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Study Protocol: A randomized controlled trial of suicide risk reduction in the year following jail release (the SPIRIT Trial)

Jennifer E. Johnson[*],
Division of Public Health, Michigan State University College of Human Medicine, 200 East 1st St Room 366, Flint, MI 48503.

Richard Jones,
Brown University Warren Alpert Medical School, 700 Butler Drive, Providence, RI 02906.

Ted Miller,
Pacific Institute for Research and Evaluation, 11720 Beltsville Drive, Suite 909, Calverton, MD 20705.

Ivan Miller,
Brown University Warren Alpert Medical School, 345 Blackstone Blvd, Providence, RI 02906.

Barbara Stanley,
Columbia University, 1051 Riverside Drive, Unit 42, New York, NY 10032.

Greg Brown,
University of Pennsylvania Perelman School of Medicine, 3535 Market Street, Room 2032, Philadelphia, PA 19104.

Sarah A. Arias,
Brown University Warren Alpert Medical School and Butler Hospital, 345 Blackstone Blvd, Providence, RI 02906.

Louis Cerbo,
Rhode Island Department of Corrections, 1375 Pontiac Avenue, Cranston, RI, 029020.

Julie Rexroth,
Genesee County Jail and Corizon Health, 1002 South Saginaw Street, Flint, MI 48502.

Holly Fitting,
The Providence Center, 528 N. Main Street, Providence, RI, 02904.

Danis Russell,
Genesee Health System, 420 West 5th Avenue, Flint, MI 48503.

Sheryl Kubiak,
Wayne State University School of Social Work, 5447 Woodward Avenue, Detroit, MI 48202.

Michael Stein,
Boston University, 715 Albany Street, Talbot Building T2W, Boston, MA 02118.

[*]Corresponding author: JJohns@msu.edu.

Christopher Matkovic,
Rhode Island Hospital, 593 Eddy Street, Providence, RI 02903.

Shirley Yen,
Brown University Warren Alpert Medical School, 700 Butler Drive, Providence, RI 02906.

Brandon Gaudiano,
Brown University Warren Alpert Medical School and Butler Hospital, 345 Blackstone Blvd, Providence, RI 02906.

Lauren M. Weinstock
Brown University Warren Alpert Medical School, 700 Butler Drive, Providence, RI 02906.

Abstract

Purpose.—This article describes the protocol for a randomized effectiveness and cost-effectiveness trial of Stanley and Brown's Safety Planning Intervention (SPI) during pretrial jail detention to reduce post-release suicide events (suicide attempts, suicide behaviors, and suicide-related hospitalizations).

Background.—With 10 million admissions per year and short stays (often days), U.S. jails touch many individuals at risk for suicide, providing an important opportunity for suicide prevention that is currently being missed. This study (N=800) is the first randomized evaluation of an intervention to reduce suicide risk in the vulnerable year after jail release. Given that roughly 10% of *all suicides* in the U.S. with known circumstances occur in the context of a criminal legal stressor, reducing suicide risk in the year after arrest and jail detention could have a noticeable impact on national suicide rates.

Design.—Pretrial jail detainees at risk for suicide were randomized to SPI during jail detention plus post-release phone follow-up or to enhanced Standard Care. Outcomes assessed through 12 months post-release include suicide events, suicide attempts, weeks of active suicide ideation, severity of suicide ideation, time to first event, psychiatric symptoms, functioning, and cost-effectiveness. Methods accommodate short jail stays and maximize trial safety and follow-up in a large sample with severe suicide risk, access to lethal means including substances and firearms, high rates of psychiatric illness, and unstable circumstances.

Conclusion.—Adequate funding was important to create the infrastructure needed to run this large trial cleanly. We encourage funders to provide adequate resources to ensure clean, well-run trials.

Keywords

Suicide; prevention; criminal justice; jail release; randomized controlled trial; cost-effectiveness

There were more than 10 million admissions to U.S. jails in 2017.[1] Jailed individuals have high rates of past-year mental health (56%) and substance use (66%) disorders,[2] and a disproportionate risk for suicide. Roughly half (40–50%) of incarcerated individuals report suicide ideation or behavior at some point in their lives, and 13–20% report having attempted suicide.[3–5] Arrest and jail detention often occur in the wake of other stressors that further exacerbate suicide risk. The epidemic of suicide *during* jail detention has been

recognized. Less attention has been paid to the high suicide risk and mortality following jail release,[6–9] as individuals re-enter their communities, are faced with financial, legal, and social stressors, and have increased access to lethal means (e.g., drugs, firearms, vehicles). Given that roughly 10% of *all suicides* in the U.S. with known circumstances occur following a recent criminal legal stressor[10] (often arrest and jail detention), reducing suicide risk in the year after jail detention could have a noticeable impact on national suicide rates.

Most (95%) people who are arrested are booked into jail.[11,12] Unlike prison, where individuals have been sentenced and often stay years, pretrial jail detainees are not yet sentenced. Most are released within days.[13] Therefore, brief interventions are required. Fortunately, previous studies support the effectiveness of brief interventions for reducing suicidality among other high-risk (e.g., emergency department, inpatient) populations. Stanley and Brown's Safety Planning Intervention (SPI; initially a single session intervention which now often includes telephone follow-up), is a brief, adjunctive suicide risk reduction intervention developed for suicidal patients presenting to urgent care settings. SPI plus phone follow-up increases treatment utilization and reduces subsequent suicide attempts among at-risk individuals in emergency rooms.[14,15] However, there is no previous large-scale randomized controlled trial (RCT) of this intervention (or any other) for reducing suicidality in the year following jail release.

This protocol paper describes an RCT to evaluate the effectiveness and cost-effectiveness of SPI plus phone follow-up, relative to enhanced standard care (SC), to reduce suicide events (attempts, suicide behaviors, suicide-related hospitalizations, and suicide deaths) among 800 male and female releasing pretrial jail detainees in 2 states. This study represents the first randomized evaluation of a suicide prevention intervention in the vulnerable year after jail release. Novel aspects of the trial include recruitment and training of embedded community counselors to bridge between jail and community mental health services, safety procedures for post-release telephone intervention sessions and outcome assessments, limited exclusion criteria (i.e., many participants are psychotic, manic, and/or using drugs and alcohol), use of both self-report and medical records from area hospitals to identify suicide attempts and hospitalizations, managing post-randomization ineligibility, and overall trial management in an extremely high-risk population. We describe the bioinformatics and workflow processes used to manage this large, complex trial in the context of high risk and multiple layers of regulation, including two interfacing custom-programmed REDCap databases for study counselor case notes, research assistant clinical interviews, and efficient reporting of the more than 1,000 expected adverse events to date.

2. Method

The SPIRIT (Suicide Prevention Intervention for at-Risk Individuals in Transition) RCT compares the Safety Planning Intervention (SPI) plus enhanced standard care (SC) to enhanced SC alone among 800 (male and female) pretrial jail detainees who are at risk for suicide events (i.e., they endorse suicidal ideation with some intent to act or a suicide attempt in the past month). SPI consists of an in-person safety planning meeting during

jail detention, and 4 post-release phone calls over 6 months post-release. Study assessments occur at baseline, and 1, 4, 8, and 12 months post-release. Outcomes include:

1. Number of suicide events (a composite of attempts, behaviors, suicide-related hospitalizations, and suicide deaths) in the year following jail release (*primary*)
2. Number of suicide attempts, weeks of active suicidal ideation, severity of suicide ideation, time to first suicide event, psychiatric symptoms, and functioning *(secondary)*
3. Hypothesized mechanisms of SPI's effect on suicide events: (a) treatment utilization, (b) suicide-related problem-solving, and (c) sense of belongingness
4. Cost, cost-offsets, and cost-effectiveness (which drive adoption and sustainability in re-entry settings[16–18])

The trial is funded by the National Institute of Mental Health (NIMH), the National Institute of Justice (NIJ), and the Office of Behavioral and Social Science Research (OBSSR). It is approved by Michigan State University's Institutional Review Board and regulatory bodies overseeing jail research in our participating jails, and NIMH's Data Safety and Monitoring Board. The trial is registered at clinicaltrials.gov (NCT02759172).

2.1. Potential population-level impact

Most individuals in the U.S. who die by suicide are not in mental health treatment at the time of their suicide.[10,19] Recent suicide prevention agendas explain that to prevent suicide on a population level, it is necessary to find individuals at risk wherever they are, and one of those places is in the justice system.[20] Our query of the National Violent Death Reporting System (NVDRS) general population data indicates that roughly 10% of *all suicides* with known circumstances occur in the context of a recent criminal legal stressor (typically arrest and jail detention).[10] Therefore, if the effects of brief suicide prevention interventions found in other at-risk populations (relative risks of 0.38 – 0.63[21–25] for attempts and 0.09 for suicide deaths[26]) hold for recently released jail detainees, implementation of this intervention could result in a noticeable reduction in U.S. suicide rates.

Because the goal of the study is to contribute to population-level suicide prevention efforts as quickly as possible, the study was designed with intervention scalability and future implementation in mind. For example, the study includes cost-effectiveness analyses to inform national decision-making about adoption of SPI in jails. Follow-up phone calls like SPI's are already known to be cost-effective in other health care settings.[27] Our research team includes collaborators from the jails and affiliated community mental health centers to provide input about the outcomes we should assess to be most persuasive to correctional behavioral health policy-makers (in this case, cost-effectiveness, service linkage, and re-arrest) to ensure that the trial has utility.[28] In addition, the study addresses known service linkage challenges between correctional and community mental health services nationally that are a priority for both systems;[4,17,29–32] better communication and cooperation between justice and community agencies has also been identified as a priority for suicide prevention.[33] SPI fits known needs of the jail and affiliated community treatment systems in which it will be provided; namely, it is a brief, flexible, low-cost intervention that

can be delivered by a broad range of clinicians in a crisis-oriented setting. The trial takes place in the community and uses the community providers who would eventually deliver the intervention in routine practice, and has minimal exclusion criteria for patient participants. Thus, this trial has been designed to be as relevant to informing real-world decisions about adoption as possible.

2.2. Preliminary Studies

2.2.1. Relevant findings from our suicide prevention research.—

We conducted an online query of suicide data from the National Violent Death Reporting System (NVDRS).[10] This system includes data from 32 states. In 2016 (the most recent year available), there were 22,517 suicides with known circumstances (92% of a total of 24,596 suicides) in the 32 NVDRS reporting states. Of the suicides with known circumstances, 8.3% occurred in the context of a recent criminal legal problem and 3.3% in the context of another kind of legal problem. Over the most recent 10 years of data (2007 – 2016), these numbers ranged from 8.2% - 9.6% (mean of 9.0%) and from 3.0% to 4.2% (mean of 3.9%) respectively. Since it is not clear how much these groups overlap, we estimate that as many as 10% of suicides with known causes occur in the context of a recent criminal or legal stressor.

Safety planning generally and SPI specifically is already the expected standard of care in non-jail settings.[34–36] A single session of SPI produced greater decreases in suicidal ideation at the 3 month outcome assessment among suicidal ED patients relative to treatment as usual (TAU), with a large between-group effect size (d=0.88).[37] Studies which added structured phone follow-up intervention included (1) SAFE VET, a large demonstration project evaluating implementation of SPI in 5 Veteran's Affairs (VA) emergency departments (EDs),[38] (2) a cohort comparison study of SPI in 8 VA EDs, 4 in which eligible patients received the intervention and 4 matched VA EDs in which patients received TAU, and (3) a cohort study of 96 veterans who visited the ED for a suicide-related concern twice over 12 months and were discharged. These studies suggest that SPI reduces suicide attempts, increase subsequent outpatient mental health and substance use treatment utilization.[38] Survey data from these studies suggests that participants use the written safety plan created in the first session and view it as helpful. SAFE VET participants stated the most helpful components of the SPI phone follow-up calls were having someone check on them regularly (75%) and feeling cared for (58%); hence, a sense of belonging[39] is a hypothesized mediator in the proposed study. As evidence of SPI's sustainability in EDs, a vast majority (90%) of ED staff indicated that SPI was acceptable and that it had become integrated into routine care.[14]

2.2.2. Relevant findings from our criminal justice intervention research.—

In our previous work, re-entering individuals[40] and their providers[41] emphasized the importance of having at least some contact with the same provider before and after release. However, released individuals often face crises within days of release, sooner than is feasible to meet them for an in-person intervention session.[40–44] Our work has found that in-person contact during incarceration and phone contact with the same person after release (*as we propose to do in the current study*) is feasible.[42] Furthermore, participants found

post-release phone sessions to be acceptable and meaningful: *"calling proves that they care."*[42,45] Although the phone numbers and locations of our target population often change, our research with recently incarcerated individuals (as well as with suicidal individuals in the community[24,25,46]) has shown that telephone intervention is feasible, acceptable, and powerful in building trust and reducing risk among these disenfranchised, often isolated, populations.

Prior to this RCT, we conducted a survey of employees (N = 61 providers, correctional officers, and administrators) in the jail in the more economically distressed of our two study locations (Genesee County Jail [GCJ] in Flint, MI). 70% of jail employee respondents expressed concern over the risk of suicide among people being released to the community. Only 4 (7%) thought the SPI was *not* feasible at GCJ, and only 2 (3%) thought that it would *not* be implemented, if found effective. Thus, jail employee perspectives support the importance, feasibility, and likely implementation of SPI.

2.3. Study Sites

Recruitment takes place at the Rhode Island Department of Corrections (RIDOC) and GCJ jails. RIDOC jail has 15,000 commitments per year;[47] GCJ has about 13,000. The average daily censuses are 680 and 600, respectively. At each site, 13–14% of detainees are female. In RIDOC, 24% are African-American and 18% are Hispanic. In GCJ, 55% are African-American and 5% are Hispanic. Private areas are available for research procedures. ***Generalizability***. Nationally, jails tend to serve metro areas or counties, covering areas similar in size to those served by the RIDOC and GCJ jails. Nationally, as in our study sites, most people passing through jails are charged with misdemeanor offenses, such as public drunkenness, trespassing, shoplifting, and public disturbances,[48] tend to be young (with most in their 20s and 30s) and to have low SES.[47,49,50] Length of stay at our sites (median of 4 days)[51] is similar to reported national rates (65% weekly turnover rate).[13]

2.4. Interventions

2.4.1. Enhanced SC control condition.—

NIMH's Road Ahead report states that, "policy makers need to know if a new program works better than what is currently available, or if it is better than doing nothing at all" (p. 10). In some cases, the most important question for informing real-world practice is: "how much better is the new program than care-as-usual and at what cost?" (p 11).[52] Because our goal was to design a study that would inform jail and community mental health policy decisions, we decided to employ an enhanced Standard Care (SC) control condition. Enhanced SC consists of treatment as usual plus monitoring and emergency referral, as is required to fulfill ethical obligations to trial participants. To determine the naturalistic effects and costs of adding SPI for at-risk pretrial jail detainees, participants in both conditions may receive other treatments available to them and we do not exclude participants receiving other treatment. We characterize treatment as usual for each condition as part of our service utilization assessment.

The current standard strategy for caring for suicidal jail detainees nationally is assessment and psychiatric stabilization while in jail with essentially no community follow-up.[53–58] Our study sites typically conduct screening (by an intake worker) and assessment of risk

(by a social worker). Individuals considered to be at acute risk of suicide are placed on psychiatric observation in the jail, where they are stabilized to the extent possible during their jail detention (i.e., they may be high, manic, or floridly psychotic when detained and may only be in jail for a few days). If jail staff determine their imminent suicide risk to decrease while they are in jail, they leave observation, enter the general jail population, and then are released with no community follow-up. If an individual on observation is released on bail, the jail asks the person picking the detainee up to take him or her to the ED for evaluation; no further follow-up is provided. If an individual on observation goes to court, the jail provides a letter asking the court to have the person evaluated by a mental health professional before releasing him or her; no further follow-up is provided. Individuals identified by the jail as having a severe mental illness (i.e., schizophrenia, bipolar disorder) are provided with post-release appointments. The study provides post-release monitoring (via research assessments) and emergency referral for trial participants on the basis of suicidality, in keeping with ethical obligations to trial participants. This should be considered enhanced standard care compared to current jail practice.

2.4.2. SPI.—Stanley and Brown's Safety Planning Intervention (SPI)[59] is a brief, adjunctive intervention designed to reduce subsequent suicidal behavior in high-risk populations. SPI has been identified as a 'Best Practice' in the joint Suicide Prevention Resource Center-American Foundation for Suicide Prevention (SPRC-AFSP) Registry. The core element of SPI is the collaborative development of the Safety Plan, which is a prioritized written list – in the patient's own words – of coping strategies and supports that individuals can use during or preceding suicidal crises. To address challenges of continuity of care across vulnerable transitions (e.g., from ED to community treatment, from inpatient to outpatient treatment), SPI often includes telephone follow-up with the same treatment provider to conduct periodic risk assessment and mood checks, review the Safety Plan, problem-solve obstacles to treatment, and assist with linkage to services. SPI incorporates evidence-based suicide prevention strategies, including facilitation of suicide-related safety skills, identification of social supports and emergency contacts, lethal means restriction, service linkage, and motivational enhancement to promote community treatment engagement.[14,59] The goal with SPI in jail settings is not to solve all of patients' challenges with a single brief intervention, but rather to intervene in targeted ways to reduce suicide risk and to improve linkage to mental health care and other needed services. Consistent with the need for rapid, flexible intervention for pretrial jail detainees, in this trial, SPI includes one in-person meeting in jail to create a safety plan and then 4–8 telephone meetings in the 6 months after release to review the safety plan and problem-solve barriers to use of safety behaviors after jail release.

In this trial, the ***initial session during jail detention*** takes place in person at the jail. It includes a comprehensive clinical suicide risk assessment and development of a Safety Plan, a prioritized list of coping strategies and sources of support that patients can use during or preceding suicidal crises. The Safety Plan uses a simple, easy-to-follow format meant to enhance individuals' sense of self-control over suicidal urges and thoughts. The in jail session begins with a risk assessment, during which the clinician obtains an accurate account of the events that transpired before, during, and after participants' self-identified most recent

suicidal crisis. This description may include the activating events as well as the patient's reactions to them. This discussion helps to facilitate the identification of warning signs to be included on the Safety Plan, as well as the identification of specific strategies or behaviors that may have been used to alleviate the crisis. The SPI hierarchically-arranged steps are: (1) Identification of warning signs; (2) Use of internal coping strategies including distraction; (3) Social contact with others who may offer support and distraction from the crisis, without discussing suicidal thoughts; (4) Contacting family members or friends who may help resolve a crisis and with whom suicidality can be discussed; (5) Professional contacts including crisis hotline number, nearest ED address, clinicians' contact; (6) Restriction of access to lethal means. Patients are instructed to first recognize when they are in or at risk for crisis (Step 1) and then to follow Steps 2 through 6 as outlined in the plan. If following the instructions outlined in Step 2 fails to decrease the level of suicide risk, then the next step is followed, and so forth. SPI conveys a very clear path to follow. Since cognitive resources are taxed during emergencies, a clear predetermined strategy is most effective to mitigate risk.[60,61]

2.4.2.2. Post-Release Telephone Sessions.: The same clinician who met with the individual in jail contacts him or her 4 times by phone at key time points (within the first week, 1 month, 3 months, and 6 months) after jail release, providing the most frequent contact in the highest risk period just after release. For individuals in crisis, clinicians have the option of scheduling an additional 4 calls. Calls have an agenda: (1) mood check and suicide risk assessment; (2) review and revise the safety plan; and (3) review treatment options and problem-solve obstacles to treatment. Clinicians ask when the person's next mental health appointment is scheduled, assess motivational and structural barriers to attendance, and help address these barriers. Clinicians can help identify treatment and other resources and facilitate appointments for patients if needed. If patients are determined to be at acute risk, we take appropriate action to maintain their safety, which may include contacting existing providers, ED referral, or calling the police.

2.4.3. Hypothesized mechanisms of SPI and fit to target population.—

The suicide risk suicide risk reduction strategies utilized in SPI with phone follow-up (including self-monitoring of crisis warning signs, internal and external coping strategies, service linkage, identification of social supports and emergency contacts, continuity of care from jail) address critical potential mechanisms of suicide reduction in our target population: treatment utilization, problem-solving, and belongingness.

2.4.3.1. Treatment utilization.: Mental health and substance use treatment utilization is strongly linked to suicide risk reduction.[62–64] SPI increases treatment utilization following suicide-related ED visits.[14,15] SPI helps problem-solve service linkage issues, which present challenges for re-entering individuals given difficulties with transportation, service availability, stigma, and trust of medical institutions. In fact, service linkage is recognized by jails as the primary, top-priority barrier to post-release health outcomes.[4,29–32] SPI also works to increase motivation for service engagement. Finally, continuity of at least one provider across the transition from jail to the community has been described as essential for post-release care.[40,41,43,45] SPI's blended in-person/phone approach delivered

by community mental health center clinicians provides this continuity, responding to recommendations of the National Confidential Inquiry (NCI) into Suicide and Homicide[33] to reduce community-level suicide rates through better communication and cooperation between justice and community mental health agencies.

2.4.3.2. Suicide-related problem solving.: There is a robust association between problem solving deficits, which are prevalent among incarcerated populations,[5,65–67] and suicide risk in community[68–70] and incarcerated[5,65,71] populations. Stressful life events, also common in our target population,[57,72–74] can also interfere with cognitive processes needed for deliberation, further priming poor and impulsive decision making.[75–77] SPI facilitates the use of safety-related coping skills (skills which reduce suicide risk[60,61]) for managing crises using a template for rehearsing safety behaviors. The written safety plan, developed when participants are in controlled setting with time to deliberate (i.e., jail), allows individuals the opportunity to make decisions now that support safety in future situations when their ability to generate and weigh options might be more limited (e.g., in the context of an acute life stressor, psychiatric symptom exacerbation, etc.) or when the environment is less controlled (i.e., less supervision, more access to lethal means). Thus, SPI helps at-risk individuals make and enact safety decisions now so that they do not need to generate, weigh, and execute options for the first time when faced with an acute crisis.[75–77]

2.4.3.3. Belongingness.: A sense of thwarted belongingness, defined as the belief that one does not have meaningful relationships with others or that others cannot relate to an individual's experience, is associated with increased suicide risk.[39] This construct of thwarted belongingness is especially relevant to criminal justice-involved populations because they are often socially marginalized. In fact, loneliness, interpersonal conflicts or stress, and having no one with whom to discuss bad news are strong predictors of suicide attempts and deaths in incarcerated samples.[57,78–81] SPI harnesses social supports and identifies contacts to reduce isolation in times of crisis, enhancing belongingness. Moreover, because recent detainees are often disenfranchised and marginalized,[41] receiving outreach in the form of caring telephone calls may also serve to increase a sense of belongingness.[42,43]

2.4.4. Clinicians.—Because external validity is a primary concern in this study, we have hired the community clinicians who would eventually deliver this intervention in regular practice to moonlight as clinicians on this study. They are recruited from the community mental health agencies contracted to provide mental health services to individuals re-entering their respective communities from jail and prison (Genesee Health System in MI and Providence Center in RI). Because these agencies' clinicians serve a large number of re-entering individuals, they are experienced in working with justice-involved clients and with common co-occurring problems, such as substance use and partner violence. In addition, these embedded clinicians can facilitate the linkage of participants to services at their respective community mental health agencies.

We hired and trained master's-level clinicians (to cover the two jails 7 days per week plus back-ups) from the two states to moonlight on this study. In-person initial training consists of reviewing the SPI rationale, materials, and strategies; audio-taped demonstrations; and live practice sessions with feedback. After the in-person training, counselors record two

mock SPI sessions, which are certified for adherence and competence by Drs. Weinstock, Stanley, and Brown before counselors can begin seeing study participants. Counselors who do need meet expectations are given feedback and record additional practice sessions until they do.

In-jail treatment sessions are recorded using credit-card sized digital audio recorders that we are able to bring in and out of the jail. Recording of phone sessions uses a digital audio recorder connected to a telephone headset system and transmitter patch. Study clinicians upload the recordings to our secure research audio/video server from their (remote) computers. Study supervisors, consultants, and fidelity raters can then listen to study intervention sessions from their (local or remote) computers, and supervision takes place by phone. Using encrypted audio recorders and a secure file transfer server allows counselors in different states to upload sessions for review by supervisors across the country. Supervision includes weekly group supervision and case discussion by phone, and individual phone consultation on an as-needed basis. Fidelity ratings occur throughout the RCT, with retraining as necessary.

2.4.5. Treatment integrity.—

We use Stanley and Brown's existing SPI fidelity rating scale, the Safety Plan Intervention Rating Scale to rate fidelity of 10% of in-jail and post-release SPI audio recordings.

2.5. Participants

Unsentenced male and female pretrial jail detainees are eligible for the study if they are: (1) 18+ years of age; (2) at risk for suicide, operationalized as a past-month suicide attempt or a response of "yes" on item 4 or 5 on the initial 5 screening questions of the Columbia Suicide Severity Rating Scale (C-SSRS),[82,83] indicating the presence of at least some active suicide ideation with some intent to act in the past month (i.e., individuals at higher risk, such as those who report intent with specific plan and/or suicide attempt/s in the last month, are also included); and (3) speak and understand English well enough to understand questionnaires when they are read aloud. We exclude people who: (1) expect to be sentenced to prison (i.e., expect to go directly to prison, not home, from the jail), (2) cannot provide the name and contact information of at least two locator persons, and/or (3) do not have access to any telephone. In our previous jail studies, most people screened (92%) *owned* a phone and virtually all had access to a phone through owning one, a relative/friend, or an agency. Some individuals are intoxicated, high, manic, and/or flagrantly psychotic when arrested and brought to the jail. We do approach individuals who are on psychiatric observation at the jail (typically for suicidality or other safety concerns), who, in the opinion of the nurse on duty, are stable enough to be approached for research. Our limited exclusion criteria (i.e., many participants are psychotic, manic, and/or substance dependent) increase generalizability of results to the full range of jailed individuals at risk for suicide. However, we do not include individuals who are too impaired to provide informed consent (i.e., are unable to respond coherently to the screening and consent process). If someone reports being or appears to be intoxicated or high, we postpone screening and consent procedures.

2.6. Recruitment

Participants who are on mental health watch at the jails (often for suicide risk) or who volunteer to be screened for the study are called into individual meetings at the jail with study staff. After obtaining potential participants' consent for screening, research assistants (RAs) screen potential participants privately to determine eligibility. RAs explain all aspects of the study, including confidentiality and its limits, and address questions. If the participant agrees, s/he signs an informed consent form and complete the baseline assessment. We ask participants if they would like us to read consent forms aloud.

Recruitment began on May 11, 2016 and ended with the recruitment of the 800th eligible participant on November 13, 2018. Our goal was to enroll an average of 30 participants (who meet study criteria and consent to participate) per month for 27 months, resulting in a randomized sample size of 800 (500 in RI, 300 in MI). We reached this goal in 30 months. Given the 2,333 commitments per month (28,000/year) at these two jails and high rates of suicidality among jailed individuals, potential participants are available; the rate-limiting factor was research staff person-power. Given that many people are arrested on the weekend and released from court on Monday, we hired enough RAs and clinicians to recruit and intervene at the jails 7 days per week.

2.7. Randomization

Randomization to SPI or enhanced SC in a 1:1 ratio occurs in the jail after the baseline assessment; therefore, all baseline assessments are blind. Randomization is stratified by jail (i.e., GCJ or RIDOC), gender, and yes/no history of suicide attempts. We do *not* stratify by jail suicide watch status because entry and clearance from watch depend on jail staff availability, meaning that watch status is not a reliable indicator of suicidality. Interventionists meet with those assigned to the intervention condition within 24 hours of randomization. Typically, we recruit participants in the morning to meet with the interventionist/s scheduled to come to the jail that afternoon or evening, including weekends (given that many people are arrested on Friday or Saturday and released Monday or Tuesday). Immediately after randomization, RAs also review the study outcome assessment schedule, means of contacting the research staff, and participants' contacts with all participants. A different RA, who is blind to intervention assignment, performs telephone outcome assessments. The study statistician, Dr. Jones, prepared the randomization schedule before the first participant was enrolled.

2.8. Retention, attrition, and power

2.8.1. Retention.—Outcome assessments (at 1, 4, 8, and 12 months post-release) are typically conducted by phone. If a participant is reincarcerated or at a local residential treatment facility, RAs conduct the outcome assessment in person. Although we have conducted in-person outcome assessments for previous trials enrolling incarcerated women,[84–86] this required RAs to travel to community locations to meet participants (it was easier for RAs to go to participants than to try to get participants to our research offices). As a way to increase efficiency in this large trial and to increase safety for RAs (often young and female) in this study which enrolls both male and female participants, we

decided to conduct outcome assessments by phone, when possible (i.e., participant is not reincarcerated).

We employ several approaches that we have found helpful in achieving low attrition rates (0–20%) in our previous intervention studies with individuals re-entering the community after incarceration (including those who were homeless).[42,44,84–86] These include study staff's strong relationships with participants and efforts to value and appreciate their study participation. RAs call and text (with permission) participants, mail them letters, and maintain a list of 2 other people who always know where participants reside. We also request (optional) releases to get updated locator information from probation and parole offices and residential treatment facilities. If a participants call (or we reach them by phone) within the interview window (+/− 31 days from the interview due date), RAs conduct the interview right then if possible. Locator information is updated at each study contact. Telephone outcome assessment (removing the need for transportation) and study team flexibility in scheduling outcome assessments (i.e., on evenings or weekends) also facilitate participant retention. Participants are remunerated $60 for each outcome assessment.

2.8.2. Attrition estimates.—Our target population is pretrial detainees who are returning to the community. We exclude individuals who expect to serve prison or jail time as part of a sentence. However, we expect 6–8% of the pretrial jail detainee participants we consent who do *not* expect to be sentenced to serve prison or jail time will be sentenced anyway. These individuals do not leave jail for the community before serving their sentences (i.e., they go directly to prison or longer-term jail accommodations, not home), meaning that they are not actually eligible for the study, which is a study of suicide prevention in the year after release from *pretrial jail detention*. Therefore, individuals who are sentenced to prison or jail time rather than being released back to the community are not followed, and have been included in our study attrition estimates. This is a standard approach taken in other re-entry studies (e.g., R01 AA021732; U01DA016191[87]) that must consent participants when their sentencing or release status is still unknown. Sentencing occurs independent of study condition, so the exclusion of these individuals from analysis (no "at-risk" community months) is unlikely to influence internal validity. We follow all remaining participants who are released from jail to the community after the index incarceration through the 12-month post-release period regardless of reincarceration, continued participation in SPI or enhanced SC, or subsequent suicide attempts or hospitalizations. Of the 92–94% of participants who are released from jail to the community after the index incarceration, we estimate that post-release outcome assessment rates will be 82% at 1 month, 80% at 4 months, 75% at 8 months, and 70% at 12 months, with 85% of participants providing data for at least one post-release outcome assessment. Therefore, we expect that 78% (85% of the 92% who are released from jail) of the 800 enrolled participants will provide evaluable outcome assessment data. Count (e.g., suicide events) data from missed assessments are gathered at later assessments when they occur, and we collect medical record and death record data on all eligible (i.e., released) participants, providing additional sources of otherwise missed data.

2.8.3. Power.—Our primary outcome (suicide events) is a composite of the number of suicide attempts (including suicide deaths), suicide behaviors (C-SSRS-defined aborted attempts, interrupted attempts, and preparatory behaviors), and suicide-related hospitalizations. Previous trials of brief suicide risk reduction interventions in other at-risk populations have described ratios rather than count outcomes, yielding relative risks of 0.38,[24,25] 0.48,[23] 0.56,[22] 0.56,[21] and 0.63 for suicide attempts (0.09 for suicide deaths[26]), 0.32[88] and 0.50[24,25] for suicide behaviors, and 0.55[24,25] for hospitalization. This study is powered to detect an effect size at the lower end of the range of y/n effect sizes of successful similar studies, RR of 0.56 for any attempts, 0.50 for any behaviors, and 0.59 for any hospitalization. In reality, our power will be better because we are measuring number of events (i.e., count outcomes), not just yes/no event occurrence.

2.8.3.1. Base rates.: The literature provides information about base rates of suicide *deaths* among general populations of jail detainees, but not suicide *events* among jail detainees with suicide ideation. Therefore, we estimated control condition event rates among suicidal jail detainees conservatively as half the rates observed in ED and inpatient studies.[24,25,46]

2.8.3.2. Clinical significance.: We express clinical significance using the area under the curve (AUC) statistic.[89] The AUC is flexible and has a direct and clinically relevant interpretation: the proportion of pairs, sampling one person exposed to the active treatment and another to the control, where the member of the pair exposed to SPI has a more favorable outcome profile. Our expected main effects translate into an AUC of 0.58, indicating that there is a 58% chance that a randomly selected participant from the enhanced SC condition will have more suicide events than a randomly selected person from the SPI condition. This corresponds to a d=.28,[89] meaning that our study is powered to detect small effects. This is the median effect size for suicide attempts reported in the literature, and we have superadequate power to detect this effect (96.5%; see below).

2.8.3.3. Estimation.: We estimated power using Monte Carlo methods and 1001 replications per condition. Assuming: (1) the outcome is a total count of three outcomes [suicide attempts (including deaths), suicide behavior, and suicide related hospitalization] analyzed with ordinal logistic regression, (2) outcomes are correlated at 0.50 and have base rates of 10%, 18% and 12% in the control group and 5.5%, 9%, and 7% in the SPI group (where these percentages reflect cumulative annual incidence), and (3) a baseline sample of 800 released persons of whom 78% are expected to provide evaluable data; using a type-I error risk of 5%, we will have 96.5% power to detect hypothesized main effects. Power is good but the study is not over-powered given the sensitivity of power to estimated effect sizes: assuming the control condition rates are as estimated, the minimum differences we can detect with 80% power would be SPI condition rates about 6.5% risk of attempts, 10.2% risk of behaviors, and 8% risk of hospitalization. The detectable effect size for ***mediation*** effects range from 0.11 to 0.13 as the correlation of the intervention and the potential mediator ranges from 0.2 to 0.5. Thus, we have power to detect any mediation effect that is clinically significant.

2.8.4. Non-Completers and Non-Responders.—Given the unpredictable lives of our target group, flexibility is important in order to make the intervention accessible to them. Participants are not be discontinued from the intervention protocol for noncompliance because it has been our experience that recently incarcerated individuals can reengage with providers, even after a period of absenteeism. Participants who report significant suicide or homicidal risk, increased psychiatric symptoms or substance use are referred to appropriate additional care, but remain in the research protocol. All participants who are released from jail are invited to continue all outcome assessments, and research staff attempt to maintain regular contact with all participants to collect data at each assessment interval. Medical and death records covering the year after release are collected for all participants.

2.9. Data quality and participant safety

2.9.1. Data quality and informatics.—The study uses a REDCap database, which is accessible via web, allowing research staff and community mental health counselors from both study sites to access it. To maintain study RA blinding, we built two linked REDCap databases using custom REDCap programming. One of the databases serves as a proxy electronic health record for study counselors. It includes caseloads, case notes, outreach attempts, and study status for each participant. It also includes a form for counselors to report adverse events. The other database serves as the participant tracking and interview database for study RAs. It includes a locator form, record of outreach attempts, field notes, interview measures, participant remuneration tracking, medical and death records reviews, and adverse events. We built custom functionality so that the two databases can communicate updates to locator information, due dates, and adverse event information.

Because this is a large trial (N = 800) of a high-risk population (justice-involved individuals at risk for suicide), we invested in custom programming for adverse event reporting. When a counselor or a RA learns of an adverse event through an SPI session, interview, or medical chart review, s/he completes an initial adverse event report. RAs enter reports directly into the main study database, and counselor adverse events are automatically copied into the main study database. Completion of the initial report triggers an automatic email to our study safety monitor, who completes the official adverse event report in REDCap. The safety monitor then emails the Safety Officer for review and electronic signature, and if the adverse event is serious, also emails one of the principal investigators for review and electronic signature. The safety monitor electronically prints and files pdf copies of each signed adverse event report and then emails pdf copies of serious adverse events to NIMH within 72 hours of the initial event report. The custom REDCap databases have allowed us to unify adverse event reports from counselors and RAs and then efficiently and smoothly execute completion of the adverse event narrative by the safety monitor, signature by a safety officer, signature by a principal investigator, and electronic submission to NIMH within 72 hours for more than 1,000 adverse events (e.g., hospitalizations, suicide attempts) to date.

We also have well-specified procedures to produce high data quality. RAs enter phone interviews directly into REDCap and transfer paper forms into REDCap. RA field folders for in-person interviews (i.e., in the jail or other controlled environments) include clear

checklists including what to do before leaving the office, each assessment, checklists for adverse events, mandatory reports, randomization, and what to do upon return to the office, as well as a clearly laid out participant inclusion/exclusion certification form. Telephone outcome assessments have similar prompts electronically programmed into REDCap. Both in-person and phone interviews are audiorecorded in case checking is needed. Interviews have both clerical (e.g., checking for completion and accuracy of forms and checklists) and clinical (e.g., checking for correct scoring and documentation of interviewer-rated instruments) checks, which are documented in REDCap.

2.9.2. Participant safety.—Following our experience with previous large suicide prevention studies,[46,90] which employed a similar protocol, primary clinical coverage for the anticipated 3,200 telephone outcome assessments is provided by mental health crisis counselors staffed at the Boys Town National Suicide Hotline. Boys Town created a dedicated telephone line through which assessment calls that surpass a specific threshold of risk will be transferred, following a "warm transfer" process between the RA and the mental health crisis counselor at Boys Town. The thresholds for "warm transfer" to Boys Town are programmed into REDCap, so that reminders pop up when a call is indicated. The RA clicks a button in REDCap that sends critical information (e.g., participant name, location, telephone contact information) via secure email to Boys' Town, and then stays on the call for the warm transfer. Boys Town has a set of specified safety procedures to follow, including assessing risk, referring to care, and calling locators or emergency services, if needed. Boys Town reports participant dispositions and outcomes back to the study via secure email in an official Call Record, within 24 hours of each contact. Study staff check this information for adverse events, complete a summary form in REDCap (e.g., duration of call, disposition), and file the Record on the secure file transfer server. Emergency referral in the jail is provided by the jail. These procedures are clearly described in the study consent form.

We have several procedures in place to maximize study staff proficiency with safety and regulatory procedures in this highly regulated trial (the study is overseen by the university IRB, the jail oversight committees, and the NIMH DSMB, and has regular independent site monitoring). All study regulatory documents are on the secure file transfer server, for simultaneous use by our two teams and co-investigators around the country. RA field folders have detailed checklists and information on emergency procedures. RAs extensively review and quiz each other on the study protocol and Manual of Operating procedures before beginning field work, and then shadow and are shadowed by other RAs before working alone. The principal investigators are also available to provide advice and support with difficult interviews, as can occur in a population with high rates of mania, psychosis, and substance use. We also have clear reporting lines and processes. Principal investigators and project coordinators meet weekly to coordinate study procedures between the two sites. One of the sites (Michigan State University) conducts telephone outcome assessments for both states (Michigan and Rhode Island). The other site (Brown University) collects and enters medical and death records and provides remuneration for participants in both states. This division of labor is efficient and makes it easier to maintain study blinding.

2.10. Assessments

Assessments take place at baseline, and at 1, 4, 8, and 12 months post-release. Baseline assessments (including informed consent, locator, and release of information paperwork) take place in person at the jail; RAs offer to read each study assessment aloud. Outcome assessments take place by telephone unless a participant is re-incarcerated or in another controlled setting without telephone access, in which case the outcome assessment take place in person.

2.10.1. Length of assessments.—Given that in jail, participants may be in distress (having just been arrested, having just gone through substance withdrawal, potentially being in psychiatric distress) and that time with participants in jail is limited, we have tried to keep the baseline interview and consent procedures to as close to an hour as possible to increase the feasibility of research procedures. Given that we conduct outcome assessments by phone, we have also tried to keep them to close to an hour and to offer a large ($60) compensation for each outcome assessment interview to offset participant costs (i.e., using phone minutes to talk with us).

2.10.2. Training assessment personnel.—Assessments are conducted by trained RAs, who are supervised by the PIs. Training procedures consist of: (a) review of relevant written materials, (b) didactic instruction, (c) practice interviews with review, feedback and reliability ratings, and (d) continued practice until certification. Following initial training, interviewers and senior staff meet regularly to review assessment tapes, address questions/issues, and monitor inter-rater reliability. Assessments are recorded using digital audiorecorders. RAs upload their recordings to our secure file transfer server for review and inter-rater reliability rating.

2.10.3. Measures.

2.10.3.1. Primary outcome.: Suicide Events is a composite score consisting of the total number of occurrences of any of the following in the year after jail release: (a) attempted suicide (includes suicide deaths), (b) suicide behaviors (preparatory acts, aborted or interrupted suicide attempts), as defined using the Columbia criteria,[82,83] and (c) suicide-related hospitalizations. We use the Treatment History Interview (THI[91]) as well as hospital records to track the number of subsequent hospitalizations and reasons for these admissions. Following the recommendation of Oquendo et al.,[92] our primary outcome measure (i.e., number of suicide events) is a broadly defined composite which reflects suicide behavior/risk.

Suicide event data are collected from all possible sources, including outcome assessments (C-SSRS, THI), (b) hospital chart reviews from relevant area hospitals, and (c) state/national registries. We collect the full hospital chart for the relevant time period and code a suicide attempt when either: (1) the hospital has a field indicating a suicide attempt and it is checked “yes,” or (2) the nurse or physician narratives indicate that the participant has made a suicide attempt or said s/he made a suicide attempt. We code a suicide death from death records if the manner of death is listed as “suicide.” Data from all sources are reviewed by research team members for congruence. All reports are classified using C-SSRS criteria. The C-SSRS

is the recommended measure of suicidal ideation and behaviors in the NIH PhenX Toolkit as a core data element in all clinical trials for suicide prevention. Although it will not be included in our suicide event composite, we also track implementation of rescue procedures (e.g. calling EMS/police, breaking confidentiality to inform clinician of high suicide risk) during SPI phone calls or study assessments and compare conditions on this variable.

2.10.3.2. Secondary outcomes.: Suicide Attempts. We separately assess and evaluate total number of subsequent attempts using the procedures described above. Weeks of active suicidal ideation during the assessment follow-up period are operationalized using the Longitudinal Interval Follow-Up Evaluation (LIFE[93]). At each assessment point, we ask participants to rate their level of suicidal ideation week by week since the last assessment on a 6-point psychiatric status rating scale. This LIFE method yields weekly scores and allows us to examine both the occurrence and *chronicity* of suicidal ideation over the assessment period. The LIFE calendar is also used to assess time to first suicide event. Severity of suicide ideation. We also assess severity of suicidal ideation using the Suicidal Intensity subscale from the C-SSRS. Psychiatric symptoms are assessed using NIH's DSM-5 Cross-Cutting Symptom Measure (DSM-5 CCSM).[94] Overall functioning is measured using the SF-12,[95] a brief, widely used measure of physical and mental health functioning that also provides our secondary cost-effectiveness measure.

2.10.3.3. Hypothesized mechanisms of SPI effects.: We define treatment utilization (*primary*) as the number of outpatient mental health and substance use visits attended in the community in the 3 months prior to baseline or since the last assessment, as indexed by the THI. Belongingness (*exploratory*) is assessed using the INQ-12.[96,97] Suicide-related problem-solving (*exploratory*) is assessed using a standard checklist of suicide safety behaviors[98] which asks whether each was utilized during the most suicidal period since the last interview. The checklist includes two subscales to minimize assessment reactivity: the sum of the number of recommended (e.g., call a friend) and the sum of the number of not recommended (e.g., use drugs) responses to suicidal thoughts or urges.

2.10.3.4. Additional outcomes.: Suicide deaths. Given the low incidence of suicide deaths, even in this high-risk sample, we do not expect to have sufficient numbers of suicide deaths (separate from the suicide event composite) for meaningful analyses. However, we track number of suicide deaths using all possible data sources, including hospital records and reviews of state and national death registries. Although our intervention does not target re-arrest directly, it is possible that by increasing service linkage, SPI could reduce rearrest; therefore, we assess number of re-arrests and will compare conditions on this variable. We also track days incarcerated in the year after the index release to weight participants by time in the community for other analyses.

2.10.3.5. *Sample descriptors* include baseline demographics.: Study inclusion criteria are based on suicide risk rather than diagnosis, but we gather some basic diagnostic information (lifetime psychosis, mania/hypomania, and major depression) using MINI modules (see Table C1).[99] We chose the MINI to keep assessment interviews to 1 hour: keeping participant burden minimal (and hence, study procedures feasible and enrollment

and outcome assessment rates high) was our primary consideration. We also assess posttraumatic stress disorder (PTSD) diagnosis, using the Life Events Checklist and PTSD Checklist for DSM-5 (LEC-PCL).[100,101] We administer the MINI modules and the LEC-PCL at 1 month post-release because: (1) we are assessing lifetime diagnosis, and (2) giving these scales at the 1-month outcome assessment best balances the length of all assessments.

2.10.3.6. Hospital and death records.: Most of RI is covered by 2 large health systems. Genesee County, MI is covered by 3 systems. As in ED-SAFE (a 7-state, 8-site suicide prevention trial),[102] we obtain releases of information from participants at study intake to conduct chart reviews at all of the hospital systems in each region. As in ED-SAFE, RAs review charts following a structured protocol, utilizing discharge codes, discharge summaries, medications, laboratory results, operation records, nursing notes, physician progress notes and other notes or comments to determine whether a suicide event occurred. ED-SAFE data showed that this approach is feasible and that it enhanced detection of suicide events over and above telephone outcome assessment, uniquely identifying 43% of the 1871 detected suicide-related events.[103] Thus, a combination of records review with phone assessment is a feasible and robust approach to detecting suicide-related events. We also search the National Death Index[104] for ICD-coded suicide deaths in our sample.

2.10.3.7. Cost-effectiveness measures.: Our grant accounting captures the costs of the SPI providers. We also track treatment received as part of standard care for the SPI and enhanced SC conditions. Standard care (including outpatient, inpatient, and ED mental health and suicide-related medical care visits) is tracked using the THI, and costs of standard care are estimated using costs for similar visits to SPI providers and charge data from state hospital and ED data systems adjusted to costs with facility-specific cost-to-charge ratios obtained from Federal cost reports. We include training costs but exclude other research costs that would not be incurred if SPI were standard care. The primary cost-effectiveness (CE) measure is the sum of suicide-related hospitalizations and medically treated and fatal suicide acts.[105] Our secondary CE measure is the SF-12, using Sengupta's HUI3 scoring[106] which measures functional status in quality-adjusted life years (QALYs). Costs (and savings) in future years are discounted to present value in the year of treatment initiation using the 3% discount rate recommended by the Panel on Cost-Effectiveness in Health and Medicine.[107] Costs and benefits are converted to same-year dollars.

2.11. Data analysis

Primary analyses will be *intent-to-treat;* we will examine dose-response effects in secondary analyses. Primary tests will be 2-sided with $p = 0.05$. Site differences will be modeled with fixed effects. Descriptive statistics will include effect sizes and measures of clinical significance (i.e., area under the curve [AUC][89]; number needed to treat [NNT]) for all major comparisons. We will separate primary hypothesis (Aim 1) from remaining hypotheses (Aims 2–4). Standard post hoc procedures will be used to adjust for multiple comparisons when testing secondary hypotheses. There is no interim analysis. Analyses will adjust for baseline levels of dependent variables, gender, and y/n history of suicide attempts. Consistent with CONSORT[108] guidelines, we will prespecify covariates and will not adjust for imbalance observed post hoc.

2.11.1. Missing Data.—We collect medical record and death record data on all participants. Self-reported count (e.g., suicide events) and historical (e.g., weekly LIFE ratings) data from missed assessments are gathered at later outcome assessments. We will use multiple imputation to deal with missing data. We will compare treatment conditions on rates of missingness and time to missingness and will test whether baseline characteristics are associated with missingness. Finally, we will perform a sensitivity analysis in which we impute extreme values for missing data to determine the sensitivity of analysis results to missing data.

2.11.2. Outcomes.—Primary. We will test the hypothesis that, relative to enhanced SC alone, SPI + enhanced SC will result in fewer suicide events over the 12 month outcome assessment period, using ordinal logistic regression with lifetime suicide attempts events at baseline as a covariate. The analysis framework will be multivariate ordinal dependent variable regression. We begin with ordinal models because our simulations suggest the count outcome will not likely exceed 3. We will explore using different models such as zero-inflated Poisson or zero-inflated negative binomial with an offset defined by the length of assessment period and time in the community (as opposed to reincarcerated), and other reasonable approaches. Determination of the appropriate modeling will be deter-mined using model selection (information) criteria and the determination will be made blind to the effect of the SPI intervention. Secondary. We will separately test the hypotheses that, relative to enhanced SC alone, SPI + enhanced SC will result in fewer suicide attempts, fewer weeks of active suicide ideation (per the LIFE calendar), lower severity of suicide ideation (C-SSRS scores), longer time to first suicide event, fewer psychiatric symptoms (DSM-5 CCSM scores), and better psychosocial functioning (SF-12 scores). For normally distributed variables (i.e., C-SSRS, DSM-5 CCSM, SF-12), analyses will use a generalized linear mixed model framework for multilevel data (e.g., SAS/proc mixed, HLM) with baseline scores as covariates. For count data (i.e., number of suicide attempts, weeks of active suicide ideation), analyses will use Poisson-class regression methods (e.g., negative binomial regression) and will include appropriate tests for zero-inflation and over-dispersion and offset defined by length of the outcome assessment period and time in the community. Time to suicide event will be analyzed using time-to-event models, beginning with semi-parametric Cox regression models assuming proportionality assumptions are met, otherwise discrete time or parametric continuous time survival models will be used. Model choice will be informed by information criteria and decisions made blind to intervention assignment. Exploratory. Although not part of formal hypotheses, we will also compare conditions on (1) rates of death by suicide, (2) number of re-arrests, and (3) number of emergency referrals generated as part of study safety procedures.

2.11.3. Mechanisms of intervention effects.—We will separately test the hypotheses that, relative to enhanced SC alone, SPI + enhanced SC will result in more treatment utilization (number of outpatient mental health and substance use visits as assessed by the THI), more sense of belongingness (INQ-12 Belongingness Scale score), and better suicide-related problem solving (as assessed by the safety behavior checklist), our proposed primary and exploratory mechanisms, using Mplus, which can accommodate both standard and Poisson-class regression methods. We will then test the hypothesis that

treatment utilization, suicide-related problem-solving skills, and belongingness (1) predict suicide events, and (2) mediate the effects of SPI on suicide events in a structural equation model framework to decompose total effects into direct and specific indirect effects. As recommended by MacKinnon et al,[109] the statistical significance of the indirect effect will be assessed using bias-corrected bootstrapped standard errors; 95% CI estimates will be provided.

2.11.4. Predictors/Personalization.—We will explore gender, race/ethnicity, lifetime suicide attempts, lifetime highest C-SSRS SI intensity score, severe mental illness (schizophrenia, bipolar disorder), substance use severity, PTSD, major depressive disorder, and number of lifetime arrests as moderators. We expect that SPI is appropriate for a full range of at-risk jail detainees.

2.11.5. Cost-effectiveness analyses.—We will use a comparative cost effectiveness (CE) analysis of SPI + enhanced SC relative to enhanced SC alone. The primary effectiveness measure is the sum of suicide-related hospitalizations and medically treated and fatal suicide acts, with a secondary measure of QALYs (see D2.12). Following widely accepted CEA guidelines[107,110], analyses will adopt a societal perspective, considering all economic costs regardless of source. If direct cost savings exceed the program costs, the program is said to offer net cost savings. We describe our statistical plan for determining mean change in and standard deviations of these measures above. The CE ratio equals $\Delta C/\Delta E$, where ΔC is the difference in costs between SPI + enhanced SC and enhanced SC alone and ΔE is the difference in the outcome measure. Using the Crystal Ball add-in to Excel, we will bootstrap 95% confidence intervals around the CER and calculate a cost-effectiveness acceptability curve[111]. Sensitivity analysis will examine CERs at 0%, 1% and 5% discount rates.

2.12. Administrative supplement: intersection between suicide outcomes and substance use

Given the overlap in risk profiles, the recognition that some overdoses may actually be undetected suicide attempts, and the high rates of substance use in our sample, we received an administrative supplement to address the intersection between suicide outcomes and substance use. We will evaluate substance use as a moderator of the effects of SPI on suicide events, and will examine SPI as a moderator of the relationship between substance use and suicide behaviors. We will also evaluate whether SPI, relative to enhanced SC, reduces overall rates of overdose, and whether SPI has a differential effect on overdose versus non-overdose suicide attempts. We define overdose as taking too much of a substance and experiencing symptoms of overdose for that substance, and measure it by self-report, supplemented with medical records. We will conduct a mixed-methods analysis of narrative sections of the participant interviews (i.e., on the C-SSRS, LIFE, Serious Adverse Event report narratives) to describe the functional associations between substance use and suicidal thoughts and behaviors in our sample. Finally, we added questions about whether participants went to the ED after their most recent accidental overdose, whether they went to the ED after their most recent suicide-related overdose, reasons why they did

or did not go to the ED in each case, and whether they disclosed suicidal intent to ED personnel.

3. Discussion

Pretrial jail detention is a marker for increased suicide risk: jail detainees are a high-risk, low-resource population with complex psychiatric, health, housing, and employment challenges,[112] who are facing a major life stressor (i.e., arrest). Release to the community decreases supervision and increases access to lethal means. Lack of education, poverty, victimization, substance use, homelessness, isolation, and poor employment skills complicate care and increase morbidity and mortality.[113–120] Suicide intervention research for this population is lacking. In fact, there are no existing research-supported approaches to reduce suicide after jail release.

This registered trial, published following CONSORT guidelines, will be the first RCT evaluating the effectiveness of any suicide risk reduction intervention for individuals leaving pretrial jail detention, a large population that contributes significantly to U.S. suicide rates. The trial takes place in community settings and tests an intervention that is scalable given resources and constraints of these settings. It is powered to examine mediators and moderators of intervention effects to help target future suicide risk reduction interventions among jail detainees whether or not SPI yields anticipated main effects. The study will also provide the data on cost-adjusted outcomes that systems need to make informed decisions about adoption, speeding implementation. Thus, the study will provide knowledge about both mechanisms and system-level intervention effects, providing maximum public health impact. Given that there are no existing research-supported approaches, if shown effective, SPI has the potential to change clinical practice and measurably reduce U.S. suicide rates.

This trial provides an example of how to manage research with two highly regulated research populations: those at risk for suicide and those involved in the justice system. Novel aspects of the trial that maximize external validity include use of embedded community mental health counselors, limited exclusion criteria, and post-randomization ineligibility. Other novel aspects of the trial (such as custom programming of two interfacing REDCap databases, use of self-report and medical records from hospitals in two states, efficient management of adverse events reported from multiple sources, a shared secure file transfer server, recruiting 800 suicidal individuals in pretrial jail detention in 29 months, and managing up to 3,200 phone outcome assessments, including numerous outreach attempts, with appropriate checking and coordination in place) are made possible by adequate funding. At maximum staffing, this project included 2 principal investigators, 15 co-investigators or consultants, 2 full-time project coordinators, 9–10 full-time RAs, 16 hourly study counselors, site monitoring, and creation and maintenance of the REDCap databases by our university bioinformatics team. Having adequate funding to hire a large and capable team greatly facilitated running this complex trial cleanly. In particular, the REDCap custom programming integrating a counselor tracking and case note system with RA tracking, interview, and medical records data, while maintaining blinding and bringing together study adverse event reporting, was money well spent. We are grateful to our funders

for setting us up to succeed, and we encourage funders to provide adequate resources to ensure clean, well-run trials.

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Table 1

Study Assessments

Assessment	Type	Time (min)	Baseline	1, 4, 8, 12 month outcome assessments
Suicidal Ideation and Behavior				
Columbia Suicide Severity Rating Scale (C-SSRS)	Interview	20	X	X
L.I.F.E. suicidal ideation and behavior	Interview	10		X
Suicide deaths: record review (state/national death registry)	Objective	0		X
Hospitalizations: Treatment History Interview, record review	Objective	0		X
Psychiatric Symptoms: DSM-5 Cross-Cutting Measure	Self-Report	7	X	X
Functioning: SF-12 from RAND Medical Outcomes Study	Self-Report	3	X	X
Hypothesized Mechanisms				
Treatment utilization: Treatment History Interview	Interview	8	X	X
Belongingness: Interpersonal Needs Questionnaire-12	Self-Report	5	X	4,8,12 only
Suicide-related problem-solving: Safety behavior checklist	Self-Report	5	X	4,8,12 only
Diagnosis:				
Mini International Neuropsychiatric Interview (MINI)	Interview	15		1 mo only
LEC-PCL for PTSD	Interview	7		1 mo only
Total patient time for interview (min)			**Consent+48**	**58–70**