Statistical Analysis Plan

Preventing Addiction Related Suicide (PARS) - Controlled Trial of Secondary Suicide Prevention

NCT03166709

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Additional Information

Study approved for funding July 2016

Redacted for names of clinics and other non-essential private information

Statistical plan can be found in C.7

Specific Aims

The goal of this study is to evaluate the effectiveness and utility of our NIDA R21 developed "Preventing Addiction Related Suicide" (PARS) program[1] by utilizing a novel stepped wedge design to evaluate PARS as a selected prevention program to increase help-seeking by clients in community addiction treatment. Studies consistently show suicide and suicidal behaviors are highly related to substance use disorders (SUDs). Recent reviews find that the **risk of suicide is 10-17 times higher for people using multiple drugs, injecting drugs, and for alcohol use disorders.**[2,3] SUDs are also related to suicidal thoughts and suicide attempts. Clients admitted for alcohol treatment report a much higher rate of lifetime suicide attempts (40-43%) than a nationally representative sample of adults (4.6%).[4–6] Further, prospective data shows that **individuals in addiction treatment had five times the odds of suicide attempt over five years compared to those not in treatment**,[7] emphasizing addiction treatment as a key opportunity for instituting suicide prevention strategies.[8]

Based on Stage I guidelines for developing and adapting behavioral interventions[9,10] and information from a Substance Abuse and Mental Health Services Administration (SAMHSA) Treatment Improvement Protocol (TIP50) on suicide and addiction,[11] we developed the Preventing Addiction Related Suicide (PARS) program. To maximize the chances of implementation, PARS was developed to be a community-friendly program with a team of community partners (i.e., administrators, counselors, clients) who advised on its scope, duration, and approach. Community leaders reviewed PARS throughout its development and pilot testing was conducted in their community treatment settings. Thus, PARS is simultaneously based on evidence-based practice **and** the goals and needs of community treatment settings. Importantly, PARS is a selected prevention program and not intervention for suicidality *per se*—it is designed for all clients in addiction treatment as a standard part of care. PARS' goal is increased help-seeking by addiction treatment clients as well as by clients' friends and family if and when they themselves become suicidal. Reaching out for help leads to care that can address and resolve suicidality. **PARS is the only published selected prevention program for this high-risk population.**

PARS is a psychoeducational program taught as a single three-hour module integrated into a standard group therapy-oriented Intensive Outpatient Program (IOP), the most common form of community addiction treatment.[12] Pilot testing of PARS in three community agencies demonstrated significant post-intervention increases in accurate information about suicide and decreases in maladaptive attitudes toward suicide. These changes at post-intervention were maintained at 1-month follow-up. Even more compelling, 1-month follow-up assessments demonstrated that the likelihood of positive help seeking for suicidality doubled for the month after PARS compared to the month before. Clients were significantly more likely to ask suicidal friends (from 9% to 22%) and family (9% to 17%) to seek help as well as to seek help themselves (4% to 9%).

Given these promising Stage I results in Stage III settings, we propose a fully-powered Stage III effectiveness trial of PARS compared to Treatment-as-Usual (TAU) using a stepped wedge design with 900 clients enrolled in 15 community addiction treatment sites (see Figure 1 for design model). We will collect outcome data post-intervention and at 1, 3, and 6 months follow-up. We propose the following research aims:

Aim 1: Compare the effectiveness of IOP integrating PARS to TAU to change beliefs about suicide and suicide prevention.

Hypothesis 1a: Clients who receive PARS will know more accurate information about suicide

Hypothesis 1b: Clients who receive PARS will have less maladaptive attitudes about suicide

Aim 2: Compare the effectiveness of IOP integrating PARS to TAU to increase help-seeking behaviors for clients and for clients' friends or family at risk of suicide.

Hypothesis 1c: Clients who receive PARS will show greater help-seeking for themselves and others

Aim 3: Evaluate whether changes in beliefs about suicide and suicide prevention—particularly regarding warning signs for suicide, including addiction, intoxication, and relapse, as well as beliefs that suicide is preventable when action is taken—are possible mechanisms by which PARS increases help-seeking behavior.

Hypothesis 2: The effect of PARS vs. TAU on changes in help-seeking will be mediated by improved information and attitudes

Exploratory Aim 4: Evaluate possible clinic-level dose effects of PARS administration such that participant outcomes improve the longer PARS is implemented within clinics.

Exploratory Aim 5: Compare the effects of PARS vs. TAU on clients' suicidality *and substance use* in the follow-up period.

By integrating PARS into IOP group treatment, community treatment agencies are in a unique position to act as key players in the national suicide prevention strategy by providing suicide prevention information, improving attitudes regarding suicide, and increasing help-seeking skills for one of the most high-risk populations for suicide. This proposal is innovative in its focus, the development of PARS in community settings, as well as the use of a stepped wedge design.

A. Background and Significance

1. Suicidal behavior is prevalent and costly in substance-abusing populations.

Suicide and suicidal behaviors are over-represented in populations with substance use disorders (SUDs) compared to the general adult population. Recent reviews find that the risk of suicide is 14 times higher for people injecting drugs, 10 times for alcohol use disorders, and 17 times for polydrug users.[2,3] Clients receiving alcohol treatment are about 10 times more likely to endorse of a lifetime history of suicide attempts (43%)[4,5] compared to a nationally representative sample of adults (4.6%).[6] Moreover, prospective data shows that individuals in addiction treatment had five times the odds of suicide attempt over five years compared to those not in treatment.[7] Suicidal behavior places a heavy burden on the health services system, resulting in more than 650,000 hospital visits and $2 billion in health care costs each year, while suicide deaths result in an annual economic burden of $44 billion.[13,14] Thus, consistent with NIDA's mission to identify and test population-level approaches for the prevention of drug-related problems, there is a need to develop and evaluate effective behavioral treatments that can be easily and widely implemented to reduce suicidal behaviors in substance-abusing populations. PARS is a prime candidate for such research, as it has shown promising results in Stage I research (i.e., intervention generation and refinement, pilot testing, and feasibility) conducted in community treatment settings (R21 DA026494). Funding the proposed Stage III research (i.e., "efficacy in the real world") trial would further evaluate PARS' effectiveness and utility in community settings.

2. Community addiction treatment is an ideal setting for targeting suicide risk in this high-risk group.

Every year, approximately 2.5 million people in the United States enter specialized addiction treatment programs.[11] By far, the most common modality of publicly funded addiction treatment available is group-based Intensive Outpatient Programs (IOP).[12] Thus, adding evidence-based, transportable suicide prevention strategies into the standard IOP treatment package has the potential to reach an enormous number of people who are at very high risk for suicide. Moreover, entering addiction treatment may represent a key window for intervention to reduce suicidal behaviors, as this transition is marked by high rates of suicidal thinking and behavior. Individuals often enter addiction treatment in the context of multiple increased risk factors for suicide: when substance use is out of control and/or is resulting in particularly severe impairment (e.g., marital or financial difficulties, severe depressive symptoms).[15] Between 10% and 40% of clients entering addiction treatment report suicidal ideation with a plan.[16,17] Roughly one out of every 25 clients entering addiction treatment report having made a suicide attempt in the 30-day period before treatment,[18] while one in four report having made a suicide attempt in the past year.[19] Moreover, suicide risk is known to be highly fluid,[20] and although most IOPs will screen patients for suicide risk at the outset of treatment, suicidal ideation and behaviors are likely to fluctuate over the course of treatment, particularly if high-risk situations such as relapse occur during treatment.[11] Thus, addiction IOPs will frequently treat people who are or have recently been suicidal,[18] and have the potential to directly intervene to reduce these problems. Clients with addiction also connect with each other during treatment, in twelve-step meetings, and in drug use. Improving accurate information and adaptive attitudes toward suicide prevention as well as how to effectively reduce risk and reach out for help may not only increase their access to care if suicidal but also increase access of their friends and family who are often also at risk.

3. Addiction treatment providers need additional training to prevent suicidal behavior.

Unfortunately, most chemical dependency counselors feel unprepared, inadequately trained, and uncomfortable addressing the issue of suicide.[21,22] Recently, there have been several efforts to respond to this need. For example, SAMHSA recently developed the Treatment Improvement Protocol number 50 (TIP50),[11] which provides best-practice guidelines for counselors and program administrators to effectively assess, manage and respond to acute suicide risk within addiction treatment programs. The TIP50 is associated with significantly increased staff self-efficacy, suicide-related knowledge, and suicide prevention behaviors.[23] Moreover, some states (e.g., Washington and Kentucky) have recently passed legislation requiring suicide prevention training for all human services personnel, including addictions counselors.[24] While these efforts are good first steps, they primarily focus on managing suicidal crises (e.g., assessing risk and determining when to refer the client to a higher level of service). Instead of aiming to treat acutely suicidal people, PARS aims to deliver an upstream prevention program to an at-risk population. This selected suicide prevention program thus has the potential to serve a dual purpose of providing prevention for clients, and providing ongoing education and training for the addiction treatment staff tasked with delivering the program.

4. Built-in therapist adherence and fidelity to model.

One of the challenges of implementing suicide prevention programs in community treatment settings is the limited resources for ongoing training. PARS was developed to easily fit within the daily work and training models of community IOPs. PARS is delivered in a single IOP session (typically, a 3-hour group therapy

session) using a detailed PowerPoint presentation (developed by the R21) to provide structure, psychoeducational content, and defined discussion periods. Clients are taught to recognize the warning signs for suicide in themselves and others and how to respond effectively by seeking support and treatment. Pilot testing showed that naïve community addiction counselors could be trained to competently and adherently deliver PARS in a single three-hour training session that utilized the same set of PARS PowerPoints that counselors later used in an IOP session with addictions clients. In this way, the PARS training model promotes faithful administration of the program without unduly burdening clinical and administrative staff. Counselors rated this model of training as very acceptable (62-69% "strongly agreed" that PARS would be acceptable and appropriate to addictions counselors, and would be beneficial to clients). Moreover, by repeatedly delivering PARS with each new IOP group cohort, counselors will be re-exposed to suicide-relevant risk assessment and help-seeking strategies, potentially continuing to improve their comfort and competence in discussing and determining suicide risk, and intervening when appropriate.

5. A selected prevention approach can expand impact and reach.

Although the empirical base for interventions to reduce suicide has rapidly developed in the last 30 years, many of these interventions have either aimed at 1) reducing suicide rates in an entire populations (universal prevention, e.g., suicide awareness media campaigns), limiting our ability to detect immediate and short-term effectiveness, or 2) only provided to individuals already presenting with acute suicidality (indicated prevention, e.g., individual cognitive-behavioral therapy for substance users with suicidal ideation or recent attempts[25]), limiting their generalizability. In contrast to these approaches, a selected prevention strategy can have greater reach and impact by offering a compromise between these approaches. Selected prevention aims to intervene before suicidal thinking or behavior develops. Rather than targeting the entire population or the specific individual, selected prevention targets all individuals within a pre-selected high-risk population—in this case, adults presenting for addiction treatment. Because selected prevention assumes that not every individual receiving the program will experience the problem of interest (i.e., suicidal ideation or behavior), it aims to increase knowledge and attitudes that will facilitate help-seeking on behalf of the client as well as his or her peers, increasing the reach of PARS to include other individuals in the client's social network. Previous randomized controlled trials have shown that comparable, school based selected suicide prevention programs upon which PARS was based result in significantly increased rates of help-seeking on behalf of self and others[26], as well as lower rates of suicidal thoughts, threats and attempts in high school students.[26–29]

6. Changing behavior through changes in beliefs about suicide has been effective.

PARS was developed by adapting existing, empirically supported suicide prevention programs to fit substance use settings and populations. The three programs that informed PARS are: 1) Signs Of Suicide (SOS)[26,27], 2) Counselors Care, Assess, Respond, Empower (C-CARE)[28–30], and 3) Coping and Support Training (CAST).[28–30] Each of these programs aims to promote help seeking through two primary mechanisms. First, by providing education about warning signs for suicide, the programs are expected to increase recognition of depressive and suicide-related symptoms, which in turn is expected to promote help seeking. Second, by reducing stigma and promoting more adaptive attitudes toward suicide, the programs are expected to reduce barriers to help seeking. A broad definition of help seeking is encouraged, including not only referrals for a mental health professional but also seeking support from other resources (e.g., case managers, crisis lines, loved ones). Evidence from previous trials supports these mechanisms of change. For example, in a randomized controlled trial of the SOS program in high school students, reductions in suicide attempts in the treatment group were mediated by self-reported increases in suicide-related information and adaptive attitudes.[26] Specifically, more adaptive attitudes and more accurate knowledge of suicide risk factors were each uniquely and significantly related to lower probability of suicide attempts, and accounted for approximately 40% of the variance in treatment outcomes. An important next step is to examine whether a similar mechanism of change explains treatment effects in substance-using populations.

7. PARS was developed to be transportable, disseminable, and community-friendly.

PARS is a psychoeducational behavioral treatment that aims to increase knowledge, attitudes, and behaviors that can promote recognition of and help-seeking for suicide risk among clients receiving addiction treatment. PARS is taught as a single three-hour module that is integrated within standard IOP therapy group treatment. From its inception, PARS was developed as a community-friendly suicide prevention program that can be easily incorporated into existing addiction treatment programs and agencies, consistent with NIDA's strategic priorities. All feasibility testing of PARS was conducted in community treatment programs.[1] Prior funding (R21 DA026494) enabled Stage I treatment development research, during which existing behavioral suicide prevention treatments were adapted and modified for substance abusing populations (Stage IA), and pilot and feasibility testing was conducted (Stage IB). The proposed project will move this promising line of research to

Stage III by conducting a large-scale, experimental test of the effectiveness of PARS in real-world, community IOP settings. Moving from Stage I to Stage III is appropriate when the intervention was developed in community settings, when Stage I has produced promising findings as well as established methods to ensure fidelity of delivery and therapist training materials, and when promoting implementation is a major goal of the research. Consistent with NIDA's research priorities, our proposal includes explicit examination of the putative mechanisms of behavioral change that were highlighted in Stage I research. In sum, the proposed research takes a critical next step by evaluating the real-world efficacy of a behavioral treatment that has the potential to reduce a prevalent, important, and costly behavior that is a major cause of death for individuals with SUD.[31]

B. Innovation

1. **Innovative use of IOPs to reduce risk of suicide:** PARS is an innovative approach that allows addiction treatment agencies to act as key players who can reduce and possibly prevent suicide in one of the most high-risk for suicide populations in the USA.[8] To our knowledge, this proposal is one of the first studies to use a randomized design to examine the effectiveness of suicide prevention within addiction IOPs.
2. **Innovative dissemination and health services impact:** PARS is innovative in being developed and evaluated in "real-world" clinical sites that provide both public and private addiction services. PARS was designed based on clinical and administrative input to not only fit the recovery philosophy and clinical approach of IOP settings but also to fit into the billing and employee models of community addiction agencies. This provides high likelihood that PARS could be readily implemented, allowing PARS to reach millions of people who seek treatment every year,[11] should it prove to be effective.
3. **Use of innovative research design:** The goal of this Stage III trial is to evaluate the efficacy of PARS while being responsive to the unique challenges of conducting randomized, controlled research in real-world, community treatment settings. In line with Stage II trials, we strive for rigorous research methods that maintain adequate internal validity. This study is therefore unique in that it combines a rigorous, randomized design with a disseminable suicide prevention program that targets a very high-risk population. In striking a balance between these two goals, we propose to use a stepped wedge randomized trial design. This design allows for a sequential roll-out of PARS to all of the community agencies enrolled in this study by the end of the trial, but promotes internal validity by randomly assigning each site to a "step" which will determine the timing of its transition from control (i.e., TAU) to treatment (i.e., PARS). Thus, while each client experiences either PARS or TAU only once, clinics differ in their exposure to PARS based on the timing of their transition to PARS in the stepped wedge design. This design has a number of benefits over the traditional RCT. Like cluster randomization, it allows randomization at the site rather than individual level which fits with a Stage III evaluation of the intervention as implemented in community treatment. Furthermore, stepped wedge trials facilitate the examination of dose-response or delay effects at the clinic level by modelling the association between the time clinics spent in the PARS phase and the effectiveness of PARS on clients. Finally, a stepped wedge design facilitates complete implementation of PARS among our 15 sites, enhancing the clinical practice benefits of this trial for our community partners.
4. **Explicit examination of treatment outcome mediators:** Because the proposed research directly examines potential mediators of treatment effectiveness (i.e., accurate information and adaptive attitudes mediating improved help-seeking behavior), this study can guide future efforts to improve the PARS program. Identifying mechanisms of treatment action may allow us to refine PARS; making it more potent and targeted by increasing the emphasis on challenging maladaptive attitudes, increasing factual knowledge, or both.
5. **Built-in counselor re-training:** As noted above, PARS could represent an innovative training strategy for counselors who are consistently updated in these competencies by repeatedly using skills taught through PARS training with each new IOP group cohort. Few studies have examined the effects of repeated training exposure on suicide prevention effectiveness for clients, thus our exploratory aim examining dose effects may make an important contribution to this literature by testing whether there are effects of repeated exposure to PARS at the clinic level on client outcomes.

C. Approach

C.1. Preliminary Studies

R21 Preventing Addiction Related Suicide (PARS) study.

As part of a NIDA R21, a pre-post pilot study of PARS was conducted with clients attending group-based IOP addiction treatment at one of three publicly funded addiction treatment agencies in Washington State.[1] All agencies were members of the NIDA Clinical Trials Network (CTN) and were in urban areas. Prior to PARS, none of the agencies included a suicide module in their IOP programs (for more detail on IOP in Washington State, see Design section C.3). Seventy-nine clients were approached, of whom 78 consented to participate.

The inclusion criterion was current participation in IOP treatment. Exclusion from participation was based on the following criteria: (1) imminently suicidal patients as well as those who had planned or attempted suicide within the past 3 months, (2) patients with cognitive or language barriers judged severe enough to impede participation (no one was excluded on either criteria). Follow-up data were collected from 64 patients at the 1-month time point, for an 82% follow-up rate. Patients were given a $25 gift card for completing each survey.

The mean age of the total patient sample was 35 years old (SD=1.20), 64% of which were male. While the modal level of education was a high school diploma (58%), an additional 17% did not complete high school education or the equivalent. Almost half (44%) of the sample was Caucasian, 26% were African American, 8% Asian, 5% American Indian/Alaskan Native, 6% more than one race, and 8% did not report race.

Thirteen IOP counselors from the three agencies described above were recruited and trained to administer PARS. After completing informed consent and receiving training, counselors answered a survey about PARS acceptability and utility in the standard working conditions at their sites. The average age of the participating counselors was 46 years and the average length of time working in the addiction field was 5.6 years with a range of 6 months to over 20 years. Eight of the 13 counselors were female (62%) and 12 were Caucasian (92%). The modal level of education was a bachelor's degree, and all had state certified chemical dependency counseling credentials as required by their agencies and Washington State.

PARS was administered as described below and in Voss et al.[1] Although none of the pilot participants reported imminent risk of suicide, several reported suicide attempts more than 3 months ago and loss of family and friends to suicide, which led to meaningful group discussion among clients during the PARS session.

As can be seen in Table 1, this pilot study of PARS demonstrated significant post-intervention increases in accurate information and decreases in maladaptive attitudes toward suicide among client participants. Significant gains compared to pre-intervention were maintained at 1-month follow-up for both information and maladaptive attitudes. Help-seeking was also significantly improved. Compared to the month before PARS, in the month following PARS, pilot participants were twice as likely to ask friends and family to seek help as well as to seek help themselves. This also highlights the fluidity of suicide risk during addiction treatment—although outpatient SUD treatment providers attempt to screen out acutely suicidal individuals at intake, instead referring them to a higher level of care, this is nonetheless a high-risk population and suicidal thoughts and behavior are not uncommon during community addiction treatment.

Table 1 R21 Pilot Study Results	Pre-Test	Post-Test	One Month
Accurate information about suicide (scores range from 0-14)	5.3	9.4***	8.1***
Maladaptive attitudes toward suicide (scores range from 9-45)	19.3	15.6***	17.3***
Asked friend to get help with suicidal thoughts/feelings in past month	9%	-	22%**
Asked family to get help with suicidal thoughts/feelings in past month	9%	-	17%*
Asked for help him/herself with suicidal thoughts/feelings in past month	4%	-	9%**
Any help-seeking in past month	15.6%	-	28.1%

*p< .05 **p < .01 ***p < .001 (as compared to pre-test)

Subject Retention in Other Longitudinal Studies.

Dr. Comtois and her team review tracking and retention procedures on an ongoing basis to continuously improve these processes. The NIDA R21 pilot study (N=78) of the proposed study had a follow-up rate of 82% at one month. However, our team has been successfully following high-risk populations for outcome assessments for six months or longer for over 22 years. For example, in a naturalistic follow-up of over 200 individuals receiving treatment for self-directed violence in a county emergency department (ED), of whom 61% met criteria for an SUD and 25% were homeless, we achieved an 80% follow-up rate at six months.[32]

Throughout the two latter projects we have used online assessment strategies to obtain questionnaire data and text-based (SMS) technology to reach out to study participants on time. This is accomplished using automated tracking systems embedded in HIPAA-protected and secure [redacted] and REDCap web-based systems. These systems allow the research team to pre-program when assessments or other study activities are due, so the system sends out the correct assessment to the correct study participant at the correct time.

[redacted]

[redacted] If that does not work, the research team is alerted in real time and can use other contact options approved by the participant on our tracking and follow-up consent form to locate the participant, complete that assessment, and obtain the correct information to program back into [redacted] for the next assessment point. [redacted] also has the capacity to track participants without a text-able phone or an email account by sending the alerts to the research team that assessments are due, prompting the team to contact the participant through traditional phone or other means agreed with that participant at baseline.

C2. Overview.

This stepped wedge effectiveness trial will randomly assign 15 community treatment settings into five groups of 3 sites each that will be randomly ordered to implement PARS in one of five steps of 6 months each (see Figure 1). The week before the session for PARS in the IOP curriculum within that step, at least 10 clients/site from each site will be consented and complete a baseline assessment. (Standard IOP groups in Washington have 12-15 clients registered and, given 98% of those approached in our pilot study consented, it is expected this will be sufficient.) Participants will be assessed post-intervention and followed up at 1, 3, and 6 months with brief online (or phone, if online or text is not feasible for the participant). Study staff will evaluate counselors at each site to assure fidelity to PARS once trained; supervising as needed throughout the study.

Figure 1 Stepped Wedge Effectiveness Trial Design

	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Group 1 (3 sites)	TAU	PARS	PARS	PARS	PARS	PARS
Group 2 (3 sites)	TAU	TAU	PARS	PARS	PARS	PARS
Group 3 (3 sites)	TAU	TAU	TAU	PARS	PARS	PARS
Group 4 (3 sites)	TAU	TAU	TAU	TAU	PARS	PARS
Group 5 (3 sites)	TAU	TAU	TAU	TAU	TAU	PARS

C3. Design.

Treatment Conditions

Control: Treatment as Usual (TAU)

Intensive Outpatient Program (IOP) guidelines in Washington State are based on State requirements.[33,34] Within these guidelines, agencies typically offer IOP consisting of three-hour groups, three times a week, over eight weeks, for a total of 24 groups (meeting both State and deferred prosecution requirements). Some programs meet less often for a longer time window up to 12 weeks. Although at least one monthly individual counseling session is required, the primary modality is a group format. IOP programs are required to provide education on specific topics, e.g., alcohol and drug education, relapse prevention, risks of drug or alcohol use during pregnancy, blood borne pathogens (including HIV/AIDS and Hepatitis), emotional, physical, and sexual abuse, and nicotine addiction. However, within a 24-group curriculum, IOP programs have wide latitude in determining group content since the required topics typically represent less than 50% of the 24 groups. Therefore the content in IOP programs across our sites is expected to be variable while the structure of session hours and attendance will be consistent. However, no IOP programs include suicide prevention.

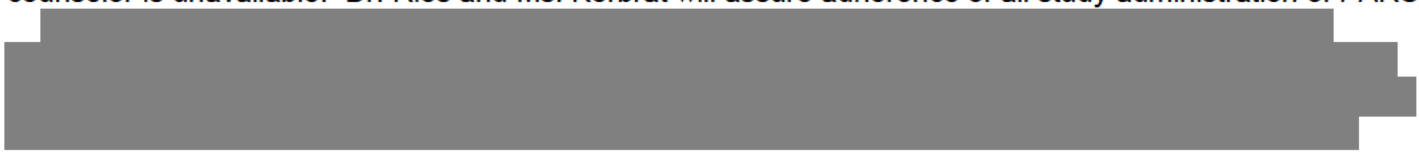
At the beginning of the study, each site will select a particular group session in their 24-session schedule to replace with PARS. *They will move that session to the place where PARS will be at the start of the study. To minimize variability between sites, the session to be replaced will be one regarding grief, depression, or coping with negative emotions. While sites vary on what exactly they teach in this general content, all have something they are willing to replace in this non-required section of their IOP, reducing site variability for this study.*

Intervention: TAU + Preventing Addiction Related Suicide (PARS)

PARS is a module designed for a single session of an IOP treatment program including a specified combination of didactic presentations and group discussions. PARS topics include: Goals and Objectives; Suicide Overview; Addiction and Suicide: A Strong Relationship; Suicide Myths and Facts; Suicide Risk Factors; Suicide Protective Factors; Common Triggers of Suicidal Thoughts and Behaviors; Warning Signs and

Guidelines for Preventing Addiction Related Suicide. The PowerPoint slides of the PARS curriculum (and also serving as the training materials) as well as the PARS adherence measure can be found in the Appendix.

The IOP counselor will administer PARS. PARS developer Dr. Ries will provide all training in PARS. In preparation for each site providing PARS, Dr. Ries will provide PARS training using the training model developed in the R21. Dr. Ries and Ms. Kerbrat (Licensed Independent Clinical Social Worker and Research Scientist) will evaluate adherence to PARS by the community treatment counselor in a practice session to assure the counselor can provide PARS with fidelity. Based on the experience from our PARS R21, training will begin one month prior to implementation to assure sufficient time and practice. To maximize the value to our community partners and assure a counselor trained in PARS is available on the day of the PARS module, multiple counselors will participate in the training so that someone can substitute if the designated PARS counselor is unavailable. Dr. Ries and Ms. Kerbrat will assure adherence of all study administration of PARS.



Both Conditions:

Any additional treatments outside of the IOP program (e.g., mental health-oriented counseling, pharmacotherapy) will be available during all phases of the stepped design. Washington State mandates self-help group attendance in addition to attendance of group and individual IOP sessions; this will also remain consistent throughout each site's participation (regardless of when PARS is implemented at each site). Documentation of all services received or referred to will be gathered from the program (with client consent).

Stepped Wedge Design

This study will use a stepped wedge design as shown in Figure 1. This design is recommended for studies in which it is beneficial to randomize at the site rather than individual level.[35–37] Such is the case in this study, as randomization at the individual level would not be feasible with our community partners, who are enrolling clients and placing them in groups based on many complex reasons including client schedules, IOP group schedules and openings, and a myriad of agency guidelines and regulations. Such a study would require conducting PARS and usual care in a research clinic setting—which is the opposite of our goal. PARS was developed in community settings and it is its effectiveness in those settings that is key. Once it was determined that randomization would be at the site level, both clustered randomized and stepped wedge designs were considered.[35,37–44] While both have benefits, the stepped wedge has the advantage of measuring dose-response (delay) effects. Furthermore, its primary disadvantage (that more assessment points were required)[35,40,42] was not determined to be a problem for the research team or community partners, as participants would complete the same assessments regardless of stepped wedge or cluster randomization.

In the proposed study, there will be six steps. Steps will be 6 months each to assure sufficient time for all data collection to occur given that some IOP programs are as long as 12 weeks and sites will vary as to which session PARS replaces in their IOP curricula. In each of the six steps of the study, baseline assessments will be conducted the week before that selected session at that site. For instance, Site A might replace session 8 with PARS but Site B might replace session 14, so baseline assessments will be conducted in week 7 at Site A and week 13 at Site B. (Data collection methods for baseline assessments described in Procedures below.) This will assure that the follow-up assessments reflect the period after PARS is administered while allowing the natural variation in IOP curriculum that is inevitable with 15 community partner sites.

As per the stepped wedge design (see Figure 1), the 15 sites will be randomly assigned to 5 groups of three sites each. At Step 1, all sites will be in the TAU condition. The 5 groups will then be randomly assigned to begin PARS at one of the subsequent 5 steps (i.e., Step 2-6). Once beginning PARS, they will continue to administer PARS through the end of Step 6. Thus, three sites per step will begin administering PARS—until by Step 6, all sites are administering PARS.

Dr. Jim Hughes, stepped wedge design expert (as can be seen in his Biosketch), has reviewed and approved our design (as noted in his Letter of Support) and is available for consultation as needed.

C4. Participants.

Setting. Participants (N=900) will be recruited from 15 community treatment sites in Washington State from the four treatment agencies that are our community partners in this study. As can be seen from their Letters of Support, our community partners are enthusiastic about PARS and see both the program and the study design

as feasible and acceptable. Sites represent urban and rural areas in Washington as well as representing sites primarily funded by private insurance and self-pay and those primarily paid by Medicaid.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Enrolled client in one of the community treatment settings
2. Over 18 years of age
3. Ability to understand written and spoken English

Exclusion Criteria

1. Any clinical medical/psychiatric condition, severity of that condition, or life situation that in the opinion of the counselors or Drs. Comtois or Ries would compromise safe and voluntary study participation (e.g., psychosis, custody conflict).

Recent suicidal behavior or suicidal ideation is not an exclusion criterion in this study. (While it was in our pilot study, no participant was excluded on this basis.) The scope of chemical dependency counselor's practice in Washington State is to screen and refer acute suicidality to other professionals – often this means outside of the IOP program if a licensed mental health counselor or psychiatric provider is not available. Suicidality is not a static phenomenon – it waxes and wanes for the suicidal individual depending on their internal state and external circumstances. In addition, many individuals do not disclose their suicidality or their suicidality is not acute in while in IOP although it may have been before or after. These individuals are standardly part of IOP programs and they are part of the mission of PARS as are those who have never been suicidal but are at high risk by virtue of substance abuse history severe enough to be in treatment. Thus, all addiction clients regardless of suicidal thoughts or attempt history will be included in the study if they are in treatment at the time of recruitment. We have reviewed with our agency partners the expected incidence of acute suicide risk during a given IOP step. They report this is a rare event. Out of over 200 clients in 15 sites receiving IOP at any given time, they estimate that that 1-3 clients (~1%)are acutely suicidal and may have been referred out.

C5. Recruitment and Consent

The sites in this study vary from 1-3 IOP groups running simultaneously. Therefore, based on a consensus of the research team and community agency for that site, one IOP group in each site will be identified as the best fit for this study based on likely longevity of the counselor over the course of the study and engagement of that counselor with the study and interest in learning PARS. If this identifies more than one group, the decision will include the group with maximum attendance. As noted above, all counselors at the site will be trained in PARS (standard PARS training model) and multiple counselors will be trained to fidelity to assure PARS is administered on schedule to the identified group. Counselors may or may not administer PARS in the other IOP groups as decided by that site. This will not impact the study treatment.

Potential client eligibility will be determined by their IOP counselors. All clients will be asked at the end of a standard treatment group in their IOP if they would like to volunteer for a study that involves staying after that group (or participating before or after one of the other IOP groups that week, if that day is not convenient). If interested, the study will be described to them by the research staff. Interested individuals will be asked to sign the consent form and then complete the baseline assessment.

C.5. Measures

Primary outcome assessments will include knowledge and attitudes toward suicide, and participants' help-seeking behavior for themselves and their family and friends. Exploratory outcomes will be suicidal ideation, threats, and behavior as measured by the Suicidal Behavior Questionnaire - Revised. Potential moderators will also be assessed including measures of drug and alcohol use, depression, physical and mental health functioning, and demographic characteristics. To promote compliance with follow-ups, outcome measures will be delivered via brief, online questionnaires or text message surveys with an option to complete questions via telephone call if participants prefer this. To keep the follow-up measures short, we selected a subset of items used in our initial pilot study that demonstrated optimal psychometric properties. (See Appendix for copies of non-standard measures)

Accurate Information about suicide. The PARS Suicide Knowledge Scale,[1] which was adapted from the Staff Suicide Prevention Survey[45] in our previous pilot trial, was condensed to 6 well-performing items that closely map onto the content of PARS. The Knowledge scale assesses factual understanding of warning signs,

triggers, and interventions for suicide. Items include "Which of the following are warning signs that a person may be thinking about suicide (Mark ALL that apply): a) giving away prized possessions, b) getting a new job, c) talking about death, d) a drug or alcohol relapse, e) increased agitation or anxiety?" Reliability for this shortened scale was good to excellent (Kuder-Richardson 20 = .79 to .99) in the pilot data.

Attitudes toward suicide. The PARS Attitude Scale,[1] originally adapted from the 14-item Staff Suicide Prevention Survey,[45] is rated on a Likert-type scale from 1 (Strongly Disagree) to 5 (Strongly Agree). This scale evaluates stigma and bias toward suicidal acts or persons, as well as perceptions that suicide is preventable if appropriate action is taken. For the proposed study, we selected a subset of seven items using the R21 pilot data to guide item selection. The seven selected items demonstrated acceptable to excellent reliability (α = .73 to .97) and sensitivity to change following PARS program (*p*s < .05) in the pilot study. Sample items include "If someone wants to kill themselves, there is not much anyone can do about it," "Asking a person whether they are feeling suicidal might cause them to do it," and "People who feel suicidal definitely want to die."

Measure	Baseline	Post Treatment	1, 3, and 6 month Follow-up
PARS Knowledge Scale	X	X	X
PARS Attitude Scale	X	X	X
PARS Behavior Scale	X		X
Self-harm Behavior Questionnaire	X		
Suicidal Behavior Questionnaire - Revised			X
ASSIST (drug use and alcohol problems)	X		
AUDIT (alcohol use and problems)	X		
Days of drug/alcohol use in past 30 days			X
PHQ-2 (depression)	X		
SF-12 (physical and mental health function)	X		
Demographics	X		
PARS Counselor Acceptability Scale		X	
PARS IOP Discharge Ratings			X

Help-seeking behavior. The PARS Behavior Scale – Client Version[1,26] consists of four items assessing help-seeking behavior for self and others. Participants report the frequency of help-seeking behavior from never ("0 times/none") to "more than 3 times." Items include: "In the past month, have you: (1)… asked a friend to get help because you were worried that he or she was having suicidal thoughts/feelings; (2)… asked a family member or relative to get help because you were worried he or she was having suicidal thoughts/feelings; (3)… asked for help because you were having suicidal thoughts/feelings; and (4)… called a crisis line/suicide hotline?" If items 1 to 3 are endorsed, participants will also be asked to report whom they asked for help. This scale had good to excellent internal consistency in the R21 study (α = .83 to .94) and items were sensitive to the effect of the PARS program.

Suicidal ideation and behavior. we will use the shorter Suicidal Behaviors Questionnaire-Revised, a four-item self-report that assesses suicide attempts, ideation, communication, and intent since the last assessment. (Time frame will be adapted for each assessment point to gather data for the

time window since the previous assessment.) The SBQ-R has excellent internal consistency (α = .83), sensitivity and specificity (.80 and .91, respectively), and convergence with the SHBQ (r = .77, p < .01).[46,47]

Drug and alcohol use. To assess baseline substance use problems, participants will complete the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST), [48] an 8-item screening tool developed by the World Health Organization to examine lifetime and recent (past three months) substance use, problems resulting from substance use, and risk of current or future harm from substance use. The ASSIST demonstrates acceptable to excellent test-retest reliability (r = .58 to .90), rater agreement (kappas = .61 to .78) and acceptability in substance users. To assess alcohol use problems at baseline, participants will also complete the Alcohol Use Disorders Identification Test (AUDIT) self-report,[49] a 10-item questionnaire that examines frequency, severity, and negative consequences of alcohol use. The AUDIT has demonstrated excellent internal consistency (α = .80 to .98), sensitivity (.74 to .92) and specificity (.71 to .94) in detecting hazardous drinking and alcohol related problems (e.g., hospital admissions, social problems, outpatient treatment, medical disorders).[49–51] At each follow-up, participants will be asked to report on how many of the past 30 days they used drugs or alcohol.

Depression, Physical and Mental Health. Two screening measures will be used to assess covariates and potential moderators (depression, physical health, mental health) of PARS outcomes. The two-item Patient Health Questionnaire (PHQ-2[52–54]) assesses recent depressive symptoms, and has excellent sensitivity (.77 to .86) and specificity (.78 to .95) in detecting major depression.[52,53] The Short-Form 12 Health Survey (SF-12) consists of 12 items assessing overall physical and mental health, and demonstrates excellent test-retest reliability over two weeks (r = .76 to .89) and convergence with other health measures.[55]

Treatment engagement will be measured by a combination of three metrics (a) % sessions attended, (b) graduated from program or terminated, and (c) clinician rating of participant's engagement in IOP treatment. Discharge plan for each client will be determined by a query of the IOP medical record as well as clinician report. (See PARS IOP Discharge Ratings in Appendix).

PARS Acceptability. Addictions counselors will complete the PARS Counselor Acceptability Scale,[1] a 13-item survey that was developed in our R21 trial to measure acceptability, ease, and perceived effectiveness of incorporating PARS into day-to-day IOP procedures where it had excellent internal consistency (α = .99).

C.6. Procedures

Baseline Assessment will be conducted by in-person group administration as described in Recruitment above. If the individual does not have time or requests an individual assessment, this will be offered at a later time or in a different room at the same time. Assessments will be completed on tablet computers.

Post-Intervention Assessment will be conducted after the PARS or TAU group session and include just the information and attitudes items as too little time has passed for other behavioral measures to be relevant.

Follow-Up Assessments will be conducted 1, 3, and 6 months after baseline assessment. Assessments will be completed using online assessments using their smart phone, text message responses, or a computer. If a participant prefers or has any technical problems, follow-up assessments can be conducted by phone. Dr. Comtois' current trials use these modalities to complete questionnaire follow-up assessments with over 500 Soldiers and Marines. Online methods are extremely effective with a very mobile population such as Service Members who move while active duty and as they separate from the military and also for those in addiction treatment who are often moving residences or homeless.

In Drs. Comtois' and Ries' ongoing trial of caring contacts via text message with suicidal active duty military personnel, we are utilizing a text messaging platform designed and maintained by [redacted] that is capable of administering surveys via text message. We have demonstrated through extensive testing and implementation that the system is fully capable of obtaining follow-up survey responses via text message. The [redacted] system records every text "question" sent by the system reliably as a success or failure (i.e., the SMS "succeeded" in delivery to the participants' mobile phone, or the SMS "failed" to go through). This function is highly reliable and our team is well-practiced in addressing any issues with undeliverable text messages. Our group uses Research Electronic Data Capture (REDCap) online surveys to reliably collect online survey data via any device with an internet connection (e.g., smartphone, tablet, desktop computer). As described in the Human Subjects section, both proposed data collection systems are HIPAA compliant and designed for clinical and research applications.[56] (See Letter of Support from [redacted] team.)

Steps to Prevent Participant Attrition. Our goal is for all participants to complete all outcome assessments regardless of treatment participation. Informed consent will include a separate tracking consent form on which participants choose tracking strategies they consent to have used (e.g., obtaining forwarding address from post office, checking social media) and provide alternative contacts to whom the study can reach out in case the

participant moves or changes contact information. We have used this tracking consent form for over 20 years of research. It finds an excellent balance between obtaining detailed information and allowing participants to only provide information they are comfortable providing. *In our previous studies, we have achieved 80% follow-up in the six months following an ER admission for self-injury in a past study[32] and an 82% six month follow-up rate for our current study of suicidal Marines and Soldiers. In addition, we have conducted a literature review of methods to achieve high subject retention in substance abuse studies.[57–59] While we already use most of these procedures, we will follow all the recommendations to minimize attrition in this study.*

Participants will be reimbursed (in a choice of gift cards) $30 for their time for each baseline, $20 for post-treatment, and follow-up assessments in increments of $10 for each 10 questions completed. To minimize attrition, participants will also be offered an addition incentive to be paid at the final 6-month assessment (or end of the 6-month assessment window if they do not complete it). The additional incentive (also in gift cards) will be $20 for completing 2 of the 3 outcome assessments and $30 for completing all outcome assessments.

C.7. Data Analytic Plan

Data screening and preliminary analyses. First, exploratory data analysis will be performed to characterize the distributional characteristics of all variables. Frequency distributions and plots will be examined to identify out-of-range values and to assess data distributions. To assess scale reliability and validity, item structure will be examined using Cronbach's alpha and factor analysis. Descriptive statistics, stratified by site and study condition, will be examined to characterize sample characteristics and assess randomization. Baseline characteristics including socio-economic status, gender, suicidality, or substance use found to vary significantly between study conditions will be included as covariates in subsequent outcome analyses. Plots of mean outcomes by assessment point, site, and study condition will be examined to characterize outcome trajectories over time and inform the parameterization of time in the longitudinal models. Because differential attrition can compromise inference about experimental effects, we will compare dropouts and completers on demographic characteristics and available outcome variables.

Primary outcome analyses**.** In the proposed stepped wedge design, 15 addiction treatment sites that initially provide TAU (Step 1) will be randomized to implement PARS beginning at one of five ensuing steps (Steps 2-6), 3 sites at a time. Participants recruited at each step will be assessed at points: baseline, post-treatment (information and attitudes only), 1, 3, and 6 months. The primary outcome analyses will be intent-to-treat analyses that include all participants, including those with incomplete follow-up data. The primary outcomes will be 1) knowledge about suicide, 2) maladaptive attitudes towards suicide, and 3) help-seeking behaviors. Each outcome will be evaluated in a separate generalized linear mixed model (GLMM)[60] to evaluate the effect of PARS program vs. Treatment As Usual on change in each outcome over time. The GLMM approach accounts for within-individual and between-group variance and is well-suited for the analyses of multisite, repeated measures data. A logit link function will be used to model dichotomous outcomes and a Gaussian link function when the outcome is relatively normally distributed.

The following regression equation depicts the basic model for each outcome: $OUTCOME_{tis} = b_0 + b_1STEP2_{is} + b_2STEP3_{is} + b_3STEP4_{is} + b_4STEP5_{is} + b_5STEP6_{is} + b_6SETTING_{is} + b_7PARS_{is} + b_8MONTH1_{tis} + b_9MONTH3_{tis} + b_{10}MONTH6_{tis} + b_{11}(PARS_{is} * MONTH1_{tis}) + b_{12}(PARS_{is} * MONTH3_{tis}) + b_{13}(PARS_{is} * MONTH6_{tis}) + u_{0s} + r_{0is} + e_{tis}$*, where t indexes the assessment, i indexes the individual, and s indexes the site. In this model, each outcome is regressed on Step, Setting (Rural vs. Urban), Treatment (PARS vs. TAU), Time (in months), and the Treatment by Time interaction. The effect of Step will be coded into contrasts of Step 1 against each subsequent step (i.e., Step 2 vs 1, Step 3 vs 1, etc.). The effect of Time will be coded into contrasts of baseline (BL) against each post-baseline assessment (i.e., BL vs. 1 month, BL vs. 3, BL vs. 6 months). To account for the cluster-randomized design, a random effect for site (*u_{0s}*) will be included to model the correlation of individuals from the same site. To account for the repeated assessments, a random effect for participant (*r_{0is}*) will be included to model the correlation of observations within the same individual. The statistical test of the treatment effect will be the magnitude and statistical significance of the Treatment by Time interactions. Comparable analyses will be use for exploratory aims with suicidality and substance use.*

Since this study will be carried out at 15 sites, there is the potential for site-specific effects. We anticipate intervention effects to be comparable across all clinics since they are all serving similar client populations and have counselors with comparable levels of experience and training. To verify that treatment effects are comparable across site, preliminary outcome analyses will incorporate indicator variables for site and their interactions with the treatment effects. A likelihood ratio test will be used to compare the models with and without site-specific effects. If the likelihood ratio tests reveal differences in treatment effect by site, these

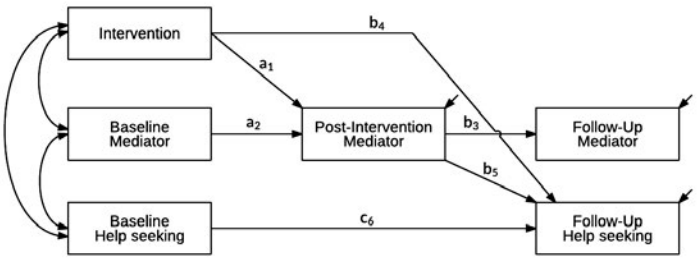
site-specific parameters will be retained in the final analyses, otherwise they will be excluded.

Secondary Analyses

Moderation Analyses. We will examine whether individual-level factors (e.g., demographic characteristics, drug and alcohol use, depression, physical and mental health functioning, treatment engagement) moderate the effect of the PARS program. To evaluate these individual-level moderators, the primary outcome analyses above will be extended to include the main effect of the moderator and its interactions with Treatment, Time, and the Treatment by Time interactions. Each moderator will first be evaluated in a separate model to ascertain whether any differences in treatment effects were associated with individual level factors. A follow-up model will evaluate the moderators simultaneously in a single model. The statistical test of moderation will be the three-way Treatment by Time by Moderator interactions.

Mediation Analyses. Secondary mediation analyses will examine whether baseline to post-intervention 1) increases in knowledge about suicide and 2) decreases in maladaptive attitudes about suicide will mediate the effect of PARS vs. TAU help-seeking behaviors. The mediation analyses will be conducted using multilevel structural equation modeling.[61] Robust standard error estimates and corrected model fit statistics (e.g., Satorra-Bentler statistic) will be utilized to accommodate non-normally-distributed dependent variables in the model.[62] Each mediator will first be evaluated in a separate model. Figure 2 illustrates the basic autoregressive regression model[63] that will be used to assess longitudinal mediation of the effect of intervention on 1-, 3-, and 6-month help-seeking behavior. An indicator variable for Step will be included as a covariate if the effect of step is statistically significant in the primary outcome analyses. The model will incorporate random effects for site and individual to account for the clustered design (i.e., repeated measures nested within individuals, nested within site). The mediated effect (a_1*b_5) and its confidence interval will be obtained using bootstrap resampling, as recommended for testing indirect effects.[64] (Note, arrows on upper right side of mediator and outcome boxes represent error terms.)

Figure 2



Dose Response Analyses. Exploratory analyses will evaluate whether Time (i.e., number of steps) in the intervention phase is associated with improved outcomes in successive steps. The following regression equation depicts the basic dose response model for each outcome: $OUTCOME_{t>0,is} = b_0 + b_1 BL\_OUTCOME_{is} + b_2 TAU\_TIME_{is} + b_3 PARS\_TIME_{is} + u_{0s} + r_{0is} + e_{tis}$, where *t* indexes the assessment, *i* indexes the individual, and *s* indexes the site. In this model, Time will be centered at the beginning of the intervention phase, such that Time = 0 will correspond to the step in which PARS was implemented at a particular site. Time will be coded as a piecewise linear function representing two phases: 1) the TAU phase: the change over time in outcomes during the control period and the 2) PARS phase: a "deflection" term representing the change in slope from the TAU phase following the implementation of PARS. To account for the cluster-randomized design, a random effect for site (u_{0s}) will be included to model the correlation of individuals from the same site. To account for the repeated assessments, a random effect for participant (r_{0is}) will be included to model the correlation of observations within the same individual. The statistical test of the dose-response effect will be the magnitude and statistical significance of the slope of Time during the intervention period.

Power Analysis**.** We base our power analysis on a stepped wedge design[35] evaluating the difference in the rate of help-seeking behavior at month 1 (post-intervention) among those receiving PARS vs. TAU. Based on our pilot study of PARS, we anticipate a 15.6% baseline rate of help seeking behavior, which we expect to increase to 28.1% at post-intervention (1-month) follow-up. Based on the proposed stepped wedge design in which 10 individuals are recruited per site in each of the 6 steps (*N* = 900), we will have 89% power to detect the 12.5% difference in the rate of help-seeking behavior. Assuming 25% fewer participants (*N* = 675, 7.5 individuals per site per step), due to under-recruitment and/or attrition, there will still be 80% power to detect an intervention effect. This represents a conservative estimate of statistical power as the full longitudinal model will leverage data from all participants, including those with incomplete follow-up data.

Missing data. Missing data may occur in several ways. First, missing data may occur due to item non-response. When missing data is limited to only a few items on a measure, we will prorate total scores for a measure by taking an average score on the measure and multiplying it by the total number of items in the scale. Missing data can also occur from attrition due to missed assessments or dropout from the study. Prior to performing any outcome analyses, we will evaluate the amount, reasons, and patterns of missing data. If the

reason for missing data is not related to the outcome of interest, then the missing data are considered to be missing completely at random and complete case analysis will still generate unbiased estimates.[65] A multiple imputation using chained equations approach will be utilized to address missing data, with the final results calculated as a pooled average across 10 multiply-imputed data sets using Rubin's methodology.[66] We will conduct sensitivity analyses to compare estimates of treatment effects with and without multiple imputation to assess the effect of missing data on statistical inference.

C.8 Dissemination Plan

Dr. Ries will lead a PARS Advisory Group as he did in the R21 study including Dr. Comtois and Ms. Kerbrat as well as Dr. Dennis Donovan, and three agency heads: [redacted] (see Letters of Support for their willingness to participate). The Advisory Group will meet periodically throughout the study and then will have multiple meetings in Year 5 to develop a dissemination plan if PARS is effective.

C.9. Time Line

	Year 1		Year 2		Year 3		Year 4		Year 5	
	0-6	7-12	0-6	7-12	0-6	7-12	0-6	7-12	0-6	7-12
Hire and train personnel										
Organize study with partners										
Step 1 (baseline for all sites)										
Step 2 (3 new sites start PARS)										
Step 3 (3 new sites start PARS)										
Step 4 (3 new sites start PARS)										
Step 5 (3 new sites start PARS)										
Step 6 (3 new sites start PARS)										
Follow-up assessments										
Conduct outcome analysis										
Disseminate study results										

C.10. Study Limitations

- We have selected only one IOP group per site to participate in the study. We decided on this approach as some sites only have one IOP group, but it does potentially limit our sample size. However, as noted in the Power Analysis section (Section C.7), we have sufficient power even with a smaller sample size as we have increased power with both the number of sites and number of steps. We will select the most stable and strongest group at each site. While this can lead to selection bias, we believe it will increase internal validity to have as strong a PARS condition as possible with a maximally motivated and stable staff. In the first controlled trial, it is important that PARS be as strong as possible to prevent abandoning a potentially effective program. Future research can determine the range of clinician motivation and skill associated with effective PARS administration.
- Our outcome assessment instruments are all brief. While this is a limitation, we have selected psychometrically strong measures *and collect clinician collateral data*. And with a sample of 900 participants, it is critical to collect as much data as possible using text message and online surveys, which require brief measures. Finally, to minimize attrition it will be critical to minimize the assessment burden.
- For our information, attitude, and help-seeking measures, we have selected the measures developed for the R21 study rather than existing measures. After a detailed review of the literature, many measures were found to be very long and repetitive, contain outdated suicide information, or both. The measures included in this study were selected because they are based on existing measures, have accurate items, show strong internal consistency in pilot work, have content validity with PARS curriculum, and are brief.
- One possible limitation to our outcome assessment protocol is the potential priming of effect by repeated assessment. However, we believe the precision will be increased and repeated assessment is necessary for mediation and dose analyses. The effect will be equated between conditions through randomization.
- Given that many clients in addiction treatment are under acute stress, drop out, and are in unstable living situations, attrition is a significant risk. Several strategies have been included to overcome this limitation including a post-intervention assessment, using established tracking strategies *based on a review of substance abuse longitudinal research recommendations*, obtaining multiple follow-up contacts, brief assessments that require little time and coordination, and subject reimbursement incentives.

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