Section 8*); associations depicted with dashed lines are hypothesized and will be assessed and measured as part of this study. The bracket around the population variables and the proximal risk factors for suicide were added to visually simplify the framework. Aim 1 of the study is designed to assess the hypothesized associations depicted with dashed lines between population variables and COVID-19 variables. Aim 2 of the study is designed to measure the association between intervention received and primary and secondary outcomes, accounting for population variables and COVID-19 variables.

Figure 2: MHAPPS Logic Model



8. Exposures and Outcomes (Variables) of Interest

8.1 Exposure Variables

The following exposure variables will be measured and assessed as part of this study: age (date of birth), sex, race, ethnicity, gender identity, sexuality, religion, zip code, living situation and number of

people at home, employment and occupation, education, school situation and extracurricular involvement (adolescents), caregiving status, financial security, domestic violence, food security, food access and eating habits related to COVID-19, physical activity, access to healthcare and mental healthcare services, local COVID-19 prevalence, perceived risk related to COVID-19, and masking and social distancing practices and beliefs. A full summary of exposure, outcomes, and process variables to be included in this study is included in protocol section 12, *Table 2.*

8.1.1 Rationale for Including Selected Exposure Variables

Age and sex are associated with loneliness and suicidal ideation and behavior. [70] Older adults already experience significant impacts mental health from isolation and social disconnectedness, and COVID-19 restrictions are predicted to magnify feelings of loneliness**.** [70-72] Adults over 35 years old are more likely to die by suicide than other age categories. [73] Additionally, children and adolescents are predicted to experience increased depression and anxiety from loneliness and social isolation during COVID-19 changes. [39] Sex differences have been observed for suicidal behavior. [23,73] CDC reports that suicidal completion is approximately 4 times more common among males than females. [73]

Though minority racial and ethnic groups have lower rates of lifetime mood disorders [74] they are expected to face greater mental distress from the pandemic due to disparities in infection and mortality rates from COVID-19. [74,75] **Race and ethnicity are also associated with risk of suicidal ideation and behavior**. The rate of suicide is approximately three times higher among Non-Hispanic Whites and American Indian/Alaska Natives (16.71 and 18.37 per 100,000 respectively) than among other racial and ethnic groups. [73]

The Health Resources & Services Administration's Federal Office of Rural Health Policy urban-rural designation for census tracts [76] will be used together with patients' zip code to classify study participants as urban or rural residents. Early evidence has shown differences in COVID-19 infection percentages and mortality rates have been observed across urban and rural areas, with rural areas often experiencing lower infection rates but higher mortality. [69,77] Additionally, compared to large urban areas, **rural residence is associated with a 45% higher rate of suicide** [73] **lower socioeconomic status,** [78] **and worse overall health outcomes.** [78]

COVID-19 has had a significant impact on the economy, leading to widespread job loss and financial stress. [79] **Financial stress is associated with an elevated risk for depression, suicide, and anxiety**. [79] Other determinants of socioeconomic status such as education, financial security, and food security are similarly related. Lack of access to and consumption of healthy foods have also been impacted by the COVID-19 pandemic.[80] Healthy eating habits and physical activity are associated with positive mental

health outcomes.[80,81] Additionally, people may have experienced challenges accessing both physical and mental healthcare services, which can lead to excess morbidity due to existing health conditions. [82]

Living situation and number of people at home may influence risk of COVID-19 exposure and degree of loneliness experienced. Homeless and transient individuals are at a greater risk of infection due to their environment. [25,83] Healthcare and other essential workers may experience stress about infecting others in their homes after exposure at work. [45] Having many people in a household may offer social support which is protective against loneliness, [84] but could also contribute to interpersonal conflict and domestic violence.[85] Overall stress related to COVID-19 may also exacerbate domestic violence. [86]

Unpaid caregivers of children, older adults, or other family members who may have physical or mental disabilities are twice as likely to have experienced elevated mental distress compared with non-caregivers. [43] Both parents and adolescents have been impacted by the changes in school environment and extracurricular activities due to COVID-19.[86,87]

People in a high-risk **occupation**, such as healthcare workers and other essential workers may face increased stress and trauma from working during the COVID-19 pandemic. [45,88,89] In contrast, people working jobs remotely may experience increased loneliness and disconnectedness. [90] Understanding how the interventions administered in this study affect people of various occupations will be important to future implementation.

Local COVID-19 prevalence and perceived risk related to COVID-19 may influence the protective health behaviors an individual engages in during the pandemic. The experience of mandatory closures of schools, businesses, and other facilities will likely vary for participants in "hot-spot" areas such as Ada, Canyon, or Blaine counties.[91,92] Additionally, the higher and individual perceives their infection risk to be, the more likely they are to engage in **social distancing** and handwashing to protect from COVID-19.[93]

Measuring masking and social distancing beliefs and practices of respondents will be key to understanding the protective behaviors of participants and the degree of increased isolation experienced during the pandemic. Masking has been shown to be an effective measure to reduce the spread of COVID-19. [94-96] Despite calls from SLHS and other agencies for universal mask wearing in Idaho, [97] a state-wide mask order has not been issued. While social distancing orders were implemented,[91] varying degrees of adherence[98] may influence the impact of those orders on mental health.

Gender identity and sexuality are strongly associated with risk of suicidal ideation and behavior. **Lesbian, gay, bisexual, transgender, or gender-nonconforming (LGBTQ+) individuals are two to seven times more likely than straight, cisgender peers to attempt suicide.**[33-38]

Religious affiliation is associated with suicidality, but the magnitude and direction of that association differs depending on the religion and its intersection with socio-cultural factors (e.g., sexuality). A recent meta-analysis found that **religiosity protects against suicidal completion**, with a pooled odds ratio of 0.38 (95% CI: 0.21-0.71).[39] Another review found that 75% of published studies identified religion as protective against suicidal ideation and behavior.[40]

8.2 Primary Outcome & Assessment

The primary outcome is loneliness. Loneliness is a well-established risk factor for suicide, [15,62,63] **depression,** [39,64-66] **psychological stress,** [66,67] **and anxiety.** [39,64,67] We therefore hypothesize that by reducing loneliness, Caring Contacts may also reduce depressive symptoms, stress, and anxiety, in addition to reducing suicidal ideation and behavior.

Loneliness will be measured at 6 months as a change from baseline score using the NIH Toolbox Social Relationship Scales loneliness measure. The NIH Toolbox is a comprehensive set of neuro-behavioral measurements that quickly assess cognitive, emotional, sensory, and motor functions.[3] The measurements were developed to be versatile, brief, and psychometrically sound. [3] The NIH Toolbox is composed of multiple batteries, one of which is the NIH Toolbox Emotion Battery. The Emotion Battery is comprised of four different domains, including the Social Relationship Scales which have items that have been validated to measure loneliness. [2]

The loneliness measure of the NIH Toolbox Emotion battery for adults 18+ is comprised of five items with rating scale responses of never, rarely, sometimes, usually, and always. Responses are then used to calculate a raw score which is converted to a t-score [99]. The version for adolescents 13-17 is comprised of 7 items. Both measures were validated using confirmatory factor analysis.[2]

8.3 Secondary Outcomes & Assessment

Secondary outcomes include suicide ideation (C-SSRS) self-harm and suicidal behavior; presence of risk factors for suicide including those theoretically related: perceived burdensomeness, and thwarted belongingness (INQ); background risk factors including stress (NIH Toolbox), alcohol and illicit drug use, depression (PHQ-9); and anxiety (GAD-7); and attendance at mental healthcare appointments. Post-traumatic stress disorder (PC-PTSD-5), burnout, and resilience will be assessed through Aim 3 only.

8.3.1 Suicidal ideation

Reduced suicidal ideation and behavior will be measured as change from baseline score at 6 months using the Columbia Suicide Severity Rating Scale (C-SSRS). [100-103] C-SSRS is widely used in practice and research and has strong psychometric properties for use with both adult and adolescent populations, which are summarized in a *Supporting Evidence* document. [102] The C-SSRS has been shown to be an effective tool to measure suicidality (diagnosis) and is sensitive to change over time, which allows measurement of the effect of treatment at 6 months. [102,104]

The C-SSRS is available in a full-length version comprised of 11 yes/no questions plus 7 multiple choice questions and space to collect and record brief narrative explanations. An abbreviated screener version of the C-SSRS consists of 5 yes/no questions related to suicidal ideation and one two-part yes/no question related to suicidal behavior. Both the full-length and screener versions of the C-SSRS are available in a 'lifetime-recent' version (to establish a baseline) and a 'since last contact' version to be administered at follow-up visits. Two versions of the C-SSRS will be used for this study: C-SSRS Lifetime-Recent Screener (given at baseline, in accordance with standard of care at SLHS), and C-SSRS Since Last Contact Screener (given at 6 months). In addition to using the C-SSRS Screeners at baseline and follow-up, the study will incorporate three items from the full-version of the C-SSRS that are not included in the screener version to measure: (1) Aborted or self-interrupted suicide attempts; (2) interrupted suicide attempts; and (3) actual suicide attempts at baseline, 6 months. Information on non-lethal self-harm, lethal means used for attempts or completions, and death by suicide will also be collected. Vital records will be used to measure suicide completion.

8.3.2 Scoring the C-SSRS

The C-SSRS lifetime-recent screener score is determined based on the highest question number (1-6B) to which a participant responds "yes". For example, a score of 5 would be assigned to a participant who responded "yes" to Question 5 and any or all preceding questions. Please consult *Appendix B* of this protocol for additional C-SSRS scoring criteria.

The additional items related to suicide attempts and lethal means will not be included in the C-SSRS score but will be compared across intervention groups.

8.3.3 Risk Factors for Suicide (INQ)

Reduced risk factors for suicide including perceived burdensomeness and thwarted belongingness will be measured at baseline and six months utilizing the Interpersonal Needs Questionnaire (INQ).[14] The INQ was developed from the Interpersonal Theory of Suicide to measure both perceived burdensomeness and thwarted belongingness which are proximal causes of desire for suicide. [15] The

INQ underwent refinement in 2012 and was reduced from 25 to 15 items. [15] Respondents indicate of 15 questions how true each is for them on a scale of 1 to 7, with 1 being "not true at all for me" and 7 being "very true for me."

The 15 items are valid and psychometrically sound for measuring perceived burdensomeness and thwarted belongingness in young and older adults.[15,105] A study in 2014 evaluated factor structure, internal consistency, and concurrent predictive validity of the INQ versions with adolescent psychiatric inpatients and found the 15 item version to have acceptable internal consistency. [106]

8.3.4 Stress

Stress level will be assessed for participants measured as a change in score from baseline at 6 months using the NIH Toolbox Stress and Self-Efficacy Scales Perceived Stress measure. This measure comes from the Emotion Battery of the NIH Toolbox and was selected because it is validated and psychometrically sound to measure individual perceptions about the nature of events and their relationship to the values and coping resources of an individual. [2] The measure is comprised of ten items which are scored and granted a t-score specific to adult or adolescent participants. [99]

8.3.5 Alcohol and Illicit Drug Use

Alcohol and illicit-drug use will be measured at baseline and 6 months with questions adapted from the Youth Risk Behavior Survey. [107] Additional questions will be included to measure self-reported changes in alcohol or illicit-drug use since the beginning of the COVID-19 pandemic.

8.3.6 Depression

Presence of depressive symptoms, depression, and depression severity will be screened for at baseline and 6 months as an indicator of mental distress. The Patient Health Questionnaire-9 (PHQ-9) is a widely used tool to screen for depression in primary care and other non-psychiatric settings.[17,19,108] The tool is composed of 9 questions each with a response of 0-3 which generate a score from 0-27 with higher scores indicating a greater degree of depression.[19] Scores are categorized in the following manner: a score of 5-9 is considered minimal depression, 10-14 is considered mild major, 15-19 is moderate major, and ≥20 is severe major.[19] The PHQ-9 has been shown to be a valid and reliable measure of depression severity in adult and adolescent populations; this study will utilize PHQ-9 adult and PHQ-A adolescent versions for the corresponding age groups.[17-19,108,109]

8.3.7 Anxiety

Anxiety will serve as an indicator of mental distress and will be screened for at baseline and six months. Symptoms of anxiety will be assessed using the GAD-7, a brief self-report scale frequently used in the identification of Generalized Anxiety Disorder. The GAD-7 was validated in 2006 as a valid and psychometrically sound measure with good sensitivity (89%) and specificity (82%). [20] The tool is similar

to the PHQ-9 in its structure and scoring with seven items and possible scores of 0-21. Higher scores indicate a greater severity of generalized anxiety symptoms [20]. Since the original validation, the tool has been confirmed as valid for detecting anxiety in both adult and adolescent populations. [21,110,111]

8.3.9 Uptake of Outpatient Mental Health Services

Current engagement and any engagement since study enrollment in outpatient mental health services will be measured as dichotomous variables (yes/no) at 6 months through self-report.

8.3.10 Post Traumatic Stress

Participants will be asked to consider their most stressful memory related to Covid-19 when responding to the PC-PTSD-5 questions. This instrument is a 5-item validated screening tool designed to identify post-traumatic stress disorder in individuals.[112]

8.3.11 Burnout (providers/staff only)

The 19-item Copenhagen Burnout Inventory is a validated tool designed to assess burnout in three domains: personal burnout, work-related burnout, and client (patient)-related burnout.[113] A second measure, the non-proprietary single-item burnout measure, will also be included to assess burnout. [114,115]

8.3.12 Resilience

The 6-item Brief Resilience Scale is a reliable measure to assess individuals' ability to adapt, recover, and thrive in the context of stress and adversity. [116]

9. Description of Interventions

9.1 Caring Contacts with Introductory Call (CC+)

Caring Contacts will consist of one introductory phone or video conversation to establish a connection between the study participant and the follow-up specialist. The introductory phone call will be unscripted, but will generally include the following elements: an introduction, if appropriate (based on participants' survey scores) a safety/wellbeing check, a review and discussion of the elements of mental distress on which the participant scored highest, a discussion of any relevant resources that may be helpful to the participant, and a description of what to expect with the caring text messages that will follow. Hotline follow-up specialists will attempt to complete the phone call over a two-week period following study enrollment. If the phone call cannot be completed in two weeks, the Hotline will initiate the text message portion of the intervention.

The call will be followed by a series of 11 personalized caring contacts sent over the course of 6 months via text message or email. [117] The frequency and cadence of caring text messages will be consistent for all participants and was determined following consultation with PLES Advisors to ensure it

is culturally and age appropriate. Caring text messages will be sent using a HIPAA-compliant program called Mosio according to the following schedule: weeks 1, 2, 3, 4, 6, 8, 10, 12, 16, 20, and 24. While there is no expectation that participants respond to the text messages, some participants may choose to respond. Hotline Follow-Up Specialists will review incoming text messages and phone calls from study participants and will respond according to the Hotline's internal operating procedures. These additional contacts will take place outside of the structured study protocol and will not be under the purview of SLHS institutional policies. Mosio will track the number and content of individual responses to study text messages, and this information will be shared with the study team. Response and ongoing contacts as part of the Hotline's processes will not alter the timing or frequency of caring contacts established by the study protocol. Data collected and stored in Mosio will become part of the study dataset and may be analyzed as part of process evaluation or other analyses.

9.2 Caring Contacts without an Introductory Call (CC)

Participants will be sent caring text messages according to the schedule above. No introductory phone or video call from the Hotline will be made.

9.3 Definition of Full Intervention

Participants must be sent at all 11 caring text messages (all participants), and complete a phone call (if randomized to CC+) to be included in the Per Protocol analysis group.

9.4 Process Evaluation

The study will include a process evaluation to assess uptake of surveys and delivery of the interventions, with process data collected and evaluated throughout the enrollment period. Specifically, the study will measure the proportion of invited survey participants who complete surveys for Aim 1. For Aim 2, the proportion of eligible participants who enroll in the clinical trial will be measured. The proportion of Aim 2 participants in the CC+ arm who are successfully contacted with an introductory phone call within two weeks of enrollment will also be measured, along with the proportion of participants in each study arm who complete the full intervention. The "dose" of each intervention received (phone call, number of text messages sent) will be recorded and assessed. Data will also be collected and reviewed to assess how well participants like the Caring Contacts messages received as part of this trial.

10. Discontinuation and Participant Withdrawal

10.1 Participant Discontinuation and Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon written request to the MHAPPS email account (mhapps@slhs.org). Additionally, study investigators may discontinue a participant from the study for the following reasons, but not limited to:

1. Lost to follow-up; unable to contact subject (see section *10.2 Lost to Follow-Up*)
2. Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant
3. Any event or situation occurs in which the safety or wellbeing of study staff is compromised by allowing a participant to continue to participate in the research
4. The participant meets an exclusion criterion or fails to meet an inclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The date of discontinuation and reason for discontinuation or withdrawal from the study will be recorded in the MHAPPS Trial study records.

10.2 Lost to Follow-Up

A study participant will be considered lost to follow-up if s/he fails to complete the 6-month outcome assessments and study staff are unable to contact the participant after at least 3 attempts. The following actions must be taken before a participant will be declared lost to follow-up.

- Study staff will attempt to contact the participant, re-send the REDCap survey or reschedule the missed phone-based assessment, counsel the participant on the importance of maintaining the assigned assessment schedule (if necessary), and ascertain whether the participant wishes to and/or should continue in the study
- The study staff will make every effort to regain contact with the participant (using text, email, phone call, and/or alternative means of contact that the participant may have included during the study enrollment process).
- Should the participant continue to be unreachable, s/he will be considered to have withdrawn from the study with a primary reason of lost to follow-up. The participant's data will be retained in study records.

11. Data & Safety Monitoring

11.1 Overview of Data & Safety Monitoring Plan

This research will include a Data and Safety Monitoring Board (DSMB). The DSMB will be convened and managed through the University of Washington's Institute of Translational Health Sciences (UW ITHS).

11.2 Role of the Data & Safety Monitoring Board (DSMB)

The DSMB will review and oversee the following elements:

1. Study enrollment by population (providers/staff, and patients (adults, adolescents))
2. Retention of study participants at 6 months
3. Data completeness and quality
4. Process evaluation data
5. Safety outcomes by intervention and population
6. Decisions related to stopping the trial early due to one or several of the elements above

11.3 Safety Outcomes

This protocol considers completed suicide, suicide attempts, and inpatient admission in the context of highly suicidal study participants as expected events. These will be routinely tracked as key safety outcomes. The following safety outcomes will be assessed for each participant at 3 and 6 months and reviewed by the Data and Safety Monitoring Board twice annually to determine whether the rate of safety outcomes differs by intervention arm:

- Death by suicide
- Attempted suicide
- Interrupted or aborted suicide attempt
- Psychiatric hospitalization for anxiety, depression, and/or suicidal ideation
- Medical hospitalization related to self-harm or attempted suicide
- Medical hospitalization related to unintentional overdose or substance use disorder

11.4 Adverse Events and Serious Adverse Events

This protocol does not include tracking of adverse events (AEs). This protocol does not include real-time tracking of serious adverse events (SAEs) for several reasons. First, as stated above, the most important events that would be defined as SAEs are expected safety outcomes in the context of study participants experiencing suicidality or other forms of mental distress. All deaths of study participants will be reviewed and assessed to determine whether the cause of death is suicide. We do not anticipate any SAEs beyond those listed as safety outcomes above, but unanticipated SAEs that occur will be reviewed by the DSMB and the IRB. Second, this research compares two models of an evidence-based intervention that has been widely studied, has an established safety record, and is already in widespread clinical practice. This is not an experimental, novel, or untested intervention with unknown safety outcomes. Finally, the most important safety question to ascertain in the context of this trial is whether rates of safety outcomes or SAEs are differential across the two intervention groups. This protocol will monitor safety outcomes collected at 6 months as part of routine study outcome assessments through

regular DSMB meetings to ensure equal ascertainment of outcomes across intervention groups. This is the most valid and reliable way to review safety data in the context of this pragmatic clinical trial.

12. Data Collection & Management

12.1 Data Collection

All data for this study will be collected via online REDCap surveys. *Table 2* includes a list of all study variables, which aim they are associated with, and which tool will be used for assessment.

Table 2: MHAPPS Trial Variables & Other Data Elements

Variables			
Outcomes	**Tool**	**Survey Collected**	**Source**
Loneliness	NIH Toolbox – Social Relationship Scales - Loneliness Scale	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Suicidal ideation & behavior	C-SSRS Screener	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Recent suicide attempts, suicide completion, & self-harm; lethal means	6-Months Suicide Attempts Survey	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Perceived Burdensomeness; Thwarted Belongingness	INQ-15	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Stress	NIH Toolbox – Perceived Stress 10	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Alcohol and Illicit drug use	Youth Risk Behavior Survey Questions	Aim 2 Baseline Survey; Aim 2 Outcome survey	REDCap
Depression	PHQ-9	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Anxiety	GAD-7	Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Uptake of outpatient mental health treatment	N/A	Aim 2 Baseline Survey; Aim 2 Outcome Survey	REDCap
Post-traumatic stress disorder	PC-PTSD-5	Aim 3	REDCap
Resilience	Brief Resilience Scale	Aim 3	REDCap
Burnout	Copenhagen Burnout Inventory; Non-proprietary single item burnout measure	Aim 3	REDCap
Exposure Variables		**Survey Collected**	**Source**
Date of birth, age in years, age category (adult/peds)		Aim 1 Survey	REDCap
Sex at birth		Aim 1 Survey	REDCap
Race and ethnicity		Aim 1 Survey	REDCap

Zip code of residence (urban/rural)		Aim 1 Survey	REDCap
Gender identity & sexuality		Aim 2 Baseline Survey	REDCap
Religion		Aim 2 Baseline Survey	REDCap
Variables related to employment and occupation of self/parent		Aim 1 Survey	REDCap
Education / maternal education		Aim 1 Survey	REDCap
Living situation (permanent, temporary)		Aim 1 Survey	REDCap
Number of people at home		Aim 1 Survey	REDCap
Caregiving for dependent(s)		Aim 1 Survey	REDCap
Financial security and food security		Aim 1 Survey; Aim 2 Baseline Survey	REDCap
Food access and eating habits and COVID-19		Aim 2 Baseline Survey	REDCap
Physical activity and COVID-19		Aim 2 Baseline Survey	REDCap
Perceived risk for COVID-19 & other COVID-19-related questions		Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Masking practices & beliefs		Aim 1 Survey; Aim 2 Outcome Survey	REDCap
Social distancing practices & beliefs		Aim 1 Survey; Aim 2 Outcome Survey	REDCap
School attendance, extracurricular activities		Aim 2 Baseline Survey (Youth)	REDCap
Access to healthcare and mental healthcare services		Aim 2 Baseline Survey; Aim 2 Outcome Survey	REDCap
Domestic violence		Aim 2 Baseline Survey	REDCap
Local COVID-19 prevalence			CDC or Idaho Department of Health & Welfare Prevalence Data
Covid-19 Exposure	Covid-19 Exposure Scale	Aim 3	REDCap
Process Variables			**Source**
Aim 1 proportion of eligible participants completing survey			REDCap
Aim 2 proportion of eligible participants enrolled			REDCap

Participant feedback on phone call (CC+ arm only)		Aim 2 Outcome Survey	REDCap
Participant feedback on content and timing of caring messages; satisfaction with caring contacts		Aim 2 Outcome Survey	REDCap
Rating of quality of "connectedness" with participant			Mosio and/or REDCap
"Dose" of follow-up contact: timing, type (phone vs text), and number of attempted and successful contacts from the Hotline			Mosio and/or REDCap
"Dose" of Caring Contact text messages: date/time of each text message sent (* 11 text messages)			Mosio and/or REDCap
Other Variables	**Tool**	**Aim Collected**	**Source**
Does cell phone on record belong exclusively to study participant or is it shared?		Aim 2 Baseline Survey	REDCap
Cell phone number, email address, contract preferences, mailing address, and alternative modes of contact		Informed Consent Form, Aim 1 Survey; Aim 2 Baseline Survey	REDCap
Eligibility and willingness to be contacted about Aim 2 participation		Aim 1 Survey	REDCap
Death			CDC or Idaho State Vital Records

12.2 Data Management

This study will employ a comprehensive data management plan. The results from the screening and baseline questionnaires (as well as informed consent documents) will be directly entered in REDCap. The patient will be assigned a unique identifier and randomly assigned to one of the two intervention arms immediately following informed consent and study enrollment. Follow-up specialists at the Hotline will review records of new participants and follow-up with patients to initiate the CC+ or CC intervention. Hotline staff will record any attempt at contact or successful contact made.

The statistics team will compile all data for each participant from REDCap on a routine basis for reports and to build and maintain a complete dataset. To protect the confidentiality of participants, data and associated documentation will be available to the PI of the study and key personnel only, under a data-sharing agreement that includes a commitment to: (1) use the data only for research purposes, (2)

secure the data using appropriate computer technology, (3) destroy or return the data after analyses are completed, and (4) not further distribute the data outside specified members of the research team in compliance with SLHS Research data privacy and sharing practices and policy.

The University of Washington Institute of Translational Health Sciences (ITHS) hosts REDCap, a secure, HIPAA-compliant web application, which will be used for building and managing online surveys and databases for this research. ITHS provides REDCap support and an array of research data curation and storage support. Other databases (such as Access, Excel) may be used for study management purposes; all such data will be kept on secured, password-protected computers.

13. Statistical Analysis

13.1 General Analytic Approach

Aim 1: Descriptive statistics will be used to summarize cross sectional survey results as well as baseline demographic and other exposure variables. Linear regression models or generalized linear regression models GLM with robust standard errors will be used to assess the association between variables of interest.

Aim 2: The primary analysis will compare the effectiveness of the two interventions (CC+ and CC) delivered to two populations (patients and providers/staff), potential confounding, effect modification, and mediation will be handled through study design (e.g. use of randomization to assign individuals to interventions), and statistically through stratification (population). Other published studies related to Caring Contacts have shown that patient-centered outcomes such as suicidal ideation change over a 6-month period in response to receipt of these interventions. [51]

Analyses will be stratified for patients and providers/staff, modeling the effects of intervention separately in these population groups. There is very little evidence regarding the effect of Caring Contacts on healthcare workers, and we hypothesize that the magnitude of effect may differ by population group. Generating evidence of the effectiveness of Caring Contacts with and without an introductory phone call in healthcare workers is the primary goal of this heterogeneity of treatment effect (HTE) analysis. **Linear regression with robust standard errors will be used to determine whether the primary outcome differs between CC+ vs CC.**

Linear regression and GLM models will be used in the analysis of the secondary outcomes. Robust/sandwich standard errors will be used to allow for departures of the observed standard errors from classic model assumptions.

All data analyses will be completed using appropriate statistical software (such as R and R Studio, SPSS, Stata, SAS, Python, and/or Microsoft Excel). Statistical significance will be determined based on a type I error (alpha) of 0.05 (two-sided). Confidence intervals will be reported in addition to p-values.

Variables will be measured through the Aim 1 survey or Aim 2 Baseline survey and reported using descriptive statistics. Potential effect modifiers will be assessed and include age, sex, gender identity, sexuality, race/ethnicity, religion, employment, urban/rural residence, drug/alcohol use, suicidal ideation at baseline, baseline depression score, baseline anxiety score, baseline stress score, baseline quality of life, measures of socioeconomic status and/or other variables related to the specified outcomes of interest. Data will be analyzed according to both an intention to treat protocol and per protocol received. Please see section *5.4 Populations for Analyses* for further detail.

This study will report the distribution of key variables to facilitate assessment of the study's internal and external validity. At a minimum, this study will report the distribution of key variables within the analytic population (key variables are defined as those that are included in the causal diagram at the beginning of the *Research Design* section of this Research Plan). Missing data will be assessed on a regular basis through routine data reports. These reports will allow the investigators to assess the cause of missing or anomalous entries, and address these if possible. If missing values cannot be retrieved, the reason for the missingness will be recorded in data comments available through REDCap. Study staff will record the reason for any participant drop-out during the 6 months of follow-up.

Aim 3: Plots and descriptive statistics will describe how the mental health outcomes vary over time. Inferential statistics will focus on C-SSRS and Copenhagen Burnout Inventory measures. Tests for the association of these mental health outcomes with COVID hospitalization rates and other pandemic measures will use generalized estimating equations with the robust (sandwich) standard error due to the non-normal distribution of outcomes. Time will be modeled using a cubic spline to allow for an expected nonlinear relationship. Analyses will include baseline demographic variables and be stratified by patients vs. patient-facing staff vs. other staff.

13.2 Power & Sample Size for Aim 2

The total sample size for the aim 2 trial is 660 participants. For each stratum (patients, providers/staff), a sample of 330 subjects (165 in each arm) allows 80% power to detect a difference of 5 units in the primary outcome (loneliness) if a minimum of 70% of participants are retained through study completion.

13.3 Duplicate Surveys

A data cleaning step will be included to identify surveys completed twice by the same individual. This may occur, for example, when an individual is both a provider/staff person and a patient at SLHS. If duplicate surveys are identified, the first will be retained, and the second will be excluded from the research.

13.4 Missing Data

Missing data will be tracked and prevented to the extent possible through participant retention measures. When missing data are unavoidable, they will be addressed through statistical analysis. With proper inclusion of variables associated with the probability of missingness, we will assess the nature of missingness; if the missing data follow a 'missing at random' framework, we will use multiple imputation. [118] The most appropriate multiple imputation technique will be determined based on the distributions of missing data and observed variables. [119-121] Multiple imputation methods incorporate the uncertainty of value estimation into parameter estimates. We will assess the sensitivity of estimates to the imputation approach and variables used in the imputation algorithm.

13.5 Sub-Group Analyses

We plan to generate different effect estimates for (1) providers and staff, and (2) patients and are statistically powered to do so. We also plan to produce separate effect estimates for the following subgroups: adult vs adolescent patients, patient-facing vs non-patient-facing providers/staff, types of providers/staff, low baseline C-SSRS score vs moderate to high baseline C-SSRS score, Hispanic vs non-Hispanic, female vs male, cisgender vs transgender or gender-nonconforming, heterosexual vs. homosexual or bisexual, and urban vs rural; however, this study has not been specifically powered to identify differing treatment effects in each of these subgroups.

14. Engaging Providers & People with Lived Experience with Suicide

The research team for this trial includes people with lived experience with suicide, research scientists, system-level medical directors and administrators, physicians, psychologists, and social workers at SLHS; community partners at Jannus, including the Hotline and Empower Idaho, and, the Idaho Federation of Families for Children's Mental Health (IFF); suicide prevention researchers as well as dissemination, biostatistics, and bioethics experts at the University of Washington.

Study staff will continue to engage and expand the scope for the existing *People with Lived Experience with Suicide (PLES) Advisory* Board to support this trial. Study staff will convene a formal PLES Advisory Board to include up to 15 people who experienced suicidality as adults or adolescents. The PLES Advisory Board will provide input related to specific questions (such as study branding, recruitment strategy, the informed consent process (including readability of consent forms), retention techniques, and the content, frequency, and timing of the messages included in Caring Contacts), and will assist with the dissemination strategy.

Study staff will continue to engage the SLHS Behavioral Health providers and a cross-functional group of stakeholders at SLHS for input on study design, conduct, and dissemination of study results. Multiple staff and providers perspectives will be represented including system- and clinic-level providers including, for example, patient access specialists, social workers, psychiatrists and psychologists, ED

physicians, pediatricians, and primary care physicians, advanced practice providers, and medical assistants and nurses. Process evaluation will be used to assess what providers and staff think about the specific messaging included in the Caring Contacts. Study staff will also engage an existing group of stakeholders within the health system who are dedicated to provider and employee well-being, to solicit input related to the MHAPPS Trial without burdening health system staff responding to COVID-19.

Study staff will continue to engage existing MHAPPS stakeholders at the state, regional, and community levels, including but not limited to public sector stakeholders, private foundations, and non-governmental organizations.

15. Risk / Benefit Analysis

15.1 Potential Risks

There are several potential risks to participation in this study. Loss of confidentiality due to the unintended release of sensitive information is one risk. This risk will be mitigated by storing all electronic data on password protected servers. Data will be shared among research partners through REDCap. REDCap is a secure, HIPAA-compliant web-based research data management application, used for building and managing online surveys, and providing a secure electronic database. REDCap is owned and managed by the University of Washington's Institute of Translational Health Sciences (ITHS). REDCap will be used as a central location for online study data storage and participant management. Use of REDCap will protect against unintended release of sensitive information.

Other potential risks include psychological distress from completing study questionnaires related to loneliness, anxiety, depression, suicidality, other mental distress, and quality of life. The frequency of contact in the follow-up intervention may also cause emotional distress. Research participants will be reminded at enrollment that they may quit the survey or skip any questions (Aim 1) or leave the study (Aim 2) at any point with no consequences to the care they receive at SLHS (patients) or their employment (providers/employees). Participants will be reminded of resources (including the Hotline and, if appropriate, behavioral healthcare services) that they can access as needed in the event of psychological distress. Participants will not be enrolled in Aim 2 of the study if they are in an acute crisis or if they are unable to provide informed consent to participate. Additionally, measures will be put in place to support any individuals who report high levels of suicide ideation during a call with SLHS study staff using a modified version of the St. Luke's Health System Red Flag Workflow, which is the standard safety protocol for any individual who contacts the health system and reports suicidal ideation. In the modified version, all individuals endorsing acute suicide risk would be connected to the Idaho Suicide Prevention Hotline using a warm-handoff. Section 16.2.2 of this protocol details how study staff will assess and respond to acute crisis.

Study staff (including anyone involved in enrollment and informed consent or delivery of the follow-up intervention or outcome measurements, and/or having access to patient-level data) will be trained on the protection of human subjects and HIPAA, with a focus on topics relevant to confidentiality. SLHS staff will assist participants in completing Aim 2 informed consent, and REDCap survey links will be sent out via text, email, or MyChart. Study staff at SLHS, University of Washington and the Hotline will have access to protected health information (PHI).
The study is designed to be low burden in terms of participants' time. The initial survey (Aim 1) will consist of up to 50 multiple choice questions. Those participants who enroll in the comparative effectiveness trial (Aim 2) will complete a baseline survey (up to 50 questions), receive 11 caring text messages over a 6-month period, and depending on intervention arm, may also receive an introductory phone call. Aim 2 study participants will complete an outcomes assessment survey online, which will consist of up to 50 questions. Participants will be reimbursed for their time.

Participants will be under no duress or pressure to participate in or complete this study.

- *Patient Participants.* Participating in this study will not impact the care they receive, and this will be clearly communicated to participants as part of the informed consent process.
- *Provider/Staff Participants.* Participating in this study will not impact their employment, and information received in this study will not be shared outside of the study staff. This will be clearly communicated to participants as part of the informed consent process.

15.2 Potential Benefits

While this study is designed to improve mental health, there is no guarantee that participants will benefit directly from the proposed interventions. Although all participants will receive an evidence-based intervention, patients randomized to receive the CC+ arm may benefit from the additional contact.

The knowledge gained through this study is expected to advance the understanding of the burden of COVID-19 on patients, providers, and staff. It is also expected to inform which version of Caring Contacts is most effective for reducing loneliness and mental distress among patients, providers, and staff. We expect the findings of this analysis to be relevant and of interest to community members and people with lived experience with suicide and mental distress, the scientific community, national and state suicide prevention hotlines, and health system leaders. SLHS leaders will benefit from information on how best to support patients, providers, and staff struggling with mental distress in the COVID-19 era.

16. Oversight for Human Subjects Protection & Regulatory Considerations

16.1 Human Subjects Protection

This study will be conducted with appropriate oversight from the St. Luke's Health System (SLHS) Institutional Review Board (IRB). The IRB will review and approve all aspects of the study once all criteria for approval have been met, including the protocol, informed consent process, and all relevant study-related documents. This includes an initial review and approval process and an annual review, as well as review of any modifications made prior to and after initiation of the study. All changes will be approved by the IRB prior to implementation. The Principal Investigator (PI) will be responsible for ensuring compliance with IRB regulations and procedures. All key study personnel will be trained in human subjects' protection.

16.2 Risks to Human Subjects

16.2.1 Characteristics of the Study Population

- Patients: Adult (aged 18 years and older) and adolescent (aged 12 – 17 years) patients who report elevated loneliness, suicide ideation, or other mental distress who have sought care at a St. Luke's primary care clinic in Idaho in the past 12 months will be eligible for participation in the proposed study.
- Providers & Employees: St. Luke's providers and employees who report elevated loneliness, suicide ideation, or other mental distress will be eligible for participation in the proposed study.

16.2.2 Involvement of Human Subjects

Suicide constitutes a significant public health concern and is a leading cause of death in the United States.[23] However, little is known about health system level interventions to prevent suicide among civilians, or adolescents. [122] Additionally, mental distress related to COVID-19 is a critically important but poorly understood aspect of the global pandemic. [25,28] This study will estimate the prevalence of several measures of mental distress in key populations and compare the effectiveness of two versions of the evidence-based Caring Contacts model. The proposed research design is a randomized clinical trial, and all study participants will receive an active evidence-based intervention. No one will receive a "placebo" or "null" treatment.

Participation in this research involves the following:

Aim 1: Survey

- Complete an online survey (10 minutes)

Aim 2: Comparative Effectiveness Trial

- Baseline (Month 0)
  - Complete study enrollment and informed consent (30 minutes)

- Complete baseline survey (20 minutes)
- Months 0-6
  - Receive Caring Contacts intervention (6 months)
  - 1 introductory phone call (one intervention arm only) (20 minutes)
  - 11 caring text messages (both intervention arms)
- Month 6
  - Complete online outcome assessment survey at 6 months (20 minutes)

Aim 3: Longitudinal Surveys (4 surveys administered every 6 months)

- Aim 3 Timepoint 1 (Aim 3 baseline)
  - Complete an online survey (15 minutes)
- Aim 3 Timepoint 2 (6 months (+/- 4 weeks))
  - Complete an online survey (15 minutes)
- Aim 3 Timepoint 3 (12 months (+/- 4 weeks))
  - Complete an online survey (15 minutes)
- Aim 3 Timepoint 4 (18 months (+/- 4 weeks))
  - Complete an online survey (15 minutes)

16.2.3 Protecting Individuals with Urgent Clinical Needs

The Aim 1 and Aim 3 survey informed consent process will be self-completed by participants, thus study staff will not have an opportunity to assess the participant's mental state prior to completion of the survey. Enrollment for Aim 2 (clinical trial) will involve a phone call with study staff (typically, a research coordinator). This protocol prioritizes individual participants' urgent clinical needs (for example, imminent risk of self-harm) above research related needs or responsibilities. Study staff will be trained that their first responsibility is to protect the safety and wellbeing of study participants (especially those experiencing suicidal crisis or another safety outcome), with duty to the research protocol taking second priority. For example, if a potential participant becomes agitated or indicates intent to harm themselves, study enrollment procedures should be halted and safety procedures (such as the modified Red Flag Workflow for those with suicide risk) would be put into place. Standard operating procedures outlining these safety protocols will be utilized.

Key study staff will complete training in suicide prevention, which includes recognizing when someone may be experiencing an acute suicidal crisis. Study staff who have completed suicide prevention training will be available should the need for consultation arise. Study staff will interact directly with participants via phone during the Aim 2 study enrollment and informed consent process. If a potential participant displays signs of acute suicidal crisis during this call, study staff will follow standard operating procedures to keep participants as safe as possible.

A participant who responds “yes” to question 5 and/or question 6 in the C-SSRS as part of one of the online surveys will be considered at high risk for suicide. In this instance, an automatic notification directly to study staff and the Hotline will be triggered in REDCap. The Hotline will attempt to do a safety check via phone as soon as possible within 6-12 hours of survey completion. At least three attempts at phone contact will be made and text messaging may be utilized as well. All individuals who complete surveys will be supplied with a list of resources that they can access if they or someone they know needs support with mental health, suicidal crisis, or social services.

16.2.4 Randomization

Randomization will occur at the individual level, with each participant randomly assigned to one of the two intervention groups.

16.3 Informed Consent Process

Consent for participation in the initial survey (Aim 1) will be completed electronically. Potential participants will be asked to read and electronically sign an informed consent document prior to proceeding with the survey questions.

Consent for participation in the comparative effectiveness trial (Aim 2) will be completed over the phone with Research Coordinators or other trained study staff. If the patient is younger than 18 years of age, his or her parent or guardian will provide written permission for the minor to participate in the study, after which the minor participant will go through an informed assent process. Those participants that assent to study participation prior to age 18 will be reconsented to continue participating if they turn 18 years old while participating in the study. Recruitment materials will be written at approximately an 8th grade reading level to maximize comprehension. Furthermore, the Patients with Lived Experience of Suicide (PLES) Advisory Board will review the informed consent documents for readability and clarity.

Employees will be assured that their decision whether to participate in the research and any responses they provide will in no way impact their employment with St. Luke’s Health System.

16.3.1 Documentation of Informed Consent

Informed consent (and assent for participants aged 12-17) will be obtained and documented for all study participants. Aim 1 informed consent documentation will occur electronically. Study staff will document each participants’ eligibility to participate in the clinical trial (Aim 2) prior to enrollment. When an Aim 2 participant signs the informed consent (or assent for participants aged 12-17) document electronically, the study staff will also sign a form attesting that they have screened for eligibility, reviewed the consent information, and responded to all questions from the participant. The informed consent form will be completed in REDCap, and the consent/assent form will be combined electronically with the staff attestation form in a single patient record. All primary data collection for this study will be

done electronically.

16.4 Bioethics Consultation

The University of Washington's Institute for Translational Health Sciences hosts a Bioethics Consultation Service that will be utilized for the duration of the study. Grant resources have been set aside for a bioethics consultation should relevant questions arise.

16.5 Inclusion of Women and Minorities

Efforts will be made to recruit women and minorities according to their representation in the research population. Given the short timeline available for MHAPPS, only English-speaking participants will be eligible for inclusion; this may result in an under-representation of non-English-speaking populations. There are no exclusion criteria based on sex/gender or minority status. Information about the distribution of races, ethnicities, and gender in our study population can be found in the *Estimated Final Racial/Ethnic and Gender Enrollment Table*.

Table 3: MHAPPS Estimated Final Racial/Ethnic and Gender Enrollment

Based on patient volumes and proportion of elevated PHQ-3 scores in primary care settings from July 2019 through June 30, 2020

	AIM 1 (Survey); AIM 3 (Surveys)			AIM 2 (Trial)		
Race	**Male (N)**	**Female (N)**	**Total (N)**	**Male (N)**	**Female (N)**	**Total (N)**
American Indian/Alaska Native	7	16	23	1	3	4
Asian	16	32	48	2	5	7
Black/African American	11	14	25	2	3	5
Hawaiian/Pacific Islander	3	6	10	1	1	2
White	1,410	2,205	3,615	156	336	492
Multi-race or Other	106	174	280	17	34	51
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	118	209	328	25	48	72
Non-Hispanic	1,436	2,237	3,672	155	333	488

16.6 Inclusion of Minors

Adolescents face a disproportionate burden of suicidal ideation[73,122] compared to adults in general and have been shown to have particularly elevated levels of suicidal ideation and mental distress related to COVID-19. [43] Additional evidence is needed to determine the most effective interventions to prevent suicide and address other forms of mental distress at the health system level for minors.[122] Adolescents who screen positive for loneliness or other forms of mental distress will be included in this study in order to address this critical gap in the literature and begin to develop an evidence base for suicide prevention among adolescents in healthcare settings.

16.7 Cost and Compensation for Participation

Costs of participating in this study include the time participants spend enrolling in the study and completing questionnaires, and the cost of receiving text messages, emails, and phone calls as part of the intervention and/or outcome assessments.

16.7.1 Participant Compensation

Study participants may receive up to $120 in compensation in the form of electronic Amazon gift cards over a 6-month period. These funds are intended to compensate participants' time spent discussing sensitive topics and are in no way meant to influence participation in the study. The compensation will be distributed as follows:

- Aim 1 Informed consent and survey: $10 Amazon gift card
- Aim 2 Informed consent and enrollment in the clinical trial: $35 Amazon gift card
- Aim 2 Six-month outcome assessment: $35 Amazon gift card
- Aim 3 Surveys: $10 Amazon gift card per survey; up to 4 surveys (up to $40 total)

16.8 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the PIs. If the study is prematurely terminated or suspended, the PIs will promptly inform all study investigators, study participants, PCORI, and the SLHS IRB, and will provide the reason for termination or suspension. Study participants will be informed, as applicable, of any changes to the study schedule.

The following circumstances may warrant termination or suspension:

- Determination of unexpected significant or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility
- Other reasonable causes not listed here

The study may resume once concerns about safety, protocol compliance, and data quality are addressed to the satisfaction of PCORI, the SLHS IRB, the Data and Safety Monitoring Board (DSMB), and other regulatory or oversight bodies.

16.9 Confidentiality & Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the DSMB, the SLHS IRB, the Hotline, and PCORI. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. For minor participants whose responses indicate suicide risk, that information may be shared with a parent or legally authorized representative. No

personally identifiable information from the study will be released to any unauthorized third party without prior written approval of PCORI and the SLHS IRB.

All research activities will be conducted in as private a setting as possible.

Authorized representatives of PCORI, the DSMB, or SLHS, including the SLHS IRB, may inspect all documents and records required to be maintained by the investigators, including but not limited to medical records for the participants of this study. The clinical study site will permit access to such records for authorized review.

Study participants' contact information will be securely stored in REDCap and/or on secure UW or SLHS servers for internal use during the study. At the end of the study, all records will be kept in a secure location in REDCap and/or on SLHS secure servers for 10 years, in accordance with SLHS data retention policy.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted via and stored on REDCap, a HIPAA compliant web-based research database. At the end of the study, all study data will be de-identified prior to publication; research data will be archived at SLHS for storage for 10 years.

16.9.1 Measures to Ensure Confidentiality of Shared Data

It is PCORI policy that results and accomplishments of the research that it funds should be made available to the public. The PIs will ensure all mechanism used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant).

16.10 Study Records Retention

Study records will be retained for 10 years, in accordance with SLHS institutional policy. No records will be destroyed before that time without the written consent of PCORI and/or the SLHS Compliance department.

16.11 Publication & Data Sharing Policy

The PI will be responsible for developing publication procedures and resolving authorship issues. This study will be conducted in accordance with all PCORI and SLHS data sharing policies and regulations. This trial will be registered at ClinicalTrials.gov, and the results of this trial will be submitted to ClinicalTrials.gov, which ensures that the public has access to the published results of this PCORI-funded research. In addition, results will be submitted for publication in peer reviewed journals. Data from this trial may be requested from other researchers 5 years after the completion of the primary endpoint by

contacting the PIs. Considerations for ensuring confidentiality of these shared data are described in section 16.9 Confidentiality & Privacy of this protocol.

16.12 Dissemination of Results

Any publication or presentation of the results of this study will be presented in aggregate form and will not include any patient identifying information.

16.13 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed.

16.14 Protocol Deviations

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Conference on Harmonization Good Clinical Practice Guidelines (ICH GCP), or SLHS IRB requirements. The noncompliance may be either on the part of the participant, investigator, study staff, or study site staff. Corrective actions will be developed by the site and implemented promptly in the event of protocol deviations, consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1 and 5.20.2

Study staff will conduct quality assurance monitoring and internal audits on a regular basis. Study staff and study site staff will be responsible for being vigilant to identify and report deviations in accordance with the SLHS IRB Procedures Manual. All deviations will be addressed in study source documents and reported to the PIs; deviations deemed reportable based on criteria in the SLHS IRB Procedures Manual will be reported to the SLHS IRB. Study staff including study site champions will be responsible for knowing and adhering to the IRB requirements.

16.15 Key Roles for Study Oversight

Table 4: Key Roles for Study Oversight, MHAPPS Trial

Principal Investigators & Data & Safety Monitoring Board Leaders	
Principal Investigator	**Data & Safety Monitoring Board Chair**
Anna Radin, DrPH, MPH, Applied Research Scientist	Ann Melvin, Chair, Data and Safety Monitoring Board
St. Luke's Health System	University of Washington Institute of Translational Health Sciences

208-381-8468	206-290-8294	
radina@slhs.org	ann.melvin@seattlechildrens.org	
IRB and Compliance		
IRB	**St. Luke's IRB**: 208-381-1406	St. Luke's IRB is the IRB of record for this research study.
Compliance	**St. Luke's 24/7 Compliance Hotline**: 1-800-729-0966	St. Luke's Health System maintains a compliance hotline that is available 24/7 to take compliance-related calls.

16.15.1 Data and Safety Monitoring Board

The Data and Safety Monitoring Board (DSMB) will convene at the beginning of the study to review the protocol, charter, and data reporting tables, then again three months after enrollment begins. The DSMB will review enrollment data and to review data for safety. Additional information on safety monitoring is included in the *Data & Safety Monitoring* section of this protocol.

16.16 Quality Assurance & Quality Control

Study staff will support each study site to perform internal quality management of study conduct, data collection, and documentation. Data reports will be routinely reviewed by study staff in consultation with the PI in order to understand how recruitment, informed consent, and retention processes are going.

Quality control (QC) measures will be implemented as follows

- Informed consent – Study staff will review both documentation of the consenting process as well as at least 10% of the completed consent documents. This review will evaluate compliance with procedures described in this protocol, accuracy, and completeness. Feedback will be provided to staff at study sites to ensure proper consenting procedures are followed.

- Protocol deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to require remediation.

Should independent monitoring of the study become necessary, the PI will provide direct access to all trial-related sites, source data/documents, and reports for the purpose of monitoring and auditing by internal SLHS auditing bodies, PCORI, and inspection by local and regulatory authorities, in compliance with SLHS legal guidance.

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APPENDIX B: C-SSRS Screening Questions & Scoring Criteria

Question #	Domain	Question	Score
1.	Ideation: Wish to be dead	Have you ever wished you were dead or wished you could go to sleep and not wake up?	1
2.	Ideation: Suicidal thoughts	Have you had any actual thoughts of killing yourself?	2
3.	Ideation: Suicidal thoughts with method (without specific plan or intent to act)	Have you been thinking about how you might do this?	3
4.	Ideation: Suicidal intent (without specific plan)	Have you had these thoughts and had some intention of acting on them?	4
5.	Ideation: Suicide intent with specific plan	Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?	5
6A. [Lifetime-Recent]	Suicidal Behavior (lifetime)	Have you ever done anything, started to do anything, or prepared to do anything to end your life?	[Not scored at baseline]
6B. [Lifetime-Recent]	Suicidal Behavior (3 mos)	*If yes to 6A*, Was this within the past 3 months?	6
6. [Since last contact]	Suicidal Behavior (since last contact)	Have you done anything, started to do anything, or prepared to do anything to end your life?	6