The SPARC Trial: Suicide Prevention Among Recipients of Care

Comparing the Effectiveness of Safety Planning Intervention Plus Follow-Up from a Suicide Prevention Hotline (SPI+) versus Safety Planning Intervention Plus Caring Contacts (SP+CC) among Adults and Adolescents Screening Positive for Suicide in Emergency Departments and Primary Care Clinics

Principal Investigator
Anna Radin, DrPH, MPH, Applied Research Scientist, St. Luke's Health System; 208-381-8468; radina@slhs.org

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List of Acronyms

AE	Adverse Event
AIMS	Advancing Integrated Mental Health Solutions
CBPR	Community-Based Participatory Research
CFR	Code of Federal Regulations
C-SSRS	Columbia Suicide Severity Rating Scale
DSMB	Data & Safety Monitoring Board
ED	Emergency Department
HIPAA	Health Insurance Portability and Accountability Act of 1996
Hotline	Idaho Suicide Prevention Hotline
ICH GCP	International Council on Harmonisation Good Clinical Practice
IRB	Institutional Review Board
ITHS	Institute of Translational Health Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
OHRP	Office of Human Research Protections
PAB	Provider Advisory Board
PCORI	Patient Centered Outcomes Research Institute
PHI	Protected Health Information
PI	Principal Investigator
PLES	People with Lived Experience with Suicide
RDoC	Research Domain Criteria
RM	Research/Medical Monitor
SAE	Serious Adverse Event

SLHS	St. Luke's Health System
SPARC	Suicide Prevention Among Recipients of Care (short title of trial)
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 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 *References* section of this protocol.

Funding for the SPARC Trial

The research described in this protocol is funded through a 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.

Principal Investigator:

Signed:_____Date: _____

Name: Anna K. Radin, DrPH, MPH

Title: Research Scientist, St. Luke's Applied Research Division

Investigator Contact information

Affiliation: St. Luke's Health System, Applied Research Division, Research Department

Address: St. Luke's Plaza, Plaza II
701 E Morrison Knudsen Dr., Research Department
Boise, ID 83712

Phone: 208-381-8468

Email: Radina@slhs.org

1. Protocol Summary

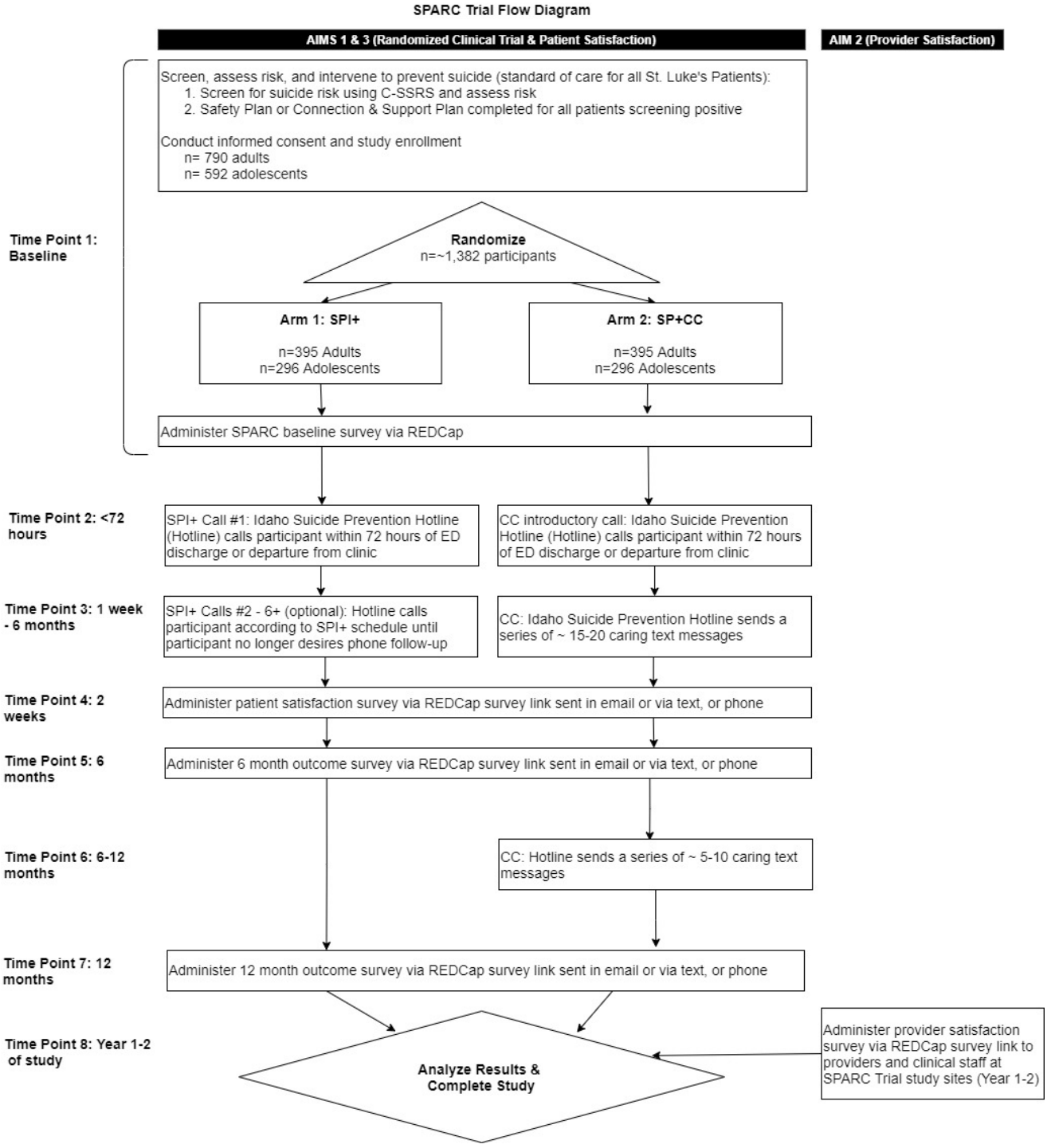
1.1 Synopsis

Title	**The SPARC Trial: Suicide Prevention Among Recipients of Care** Comparing the Effectiveness of Safety Planning Intervention Plus Follow-Up from a Suicide Prevention Hotline (SPI+) versus Safety Planning Intervention Plus Caring Contacts (SP+CC) among Adults and Adolescents Screening Positive for Suicide in Emergency Departments and Primary Care Clinics
Contract Number:	PCORI HIS-2018C3-14695
Study Description	Randomized controlled trial to determine the best brief suicide prevention intervention for adults and adolescents who screen positive for suicidal ideation or behavior in emergency departments or primary care clinics.
Specific Aims	**Aim 1:** Compare the effectiveness of two brief suicide prevention interventions (safety planning intervention plus structured phone-based follow-up from a suicide prevention hotline (SPI+), versus safety planning intervention plus caring contacts (CC)) to (a) reduce suicidal ideation and behavior, (b) reduce loneliness, (c) reduce return to care for suicidality, and (d) increase uptake of outpatient mental healthcare services over 12 months among adult and adolescent patients screening positive for suicide in emergency departments (EDs) and primary care clinics. **Aim 2:** Assess the acceptability of connection and support planning and the safety planning intervention, with or without follow-up among providers and clinical staff in EDs and primary care clinics. **Aim 3:** Assess the acceptability of SPI+ and SP+CC among adult and adolescent patients.
Outcomes	The primary outcome is suicidal ideation and behavior (measured at 6 and 12 months using the Columbia Suicide Severity Rating Scale (C-SSRS)).[1] Secondary outcomes include loneliness (measured using the NIH Toolkit Loneliness Scale), uptake of outpatient mental health services, and return to care for suicidality at 6 and 12 months.
Study Population	Adults (aged 18+) and adolescents (aged 12-17) who screen positive for suicidal ideation or behavior using the Columbia Suicide Severity Rating Scale (C-SSRS) at one of the study sites and complete a Safety Plan or Connection & Support Plan will be eligible to participate. The total sample size is 1,382 (n=592 adolescents + n=790 adults). Secondary study population includes clinic providers/staff.
Description of Study Sites	A total of 32 study sites were selected within St. Luke's Health System in Idaho. Randomization will occur at the individual level. Study sites include 9 EDs and 23 primary care clinics.

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, 2 weeks, 6 months, and 12 months.

1.2 Schema / Study Flow Diagram

Figure 1: SPARC Trial Flow Diagram



2. Research Question & Specific Aims

Research Question: What is the best brief suicide prevention intervention for adults and adolescents who screen positive for suicidal ideation or behavior in emergency departments or primary care clinics?

Specific Aims.

- **Aim 1:** Compare the effectiveness of two brief suicide prevention interventions (safety planning intervention or connection and support planning plus structured follow-up from a suicide prevention hotline (SPI+), versus safety planning intervention or connection and support planning plus caring contacts (SP+CC)) to (a) reduce suicidal ideation and behavior, (b) reduce loneliness, (c) reduce return to care for suicidality, and (d) increase uptake of outpatient mental healthcare services over 12 months among adult and adolescent patients screening positive for suicide in emergency departments (EDs) and primary care clinics.
    - **Aim 1 Hypothesis:** We hypothesize that compared to SPI+, SP+CC will result in lower levels of suicidal ideation and behavior, reduced loneliness, reduced return to care for suicidality, and an increase in uptake of outpatient mental healthcare services for adults and adolescents screening positive for suicide.

- **Aim 2:** Assess the acceptability of connection and support planning and the safety planning intervention, with or without follow-up among providers and clinical staff in EDs and primary care clinics.

- **Aim 3:** Assess the acceptability of SPI+ and SP+CC among adult and adolescent patients.

3. Introduction

3.1 Background

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.[3] 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.[3] Idaho's suicide rate is the sixth highest in the US, 50% above the national average.[3] In 2016, nearly 45,000 individuals in the U.S. died by suicide,[3] roughly equivalent to one suicide every 12 minutes.

Half of suicide decedents seek healthcare – often in EDs or primary care settings – within a month of their death.[4] Health systems have an obligation to address suicidal ideation and behavior in the patient populations they serve. There is an urgent need to identify evidence-based interventions that can be realistically implemented in such settings. The Patient-Centered Outcomes Research Institute (PCORI) recently identified suicide reduction among adolescents as a priority topic for research.[5] Additionally, PCORI has called for a randomized controlled trial evaluating the comparative effectiveness of a safety planning intervention versus usual care in EDs and primary care clinics.[6]

Safety planning (with or without follow-up) is evidence-based and recommended as standard of care for patients at risk for suicide in EDs and primary care settings by the Joint Commission,[7] the National Action Alliance for Suicide Prevention[4], and the Suicide Prevention Resource Center.[8,9] Safety planning (with or without follow-up) is a key component of suicide prevention protocols in hundreds of healthcare organizations, including the Veterans Health Administration (VA).[4] Safety planning is a brief clinical intervention that involves working collaboratively with suicidal patients to complete an individualized action plan to mitigate recurrent suicidal thoughts and behaviors. In health care settings, safety planning is sometimes combined with follow-up contact, which may further reduce suicidal behavior.[4,10] In a recent cohort study, **safety planning plus follow-up (SPI+) yielded a 50% reduction in suicidal behavior and a doubling of uptake of outpatient mental health treatment** among veterans in EDs compared to usual care (which did not include safety planning) over six months following a suicide attempt.[11]

SLHS universally screens for suicidality in EDs and primary care clinics. SLHS conducts screening for suicide risk for patients 12 and older in all EDs and primary care clinics using the Columbia Suicide Severity Rating Scale (C-SSRS).[1,15,16] The C-SSRS helps providers stratify patients into low, moderate, or high-risk for suicide, which informs clinical decision-making in developing an individualized treatment and disposition plan.

Safety planning with and without follow-up from the Idaho Suicide Prevention Hotline are currently in clinical practice at St. Luke's Health System (SLHS) in Idaho. The Safety Planning Intervention (SPI) is designed to support individuals at moderate or high risk for suicide. There are no brief health-system based suicide prevention interventions designed specifically for people experiencing low levels of suicidal ideation. To address this gap in the scientific literature, SLHS partnered with suicide prevention experts at the University of Washington, the University of Pennsylvania, and Columbia University to develop an evidence-informed intervention called Connection and Support Planning (CSP). CSP includes several key components of the SPI (psychoeducation, social support, professional resources, and lethal means counseling, plus reasons for living), but excludes the components that are only appropriate for people who have experienced acute suicidal crisis (suicide risk curve, warning signs, distraction techniques). SLHS will use CSP instead of SPI for patients experiencing low levels of suicidal ideation at provider discretion. This protocol uses the terms "safety planning" to describe use of either the Safety Planning Intervention or the Connection & Support Plan, whichever is clinically indicated based on the patient's risk and the provider's judgment. At SLHS, collaborative safety planning is routinely completed with patients seen in EDs who screen positive for suicide. ED Social Workers support safety planning in-person whenever possible. In five critical access hospitals with limited ED social work staffing, safety planning is supported by social workers at the larger hospitals virtually using video visits when an in-person social worker is not available. SLHS EDs provide safety planning plus follow-up support from the Hotline in the form of phone calls after discharge from the health system. **Safety planning is currently completed less consistently with patients screening positive for suicide in primary care settings** at SLHS (and nationally)[4] and has historically been contingent on the availability of behavioral health resources (staff) at the clinic. Staffing in SLHS primary care sites typically consists of medical doctors, physician assistants and/or nurse

practitioners, medical assistants, a clinic manager, and office support staff, but rarely includes social workers or other providers specializing in behavioral health. SLHS has integrated behavioral health staff into eight of the fifty-three SLHS primary care clinics based on the evidence-based Collaborative Care Model,[12] developed by University of Washington (UW) and disseminated by the Advancing Integrated Mental Health Solutions (AIMS) Center.[17] Collaborative Care cannot practically be deployed in all clinics due to the need to strategically allocate scarce resources. To provide behavioral health support to non-Collaborative Care clinics, SLHS plans to utilize video visits with Collaborative Care social workers to support safety planning at all primary care clinics participating in the SPARC Trial.

Both SPI+ and SP+CC are evidence-based interventions that are recommended and commonly used in clinical practice nationally;[4] both are currently in practice at SLHS. However, **these interventions have never been compared head- to-head.** Developing a standardized protocol for a safety planning intervention plus follow-up with patients who are at risk for suicidal behavior is a key priority for SLHS. **Providers and system-level leaders have called for evidence to determine which safety planning intervention (SPI+ vs. SP+CC) works best to reduce suicidal ideation and behavior**.

There are several key gaps in the suicide prevention literature that this study is designed to address. **SPI+ and SP+CC have not been rigorously tested in the primary care setting, or among civilian or adolescent populations.**[6] The evidence for safety planning in healthcare settings is based primarily on studies conducted with adult veterans in VA Emergency Departments.[18-21] Most literature related to the secondary prevention of suicide tests interventions among patients who have already attempted suicide.[18-20,22,23] Few health system-based suicide prevention intervention studies include patients who screen positive for suicide but may not have experienced acute crisis.[6] Most evidence for safety planning is derived from studies with observational designs.[6,19,20,24] Finally, seven of the ten US states with highest suicide rates (including Idaho) are in the Intermountain West Region,[3] and US suicide rates in rural areas are 45% higher than in cities,[25] yet no large-scale suicide prevention trials have been implemented in these settings.

4. Significance

This study is aligned with patient and provider priorities and will generate evidence to improve outcomes that matter to suicidal patients. The proposed study reflects extensive input and enthusiastic support from a wide variety of stakeholder partners within SLHS, at academic institutions, and in the communities SLHS serves, who have been consulted during the study design process. **This study is patient-centered and incorporates extensive input from people with lived experience with suicide.** With support from Empower Idaho, the study team convened and met with people with lived experience with suicide (PLES) to solicit input on the study. The Principal Investigator (PI) also convened a SLHS Provider Advisory Board (PAB), which included social workers and physicians who work in Behavioral Health, EDs, primary care clinics, and at the health system level, to solicit feedback on the design of the study and the best way to integrate this research into clinic workflows. Additionally, **the study team consulted with dozens of providers and leaders at SLHS representing all levels of the healthcare system and have**

adapted the study based on their feedback.

The proposed research fills key gaps in evidence and is aligned with PCORI research priorities. This study will provide high-quality data collected with scientific rigor to determine whether SPI+ or SP+CC more effectively improves outcomes among suicidal adolescents and adults in EDs and primary care settings. Specifically, this will be the first randomized controlled trial to study safety planning, and the first to directly compare SPI+ versus SP+CC. This will be the first safety planning study to report age-stratified results for suicidal adult and adolescent patients. Study sites will include both EDs and primary care clinics in a private non-profit health system which more closely resembles typical American civilian healthcare settings than VA settings. The study population will include both urban and rural residents in a state with a high prevalence of suicide.[3] The study will assess the impact of safety planning with patients who screen positive for any level of suicidal ideation or behavior, including those who may not have experienced an acute crisis, constituting the first published data on the effects of SPI+ and SP+CC on with patients experiencing low- levels of suicidal ideation.

This pragmatic study is designed to optimize dissemination and implementation potential and scalability. It will take place in a typical US health system not directly linked with an academic medical school or school of public health, with busy primary care clinics and EDs. The intervention design is innovative in that it capitalizes on the use of technology (tablets or telephones) and centralized resources (social workers) to complete safety planning for both urban and rural populations when appropriate on-site staff is not available. Both follow-up interventions will be delivered in partnership with an established community resource (the Hotline). This approach allows the health system to consistently deliver high quality care for suicidal patients without over-burdening ED and primary care providers. 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 staff and resource constraints, including those serving rural populations. The Hotline follow-up models compared in this study are feasible even in resource-limited settings where clinic staff may not be available to consistently follow- up with suicidal patients.

This study will have immediate and enduring public health impact. The interventions being compared are feasible and are currently in wide-spread use in multiple clinical settings.[4] Data from this study will allow healthcare providers and leaders to select and scale-up the best intervention for patients at risk for suicide. Reducing suicidal ideation and behavior and loneliness will ultimately reduce the risk of death by suicide.[6,26,27]

5. Research Methods

5.1 Study Design

5.1.1 Aim 1: Randomized Controlled Trial

Aim 1 (primary analysis) is a randomized controlled trial with individual patients randomly assigned to receive either SPI+ or SP+CC. The study objectives and primary outcomes pertain to the individual level.

5.1.2 Aims 2 & 3: Patient and Provider Satisfaction Surveys

Aims 2 & 3 are designed to assess the acceptability of the interventions among providers and clinical staff, and patients. Patient and provider surveys will be used to collect cross-sectional quantitative and qualitative data for Aims 2 and 3. Specifically, patients will be asked to rate and describe their safety planning and follow-up experience. Patient satisfaction surveys will be given to all participants at 2 weeks following enrollment, and additional satisfaction questions will be included in their 12-month outcomes survey to assess satisfaction with the phone calls and/or caring text or email messages received.

Provider surveys focus on the ease of implementing the suicide screening, assessment, safety planning intervention, and connection and support plan, and providers' and staff's satisfaction with the level of care their patients received. Providers and staff will be invited to complete surveys during year 1 or 2 of the study. Surveys include multiple choice questions and open- ended items.

5.2 Randomization

Randomization will occur at the individual level. Patients will be randomized to either SPI+ or SP+CC by the study statistician using appropriate software.

5.3 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 providers or study participants to the comparator received is not feasible. The PI and research coordination team will conduct study enrollment and fidelity monitoring activities that may reveal the treatment assignment of individual participants.

6. Study Population

The primary study population for this research is adult and adolescent patients in Emergency Departments and primary care settings in the St. Luke's Health System who are identified as being at risk for suicide and have a completed Safety Plan or Connection & Support Plan.[1]

This study will recruit 1,382 participants (790 adults and 592 adolescents) from 32 clinical sites:
9 EDs and 23 primary care clinics.

The secondary study population for this research consists of providers and clinical staff at study sites. This population will be recruited to participate through email invitation. Employee email addresses will be obtained, for example, through the use of site champions/liaisons or Digital and Analytics analysts. Although there is no estimated sample size for this population, sufficient participation is anticipated to complete Aim 2 of this protocol.

6.1 Inclusion & Exclusion Criteria

6.1.1 Selection of Study Sites

All SLHS EDs (n=9) and primary care clinics (n=53) were initially considered for inclusion as study sites. Sites located outside of Idaho (n=1) were excluded. Sites with enough patients screening positive for suicide annually (based on data from 2018) to enroll approximately 40 adults and/or 25 adolescents within approximately 12 months were considered eligible for inclusion.

6.1.1.1 Sites Selected for Inclusion in the Study

The 32 study sites were selected with an effort to identify sites representing a diversity of primary care practices (pediatrics, internal medicine, and family medicine), geographic locations, and populations. All EDs were included as study sites. Selected study sites were approved by Primary Care, Children's, and Acute Care Service Line Leaders and site-level leaders.

6.1.2 Study Participant Inclusion & Exclusion Criteria

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

Inclusion Criteria

- Patient at SLHS ED or primary care study site
- ≥ 12 years of age (adult ≥18 years of age or adolescent 12-17 years of age)
- Positive screen for suicidal ideation or behavior using C-SSRS (any C-SSRS score >0), or current /most recent visit is related to suicide attempt
- Completed safety plan or connection & support plan as part of current/most recentvisit
- Access to a phone (cellular or landline) for the duration of the study with the ability to receive calls
- The ability to send and receive email messages (required) and text messages (optional)
- English or Spanish speaking and reading

Exclusion Criteria

- Patients who are unable or unwilling to provide informed consent to participate will be excluded

from the study.

- Examples may include but are not limited to patients who present with acute or chronic cognitive impairment that would preclude their ability to consent (i.e. acute psychosis, intoxication, or intellectual disability).

- Patients who are inappropriate for study participation based on provider clinical judgement.

6.1.3 Inclusion and Exclusion Criteria for Provider Satisfaction Survey

Inclusion Criteria

- Provider or clinical staff (such as physician, advanced practice provider, nurse, medical assistant, or social worker) at SLHS SPARC Trial Study Site
- Read and write in English

Exclusion Criteria

- Providers or staff who work at multiple study sites may only complete one survey, and it should be linked with the site at which they spend most time

6.2 Recruitment Strategy

SLHS routinely screens patients 12 years of age and older for suicide risk in EDs and primary care clinics. Patients who screen positive using the C-SSRS should complete a safety plan (moderate to high risk/provider judgment) or a connection and support plan (low risk/provider judgment) with a provider or clinical staff as part of standard of care. Following safety planning or connection and support planning, based on clinical judgment, patients should be introduced and invited to participate in the SPARC Trial by the provider or staff and may be given a brief hand-out describing the study. If the patient is interested in learning more, a video visit with a centrally-located Research Coordinator will be ordered through Epic or a phone call will be initiated to conduct informed consent and study enrollment.

Additionally, patients who express interest in the study but are unable to complete study enrollment and informed consent while in the clinic or ED may agree to be contacted by a Research Coordinator after they leave SLHS. In this case, study staff may contact the potential participant to review eligibility criteria, answer questions and gain informed consent. Study staff will reach out via text or email as soon as possible within 3 business days of the clinic or ED encounter to invite the potential participant to schedule a phone call or video visit. An opt out option (such as STOP or NONE) will be provided for individuals who do not wish to proceed, and the study team will not call potential participants who have not responded in writing to express interest in continuing. Study enrollment and informed consent will be conducted using videoconference or telephone to connect patients to centrally located study staff. 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.

6.3 Retention

A variety of methods will be used to improve retention of research participants. A primary phone

number and an email address are required. Contact information will be collected at baseline, and participants may opt 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. Email, text messages, phone calls, or other forms of contact may be used for retention purposes or to assist with scheduling and completing study surveys.

6.4 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 duration of the study and completed the minimum assigned intervention (e.g. received at least one phone call (SPI+), or were sent at least 4 caring contacts (SP+CC)).
4. **Additional Populations**: Additional datasets may be developed to complete sensitivity analyses, for example, where missing data have been imputed using different techniques.

7. Study Procedures

Pre-Consent – All participants (All activities are standard of care)

- C-SSRS screening for suicide risk at clinic or ED visit
- Development of safety plan or a connection and support plan

Baseline / Enrollment Visit – All participants (During/following clinic or ED visit)

- Study enrollment and informed consent
- Baseline Survey
    - Baseline survey includes questions related to demographics, socioeconomic status, gender identity, sexuality, religion, drug and alcohol use, quality of life, loneliness, self-harm and suicidal behavior.

Follow-Up Intervention – SPI+ participants

- Follow-up phone calls from the Hotline
    - 1 call within 72 hours of study enrollment to connect with the participant.
    - Series of 1-6 phone calls, based on participant's preference.
        - See *Description of Interventions*.

Follow-Up Intervention – SP+CC participants

- Follow-up phone call and caring text or email messages from the Hotline
    - 1 call within 72 hours of study enrollment to connect with the participant.
    - 25 personalized caring text or email messages sent according to a standardized schedule over a 12-month period.
        - See *Description of Interventions*.

2-Week Patient Satisfaction Survey – All participants (REDCap survey link sent via text or email)

- Patient satisfaction survey related to intervention received

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

- 6-Month Outcomes Survey
    - Outcomes survey includes loneliness, suicide risk, self-harm and suicidal behavior, behavioral health treatment.

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

- 12-Month Outcomes Survey
    - Outcomes survey includes loneliness, suicide risk, self-harm and suicidal behavior, behavioral health treatment, and patient satisfaction.

Assessing Provider Satisfaction (Aim 2)

Providers and staff in study sites will be emailed an invitation to complete a survey during year 1 or 2 of the study. Providers and staff will complete surveys using a REDCap link delivered via email. A statement will be included in the survey invitation email indicating that opening the link and completing the survey constitutes provider/staff consent to participate in the survey. These surveys will be confidential and no personal health information will be collected.

7.1 Schedule of Activities

Table 1: Schedule of SPARC Trial Activities

	Time Point 1: Study Enrollment & Baseline	Time Point 2: ~72 hours following study enrollment	Time Point 3: Week 1 – 6 months	Time Point 4: 2 weeks	Time Point 5: 6 months	Time Point 6: 6-12 months	Time Point 7: 12 months	Timepoint 8: Year 1 or 2

Informed Consent/Assent	X							
SPARC Baseline Survey	X							
6-month Outcome Survey					X			
12-month Outcome Survey							X	
Phone call with Hotline (scheduled/initiated)		X	SPI+ arm only					
Caring text or email messages sent from Hotline		CC+ arm only	CC+ arm only			CC+ arm only		
Patient satisfaction survey				X			X	
Provider satisfaction survey								X
Safety Outcomes reporting					X		X	

8. Causal Framework

The causal mechanisms of suicide are complex and are not well understood, particularly those responsible for the transition between suicidal ideation and action.[29,30] The National Institute of Mental Health (NIMH) has developed a framework for developing novel interventions to prevent or treat mental health disorders that they call the Research Domain Criteria (RDoC).[31,32] NIMH RDoC have not been enumerated specifically for suicide.[30] To conceptualize the hypothesized causal pathways between the two evidence-based interventions (SPI+ and SP+CC) and suicidal ideation and behavior, we borrowed pertinent constructs from the general behavioral health RDoC and embedded these within a Social-Ecological Model[33] (SEM). Both SPI+ and SP+CC are complex interventions that act upon multiple domains and constructs. Safety planning includes six distinct elements; SPI+ follow-up includes at least one Hotline phone call; SP+CC includes one Hotline phone call and a series of caring text messages. The table below describes how the various elements of safety planning and structured follow-up relate to selected domains and constructs. The NIMH RDoC also include physiological and biological domains that are relevant to suicidal causal pathways; however, we have excluded these domains here because the compared interventions do not act directly on those levels.

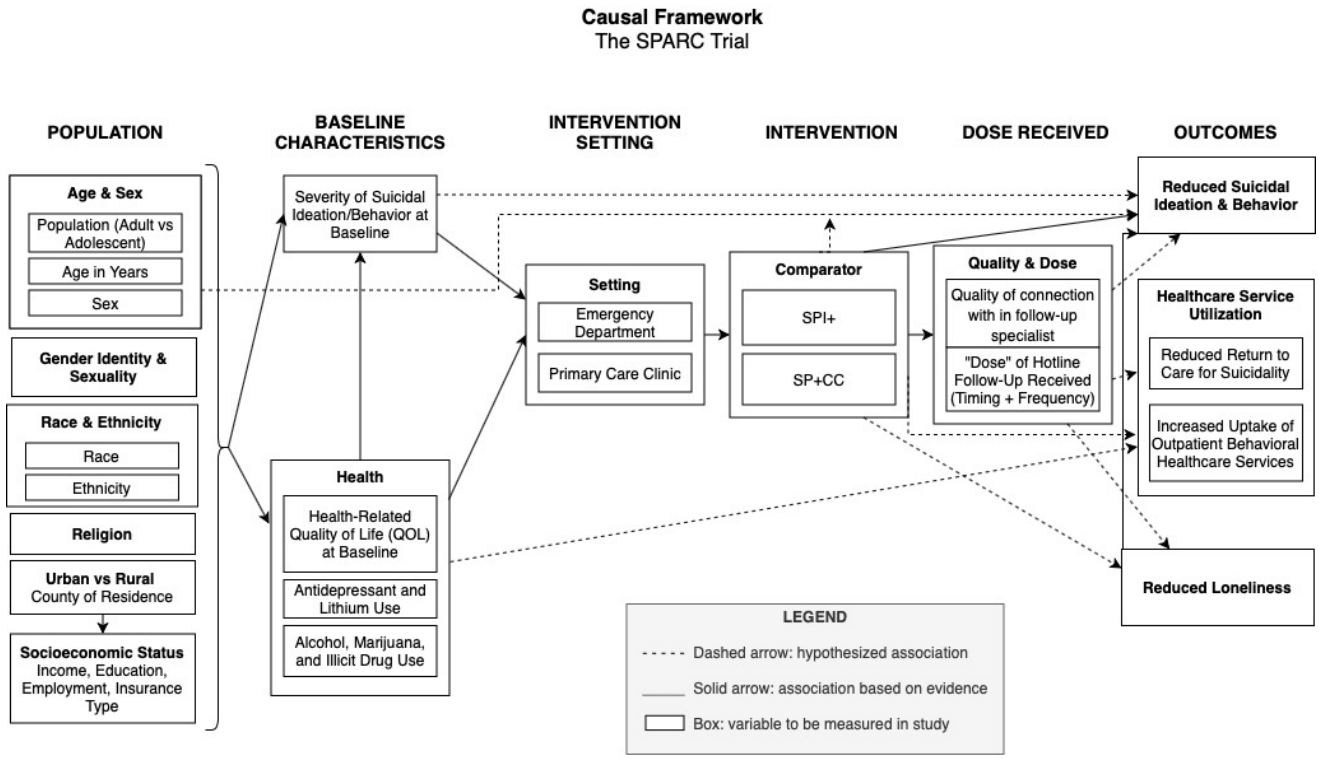
Table 2: Mapping Elements of the SPARC Trial Interventions onto the Social-Ecological Model (SEM)

PSYCHOLOGICAL / INTRAPERSONAL DOMAIN	
Internal thoughts & feelings	**Safety Planning Element #1**: Warning signs (thoughts, mood, images, behavior) that a crisis may be developing **Follow-Up: Caring Contacts** text messages aim to make patients feel supported and cared for
Behavior	**Safety Planning Element #2**: Coping strategies and distractions (things I can do to take my mind off my problems without other people (meditation, physical activity, etc.))
INTERPERSONAL DOMAIN	

Social support and Affiliation & Attachment	**Safety Planning Element #3**: People and social settings that provide distraction **Safety Planning Element #4**: Trusted people whom I can ask for help **Follow-Up: Hotline Phone Call(s)** provides opportunity to receive social support from Hotline follow-up specialists **Follow-Up: Caring Contacts** text messages provide non-demanding messages of social support
Professional support	**Safety Planning Element #5**: Professionals or agencies I can contact during a crisis **Follow-Up: Hotline Phone Call(s)** Hotline follow-up specialists are trained to provide support to suicidal individuals **Follow-Up Hotline Phone Calls(s)** Hotline staff counsel patients on how to navigate barriers to seeking care
ENVIRONMENTAL DOMAIN	
Making environment safe	**Safety Planning Element #6**: Restricting lethal means **Follow-Up Hotline Phone Call(s)** Hotline staff reinforce the importance of lethal means restriction and this is a key focus of the phone call(s)

The causal framework 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 the paragraphs that follow the framework); associations depicted with dashed lines are hypothesized and will be assessed and measured as part of this study. The bracket around the population variables was added to visually simplify the framework; it represents solid arrows from each of the variables under population to each of the baseline characteristic variables.

Figure 2: SPARC Trial Causal Framework



9. Exposures and Outcomes (Variables) of Interest

9.1 Exposure Variables

The following exposure variables will be measured and assessed as part of this study: age, sex, gender identity, sexuality, race, ethnicity, religious affiliation, religious behavior, socioeconomic status (including income, education, employment, and insurance type), rural/urban residence, alcohol use, overall health / presence of co-morbidities, medication use, marijuana, and illicit drug use. A full summary of exposure, outcome, and process variables to be collected as part of this study is included in *Table 4: SPARC Trial Variables of Interest and Other Data Elements*. Key exposure variables known to influence suicide risk will be collected to evaluate potential differential distribution among intervention groups, which may not be perfectly controlled for randomization.

9.1.1 Rationale for Including Selected Exposure Variables

Age and sex are associated with suicidal ideation and behavior.[30] Adults over 35 years old are more likely to die by suicide than other age categories.[25] CDC reports that suicidal completion is approximately 4 times more common among males than females.[25] The age/sex distribution of suicidal ideation and behavior differs from that of suicidal completion. Routine data from 492,797 patients seen in SLHS EDs

and primary care clinics (SLHS data) indicate that in this population, the likelihood of screening positive for suicidal ideation or behavior is similar among adult females and adult males (2%) but is twice as common among adolescent females (8%) as among adolescent males (4%).[34] Overall, adolescents in this population experience higher rates of suicidal ideation (6%) than adults (2%).[34] The scientific literature is limited regarding the effect of safety planning with adolescents. We hypothesize that age may moderate the effect of the comparators on outcome variables and may differ for suicidal adult versus adolescent participants**; the current study will be powered to report results stratified by agecategory.**

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.[35-40]**

Race and ethnicity are also associated with each of the baseline characteristics. **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.**[25]

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).[41] Another review found that 75% of published studies identified religion as protective against suicidal ideation and behavior.[42]

The Health Resources & Services Administration's Federal Office of Rural Health Policy urban-rural designation for census tracts[43] will be used together with patients' home addresses to classify study participants as urban or rural residents. Compared to large urban areas, **rural residence is associated with a 45% higher rate of suicide**,[25] **lower socioeconomic status,[44] and worse overall health outcomes.[44]** Thirty-five of Idaho's 44 counties are classified as rural[43] and we have included study sites serving urban and rural residents. Geographic location and urban/rural location were included as matching criteria in order to ensure an equal distribution of rural clinics in intervention groups.

Financial crises and low socio-economic status (SES) are associated with an increase in suicidality.[3] The study will collect data related to SES including income, education, and employment through a Baseline Survey using standard questions from the US Census Bureau's 2019 American Community Survey.[45]

Health-related quality of life is a key predictor of overall physical and mental wellbeing. Quality of life will be measured at baseline using the Euro-Qol tool (EQ-5D-5L for adults and EQ-5D-Y for adolescents).[2] The EQ-5D-5L is a five-question survey that includes five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Many physical and behavioral comorbidities and use of certain medications are associated with suicide risk. A recent study found that at least occasional

marijuana use and alcohol use among adolescents with suicidal ideation are associated with an increase in suicide attempts.[46]

9.2 Primary Outcome & Assessment

The primary outcome of interest (suicidal ideation and behavior) and the secondary outcomes (loneliness, uptake of outpatient mental healthcare services, and ED utilization for suicidality) **were selected because these are the outcomes that people with lived experience with suicide (PLES) and the Provider Advisory Board (PAB) indicated were most important to patients, caregivers, and providers.** Outcomes will be measured at baseline (immediately prior to study enrollment as part of usual care for all patients (suicide risk) or immediately following study enrollment (loneliness)), and at 6 months (+/- 4 weeks), and 12 months following study enrollment (+/- 4 weeks).

Aim 1: **The primary outcome is reduced suicidal ideation and behavior** (measured as change from baseline score at 6 and 12 months using the Columbia Suicide Severity Rating Scale (C-SSRS)).[1,15,16,47] The 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.[16] The C-SSRS was developed in American English and has been translated to multiple languages; the Spanish language version has been validated.[16,48] 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 and 12 months.[16,49]

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 and 12 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, and 12 months. 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.

In EDs, C-SSRS screening is routinely administered by nurses during triage as standard of care, while in primary care clinics the C-SSRS screener will be self-administered by patients. The C-SSRS delivered as standard of care in either setting will be used as the basis for determining eligibility for completing a safety plan and eligibility for study enrollment. However, in ED settings, the C-SSRS will be re-

administered in a self-complete format for study participants as part of their baseline surveys, from which change in severity of suicidality will be measured when they self-complete the C-SSRS as part of 6 and 12-month outcome surveys.

The two C-SSRS scores collected during the baseline visit in EDs (nurse-administered vs. self-administered) will be compared as a sub-analysis to assess for any systematic differences in score. The results of this sub-analysis may inform future clinical practice as it relates to C-SSRS administration in SLHS EDs and other settings.

Table 3: C-SSRS Screening Tools by Timepoint, SPARC Trial

Timepoint	C-SSRS Assessment Used
Baseline Survey	Lifetime-Recent C-SSRS Screener (6 questions)
6- and 12-month Outcomes Survey	Since Last Contact C-SSRS Screener (6 questions)

9.2.1 Scoring the C-SSRS

The C-SSRS lifetime-recent screener score is determined based on the highest question number (1-6) 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 A* 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.

9.3 Secondary Outcomes & Assessment

Secondary outcomes include reduced loneliness, increased uptake of outpatient mental health services, and reduced return to care for suicidality.

9.3.1 Loneliness

Loneliness is a well-established risk factor for suicide,[70-72] depression,[73-76] psychological stress,[76,77] and anxiety.[73,74,77] Loneliness will be measured at baseline, 6 and 12 months 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.[78] The measurements were developed to be versatile, brief, and psychometrically sound.[78] 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.[79] 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.[79]

9.3.2 Uptake of Outpatient Mental Health Services

Uptake of outpatient mental health services will be measured at 6 and 12 months in two ways: through self-report, and (wherever possible) directly via electronic health records or using internal claims data.

9.3.3 Return to Care for Suicidality (ED utilization)

Return to care for suicidality will be assessed for study participants through self-report at 6 and 12 months and by measuring ED utilization using an electronic health records query to review the number of times each patient returned to SLHS ED, the primary diagnosis, and the reason code (ICD-10). SLHS uses EPIC[54] electronic health records system, and study staff will work with an informational technology expert trained in EPIC to support data extraction to assist with measuring this outcome. Additionally, study staff may also review available ED dashboards/EDIE System that includes health systems outside of SLHS to measure use of non-SLHS EDs during the study period.

9.3.4 Assessing Bias in Self-Reported Measures

In addition to self-reported uptake of care, for patients referred to a provider within SLHS, study staff will measure whether they attended one or more outpatient mental healthcare appointments or returned to care (ED utilization) for suicidality by looking at their electronic medical record in EPIC, reviewing an ED dashboard/EDIE System and by utilizing claims data when possible. However, we do not anticipate having complete data for patients who see a provider outside of SLHS. For these participants, study staff may review data in EPIC Care Link, or via other means to measure uptake of outpatient mental health treatment. Discrepancies are expected between data on uptake of treatment and care-seeking related to suicide from self-report compared to the data that can be directly measured. The analytic team will estimate the extent and direction of bias in a sub-set of participants from each comparator group who were referred to an SLHS provider by comparing self-reported uptake of outpatient mental healthcare services with what is recorded in EPIC. This will allow estimation of the degree of bias present in the self-reported data and determination of whether the extent of bias differs between the two comparator groups.

10. Description of Interventions

10.1 Safety Planning & Connection and Support Planning

Both intervention arms include safety planning or connection and support planning. **Safety Planning is defined according to recommendations for usual care from the Joint Commission and the Suicide Prevention Resource Center's Evidence-Based Practices, and includes screening, clinical management, safety planning as described by Stanley and Brown,[55] careful discharge planning, and referral to outpatient**

mental health services.[7-9,14] Safety planning is designed to be completed collaboratively with patients at risk for suicide and is comprised of an individually tailored plan of actions to take if suicidal ideation or a crisis recur.[21,55,56] Specifically, safety planning is a therapeutic clinical intervention that begins with a suicide narrative and includes each of the following six elements:

1. Identifying potential warning signs of suicidal crisis,
2. Utilizing internal coping strategies,
3. Engaging social contacts and settings that provide distraction,
4. Engaging family and friends for social support to resolve the crisis,
5. Reaching out to mental health professionals including suicide prevention hotlines, and
6. Restricting access to lethal means.[55,56]

A full safety plan is clinically indicated for any patient with a moderate to high risk for suicide (generally, a C-SSRS score of 3-6, plus clinical judgement of their provider), or any patient whose current visit is related to a suicide attempt. Collaborative safety planning is distinct from "No Suicide Contracts," which elaborate what patients will *not* do, are not individually-tailored, are not evidence-based, and may actually be iatrogenic.[57]

A connection and support plan will be completed in lieu of a safety plan for patients with low levels of suicide risk (generally a C-SSRS score of 1-2 and/or clinical judgement of their provider). The connection and support plan will include psychoeducation on suicide prevention; a discussion of social support; sharing of crisis resources (including the Hotline) and contact information for professional resources such as therapists, as well as a discussion of when to engage those resources; lethal means counselling focused on firearms safety and medication safety generally; and reasons for living.

10.2 Safety Planning Intervention Plus Phone-Based Follow-Up (SPI+)

The Safety Planning Intervention (SPI+) [1-7] includes safety planning plus a structured telephone-based intervention following discharge from the emergency department or departure from a primary care clinic. For the SPARC Trial, Hotline follow-up specialists will call participants within 72 hours of study enrollment to (1) conduct a brief suicide risk assessment; (2) review and revise the participant's connection and support plan or safety plan; and (3) provide support with treatment engagement, if indicated. Participants will receive at least one and optional additional phone calls as part of the SPI+ follow-up intervention generally delivered according to the following schedule: days 3, 7, 14, 30, 60, 90. [8,9] Modifications may be made to the schedule due to weekends, holidays, or participant availability, and additional calls may be scheduled as desired by the participant. The follow-up will stop once the participant is successfully engaged in outpatient treatment or does not desire further follow-up support. In instances where participants cannot be reached for an initial phone call within 72 hours, Hotline staff will continue to attempt to schedule and complete the phone call. A minimum of three attempts to schedule and complete each phone call will be made.

This version of the intervention differs from the Stanley/Brown SPI+ model in that the structured follow-up

will be conducted by Hotline follow-up specialists, rather than by specially trained social workers or psychologists. In this pragmatic clinical trial, we are committed to testing a model that could be feasibly scaled up and replicated in other rural and resource-limited settings. The schedule was adopted from similar military follow-up programs: the Marine Intercept Program[9] and the Navy Sailor Assistance and Intercept for Life (SAIL) Program.[8] We selected this schedule given that we wanted to offer a longer follow-up window than the traditional SPI+ in order to support treatment engagement because connecting with outpatient behavioral health treatment (such as a counselor or therapist) typically takes 4-6 weeks for patients at low risk for suicide in our health system.

10.4 Safety Planning Intervention + (SP+CC)

SP+CC will include safety planning, plus caring contacts from the Hotline**.** Suicide prevention hotlines have been shown to be an effective means of mitigating active suicide risk.[58,59] **SP+CC follow-up will consist of one phone conversation, whenever possible within the first 72 hours following study enrollment,** to connect and establish rapport between the follow-up specialist and participant. In instances where participants cannot be reached within 72 hours, Hotline staff will make at least three attempts. If the phone call cannot be successfully completed after at least three attempts, the caring contacts will be started without the phone call.

The call will be followed by a series of 25 personalized caring contacts sent over the course of 12 months via text message or email.[60] The frequency and cadence of caring text or email messages will be consistent for all participants according to a schedule that was developed in consultation with PLES Advisors to ensure it is culturally and age appropriate. Caring text or email messages will be sent according to the following schedule: three in the first week, 6 weekly, 6 bi-weekly, 4 monthly; two bi-monthly, and one each for the participant's birthday, Thanksgiving, Christmas, and New Year's (total of 25 over 12 months).[60] The exact schedule and content of the messages may vary slightly to account for weekends and holidays (messages will generally be sent M-F during working hours). 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. The number of individual responses, content, and timing of text or email messages will be tracked and 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 be the study protocol.

10.5 Definition of Minimal Intervention

To be considered a recipient of the study interventions, participants must have completed a connection and support plan or a safety plan at St. Luke's. If randomized to the SPI+ comparator, participants must receive at least one phone call from the Hotline. If randomized to the SP+CC comparator, participants

must be sent at least 4 caring text or email messages.

10.6 Process Evaluation & Fidelity

The quality of safety planning has been shown to affect patient outcomes.[61,62] Providers in both comparator groups will be trained on suicide screening and safety planning to minimize variation in these elements across intervention groups. The study will include a process evaluation to assess the consistency with which screening and safety planning interventions are completed, with process data collected and evaluated throughout the enrollment period using a dashboard.

The timing, type (phone vs text vs email), and number of attempted and successful contacts from the Hotline ("dose" and timing of follow-up contact) will be tracked and recorded by the Hotline for each study participant. Additionally, study staff will measure the fidelity of the follow-up interventions in several ways. For SPI+, Hotline follow-up specialists will be asked to follow a call template that includes essential elements of the intervention. Study staff will review these sheets routinely and will listen to a subset of calls to validate that the templates have been accurately completed. For SP+CC, study staff will review the text chat routinely to ensure that the tone and timing of text responses is aligned with the Caring Contacts model.

11. Discontinuation and Participant Withdrawal

11.1 Discontinuation of Study Intervention / Experimental Manipulation

Participants may choose to discontinue the follow-up intervention 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 follow-up surveys, even if they are not participating in the assigned intervention.

11.2 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 SPARC Trial email account (sparc@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 *12.3 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 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, or at the PI's discretion.
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 SPARC Trial study records.

11.3 Lost to Follow-Up

A study participant will be considered lost to follow-up if s/he fails to complete both 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).
- Should the participant continue to be unreachable, s/he will be considered lost to follow-up and will be withdrawn from the study.

12. Data & Safety Monitoring

12.1 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 serve on the DSMB. The DSMB will be convened and managed through the University of Washington's Institute of Translational Health Sciences (UW ITHS).

12.2 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 6 and 12 months
3. Data completeness and quality
4. Safety outcomes by intervention arm and population (adults, adolescents)
5. Interim analyses to assess whether one intervention is significantly more effective than the other

6. Decisions related to stopping the trial early due to one or more of the elements above

12.3 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 6 and 12 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
- Medical hospitalization related to self-harm or attempted suicide

12.4 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, this research compares two evidence-based interventions that have been widely studied, have an established safety record, and are already in widespread clinical practice, including within SLHS. These are not experimental, novel, or untested interventions 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. Given that the two interventions include different types and frequency of contact with study participants, 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 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.

12.5 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 urgent clinical needs of a participant (such as imminent risk of self-harm) during study enrollment or one of the outcome assessments, that individual's needs should be placed above any responsibilities related to the study protocol. The goal of the RM review is to monitor this when potential issues are flagged by the PI and help ensure that study personnel are prioritizing individual participant's urgent clinical needs appropriately.

13. Data Collection & Management

13.1 Data Collection

Baseline data are either already collected and recorded in EPIC as standard of care for all patients (demographic data, C-SSRS) or will be completed by the participant via REDCap survey immediately following enrollment and informed consent (Baseline Survey). Outcome data will be collected via REDCap survey or over the phone at 6 months and 12 months. *Table 4* includes a list of all study variables for the primary analysis, the tool to be used for data collection or source of the data, the frequency/timing with which they will be collected, whether they are routinely collected or will be collected specifically for the SPARC Trial, and which entity will collect them. Patient and provider satisfaction surveys will collect additional quantitative and qualitative data and will be collected via REDCap survey.

Table 4: SPARC Trial Variables of Interest and Other Data Elements

Variable	Tool/Source	Routinely collected as standard of care	Mode of contact	Who will collect
Outcomes (6 months)				
Suicidal ideation & behavior	C-SSRS	No	REDCap survey (text, email, or phone)	SLHS
Recent suicide attempts, suicide completion, & self-harm; lethal means	6- and 12-Months Suicide Attempts Survey, Vital Records, EPIC	No	REDCap survey (text, email, or phone)	SLHS
Loneliness	NIH Toolkit Loneliness Scale	No	REDCap survey (text, email, or phone)	SLHS
Uptake of outpatient mental health treatment	Self-report, EPIC, Claims data	Yes	REDCap survey (text, email, or phone)	SLHS

Return to ED for suicidality	Self-report, EPIC, EDIE, Claims data	Yes	REDCap survey (text, email, or phone)	SLHS
Outcomes (12 Months)				
Suicidal ideation & behavior	C-SSRS	No	REDCap survey (text, email, or phone)	SLHS
Recent suicide attempts, completion, & self-harm; lethal means	6- and 12-Months Suicide Attempts Survey; Vital Records, EPIC	No	REDCap survey (text, email, or phone)	SLHS
Loneliness	NIH Toolkit Loneliness Scale	No	REDCap survey (text, email, or phone)	SLHS
Uptake of outpatient mental health treatment	Self-report, EPIC, Claims data	Yes	REDCap survey (text, email, or phone)	SLHS
Return to ED for suicidality	Self-report, EPIC, Claims data, EDIE	Yes	REDCap survey (text, email, or phone)	SLHS

Exposures (Baseline)				
Age in years, age category (adult/peds)	EPIC	Yes	n/a	SLHS
Sex	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 & sexuality	Baseline Survey	No	REDCap survey (In-person, phone, or video chat)	SLHS
Marijuana and drug use	Baseline Survey	No	REDCap survey (In-person, phone, or video chat)	SLHS
Alcohol use	Baseline Survey	No	REDCap survey (In-person, phone, or video chat)	SLHS
Religion	Baseline Survey	No	REDCap survey (In-person, phone, or video chat)	SLHS
Socioeconomic status (employment, education / maternal education, housing stability, income)	Baseline Survey	No	REDCap survey (In-person, phone, or video chat)	SLHS
History of suicide attempts & self-harm; lethal means	Baseline Suicide Attempts Survey	No	REDCap survey (In-person, phone, or video chat)	SLHS
Insurance Provider	EPIC	Yes	n/a	SLHS
Suicidal ideation & behavior at baseline (standard of care)	C-SSRS (in EPIC)	Yes	n/a	SLHS
Suicidal ideation & behavior at baseline (ED only, self-report)	C-SSRS / Baseline Survey (ED only)	No	REDCap survey (In-person, phone, or video chat)	SLHS
Quality of life at baseline	Euro-Qol	No	REDCap survey (In-person, phone, or video chat)	SLHS
Loneliness	NIH Toolkit Loneliness Scale	No	REDCap survey (text, email, or phone)	SLHS
Antidepressant and Lithium use	EPIC	Yes	n/a	SLHS
Clinic or ED name	EPIC	Yes	n/a	SLHS

Intervention assignment	REDCap	No	n/a	SLHS
Patient Satisfaction Survey (2 weeks & 12 months)				
Patient satisfaction with interventions	Patient Satisfaction Survey	No	REDCap survey (text, email, or phone)	SLHS
Provider Satisfaction Survey (Year 1 or 2)				
Provider satisfaction with interventions and suicide prevention workflows	Provider Satisfaction Survey	No	REDCap survey (email, Provider Portal, or other)	SLHS
Process Variables				
Screening rates by clinic and provider	EPIC	Yes	n/a	SLHS
Rate of safety planning by clinic	EPIC	Yes	n/a	SLHS
"Dose" of follow-up contact: timing, type (phone vs text), and number of attempted and successful contacts from the Hotline	Hotline	No	n/a	Hotline
"Dose" of Caring Contact text messages: date/time of each text message sent (* 25 text messages)	Hotline	No	n/a	Hotline
Other Variables				
Medical record number	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, Claims data	Yes	n/a	SLHS
Referral(s) related to behavioral health	EPIC	Yes	n/a	SLHS
Does cell or landline phone on record belong exclusively to study participant or is it shared?	Baseline Survey	No	REDCap survey (in person, phone, or video chat)	SLHS
Alternative modes of contact	Contact Form	No	REDCap survey (in person, phone, or video chat)	SLHS
Death	State Vital Records	Yes	n/a	Idaho Department of Health & Welfare

13.2 Data Management

This study will employ a comprehensive data management plan. Study data will be directly entered in REDCap or Mosio (a HIPAA-compliant text messaging platform) or will be exported from Epic and uploaded to REDCap by study staff. Down-time procedures utilizing paper-based surveys and forms to collect data from participants will be developed. Paper forms and surveys that include PHI will be kept secure according to standard procedures by clinical staff and study staff. Each patient will be assigned a unique identifier and allocated to one of the two intervention arms based on random assignment using appropriate software. The statistics team will compile study data 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 and trained study staff only, under a data-sharing agreement that includes a commitment to: (1) use the data only for research purposes or to ensure participant safety, (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.

Provider satisfaction surveys will be captured in REDCap as confidential surveys and provider and staff email addresses will be stored in REDCap and/or on secured password-protected computers.

14. Statistical Analysis

14.1 General Analytic Approach

The primary analysis will compare the effectiveness of the two interventions delivered in the two settings (EDs and primary care), accounting for the other covariates of interest. Potential confounding, effect modification, and mediation will be handled through study design (e.g. individual randomization), through stratification (age category), and use of multilevel modeling to account for geographic clustering. Other published studies related to caring contacts and safety planning with and without follow-up have shown that the selected patient-centered outcomes change over a 6-12-month period in response to receipt of these interventions.[24,63]

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.

Aim 1: Analyses will be stratified for adults and adolescents, modeling the effects of intervention separately in these age groups. There is very little evidence regarding the effect of safety planning, caring contacts, or follow-up phone calls on adolescent populations, and we hypothesize that the magnitude of effect may differ by age group. Generating evidence of the effectiveness of these interventions in suicidal adolescents is the primary goal of this heterogeneity of treatment effect (HTE) analysis. **Appropriate statistical analyses will be used to determine whether outcomes differ between the intervention arms**.

Interaction between the interventions and settings will be assessed. Variables will be measured at baseline and reported using descriptive statistics. Potential effect modifiers will be assessed and include age, sex, gender identity, sexuality, race/ethnicity, religion, urban/rural residence, drug/alcohol use,

suicidal ideation and behavior at baseline, baseline quality of life, baseline loneliness, medication use, 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 12 months of follow-up.

Aims 2 & 3: Descriptive statistics will be used to summarize quantitative survey results.

14.2 Power & Sample Size

Power and sample size calculations for the primary analysis are summarized for each of the age population strata below:

- **Adults**: in order to have 90% power to detect a difference of 1 unit in the primary outcome (C-SSRS score), SD=2, allowing for up to 30% dropout, the study requires a sample size of 790
- **Adolescents**: in order to have 80% power to detect a difference of 1 unit in the primary outcome (C-SSRS score), SD=2, allowing for up to 30% dropout, the study requires a sample size of 592

14.3 Missing Data

Missing data 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.[65] The most appropriate multiple imputation technique will be determined based on the distributions of missing data and observed variables.[66-68] 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.

14.4 Planned Interim Analyses

An interim analysis will be conducted at 50% enrollment (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.

14.5 Sub-Group Analyses

We plan to generate different effect estimates for the following subgroups: 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.

15. 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 and social workers in EDs and primary care 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, the University of Pennsylvania, and Columbia University.

Study staff will continue to engage and expand 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 either directly or through a loved one. 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 and frequency of follow-up contact), and will assist with the design of the patient satisfaction surveys and dissemination strategy.

Study staff will continue to engage providers through SLHS for input on study design, conduct, and integration of this research into clinic workflows. Routine meetings will be held with providers and health system staff representing multiple perspectives, such as system- and clinic-level providers, patient access specialists, social workers, psychiatrists and psychologists, ED physicians, pediatricians, and primary care physicians, advanced practice providers, and medical assistants and nurses.

Study staff will continue to engage stakeholders at the state, regional, and community levels, such as public sector stakeholders, private foundations, and non-governmental organizations.

16. Risk / Benefit Analysis

16.1 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 computers. Data will be shared among research partners through REDCap, Mosio, and other secure HIPAA-compliant means (such as secure email). 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 will be used as a central location for online study data storage and participant management.

Other potential risks include psychological distress from completing study questionnaires. The contact in the follow-up intervention may also cause emotional distress. Research participants will be reminded at enrollment that they may 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.

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 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. Patient participants will be compensated for their time. Providers who complete the Provider Satisfaction Survey will not be compensated for their time.

Patients will not be enrolled in the study if a provider or study staff determines that they are unable to consent to participate.

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.

16.2 Potential Benefits

While this study is designed to improve outcomes, there is no guarantee that participants will benefit directly from taking part in the study. Both interventions being tested through this trial are evidence-based, in widespread clinical use, and expected to improve patient outcomes. Patients seen at study clinics have an opportunity to benefit from follow-up with the Hotline, regardless of whether they opt to participate in the proposed research. This study will allow SLHS to improve the quality and consistency of care that individuals screening positive for suicide receive at study sites. Key SLHS providers will be trained on safety planning and connection and support planning. Individuals who consent to participate in the study will receive appropriate monetary compensation for their time (see *Cost/Compensation for Participation* section in this protocol).

The knowledge gained through this study is expected to advance the science of preventing suicide in healthcare settings. We expect the findings of this study to be relevant and of interest to the scientific community, and SLHS Administrators will benefit from information on how best to refine existing clinical protocols for screening for suicide risk.

17. Oversight for Human Subjects Protection & Regulatory Considerations

17.1 Human Subjects Protection

This study will be conducted with oversight from the 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, except where necessary to eliminate apparent immediate hazards to subjects. 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. Participation by staff from the University of Washington will be reviewed and monitored by the UW Human Subjects Division.

17.2 Risks to Human Subjects

17.2.1 Involvement of Human Subjects

Suicide constitutes a significant public health concern and is a leading cause of death in the United States.[3] However, little is known about health system level interventions to prevent suicide among civilians or adolescents.[6] This study will fill key gaps in the literature outlined in the *Background* section of the Research Plan. The two treatments being compared in this study are both evidence-based suicide prevention interventions.[8,9,19-21,56,69] No one will receive a "placebo" or "null" treatment.

17.2.2 Protecting Individuals with Urgent Clinical Needs

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. The independent Research/Medical Monitor (RM) will assist with monitoring this by reviewing situations where individual study participants' needs conflicted 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.

17.3 Informed Consent Process

When a patient expresses interest in participating in the study, study staff will complete the informed consent process with them. If the patient is younger than 18 years of age, his or her legally authorized representative will provide written permission for the minor to participate in the study; the minor participant will also go through an informed assent process. Participants that assent to study participation prior to age 18 will be reconsented to continue participating if they turn 18 years old while enrolled in the study. Recruitment materials will be written at an age-appropriate reading level to maximize comprehension. Furthermore, the People with Lived Experience with Suicide (PLES) Advisory Board will review the informed consent documents for readability and clarity.

17.3.1 Documentation of Informed Consent

Informed consent (and assent for participants aged 12-17) will be obtained and documented for all primary study participants. Study staff will document each participants' eligibility to participate in the study prior to enrollment. When the participant signs the informed consent/assent 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 generally 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.

A waiver of documentation of consent will be requested from the IRB for the patient and provider/staff populations. A consent statement will be included and completion of the survey will constitute consent to participate.

17.4 Bioethics Consultation

The University of Washington's Institute for Translational Health Sciences hosts a Bioethics Consultation Service that will be utilized as needed for the duration of the three-year study. Grant resources have been set aside for an extensive initial bioethics consultation which was completed prior to IRB submission of this protocol, as well as a series of ongoing consultations with bioethicists.

17.5 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. Information about the distribution of races, ethnicities, and gender in our study population (people screening positive for suicide in SLHS Emergency Departments and Primary Care settings) can be found in the *Estimated Final Racial/Ethnic and Gender Enrollment Table*.

Table 5: SPARC Trial Estimated Final Racial/Ethnic and Gender Enrollment

Based on proportion of SLHS patients screening positive for suicide in EDs or primary care settings in 2018[34]

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	4	5	9
Asian	3	9	12
Black/African American	6	4	10
Hawaiian/Pacific Islander	2	2	4
White	446	760	1206
Multirace	48	93	141
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	45	96	141
Non-Hispanic	463	778	1241

17.6 Inclusion of Minors

Adolescents face a disproportionate burden of suicidal ideation[34] compared to adults, and additional evidence is needed to determine the most effective suicide prevention interventions at the health system level for minors.[5] Adolescents who screen positive for suicide 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.

17.7 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 $125 total over 12 months) in the form of online gift cards. Participants 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: $35
- Two-week satisfaction survey: $10
- Six-month follow-up: $40
- 12-month follow-up/study completion: $40

17.8 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 PI. If the study is prematurely terminated or suspended, the PI 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
- Demonstration of efficacy that would warrant stopping
- 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.

17.9 Confidentiality & Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the DSMB, the SLHS IRB, 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. 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 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 and Mosio, HIPAA compliant web-based platforms. 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.

17.9.1 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 PI 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).

17.10 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.

17.11 Publication & Data Sharing Policy

The SPARC Trial Executive Board 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 PI. Considerations for ensuring confidentiality of these shared data are described in the 16.9 Confidentiality & Privacy section of this protocol.

17.12 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.

17.13 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 would not expect to see a significant difference in this outcome between the two intervention groups over the duration of this three-year study, thus we have not included death as a primary or secondary outcome for this study. However, the study team plans to follow-up on participants over time in order to assess the effect of these interventions on death by suicide over a 5- 10 year period. National Death Index Plus data from CDC will be obtained for the purpose of assessing death and cause of death of participants enrolled in the study. These data will be accessed only for those participants who are defined in the ITT and the Per-protocol populations for up to ten years following study enrollment.

17.14 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.

17.15 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 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 PI; deviations deemed reportable based on criteria in the SLHS IRB Procedures Manual will be reported to the SLHS IRB. Study staff will be responsible for knowing and adhering to the IRB requirements.

17.16 Key Roles for Study Oversight

Table 6: Key Roles for Study Oversight, SPARC Trial

Principal Investigator & Data & Safety Monitoring Board Leaders		
Principal Investigator	**Data & Safety Monitoring Board Chair**	**Research & Medical Monitor (RM)**
Anna Radin, DrPH, MPH, Applied Research Scientist	Ann Melvin, Chair, Data and Safety Monitoring Board	Greg Simon, MD, MPH, Psychiatrist, Behavioral Health Service Line, and Investigator
St. Luke's Health System	University of Washington Institute of Translational Health Sciences	Kaiser Permanente & Kaiser Permanente Washington Health Research Institute
208-381-8468	206-290-8294	206-287-2979
radina@slhs.org	ann.melvin@seattlechildrens.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.

17.16.1 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 six months after enrollment begins. The DSMB will meet regularly to 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.

17.17 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 each site is performing in terms of suicide screening rate, study enrollment rate, completeness of data, and documentation of required processes such as informed consent. Study staff will conduct supportive supervisory visits and/or phone calls or email check-ins with each study site routinely and as needed based on site performance.

Quality control (QC) measures will be implemented as follows:

- Informed consent – Study staff will review both documentation of the consenting process as well as a representative sample 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.

- Intervention fidelity – Study staff will monitor the degree to which follow-up interventions are delivered with fidelity. Procedures for assessing and ensuring fidelity are described in the *9.4 Process Evaluation & Fidelity* section of thisprotocol.

- 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 A: 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