Group ("Project Life Force") versus Individual Suicide Safety Planning: A Randomized Clinical Trial

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Abstract

One in five suicide deaths is a Veteran and in spite of enhanced suicide prevention services in the Veterans Health Administration (VHA), twenty Veterans die by suicide each day. One component of the VHA's coordinated effort to treat high-risk suicidal Veterans, and diminish suicide risk, is the use of the safety plan. The current study aims to examine a novel intervention integrating skills training and social support with safety planning for Veterans at high-risk for suicide, "Project Life Force" (PLF). A randomized clinical trial (RCT) will be conducted examining if Veterans who are at high-risk for suicide will benefit from the novel group intervention, PLF, compared to Veterans who receive treatment as usual (TAU). We plan to randomize 265 Veterans over the course of the study. The primary outcome variable is the incidence of suicidal behavior, during follow-up, established using a rigorous, multi-method assessment. Secondary outcomes include depression, hopelessness, suicide coping and treatment utilization. Exploratory analyses include safety plan quality and belongingness for those in both arms as well as group cohesion for those in the PLF intervention. Strengths and limitations of this protocol are discussed.

Keywords: suicide, treatment, group, safety plan, depression, veteran

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Introduction

In the United States, Veterans have a significantly higher suicide risk relative to the general population.[1] Veterans account for about 20% of suicide deaths and, despite the Veterans Health Administration's (VHA) provision of enhanced suicide prevention services, an estimated 20 Veterans die by suicide each day.[2] This highlights an urgent need to develop additional, empirically validated, interventions for suicidal Veterans.

One component of the VHA's efforts to diminish suicide risk is the Safety Planning Intervention (SPI).[3] Considered best practice, the SPI is developed collaboratively with the patient and therapist and involves identification of: personal warning signs of suicide; internal coping strategies; social contacts or settings offering support and distraction from suicidal thoughts; contact information for VHA professionals, the crisis line and emergency services; and specific steps for how to make the immediate environment safer.[3] The patient takes the safety plan home for their use during a suicidal crisis. Safety planning is based on the idea that suicide risk fluctuates over time, aims to prevent suicidal crises from escalating, as well as presenting individuals from acting on their suicidal urges.[3]

Stanley and colleagues (2018) recently administered the SPI in emergency departments to Veterans with suicidal behavior.[4] Participants who completed the SPI, and received at least two structured follow-up phone calls, were half as likely to exhibit suicidal behavior.[4] They were also more than twice as likely to attend at least one mental health appointment than usual care.[4] Therefore, the SPI may be an efficacious intervention.

To further explore the utility of the SPI, 20 Veterans participated in semi-structured longitudinal interviews and expressed that creating the SPI was a helpful experience.[5] However, only 70% were able to identify contacts to call and, at follow up, only 65% reported having reviewed their plans at least once during the prior month.[5] Data from this study suggested several avenues to maximize the utility of the SPI. Specifically, there was a need for an intervention surrounding the SPI that: addressed coping skills to use in crisis (e.g., skills training), had ways to make the plan more accessible (e.g., mobile format), assisted in identifying individuals to call for help and how to share the plan with them. [5-7] These gaps formed the basis of a new group safety planning intervention, "Project Life Force" (PLF).

This study aims to maximize SPI utility by examining a novel intervention for high-risk suicidal Veterans, PLF. The PLF intervention augments the SPI with skills training and psychoeducation to maximize use and effectiveness of the plan in a group setting. Research suggests groups mitigate loneliness and increase a sense of belonging. [8] This group format is in line with the interpersonal psychological theory (i.e., that those who die by suicide have a low sense of belonging).[9, 10] Furthermore, the relation of "military unit cohesion" and suicide risk, suggests that increasing unit cohesion may have a protective effect.[11] Overall, PLF aims to enhance safety planning for even acutely-suicidal Veterans by including suicide-related coping skills (e.g., emotion regulation) and building of social support.

Methods

Overview of Study Design

This study is a two-armed, blinded, randomized clinical trial (RCT) comparing the efficacy of the intervention, PLF, to the control- treatment as usual (TAU).

Intervention. PLF is a manualized, weekly, 90-minute, group treatment, lasting 10-weeks (with an optional monthly booster for the first three months following completion of the 10-week group). This coincides with the time frame for enhanced monitoring of Veterans identified as "high-risk" at the VHA. Session content is described in **Table 1.**

Table 1. Project Life Force Session Outline[12]		
Session Number and Focus		**Skill Covered**
1	**Introduction, psychoeducation about suicide, safety plan step #5- crisis numbers, meet local Suicide Prevention Coordinators**	**Crisis Management Skills Urge Restriction**
2	**Safety plan step #1 - Identification of Warning Signs**	**Emotion Recognition Skills**
3	**Safety plan step #2 - Internal Coping Strategies**	**Distress Tolerance and Coping Skills**
4	**Safety plan step #3 - Identifying people to help distract**	**Making Friends Skills**
5	**Safety plan step #4 - Sharing safety plan with Family**	**Interpersonal Skills & Asking For Help**
6	**Safety plan step #5 - Professional Contacts**	**Skills to Maximize Treatment Efficacy & Adherence**
6	**Safety plan step #6 - Making the Environment Safe**	**Means restriction, Psychoeducation about Methods**
7	**Improving Access to the safety plan**	**Use of Safety Planning Mobile Apps**
8	**Physical Health Management**	**Skills to Maximize Physical Health and Wellbeing**
9	**Building a Positive Life**	**Building Reasons for Living**
10	**Recap/Review**	**Recap, sharing of safety plans**
11	**Add on session – Only if needed**	**Dealing with a suicide death of a group member**
1-3	**Optional Boosters**	**Review safety plan usage and address obstacles**

The first six sessions of PLF correspond to the steps of the safety plan and teach skills to maximize the use of that particular step of the plan. In addition to teaching patients to distract themselves during a crisis, this is when participants of the group are also taught emotion regulation skills, fostering positive emotion, and developing social support (in the specific context of implementing a safety plan). The next three sessions of PLF include modules on physical health management, education pertaining to suicide risk, and introduction of suicide

prevention mobile applications. The last session is a recap and review of previous session content and group members' safety plans. If needed there is an add on session for how to deal with the suicide death of a PLF group member. Also, three optional monthly boosters are offered after completion of the 10-sessions to review safety plan usage and address obstacles to using the plan.

Two therapists run the PLF intervention arm of this study so one therapist can leave for a group member emergency at any time. All interventionists follow the manual with 80 pages of session handouts that was developed and tested for acceptability and feasibility with a Small Projects in Rehabilitation Research (SPiRE) grant awarded to Principal Investigator (PI), Dr. Marianne Goodman. All PLF therapists participate in a one-day in person training to review components of the PLF treatment manual, instruction in group therapy principles and suicide prevention didactics. Virtual group supervision continues with sites discussing sessions. At an independent site, Columbia University Medical Center (CUMC), Co-Investigator Dr. Barbara Stanley oversees review of 20% of randomly selected audio recorded PLF sessions for fidelity to the PLF manual. An objective scale developed to assess core features of its structure, contents and treatment principles along with general clinical competence (e.g., building rapport, crisis management, etc.) is used. Clinicians are required to maintain a total score of 37 or above on each session, rated on a 4-point Likert scale (where 0 = unacceptable and 3 = excellent), to demonstrate adequate adherence to the intervention. Ratings include 10 general competence items and 3-4 session specific items. Clinicians whose ratings fall below this criterion are given additional supervision and their adherence are monitored until adequate adherence is regained.

Treatment as usual. The control condition is TAU. For the purpose of this study, TAU is the current standard of care for suicidal individuals being discharged from an inpatient unit, or

on the high-risk list. These patients are mandated by the VHA to receive an individual safety plan as part of their usual clinical care. All safety plans by participants are assessed for quality (described in section on safety plan quality assessment).

Veterans in both conditions receive mandated monitoring, outreach, and involvement of suicide prevention coordinator staff and clinical team management that constitutes standard VHA care for suicidal individuals. The only difference between conditions is that PLF participants also attend the group described above to augment their safety plans.

Aims and hypotheses. The main objective of the RCT described herein is to examine if Veterans who are at high-risk for suicide will benefit from the novel group intervention, PLF, compared to Veterans who receive TAU (e.g., individual safety planning). The specific aims and hypotheses of PLF are:

Aim 1: To conduct a multi-site RCT of a group safety planning intervention, "PLF" versus TAU in 265 suicidal Veterans.

Hypothesis A1: Compared to TAU, Veterans who participate in PLF, will demonstrate a decrease in suicidal behavior.

Hypothesis A2: Compared to TAU, Veterans who participate in PLF will show a decrease in depression and hopelessness.

Hypothesis A3: Compared to TAU, Veterans who participate in PLF will have increased compliance and more positive attitudes towards with mental health treatment.

Hypothesis A4: Compared to TAU, Veterans who participate in PLF will have increased suicide-related coping.

Exploratory Aim 2: To test whether improved belongingness impacts treatment response in PLF>TAU.

Exploratory Aim 3: To test whether group cohesion partially mediates treatment response in PLF.

Exploratory Aim 4: To test whether the change in safety plan quality (post intervention - baseline) is greater PLF>TAU, as well as whether the change in safety plan quality partially mediates treatment response in the follow up period.

Procedures

This study will include multiple sites and is approved by the IRB at the James J. Peters Veterans Administration Veterans Center (JJPVAMC), located in Bronx, NY, and Corporal Michael Crescenz Veterans Affairs Medical Center (CMCVAMC), located in Philadelphia, PA. CUMC, located in New York, NY, will perform regulatory, assessment training and oversight functions.

Eligibility. Subjects identified for use of a safety plan are recruited for the study. Within the VHA this means the Veteran was recently discharged from inpatient hospitalization after admission for suicidal ideation or attempts, or placed on the high-risk list. Veterans placed on the high-risk list have acute risk factors for suicide (e.g., a verified suicide attempt) and is recommended by their provider for enhanced care by the Suicide Prevention Program.

Inclusion criteria includes:

- 18 to 89 years of age
- Hospitalization on an inpatient unit for suicidal ideation or attempts, or placement on the high-risk suicide list maintained by suicide prevention coordinators
- Concurrence from the patient's mental health provider for the Veteran to participate in the study and the provider is willing to work with the research team.

Exclusion criteria includes:

- Unable to provide informed consent or complete study requirements
- Unable to speak English
- Cognitive difficulties that impair consent capacity
- Unable or unwilling to provide at least one verifiable contact for emergency or tracking purposes
- Unable to attend outpatient group treatment program or tolerate group therapy format
- Active alcohol or opiate dependence requiring medically supervised withdrawal
- Schizophrenia diagnosis
- Current participation in another intervention RCT

Randomization. Over the four-and-a-half-year course of PLF, staff will continue to consent, baseline, and randomize 265 Veterans. Following the baseline assessment, described below, Veterans are randomized into PLF or TAU (50% to each condition). Randomization, supervised by the statistician, will use a computer generated permuted blocked randomization, with condition order permuted within blocks of varying size (e.g., two, four, and six).[13] Since suicide attempt history is associated with subsequent suicidal behavior randomization is stratified by a history of suicide attempts (none vs. at least one past suicide attempt(s)), as measured by the C-SSRS.[14] An independent research assistant will place treatment assignments in separate envelopes according to the randomization sequence developed using the "blockrand" library in the statistical software R to be opened upon baseline completion. [15, 16]

Assessments. Veterans in both groups receive assessments at 4-time points: baseline, 3-month, 6-month and 12-month. The research assessors who enroll participants in the study are trained by Dr. Stanley to administer the assessments. Dr. Stanley also trains the assessors through a series of conference calls in which all those conducting ratings will participate and

consist of didactic review of the measures and their administration. Assessors will practice role-plays and will record two role-plays for each measure. Raters will audio record baseline assessments and 10% are selected at random for review.

Demographic data is collected using the PhenX Measures for Mental Health and suicide measures are collected as detailed in the PhenX common data elements for suicide. [17] A few additional measures are also used to examine the study's aims.

The primary outcome of suicide is suicide behavior. Suicide behavior will be examined through multiple sources, which is further defined below. However, the in-person assessment used to examine this primary outcome will be the C-SSRS. [18] This tool has been used in many treatment trials. [19-21] It has also been used in studies measuring treatment emergent suicidal events during pharmacotherapy. [22-24] The C-SSRS is supplemented with additional items to be fully consistent with the CDC nomenclature. [25] The nomenclature and definitions for suicide-related behaviors will follow the Center for Disease Control and Prevention's (CDC) definitions. [26] Suicidal behavior over the 12-month time frame is a cumulative outcome such that detection of suicidal behavior at any of the outcome points, or by any method, leads to a "positive" indication for the suicidal behavior composite. Additionally, at month-42, to measure any deaths by suicide, each site's research assistant will query the site's state vital statistics registry for all individuals on this list. For all those who are found to be deceased, data is abstracted pertaining to his/her death and the probability of suicide from the Death Certificate. The 12-month delay in review is necessary because of the well-known lag in recording deaths in state vital statistics registries.

See **Table 2** for all the self-report and interview assessments completed by participants to answer the secondary and exploratory research questions. All assessments will be given to both

PLF and TAU, except measures of group cohesion will only be completed by those in the PLF arm. Assessments also used as screeners for eligibility at baseline are noted in the study purpose.

Table 2. Self-Report and Interview Study Assessments, Schedule and Purpose.

Measure	Description	Source	Time-Point (Month)	Study Purpose
Columbia Suicide Severity Rating Scale (CSSRS)– current & since last visit version[18]	Current: Lifetime and recent history of suicide related behaviors; severity of ideation; intensity of ideation subscales. Since Last Visit: assesses suicide related behaviors and severity/intensity of ideation since the participant's last visit.	Interview	0,3,6,12	Screener; Primary Outcome; Study Management
Beck Depression Inventory-II (BDI-II) [27]	21-items Depression	Self-report	0,3,6,12	Secondary Outcome
Beck Hopelessness Scale (BHS) [28]	20-item; Hopelessness positive and negative beliefs about the future	Self-report	0,3,6,12	Secondary Outcome
Self-report log based on the Modified Cornell Services Index (MCSI) [29]	Use of mental health services & medication use recorded by subject and compared with medical record	Interview	3, 6,12	Secondary Outcome
Attitudes Towards Seeking Professional Help[30]	10-item; Attitudes towards professional help	Self-Report	0,3,6,12	Secondary outcome
Suicide-Related Coping Measure (SRCM) [31]	17-item; Knowledge and self-assurance in using internal coping strategies, and external sources, to regulate suicidal thoughts and urges	Self-report	0,3,6,12	Secondary outcome
Group Cohesion Scale-Revised[32]	25-item; Group process outcomes for those randomized to PLF	Self-report	1,5,10 (weeks)	Mediator
Interpersonal Needs Questionnaire[9]	10-item; perceived burdensomeness and thwarted belongingness	Self-report	0,3,6,12	Mediator

	Questionnaire			
Buss-Perry Aggression Questionnaire[33]	29-items; Aggression	Self-report	0,3,6,12	Descriptive
Barratt Impulsiveness Scale[34]	30-items; Impulsivity	Self-report	0,3,6,12	Descriptive
Reasons for Living Scale- Military Version[35, 36]	69-items; reasons for living including six military specific categories	Self-report	0,3,6,12	Descriptive
Attitudes Towards Suicide Scale[37]	37-items; attitudes towards suicide	Self-report	0,3,6,12	Descriptive
Insomnia Severity Index[38]	7-items; Sleep	Self-report	0,3,6,12	Descriptive
Beck Lethality Scale[39]	8-items; Lethality of participants past suicide attempts	Interview	0,3,6,12	Descriptive
Self- Injurious Thoughts and Behaviors Interview[40]	50-items; Self-injurious thoughts and behaviors (e.g., non-suicidal self injury; suicide attempts)	Interview	0	Descriptive
Suicide Intent Scale[41]	20-items; Suicide attempt history	Interview/ Self-report	0,3,6,12	Descriptive
Beck Scale of Suicidal Ideation (BSI) [42]	21- item; Suicide ideation	Self-report	0,3,6,12	Descriptive
World Mental Health Composite International Diagnostic Interview[43]	14-items; Suicide ideation and attempts	Interview	0,3,6,12	Descriptive
Behavioral Risk Factor Surveillance System State (BRFSS) Questionnaire[44]	3-items; Examines access to firearms	Interview	0,3,6,12	Descriptive
Mini-International Psychiatric interview[45]	Major Depressive Disorder, Mania/Hypomania, Post-Traumatic Stress Disorder, Generalized Anxiety Disorder, Psychotic, Anti-Social Personality, Alcohol Use Disorder, Substance Use Disorder	Interview	0	Screener; Descriptive

The Ohio State University Traumatic Brain Injury Identification Method[46]	TBI Diagnosis	Interview	0	Descriptive
McLean Screening Instrument for BPD[47]	10-items; Borderline Personality Disorder	Self-Report	0	Descriptive
Mini Mental State examination (MMSE) [48]	Cognitive Impairment	Interview	0	Screener; Descriptive

Medical record abstraction. To identify suicidal ideation and behaviors, participants medical records on Computerized Patient Record System (CPRS; e.g., the computerized medical chart by all clinicians at the VHA) will be reviewed. Specifically, this review will examine visits to the emergency room and inpatient hospitalizations nationally to detect any suicide-related outcomes. Records are reviewed at the end of the 12-month follow-up.

Additionally, outpatient mental health treatment utilization will be quantified using CPRS. Research staff will count out of the number of outpatient non-PLF mental health visits, attended by participants three months prior to the intervention and compare it to the number of outpatient visits attended during and three months post intervention. Missed appointments will be identified with queries through the IT department at the VA.

Safety plan quality assessment. Safety plan quality is assessed at baseline and post intervention as an exploratory measure according to the methodology of Brief Safety Plan Scoring Form (SPISA-Brief).

SPISA-Brief grades each subsection of the safety plan. If there is no text present then it gets 0 points, if response the was “Poor” it gets 1 point, and if the response was “Sufficient” it gets 2 points. These points are then summed to create a total quality score. A complete score from 0=Poor to 6=Excellent is given to the safety plan for a global impression of overall quality. The assessor can also add any additional qualitative comments.[49]

At follow-up, chart abstraction will determine whether there were any inquiries about use of the safety plan, or revision. All collaboration and follow-up items are dichotomized into yes/no responses. [50] Safety plan quality assessments are performed by blind raters at the JJPVAMC and CMCVAMC. Dr. Stanley, and her CUMC staff, will provide training on the SSP quality assessment and insure ongoing fidelity.

Vital Statistics Protocol

For each site, a list of participants is generated that consists of: (a) participants who are suspected or known to be deceased, gleaned either from an interview with a loved one or review of medical records; and (b) individuals who were not interviewed successfully at the 6- and 12-month assessments (i.e., lost to follow-up). At month 42, each site's research assistant will query the site's state vital statistics registry for all individuals on this list. For all those who are found to be deceased, data is abstracted pertaining to his/her death and the probability of suicide from the Death Certificate. The 12-month delay in review is necessary because of the well-known lag in recording deaths in state vital statistics registries.

Data Analysis

Linear mixed models are used to examine changes in primary and secondary outcomes for Veterans over time and to examine whether the effects of PLF and TAU on these outcomes vary with time adjusted for the time-dependent treatment, covariates of interest and imbalanced baseline prognostic factors, using data reduction methods as appropriate. For the PLF subjects, individual's random effect is nested within the group they are assigned to, while for TAU subjects, they are nested within the clinician effect.

All data is entered into a REDcap database by research staff, on a VHA computer, constructed by the data manager. Preliminary analyses will include computing descriptive

statistics and inspecting features and patterns of data to determine whether data transformations are needed. Quantitative measures are graphed and their distribution inspected for any outlier value, which will be winsorized. All principal analyses are conducted based on the intent-to-treat principle, therefore, all Veterans with data are included, regardless of the actual treatment received. For subjects who drop out during the study, their data up to that point are used, but not carried forward to subsequent time points.

Sample Size. This study was powered for testing our main hypothesis regarding the difference in suicidal behavior rate between the two randomization groups post-intervention. For the survival analysis comparing the PLF and TAU treatment conditions, a 20% dropout was assumed in both groups based on previous safety planning data to date using SAFE-VET, exponential hazard functions, and considered four scenarios of suicide behavior reduction of PLF over TAU. A base rate of 49% for SB in the TAU group was assumed based on work by Miller et al., (2017). [51] A published formula was then used for the Variance Inflation Factor for the weighted log-rank test, to adjust the required sample size for within-group, and within-clinician, dependence.[52] N=5 subjects were assumed per group or clinician. Based on previous literature we estimated an Intra Class Correlation (ICC) for suicidal behavior within the groups of r=0.0 and ran the power analysis using the power calculator "proc power" from SAS. The statistician calculated the minimal sample size needed for 80% power to detect a 35% difference in the post-intervention rate of suicidal behavior between the two groups. We found that we need a total of N=265 subjects, or N=133/group. For informational purposes, we also calculated the minimal detectable effect size for the longitudinal analysis of the quantitative outcomes. We used the power calculator for longitudinal data analysis from the longpower library in R and a Bonferroni correction for k=3 tests. Assuming a correlation parameter of r=0.3 for the quantitative measures,

our selected sample size results in 80% power to detect a difference of at least Cohen's d=0.40, a moderate effect size. [15,53]

Primary outcome. Suicidal behavior is the primary outcome measure. For the purpose of this protocol, suicidal behavior is defined by multiple sources because it is often undercounted if data is collected only from one source. Specifically, the current protocol uses a multi-method assessments follow-up to ensure accurate measurement. Our strategy includes in-person follow-up assessments (e.g., the C-SSRS, as mentioned above) in addition to medical records review and vital statistics registry review (described below). We will obtain data for all types of suicidal behavior including suicides, suicide attempts, interrupted attempts, aborted attempts, and preparatory behavior for suicide. The nomenclature and definitions for suicide-related behaviors will follow the CDC definitions. Suicidal behavior over the 12-month time frame is a cumulative outcome such that detection of suicidal behavior at any of the outcome points or by any method described above (e.g., C-SSRS, medical records, or vital statistics registry) leads to a "positive" indication for the suicidal behavior composite.

The effect of treatment on this suicidal behavior composite is examined through a Cox Proportional Hazard Regression, with treatment condition (PLF vs. TAU) and baseline suicidal behavior level as predictors, and incidence and time to the first suicidal behavior during the study as the outcome variables. Random effects (cluster effects) are included for the treating clinician (TAU group subjects) or the PLF group (for the PLF subjects). Kaplan-Meier estimates of the cumulative hazard function for both groups and all clusters (clinician/PLF within site) are graphed and the proportionality assumption checked. If the hazard functions are not proportional, the non-parametric log-rank test is used instead, with treatment condition as predictor, and we will use a sensitivity analysis to test the effect of baseline suicidal behavior severity by splitting

the treatment conditions by the two strata (presence/absence suicidal behavior). This analysis would not account for clustering by clinician/PLF group, and thus would be used in conjunction with a mixed effect logistic regression analysis with binary outcome measure, with subject- and clinician/PLF group-specific random effects.

Secondary outcome. For secondary outcomes, separate longitudinal mixed effect regression models are fit for post-randomization repeated measures of depression severity, hopelessness, and coping as outcome variables. Baseline score on the scale, randomization condition, site and time point are used as fixed predictors, subject-specific random intercepts, and a "first-order autocorrelation structure" (AR(1)) within-subject correlation structure. Subject-specific random effects are nested within a clinician effect for the TAU condition participants and PLF group indicator for the PLF participants, to explain some of the between-subject variability. Significantly lower post-baseline average depression/hopelessness, and higher average coping level in the PLF vs. the TAU participants are expected. The treatment-by-time point interaction is also tested. Mixed-effect models can be fit to data with dropout or missing values as long as the data is missing at random, thus, attrition will not necessarily reduce the number of participants included in these analyses.

Exploratory aims. For exploratory aims differential effects on belongingness by treatment condition (PLF vs. TAU), and if they are partially mediated by treatment response (e.g., suicidal behavior, suicidal ideation, depression, hopelessness), will be explored. To test whether differential effects on belongingness by treatment condition partially mediate treatment response, it will first be determined whether the treatment condition (PLF vs. TAU) is associated with higher Interpersonal Needs Questionnaire (INQ) during post-randomization time points using two longitudinal mixed effect regression models, similar to the ones for the quantitative

outcomes in Aim 1.[51] Treatment (or rather, randomization) group is treated as a fixed effect in the main analyses in Hypotheses 1.2 and 1.3. The statistician will allow for a random intercept to acknowledge individual differences within groups, in the INQ and other outcomes, that persist throughout the study. Subject-specific (random) treatment effects will be explored, and, if the random treatment effect's variance is found to be significant, it will be reported on in any resulting manuscript. Lastly, post-randomization INQ scores are tested to see if they are associated with rates of suicidal behavior and the other outcome variables described in Aim 1. Quantitative measures from Aim 1 that show significant group differences are tested for an association with the candidate mediator variables using mixed effect regression models on a lagged basis, such as the mediator measured at one-time point predicts outcome at the next time point.

For the suicidal behavior outcome, generalized linear mixed effects regression models (using a logit link for the dichotomous suicidal behavior outcomes or a Poisson distribution for the count of suicidal behavior outcome) are employed to test time-varying associations between the longitudinal outcome at a given time point with the potential mediator measured at the previous time point (e.g., 3 and 6 months). To test for partial mediation relationship(s), the mixed effects models for the outcome described above are refit using the randomization group (PLF vs. TAU) as an additional predictor. A 15% reduction in intervention effect is considered evidence of mediation. The difference between the randomized intervention effects on outcome at each assessment point in this model will also be compared with the analogous results of the ITT analyses from Aim 1.

To test whether group cohesion mediates treatment response in PLF, research staff will test the association between the group cohesion measure, (i.e. the Group Cohesion Scale-

Revised) obtained at baseline, 5 and 10 weeks, and the outcome variables described in Aim 1, using the models described above.[32] However, unlike in Aim 1, treatment condition is replaced by the social cohesion measure. Only participants in PLF are measured for group cohesion. A significant coefficient for the group cohesion variable is interpreted as evidence for an association of the treatment effect and group cohesion.

To test whether the change in Safety Plan Quality (SPQ; post intervention - baseline) is greater in PLF than in TAU, as well as whether the change in safety plan quality partially mediates treatment response in the follow up period, a mixed effect model, (also known as hierarchical linear model; HLM), is used to compare the change in quantitative SPQ score. This model was chosen because the subjects in this protocol are nested within clinician/PLF groups and a mixed effect model is often chosen when subjects are clustered in some way (e.g., by clinician or PLF treatment groups). For example, within this protocol when the treatment is delivered in groups, or by the same clinician for several subjects, these mixed effect models allow the statistician to adjust for correlations between the subjects in the same group, or treated by the same clinician (e.g., clusters). These scores are adjusted for random clinician effect (for the TAU subjects) and PLF group effect (for the PLF subjects). If the difference is found to be significant, the association between the change in SPQ and the outcome during the follow-up (suicidal behavior) in a Cox PH model with random (cluster) effect as described in Aim 1.1, and with mixed effect regression models for the quantitative outcomes in Aim 1.2 and 1.3 are tested. Mediation models for each outcome separately are fit as appropriate based on the above results.

Discussion

This study is the first RCT to examine outpatient group suicide safety planning. Overall, this trial study aims to study the efficacy of PLF (10-session manualized treatment with three

optional boosters) versus TAU. The researchers hypothesize that Veterans who participate in PLF will show a decrease in suicidal behavior, depression and hopelessness, display increased compliance, and a more positive attitude, towards mental health treatment, and show improved suicide-related coping. Exploratory aims for this study include: testing whether improved belongingness and group cohesion (of those in PLF) impacts treatment response. Lastly, this study aims to test whether the change in safety plan quality after PLF partially mediates treatment response in the follow up period. To test these outcomes there are four assessment periods. After this data is entered and cleaned, our statistician will run different models depending on the outcome.

This project has multiple strengths:

1) This study examines a novel intervention that further develops and maximizes the evidence- based strategy of suicide safety planning.

2) The PLF intervention is a group format, which can be easily and cost-effectively implemented throughout the VHA and military with potential for widespread adoption and impact.

3) The PLF intervention is one of the first manualized outpatient group interventions for suicide prevention and may catalyze interest in the development of other group-based interventions.

4) This projects study design includes a rigorous, multi-method outcome assessment plan for suicidal behavior.

5) The research team is highly experienced and internationally renowned including the developers of the suicide safety plan.

6) If successful, the results of the project are able to be disseminated widely in VHA populations.

Despite these strengths there are limitations of this project. These include:

1) Being unable to detect effects on suicide death because of the sample size given the low base rate of completions. Instead the focus is on suicidal behaviors that are an important predictor of eventual suicide death.[17]

2) The research team decided to conduct an efficacy study as opposed to an effectiveness study by using research clinicians, not VHA staff clinicians because this is the first RCT of the PLF intervention and at this stage, it is necessary to maximize internal validity.

3) It could be argued that our control condition does not adequately control for clinical interaction. PLF adds 15-18 hours of clinical interaction that is not matched in TAU. However, at this stage, the aim is to show that PLF is superior to TAU. Unpacking the specific elements for the reduction in suicidal behavior, is a focus of future research.

4) Due to the lack of applicable preliminary data, power for the mediation analyses was calculated under the independence assumption (without random effects). Effect sizes are going to be emphasized over significance testing for these analyses.

This study will provide significant advancement in treatments for Veterans at high risk for suicide. To our knowledge there are no outpatient group treatments that are suicide specific and openly talk about suicide as well as related experiences. If it is found that the PLF intervention impacts Veterans as hypothesized, this could have many implications about future directions for treating suicide within the VHA system and beyond. Dissemination of results will be important to further build understanding of suicide, and its treatments, especially in a

population at such high risk for suicide as Veterans. Results from the study hope to fill these gaps in the literature.

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