The SPRING Trial: Comparing Suicide Prevention Interventions to Guide Follow-up Care

Comparing the Effectiveness of Two-Way Caring Contacts Texts vs One-Way Caring Contacts Texts vs Enhanced Usual Care to Reduce Suicidal Behavior in Youth and Adults Screening At-Risk for Suicide in Primary Care or Behavioral Health Clinics: The SPRING Trial

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Confidentiality Statement

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List of Acronyms

AE	Adverse Event
AFSP	American Foundation for Suicide Prevention
AIMS	Advancing Integrated Mental Health Solutions
CBPR	Community-Based Participatory Research
CC1	One-Way Caring Contacts Text Messages
CC2	Two-Way Caring Contacts Text Messages
CFR	Code of Federal Regulations
C-SSRS	Columbia Suicide Severity Rating Scale
DSMB	Data & Safety Monitoring Board
ED	Emergency Department
GMS	General Mattering Scale
HASS	Harkavy-Asnis Suicide Scale
HIPAA	Health Insurance Portability and Accountability Act of 1996
Hotline	Idaho Crisis and Suicide Hotline
ICH GCP	International Council on Harmonisation Good Clinical Practice
INQ-15	Interpersonal Needs Questionnaire - 15
IRB	Institutional Review Board
ITHS	Institute of Translational Health Sciences
NDA	National Institute of Mental Health Data Archive
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NSSI	Non-Suicidal Self-Injury
OHRP	Office of Human Research Protections

PHI	Protected Health Information
PHQ-2	Patient Health Questionnaire-2
PHQ-9	Patient Health Questionnaire-9
PHQ-A	Patient Health Questionnaire for Adolescents
PI	Principal Investigator
PLES	People with Lived Experience with Suicide
REDCap	Research Electronic Data Capture
RM	Research/Medical Monitor
SAE	Serious Adverse Event
S-BACC	Spring Brief Assessment of Capability to Consent
SITBI-R	Self-Injurious Thoughts and Behaviors Interview - Revised
SLHS	St. Luke's Health System
SPRING	Comparing the Effectiveness of Suicide Prevention Interventions to Guide Follow-up Care
UAP	Unanticipated Problem
UC	Usual Care
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 American Foundation for Suicide Prevention. The Principal Investigator 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 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

18. References section of this protocol.

Funding for the SPRING Trial

The research described in this protocol is funded through a *20% by 2025 Research Focus Grant* from the American Foundation for Suicide Prevention, award # TBT-0-022-22. The title of the awarded proposal is: “Effectiveness of Two-Way Caring Texts vs One-Way Caring Texts vs Usual Care: A Pragmatic Randomized Controlled Trial.”

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.

Principal Investigator:

Signed: _____ Date: _____

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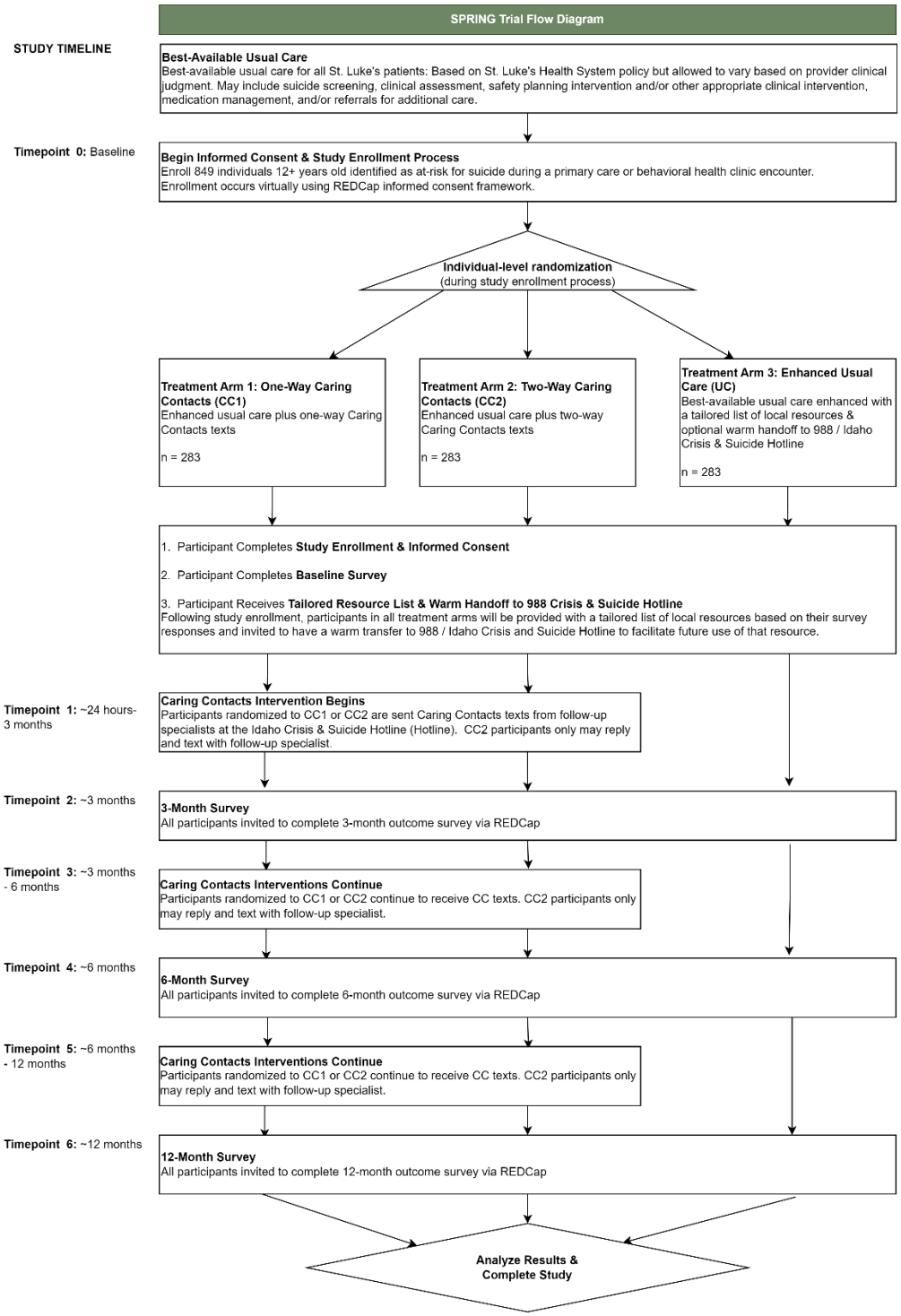
1. Protocol Summary

1.1 Synopsis

Title	The SPRING Trial: Comparing the Effectiveness of Suicide Prevention Interventions to Guide Follow-up Care Models
Contract Number:	AFSP TBT-0-022-22
Study Description	Pragmatic randomized controlled trial to compare the effectiveness of two-way Caring Contacts text messages (CC2) versus one-way Caring Contacts text messages (CC1) versus best available usual care alone (UC) for suicide prevention.
Specific Aims	1. Measure the effectiveness of augmenting best available usual care with two-way Caring Contacts text messages (CC2) and one-way Caring Contacts texts (CC1) compared to best available usual care alone (UC) for preventing suicidal behavior. *Hypothesis*: CC2 and CC1 are more effective than usual care. 2. Determine whether CC1 are noninferior to CC2 for preventing suicidal behavior. *Hypothesis*: CC1 are inferior to CC2. 3. Describe the feasibility of implementing CC2 and CC1 in partnership with a state crisis and suicide prevention hotline. *Hypothesis*: CC2 will require more resources than CC1 but both will be acceptable and feasible to deliver through a state crisis and suicide hotline.
Outcomes	The primary outcome is suicidal behavior, measured by the difference between study arms in the average area under the curve of the Active Suicidal Behavior Sub-Scale of the Harkavy-Asnis Suicide Scale (HASS).[1] Secondary outcomes include suicidal ideation, (HASS), [1] suicide attempts (Columbia Suicide Severity Rating Scale (C-SSRS)),[2]use of crisis care for suicidality (electronic health records), and use of outpatient mental health services (self-report). All outcome measures will be assessed at baseline, 3, 6, and 12 months.
Study Population	Adolescents (aged 12-17) and adults (18+) who screen positive for suicidal ideation or behavior using the Columbia Suicide Severity Rating Scale (C-SSRS) at one of the study sites will be eligible to participate.
Description of Study Sites	Participants will be recruited from primary care clinics and outpatient behavioral health clinics at St. Luke's Health System in Idaho.
Study Duration	This study will last for 3 years, with survival assessed for up to 10 years.
Participant Duration	Participants will be followed for 12 months. Participants will complete assessments at baseline, 3 months, 6 months, and 12 months.

1.2 Schema / Study Flow Diagram

Figure 1: SPRING Trial Flow Diagram



2. Research Questions & Specific Aims

2.1 Research Questions: Do Caring Contacts text messages improve outcomes for patients at risk for suicide? Are one-way Caring Contacts texts inferior to two-way Caring Contacts texts?

2.1 Specific Aims

1. Measure the effectiveness of augmenting best available usual care with two-way Caring Contacts text messages (CC2) and one-way Caring Contacts texts (CC1) compared to best available usual care alone (UC) for preventing suicidal behavior.
    - *Hypothesis*: CC2 and CC1 are more effective than usual care.
2. Determine whether CC1 are noninferior to CC2 for preventing suicidal behavior.
    - *Hypothesis*: CC1 are inferior to CC2.
3. Describe the feasibility of implementing CC2 and CC1 in partnership with a state crisis and suicide prevention hotline.
    - *Hypothesis*: CC2 will require more resources than CC1 but both will be acceptable and feasible to deliver through a state crisis and suicide hotline.

3. Introduction

3.1 Background

Suicide is a leading cause of death in the United States (US); [4] nearly 840,000 lives were lost to suicide from 1999-2020. [5] Idaho's suicide rate is consistently among the top ten nationally, and in 2020 was the fifth highest in the US, 72% higher than the national average.[5] The American Foundation for Suicide Prevention (AFSP) has called for research to identify effective interventions that, if implemented at scale, could reduce suicide deaths by 20% by 2025.[6] **Caring Contacts is one of the few evidence-based interventions shown to reduce suicide deaths,** [7,8] **and it is feasible to implement at scale, including in rural and low-resource settings.**[9-11]

The Caring Contacts model involves sending **brief, non-demanding expressions of care to suicidal individuals, to let them know that they are being thought of and as a gentle reminder that help is available if needed**. The first Caring Contacts efficacy trial randomized patients with recent suicide attempts who refused ongoing care to receive either typed caring letters or no further contact. The mean probability of suicide-free survival after two years was significantly higher in the contact arm (0.983, 95% CI: [0.977, 0.989]) than in the no contact arm (0.964, 95% CI: [0.957, 0.971]).[7] In other randomized controlled trials, Caring Contacts have proven effective when delivered by post cards,[12,13] and more recently, two-way text messages. [14] A recent trial of text message-based Caring Contacts found that compared to usual care, Caring Contacts were associated with lower odds of experiencing any suicidal ideation since baseline (OR: 0.56, 95% CI: [0.33, 0.95]) and lower odds of suicide attempt

(OR: 0.52, 95% CI: [0.29, 0.92]). [14] A systematic review and meta-analysis concluded that Caring Contacts is protective against attempts at 12 months (RR: 0.57, 95% CI: [0.40, 0.80]), but the effect on suicide deaths was inconclusive. [8] The authors recommend additional efficacy and effectiveness research.

As the evidence base for Caring Contacts has expanded, interest in scaling up the intervention has too. Several key implementation questions remain. Efficacy trials published to date have involved two-way Caring Contacts in which participants had met the sender – either in person, or by phone - and were invited to reply to them if they chose to do so. [7,12-14] A recently completed randomized controlled trial by our team found no significant difference in loneliness (adjusted mean difference: -1.0, 95% CI: [-3.0, 1.0]) or suicidal ideation and behavior (adjusted mean difference: 0.2, 95% CI: [0.0, 0.5]) between participants receiving two-way caring texts from someone they had spoken with and gotten to know over the phone versus someone they never met.[11] It may not be necessary to introduce the Caring Contacts recipient and sender for the intervention to be effective.

However, in practice, Caring Contacts programs delivered at scale often only offer one-way contacts, [15-17] which are simpler and less resource intensive to manage. **Sending one-way text messages to which recipients cannot reply or interact with the sender is meaningfully different than two-way caring texts**. The hypothesized causal mechanism of Caring Contacts is to make people feel valued and cared; one-way texts may not achieve that goal and could potentially even have the opposite effect, as many technology-literate Americans are likely to understand that one-way messages may be pre-scheduled and sent in bulk. In other fields of biomedical research, two-way texting interventions have been shown to be more effective than otherwise similar one-way texting interventions. For example, a meta-analysis (8 randomized clinical trials, pooled n=1,994 patients) comparing two-way texting interventions to one-way texting interventions for improving medication adherence found that two-way texting significantly improved adherence (23% improvement, 95% CI: [13%-35%]), while one-way texting had no significant effect.[18] **Despite their wide adoption, it remains unknown whether one-way caring text messages are effective as they have never been compared to two-way texts nor to usual care**.

3.2 Significance

The proposed research would provide high quality evidence to determine whether one-way Caring Contacts is better than best available usual care alone and at least as effective as two-way Caring Contacts. Delivering two-way Caring Contacts via text is more operationally complex and resource intensive than sending one-way messages that don't require monitoring or responses. Research is needed to justify the additional expense and effort required to scale-up the evidence-based two-way Caring Contacts.

In the proposed study, Caring Contacts would be delivered by a trusted community resource – the Idaho Crisis and Suicide Hotline (Hotline) – in partnership with an established research team at St. Luke's

Health System (SLHS). Our previous research has shown this model is feasible, including in rural areas and states with limited resources such as ours. Nationally, the Suicide Lifeline fielded over 3.3 million contacts in 2020. The introduction of 988, a three-digit dialing code that callers across the United States can use to access mental health and crisis support is expected to result in 6-12 million contacts in year one and 13-40 million annual contacts by year five. [19] Part of the vision of the transition to 988 is equipping state crisis and suicide prevention hotlines to "reduce the deadly gaps in the existing fragmented behavioral health crisis care system by enabling Lifeline/988 centers to stay in contact and follow up with those in crisis."[19] **There is promise in scaling up Caring Contacts to deliver 988 follow-up support, but it is critical that the version being delivered at scale be evidence-based.**

Insurance companies and electronic health records companies have also expressed a growing interest in Caring Contacts. SLHS has been collaborating with Epic Systems Corporation, which provides electronic health records software to hospitals serving 78% of patients in the US,[20] on suicide prevention clinical workflows and Caring Contacts. Epic is actively designing Caring Contacts modules that health systems could adopt for use with *MyChart*, their mobile electronic health record and patient-provider messaging system. The results of this study could also inform that work as Epic is currently developing one-way Caring Contacts. **This research is urgently needed to inform decisions about which model of Caring Contacts to implement at 988 Lifeline centers, and for follow-up support from health systems, crisis centers, and other settings across the United States and beyond.**

4. Research Methods

4.1 Study Design

The proposed study is a pragmatic randomized controlled trial with participants assigned to one of three intervention arms: two-way caring text messages (CC2), one-way caring text messages (CC1), and best available usual care alone (UC).

4.2 Randomization

Randomization will occur at the individual level. Participants will be randomized in a 1:1:1 ratio to one of the three intervention arms. The study statistician will generate a random list of treatment assignments with varying block sizes. Research Electronic Data Capture (REDCap) [21,22] will pull the next treatment assignment from the list at the time of randomization. The list will be concealed from the study staff conducting enrollment. Randomization will occur prior to enrollment during the informed consent process so that participants can see the intervention arm to which they were randomized before they decide whether to enroll in the study, but remain masked to the other treatment conditions.

4.3 Masking

This trial will be single masked, with most members of the study team including the senior statistician

masked to aggregate data by treatment arm. Participants will be aware of their own treatment but unaware of alternative treatment arms. Masking interventionists or participants to the assigned intervention is not feasible due to the nature of the intervention.

5. Study Population & Setting

The primary study population for this research is adolescent and adult patients identified as at risk for suicide during a primary care or behavioral health clinic encounter at St. Luke's Health System in Idaho. Study sites will include up to 60 SLHS primary care clinics and up to 25 ambulatory behavioral health clinics.

5.1 Inclusion & Exclusion Criteria

5.1.1 Inclusion Criteria

- Adolescents (12-17 years old) and adults (18+)
- Response of "yes" to at least one item on the Columbia Suicide Severity Rating Scale (C-SSRS) six-item screener at a SLHS primary care or behavioral health clinic, *or* electronic health record or provider note from an eligible encounter indicates suicide risk
    - Eligible encounters may include in-person clinic encounters, virtual encounters, or telephone encounters including suicide risk triage telephone encounters
- Ability to send and receive text messages
- Ability to receive phone calls
- Ability to receive emails
- Participant and legal guardian (if applicable) speak, read, and understand English
    - Accommodations may be made for individuals with impaired hearing

5.1.2 Exclusion Criteria

- Individuals who participated in a previous SLHS randomized controlled trial related to Caring Contacts (SPARC Trial or MHAPPS Trial)
- Patients who are unable or unwilling to provide informed consent*, for example, due to acute or chronic cognitive impairment (i.e.: acute psychosis, intoxication, or intellectual disability).
- Primary Care Provider, Behavioral Health Provider, or Principal Investigator determines that participation in the research is not in the best interest of the patient or the study team.

**The SPRING Brief Assessment of Capability to Consent is included as an appendix and will be used by trained Research Coordinators as needed to assess ability to provide informed consent for the study.*

5.2. Statistical Power and Sample Size

Because the study is designed to assess both the effectiveness of Caring Contacts as compared to usual care as well as the noninferiority of CC1 as compared to CC2, there are two components to the sample size and power calculations. Both assume a standard deviation of 5 in the area under the curve (AUC) of

HASS Active Suicidal Behavior Subscale scores over 12 months based on previously published studies [23]and data from an ongoing trial with suicidal patients at SLHS.[9] With a sample size of 759, we will have 80% power to detect a true difference between the CC arms and the UC arm of 1.26 units in the AUC of HASS scores over 12 months accounting for one formal interim analysis for efficacy. Similarly, a sample size of 759 will allow 89% power to determine noninferiority of CC1 to CC2 if the two interventions are truly equivalent, when using a noninferiority margin of 1.0. **We plan to enroll 849 participants to account for up to 30% potential lost to follow-up.**

Power for superiority

Improvement in CC arm compared to UC arm	Power	Sample Size per Arm	Total Sample Size
1.26	80%	253	759

Power for noninferiority

Noninferiority Margin	True difference between CC1 and CC2	Power	Sample Size per Arm	Total Sample Size
-1.0	0	89%	253	759

5.3 Recruitment Plan

SLHS routinely screens primary care and behavioral health patients aged 12 and older for suicidality using the C-SSRS. [24-30] Patients generally self-complete the C-SSRS screener on an iPad or on paper; screeners are sometimes completed together with clinic staff or provider. Patients who respond "yes" to any of the six items on the C-SSRS screener may be notified by a message on the screening iPad/tablet or paper screener that they may be eligible for a research study and will be given the opportunity to opt into contact from the research team to learn more or defer until they can discuss with their provider. Additionally, providers or social workers may refer patients to the study. Research coordinators will contact patients who opt in by text message, phone, or email to schedule a time for a study enrollment call. Informed consent and study enrollment will be completed over the phone using the REDCap informed consent framework. Texting to schedule phone-based consent and enrollment has been successful and well-received by our participants in other studies. Accommodations may be made for patients with hearing impairment.

5.4 Retention

A variety of methods will be used to improve retention of research participants. A contact sheet will be provided at enrollment allowing patients to share additional contact information (including alternative phone numbers, or email addresses) that may be used to contact participants for retention purposes. A primary phone number, a secondary phone number/emergency contact, and an email address are required; providing additional sources of contact on the contact sheet is optional. Email, text messages, phone calls, or other forms of contact may be used for retention purposes or to assist with scheduling and completing surveys, including retention texts, which may be sent in between survey periods.

5.5 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 and the baseline survey will be included in this dataset.
2. **Safety Analysis Dataset**: The safety analysis will include data for all participants who completed study enrollment and the baseline survey (e.g., the ITT Analytic Population Dataset).
3. **Per-Protocol Analysis Dataset**: Data for a subset of participants who were retained for the duration of the study and received the assigned intervention.
4. **Additional Datasets**: Additional datasets may be developed to complete sensitivity analyses, for example, where missing data have been imputed using different techniques.

6. Study Procedures

Pre-Consent – Best available usual care according to SLHS policy. Generally available to all patients but adherence to standard workflows may vary and actual delivery of each of the below is based on individual patient needs, staff/provider availability, and provider clinical judgment.

- C-SSRS screening for suicide risk at primary care or behavioral health clinic encounter *(*Generally during clinic encounter; screening may be completed in advance via myChart, on iPads or paper during the encounter, virtually, or in-person).
- Clinical risk assessment
- Development of safety plan or a connection and support plan or other appropriate clinical intervention
- Referrals to other care
- Medication management

Pre-Screening – Review of eligibility prior to contacting patient

- Study staff may review medical records of patients referred to the study or who indicate interest in learning more about the study after being identified as potentially eligible.
    - The medical record review allows study staff to carefully review eligibility criteria, and to identify patients with evidence of cognitive impairment or intellectual disability so that they can plan to utilize the S-BACC form to assess capability to provide informed consent.

Baseline / Enrollment Call – All participants (virtual/by phone, following clinical encounter)

- Informed consent (including randomization) and study enrollment
- Baseline survey
- Sharing of tailored resource list

- Optional warm hand-off to 988

Follow-Up Intervention – CC1 & CC2 participants only (Baseline – 12 months)

- CC1: one-way text messages; participants may not reply
- CC2: two-way text messages to which participants may reply if they choose

3-Month Outcome Assessment – All participants (± 4 weeks variance window) (REDCap survey link sent via email, text, or phone call)

- 3-Month Outcome Survey

6-Month Outcome Assessment – All participants (± 4 weeks variance window) (REDCap survey link sent via email or text, or phone call)

- 6-Month Outcome Survey

12 Month Outcome Assessment – All participants (± 4 weeks variance window) (REDCap survey link sent via email or text, or phone call)

- 12-Month Outcome Survey

6.1 Schedule of Activities

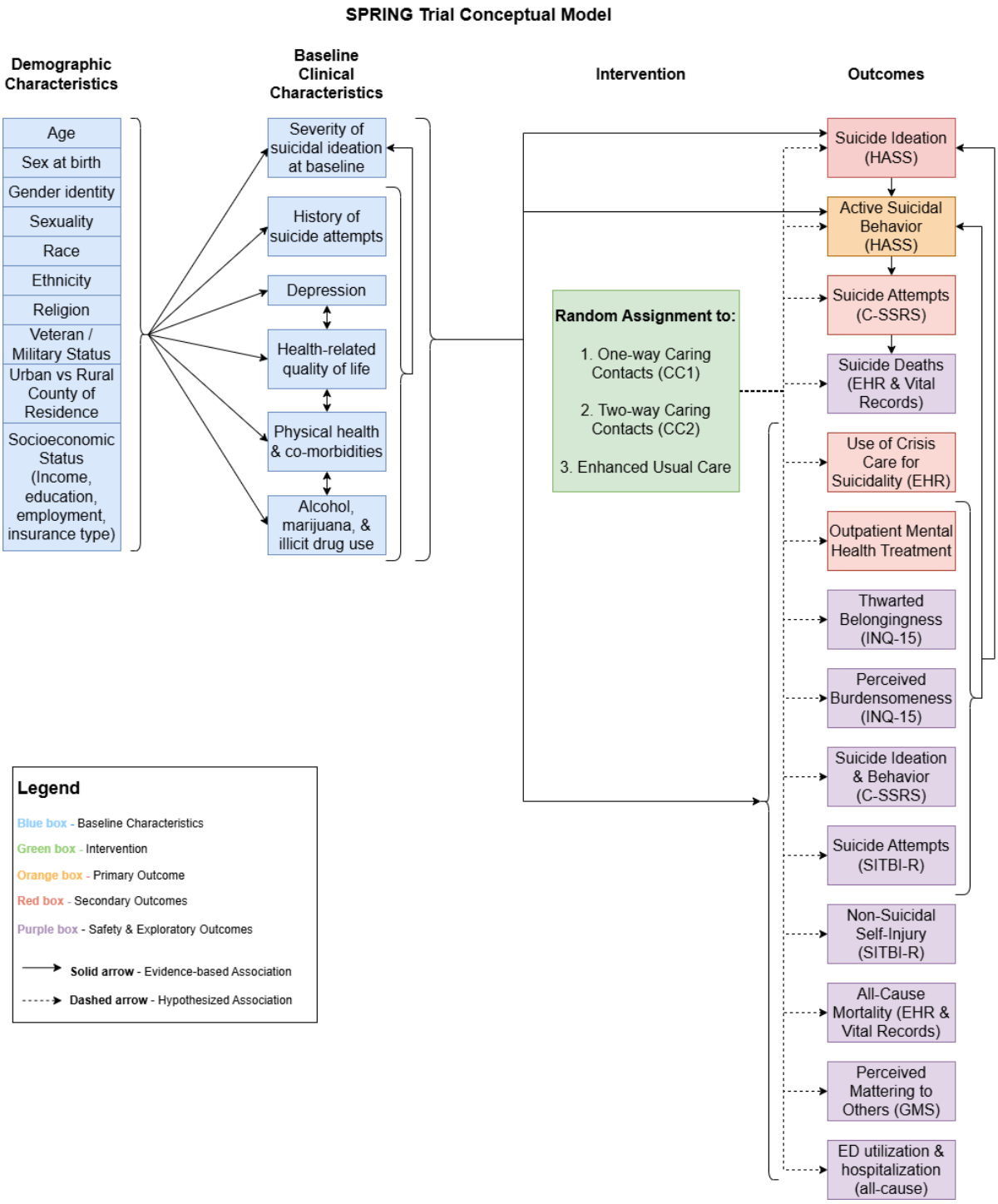
Table 1: Schedule of SPRING Trial Activities

	Pre-Consent (Usual Care)	Study Enrollment & Baseline	Baseline – 12 months	3 months	6 months	12 months
Columbia Suicide Severity Rating Scale (C-SSRS) screening/clinic encounter to establish eligibility	X					
Receipt of best available usual care (e.g. screening, assessment, clinical intervention, referrals, medication management, crisis care, etc.)	X		X			
Informed consent/assent		X				
Baseline survey		X				
Tailored resource list shared with participant & warm handoff to 988 offered (all participants)		X				

Caring text messages (CC1 & CC2 intervention arms only)			X			
3-Month outcome survey				X		
6-Month outcome survey					X	
12-Month outcome survey						X

7. Conceptual Model

Figure 2: SPRING Trial Conceptual Model



8. Study Measures

Key variables to be collected for this study are summarized in ***Table 2***.

8.1 Primary Outcome

Suicidal behavior is the primary outcome and will be measured using the Harkavy-Asnis Suicide Scale (HASS) Active Suicidal Behavior Subscale. The HASS includes three sub-scales, each of which have been validated for self-report, with strong psychometric properties in adolescents and adults. [23] [1] The Active Suicidal Behavior Subscale of the HASS asks about the frequency of each of five active suicidal behaviors, including suicide attempt planning, and actual and aborted/interrupted suicide attempts. Participants respond using the Likert scale response options used by Asarnow et al. in their validation study, [23] which will be modified to fit the time period based on each survey (past six months will be used for baseline and 12-month outcome surveys, and past 3 months will be used for 3- and 6-month outcome surveys). Each of the sub-scales of the HASS are scored separately. Scoring is completed by summing the number of the associated response category for all the items in the sub-scale. [23]

The primary outcome will be the cumulative risk of suicidal behavior assessed using area under the curve of the HASS scores over the 12-month study period. The area under the curve summary measure will be calculated for each participant.

8.2 Secondary Outcomes

Secondary outcomes include suicide attempts, suicide ideation, suicide-related ED utilization and hospitalization, and outpatient mental health treatment. Suicide attempts will be measured using the Columbia Suicide Severity Rating Scale (C-SSRS).[2,30-32,33] Suicidal ideation will be measured using the Passive Suicidal Ideation Subscale of the HASS, which includes 12 items. [23] Suicide-related ED utilization and hospitalization will be assessed by self-report and using electronic medical records. Outpatient mental health treatment will be self-reported and assessed using electronic medical records. Reason for visit/diagnoses may be reviewed in electronic medical records for any inpatient or outpatient encounters that occur during the study period. All outcomes will be measured at baseline, 3 months, 6 months, and 12 months.

8.3 Exploratory & Safety Outcomes

Exploratory and safety outcomes include thwarted belongingness, perceived burdensomeness, a combined measure of suicidal ideation and behavior, suicide attempts (including actual, aborted, or interrupted attempts), perceived mattering to others, non-suicidal self-injury, all-cause ED utilization and hospitalizations, suicide deaths, and all-cause mortality. Thwarted belongingness and perceived burdensomeness will be measured using the 15-item version of the Interpersonal Needs Questionnaire. [34-37] Suicide attempts, including a count, will be measured using the Self-Injurious Thoughts and Behavior Interview - Revised (SITBI-R) which is valid for self-report in adolescents and adults. [3,33] A combined indicator of suicidal ideation and behavior will be assessed using the Columbia Suicide Severity Rating

Scale self-report 6-item screener for primary care (C-SSRS).[24-30] The C-SSRS self-report screener is widely used in clinical practice, including at SLHS, and will be used to determine eligibility for the study. Participants will also self-complete the C-SSRS at baseline following enrollment, and at 3, 6, and 12 months. The C-SSRS self-report 6-item screener has strong psychometric properties for use with both adolescent and adult and populations, including excellent sensitivity and specificity,[38] convergent validity, [2] and incremental validity.[2] The C-SSRS self-report screener is widely used in clinical practice, including at SLHS, and will be used to determine eligibility for the study. Participants will also self-complete the C-SSRS at baseline following enrollment, and at 3, 6, and 12 months. The C-SSRS self-report 6-item screener has strong psychometric properties for use with both adolescent and adult and populations, including excellent sensitivity and specificity,[38] convergent validity, [2] and incremental validity.[2] Non-suicidal self-injury will be measured with items from the SITBI-R. The General Mattering Scale (GMS) [39-41] will be used to assess the extent to which participants believe they matter to other people. The frequency of suicide attempts (including actual attempts, interrupted attempts, and self-aborted attempts) will be measured using the two-item Suicide Attempts Sub-Scale of the HASS.[23] All-cause ED utilization and hospitalizations are positively associated with mental health diagnoses. [42] The number of and reason for visit/diagnoses for ED encounters and hospitalizations will be assessed using electronic medical records. The manner and cause/lethal means of suicide deaths and all deaths will be assessed based on electronic medical records and vital records.

8.4 Other Measures

We will collect data on **age and sex at birth**, as well as **gender identity and sexual orientation,** all of which are strongly associated with risk of suicidal ideation and behavior.[5,43,44] Gender identity and sexual orientation will be assed using questions from CDC's Youth Risk Behavior Surveillance System Questionnaire.[45] Suicide rates differ by **race and ethnicity,** [5] which will be self-reported using US Census categories.[46] **Religious affiliation** and practice 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). [47] We will include items from a recent Pew Research Religious Landscape Study to assess religiosity. [48] Compared to other adults, **active-duty military or veterans** face a 57.3% higher adjusted suicide rate. [49] The Health Resources & Services Administration's Office of Rural Health Policy urban-rural designation for census tracts[50] will be used to classify participants as **urban or rural residents**. Compared to large urban areas, residence in the most rural and remote parts of the US is associated with a 96% higher rate of suicide,[5] lower socioeconomic status,[51] and worse overall health outcomes. [51] Thirty-five of Idaho's 44 counties are classified as rural. [50]**Financial crises and low socio-economic status (SES**) are associated with increased suicidality.[52] We will collect data related to SES including income, education, and employment using questions from the US Census Bureau's American Community Survey.[46] **Lethal means** for planned and actual suicide attempts will be self-reported.[26] **Utilization of 988 will be self-reported** by participants to determine how different sub-groups & treatment arms used this resource before and during the study.

9. Description of Interventions

9.1 Enhanced Usual Care Alone (UC)

Participants randomized to the UC arm will receive best available usual care from the health system, such as standardized clinical assessments, the safety planning intervention or other intervention(s), appropriate referrals and/or medication management through a system wide electronic health record system-assisted suicide care clinical workflow. Usual care will vary based on patient clinical needs, availability of providers/staff, and provider clinical judgment. Following study enrollment, all participants will be given a list of resources, offered a warm hand-off to 988, and encouragement to call or text 988 as needed.

9.2 Two-way Caring Contacts (CC2)

In addition to receiving enhanced usual care as described above, a series of 25 standardized outgoing Caring Contacts text messages will be sent to participants randomized to the CC2 intervention arm through our online texting platform. To remind participants that they can respond, the outgoing texts will periodically invite replies in a non-demanding way, e.g., "Hope you're doing well this week, Anna. Feel free to text me back if you feel like it, I'm here for you." Responses to CC2 participant replies will be unscripted and individually tailored.

9.3 One-way Caring Contacts (CC1)

In addition to receiving enhanced usual care as described above, CC1 participants will be sent 25 caring texts, such as "Even though know we do not personally know each other, we truly value your wellbeing and are thinking of you. If you'd like to connect with someone, feel free to call or text 988 anytime – their team would be happy to hear from you." CC1 participants will not be able to reply to the texts and the online texting platform will block incoming messages. This will be clearly communicated to CC1 participants during the informed consent process and they will be asked to sign off on understanding this and other key points before enrolling in the study.

9.4 Process Evaluation & Fidelity Monitoring

The study will include regular monitoring of study enrollment and other key study processes as well as fidelity of delivery of the active follow-up interventions. The timing and content of all contacts from the Hotline to participants will be tracked and recorded by the Hotline for each study participant. Study staff will review a selection of incoming and outgoing text messages to ensure adherence to the schedule and content outlined in study documents (scheduled/standard texts) and Jerome Motto's principles of Caring Contacts [53] (unscripted text replies to participants).

10. Discontinuation and Participant Withdrawal

10.1 Discontinuation of Study Intervention

Participants may voluntarily discontinue the study intervention at any timepoint by contacting study staff. When a participant discontinues the intervention but remains in the study, remaining study procedures will be completed as indicated in the study protocol.

Data to be collected at the time of study intervention discontinuation will include the following:

- The date of discontinuation of the intervention
- The reason(s) for discontinuing the intervention (if available)

The participant will be eligible to complete future assessments (3-, 6-, and 12-month outcome surveys), even if they decide to withdraw from the intervention.

10.2 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 SPRING Trial email account (spring@slhs.org). Additionally, study investigators may discontinue a participant from the study for the following reasons:

1. Lost to follow-up; unable to contact subject (see section *10.3 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 feasible or 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
5. The PI determines keeping the participant in the study is not in the best interest of the participant, study staff, St. Luke's and study partners, and/or the study itself.

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

10.3 Lost to Follow-Up

A study participant will be considered lost to follow-up if s/he fails to complete all remaining study follow-up 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, 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.

11. Data & Safety Monitoring

11.1 Overview of Data & Safety Monitoring Plan

This research will include a designated Research/Medical Monitor (RM), a clinician with appropriate psychiatric and medical training and experience reviewing safety outcomes for suicide prevention clinical trials. This research will also include a Data and Safety Monitoring Board (DSMB). The RM will also chair the DSMB. The DSMB will be convened and managed in partnership with the University of Washington's Institute of Translational Health Sciences (UW ITHS). The study team will monitor survey responses and follow a standard procedure approved by the DSMB to assess safety for those participants reporting acute risk for suicide on a survey.

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

The DSMB will review and oversee the following elements:

1. Study enrollment by study site and population (adults, adolescents)
2. Retention of study participants at 3, 6, and 12 months
3. Data completeness and quality
4. Intervention fidelity data
5. Safety outcomes by intervention and age category (adults, adolescents)
6. Sample size assumptions vs observed data and whether to recalculate sample size
7. Interim analyses to assess whether one intervention is significantly more effective than the other(s)
8. Decisions related to stopping the trial early due to one or several of the elements above

11.3 Safety Monitoring

This protocol considers completed suicide, suicide attempts, and inpatient admission in the context of 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, 6, and 12 months and reviewed by the Data and Safety Monitoring Board according to the DSMB charter to determine whether the rate of safety outcomes differs by intervention arm:

- Death by suicide
- Attempted suicide
- Interrupted or aborted suicide attempt
- Psychiatric hospitalization

- Medical hospitalization related to self-harm or attempted suicide

Participants' electronic medical records may be accessed to assess and monitor safety outcomes, including following death.

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. 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, 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. Given that the CC2 intervention includes frequent contact with study participants (and the CC1 and UC conditions do not), if the study were to monitor AEs and/or SAEs in real-time, differential rates of ascertainment would be expected. Any attempt to compare rates of AEs or SAEs across intervention groups could be substantially biased due to differential ascertainment. Instead, this protocol will monitor safety outcomes collected at 3, 6, and 12 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.

11.5 Role of the Research / Medical Monitor (RM)

The RM for this protocol will participate as a subject matter expert on the DSMB and will also conduct an independent review of study personnel's responses to study participants who experience suicidal crisis or one of the safety outcomes in the context of study-related activities. If study personnel (such as research coordinators, or clinic/ED staff or providers) become aware of a clinically complex situation during the study, that participant's needs should be placed above any responsibilities related to the study protocol. The goal of the RM review is to assess participant safety and determine what is in the participant's best interest this when potential issues are flagged by the PI.

12. Data Collection & Management

12.1 Data Collection

All data will be self-reported by participants using online surveys [21,22] sent by text or email, based on participant preference, or extracted from the electronic health record (Epic). Caring Contacts data will be captured from our online texting platform.[54]

Table 2: SPRING Trial Key Variables & Other Data Elements

Variable	Tool/Source	Routinely collected as usual care	Mode of contact	Who will collect
Primary, Secondary, Safety & Exploratory Outcomes (Baseline + 3, 6, 12 months)				
Primary Outcome				
Suicidal behavior	HASS Active Suicidal Behavior Sub-Scale (all surveys)	No	REDCap survey	SLHS
Secondary Outcomes				
Suicidal ideation	HASS Passive Suicidal Ideation Sub-Scale (all surveys)	No	REDCap survey	SLHS
Suicide attempts	C-SSRS (all surveys)	No	REDCap survey	SLHS
Outpatient mental health treatment	Self-report, Epic, Claims data (all surveys)	Yes	REDCap survey	SLHS
Use of crisis care (ED visits, hospitalizations) for suicidality	Self-report, Epic, Claims data (all surveys)	Yes	REDCap survey	SLHS
Safety & Exploratory Outcomes				
Perceived burdensomeness & thwarted belongingness	INQ-15 (all surveys)	No	REDCap survey	SLHS
Perceived mattering to others	GMS (all surveys)	No	REDCap survey	SLHS
Non-suicidal self-injury (NSSI)	SITBI-R (all surveys)	No	REDCap survey	SLHS
Suicidal ideation	SITBI-R (all surveys)	No	REDCap survey	SLHS
Suicidal ideation & behavior	C-SSRS (all surveys)	No	REDCap survey	SLHS
Suicide Plans & Preparatory Acts	SITBI-R (all surveys)	No	REDCap survey	SLHS
Suicide attempts	HASS Suicide Attempts Sub-Scale (all surveys) and SITBI-R (all surveys)	No	REDCap survey	SLHS
Suicide deaths including cause of death	Vital records, Epic	Yes	N/A	Idaho Dept of Health & Welfare, SLHS
All-cause mortality including manner & cause of death	Vital records, Epic	Yes	N/A	Idaho Dept of Health & Welfare, SLHS
ED utilization or hospitalization (all-cause), including number and diagnoses/reason for visit	All surveys, Epic	Yes	REDCap survey	SLHS
Current Suicidal Crisis	All surveys	No	REDCap survey	SLHS
Use of 988 or suicide hotline	All surveys	No	REDCap survey	SLHS
Sociodemographic & Other Exposure Variables				
Age in years at enrollment	Epic, Informed Consent Form	Yes	REDCap survey	SLHS
Sex assigned on birth certificate	Epic	Yes	n/a	SLHS

Race and ethnicity	Epic	Yes	n/a	SLHS
Address including Zip code of residence (urban/rural)	Epic	Yes	n/a	SLHS
County of residence (urban/rural)	Epic	Yes	n/a	SLHS
Gender identity, pronouns, transgender status, & sexual orientation	Baseline survey	No	REDCap survey	SLHS
Marijuana and illicit drug use	Baseline survey, 3, 6, and 12-month outcome surveys	No	REDCap survey	SLHS
Alcohol use	Baseline survey, 3, 6, and 12-month outcome surveys	No	REDCap survey	SLHS
Religion & religious practice	Baseline survey	No	REDCap survey	SLHS
Military / veteran status	Baseline survey	No	REDCap survey	SLHS
Socioeconomic status (employment, education / maternal education, housing stability, income, food/income security)	Baseline survey	No	REDCap survey	SLHS
Depression	Baseline survey (PHQ-A / PHQ-9)	No	REDCap survey	SLHS
History of suicide attempts & self-harm; lethal means	Baseline survey	No	REDCap survey	SLHS
Insurance Provider	Epic	Yes	n/a	SLHS
Suicidal ideation & behavior at referring encounter (usual care)	C-SSRS (in Epic)	Yes	n/a	SLHS
Quality of life at baseline	Baseline survey Euro-Qol	No	REDCap survey	SLHS
Overall health (presence of co-morbidities) at baseline	Epic	Yes	n/a	SLHS
Treatment history and medication use	Epic, REDCap surveys	Yes	REDCap survey	SLHS
Referring clinic name & referring provider	Epic	Yes	n/a	SLHS
Intervention assignment (CC2, CC1, UC)	REDCap	No	n/a	SLHS
Patient Satisfaction				
Patient satisfaction with study intervention	Outcome surveys	No	REDCap survey	SLHS
Process Variables				
Screening rates & results by clinic and provider; referral rates by clinic & provider	Epic / D&A dashboard	Yes	n/a	SLHS
Safety Planning/Connection & Support Planning completion	Epic / D&A dashboard / REDCap / Mosio	No	n/a	SLHS
Individual who completed safety plan	Epic / REDCap / Mosio	No	n/a	SLHS

"Dose" of follow-up contact: timing, type (phone vs text), and number of attempted and successful contacts from the Hotline; # outgoing & incoming texts + content of texts	Mosio	No	n/a	Hotline
Other Variables				
Medical record number (MRN) & encounter number (CSN)	Epic	Yes	n/a	SLHS
Encounter date(s) and time(s)	Epic	Yes	n/a	SLHS
Clinic specialty/type	Epic	Yes	n/a	SLHS
Provider(s)	Epic	Yes	n/a	SLHS
Referral(s)	Epic	Yes	n/a	SLHS
Insurance type	Epic	Yes	n/a	SLHS
Does cell phone on record belong exclusively to study participant or is it shared?	Baseline survey	No	REDCap survey	SLHS
Alternative modes of contact	Baseline survey	No	REDCap survey	SLHS
Death (manner and cause), including suicide deaths and all-cause mortality	Epic and vital records	Yes	n/a	SLHS & Idaho Department of Health & Welfare

12.2 Data Management

Data management will occur using the Research Electronic Data Capture (REDCap) [21,22] tool, a HIPAA-compliant web-based research application used for building and managing online surveys and providing a secure electronic database. Our instance of REDCap is owned and managed by the University of Washington's Institute of Translational Health Sciences. REDCap will be used as the central location for online study data storage and participant management. The database is safeguarded against unauthorized access by established security procedures; appropriate backup copies of the database and related software files will be maintained. The statistics team will compile data from REDCap on a weekly basis for reports and to build and maintain a complete dataset. Baseline data from participants' electronic health records will be entered via REDCap data extraction forms. Twilio, a HIPAA-compliant texting platform integrated into REDCap, will be used to send survey links and survey reminders to participants. Mosio, [54] our HIPAA-compliant online texting platform, will be used to deliver Caring Contacts, to schedule enrollment calls, to send retention texts and survey reminders, and to make phone calls. Mosio records any attempt at contact and successful contact made. To protect the confidentiality of participants, data and associated documentation will be available to approved study 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 technology; and (3) destroy or return the data after analyses are completed.

13. Statistical Analysis

13.1 Data Analysis

13.1.1 Primary Analysis

The primary analysis population is the intention to treat population: all randomized participants who complete a baseline survey, grouped with the treatment arm to which they were randomized regardless of treatment delivered. An area under the curve analysis will be used to assess HASS score as a measure of cumulative risk across the 12-month study period. A linear model with indicator variables for the treatment arms and an indicator of age at enrollment, using heteroskedasticity robust variances will be used in the primary model. Multiple imputation will be used to account for missing outcome data and Rubin's rule will be used to combine results across imputations. The primary analysis will use a gatekeeping procedure: first, the Caring Contact arms will be compared to usual care; if both CC arms are statistically significantly superior to usual care, then a noninferiority comparison will be done for the two Caring Contact study arms using a noninferiority margin of 1.0.

13.1.2 Secondary Analyses

The analyses of secondary outcomes will use linear models similar to the primary analysis; for binary outcomes, a generalized linear model will be fit with the identity link to allow for the estimation of the risk difference. Analyses will be performed using standard statistical software such as R or SAS. A two-sided type-I error of 0.05 will be used as the threshold to determine statistical significance. Confidence intervals will be reported in addition to p-values.

13.1.3 Subgroup Analyses

Subgroup analyses will be completed based on age at enrollment (12-17; 18-24; 25-49; 50+), sex at birth (female vs. male), gender identity (cisgender vs. transgender or gender nonconforming), sexual orientation (heterosexual vs. homosexual, bisexual, or other) and area of residence (urban vs. rural), and place of recruitment (primary care vs behavioral health clinic). To allow for formal testing of heterogeneity of the treatment effect across subgroups, a linear model of the AUC summary measures will be fit with indicator variables for the CC treatment arms and adolescent age, the subgroups of interest and the interaction between subgroup and treatment. The effect of each CC treatment, compared to usual care, will be reported along with the 95% confidence interval for the difference in means and the p-value testing for the interaction of group with treatment.

13.2 Planned Interim Analyses

An interim analysis is planned for when 50% of 6-month outcome data are available (or as determined by the Data Safety and Monitoring Board) to assess grounds for early stopping if one of the arms is

overwhelmingly more effective than the other, and/or to re-calculate sample size if the observed data depart from the assumptions used for the initial sample size calculations.

With input from the DSMB, prior to initiation of the trial, we will finalize a monitoring plan to guide dropping an arm or early termination of the study. Factors influencing stopping decision may include (a) formal stopping rules based upon the primary analysis, (b) information on safety outcomes by treatment group, (c) consistency between results for primary and secondary outcomes, and (d) consistency of treatment effects across subgroups. The proposed formal stopping boundaries will be symmetric, two-sided designs which are included in the unified family of group sequential stopping rules. [55,56] Point estimates from interim analyses will be based on the bias adjusted point estimate. [57] Confidence intervals and p-values will be calculated from the ordering of the outcome space based upon the maximum likelihood estimate. [58]

Table 3: Upper and Lower Stopping Boundaries for Planned Interim Analyses

			Lower Stopping Boundary			
Analysis	**Sample Size**	**Prop. Max Stat Info**	**Absolute Difference**	**Adjusted Difference**	**95% Confidence Interval**	**P-value**
Interim	380	0.50	-1.56	-1.44	(-2.54, -0.20)	0.013
Final	759-849	1.00	-0.90	-0.83	(-1.76, 0.00)	0.043

			Upper Stopping Boundary			
Analysis	**Sample Size**	**Prop. Max Stat Info**	**Absolute Difference**	**Adjusted Difference**	**95% Confidence Interval**	**P-value**
Interim	380	0.50	1.56	1.44	(0.20, 2.54)	0.013
Final	759-849	1.00	0.90	0.83	(0.00, 1.76)	0.043

Note: sample sizes given are the cumulative number of study participants with the six-month outcome available at the time of analysis; we expect about 2/3 of that number will be available for the comparison of each two study arms. These calculations assume a standard deviation of 5; at the time of

the analysis, the estimated standard deviation from the study data will be used. The boundaries used will be adjusted accordingly. The schedule of the interim analyses may be tweaked slightly based on the DSMB schedule. The information fraction will be updated to account for these differences as well as participants with partial outcomes available. The p-value boundaries are nominal two-sided p-values.

13.3 Assessing Long-Term Survival

One important outcome of interest in any suicide prevention research is death by suicide. Given the rare nature of this event, we most likely will not see a significant difference in this outcome between the two intervention groups over the duration of this three-year study. However, the study team plans to follow participants over time in order to assess the effect of these interventions on death by suicide over a 5-10 year period. Vital records data will be obtained for the purpose of assessing death and cause of study death of participants. These data will be accessed only for those participants who are defined in the Modified ITT and the Per-protocol populations for up to ten years following study enrollment.

13.4 Assessing Agreement between Suicide Outcome Measures

A sub-analysis is planned to review the extent to which agreement exists in self-reported outcomes from three validated survey instruments included in baseline and outcome surveys for this trial: the Harkavy-Asnis Suicide Scale (HASS), the Columbia Suicide Severity Rating Scale (C-SSRS), and the Self-Injurious Thoughts and Behaviors Interview – Revised (SITBI-R). There is not agreement in the suicide prevention research community on the best instrument to assess suicidal behavior. Comparing the distribution of self-reported outcomes across these three tools may contribute valuable information such as any differences in consistency by socio-demographic factors.

14. Engaging People with Lived Experience with Suicide

This research will be informed at all phases by an advisory board of people with lived experience with suicide (PLES). SLHS will convene an existing PLES advisory board which currently supports two other suicide prevention and mental health clinic trials. First convening in 2020, the PLES Advisory Board consists of 15 members and is supported by behavioral health clinicians to ensure the safety of members of the group. PLES Advisory Board meetings are structured to facilitate continuous co-learning between the research team and advisory board members. Board members share feedback on topics such as the title of the study to recruitment materials, the verbiage of Caring Contacts, retention strategies, dissemination of results, and ensuring the research reflects the perspective of local community members.

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. Potential loss of privacy is a known risk to this research. If a participant shares a phone or email with someone else, there is a chance for access to messages intended for the participant. Minor's texts or emails may be accessible by their parents or legal guardian. Potential participants are informed of privacy risks during the informed consent process.

Other potential risks include psychological distress from completing study questionnaires related to suicidal ideation and behavior. Research participants will be reminded at enrollment that they may discontinue the intervention or leave the study at any point with no consequences to the care they receive at SLHS and will be reminded of resources (such as the Hotline) that they can access as needed in the event of psychological distress. Participants will be under no duress or pressure to participate in or complete this study. 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.

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 informed consent and baseline surveys, and survey links will be sent out via text or email, or study staff will assist participants in completing 3-, 6-, and 12-month outcome surveys over the phone. 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. Participants will be reimbursed for their time with electronic gift cards.

15.2 Potential Benefits

While this study is designed to improve follow-up support for individuals at risk for suicide, there is no guarantee that participants will benefit directly from taking part in this study. Both active follow-up conditions (CC1 and CC2) being tested through this trial are in widespread clinical use as standard of care at reputable health systems and are expected to improve patient outcomes. All individuals who consent to participate in the study will be offered a tailored list of resources and appropriate compensation for their time (see *Cost/Compensation for Participation* section in this protocol).

This research is expected to advance the science of suicide follow-up support and the Caring Contacts model, allowing SLHS and other health systems to make an evidence-informed choice about how best to deliver follow-up support to patients with suicide risk.

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, including the protocol, informed consent process, and all relevant study-related documents. This includes an initial review and approval process and continuing review as determined by the IRB, 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 Involvement of Human Subjects

Suicide constitutes a significant public health concern and is a leading causes of death in the United States. [59] This study will fill key gaps in the scientific literature outlined in the *Background* and *Significance* sections of this protocol. The two Caring Contacts models being compared in this study are both in widespread clinical practice at reputable health systems in the US. However, they have never been compared to see which is most effective, and have not been rigorously evaluated in adolescents.

16.2.2 Protecting Individuals with Urgent Clinical Needs

This protocol prioritizes individual participants' urgent clinical needs (for example, imminent risk of suicide or 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. The independent Research/Medical Monitor (RM) will assist with monitoring this by reviewing situations where individual study participants' needs may conflict with the study protocol. If the RM determines that the participant's needs were not appropriately prioritized, remediation strategies will be developed to modify processes and ensure that participants are better protected in the future. The role and qualifications of the RM are further described in the *Data and Safety Monitoring* section of this protocol.

16.3 Informed Consent Process

Before participants enroll in the study, study staff will complete informed consent. If the patient is younger than 18 years of age, his or her parent, guardian, or legally authorized representative will provide written consent for the minor to participate in the study and the minor will provide written assent to participate. Those participants that assent to study participation prior to age 18 will reconsent as adults once they turn 18 before any additional outcome surveys are completed. Participants who turn 18 during the study may be invited to consent as adults using a text message with a link to the informed consent form in REDCap. A phone call for consenting participants who were consented as minors and turn 18 years old during the study will be optional, not required. Recruitment materials will be written at an age-appropriate reading level to facilitate comprehension. Furthermore, the People with Lived Experience with Suicide (PLES) Advisory Board will review and contribute to the informed consent documents for readability and clarity.

16.4 Documentation of Informed Consent

Informed consent (and assent for minors) will be obtained and documented for all study participants. Study staff will document each participants' eligibility to participate in the study prior to enrollment. When the participant signs the informed consent (or assent for participants aged 12-17) documents, 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 process will be completed in REDCap, and the consent/assent form will be combined electronically with attestation form in a single patient record. All primary data collection for this study will be done electronically, except in the event of technology failure, when paper-based back-up forms may be used.

16.5 Inclusion of Women and Minorities

Efforts will be made to recruit females and minorities according to their representation in the research population. There are no exclusion criteria based on sex/gender or minority status.

16.6 Inclusion of Minors

Adolescents face a disproportionate burden of suicidal ideation compared to adults, [4,60] and additional evidence is needed to determine the most effective form of follow-up care for minors. Adolescents who screen positive for suicide will be included in this study in order to address this critical gap in the literature and contribute to the evidence base for Caring Contacts among adolescents with suicidal ideation.

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.

Study participants will receive financial compensation for their time (up to $130 total over 12 months) in the form of online gift cards. Participants who complete a tax form will receive a compensation email including a link to the online gift card following completion of each survey. 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:

- Baseline/Enrollment: $30
- Three-month outcome survey: $30
- Six-month outcome survey: $30
- Twelve-month outcome survey/study completion: $40

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 PI will promptly inform all study investigators, study participants, AFSP, 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
- Demonstration of differential efficacy that would warrant stopping
- 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 AFSP, 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, and AFSP. 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. No personally identifiable information from the study will be released to any unauthorized third party without prior written approval of AFSP and the SLHS IRB.

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

Authorized representatives of AFSP, 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 for internal use during the study. At the end of the study, all records will be kept in a secure location 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.

16.10 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 AFSP 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 AFSP 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 AFSP-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 PI. Considerations for ensuring confidentiality of these shared data are described in the *16.9 Confidentiality &* Privacy section of this protocol.

16.11.1 National Institute for Mental Health Data Archive (NDA)

It is American Foundation for Suicide Prevention (AFSP) policy that results and data collected through the research that it funds should be made available to the public. Data from this research will be submitted to the National Institute of Mental Health Data Archive (NDA) per AFSP grant requirements. The PI will ensure all mechanisms 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., adherence to NDA requirements).

NDA is a large database where de-identified study data from many NIH studies are stored and managed, allowing researchers to learn new and important things about brain science at a more rapid pace.

Data will be de-identified using the GUID Tool, which is loaded on to a SLHS computer. Participants' First Name, Middle Name, Last Name, Sex, Date of Birth, and City/Municipality of Birth may be entered into the SLHS GUID tool to create a unique identifier. The SLHS GUID tool generates a series of one-way hash

codes based on the information entered, without the PHI ever leaving the SLHS computer. The hash codes are encrypted and securely sent to the GUID system at NDA.

If the hash codes match an existing hash code, the GUID associated with that hash code is sent back to the study staff. The GUID is an alphanumeric code that is randomly and persistently linked to the hash codes within the secure NDA GUID system and cannot be traced back to the information entered by study staff. If the hash codes do not match an existing hash code in the NDA GUID system, a new GUID is created and sent back to the SLHS GUID Tool.

With the NDA GUID Tool, the same participant information will return the same GUID whenever or wherever it is entered. This allows NDA to anonymously link participant data records across time and locations, without ever receiving identifying information. The ability to link participant records and the protection of participant confidentiality are both critical components of NDA data sharing.

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. Results of the study may be shared with study participants using contact information provided during study enrollment, such as email.

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 Council on Harmonisation Good Clinical Practice (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, SPRING Trial

Principal Investigators & Data & Safety Monitoring Board Chair		
Principal Investigator	**Data & Safety Monitoring Board Chair, Research & Medical Monitor**	
Anna Radin, DrPH, MPH, Applied Research Scientist	Greg Simon, MD, MPH, Psychiatrist, Behavioral Health Service Line, and Investigator	
St. Luke's Health System	Kaiser Permanente & Kaiser Permanente Washington Health Research Institute	
208-381-8468	206-287-2979	
radina@slhs.org	Gregory.E.Simon@kp.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

A Data and Safety Monitoring Board (DSMB) will convene at the beginning of the study to review the protocol, develop a charter and data reporting tables. The DSMB will meet again approximately five times after enrollment begins and ad hoc as needed to review safety or scientific issues.

16.16 Quality Assurance & Quality Control

Study staff 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 to monitor study adherence to the study protocol, study enrollment rate, completeness of data, and documentation of required processes such as informed consent

Quality control (QC) measures will be implemented as follows

- Informed consent – Study staff and others in the Department such as the Compliance Coordinator will review documentation of the consenting process and completed consent documents. This review will evaluate compliance with procedures described in this protocol, accuracy, and completeness.

- Intervention fidelity – Study staff will monitor the degree to which CC1 and CC2 from the Hotline are delivered with fidelity to specified content and cadence (scheduled/standard outgoing texts) and to Motto's principles of Caring Contacts (replies to incoming texts).

- 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 be in need of 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, AFSP, and inspection by local and regulatory authorities, in compliance with SLHS legal guidance.

17 Institutional Roles

17.1 St. Luke's Health System, Boise, ID – Primary Research Institution

St. Luke's Health System (SLHS), based in Boise, Idaho, is the primary research institution. As the only Idaho-based, not-for-profit, community-owned, and community-led health system, St. Luke's Health System (SLHS) is well-positioned to take a leadership role in the region's population health. SLHS has a history of conducting rigorous suicide prevention research focused on Caring Contacts and a robust Research Department, which includes 76 staff supporting 286 currently approved studies. SLHS will be responsible for the majority of research administration, including recruitment, informed consent, and data collection through administration of surveys. The SLHS IRB is responsible for reviewing, approving, and overseeing research involving human subjects at SLHS to ensure that participants' safety, rights, and welfare are protected.

17.2 Idaho Crisis and Suicide Hotline (Hotline), Boise, ID – Intervention Delivery

The Hotline will be responsible for delivering the Caring Contacts interventions to study participants. The Hotline supports Idahoans statewide and is accredited through the International Council of Helplines. The Hotline will develop and adhere to standard operating procedures to ensure consistency in the delivery of the intervention, and a robust system of quality controls to ensure every participant receives the best possible support. The Hotline is familiar with delivering Caring Contacts interventions in the context randomized controlled trials and is uniquely prepared to support the proposed study.

17.3 University of Washington (UW), Seattle, WA – Subject Matter Expertise and Biostatistics Support

UW is a premier research institution that includes more than 270 specialized research centers. UW will contribute subject matter expertise from the *Department of Psychiatry and Behavioral Sciences* and the

Center for Suicide Prevention & Recovery. Faculty and Staff from UW will support the REDCap build and maintenance, and advise on all aspects of the study, from operational considerations to research methods and participant safety considerations. Faculty and staff from the *Department of Biostatistics* will lead data cleaning and data analysis work, as well as advising on study design and other methods considerations throughout the study.

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Appendix A: C-SSRS Screening Questions & Scoring Criteria

Question #	Category	Question	Score
1.	Category 1. Wish to be dead	**Have you [ever] wished you were dead or wished you could go to sleep and not wake up?**	1
2.	Category 2. Non-specific Active Suicidal Thoughts	**Have you had any actual thoughts of killing yourself?**	2
3.	Category 3 – Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act	**Have you thought about how you might do this?** *(For example, "I thought about taking an overdose but I never worked out the details about when, where, and how I would do that and I would never act on these thoughts.")*	3
4.	Category 4 – Active Suicidal Ideation with Some Intent to Act, without Specific Plan	**Have you had any intention of acting on these thoughts of killing yourself, as opposed to you have the thoughts but you definitely would not act on them?** *(For example, "I had the thought of killing myself by taking an overdose and am not sure whether I would do it or not.")*	4
5.	Category 5 – Active Suicidal Ideation with Specific Plan and Intent	**Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?** *(For example, "I am planning to take 3 bottles of my sleep medication this Saturday when no one is around to stop me.")*	5
6. [Lifetime-Recent]	Category 6 – Preparatory Acts or Behavior (lifetime)	**Have you done any of the following:** • Attempted to kill yourself, even if ending your life was only part of your motivation • Started to do something to end your life but someone or something stopped you before you actually did anything? • Started to do something to end your life but you stopped yourself before you actually did anything	[Not scored at baseline]

		• Taken any steps towards making a suicide attempt or preparing to kill yourself *(Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn't jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.)*	
6A. [Lifetime-Recent]	Category 6 – Preparatory Acts or Behavior	[In your lifetime]	[Not scored at baseline]
6B. [Lifetime-Recent]	Category 6 – Preparatory Acts or Behavior	[In the past 3 months]	6
6. [Since last contact]	Category 6 – Preparatory Acts or Behavior	**In the past 3/6 months, have you done anything, started to do anything, or prepared to do anything to end your life?** *(For example: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind about hurting yourself or it was grabbed from your hand, went to the roof to jump but didn't; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.)*	6
7.	Category 7 – Aborted Attempt	**Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?** *An aborted or self-interrupted attempt is when a person begins to take steps toward making a suicide attempt but stops themselves before they actually do anything that could be harmful.*	7

8.	Category 8 – Interrupted Attempt	**Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?** *An interrupted attempt is when a person is interrupted (by an outside person or circumstance) from starting the potentially self-injurious act (if not for that, actual attempt would have occurred).*	8
9.	Category 9 – Actual Attempt (non-fatal)	**Have you made a suicide attempt?** *A suicide attempt is any act where a person had any intent or desire to die, even if they were not hurt.*	9
10.	Category 10 – Completed Suicide	*Note: Completed suicide will be assessed using vital records and electronic health records; not included as a survey question*	10

Appendix B: SPRING Brief Assessment of Capacity to Consent (S-BACC)

Last reviewed/updated: 7/27/2023

When to use:

Use the S-BACC any time it is not clear whether a potential participant is capable of providing informed consent. This may include but is not limited to:

1. Any time a potential participant's chart includes any indication of cognitive impairment or intellectual disability in either the **referring provider's not**e, or in the **problem list**.
    a. The following is a non-exhaustive list of examples of **terms or conditions that would be considered cognitive impairment**:
        i. Cognitive impairment, intellectual disability, Alzheimers, dementia, amnesia, delirium, Asperger's, memory loss, cognitive delay, developmental delay, intellectual delay, severe traumatic brain injury TBI)
    b. The following conditions *if occurring in the absence of one of the cognitive impairments listed above* would not independently necessitate use of the S-BACC: Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD), learning disabilities, and Autism Spectrum Disorder (ASD / Autism), mild Traumatic Brain Injury (TBI)
    c. Please err on the side of caution and complete the S-BACC if you are unsure whether something you see in the chart falls into the categories of cognitive impairment or intellectual disability, or if you have any concerns about the individual's capacity to provide informed consent.
2. Any time a potential participant seems distracted during the informed consent process or gives any indication that they are confused or not following the discussion.
3. Consult the PI for direction if you are unsure and remember: it is always okay to complete an S-BACC if you are unsure.

How to introduce the S-BACC

The S-BACC has been built into the REDCap ICF framework and Research Coordinators will be prompted to indicate whether or not they need to implement the S-BACC during each enrollment. When appropriate, consider the following scripting:

> *Thank you. I will send a link to you with an informed consent form that describes the study in more detail. We can review the document together, and I will answer any questions you may have. I will also ask you a few questions to confirm that you have fully understood the study before you decide whether or not to participate. As we go through this, please wait for my instructions to continue onto the next page on the iPad, especially when you see a "STOP" at the top of the screen. Would you prefer me to email or text the link to you?"*

Assessment Item	Score 1 (Correct)	Score 0 (Incorrect)
1. Why are you considering doing this study?	Mentions suicide, support, someone checking in, someone to talk to, wanting to help others, wanting to participate in research, etc. Demonstrates understanding of why they were referred and what the study is about. *Note: if they mention gift cards, please probe for other reasons to ensure they understand the purpose of the study.*	Clearly does not understand the purpose of the study or why they were referred
2. Are you required to be in this study?	No	Yes
3. If you decide not to participate in this study, can you still receive normal care from St. Luke's and the Idaho Crisis and Suicide Hotline?	Yes	No
4. If you participate in this study, what are some things you may be asked to do?	Receive phone calls / texts or emails; complete surveys.	Does not mention phone calls or texts/emails, or surveys
5. What are some of the risks or discomforts that people may experience in this study?	Discomfort, confidentiality/privacy	Cannot think of any risks or lists incorrect risks
6. What should you do if you have questions or you change your mind about participating?	Contact [you]/study team; knows they can withdraw from study	Doesn't know they can withdraw, can't describe who they would contact with questions or how

Implementing and Scoring the S-BACC

Potential participants who are capable of providing informed consent may not answer the question completely on their first try. It is okay for research coordinators to probe and re-word the question, or to remind them where in the informed consent form they can find that information. However, participants must be able to correctly answer each item in order to be considered capable of providing informed consent for SPRING.

When someone cannot correctly answer all questions on the S-BACC

Some potential participants will be unable to demonstrate capability to provide informed consent. In these cases, they are **not** eligible to participate in the study. Consider the following scripting:

Thank you so much for your time today. Unfortunately, you are not eligible to participate in the study at this time. I want to make sure you know that you can still reach out to the Idaho Crisis and Suicide Hotline any time you may need someone to talk to, even if you are not in crisis. It's a great resource and is available 24/7. Call or text 988.

How to document use of the S-BACC

Any time you use the S-BACC, it's important to include a detailed REDCap tracking note, outlining the following:

- What made you decide to use the S-BACC?
- Describe how the conversation went – were questions asked/answered? Did the participant seem to follow the conversation well?
- Describe how they scored on the S-BACC, and include any questions missed, as well as your overall impression of the person's capability to provide informed consent.
- For minor participants, indicate whether you had concerns about the capacity to consent of the consenting adult, the assenting minor, or both.

Notes on development of the S-BACC

The S-BACC was developed based on the UBACC, which is a psychometrically sound instrument designed to assess capability to provide informed consent for research. The UBACC developers recommend tailoring a sub-set of the items from the UBACC to the specific research study for which it is being used, which we have done for SPRING in creating the S-BACC. We also consulted the list of critical items to review during informed consent from the St. Luke's Health System Research Department's "Consenting & Assessing Comprehension Quick Guide", v. 3.27.19 and ensured those items were highlighted in the questions selected for inclusion in the S-BACC.

The list of conditions considered as cognitive impairment, and those excluded, were developed together with one of the SPARC/SPRING study clinicians, Amelia Doty-Jones, LCSW.

The S-BACC was reviewed and revised in consultation with the SPARC/SPRING Lived Experience Advisory Board.

REFERENCE

Dilip V. Jeste, MD; Barton W. Palmer, PhD; Paul S. Appelbaum, MD; Shahrokh Golshan, PhD; Danielle Glorioso, BS; Laura B. Dunn, MD; Kathleen Kim, MD, MPH; Thomas Meeks, MD; Helena C. Kraemer, PhD. A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. Arch Gen Psychiatry/ Vol 64 (no. 8), Aug 2007.

UCSD Brief Assessment of Capacity to Consent (UBACC)

1. What makes you want to consider participating in this study?
2. Do you believe this is primarily research or primarily treatment?

3. Do you have to be in this study if you do not want to participate?
4. If you withdraw from this study, will you still be able to receive regular treatment?
5. If you participate in this study, what are some of the things that you will be asked to do?
6. Please describe some of the risks or discomforts that people may experience if they participate in this study.
7. Please describe the 2 serious risks associated with the study.
8. Please describe some of the possible benefits of this study.
9. Is it possible that being in this study will not have any benefit to you?
10. Who will pay for your medical care if you are injured as a direct result of participating in this study?

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