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Title: Suicide Safety Planning Group Treatment - "Project Life Force"

2) Background and Significance.

2A. Suicide in the VA. The prevention of suicide and treatment of those at greatest risk remains a national priority for both civilians and Veterans, as evidenced by the 2012 calls to action for suicide prevention from the United States Public Health Service and the Surgeon General, and President Obama's August 31, 2013 executive order pleading for stronger suicide prevention and treatment efforts in the VA. However, even with the VA's implementation of extensive services nationwide to high-risk Veterans, there were over 8,000 completions, averaging 22 deaths daily¹ and over 15,000 Veteran suicide attempts in 2012¹². These statistics highlight the urgent need for the development of additional suicide prevention, rehabilitation and recovery-based interventions for suicidal Veterans.

2B. Specific VA treatment efforts targeting suicidal Veterans. Recommendations from the 2011 RAND study on suicide prevention and treatment for active duty soldiers³ emphasize the need to provide "high quality mental health care." The VA has thus implemented a large-scale effort for suicidal Veterans targeting ready access to high quality care, public education and specialized services to those at highest risk. Each VA hospital now employs a Suicide Prevention Coordinator (SPC), who closely monitors all patients who are at high risk (HR) of suicide. The SPC also makes sure that each of these patients completes a VA-mandated Safety Plan developed by Drs. Stanley and Brown^{4,5}. This plan mirrors recommendations from the Suicide Prevention Resource Center and Suicide Prevention Action Network (Department of Veteran Affairs. SPRC Best Practices Registry: Section III, 2011).

2C. Interventions to prevent suicide- VA Suicide Safety Plan.

2C.1. Safety Plan description. The Suicide Prevention Resource Center (<http://www.sprc.org>) has designated the Safety Plan as a 'best practice,' which means that the intervention meets programmatic guidelines and standards of accuracy and safety. The SSP is strongly recommended by an array of governmental and not-for-profit agencies both in the US and in Canada.

The VA SSP is a prioritized, sequential written list of coping strategies and sources of support developed collaboratively by patient and clinician to mitigate suicide risk after hospitalization for suicide attempt or self-harm^{4,5}. In 2008, the US Department of Veterans Affairs (VA) mandated that clinicians oversee the construction of a SSP for every patient meeting these criteria. The patient takes the SSP home for his/her use during (or at the onset of) suicidal crises. The SSP instructs one to: recognize personal warning signs of suicide; use internal coping strategies; engage social contacts that can offer support and serve as distraction from suicidal thought; contact family members or friends who may help resolve a crisis; provide contact information for VA professionals to help; and, how to make the immediate environment safer (see **Appendix 1**).

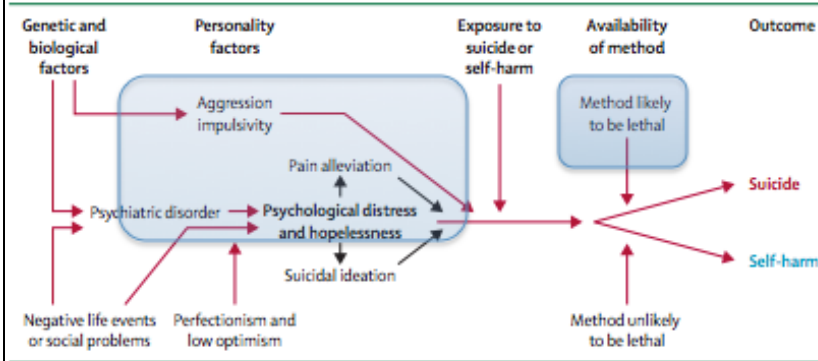
2C.2. Efficacy Data Pertaining to the VA Suicide Safety Plan. Since safety planning was instituted nationwide, minimal data have been collected to show: 1) how SSPs are constructed, 2) actual use patterns by Veterans, and 3) the extent to which Veterans perceive them to be helpful. Data from the Inspector General (OIG) report titled "Combined Assessment Program Summary Report: Re-Evaluation of Suicide Prevention Safety Plan Practices in Veteran's Health Administration, 2011, pertains to implementation rates only¹³. Unpublished usability and perceived helpfulness data from Dr. Stanley and her colleagues, of 100 non-hospitalized, moderate risk Veterans who received a Safety Planning Intervention found that only 61% used the plan, and of these individuals, 10% used it daily, 66% used it when they had difficulty. 99% found aspects of the SSP helpful and an overall satisfaction rating was (1-5 scale; 1=high; 5=low) was very high (1.3±.5) (Dr. Stanley, personal communication). *These data demonstrate the perceived helpfulness of safety planning, but also highlight a significant percentage that did not use the intervention. Additional studies are needed in higher risk cohorts, with extended longitudinal follow-up and in identifying strategies to maximize SSP use. The Project Life Force Intervention addresses these gaps.*

2D. Theoretical Model. Figure 1, describes Hawton and colleagues¹⁴ stress-diathesis conceptual model of suicide detailing interactions between genetic/biological and personality factors, environmental stressors, and psychiatric disturbance that precipitate psychological distress, hopelessness and suicidal ideation. Exposure to suicide and availability of means, move suicidal ideation toward action. The skills training and psychoeducation of the PLF intervention directly targets items in Figure 1 shaded in blue.

3) Significance and Innovation.

Suicide treatment research has been hampered by a paucity of empirical studies. Research on suicidal

Figure 1. Proposed conceptual model for suicide (From Hawton et al, 2012)¹⁴



The Proposed Suicide Safety Plan Intervention, Project Life Force (PLF) teaches skills that target: 1) individual differences in aggression and impulsivity, 2) medication and treatment compliance for psychiatric disorders, 3) emotion regulation strategies to alleviate psychological distress, 4) instilling hope, & 5) psychoeducation limiting access to means. Item shaded in blue are addressed with the PLF intervention.

populations is difficult due to the inherent risk of studying these patients and lack of evidence-based treatment interventions targeting both suicide prevention and recovery for those who do not die from their suicidal symptomatology.

This application proposes a novel clinical group intervention integrating DBT skills with the mandated VA suicide safety planning to reach high-risk suicidal Veterans, including those who have just been discharged from a psychiatric inpatient unit. This short term, 12-session group therapy intervention is designed to

complement VA mandated monitoring requirements, and primary purpose is to enhance the *safety plan with the necessary instruction in emotional regulation, interpersonal/friendship and distress tolerance skills to enable even acutely suicidal Veterans to be able to implement steps of the safety plan*. The group format allows Veterans to learn from each other, offers social support, and mitigates the sense of isolation and loneliness that has been associated with suicide¹¹. The group is designed to be a helpful adjunctive treatment, with close communication and feedback to the Veteran's primary psychiatric outpatient team. The aim of this intervention is to foster recovery from suicidal symptomatology, integrate the suicidal veteran back into treatment, his family, and society.

4) **Preliminary Work.**

4.1. Suicide Prevention- Qualitative Safety Planning Pilot Study. Twenty suicidal Veterans across two sites (James J. Peters VA (JJPVA) and Manhattan VA) participated in two semi-structured interviews, the first upon completing the SSP and the second a month later. The majority of Veterans found SSP construction to be a helpful experience, however, 30% were unable to identify contacts to call. At follow-up, only 65% Veterans reported having reviewed their plans at least once in the month. Even participants who reported benefits offered criticisms. A common complaint was that in crisis, the strategies listed on the SSP were inadequate and coping skills were difficult to access. Some reported difficulty in keeping track of the sheet of paper on which the plan was written. Most said they would prefer to have the plan in a more compact form, or in a mobile electronic format. For some, the most important use of the plan was sharing it with others, including family and close friends. *These pilot data demonstrate several avenues to maximize the utility of SSP including: 1) the need to incorporate the teaching of distress tolerance and emotion regulation skills⁹, 2) potential use of mobile SSP Application¹⁰, 3) helping identify individuals one can call for help and, 4) develop more detailed ways how to share the plans with others. These strategies are directly incorporated into our PFL intervention.*

4.2. Suicide Prevention- randomized clinical trial (RCT). The PI (Dr. Goodman) has extensive clinical and research experience with high risk suicidal Veterans, including the development of a DBT Clinical Program since 2002, and two current Department of Defense (DoD)-funded studies including a four-year RCT (with 18-month follow-up) of DBT for suicidal Veterans. This project also includes an extensive baseline assessment (5-6 hours) identifying suicide risk factors. *Baseline recruitment to date exceeded project goals; 368 consented participants and 324 completed assessments. RCT recruitment of suicidal inpatients has been brisk with 93 randomized to our trial. 59% of subjects completed the 6-month trial, and 51% were retained at the 12-month follow-up. Additionally, recruitment for our DoD supplement examining affective startle in suicidal Veterans is ahead of schedule (n=165). These numbers highlight our ability to recruit and retain large numbers of suicidal Veterans and successfully conduct treatment trials in this population. The current proposal will benefit from our current suicidal*

inpatient recruitment infrastructure as well as expansion into populations of suicidal outpatients.

5) Research Design and Methods.

5A. Overview. The current study proposes to finalize development of “Project Life Force” (PLF) manual and to conduct a small-randomized trial (n=40) in suicidal Veterans to examine the feasibility, acceptability and preliminary efficacy of the intervention.

TABLE 1- Project Life Force Session Content

Session #	Focus	Skill Covered
1	Veteran introduction, psychoeducation about suicide, review of current SSP	DBT Crisis Management Strategies/ Managing Extreme Emotions
2	SSP step of: Identification of Warning Signs	DBT Emotion Recognition Skills
3,4	SSP step of: Distractions	DBT Distress Tolerance Skills
5,	SSP step of: Identifying People to Call	Making Friends Skills
6	How to share Suicide Plan with Family	DBT Interpersonal Skills
7	SSP step of: Professional Contacts	Skills to maximize treatment efficacy and adherence
8	SSP step of: Making Environment Safe	Psychoeducation about suicide methods, gun safety
9	Increasing Access to the SSP	Use of technology applications
10	Physical Health Management	DBT ER Skills-Decreasing Vulnerability to Negative Emotion
11	Building a Life Worth Living	DBT ER Skills- Accumulating Positives/ Building Mastery, Community Reintegration
12	Recap, Sharing of finalized safety plans	

5B. Phase 1:

Development of PLF

5B.1. Project Life Force Clinical Intervention:

is a manualized, weekly 90-minute group treatment lasting 3 months coinciding with the time frame for enhanced monitoring of Veterans identified as “high-risk”. Session content is described in **Table 1**. The use of DBT skills⁹ in PLF differs from other DBT interventions in that it focuses primarily

on emotion regulation (ER), distress tolerance and interpersonal effectiveness *in the specific context of implementing a safety plan*. Mindfulness is not covered. PLF is augmented with additional skill modules on strengthening friendships and education pertaining to suicide risk, suicide means restriction and suicide prevention mobile Apps.

This is an open-group format, with new members joining throughout the 12-week cycle to allow immediate access to the skills and accommodate the need for expeditious safety planning for higher risk Veterans. While traditional DBT skills groups enter patients at designated points (e.g. the beginning of new skills modules), there is a growing evidence base of the effectiveness of DBT skills groups offered in more flexible frameworks, including drop-in formats¹⁵. Our open-group framework facilitates ease of entry. Since the program runs continuously, Veterans who join after session #1, can pick up any missed material in the next cycle. This project will randomize subjects over a one-year time frame to 12 weeks of either TAU or PLF. The study will include 4 cycles of the PLF intervention. See **Appendix 2** for PLF handouts and more detail on individual session lesson plans. PLF session format will be modeled after DBT skills groups and include: 1) brief check in and any follow up pertaining to use of the safety plan, 2) homework review, 3) teaching of new material and skill, 4) in-class practice of the skill, and 5) assignment of homework/ outside practice/development of safety plan.

5B.2. Finalize PLF manual: With input and feedback from co-investigators Drs. Barbara Stanley (SSP original developer), Deborah Perlick (clinical trial development, family interventions), David Banthin (DBT, psychotherapy engagement), Lisa Dixon (health services, implementation) and Rachel Yehuda (PCC Director), the PI will finalize the PLF manual and associated handouts. We will also create a tool for assessing fidelity to PLF (see **5C.3.1**).

5C. Phase 2, Randomized Clinical Trial: 40 suicidal Veterans will be randomized to PLF and TAU to examine the feasibility, acceptability and preliminary efficacy of PLF.

5C.1. Study Site. The study will recruit 40 suicidal Veterans over 1 year from the James J. Peters VAMC (JJPVA) (Bronx, NY). The JJPVA has functioned as the main site of recruitment for Dr. Goodman’s DoD study on suicidal behavior that recruited and *successfully assessed 324 suicidal Veterans* over the course of the study. The current proposal will benefit from the infrastructure already in place for recruitment of HR suicidal Veterans. JJPVA has a 30-bed psychiatric inpatient unit, an

average length of stay of 12 days and over 518 psychiatric admissions last year. Approximately 18% (n=82) of these admissions involved suicidal symptomatology, requiring the construction. Safety Plans prior to discharge. In addition, we will also recruit from outpatient clinicians and suicide prevention coordinators who have identified Veterans requiring a SSP; a strategy we used for our qualitative pilot study on safety planning (see **preliminary work**, section 4.1). We do not anticipate any difficulty recruiting 40 subjects across inpatient and outpatient services.

5C.2. Veteran Participants. 40 Subjects identified for use of a safety plan (e.g. discharged from inpatient hospitalization for suicidality, placed on the high-risk list, or outpatients who evidence increase in suicidality but not severe enough to warrant hospitalization) will be recruited for the study. Inclusion Criteria include: 1. Veterans ≥ 18 ; 2. Able to give consent; 3. Recent Suicidality and recommendation for a SSP initial construction or revision. Exclusion Criteria include: 1. Does not speak English. 2. Schizophrenia diagnosis. 3. Inability to tolerate group therapy format.

5C.3. Experimental Condition- PLF. The pilot will use the PLF intervention finalized during Phase 1a of the proposed project. PLF is a 90-minute, 12 sessions, held weekly run by two clinicians using the final version manual and handouts from Phase 1a (see research plan, **5B.1**, and **appendix 2** for current version) with the stated purpose of developing, refining and implementing the SSP. The treatment is adjunctive and SSPs developed in the PLF Intervention will be shared with the Veteran's treatment team for feedback/approval. Veterans randomized to PLF will continue with their psychiatrist, case manager and services by the suicide prevention coordinator as indicated.

5C.3.1. PLF Training and Fidelity. Our research team (Drs. Goodman, Perlick, Dixon) has experience developing psychosocial interventions and establishing their fidelity. Similar to our DBT RCT for suicidal Veterans (see **preliminary work**, section 4.2), PFL training will include weekly supervision with therapists and videotaping and review of sessions for fidelity using an objective scale. This adherence scale will be finalized with assistance by Dr. Perlick during phase 1a of the project, and include ratings along a 5 point Likert scale (0- unacceptable, 5- excellent) assessing core features of the framework, content and principles of the treatment for each session along with competence variables including ability to manage the group, build rapport, manage crises. For the PLF RCT (phase 2), ratings will be performed by an independent rater on randomly selected group sessions. Overall ratings require an average score of 4 or above for adequate adherence to the intervention.

5C.4 Comparison Condition- TAU. The comparison condition, treatment as usual (TAU) will consist of the standard treatment delivered to suicidal Veterans in the VA including visits with the outpatient psychiatrist and case manager, with content of sessions and treatment appointment intervals determined by the subject's treatment team and suicide prevention coordinator's suggestions.

5C.5. Randomization Procedure. After the baseline assessment, participants will be informed of their assigned condition. Subjects will be assigned to study group using a blocked randomization plan with blocks of random sizes. Block sizes will be of either 2, or 4. The blocking will aid in keeping investigators blinded to study group assignment. A total of 20 Veterans are randomized to each group.

5C.6. Participant Assessment.

5C.6.1. Subject Characterization (see Table 2).

1. Clinical Characteristics- Lifetime suicide attempts: Columbia Suicide History Form (CSHF) records lifetime suicide attempts & methods, including lethality, precipitant, and surrounding circumstances (5-10 minutes). The scale has inter-rater reliability of 0.97, and been used extensively in prospective suicide studies¹⁶.

2. Demographics: The study team will collect data via EHR- age; ethnicity, psychiatric treatment history, including medications; medical history; years of education; marital, housing and employment.

3. Diagnosis: It is well known that certain mental illnesses place individuals at high risk for suicide. These include MDD, bipolar disorder, borderline and antisocial personality disorders, substance abuse and schizophrenia. Diagnosis will be determined by chart review.

Table 2. Subject Characterization

Type of Data	Variables	Data Source
Diagnostic	Psychiatric diagnosis	Chart Review
Demographic	Age, sex, ethnicity, marital/family status, education, employment, housing status	Chart Review
Suicide History	Number of Suicide Attempts	Columbia Suicide History Form

5C.6.2. Measurement of Feasibility and Acceptability of PLF. To examine feasibility we will track participation, retention and dropout in PLF by measuring the number of session and specific sessions each Veteran attends, and clinician preparation and supervision time allocated to the intervention. For acceptability of PLF, participants will complete a brief survey (see **Appendix 3**) soliciting feedback upon completion of the PLF intervention at the 3-month assessment point.

5C.6.3. Efficacy Outcomes and Measures Overview. Veteran participants will be assessed in-person at baseline and at months 1, 3 and 6 (e.g. 3 months post intervention). These time points were specifically selected to allow us in order to collect information on the creation of the plan (baseline) and its use during the highest-risk period (first 4 weeks) and after acute symptom stabilization (12 weeks) (see **table 3**).

5C.6.3a. Primary Outcome Measure. Suicidal ideation will be measured using **The Beck Scale for Suicide Ideation (BSI)**¹⁷: 21-item self-report designed to assess severity of suicidal

attitudes and plans for suicide (5 to 10 minutes). It is based on the semi-structured interview, the Scale for Suicidal Ideation. BSI is internally consistent, high internal reliability (Cronbach α coefficients .87-.97)^{18,19} and moderate test-

Table 3. Clinical Assessment Measures and Schedule

Outcome	Measures	Baseline	Month 1	Month 3	3 Months follow-up
Primary: Suicidal ideation	Beck Scale for Suicidal Ideation (BSI)	X	X	X	X
Secondary: Hopelessness/ Depression	Beck Hopelessness Scale (BHS)	X	X	X	X
	Beck Depression Inventory (BDI)	X	X	X	X
Reasons for living	Reasons for Living Scale	X	X	X	X
Outpt MH Treatment utilization	Count of CPRS mental health visits in previous 90 days	X			X
Exploratory: Community reintegration	Computer Adaptive Test version of the Community Reintegration of Injured Service Members measure	X	X	X	X

retest reliability ($r=.54$)²⁰. A principal factor analysis identified 3 factors for the BSI: desire for death, preparation for suicide and actual suicide desire¹⁵.

5C.6.3b. Secondary Outcome Measures: proximal psychosocial outcomes include depression, hopelessness, reasons for living, and outpatient mental health treatment utilization.

Beck Depression Inventory-II (BDI-II)²¹ consists of 21 items related to symptoms of depression and is scored based on a Likert scale. Widely used in adults and adolescents, it has high internal consistency (Cronbach coefficient $\alpha = .92$).

The Beck Hopelessness Scale (BHS)²² is a 20-item self-report measure with true-false items that assess hopelessness and the extent of positive and negative beliefs about the future. Adequate reliability and concurrent validity data exist for this measure²³.

The Reasons for Living Inventory (LRFL)²⁴ is a 48-item self-report measure with 6 subscales: Survival and Coping Beliefs (24 items), Responsibility to Family (7 items), Child-Related Concerns (3 items), Fear of Suicide (7 items), Fear of Social Disapproval (3 items), and Moral Objections (4 items). These beliefs and expectations about not dying by suicide are rated on a 6-point Likert scale. The LRFL has high internal reliability and good test-retest reliability²⁵.

Outpatient Mental Health Treatment Utilization: Using CPRS we will count the number of outpatient mental health visits attended by participants prior to the intervention and compare to the number of outpatient visits attended 3 months post intervention.

5C.6.3c. Exploratory Measure: **The Computer Adaptive Test version of the Community Reintegration of Injured Service Members measure (CRIS-CAT)**²⁶ consists of three scales measuring extent of, perceived limitations in, and satisfaction with community integration, has minimal patient burden and sound measurement properties including reliability, and predictive validity.

5D. Data Analytic Plan.

5D.1. Preliminary analyses. We will perform descriptive analyses to detect potential errors, check for missing data, identify outliers and ascertain whether there is sufficient dispersion for analyses, and that variable distributions accord with our statistical models. If the distribution of our

outcome measures does not accord with the assumptions of our statistical models, the appropriate power or logarithmic transformations will be used or we will create categorical variables as necessary. While patients were randomly assigned to our two study groups, we will also check for differences in demographics variables and baseline measures using chi-square tests, or t-tests, as appropriate.

5D.2. Missing Data. In handling missing data, all analyses will be intent to treat. For primary and secondary outcome measures, every effort will be made to assess all study participants at 1, 3 and 6-month time points. A direct likelihood approach in the analysis of mixed models²⁷ will be used. This method has the advantage of using all available data, and does not require any imputation.

5D.3. Analytic Strategy: Feasibility and Acceptability. Rates of recruitment, engagement, and attendance will be compared to published reports of similar type interventions. Acceptability will be analyzed with qualitative methods described in section 5C.6.2.

5D.4. Quantitative Analytic Strategy: Efficacy. We will first explore if any demographic features (e.g. gender, chart diagnosis) influence number of sessions attended and will include these demographic variables as covariates in our analyses where appropriate. The primary endpoint is self-reported suicidal ideation and secondary endpoints include self-reported measures of depression, hopelessness, reasons for living, and a treatment utilization measure of number of outpatient mental health visits attended. All of these metrics, except for treatment utilization, are continuous scales that will be measured at baseline and again at months 1, 3, and 6. For these outcomes, linear mixed models for longitudinal data²⁸ will be used for analysis. In these models, the fixed effects will be time, treatment group, and the interaction between time and treatment. The random effects will be the subjects. The interaction term in each model will test whether the trend in response over time differs between the treatment groups. The last secondary outcome, number of outpatient mental health visits attended, measures counts. A Poisson regression model will be fit to these data using Generalized Estimating Equations (GEE)²⁸ and the model will allow for testing whether the rate of outpatient visits for mental health differs between the two treatments. All statistical tests will be two-tailed with an alpha =.05.

For the Exploratory Aim, an Analysis of Covariance model with an interaction term will be used. In this model the outcome variable will be the CRIS-CAT score, the binary treatment variable will be whether the subject received PLF or TAU, the covariate will be the BSI, and the interaction will be that between the treatment variable and the Beck scale covariate. If there is no interaction, then the focus will be on the treatment effect. In this situation the regression lines relating CRIS-CAT to BSI will be parallel, and the treatment effect will measure the distance between the parallel lines providing a measure of the improvement in community integration over the entire range of the BSI in subjects receiving PLF compared to patients receiving TAU. On the other hand, if there is a significant interaction, this will correspond to a situation of intersecting regression lines for the two treatment groups. In such a circumstance, the improved community integration of one treatment group will be limited to a sub-range of the Beck scale.

5D.5. Power and Sample Size Justification.

Although this is a pilot study with the purpose of investigating feasibility and collecting preliminary data to aid in planning a larger study, power calculations were carried out for the proposed sample size of 40 enrollees. With 20 subjects randomized to each of the two treatment groups, there will be 80% power to detect an effect size of 0.91. We recognize that this effect size is probably larger than the true effect size for these treatments, but one of the outcomes of this pilot trial will be the data allowing us to improve the required sample size estimates for a future study.

Figure 2--Study Time Line

6) Time Line. (See Figure 2)

RCT Recruitment is ongoing and Veterans can enter at any point during the RCT. During this time frame, we expect to recruit 4-5 Veterans/month from both inpatient and outpatient services.

<u>activity</u>	Month 1-6		Month 7-12		Month 13-18		Month 19-24	
<i>Hire/train staff</i>								
<i>Finalize Manual & Obtain IRB approval</i>								
<i>Conduct RCT</i>								
<i>Conduct follow-ups</i>								
<i>Data analysis/papers</i>								