Suicide Prevention for Sexual and Gender Minority Youth

Protocol Number: HS-2020-0076

National Clinical Trial (NCT) Identified Number: NCT04757649 (Case Series), NCT05087966 (Open Trial)

Principal Investigators: Drs. Aaron Blashill and Kristen Wells

Sponsor: San Diego State University

Grant Title: Suicide Prevention for Sexual and Gender Minority Youth

Grant Number: 1R61MH120236-01A1

Funded by: National Institute of Mental Health

Version Number: 1.5; 11.30.2021

Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale
6.6.4	Removal of guidelines for suicidality-related clinical worsening in the context of adverse event reporting.	We removed specific guidelines for determining suicidality-related clinical worsening following the recommendations from the DSMB. These will be added to the study MOP.

Table of Contents

STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

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

Principal Investigator or Clinical Site Investigator:

Signed: _____ Date: 11/30/2021

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

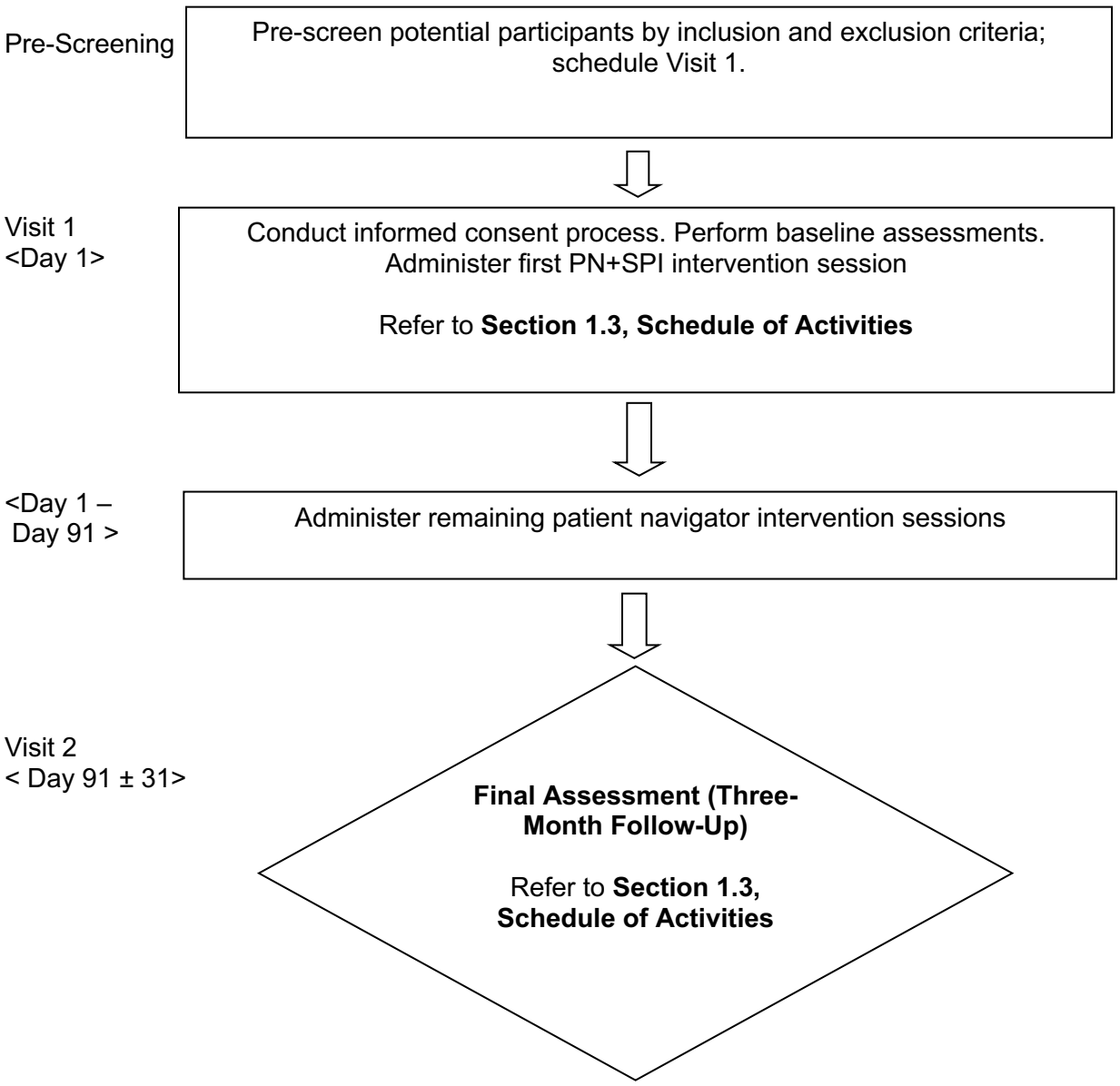
Title:	Suicide Prevention for Sexual and Gender Minority Youth
Grant Number:	1R61MH120236-01A1
Study Description:	In the case series, participants will be screened for eligibility and then complete the initial baseline assessment. During the baseline appointment, participants will receive the first module of the Patient Navigator+Safety Planning Intervention (PN+SPI), consisting of the intake, introduction to navigation, and the SPI. Participants will then receive PN services for a period of three months. At three-months, participants will complete a final follow-up assessment. There are no formal hypotheses associated with the case series. In the open trial, participants will be screened for eligibility and then complete the initial baseline assessment. During the baseline appointment, participants will receive the first module of the PN+SPI intervention, consisting of the intake, introduction to navigation, and the SPI. Participants will then receive PN services for a period of six months. Participants will complete a three-month follow-up assessment and a six-month follow-up assessment. For the open trial, it is hypothesized that PN+SPI participants will display decreases in thwarted belongingness and increases in suicide-related coping skills (the hypothesized mechanistic targets of the intervention). We will also assess the feasibility and acceptability of the PN+SPI intervention during the open trial. The R61 phase (e.g., case series and open trial) precedes a potential R33 phase, in which the theoretical targets of the intervention will be further tested in a RCT (PN+ SPI vs. SPI alone). A detailed schematic describing all visits and a schedule of assessments is included in **Section 1.2, Schema and Section 1.3, Schedule of Activities.**
Objectives/Endpoints:	The primary objective of the case series is to obtain feedback on study procedures and the PN+SPI intervention. The primary objective of the open trial is to assess the acceptability and feasibility of the PN+SPI intervention, as well as the preliminary impact on the purported mechanisms of action of the PN+SPI intervention (e.g. decreasing thwarted belongingness, increasing suicide-related coping skills). There are no secondary objectives in either the case series or open trial.

Study Population:	The case series will consist of up to 10 sexual and gender minority participants, aged 15-29, located in San Diego. The open trial will consist of 30 sexual and gender minority participants, aged 15-29, located in San Diego. The participants in both the case series and open trial are generally physically healthy but are currently experiencing suicidal ideation and have attempted suicide in the past.
Description of Sites/Facilities Enrolling Participants:	San Diego State University (SDSU) is the only site enrolling participants for both the case series and open trial.
Description of Study Intervention/Experimental Manipulation:	The study intervention integrates a brief (30 minute), empirically supported, single-session suicide prevention intervention (Safety Planning Intervention; SPI) with patient navigation (PN) services (PN+SPI). Intervention dose will vary by participant based on their individual needs. All PN+SPI intervention sessions will be administered individually. The first PN+SPI intervention session will occur either remotely or in-person. After the initial session, the remaining intervention sessions will occur according to the participant's preferred contact method (e.g., Zoom-based, over the phone).
Study Duration:	The estimated time from when the study opens to enrollment until completion of data collection is five months for the case series and fifteen months for the open trial.
Participant Duration:	In the case series, it will take three months for each individual participant to complete all study related tasks. In the open trial, it will take six months for each individual participant to complete all study-related tasks.

1.2 SCHEMA

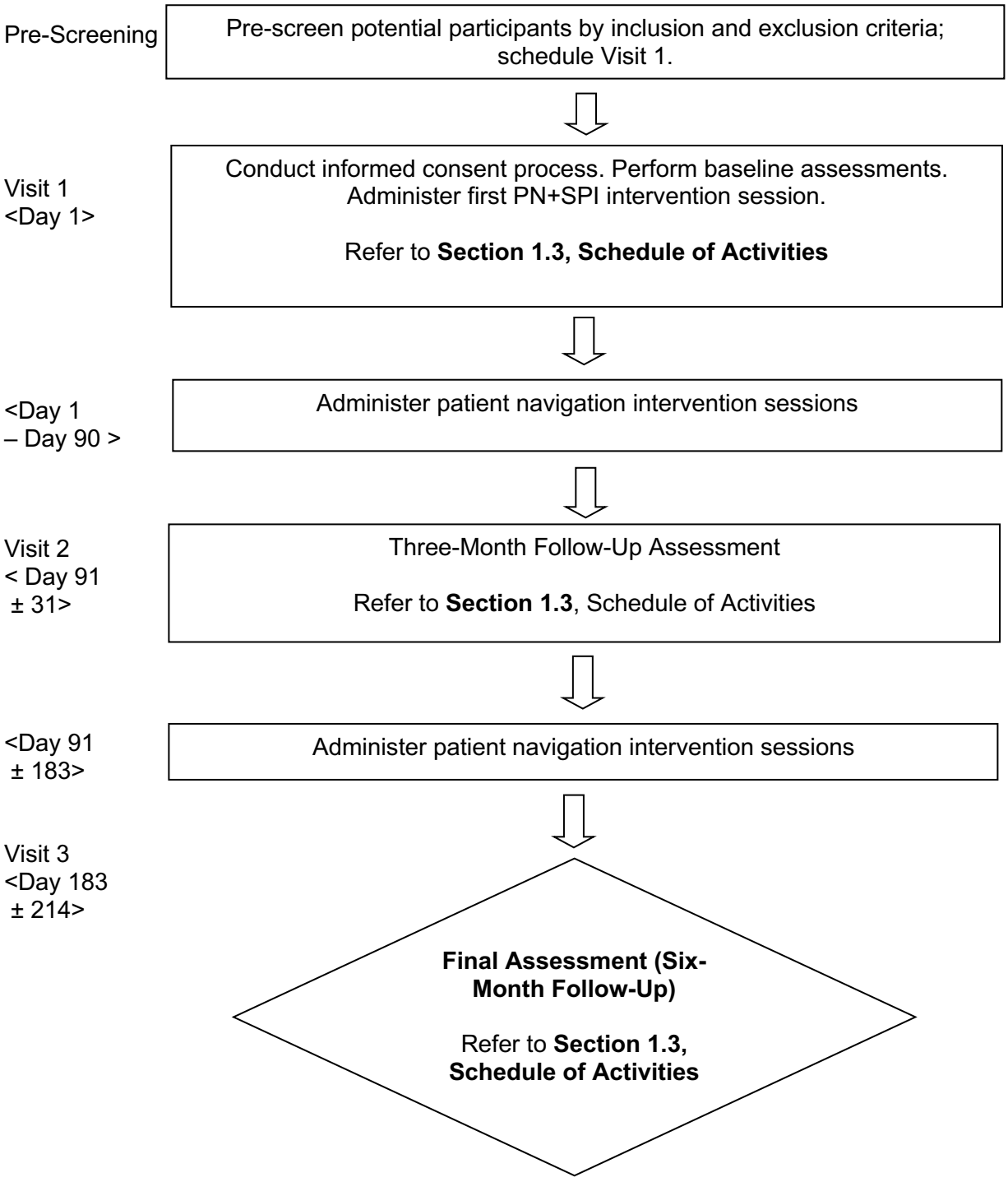
Case Series Flow Diagram

Total *N* = 10



Open Trial Flow Diagram

Total *N* = 30



1.3 SCHEDULE OF ACTIVITIES

Case Series Schedule of Activities

	Phone Screening	Baseline <Day 1>	Intervention Sessions <Day 1 – 90>	Three-Month Follow-Up <Day 91 ±31>
Verbal Phone Screen Consent	X			
Phone Screener	X			
Informed Consent		X		
Demographics		X		
Psychiatric Diagnoses		X		
Suicidality Assessment (Columbia-Suicide Severity Rating Scale)		X	X	X
Other clinician--administered assessments (including Medical Care and Conditions)		X		X
Other self-report questionnaires		X		X
PN+SPI Intervention		X	X	
PN Intervention Encounter Data Collection		X	X	
Study + Intervention Feedback (Open Ended Survey + Interview Questions)				X
Adverse Events Reporting		X	X	X

Open Trial Schedule of Activities

	Phone Screening	Baseline <Day 1>	Intervention Sessions <Day 1 – 90>	Three-Month Follow-Up <Day 91 ± 31>	Intervention Sessions <Day 91 ± 183>	Six-Month Follow-Up <Day 183 ± 214>
Verbal Phone Screen Consent	X					
Phone Screener	X					
Informed Consent		X				
Demographics		X				
Psychiatric Diagnoses		X				
Suicidality Assessment (Columbia-Suicide Severity Rating Scale)		X	X	X	X	X
Other clinician-administered assessments (including Medical Care and Conditions)		X		X		X
Other self-report questionnaires		X		X		X
Outcome Evaluation						
Thwarted Belongingness (Interpersonal Needs Questionnaire)		X		X		X

Suicide-Related Coping Skills (Suicide-Related Coping Skills Scale)		X		X		X
PN+SPI Intervention		X	X		X	
PN Intervention Encounter Data Collection		X	X		X	
Key Informant Interview						X
Satisfaction with Mental Health Services (Client Satisfaction Questionnaire-8)				X		X
Satisfaction with Interpersonal Relationship with PN				X		X
Study Satisfaction (Open Ended Survey Questions)				X		X
Adverse Events Reporting		X	X	X	X	X

2 INTRODUCTION

2.1 STUDY RATIONALE

Death by suicide is one of the leading causes of mortality in the United States. One group that is at a particularly heightened risk of suicide are sexual and gender minorities (SGMs). SGM is an umbrella term to describe individuals who: 1) identify as non-exclusively heterosexual (e.g. gay,

lesbian, bisexual, pansexual, asexual, queer); and/or 2) report same-gender attraction; and/or 3) identify as a gender different than their birth sex (e.g. transgender, gender non-binary, genderqueer). Despite the fact that SGMs are at a high risk of suicide attempts and death by suicide, no known suicide prevention programs exist for this vulnerable population. Therefore, the purpose of the present study is to develop and test a novel suicide prevention intervention designed to reduce suicide attempts among SGM youth and emerging adults. The proposed intervention will integrate a single-session, empirically supported suicide prevention intervention (Safety Planning Intervention; SPI) with patient navigation (PN) services (PN+SPI). PN may be particularly well suited to address the needs to young SGMs at risk of suicide, given its focus on cultural sensitivity and its high level of flexibility to address patients' specific needs. Patient navigators work with the individual patient, the patient's significant others, the health care system, and community services to improve adherence to recommended health care and healthy behaviors. The SPI is a 30-minute behavioral intervention to reduce suicide attempts by providing individuals with specific actionable behaviors they can engage in to reduce the likelihood of acting on suicidal urges, including: 1) identification of suicidality warning signs; 2) implementing personal coping strategies; 3) connecting with mental health professionals; 4) connecting with friends and/or family for support; 5) connecting with mental health professionals; and 6) reducing access to means of completing suicide. Patient navigators will deliver the SPI and continue frequent contact for the purpose of providing motivational enhancement, problem-solving, reinforcing coping strategies, and connecting participants to social support and mental health resources (e.g. SGM-specific support groups from the community). The aims of this R61 phase are to refine the PN+SPI intervention content and procedures, assess acceptability and feasibility, and test if the intervention impacts propertied targets (i.e. thwarted belongingness and suicide-related coping skills). The first phase of the R61 study is to conduct a case series and the second phase is to conduct an open-phase trial. The case series will be used to obtain participant feedback on study procedures and the PN+SPI intervention for the purpose of improving approaches for the open-phase trial. Thus, it has no hypotheses. Based on the minority stress model and the interpersonal theory of suicide, in the open-phase trial, we hypothesize that the PN+SPI intervention will reduce suicide attempts through 2 proposed targets: 1) decreasing thwarted belongingness (e.g. through interactions with the PN and connection with SGM-specific support groups) and 2) increasing suicide-related coping skills. The PN+SPI overtly develops with participants both internal and external coping skills to rely on during suicidal crises. For example, internal coping skills refers to distraction from suicidal thoughts and urges, whereas external coping skills refers to means restricting (i.e. restricting access to lethal means to act on suicidal urges) in addition to reaching out to others (e.g. friends, family, PN, mental health provider) when in crisis. Therefore, the clinical outcome of interest are effect size estimates of changes in thwarted belongingness and suicide-related coping.

2.2 BACKGROUND

Death by suicide is a leading cause of mortality in the United States[1]. Indeed, among the entire U.S. population, suicide is the 10th leading cause of death[1]. Death by suicide accounts for even more premature mortality among youth and emerging adults. For instance, suicide is the 2nd leading cause of death among individuals between the ages of 15 and 34[1]. Moreover, among the U.S. population, there is an increasing trend in the incidence of suicide attempts[2] and death by suicide[3]. This trend has also been found among youth and emerging adults[4,5]. In addition to the prevalence and increasing incidence in the U.S., the psychological and financial burden of suicide is immense. Not only does suicide lead to substantial distress among family and friends of people who died by suicide[6-8], the economic impact is striking. In 2013, it was estimated that suicide

attempts and death by suicide cost $93.5 billion in the U.S.[9]. Additionally, there are specific vulnerable populations that experience disproportionate rates of suicide.

Sexual and gender minorities (SGMs) are a vulnerable population, for which substantial mental health disparities have been demonstrated[10-16]. Further, SGM youth also are at a substantial risk for suicidality, with 23% of sexual minority youth reporting one or more suicide attempts (in the past 12 months) versus 5.4% of heterosexual youth[17]. Meta-analytic findings have also echoed these results, with sexual minority adolescents and emerging adults reporting 2.26 increased odds of suicide attempts compared to their heterosexual counterparts[18]. Gender minorities are also at substantially elevated risk compared to the general population, with 45% of 18-24-year-old transgender individuals reporting history of one or more suicide attempts[19]. However, to date, no known suicide prevention programs have been developed and tested among SGM, a notable gap in the literature, given the substantial suicide disparities noted among this vulnerable population. Therefore, the purpose of this study is to adapt and test a patient navigation (PN) intervention for SGM youth/emerging adults designed to reduce suicide attempts among SGM youth.

One of the leading models of suicide behaviors is the interpersonal theory of suicide[20-23]. The core tenants of the interpersonal theory of suicide include the constructs of thwarted belongingness, perceived burdensomeness, and capability for suicide. Together, these constructs are meant to explain variance in the ideation-to-action framework – that is, illuminating pathways from suicidal desire to suicidal behavior (i.e., fatal and non-fatal suicide attempts). Thwarted belongingness denotes an unmet need to belong socially, which includes components of loneliness, having few friends, social withdrawal, and/or interpersonal conflict. Perceived burdensomeness is defined as an internal miscalculation that one's death would be more valuable to others than their life would be. Capability for suicide includes a genetic predisposition and a learned lowering of one's fear of death and increasing pain tolerance through repeated exposures to painful events. This model suggests that the interaction amongst thwarted belongingness, perceived burdensomeness, and capability for suicide, synergistically places individuals are increased risk for suicide attempts. Empirically, recent meta-analytic findings have supported this model, noting significant main effects of thwarted belongingness, perceived burdensomeness, and capability for suicide on suicide attempts and risk (i.e. attempts in the context of current ideation)[20]. Of note, significant 2-way interactions with thwarted belongingness and perceived burdensomeness (and 3-way interactions with all variables) were significant in predicting suicide attempts and suicide risk, with thwarted belonginess demonstrated an r = .33 main effect with suicide risk.

The leading theoretical model to explain health disparities, including suicide attempts, among SGMs, is the minority stress theory[24-27]. The minority stress theory posits that in addition to general stressors, distal minority stressors (e.g. discrimination, prejudice, and victimization towards SGMs) and proximal minority stressors (e.g. discrimination, prejudice, and victimization towards SGMs) and proximal minority stressors (e.g. internalization of anti-SGM messages, concealment of one's identity, and expectations of rejection) lead to poor mental health outcomes and suicide attempts. Critically, variables have also been identified which buffer the effects of these stressors on negative mental health outcomes, namely social support (broadly, and specific to other SGM members) and coping skills[11,28-31]. Integrating minority stress theory with the interpersonal theory of suicide provides a strong conceptual model for understanding suicide risk amongst SGM youth. Both models highlight modifiable buffering variables, that if addressed, would theoretically allay suicide attempts. For example, the minority stress theory posits that increasing social support (broadly, and specifically from other SGMs) and coping skills, attenuates the association of minority stressors to negative mental health outcomes (e.g. suicide attempts).

Social support from minority stress theory conceptually overlaps greatly with thwarted belongingness from the interpersonal theory of suicide. Here too, the model implies, and its authors have provided compelling arguments, that reducing thwarted belongingness (such as through fostering interpersonal connectedness related to social support) would also attenuate the associations between perceived burdensomeness and capability for suicide with suicide attempts and risk.

Thus, the proposed brief and scalable PN+SPI does not aim to directly target upstream minority stressors, or general stressors, or address perceived burdensomeness or capability for suicide. Rather, the PN+SPI aims to modulate two theoretical targets to suicide attempts among SGMs – poor coping skills and thwarted belongingness. If the PN+SPI increases coping skills, a subsequent reduction in suicide attempts is expected, both through adaptive coping skills (e.g. suicide means restriction, distraction skills) and also through attenuating the association between stressors and suicide attempts. Similarly, if the intervention decreases thwarted belongingness, a subsequent reduction in suicide attempts is expected, both through an increased sense of belonging (e.g. through general and SGM-specific social support) and also through attenuating the associations between: 1) perceived burdensomeness; 2) capability for suicide; and 3) stressors, on suicide attempts.

PN may be particularly well suited to address the needs to young SGMs at risk of suicide, given its focus on cultural sensitivity and its high level of flexibility to address patients' specific needs. Patient navigators work with the individual patient, the patient's significant others, the health care system, and community services to improve adherence to recommended health care and healthy behaviors. There have been few PN interventions developed or tested to assist patients experiencing mental health or developmental conditions. Research indicates that the PN approach has been used to assist patients with serious mental illness[32-35], depression[36,37], autism spectrum disorder[38-40], and traumatic brain injuries. Existing studies of PN applied to mental health conditions have several limitations. For example, no known study has evaluated whether PN can assist patients with suicide risk. In fact, most studies have excluded patients who expressed suicidal ideation, leading to significant gaps in knowledge regarding the best ways to assist suicidal populations.

The SPI[41] is a 30-minute behavioral intervention to reduce suicide attempts by providing individuals with specific actionable behaviors they can engage in to reduce the likelihood of acting on suicidal urges, including: 1) identification of suicidality warning signs; 2) implementing personal coping strategies; 3) connecting with mental health professionals; 4) connecting with friends and/or family for support; 5) connecting with mental health professionals; and 6) reducing access to means of completing suicide. In a recent trial of the SPI, 1,640 patients with suicide risk received either the SPI or usual care and were followed for six months. Results indicated that participants who received the SPI significantly reduced suicidal behaviors compared to the comparison condition, with 45% fewer suicide attempts noted among the SPI participants compared to usual care[42].

The PN+SPI intervention is a multi-level intervention and will target several hypothesized mechanistic targets that theoretically underlie the impact of the PN+SPI on reduction in suicide attempts. One proposed target of the intervention is decreased thwarted belongingness (e.g. through interactions with the PN and connection with SGM-specific support groups). For example, in a recent meta-analysis of over 100 unique samples, thwarted belongingness was significantly associated with increased suicide risk (r = .33)[20]. Additionally, among a sample of sexual minority and heterosexuals, the association between thwarted belongingness and suicide ideation was

stronger amongst SMs and SM participants with a history of suicide attempts reported substantially higher thwarted belongingness compared to SMs with no history of suicide attempts (*d* = .54)[43]. SMs also report greater thwarted belongingness compared to their heterosexual peers (*d* range from .80 to .97)[44]. Related, thwarted belongingness has also been found to predict suicide attempts among gender minority youth (Odds Ration [OR] = 2.88)[20,44,45].

Another set of hypothesized targets are suicide-related coping skills. The PN+SPI overtly develops with participants both internal and external coping skills to rely on during suicidal crisis. For example, internal coping skills refers to distraction from suicidal thoughts and urges, whereas external coping skills refers to means restriction (i.e. restricting access to lethal means to act on suicidal urges) in addition to reaching out to others (e.g. friends, family, PN, mental health provider) when in crisis[46]. Means restriction has previously been shown to reduce suicide attempts at both the population and individual level[47,48]. Indeed, recent meta-analytic data underscore the efficacy of means restriction and lower odds of death by suicide[49]. Further, greater use of internal and external suicide-related coping skills have both been significantly associated with lowered suicidal ideation intensity, severity, and lower likelihood of suicide attempts[46].

Positive results from this project would elucidate pathways in which brief suicide prevention programs may confer reduction in suicide attempts among vulnerable populations. Negative results would also confer crucial information on theoretically informed pathways which may not be active in prevention programs, which subsequently may encourage researchers to postulate alternative targets as brief suicide prevention programs are created and refined. We anticipate that decreasing thwarted belongingness, and increasing internal and external coping, will have significant clinical meaningfulness as all three targets will subsequently reduce suicidal behavior. There are currently no known existing suicide prevention approaches designed for SGM and none that has utilized PN, thus the proposed study is likely to have a significant clinical benefit and impact on the field of suicide prevention research.

2.3 RISK/BENEFIT

2.3.1 KNOWN POTENTIAL RISKS

Case Series and Open Trial Potential Risks:

It is unlikely that participants will be at any risk for physical harm as a result of study participation. Participants may reflect on unpleasant memories or talk about certain things that they may find distressing and may experience anxiety as a result. As with any study of participants with suicidal ideation, there is always the risk of symptoms worsening and the possibility of suicide attempts. Other potential risks include the possibility that confidentiality could be breached, as well as possible discomfort about treatment sessions and assessments being audio-recorded for supervision and treatment adherence checks.

2.3.2 KNOWN POTENTIAL BENEFITS

Case Series and Open Trial Potential Benefits:

All participants will have the opportunity to participate in a suicide prevention program. Each participant will receive the SPI which is the ‘gold-standard’ intervention for suicide prevention.

Additionally, each participant will receive the services of a patient navigator who will help them connect to resources in the community, problem-solve barriers to treatment, and reinforce coping skills. Lastly, all participants, regardless of eligibility status, will be provided with referrals to local mental health providers, and local/national suicide crisis hotlines, including The Trevor Project, which specializes in suicide prevention for sexual and gender minority youth/emerging adults.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Case Series and Open Trial Assessment of Potential Risks and Benefits:

As stated above, participants may reflect on unpleasant memories or talk about certain things that they may find distressing and may experience anxiety as a result. However, it is necessary that we ask these potentially emotionally upsetting items in order to adequately evaluate the PN+SPI intervention. Participants will be advised during the informed consent process and throughout the study that they may decline to answer any study questions, that participation is voluntary, and that they may withdraw from the study at any time.

To partially address participants' risk of distress and potential breaches of confidentiality, we have obtained a waiver of parental consent from the IRB and an approval of minor's (age 15 to 17) ability to self-consent, which is consistent with the U.S. Department of Health and Human Services Office of Human Research Protections guidelines:

> An IRB may waive the requirements for obtaining parental or guardian permission if it makes and documents the findings under either 45 CFR 46.116(c) or (d). In addition to the provisions for waiver contained in 45 CFR 46.116(c) or (d), if the IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the parental permission requirements provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law (45 CFR 46.408(c)).

Per Fisher, Arbeit, Dumont, Macapagal, and Mustanski[50], failure of IRBs to approve these requests represents a significant barrier to sexual and gender minority youth engagement in research protocols due to fear of being stigmatized and/or victimized if guardian permission leads to disclosure of their sexual orientation or gender identity[51-53]. The results of IRBs' failure to approve these requests can subsequently result in more limited and unrepresentative samples[54], which may bias results which undermine the generalizability of findings to sexual and gender minority youth who live in a non-accepting familial environment. Indeed, results from a sample of 60, 14-17 year-old sexual and gender minority youth indicated that the vast majority reported that requiring parental consent for research studies would prevent them from participating. Additionally, participants demonstrated strong knowledge of the informed consent process, including risks/benefits, random assignment, and confidence in dissenting to research practices with which they did not feel comfortable[50].

Given that we have obtained a waiver of parental consent for the reasons described above, we do not plan to alert parents/caregivers if a minor enrolled in the study reports immediate suicidal intent. Rather, we will require all participants at baseline to identify at least one trusted adult whom the study staff would contact in case of a psychiatric emergency or difficulty in contacting the

participant. If study staff were to alert parents/caregivers, it could potentially be detrimental to the participant's well-being, particularly in the context of a suicidal crisis, if the family member(s) were not aware of, and/or supportive of, the participant's sexual or gender identity.

The patient navigation procedures will facilitate receipt of high-quality mental health care. The intervention will be implemented by a social work navigator who will be under the supervision of Dr. Blashill, a licensed clinical psychologist, and Dr. Wells, a trained clinical psychologist. The assessment of intervention fidelity will also help to ensure that clinical protocols are being implemented as designed. Study navigators will also have ready access to the Principal Investigators, as well as their direct supervisor at the Family Health Centers of San Diego (FHCSD). In all cases, participant health and safety have priority over study protocol. Study procedures do not preclude participant referral for additional care and treatment.

Other potential risks include the possibility that confidentiality could be breached, as well as possible discomfort about treatment sessions and assessments being audio-recorded for supervision and treatment adherence checks. Participants will be advised that they can refuse to be audio-recorded. All data will be kept confidential, under lock-and-key, or electronically and password protected, accessible only to trained study staff. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock-and-key or electronically and password protected, again accessible only to trained study staff. All digital audio recordings of sessions will be uploaded to the study computer immediately post-session and the file deleted from the digital recorder. Computer files will be secured by password and will be accessed only by authorized study personnel. These procedures will be implemented to provide study participants with the assurance of confidentiality around very sensitive and personal information.

The purpose of the study is to develop and test a PN+SPI prevention program for SGM youth and young adults. Despite the vulnerability of these populations to suicide, there are currently no known suicide prevention programs for them. Results from the study will provide important information which could reduce the mortality of these populations.

3 STUDY DESIGN

3.1 OVERALL DESIGN

There are no hypotheses associated with the case series given that the purpose of the case series is to obtain feedback on study procedures and the PN+SPI intervention. For the open trial, we hypothesize that PN+SPI participants will display decreases in thwarted belongingness and increases in suicide-related coping skills (the hypothesized mechanistic targets of the intervention). We will also assess the feasibility and acceptability of the PN+SPI intervention during the open trial.

As stated, the case series (up to 10 participants) will be conducted to refine study procedures and the PN+SPI intervention. In terms of trial type, the open phase trial is a within-subjects trial. All participants in the case series and open trial will be assigned to the PN+SPI intervention. Therefore, no randomization or control group will be used.

The case series (N = 10) is a one group, one arm study. Participants in the case series will receive up to three months of the patient navigation plus safety planning intervention, at which

point they will complete a three-month follow-up assessment. The open phase trial (N = 30) is also a one group, one arm study and will follow the same approach; however, there will be both a three-month and six-month follow-up assessment, and intervention services will be provided for six months. The R61 phase (e.g., case series and open trial) precedes a potential R33 phase, in which the theoretical targets of the intervention will be further testes in a RCT.

The study intervention includes patient navigation (PN) for SGM youth/emerging adults designed to target mechanisms (i.e. decreasing thwarted belongingness and increasing suicide-related coping skills) that theoretically underlie suicide. The study intervention integrates a single-session, empirically supported, suicide prevention intervention (Safety Planning Intervention[41]; SPI) with PN services (PN+SPI).

During the first PN+SPI session, the patient navigator will deliver the SPI and assess barriers to accessing mental health care services and SGM social support services. After the initial session, the patient navigator will continue frequent contact for the purpose of providing motivational enhancement, problem-solving, reinforcing coping strategies, and connecting participants to social support and mental health resources (e.g. SGM-specific support groups within the community). The planned PN content is described in **Table 1 (see below)** and includes 7 modules that can be delivered using a flexible approach. In other words, patient navigators will deliver the modules based on the particular concerns and needs of each participant, and modules can be repeated.

Table 1:

Module	Construct	Content
1. Introduction to patient navigation	• Understanding of the patient navigation intervention and role of the patient navigator	• Conducting a patient navigation intake assessment • Explaining the navigation intervention and the role of the navigator
2. Psychoeducation on minority stress and how it can lead to self-harm behaviors	• Minority stress (e.g., internalized homophobia, internalized transphobia) • Perceived burdensomeness	• Introduction to minority stressors • Exploration of the influence of minority stressors on participants' day-to-day lives • Identify how minority stress triggers risk of self-harm
3. Assessing and addressing barriers to SGM-affirming mental health services	• Access to mental health services • Thwarted belongingness • Coping skills (e.g. reaching out to others)	• Systematically assessing barriers to mental health services on an ongoing basis (i.e., insurance, transportation, unsure how to find a provider, substance use, violence victimization) and generating possible solutions • Providing a list of SGM-affirming mental health services and assisting participant with identifying a service that best meets their needs

		• Developing resources to address specific barriers • Identifying and implementing actions to assist the participant in implementing barrier-reducing strategies • Assessing whether action(s) reduced barrier(s) • Problem solving for seeking affirming mental health care and generating possible solutions • Role playing activities for practicing communication
4. Assessing and addressing barriers to local SGM support resources	• Minority stress (e.g., concealment, rejection sensitivity) • Thwarted belongingness	• Systematically assessing barriers to SGM-specific support resources on an ongoing basis (i.e., financial, transportation, unsure how to find resources, substance use, violence victimization) and generating possible solutions • Providing a list of SGM-specific support resources and assisting participant with identifying a resource that best meets their needs • Developing resources to address specific barriers • Identifying and implementing actions to assist the participant in implementing barrier-reducing strategies • Assessing whether action(s) reduced barrier(s) • Problem solving for seeking SGM support resources and generating possible solutions. • Role playing activities for practicing communication
5. Decision Making Support	• Coping skills • Means restriction • Access to mental health services • Minority stress (e.g., concealment, rejection sensitivity) • Thwarted belongingness	• Decisional balance sheets re seeking SGM-affirming mental health services and SGM support resources • Motivational enhancement and goal setting for seeking SGM-affirming mental health services and SGM support resources

6. Suicidal Crisis Management	• Coping skills • Means restriction • Access to mental health services	• Assessing the participant's suicide risk • Reviewing and reinforcing the participant's Safety Plan • Providing other patient navigation services if warranted • Providing emergency services if necessary • Assisting participants in obtaining a higher level of mental health care if necessary
7. PN intervention review and wrap-up	• Coping skills • Means restriction	• Reinforcing lessons learned during the intervention related to minority stress and its impact on risk of self-harm • Reviewing, reinforcing, and updating the coping strategies plan in the SPI • Reviewing, reinforcing, and updating the means restriction plan in the SPI • Identifying problems which may occur in the future and generating solutions for seeking help and support

To develop the content described in **Table 1**, the research team will hold a series of meetings with a participatory planning group (PPG) and conduct the following steps specified in Intervention Mapping:[55] 1) reviewing various PN interventions developed by Dr. Wells along with the SPI; 2) creating a logic model of the health problem (e.g. suicide); 3) creating a logic model of the integrated PN+SPI; 4) assessing intervention fit and planning adaptations; and 5) making adaptations. The Intervention Mapping approach guides the adaptation process, including delivery fit, design features, and cultural (i.e. SGM) relevance. The research team will develop and initial draft of patient-focused materials, along with a manual for the patient navigators with the SPI plus PN modules. In subsequent meetings, drafted materials and protocols will be revised based on PPG feedback. The PPG will review the final draft of the intervention prior to its production for use in the open trial. It is anticipated that only two rounds will be needed to refine the SPI+PN intervention and study procedures in preparation for the open trial.

3.2 JUSTIFICATION FOR INTERVENTION

PN interventions are flexible by design to address participant's unique barriers to care; the content and pace of the intervention is delivered according to the needs and concerns of the participant.

All participants will receive the SPI during the first intervention session. At this time, the patient navigator will also assess barriers to accessing mental health care services and SGM social support services. After the initial session, the patient navigator will contact participants using their preferred method (e.g. over the phone) one time per week (at minimum) for the next seven weeks

and then monthly (at minimum) for the remainder of the intervention period. It is possible that some participants will require additional assistance from the patient navigator. As a result, the length, number, and frequency of intervention contacts will vary based on the participants' needs.

The minimum-acceptable participation in the intervention is the completion of the first session of PN+SPI, which is the intake, introduction to navigation, and the SPI. Please see **Section 2.2** for more information about the justification for the intervention.

3.3 END-OF-STUDY DEFINITION

In the case series, a participant is considered to have completed the study if they have completed the baseline assessment, at least 1 intervention session, and the 3-month follow-up assessment. In the open trial, a participant is considered to have completed the study if they have completed the baseline assessment, at least 1 intervention session, and the 3-month and 6-month follow-up assessments.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

Case Series and Open Trial Eligibility Criteria:

In order to be eligible to participant in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and availability for the duration of the study
3. Age 15 to 29 years
4. Identifies as gay, lesbian, bisexual, transgender, genderqueer, asexual, pansexual, non-binary, or another non-exclusively heterosexual or cisgender identity, and/or reports same-gender romantic attraction, and/or reports same-gender sexual behavior in the past 12 months
5. Resides in San Diego County, California
6. Speaks English
7. Reports suicidal ideation over the past two weeks during phone screen, as indicated by the clinician-administered Columbia-Suicide Severity Rating Scale (C-SSRS) Baseline version
8. Reports a lifetime history of one or more suicide attempts (i.e., actual and interrupted suicide attempts, not aborted attempts)

4.2 EXCLUSION CRITERIA

Case Series and Open Trial Exclusion Criteria:

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Reports immediate (i.e., within 10 days) intention and plan to attempt suicide based on PI evaluation (as guided by responses to the C-SSRS). This may include past-two-week intent and plan.

4.3 SCREEN FAILURES

Screen failures in both the case series and open trial are defined as participants who consent to participate in this study but are not subsequently entered in the study. To verify if participants meet the past-two-week suicidal ideation criterion assessed during phone screen, participants' past-month suicidal ideation will be evaluated during the baseline assessment, creating overlap between reference periods and reducing the number of screen failures. Some individuals who do not meet the inclusion criteria or do meet the exclusion criterion for participation in this trial (screen failure) may be rescreened if their response to the criterion or criteria that excluded them from the study changes over time. Examples include a participant who did not have suicidal ideation during the initial telephone screening, but at a subsequent screening reports suicidal ideation. Rescreened participants will be assigned the same participant number as for the initial screening.

4.4 STRATEGIES FOR RECRUITMENT AND RETENTION

We do not have an anticipated number to be screened in order to reach the target enrollment size for the case series. We will use data collected as part of the case series to help us determine the anticipated number to be screened in order to reach the target enrollment size in the open trial.

The anticipated accrual rate over the course of the case series is five participants per month over two months (total N = 10). The anticipated accrual rate over the course of the open trial is five participants per month over six months (total N = 30).

A broad recruitment strategy will be used to recruit diverse participants within the greater San Diego area via a variety of methods, including FHCSD outreach programs, support groups, flyering local LGBT community centers, gay-identified/friendly coffee shops, gyms, and bars. We will also utilize online recruitment methods, including targeted ads through Facebook/Instagram, and use of geolocation social networking mobile applications tailored to SGM (e.g. Grindr, Scruff, Jacked). Finally, we will also recruit from the BISH Lab registry, a database of diverse SGM community members who are willing to be contacted for research projects. This multi-method approach has been in our current and previous studies sampling SGM, is a frequently used method among researchers studying SGM[56] and is cost-effective[57]. We already have developed several recruitment flyers and ads for other studies that can be modified to recruit participants that reflect the ethnic and racial diversity of San Diego County. We have also budgeted funding for the expenses related to study recruitment to help ensure our success.

An electronic tracking system will be developed for use by the project director and outcome assessors that will track participants in order to schedule and complete follow-up assessments. This system will provide the outcome assessors with a calendar of participants to contact for follow-up visits within one month of each's participant's next scheduled follow-up appointment (if they are unable to schedule the follow-up appointment at the time of the previous appointment). The outcome assessors will be responsible for documenting both baseline and each follow-up data collection encounter in the system. At the baseline assessment participants will complete a locator form which asks permission for study staff to contact participants via phone, text, email,

social media (Facebook) and mail. We also ask participants for their preferred contact method, although we will use multiple methods of contacting participants, as necessary. Additionally, we ask participants for the name and contact information of close friends/family member whom the study could contact in the event that staff are unable to connect with the participant. We also provide evening and weekend appointments to accommodate participants' schedules. Further, we provide phone/text reminders regarding study appointments and confirm appointments with participants several times in advance. Participants will be provided with incentives (compensation via gift cards) to participate in each data collection session. These incentives will be provided in recognition of the time and effort the participant is providing to the study team, as well as costs for travel. The study team will meet weekly to discuss study enrollment and retention rates, as well as challenges faced in both recruitment and retention. These challenges, as well as the steps taken to overcome them, will be part of the feasibility data collected by the study team. However, it is expected that these strategies will prove successful based on our previous history using them. For example, in Dr. Blashill's and Wells' ongoing R34 HIV prevention trial sampling young sexual minority men in the San Diego area, the project team has retained 100% of our sample 6 months post-baseline.

This grant is focused on recruiting and retaining participants from historically under-represented populations. We will be using strategies for recruitment and retention which have been optimized in other studies (described above).

Furthermore, the PN+SPI intervention and subsequent intervention materials will be developed with the assistance of the PPG, consisting of mental health providers at FHCSD, potential program implementers, young SGMs, and community members who interact with or deliver services to people who may benefit from the intervention. This will help ensure that the PN+SPI intervention approach focuses on the needs of the population, as well as utilizes intervention materials that are acceptable from the population. Lastly, study staff are well-trained to be strong at being able to communicate and work with the communities that we serve.

The age range for this study is restricted to ages 15-29. The lower bound age of 15 was selected as epidemiological research has identified age 15+ as a critical period for suicide risk. Additionally, there are developmental, ethical, and legal aspects to consider in suicide prevention work with children. Further, our upper age limit of 29 years was chosen given this encapsulates the developmental period of emerging adulthood, another critical period of lifespan development and suicide risk.

Potential participants are requested to contact study personnel via email, telephone, or by completing a brief Qualtrics survey. A trained member of the study team will contact each interested participant to explain the study, obtain verbal consent for pre-enrollment screening, and conduct the screening process. Those who meet screening criteria will be scheduled for the enrollment (baseline) study visit. At the time of the enrollment appointment, a trained member of the study team will provide more information about the study and engage in an informed consent process for the purpose of study participation. Individuals who provide written informed consent will be asked to complete baseline surveys, which, together with the clinical interview, will be reviewed to confirm whether the participants meet criteria to participate. To verify if participants meet the past-two-week suicidal ideation criterion assessed during phone screen, participants' past-month suicidal ideation will be evaluated during the baseline assessment, creating overlap between reference periods and reducing the number of screen failures. Reasons for non-participation of potential participants will be documented.

As mentioned above, participants will be compensated for study participation. Specifically, participants will receive a $75 gift card after completing the initial baseline assessment and a $50 gift card after completing each follow-up assessment. Case series participants can earn a total of $125 in gift cards if they complete both data collection sessions (baseline and three-month follow-up). Open trial participants can earn a total of $175 in gift cards if they complete all three data collection sessions (baseline, three-month, and six-month follow-up). As mentioned, these incentives will be provided in recognition of the time and effort the participant is providing to the study, as well as costs for travel. The amount that participants will be compensated ($75 for baseline, $50 for follow-ups) has been deemed appropriate in Southern California for the amount of time, effect, and travel required to complete study assessments. All incentives will be given directly to the participants, including those who are minors.

5 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

5.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

5.1.1 ADMINISTRATION AND/OR DOSING

All PN+SPI intervention sessions will be conducted by social work navigators who will be hired by our clinical partner, Family Health Centers of San Diego, based on their familiarity with the intended audience, young SGMs. The first intervention session will be held immediately following study enrollment (i.e. during the baseline assessment). While the COVID-19 outbreak is on-going, this session will be conducted online via Zoom (a secured video calling platform with audio and video capabilities) instead of in-person to ensure proper care and safety of participants and study staff. All participants will receive the SPI during this first intervention session. Additionally, the patient navigator will assess barriers to accessing mental health care services and SGM social support services at this time.

Given that PN interventions are flexible by design in order to address participants' unique barriers to care, the PN+SPI intervention will not be administered according to any predetermined frequency or schedule. At minimum, the patient navigator will contact participants using their preferred method (e.g., over the phone) one time per week for the next seven weeks and then monthly for the remainder of the intervention period. However, some participants may require additional assistance from the patient navigator. Therefore, the patient navigator will deliver the intervention modules based on the particular concerns and needs of each participant, repeating modules as needed. As a result, there is no predetermined number of intervention sessions constituting a complete or "full-dose" intervention. We will monitor the dose of patient navigation (as measured by the quantitative variables of frequency of service delivery, amount of time spent with participants, and actions taken) by utilizing a PN encounter form. Lastly, participants will not interact with other participants or with a shared interventionist throughout the duration of the study.

5.2 FIDELITY

5.2.1 INTERVENTIONIST TRAINING AND TRACKING

The patient navigators, who will be social workers, will be extensively trained (e.g., through didactics and role playing) by the study team using training manuals developed in collaboration

with the PPG and via the Patient Navigation Research Program (PNRP)[58] training approach. Patient navigators will be trained on all SOPs that are relevant to their work (i.e., child and elder and dependent adult abuse and neglect) and will have significant training in safety monitoring. This training will include didactic approaches as well as active learning, such as role playing with the investigative team and community members. General PN training will focus on the history of PN, establishing rapport, professionalism in PN, and documenting the PN services provided. In addition, more specific training will be provided in how to administer the SPI content of the integrated intervention, as well as the 7 PN intervention modules, one of which includes addressing suicidal crises. Based on prior PN studies, it is anticipated that training will last at least 2-3 weeks to allow the patient navigators adequate time to practice delivering intervention modules, documenting care provided, and following study data collection protocols. However, training may be extended depending on each navigator's needs. All staff who will be interacting with participants will be trained in the techniques of the UWRAP as it pertains to their role in the project.

Intervention fidelity will be assessed via audio-recordings and observation conducted by the study project director. Audio-recordings, considered the gold standard in treatment fidelity[59], will be evaluated by the trained project director who will code the recordings using a checklist to track whether the interventionists delivered PN+SPI according to the manual. Using an approach developed by the PNRP, patient navigators will record process data related to the PN services provided, including: 1) number of encounters, 2) length of time of each encounter; 3) barriers experienced by patients; and 4) actions taken to reduce barriers. Patient navigators will keep copies of the participants' safety plans and the SPI suicide risk curve. The patient navigators will also be asked to keep detailed qualitative notes regarding telephone, text, and in-person encounters with participants, including participants' progress in obtaining mental health services, successes in implementing the PN intervention, and challenges in implementing the PN intervention. A Research Program Manager at FHCSD will provide day-to-day supervision of the patient navigators and will meet with the navigators weekly and document successes and challenges to PN intervention implementation through a weekly written report. Dr. Blashill, a licensed psychologist, and Dr. Wells will also provide the patient navigators with weekly, and as needed clinical supervision.

5.3 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

We will track participants' attendance at intervention sessions and exposure to intervention materials by utilizing a PN encounter form. Here, patient navigators will record process data related to the PN services provided, including: 1) number of encounters, 2) length of time of each encounter; 3) barriers experienced by patients; and 4) actions taken to reduce barriers. This information will be recorded using the PN encounter form. Patient navigators will keep copies of the participants' safety plans and the SPI suicide risk curve. The patient navigators will also keep detailed qualitative notes regarding telephone, text, and in-person encounters with participants, including participants' progress in obtaining mental health services, successes in implementing the PN intervention, and challenges in implementing the PN intervention.

We will examine intervention adherence during the case series and open trial by calculating the number of PN encounters, number of intervention modules delivered, and how often each module is delivered. We will also review the progress notes to determine if participants carried out plans described in the progress notes (i.e., contact a mental health provider, enroll in a support group).

6 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

If a subject chooses to discontinue from PN+SPI intervention but agrees to remain in the study, remaining study procedures (assessments) will be completed as indicated by the study protocol.

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

- The reason(s) for discontinuing the participant from the intervention, and methods for determining the need to discontinue
- If the participant is due to complete assessments within 2 weeks of being discontinued from the study intervention, those assessments will be administered at the time of discontinuation; if the next scheduled assessments are more than 2 weeks from the discontinuation date, the discontinued participant will wait for the next scheduled assessment. Thereafter, the participant will be included in all future scheduled assessments, even though not participating in the intervention.

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

In both the case series and open trial, participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue a participant from the study for the following reasons:

- The participant can no longer participate in the remainder of the study (e.g. long-term prison sentence, long-term hospitalization); or
- The participant loses their legal right to provide consent to participate for the remainder of the study.

The reason for participant discontinuation or withdrawal from the study will be recorded in an electronic system of tracking developed by the research team. Subjects who sign the informed consent form and receive the study intervention, and subsequently withdraw, or are discontinued from the study will not be replaced.

6.3 LOST TO FOLLOW-UP

For the case series, a participant will be considered lost to follow-up only if they fail to complete the three-month follow-up assessment within 31 days of when it was scheduled to be completed. For the open trial, a participant will be considered lost to follow-up only if they fail to complete the six-month follow-up assessment within 31 days of when it was scheduled to be completed. Otherwise, study staff will continue to attempt to contact the participant, unless the participant decides to withdraw from the study or 31 days has passed following the last scheduled follow-up.

The following actions will be taken to minimize loss to follow-up and missing data:

- At the baseline assessment, participants will complete a locator form, which asks permission for study staff to contact participants via phone, text, email, and mail. We also ask participants for their preferred contact method, and for the name and contact information of close friends/family member whom the study could contact in the event that staff are unable to connect with the participant. Study staff will utilize these multiple contact methods to schedule, or re-schedule, follow-up assessments as necessary.
- Study staff will contact participants on multiple days and times.
- Participants will be given multiple appointment reminders and study staff will confirm the scheduled appointment with the participant multiple times.
- Study staff will contact participants to schedule follow-up appointments within a month of each participant's next scheduled follow-up appointment (if they are unable to schedule the follow-up appointment at the time of the previous appointment).
- Upon rescheduling follow-up assessments, study staff will counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to continue in the study.
- The study team will meet weekly to discuss challenges faced in contacting participants and completing follow-up assessments and how to potentially overcome them.

6.4 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Case Series:

Participants will complete the initial baseline assessment to confirm eligibility. Prior to beginning the baseline assessment procedures, a trained member of the study team will obtain informed consent. If the participant consents to participate in the study, the baseline assessment will be performed. Participants will complete self-report questionnaires (see below), clinician-based interviews (see below), and the first SPI+PN session (intake, introduction to navigation, and the SPI).

Post-baseline, participants will receive PN services for a period of three-months. Patient navigators will record PN intervention encounter data (see below). Participants will then complete a three-month follow-up assessment, consisting of clinician-based interviews (see below) and providing study and intervention feedback through open-ended survey questions (see below).

- Administration of self-report questionnaires:
    - Participants will complete self-report questionnaires in Qualtrics (either done remotely from their homes, or on a computer within the lab).
    - Self-report questionnaires include:
        - Demographics survey
            - Assesses demographic items (e.g. age, race, ethnicity, sex assigned at birth, gender identity, sexual orientation, relationship status, country of origin, U.S. citizen status, primary language, current grade in school or education level, health insurance status, employment status, income (if applicable))
        - Interpersonal Needs Questionnaire-15 (INQ-15)[63,64]
            - Assesses thwarted belongingness and perceived burdensomeness

    - INQ-15 has good structural validity, internal consistency, and concurrent validity
- Suicide-Related Coping Scale (SRCS)[65]
    - Assesses external coping and internal coping
        - SRCS has good structural validity, internal consistency, sensitivity to change, and concurrent validity
- Acquired Capability for Suicide Scale – Fearlessness about Death (ACSS-FAD)[66]
    - Assesses capability for suicide
        - ACSS-FAD has strong psychometric properties
- Minority Stressors self-report questionnaires
    - Heterosexist Harassment and Rejection Scale (HHRDS)[67]
    - Internalized Homophobia Scale (IHP)[68]
    - Sexual Orientation Concealment Scale (SOCS)[69]
    - Gay-Related Rejection Sensitivity Scale (GRS)[70]
    - Sexual Minority Women Rejection Sensitivity Scale (SMW-RSS)[71]
    - Gender Minority Stress and Resilience Measure (GMSR)[72]
        - Assess distal minority stress (e.g., victimization, rejection, and discrimination) and proximal minority stress (e.g., non-disclosure and internalized transphobia)
- Intersectional Discrimination Index (InDI)[73]
    - Assesses intersectional discrimination
- Social support self-report questionnaires
    - Patient-Reported Outcome Measurement Information System (PROMIS) Emotional Support Scale – Short Form 8a[74]
    - Patient-Reported Outcome Measurement Information System (PROMIS) Informational Support Scale – Short Form 8a[74]
    - Patient-Report Outcome Measurement Information System (PROMIS) Instrumental Support Scale – Short Form 8a[74]
- Hurt, Insult, Threaten Screen (HITS)[75]
    - Assesses intimate partner violence
- McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD)[76]
    - Assesses borderline personality disorder symptomology
- Client Satisfaction Questionnaire-8 (CSQ-8)[77]
    - Assesses satisfaction with mental health care services received
        - CSQ-8 has high internal consistency
- Satisfaction with Interpersonal Relationship with PN[78]
    - Assesses satisfaction with care provided by a patient navigator
        - Satisfaction with Interpersonal Relationship with PN has high internal consistency
- Dysmorphic Concern Questionnaire (DCQ)[79]
    - Assesses dysmorphic symptoms
    - Adapted with modified instructions to better capture the Body Dysphoric Disorder phenotype and identify participants whose concerns were due to an objective disfigurement caused by a medical condition or injury[80]
- Eating Disorder Examination-Questionnaire (EDE-Q)[81]
    - Assesses eating disorder pathology

        - Adapted with modified instructions to improve the measure's utility when evaluating objective binge eating in patients with Binge Eating Disorder[82]
    - Adult ADHD Self-Report Screening Scale for DSM-5 (ASRS-5)[83]
        - Assesses ADHD symptomatology
    - Satisfaction with Mental Health Care
        - Three open-ended questions created by investigative team
    - Open-ended survey questions
        - Used to obtain study and intervention feedback
- Clinician-administered interviews
    - Columbia-Suicide Severity Rating Scale (C-SSRS)[60]
        - Assesses suicidal ideation, intent, plan, and behaviors
        - C-SSRS has strong psychometric properties (i.e. evidence of internal consistency, construct validity, predictive validity, incremental validity, and sensitivity to change)
    - Diagnostic Interview for Anxiety, Mood, Obsessive-Compulsive and Related Neuropsychiatric Disorders (DIAMOND)[61]
        - Semi-structured diagnostic interview
        - Assesses psychiatric diagnoses among adults (aged 18+)
            - DIAMOND has very good inter-rater reliability, test-retest reliability, and convergent and divergent validity
        - Modules regarding the following disorders will be administered depending on responses to screening questions: Anxiety and Mood Disorders, Trauma and Stressor-Related Disorders, and Psychotic Disorders
    - Schedule for Affective Disorders and Schizophrenia for School-Age Children (K-SADS)[62]
        - Computer-administered diagnostic interview
        - Assess psychiatric diagnoses among children (aged 15-17 in this study)
        - Modules regarding the following disorders will be administered depending on responses to screening questions: Anxiety and Mood Disorders, Trauma and Stressor-Related Disorders, and Psychotic Disorders
    - Cornell Services Index (Psychological Services section)[84] - Adapted
        - Assesses the type(s) of psychological services obtained, the type of provider, the site of service, the reason for the visit, the frequency of service, and the number of minutes per visit during the past three months
        - Has good re-test and interrater reliability
        - Adapted by the study team to also collect data on:
            - Comorbid medical conditions
            - Medications prescribed
            - Date participant attended first mental health appointment following study enrollment
            - Number of mental health appointments attended following study enrollment
            - Types of mental health providers who treated the participant following study enrollment
    - Addiction Severity Index - Lite Version (ASI-Lite)[85]
        - Assesses substance use
    - Interview questions to obtain feedback on the study and the intervention.
- Patient Navigator Data Collection
    - Patient navigators will audio-record PN sessions

- Patient navigators will record process data related to the PN provided, including:
  - Number of encounters
  - Length of time of each encounter
  - Barriers experienced by patients
  - Actions taken to reduce barriers
- Patient navigators will keep detailed qualitative notes regarding telephone, text, and in-person encounters with participants, including participants' progress in obtain mental health services, successes in implementing the PN intervention, and challenges in implementing the PN intervention
- Patient navigators will keep copies of the participants' safety plans and the SPI suicide risk curve

Open Trial:

Participants will complete the initial baseline assessment to confirm eligibility. Prior to beginning the baseline assessment procedures, a trained member of the study team will obtain informed consent. If the participant consents to participate in the study, the baseline assessment will be performed. Participants will complete self-report questionnaires (see below), clinician-based interviews (see below), and the first SPI+PN session (intake, introduction to navigation, and the SPI).

Post-baseline, participants will receive PN services for a period of six-months. Patient navigators will record PN intervention encounter data (see below). Participants will complete a three-month follow-up assessment, consisting of self-report questionnaires (see below) and clinician-based interviews (see below). Finally, participants will complete a six-month follow-up assessment, consisting of self-report questionnaires (see below), clinician-based interviews (see below), and a key informant interview.

- Administration of self-report questionnaires:
  - Participants will complete self-report questionnaires in Qualtrics (either done remotely from their homes, or on a computer within the lab).
  - Self-report questionnaires include:
    - Demographics survey
      - Assesses demographic items (e.g. age, race, ethnicity, sex assigned at birth, gender identity, sexual orientation, relationship status, country of origin, U.S. citizen status, primary language, current grade in school or education level, health insurance status, employment status, income (if applicable))
    - Interpersonal Needs Questionnaire-15 (INQ-15)[63,64]
      - Assesses thwarted belongingness and perceived burdensomeness
        - INQ-15 has good structural validity, internal consistency, and concurrent validity
    - Suicide-Related Coping Scale (SRCS)[65]
      - Assesses external coping and internal coping
        - SRCS has good structural validity, internal consistency, sensitivity to change, and concurrent validity
    - Acquired Capability for Suicide Scale – Fearlessness about Death (ACSS-FAD)[66]

- Assesses capability for suicide
    - ACSS-FAD has strong psychometric properties

- Minority Stressors self-report questionnaires
    - Heterosexist Harassment and Rejection Scale (HHRDS)[67]
    - Internalized Homophobia Scale (IHP)[68]
    - Sexual Orientation Concealment Scale (SOCS)[69]
    - Gay-Related Rejection Sensitivity Scale (GRS)[70]
    - Sexual Minority Women Rejection Sensitivity Scale (SMW-RSS)[71]
    - Gender Minority Stress and Resilience Measure (GMSR)[72]
        - Assess distal minority stress (e.g., victimization, rejection, and discrimination) and proximal minority stress (e.g., non-disclosure and internalized transphobia)
- Intersectional Discrimination Index (InDI)[73]
    - Assesses intersectional discrimination
- Social support self-report questionnaires
    - Patient-Reported Outcome Measurement Information System (PROMIS) Emotional Support Scale – Short Form 8a[74]
    - Patient-Reported Outcome Measurement Information System (PROMIS) Informational Support Scale – Short Form 8a[74]
    - Patient-Report Outcome Measurement Information System (PROMIS) Instrumental Support Scale – Short Form 8a[74]
- Hurt, Insult, Threaten Screen (HITS)[75]
    - Assesses intimate partner violence
- McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD)[76]
    - Assesses borderline personality disorder symptomology
- Client Satisfaction Questionnaire-8 (CSQ-8)[77]
    - Assesses satisfaction with mental health care services received
        - CSQ-8 has high internal consistency
    - Adapted by the study team to assess for satisfaction with patient navigation services received in addition to assessing for satisfaction with mental health care services received
- Satisfaction with Interpersonal Relationship with PN[78]
    - Assesses satisfaction with care provided by a patient navigator
        - Satisfaction with Interpersonal Relationship with PN has high internal consistency
- Dysmorphic Concern Questionnaire (DCQ)[79]
    - Assesses dysmorphic symptoms
    - Adapted with modified instructions to better capture the Body Dysphoric Disorder phenotype and identify participants whose concerns were due to an objective disfigurement caused by a medical condition or injury[80]
- Eating Disorder Examination-Questionnaire (EDE-Q)[81]
    - Assesses eating disorder pathology
    - Adapted with modified instructions to improve the measure's utility when evaluating objective binge eating in patients with Binge Eating Disorder[82]
- Adult ADHD Self-Report Screening Scale for DSM-5 (ASRS-5)[83]
    - Assesses ADHD symptomatology

        - Difficulties in Emotion Regulation Scale-16[86]
            - Assesses emotion regulation
        - Satisfaction with Mental Health Care
            - Three open-ended questions created by investigative team
- Clinician-administered interviews
    - Columbia-Suicide Severity Rating Scale (C-SSRS)[60]
        - Assesses suicidal ideation, intent, plan, and behaviors
        - C-SSRS has strong psychometric properties (i.e. evidence of internal consistency, construct validity, predictive validity, incremental validity, and sensitivity to change)
    - Diagnostic Interview for Anxiety, Mood, Obsessive-Compulsive and Related Neuropsychiatric Disorders (DIAMOND)[61]
        - Semi-structured diagnostic interview
        - Assesses psychiatric diagnoses among adults (aged 18+)
            - DIAMOND has very good inter-rater reliability, test-retest reliability, and convergent and divergent validity
        - Modules regarding the following disorders will be administered depending on responses to screening questions: Anxiety and Mood Disorders, Trauma and Stressor-Related Disorders, and Psychotic Disorders
    - Schedule for Affective Disorders and Schizophrenia for School-Age Children (K-SADS)[62]
        - Computer-administered diagnostic interview
        - Assess psychiatric diagnoses among children (aged 15-17 in this study)
        - Modules regarding the following disorders will be administered depending on responses to screening questions: Anxiety and Mood Disorders, Trauma and Stressor-Related Disorders, and Psychotic Disorders
    - Cornell Services Index (Psychological Services section)[84] - Adapted
        - Assesses the type(s) of psychological services obtained, the type of provider, the site of service, the reason for the visit, the frequency of service, and the number of minutes per visit during the past three months
        - Has good re-test and interrater reliability
        - Adapted by the study team to also collect data on:
            - Comorbid medical conditions
            - Medications prescribed
            - Date participant attended first mental health appointment following study enrollment
            - Number of mental health appointments attended following study enrollment
            - Types of mental health providers who treated the participant following study enrollment
    - Addiction Severity Index - Lite Version (ASI-Lite)[85]
        - Assesses substance use
- Patient Navigator Data Collection
    - Patient navigators will audio-record PN sessions
    - Patient navigators will record process data related to the PN provided, including:
        - Number of encounters
        - Length of time of each encounter
        - Barriers experienced by patients
        - Actions taken to reduce barriers

  - Patient navigators will keep detailed qualitative notes regarding telephone, text, and in-person encounters with participants, including participants' progress in obtain mental health services, successes in implementing the PN intervention, and challenges in implementing the PN intervention
  - Patient navigators will keep copies of the participants' safety plans and the SPI suicide risk curve
- Key informant interview

6.5 SAFETY ASSESSMENTS

The Columbia-Suicide Severity Rating Scale (C-SSRS) will be used by the trained telephone screeners, assessors, and patient navigators to assess participant safety throughout both the case series and open trial. The Principal Investigators will train all personnel to use the C-SSRS and will be providing ongoing supervision. The C-SSRS is a clinician-based interview that assesses five types of suicidal ideation of increasing severity and four types of suicidal behavior, as well as the intensity of suicidal ideation. During the phone screen, items from the C-SSRS will be administered to determine participant eligibility, as well as assess participant safety. The C-SSRS will be administered during the baseline assessment to confirm participant eligibility, as well as assess participant safety. The C-SSRS will additionally be administered during each major assessment sessions and at the beginning of each intervention session.

Preliminary verification of eligibility will be completed (over the phone) in advance of the full baseline assessment visit. To manage suicide risk during the telephone screening or assessments (completed in person or remotely), the University of Washington Risk Assessment Protocol (UWRAP)[87] will be used. Those who have enrolled in the study will receive additional support from their navigators following all assessments. A summary of how the UWRAP will be administered is as follows:

<u>Phone Screen:</u>

1. Administer the introductory language and then administer and obtain verbal consent for telephone screening.
2. Administer the location/emergency contact items.
3. Administer the demographic inclusion criteria questions.
4. Administer items from the University of Washington Risk Assessment Protocol (UWRAP) regarding impairment as a result of substance use and the pre-assessment risk protocol (1: stress level; 2: urge to harm oneself; 3: intent to kill oneself; 4: urge to use substances) on a 1-7 point scale.
5. Administer items 1-3 from the UWRAP mood improvement protocol.
6. Administer phone screening items adapted from the Columbia-Suicide Severity Rating Scale.
7. Administer the UWRAP debrief checklist item 1 (obtain feedback on the telephone screening) plus items regarding re-assessment of risk (1: stress level; 2: urge to harm oneself; 3: intent to kill oneself; 4: urge to use substances) on a 1-7 point scale.
8. Administer the UWRAP debrief checklist items 5 and 6 (i.e., coping with negative feelings and suicidal ideation and description of fun activities planned for the day).
9. If potential participant has no suicidal intent and plan, engage in chit-chat and/or suggest

that they engage in the other activities in the UWRAP mood induction protocol item 4 before returning to their daily activities (for example, listen to music)
10. If a potential participant has suicidal intent and/or plan, administer the UWRAP debrief checklist items 8 and 9 (strategies to reduce suicide risk) and then UWRAP mood induction protocol item 4. The person conducting the phone screening should stay on the telephone with the potential participant while they do their activity or chat). After the potential participant has completed their mood induction activity, the phone screener should administer item 5 on UWRAP mood induction protocol (i.e., rating the effect of the activity on their mood).
11. Consult with the clinician “on call” for those with suicidal intent and plan who are unable to guarantee that they will use behavior strategies (for example, to keep themselves safe for 24 hours) who may then contact emergency services.
12. The Principal Investigators should be contacted when any participant expresses suicidal intent and/or plan, based on their responses to the Columbia-Suicide Severity Rating Scale.

Baseline Assessment:

1. Administer the introductory language and then engage in the informed consent procedures for the study.
2. Administer the location/emergency contact items.
3. Administer three items from the University of Washington Risk Assessment Protocol (UWRAP) regarding impairment as a result of substance use and the pre-assessment risk protocol (1: stress level; 2: urge to harm oneself; 3: intent to kill oneself; 4: urge to use substances) on a 1-7 point scale.
4. Administer items 1-3 from the UWRAP mood improvement protocol.
5. Complete the baseline assessment.
6. Administer the UWRAP debrief checklist item 1 (obtain feedback on the telephone screening) plus items regarding re-assessment of risk (1: stress level; 2: urge to harm oneself; 3: intent to kill oneself; 4: urge to use substances) on a 1-7 point scale.
7. Administer the UWRAP debrief checklist items 5 and 6 (i.e., coping with negative feelings and suicidal ideation and description of fun activities planned for the day).
8. If participant has no suicidal intent and plan, engage in chit-chat and/or suggest that they engage in the other activities in the UWRAP mood induction protocol item 4 before returning to their daily activities (for example, listen to music)
9. If the participant remains distressed, administer the UWRAP mood induction protocol item 4. Stay on the videoconference/or with the potential participant while they do their activity or chat. After the participant has completed their mood induction activity, administer item 5 on UWRAP mood induction protocol (i.e., rating the effect of the activity on their mood).
10. Consult with the clinician “on call” for those with suicidal intent and plan who are unable to guarantee that they will use behavior strategies (for example, to keep themselves safe for 24 hours) who may then contact emergency services.
11. The Principal Investigators should be contacted when any participant expresses suicidal intent and/or plan, based on their responses to the Columbia-Suicide Severity Rating Scale.
12. Transfer participant to the patient navigator. The patient navigator will implement the intake session of the patient navigation intervention, which includes the Safety Planning Intervention.

Follow-up Assessment:

1. Administer the introductory language and the location/emergency contact items.
2. Administer three items from the University of Washington Risk Assessment Protocol (UWRAP) regarding impairment as a result of substance use and the pre-assessment risk protocol (1: stress level; 2: urge to harm oneself; 3: intent to kill oneself; 4: urge to use substances) on a 1-7 point scale.
3. Administer items 1-3 from the UWRAP mood improvement protocol.
4. Complete the follow-up assessment.
5. Assessor administer the UWRAP debrief checklist item 1 (obtain feedback on the telephone screening) plus items regarding re-assessment of risk (1: stress level; 2: urge to harm oneself; 3: intent to kill oneself; 4: urge to use substances) on a 1-7 point scale.
6. Assessor administer the UWRAP debrief checklist items 5 and 6 (i.e., coping with negative feelings and suicidal ideation and description of fun activities planned for the day).
7. If participant has no suicidal intent and plan, the assessor should engage in chit-chat and/or suggest that they engage in the other activities in the UWRAP mood induction protocol item 4 before returning to their daily activities (for example, listen to music)
8. If the participant remains distressed, the assessor should administer the UWRAP mood induction protocol item 4. The assessor should stay on the videoconference/or with the potential participant while they do their activity or chat. After the participant has completed their mood induction activity, the assessor should administer item 5 on UWRAP mood induction protocol (i.e., rating the effect of the activity on their mood).
9. Consult with the clinician “on call” for those with suicidal intent and plan who are unable to guarantee that they will use behavior strategies (for example, to keep themselves safe for 24 hours) who may then contact emergency services.
10. The Principal Investigators should be contacted when any participant expresses suicidal intent and/or plan, based on their responses to the Columbia-Suicide Severity Rating Scale.
11. Transfer participant with suicidal intent and plan to the patient navigator. The patient navigator will go over the safety plan with the participant and will administer PN module 6: Suicidal Crisis Management.

6.6 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

6.6.1 DEFINITION OF ADVERSE EVENTS

The National Institutes of Health follows OHRP guidance on the definitions of adverse events and the associated reporting expectations. Thus, an adverse event is defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated w/ subject’s participation in research, whether or not considered related to subject’s participation in the research; encompasses both physical and psychological harm. This study will also capture non-medical events that may be behavioral (i.e., self-harm) or social (e.g., child protective services involvement with the family).

6.6.2 DEFINITION OF SERIOUS ADVERSE EVENTS

According to the SDSU Human Research Protection Program and OHRP guidance, **(from SDSUHRPP Standards and Practices v. 02.13.19; also definition in OHRP guidance, which NIH follows),** an adverse event is considered serious if it: 1) Results in death; 2) is life

threatening; 3) requires inpatient hospitalization; 4) results in persistent or significant disability or incapacity; 5) results in congenital anomaly or birth defect; or 6) risks the subject's health and may require medical or surgical intervention to prevent one of the outcomes listed above. For the purpose of this study, hospitalization is defined as an inpatient hospital stay equal to or greater than 24 hours (inclusive of ER visits of 24 hours or longer).

6.6.3 CLASSIFICATION OF AN ADVERSE EVENT

6.6.3.1 SEVERITY OF EVENT

The Principal Investigators, in consultation with physician Co-Investigator Dr. Ramers and other Co-Investigator Dr. Weersing, if necessary, will assess the severity of adverse events as either: 1) Grade 1: Mild; 2) Grade 2: Moderate; 3) Grade 3: Severe; 4) Grade 4: Life threatening; or 5) Grade 5: Death. The following definitions will be used to assign a severity rating:

1. **Grade 1 Mild:** asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention indicated.
2. **Grade 2 Moderate:** minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activity of daily living.
3. **Grade 3 Severe or medically significant but not immediately life-threatening:** hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living.
4. **Grade 4 Life-threatening consequences:** urgent intervention indicated.
5. **Grade 5 Death related to adverse event.**

Because the study focuses on suicide prevention, adverse events related to suicidal ideation, suicidal behaviors, and other types of self-harm will be graded for severity using the following guidelines:

Grade 1:

1. Worsening of suicidal ideation from baseline or last assessment

Grade 2:

1. Development of new suicide intention or plan
2. Engaging in self-harm behaviors which do not require hospitalization
3. Engaging in self-harm behaviors which require an ER visit but not inpatient hospitalization

Grade 3:

1. Suicide attempt or other type of self-harm which requires hospitalization but is not immediately life threatening.
2. Suicide attempt or other type of self-harm which is disabling
3. Suicide attempt or other type of self-harm which limits self-care activities of daily living

Grade 4:

1. Suicide attempt or other type of self-harm which is life threatening and requires urgent intervention

Grade 5:

1. Death by suicide
2. Death from another type of self-harm
3. Death from any cause

6.6.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Adverse events may be caused by one or more of the following:

1. the procedures involved in the research;
2. an underlying disease, disorder, or condition of the subject; or
3. other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the subject.

In general, adverse events that are determined to be at least partially caused by (1) would be considered related to participation in the research, whereas adverse events determined to be solely caused by (2) or (3) would be considered unrelated to participation in the research.

All adverse events will be rated by the Principal Investigators (in consultation with physician study Co-Investigator Dr. Ramers and other Co-Investigator Dr. Weersing, if necessary) on the degree to which they are related to the study intervention using the following attribution scale and definitions:

1. **Not related:** The adverse event is clearly not related to the study intervention.
2. **Unlikely related:** The adverse event is doubtfully related to the study intervention.
3. **Possibly related:** The adverse event may be related to the study intervention.
4. **Probably related:** The adverse event is likely related to the study intervention.
5. **Definitely related:** The adverse event is clearly related to the study intervention.

In considering the degree to which the adverse event is related to the intervention, the Principal Investigators and Co-Investigators will consider:

1. Whether the adverse event is a known reaction of the intervention?
2. Whether the adverse event is similar to other adverse events listed in the study protocol and consent documents?
3. Whether the adverse events occurred before in this study?
4. Whether the adverse event is reasonably temporally related to the intervention?
5. Whether the adverse event was present at the baseline assessment of the participant?
6. Whether the adverse event can be reasonably explained by the participant's clinical disease status?
7. Whether there are any other potential causes for the adverse event?

6.6.3.3 EXPECTEDNESS

The Principal Investigators (in consultation with physician study Co-Investigator Dr. Ramers and other Co-Investigator Dr. Weersing, if necessary) will be responsible for determining whether an

adverse event (AE) is expected or unexpected. The following definition will be used to determine the expectedness of the AE:

OHRP defines *unexpected adverse event* as any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is **not** consistent with either:

1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

According to OHRP's unanticipated problems involving risks and adverse events guidance (2007)[88], the vast majority of adverse events occurring in the context of research are *expected* in light of (1) the known toxicities and side effects of the research procedures; (2) the expected natural progression of subjects' underlying diseases, disorders, and conditions; and (3) subjects' predisposing risk factor profiles for the adverse events.

By the definition above, the following adverse events are expected for the study: non-suicidal self-injury, suicidal ideation, suicidal intent, suicidal plan, suicide attempts, hospitalization related to suicide attempt or self-harm, and death from suicide or self-harm. Additionally, given that SGM youth (particularly those with a history of suicide attempts and ideation) experience elevated health disparities compared to the general population on many mental health/substance use markers, we also expect significant comorbidities, including psychiatric and substance use disorders, to be reported over the course of the study.

All adverse events will be rated on whether or not they were expected (Yes, No) according to OHRP criteria and in consideration of the adverse events expected for this study.

6.6.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

Adverse events will be ascertained by the following methods: 1) spontaneously reported symptoms; 2) observed symptoms and signs; 3) other people's reports (e.g., parent, guardian, health care provider, child protective services, trusted adult); and through 4) regular assessments using validated questionnaires. The University of Washington Risk Assessment Protocol (UWRAP) will be administered during each major assessment session (Case Series: baseline, 3-month follow-up; Open Trial: baseline, 3-month follow-up, 6-month follow-up). The Columbia-Suicide Severity Rating Scale (C-SSRS) will also be administered during each major assessment session and at the beginning of each virtual, phone, or in person intervention session, to assess suicidal ideation, intent, plans, and behaviors. The UWRAP and C-SSRS are being utilized to identify suicide-related AEs and SAEs. All staff interacting with study participants will be trained to observe participants for signs of injury or illness during virtual and in person assessments. If any injury or illness appears to be related to child abuse and neglect, study staff will also follow the standard of practice for child abuse and neglect, in addition to

documenting an adverse event. Study staff will also be trained to document spontaneously reported symptoms or other information about adverse events when reported by a participant or another person. If the adverse event is reported to the study team by another person, a member of the study team will attempt to verify the adverse event by contacting the study participant. Suicidality-related clinical worsening is not solely defined by increases in C-SSRS scores. Clinical worsening is determined on a case-by-case basis by the Principal Investigators, if needed in consultation with Drs. Ramers and Weersing.

6.6.5 ADVERSE EVENT REPORTING

The Principal Investigators are responsible for reporting adverse events to the SDSU IRB according to the timelines established in the IRBs reporting policies and will be assisted in submitting reports by the research coordinator. For all adverse events that are deemed expected and/or unrelated to the study, a summary should be submitted to the NIMH PO with the annual progress report. Adverse events that are not SAEs will be included in the DSMB full data report that is submitted once a year.

6.6.6 SERIOUS ADVERSE EVENT REPORTING

The Principal Investigators are responsible for reporting serious adverse events to the SDSU IRB according to the timelines specified by the IRBs reporting policies and will be assisted in submitting reports by the research coordinator. According to SDSU IRB policy, all study-related serious adverse events must be reported to SDSU IRB within 24 hours. A summary of serious adverse events that are deemed expected and/or unrelated to the study will be submitted to the NIMH PO with the annual progress report. Unexpected Serious Adverse Events related to study participation will be reported to the NIMH PO within 10 business days of the study team becoming aware of the serious adverse event. SAEs will be reported to the DSMB in the data reports submitted three times a year. Expedited reporting will be provided to the Board for all deaths and unexpected and related SAEs. For deaths, the report will be submitted within 5 business days, and for unexpected and related SAEs, the report will be submitted within 10 business days.

6.7 UNANTICIPATED PROBLEMS

6.7.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP):

OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated problems can include experiences such as protocol deviations, data breaches, having study-related data or documentation unsecured and stolen.

6.7.2 UNANTICIPATED PROBLEMS REPORTING

Unanticipated problems that are serious adverse events (SAEs) will be reported by the investigator to the SDSU IRB within 24 hours. Unanticipated problems which can cause serious risks to others are reported to the NIMH PO and the DSMB within 10 business days of the investigator learning of the event. Any other unanticipated problem will be reported by the investigator to the SDSU IRB, the NIMH PO, and the NIMH DSMB within 10 business days.

The unanticipated problem report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an unanticipated problem
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem

6.7.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

Participants will be informed individually about unanticipated problems which may impact their current and future health and privacy via their preferred method of communication (e.g. phone, text, mail).

7 STATISTICAL CONSIDERATIONS

7.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

The purpose of the case series is to obtain feedback on study procedures and the PN+SPI intervention. Therefore, there are no formal hypotheses associated with the case series. Only descriptive statistics will be calculated.

For the open trial, it is hypothesized that PN+SPI participants will display decreases in thwarted belongingness and increases in suicide-related coping skills (the hypothesized mechanistic targets of the intervention). We will also assess the feasibility and acceptability of the PN+SPI intervention during the open trial.

7.2 SAMPLE SIZE DETERMINATION

For the open pilot, N = 30 was selected based on recommendations in the field which specify 15 to 30 participants per condition are satisfactory for pilot trials. Given the open pilot includes a single condition, we planned for the upper limit sample size based on these recommendations[89].

7.3 POPULATIONS FOR ANALYSES

There are no quantitative analyses for the case series. For the open pilot, the analysis population will include any participant who participated in one or more intervention sessions. Given that the first intervention session occurs during the initial baseline appointment, this means that all participants should be included in the analyses.

7.4 STATISTICAL ANALYSES

7.4.1 GENERAL APPROACH

In the case series and open trial, descriptive statistics will be presented as frequencies and percentages (for binary and categorical variables), means with standard deviations, and range (for continuous variables).

In the open trial, qualitative data will be saved in a text file to import into NVivo[90] for analysis. Drs. Wells and Blashill will review the qualitative data using a content analysis technique, which identifies emergent themes occurring during discussion. Code mapping[91] will be used to develop a preliminary set of codes (themes) corresponding to each potential strength of the PN+SPI as well as every potential aspect for improvement. Then, Drs. Wells and Blashill will independently code the remaining data and meet to discuss coding. Once coded, the data will be summarized by theme.

Inferential tests and checks of assumptions underlying statistical procedures will not be performed in either the case series or open trial. No corrective procedures will be applied.

7.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

As the purpose of the case series is to obtain feedback on study procedures and the PN+SPI intervention, no statistical analyses will be conducted.

In the open trial, the feasibility and acceptability of the PN+SPI intervention will be assessed descriptively and therefore will not involve any statistical analyses. However, we will examine the preliminary impact of the PN+SPI intervention on the purported mechanisms of action (e.g. decreasing thwarted belongingness, increasing suicide-related coping skills). This will be done by testing within-person changes in thwarted belongingness and suicide-related coping skills by calculating Cohen's d. If missing data are minimal (e.g. 5% or less) available item analysis will be conducted. If greater than 5% of data are missing, multiple imputation will be conducted. Outliers will be defined as ± 3.3 standard deviations from the mean and will be Windsorized to the next highest non-outlier value. This approach retains the rank order of the outlier, without the outlier exerting a disproportionate effect on the sample.

7.4.3 BASELINE DESCRIPTIVE STATISTICS

In both the case series and open trial, baseline descriptive statistics will be used to describe the sample in terms of sociodemographics and psychiatric diagnoses. There is only one treatment group (PN+SPI) so intervention groups cannot be compared. Inferential statistics will not be used.

8 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

8.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

8.1.1 INFORMED CONSENT PROCESS

8.1.1.1 CONSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

For both the case series and open trial, participants will initially be screened for eligibility via a phone screen conducted by a trained member of the study team. Prior to beginning the phone screen, a trained member of the study team will obtain verbal consent for pre-enrollment screening. The IRB-approved verbal informed consent form will be read verbatim to all study participants over the phone. It describes in detail the phone screening procedure and associated risks. During the COVID-19 pandemic, all study procedures, including consenting, will be conducted virtually.

Those who meet the screening criteria will be scheduled for an initial baseline appointment. At the time of the baseline appointment, a trained member will engage in a discussion with all participants and using a written/digital informed consent form that describes in detail the study intervention, study procedures, information about potential risks and benefits of participation, and information regarding whom they can contact if they have any further questions. It will also state that participation is voluntary, that participants can refuse to answer any question, they can withdraw from the study at any time, and that study participation is in no way related to participating in other studies at San Diego State University. Written/digital documentation of informed consent will be completed prior to starting the intervention. The following consent materials are submitted with this protocol:

1. Telephone Screening Consent **(see attachment 6)**
2. Informed Consent Case Series **(see attachment 7)**
3. Informed Consent Open Trial **(see attachment 8)**

8.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

The verbal informed consent for the phone screen will be administered by a trained member of the study team. Prior to beginning the phone screen, the study team member will read the verbal informed consent verbatim to the participant and answer any questions that they may have. The study team member will then ask if they would like to take part in the screening process today. If the participant provides their verbal consent to participate, the study team member administering the informed consent will document that the participant provided their consent to answer the screening questions. This will be done by having the study team member sign the telephone screening consent form.

The informed consent for the case series, as well as open trial, will be administered by a trained member of the study team. This will be done at the beginning of the baseline assessment prior to beginning study procedures. At this time, the study team member will verbally go through the informed consent with the participant and answer the participant's questions. The study team member will then give the participant time to review the consent form at their own pace and answer any further questions that they may have. The study team member will then ask the participant if they would like to take part in the study. If the participant does wish to participate, the study team member will have the participant sign the informed consent form. The study team member will then sign the informed consent form themselves and provide the participant with a copy of the informed consent form.

Given that we have obtained a waiver of parental consent form from the IRB and an approval of minor's ability to self-consent, the procedure for administering informed consent for minors in the case series, as well as open trial, will be the same as for adults. These consent procedures use eight-grade verbiage to facilitate comprehension by both minors and adults. We will not re-consent children who become adults or are emancipated during the study.

We will not obtain consent from speakers of language other than English, as the ability to speak English is one of the inclusion criteria required for study enrollment. We will assess competency and comprehension/understanding through discussing the informed consent with the participant. Similarly, we will not obtain surrogate consent for those unable to consent on their own behalf, as the ability to provide informed consent is one of the inclusion criteria required for study enrollment.

8.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, sponsor/funding agency (NIMH), and regulatory authorities (OHRP, DSMB). If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the SDSU Institutional Review Board (IRB), the DSMB, funding agency (NIMH), and OHRP and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable

If suspended, the study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor/funding agency (NIMH), IRB, or other relevant regulatory or oversight bodies (OHRP, DSMB).

8.1.3 CONFIDENTIALITY AND PRIVACY

All data will be kept confidential, under lock-and-key, or electronically and password protected, accessible only to trained study staff. All participants will be assigned a four-digit ID number (e.g. "1001") upon scheduling the initial baseline assessment. Participants' data will be identified by

this ID number only, and a link between names and ID number will be kept separately in a password protected participant contact electronic file, accessible only to study staff.

Research files (for example, surveys, interviews, audio files) will be kept at SDSU. All research data collected from participants will be stored in a separate password protected file in a separate electronic drive. All digital audio recordings of sessions will be uploaded to the study computer immediately post session and the file deleted from the original recorder. Physical copies of some data (e.g. clinician-based assessments) will only include participant IDs, and will be stored in a locked filing cabinet, within a locked room, in a locked suite. Only trained study staff will have access to electronic and physical data.

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

The computers where study data will be stored may be connected to the internet. Study data may be stored on a university-managed Google drive which can only be accessed using a password-protected login. The study Google drive follows university IT security procedures. Access to the study Google drive will be limited to study staff. Some of the study data will be collected using the Qualtrics survey system. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data. Access to the study survey and data will be limited to study staff who must use a password to access study surveys and data.

Physical copies of data will be retained for seven years after the completion of the study. After seven years, identifiable computer files will be erased and the paper surveys will be shredded. Audio recordings will be retained for three years after the completion of the study. After three years, the audio files will be erased. Permission will not be required to destroy physical copies of data or audio recordings.

The investigative team will work with the Institutional Review Board that regulates the study, as well as Family Health Centers of San Diego, to coordinate the data sharing process. Any information that could potentially identify a participant will be removed prior to distributing the data. All investigators funded under this funding opportunity announcement are expected to share data collected as part of an award. Thus, in accordance with National Institute of Mental Health policy, we will prepare and submit de-identified data to the National Data Archive (NDA). In addition, instructions for contacting the Multiple Principal Investigators will be placed on their lab websites so that researchers interested in using the data can contact them directly to obtain the de-identified data. The research team will require that any recipients of the data execute a data sharing agreement with San Diego State University that will obligate recipients to: 1) use data only for research; 2) not identify an individual participant; 3) commit to securing data using appropriate computer technology; and 4) commit to destroying or returning data after analyses are completed or three years have passed

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide

reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

8.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Biospecimens are not being collected for this study. Data collected will be analyzed and stored at San Diego State University. After the study is completed, the de-identified, archived data will be transmitted to and stored at the National Data Archive for use by other researchers including those outside of the study. Permission to transmit data to the NDA will be included in the informed consent.

When the study is completed, access to the de-identified study data will be provided through the NDA. Researchers can also request the data directly from the Multiple Principal Investigators.

Genetic testing will not be performed as part of the study.

8.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Principal Investigator**
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There are no study leadership committees or country-specific administrative requirements or functions that materially affect the conduct of the study for either the case series or open trial.

8.1.6 SAFETY OVERSIGHT

Safety oversight will be under the direction of a NIMH Data and Safety Monitoring Board (DSMB) composed of individuals with the appropriate expertise, including, at minimum, one content-related or therapeutic area expert and a biostatistician. Members of the DSMB will be independent from the study conduct and free of conflict of interest. The board will meet via teleconference 3 times per year. The DSMB will operate under the rules of an approved charter that clearly outlines what data points will be monitored, how the data will be monitored, and the monitoring schedule. The DSMB review will include, at minimum: enrollment data, safety data, and data and protocol

integrity. These will be provided to the Board for review in advance of each meeting. Any DSMB member can request an additional meeting or additional information should they desire it. The DSMB will issue meeting minutes that will be provided to the Principal Investigators following each review/meeting. This report will include any significant actions taken and the final recommendations with regard to the study's continuation. These reports will be submitted to the NIMH Program staff in the annual progress report.

8.1.7 QUALITY ASSURANCE AND QUALITY CONTROL

Both the case series and open trial will have a written Manual of Procedures (MOP) detailing the study's organization, operations, procedures, data collection, data management, and quality control. This MOP will be developed by the PIs in collaboration with study team members, and the MOP will be provided to research staff during their training. The MOP will be regularly reviewed by the Principal Investigators to ensure that the operating procedures described in the MOP are accurate. If any procedures have been changed or modified, the MOP will be updated and distributed to research staff. Each page of the MOP will be numbered and dated and contain a version number that will be updated with each revision to ensure that the correct version of the MOP is used by study staff.

All essential documents pertaining to the conduct of the study will be contained in an electronic regulatory binder. This regulatory binder will be maintained by study staff and will contain the following documents:

1. IRB-related documents
    - All versions of IRB-approved protocols and amendments
    - All versions of IRB-approved informed consent forms
    - All versions of IRB-approved recruitment advertisements
    - IRB continuing review submissions and approvals
    - IRB compliance documentations
2. DSMB-related documents
    - DSMB reports and approvals
    - DSMB charter
3. NIMH-related documents
    - Documents related to NIMH grants management (e.g. grant application, grant award, financial documents)
    - NIMH progress report submissions and correspondence
    - Reportable events
4. Study staff training and qualifications documents
    - Curriculum vitae (CV) for those listed on delegation of authority log
    - Documentation of current licensure for PIs and all sub-investigators
    - Documentation of human subjects protection training and GCP training
    - Documentation of study-specific training
5. Ongoing study operations documents
    - Manual of Procedures (MOP)
6. Study logs and templates documents
    - Delegation of authority log

- Subject screening and enrollment log template
- Confidential subject identification code template
- Protocol violations and deviations log
- Adverse event/serious adverse event log
- Sample source documents

The study staff will be responsible for ensuring that all essential documents in the regulatory binder are complete and current.

The research team will receive ongoing training and feedback via quality control checks. The following quality control (QC) procedures will be implemented in both the case series and open trial:

Good Clinical Practice (GCP) - Study staff who directly interact with participants will complete GCP training requirements in accordance with the principles of the International Conference on Harmonisation (ICH) E6 (R2). Each staff member's completion of GCP training requirements will be documented in a GCP training log created by the study team, as well as maintained in the regulatory binder. All other study staff is required to complete the CITI Human Subjects Research (HSR) – Social-Behavioral course required by SDSU.

All study staff members are responsible for ensuring that their GCP and/or HSR training is up-to-date. The Principal Investigators understand and accept responsibility for overseeing the conduct of the study in accordance with GCP.

Safety Monitoring — Study staff will monitor whether documentation related to safety protocols indicates that safety protocols have been appropriately followed. This will include SOPs for the telephone screening and all assessments as well as the patient navigation intervention Module 10. Documentation will include forms completed for the screening, assessments, and intervention, along with the progress notes for the patient navigation intervention.

Informed Consent — Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed. Study staff will be responsible for updating the informed consent in the regulatory binder every time the IRB approves a new version.

Source Document Verification (SDV) — Study staff will confirm that accurate, complete, and current source documentation is maintained. SDV will be ongoing.

Data Integrity — Data collection will occur in the form of self-report questionnaires, clinician-administered verbal assessments, logs of patient navigation encounters, observations of study team members, and key informant interviews. All study data will ultimately be entered into study databases. To ensure accuracy, trained study team members will regularly perform data verification and data cleaning procedures.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study.

Protocol Deviations — The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a

level of concern. All protocol deviations will be documented in a protocol deviation and violation tracking log created by the study team, as well as maintained in the regulatory binder. Protocol versions will be updated in a regulatory binder with each IRB-approved revision.

8.1.8 DATA HANDLING AND RECORD KEEPING

8.1.8.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the trained study team members under the supervision of the principal investigators. The investigators will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Source data will be recorded in either electronic or paper form. Source data includes self-report surveys, clinical interviews, key informant interviews, patient navigation encounter forms, and audio recordings of patient navigator sessions and interviews conducted as part of the study. All processing of source data will be ongoing.

All paper source data (e.g. clinical interviews) will be entered into an electronic study database directly from the source documents to ensure that it is consistent with the data recorded on the source documents. Additionally, double data entry will be performed by trained study team members.

Most surveys will be completed by participants directly in Qualtrics, reducing the need for data entry.

All audio files will be transcribed verbatim by a research assistant and verified by a second research assistant.

Source data will may be stored on a university-managed Google drive which can only be accessed using a password-protected login. The study Google drive follows university IT security procedures. Access to the study Google drive will be limited to study staff. Some of the study data will be collected using the Qualtrics survey system. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data.

A study codebook will be developed for all survey and interview data.

8.1.8.2 STUDY RECORDS RETENTION

Physical copies of data will be retained for seven years after the completion of the study. After seven years, identifiable computer files will be erased and the paper surveys will be shredded. Audio recordings will be retained for three years after the completion of the study. After three years, the audio files will be erased. Permission will not be required to destroy physical copies of

data or audio recordings. Aggregated, de-identified data will be retained indefinitely for data sharing purposes, as required by NIMH.

8.1.9 PROTOCOL DEVIATIONS

According to the SDSU Human Research Protection Program, a protocol deviation is defined as when there is inconsistency between the procedures carried out in a study and the procedures stated in the research protocol, or when regulations regarding the manner in which research is being conducted are not being followed (**from SDSUHRPP Standards and Practices v. 02.13.19).** The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the investigator to use continuous vigilance to identify and report deviations to the SDSU IRB within 5 days. All deviations will be addressed in study source documents, and reported to NIMH PO with the annual progress report. All protocol deviations will also be reported to the DSMB annually in the full data report. These reports should indicate that the monitoring entities (PI, IRB, DSMB) and appropriate regulatory entities have been notified in accordance with the approved monitoring plan and federal regulations.

8.1.10 PUBLICATION AND DATA SHARING POLICY

San Diego State University is committed to the principle of rapid data, model, and software release to the scientific community. We will adhere to the Data Sharing Policy developed by the National Institutes of Health as well as specific policies of the National Institute of Mental Health.

The goals for dissemination of our research are to directly share the study findings and materials: 1) with the research community via scholarly publications in peer-reviewed public health, behavioral science, and medical journals and presentations at professional conferences; 2) with the community and public via a variety of channels, including presentations in the community and at FHCSD and; 3) with researchers and the public on websites, including the websites of the Multiple Principal Investigators, the SDSU HealthLINK Center, and the Center for Research on Sexuality and Sexual Health (SASH). Decisions regarding dissemination will be made by the research team in collaboration with the Participatory Planning Group.

The study team will adhere to the National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

Publication of data shall occur during the project, if appropriate, or at the end of the project, consistent with normal scientific practices. Research data which documents, supports, and validates research findings will be made available after the main findings from the final research data set have been accepted for publication. Such research data will be de-identified to prevent the disclosure of personal identifiers.

8.1.11 CONFLICT OF INTEREST POLICY

There are no conflicts of interest to report for either the case series or open trial.

8.2 ABBREVIATIONS AND SPECIAL TERMS

ACSS-FAD	Acquired Capability for Suicide Scale – Fearlessness about Death
AE	Adverse Event
ASRS-5	Adult ADHD Self-Reporting Screening Scale for DSM-5
BISH	Body Image, Sexuality, and Health
CFR	Code of Federal Regulations
COC	Certificate of Confidentiality
COVID-19	Coronavirus Disease 2019
CSQ-8	Client Satisfaction Questionnaire-8
C-SSRS	Columbia-Suicide Severity Rating Scale
CV	Curriculum Vitae
DCQ	Dysmorphic Concern Questionnaire
DERS	Difficulties in Emotion Regulation Scale
DIAMOND	Diagnostic Interview for Anxiety, Mood, Obsessive-Compulsive and Related Neuropsychiatric Disorders
DSMB	Data Safety Monitoring Board
EDE-Q	Eating Disorder Examination-Questionnaire
ER	Emergency Room
FHCSD	Family Health Centers of San Diego
GCP	Good Clinical Practice
GRS	Gay-Related Rejection Sensitivity Scale
GMSR	Gender Minority Stress and Resilience Measure
HHRDS	Heterosexist Harassment, Rejection, and Discrimination Scale
HHS	Secretary, Health and Human Services
HIV	Human Immunodeficiency Virus
ICH GCP	International Council on Harmonisation Good Clinical Practice
IHP	Internalized Homophobia Scale
INQ-15	Interpersonal Needs Questionnaire-15
IRB	Institutional Review Board
IT	Information Technology
K-SADS	Schedule for Affective Disorders and Schizophrenia for School-Aged Children
LGBT	Lesbian, Gay, Bisexual, Transgender
MOP	Manual of Procedures
NCT	National Clinical Trial
NDA	National Data Archive
NIH	National Institutes of Health
NIHGPS	National Institutes of Health Grants Policy Statement
NIMH	National Institute of Mental Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
PN	Patient Navigation
PNRP	Patient Navigation Research Program

PN+SPI	Study Intervention Name
PO	Program Officer
PPG	Participatory Planning Group
QC	Quality Control
RCT	Randomized Control Trial
SAE	Serious Adverse Event
SASH	Center for Research on Sexuality and Sexual Health
SDSU	San Diego State University
SDSUHRPP	San Diego State University Human Research Protection Program
SDV	Source Document Verification
SGM	Sexual and Gender Minorities
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOCS	Sexual Orientation Concealment Scale
SOP	Standard Operating Procedure
SPI	Safety Planning Intervention
SRCS	Suicide Related Coping Scale
TLS	Transfer Layer Security (also known as HTTPS)
UP	Unanticipated Problem
US	United States
UWRAP	University of Washington Risk Assessment Protocol

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