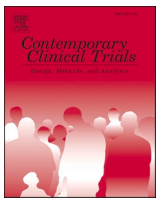
Contemporary Clinical Trials 131 (2023) 107268

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



Comparative effectiveness of safety planning intervention with instrumental support calls (ISC) versus safety planning intervention with two-way text message caring contacts (CC) in adolescents and adults screening positive for suicide risk in emergency departments and primary care clinics: Protocol for a pragmatic randomized controlled trial

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ARTICLE INFO

Keywords:
Suicide
Suicidal ideation
Adolescent
Adult
Ambulatory care
Emergency department
Brief contact intervention
Safety planning intervention
Caring contacts
Mental health

ABSTRACT

Background: Suicide is a leading cause of death in adolescents and adults in the US. Follow-up support delivered when patients return home after an emergency department (ED) or primary care encounter can significantly reduce suicidal ideation and attempts. Two follow-up models to augment usual care including the Safety Planning Intervention have high efficacy: Instrumental Support Calls (ISC) and Caring Contacts (CC) two-way text messages, but they have never been compared to assess which works best. This protocol for the *Suicide Prevention Among Recipients of Care (SPARC) Trial* aims to determine which model is most effective for adolescents and adults with suicide risk.

Methods: The SPARC Trial is a pragmatic randomized controlled trial comparing the effectiveness of ISC versus CC. The sample includes 720 adolescents (12–17 years) and 790 adults (18+ years) who screen positive for suicide risk during an ED or primary care encounter. All participants receive usual care and are randomized 1:1 to ISC or CC. The state suicide hotline delivers both follow-up interventions. The trial is single-masked, with participants unaware of the alternative treatment, and is stratified by adolescents/adults. The primary outcome is suicidal ideation and behavior, measured using the Columbia Suicide Severity Rating Scale (C-SSRS) screener at 6 months. Secondary outcomes include C-SSRS at 12 months, and loneliness, return to crisis care for suicidality, and utilization of outpatient mental health services at 6 and 12 months.

Discussion: Directly comparing ISC and CC will determine which follow-up intervention is most effective for suicide prevention in adolescents and adults.

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https://doi.org/10.1016/j.cct.2023.107268
Received 31 March 2023; Received in revised form 24 May 2023; Accepted 11 June 2023
Available online 14 June 2023

1. Introduction

1.1. Background

Suicide is the second leading cause of death for adolescents aged 12–17 and the fifth leading cause of death for adults aged 18–65 in the United States (US) [1]. People experiencing suicidal ideation are particularly vulnerable during periods of healthcare transition. Nearly half of suicide deaths occur within a month of an Emergency Department (ED), primary care, or other healthcare encounter [2]. Usual suicide care in EDs or primary care clinics typically includes completing a Safety Planning Intervention (SPI). Delivering a SPI together with an evidence-based follow-up support intervention (such as Instrumental Support Calls (ISC) [3] or two-way text message Caring Contacts [4–9]) after patients return home following an episode of care can significantly reduce suicidal ideation and behavior [3–9]. However, despite promising efficacy and feasibility data, these follow-up support interventions are not yet in widespread clinical practice in most health systems, and it is unknown which intervention is most effective. *Suicide Prevention Among Recipients of Care (SPARC)* is a randomized controlled trial designed to compare the effectiveness of ISC and CC follow-up support models to prevent suicidal ideation and behavior in adolescents and adults. This article describes the SPARC study design and protocol.

2. Specific aims & hypotheses

The trial's primary aim is to compare the effectiveness of ISC vs CC to reduce suicidal ideation and behavior, measured using the Columbia Suicide Severity Rating Scale (C-SSRS) screener at 6 months, in adolescents (12–17 years) and adults (18+ years) screening positive for suicide risk in EDs and primary care clinics. Secondary aims include comparing the effect of the interventions on suicidal ideation and behavior at 12 months, and loneliness, return to crisis care for suicidality, and uptake of outpatient mental healthcare services at 6 and 12 months. We hypothesize that compared to ISC, CC will improve outcomes for adolescents and adults.

3. Methods

3.1. Study design & oversight

This protocol is for a pragmatic comparative effectiveness randomized controlled trial. The St. Luke's Health System Institutional Review Board (IRB) approved and will oversee implementation of the study.

3.2. Conceptual model

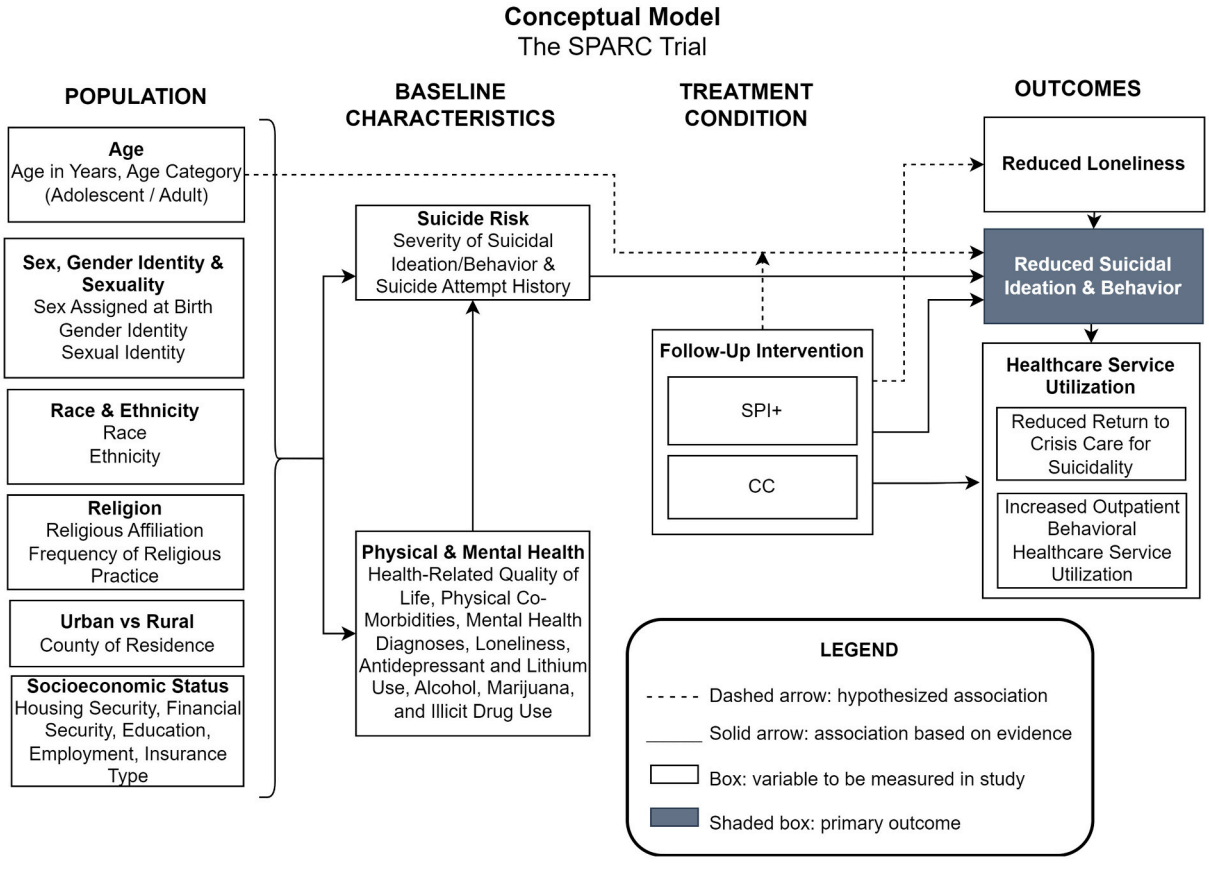
3.3. Randomization, stratification, and masking

3.3.1. Randomization & stratification

Participants will be randomized 1:1 and stratified by age category (adolescent/adult). The lead statistician will generate a random list of treatment assignments for each stratum. The list will be concealed from study staff and will use varying block sizes to minimize the possibility of guessing treatment assignments. At the time of randomization, REDCap (Research Electronic Data Capture) [10,11] will determine the next treatment assignment from the list.

3.3.2. Masking

This trial will be single masked, with most members of the study team, including the principal investigator and senior statistician, masked to aggregate data by treatment arm. Participants will be aware of the treatment condition to which they are assigned but unaware of the



Conceptual model for the SPARC Trial

alternative treatment condition. Masking interventionists or study participants to treatment assignments is not feasible due to the nature of the intervention

3.4. Study setting

The primary research location is St. Luke's Health System (St. Luke's), a large, regional non-profit health system in Southwestern Idaho. Idaho's suicide rate is consistently among the highest in the US, 76% higher than the national average [12]. The study population for this trial is adolescent and adult patients who screen at risk for suicide during an encounter at any of nine St. Luke's EDs or thirty-six St. Luke's internal medicine, family medicine, or pediatrics clinics. This study will recruit 1510 participants (720 adolescents and 790 adults).

3.5. Eligibility criteria

3.5.1. Inclusion criteria

- Patient at St. Luke's ED or primary care study site
- Adolescent aged 12–17 years or adult ≥18 years
- Positive screen for suicide risk using the Columbia Suicide Severity Rating Scale (C-SSRS) (any C-SSRS score > 0), or clinic/ED encounter related to suicidal ideation/attempt
- Access to a phone (cellular/landline) with ability to receive calls
- Ability to send and receive emails (required) and text messages (optional)
- English or Spanish speaking and reading
  - Accommodations may be made for individuals who are hearing-impaired.

3.5.2. Exclusion criteria

- Patients who participated in a recently completed Caring Contacts trial at St. Luke's
- Patients who are unable or unwilling to provide informed consent to participate
  - For example, patients who present with acute or chronic cognitive impairment that would preclude their ability to consent
  - Capacity to consent may be assessed by research coordinators at the time of enrollment if the participant seems intoxicated, confused, or if the medical record indicates cognitive impairment or intellectual disability. The *SPARC Brief Assessment of Capacity to Consent (S-BACC)* will be used for these assessments (see *Supplemental Materials*).
- Patients who are inappropriate for study participation based on the referring provider's clinical judgment.

3.6. Engagement with people with lived experience with suicide

We will convene a local advisory board of people with lived experience with suicide (PLES). Advisors will provide input on study-related topics such as study branding, recruitment strategy, informed consent, retention, intervention delivery, and dissemination strategy. The PLES Advisory Board will include up to fifteen people and advisors will receive stipends for participating. Two licensed behavioral health clinicians will participate in each meeting to ensure safety and provide support in case conversations are difficult or triggering. The PLES Advisory Board will convene virtually every two months for the first year and quarterly thereafter for the duration of the trial to ensure all aspects of the study are participant-centered and informed by lived experience.

3.7. Study procedures

3.7.1. Recruitment strategy

St. Luke's universally screens patients 12 years of age and older for suicide risk in EDs and primary care clinics referring patients to SPARC. Potentially eligible patients will be invited to participate by their clinic or ED provider and referred to the study. Informed consent will be conducted virtually with all participants using REDCap's informed consent framework, which collects digital timestamps and finger signatures. Patients will either be invited to complete informed consent and study enrollment via video visit while still in the clinic or ED or will be invited by text or email to schedule an enrollment over the phone after they have returned home, depending on the workflow preferred by referring clinics/EDs.

3.7.2. Best available usual care provided to both treatment conditions

Participants in both intervention arms will be offered a Safety Planning Intervention, as described by Drs. Stanley and Brown [13], or a Connection and Support Plan (CSP) as described below. Safety Planning is a therapeutic clinical intervention that begins with a narrative of the suicide risk incident and includes identifying potential warning signs of suicidal crisis, utilizing internal coping strategies, engaging social contacts and settings that provide distraction, engaging family and friends for social support to resolve the crisis, reaching out to professionals, restricting access to lethal means, and a brief list of reasons for living, summarized in the Safety Plan [13].

A full Safety Planning Intervention is clinically indicated for patients who have experienced a suicide risk incident, which includes those with moderate or high risk for suicide (C-SSRS screener response of “yes” to items 3–6, and/or recent suicide attempt and/or provider clinical judgment).

A Connection and Support Plan (CSP) may be completed in lieu of a Safety Plan for patients with low levels of suicide risk (C-SSRS score of 1–2/provider clinical judgment). The CSP was developed based on evidence-based components of the Safety Planning Intervention at the recommendation of Drs. Stanley and Brown as those without a history of suicide crisis or attempts are not clinically appropriate for the Safety Planning Intervention. It includes psychoeducation on suicide prevention; a discussion of social support options; sharing of crisis resources such as 988, and contact information for professional resources such as therapists, as well as a discussion of when to engage those resources; lethal means counseling focused on firearm safety and medication safety; and reasons for living.

Safety Plans or CSPs may be completed with ED social workers, Collaborative Care [14] social workers, or primary care providers as part of standard care prior to study enrollment. Alternately, participants without a Safety Plan or CSP documented in their medical record may complete one with non-clinician follow-up specialists at the Idaho Crisis and Suicide Hotline (Hotline), generally during their initial phone call. Hotline follow-up specialists received the same 4-h Safety Planning Intervention training led by Drs. Stanley and Brown available to St. Luke's clinicians. Participants may decline a Safety Plan or CSP and still take part in the study.

3.8. Description of study treatment conditions

Participants will be randomly assigned to either the ISC or CC treatment condition.

3.8.1. Phone-based instrumental support calls (ISC)

The ISC condition closely resembles Stanley & Brown's SPI+ [3], which can reduce suicidal behavior by half and double the likelihood that patients attend mental health treatment. ISC consists of semi-structured telephone-based instrumental support after a patient completes a Safety Plan or CSP and returns home following an ED or clinic encounter or inpatient hospitalization. Trained Hotline follow-up

specialists will reach out to schedule a call with participants typically within 24 h of study enrollment (up to 72 h). The purpose of ISC calls is to (1) conduct a brief suicide risk assessment; (2) review and revise (or create if not completed at the ED/clinic encoutner) the participant's Safety Plan or Connection and Support Plan; and (3) provide support with behavioral health treatment engagement, if indicated *(see ISC call notes template in Supplemental Materials*). Support with treatment engagement may include sharing websites or phone numbers for local mental healthcare providers or help addressing psychological readiness or other barriers to attending mental healthcare appointments.

ISC participants will receive at least one phone call; five additional calls will be offered according to the following schedule: week one, week two, one month, two months, and three months. Modifications may be made to the schedule due to weekends, holidays, or participant availability. Participants can opt out of calls if they have initiated outpatient behavioral health treatment or do not feel they do not need or want them. They can also request extra calls as needed during the twelve-month follow-up period. This flexibility with the number of calls and schedule was recommended by our PLES Advisory Board as it allows tailoring of the intervention to individuals' needs and was considered pragmatic. Our version of the intervention differs from the Stanley/Brown SPI+ model [3] in that the structured follow-up will be conducted by trained Hotline follow-up specialists, rather than by social workers or psychologists. The call schedule was adopted from similar military follow-up programs [15,16], and was selected because connecting with outpatient behavioral health treatment typically takes at least six weeks for patients at low risk for suicide in our health system.

3.8.2. Two-way text message caring contacts (CC)

Two-way CC texts have been shown to halve the odds of suicide ideation and attempts [9]. The CC condition consists of an initial phone conversation after patients return home to connect and establish rapport between the trained Hotline follow-up specialist and participant, followed by a series of twenty-five caring messages sent by the same specialist over 12 months by text (*see Supplemental Materials for list/schedule of Caring Contacts)* or by email, if the participant cannot send/receive texts. The content and cadence of CC messages was developed in consultation with the PLES Advisory Board. CC will be sent according to the following schedule: three in the first week, five weekly, seven bi-weekly, four monthly; two bi-monthly, and one each for the participant's birthday, Thanksgiving, Christmas, and New Year's. The exact schedule and content of the messages may vary slightly to account for weekends and holidays. Participants may respond to texts or emails but will not be required to do so. Hotline follow-up specialists will review all incoming text messages from study participants and send personalized, unscripted responses that adhere to Motto's key principles for Caring Contacts [6].

3.9. Participant safety

Follow-up specialists may contact participants outside of the standard intervention protocol to ensure safety during times of acute crisis. Participant safety will also be assessed by text or phone call following report of moderate risk (adolescents) or high risk (adolescents and adults) for suicide on a survey. Parents/guardians of minors will be contacted if study clinicians believe participants are experiencing higher levels of suicide risk than that which was recently documented in their medical record.

3.10. Intervention fidelity

The timing, type (phone vs text vs email), and number of attempted and successful contacts from the Hotline will be recorded for each study participant. For ISC, Hotline follow-up specialists will follow a call template that includes essential elements of the intervention. Study staff will review call notes routinely and will listen to a random subset of calls to validate that key components of the intervention have been completed. For CC, study staff will listen to a random subset of initial call recordings and will review text message exchanges routinely to ensure that the timing of outgoing texts is aligned with the schedule in the protocol, and that the tone and content of text exchanges are consistent with the Caring Contacts model.

3.11. Retention

Several methods will be used to assist with participant retention. A primary phone number and an email address are required, and participants may share additional contact information. Amazon e-gift cards will be used to compensate participants for their time completing surveys. REDCap will send an invitation to complete each survey by text, email, or via phone call with a research coordinator, according to participant preference. A series of reminders will be sent through REDCap and Mosio using texts, emails, and phone calls to participants along with their survey link until the survey is complete, the window for survey completion (4-week variance) has closed, or the participant declines to complete the survey.

3.12. Data collection

Baseline data such as demographics, clinical diagnoses, and qualifying C-SSRS score will be collected from electronic health records. Participants will provide other baseline data, including the baseline C-SSRS via an online REDCap survey during the enrollment call immediately following informed consent. Outcome data will be collected via REDCap survey or over the phone at 6 and 12 months.

3.13. Measures

3.13.1. Primary outcome

The primary outcome is suicidal ideation and behavior at 6 months following enrollment, measured using the Columbia Suicide Severity Rating Scale self-report 6-item screener for primary care (C-SSRS) [17–23]. The C-SSRS self-report screener is widely used in clinical practice, including at St. Luke's. The C-SSRS score from the referring encounter will determine eligibility for the study. Participants will also self-complete the C-SSRS in the baseline survey following enrollment, and at 6 and 12 months. Participants with C-SSRS responses of “yes” to items 1 and/or 2 only are considered “low risk”, responses of “yes” to items 3 and/or 6A (lifetime suicide attempt) are considered “moderate risk”, and responses of “yes” to items 4, 5, and/or 6B (recent suicide attempt) are considered “high risk”. The C-SSRS self-report 6-item screener has strong psychometric properties for both adolescent and adult populations, including excellent sensitivity and specificity [24], convergent validity [25], and incremental validity [25].

3.13.2. Secondary outcomes

Secondary outcomes include loneliness, uptake of outpatient mental health services, return to crisis care for suicidality, and C-SSRS at 12 months.

3.13.2.1. Loneliness. Loneliness is a well-established risk factor for suicide [26–28], depression [29–32], psychological stress [32,33], and anxiety [29,30,33]. Loneliness will be measured at baseline, 6 and 12 months using the NIH Toolbox Social Relationship Scales Loneliness measure [34,35]. The measure is brief and psychometrically sound [34,35].

3.13.2.2. 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 directly via electronic health records or internal claims data.

3.13.2.3. Return to crisis care for suicidality. Return to care for suicidality will be assessed for study participants through self-report at 6 and 12 months and using electronic health records to review the number of times participants used the ED or were hospitalized, the primary diagnosis, and the reason for visit.

3.13.3. Covariates

Covariates include age, sex at birth, gender identity, sexuality, race, ethnicity, religious affiliation and practice, urban-rural designation for zip code of residence, socioeconomic status including financial security, education, and insurance provider, C-SSRS score at the qualifying encounter, comorbidities including cancer, diabetes, obesity, chronic kidney disease, chronic obstructive pulmonary disorder, HIV/AIDS, alcohol or illicit substance use, health-related quality of life [36–38], mental health diagnoses, antidepressant use, lithium use, and lethal means for suicide.

3.14. Statistical analysis

Analyses will compare the effectiveness of ISC and CC. The primary analysis population will be the intention-to-treat (ITT) population, which will include data for all eligible participants who complete enrollment and the baseline survey, regardless of intervention delivery. Data analyses will be completed using appropriate statistical software (such as R, R Studio, and SAS), using a type I error (alpha) of 0.05 (two-sided) to determine statistical significance. Analyses will be performed separately for adolescents and adults, except for a heterogeneity of treatment effects sensitivity analysis.

The primary analysis will use a linear model to test for differences between treatment groups in mean C-SSRS score at 6 months in the ITT population. The 6- and 12-month C-SSRS scores will be analyzed in the same model. The primary analysis will use a Generalized Estimating Equations (GEE) model with the identity link to test for differences between treatment arms in mean C-SSRS score at 6 months and 12 months, adjusting for C-SSRS score collected during the study baseline survey, time point, and the interaction between time point and treatment arm [39]. Hot deck multiple imputation will be used to account for participant drop out and missing outcomes [40–43]. We will assess the sensitivity of estimates to the imputation approach and variables used in the imputation algorithm, including the possibilities that missing data are more likely to reflect poor outcomes or that the missing data mechanism varies by treatment arm. A tipping point analysis will be included to assess how extreme the missing data would have to be to change the conclusions of the study [40,41].

The estimated treatment effect on the 12-month C-SSRS outcome will be considered a secondary outcome. Secondary outcomes will be modeled in a similar manner. The two age cohorts will be modeled separately, with time point included as a covariate, along with an interaction between treatment effect and time point. This will allow for reporting of the effect separately in each age stratum at each time point as well as testing whether the effect differs significantly over time. GEE with an identity link will be used to estimate the difference in means for continuous outcomes; for binary outcomes, GEE models with an identity link will allow for the estimation of the difference in proportions. The ITT population will be used for all analyses of primary and secondary outcomes, with multiple imputation used to account for missing outcome data. Baseline score will be included as a covariate for loneliness outcomes. Robust/sandwich standard errors will be used to allow for departures of the observed standard errors from classic model assumptions.

3.14.1. Sub-group analyses

Effect estimates will be generated for the following subgroups: low baseline C-SSRS score vs moderate or 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. This study has not been specifically powered to identify differing treatment effects in these subgroups.

3.14.2. Assessing long-term survival

Death by suicide is an important outcome in any suicide prevention research. Given the rare nature of this event, we would not expect to see a significant difference in this outcome between the two treatment arms over a 12-month follow-up period, thus we have not included death as a primary or secondary outcome for this study. However, we will assess the effect of these interventions on death by suicide over a 10-year period using state vital records to assess mortality and cause for death of participants in the ITT population.

3.15. Statistical power and sample size

The minimally clinically important difference (MCID) in the primary outcome (C-SSRS score) was specified a priori as 0.5 units, equivalent to half of one standard deviation [34,44]. With this MCID, power and sample size calculations for the primary analysis are summarized for each stratum below. During the trial, in their regular review of the safety and effectiveness data, the Data Monitoring Committee (DMC) noted that retention among adolescents was higher than planned (85% rather than 70%) and that the standard deviation (SD) of the primary outcome was higher than expected (2.3 rather than 2.0). The DMC recommended re-calculating the sample size to ensure the trial is adequately powered. The power and sample size calculations below include the original adult calculations and the revised adolescent calculations, which include observed values for standard deviation and retention.

- **Adolescents**: with a sample size of 720, the study will have 80% power to detect a difference of 0.5 units in the primary outcome (C-SSRS score), with SD = 2.3, allowing for up to 15% dropout.
- **Adults**: with a sample size of 790, the study will have 90% power to detect a difference of 0.5 units in the primary outcome (C-SSRS score), with SD = 2, allowing for up to 30% dropout.

4. Discussion

4.1. Summary of the trial protocol

Both ISC and CC have promising efficacy data and are feasible to implement at scale, including in low-resource settings [3,27,45–48], but it is important to know which works best. The SPARC Trial will be the first study to directly compare these interventions in adolescents and adults at risk for suicide.

4.2. Innovation & public health impact

This study is novel in several ways. Most prior research on ISC and CC was completed with active-duty military or veteran populations, meaning older adults and women were likely under-represented, and adolescents were excluded altogether. Limited research on these interventions has occurred in rural and frontier areas or Intermountain West states, despite disproportionately high suicide rates in these areas. Additionally, most previous studies recruited participants at high-risk for suicide, while this study includes individuals at low, moderate, or high risk. This pragmatic study is designed to address these gaps, while optimizing 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 referrals generated in busy primary care clinics and EDs. Both follow-up interventions – and in some cases, also the Safety Plan or CSP – will be delivered by trained specialists at the Idaho Crisis and Suicide Hotline. This models a health system-community partnership that could be realistically replicated by other clinics and health systems faced with staffing and resource constraints, including those serving rural populations.

4.3. Strengths

The SPARC Trial is innovative and will contribute to filling key gaps in the suicide prevention literature. Idaho is culturally and geographically similar to many states with high suicide rates in the US. Many residents reside in rural and frontier areas where suicide rates tend to be higher and mental health resources are limited. This study is statistically powered to report results separately for adolescents for whom limited data on ISC and CC are available. Suicide prevention studies often only include participants with a suicide attempt history; this study includes participants with a wider spectrum of risk. The study will utilize non-clinician follow-up specialists at the Idaho Crisis and Suicide Hotline to deliver evidence-based interventions virtually, making the interventions feasible to deliver at scale even in low-resource settings, including rural areas.

4.4. Limitations

Residents of rural and frontier areas and Intermountain West states are important to include in suicide prevention research. However, there is limited racial and ethnic diversity in this region. This will limit generalizability of findings to racial and ethnic minorities. This study does not have a non-active control arm, which means that the study will be unable to draw conclusions about the efficacy of either intervention compared to a control condition. Previous studies have published efficacy data for adults [3,6].

5. Conclusions

This study is expected to have immediate and enduring public health impact. All participants will receive an evidence-based intervention that may significantly reduce their suicide risk. Data from this study will allow healthcare and community leaders to select and scale up whichever of these brief contact interventions is most effective for reducing suicidal ideation and behavior among patients at risk for suicide.

Funding & other support

Research reported in this publication was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (HIS-2018C3-14695). The information presented in this publication is solely the responsibility of the authors and does not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Data and Safety Monitoring was provided by the Institute of Translational Health Sciences at the University of Washington, supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1 TR002319. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Study data were collected and managed using REDCap electronic data capture tools[1] hosted at the Institute of Translational Health Sciences. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

REDCap at ITHS is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1 TR002319.

[1] Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009 Apr;42(2):377–81.

Clinical trial registration

The SPARC Trial is registered at ClinicalTrials.gov (NCT04893447).

CRediT authorship contribution statement

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Declaration of Competing Interest

The authors have no competing interests to declare.

Data availability

Data will be made available on request.

Acknowledgements

We gratefully acknowledge the support of Mira Grieser, Louisa Fresquez-Hudson, Tricia Ramgoolie and our entire team at the Patient-Centered Outcomes Research Institute (PCORI), our Applied Research, regulatory, and compliance coordinators and IRB analysts at St. Luke's, especially Nicole Russell, Bradi Hutchison, Ella Wardell, Sarah Pedersen, Denise Strasser, and Jana Thomas. We are grateful to Lee Flinn for her

leadership and support at the Idaho Crisis and Suicide Hotline, and for our amazing team of follow-up specialists, including Jessica Torres and Maggie Harper. We appreciate the whole St. Luke's team that prioritized and supported this work, especially our executive sponsors, Dr. Jim Souza and Dr. Bart Hill, our Communications lead, Joy Prudek, our Research Finance lead, Terri Lawrence, our Legal team, David Barton and Aubrey Lyon, our Risk Management and Compliance Leads, Steve Skaggs, and Steve Pitts, Research Department Leaders including Dr. James Loveless, Janet Hines, Katelyn Penney, and Jeanette Gibbon, plus Rick Bassett and all members of the St. Luke's IRB. We are grateful to Amy Hicks and Mallorie Getto for lending their clinical expertise to help keep participants safe, along with the whole Collaborative Care Social Work team and all our colleagues in the Behavioral Health Service Line. We would like to thank the hundreds of St. Luke's physicians, advanced practice providers, and social workers in primary care and EDs who referred their patients to the study. We recognize with gratitude the contributions of Dr. Greg Brown and Dr. Barbara Stanley for developing and delivering an excellent training on the Safety Planning Intervention, and to Dr. Chris DeCou for leading the design of the Connection and Support Plan for patients at low risk for suicide. Special thanks to Alan Godjics for creating the enduring version of the Safety Planning Intervention and Connection and Support Plan trainings. We wish to recognize the meaningful contributions of all members of our People with Lived Experience with Suicide Advisory Board with special thanks to Alana Bruner and Jeremy Stockett for supporting and engaging in our work with this group. Finally, we would like to extend our deepest thanks to our SPARC Trial participants, who made space in their lives to participate in this study during an exceptionally challenging time.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2023.107268.

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