SAFER: A Brief Intervention Involving Family Members in Suicide Safety Planning

Study Protocol and Statistical Analysis Plan

While support for involvement of family members in care has to address suicide risk been discussed in many national trainings for VA mental health (Glynn, personal communication), this work has been hampered by the lack of research on effective conjoint interventions to address suicide risk in adults. To date, we are aware of only one intervention study evaluating a relative-inclusive intervention to address suicide risk in adults (Anastasia, Humphries-Wadsworth, Pepper, & Pearson, 2015). Though this trial has positive results, it tested a hospital division program including primarily females, so its generalizability to a primarily male outpatient Veteran population is unknown.

To fill this gap in research and clinical care, Safe Actions for Families to Encourage Recovery (SAFER) was developed.

The Safe Action for Families to Encourage Recovery (SAFER) intervention is a family-based SPI treatment. Specifically, SAFER aims to help Veterans cope more effectively, improve communication, limit feelings of burdensomeness while building a more robust support system and sense of belonging, all in the service of lessening suicide risk. Simultaneously, for families, SAFER targets their support of Veteran coping, communication, and lessens feelings of being burdened by the Veteran.

The SAFER intervention was developed as a manualized, 4-session 90-minute dyad-based approach that includes psychoeducation about suicide risk and focuses on building a Veteran and supporting partner safety plan (see **Table 1)**. Open label pilot testing of the intervention on six Veteran couples enabled to the research team to finalize the manual and session content and resulted in promising feasibility and acceptability data on the dyad format. In order to test the initial efficacy of the SAFER intervention, a small randomized clinical trial was

designed comparing SAFER to a control condition – individual Safety Planning Intervention (I-SPI) that entailed creating a safety plan individually and is the standard of care in VA practice.

The specific hypotheses of this randomized control trial were:

Study Hypotheses

Hypothesis 1. Veterans participating in SAFER will experience reduced severity of suicidal ideation in comparison to Veterans completing I-SPI.

Hypothesis 2. Veteran-supporting partner dyads participating in SAFER will show improved suicide related coping in comparison to I-SPI. Specifically, we predicted Veterans would experience improvement in suicide-specific coping (Hypothesis 2A) and the supporting partner would demonstrate greater resource knowledge and support of Veteran's coping efforts (Hypothesis 2B).

Hypothesis 3. Veteran- supporting partner dyads participating in SAFER will show reductions compared to I-SPI on interpersonal appraisals that are related to suicide risk. Specifically, we predicted Veterans would experience reduced perceived burdensomeness and thwarted belongingness (Hypothesis 3A) while supporting partners would experience reduced caregiver burden (Hypothesis 3B).

Methods

Overview

The study is designed as a randomized controlled study comparing SAFER to I-SPI in a sample of thirty-nine Veteran-supporting partner dyads struggling with recent or past suicidal ideation. Outcomes were evaluated using two follow-up assessments (post-treatment and extended follow-up) that were. Due to the difficulty of recruiting this specialized sample, participants were re-contacted for a given assessment until it was finally completed. All

procedures and instruments were approved by an institutional review board. Given the novel nature of the SAFER intervention, the sample intentionally was recruited for having moderate to high, but not extreme immediate risk.

Participants

Eligible Veterans were at moderate risk for suicide, defined as: having endorsed recent passive or active suicidal ideation (within the past 3 months) or a lifetime history of a suicide attempt. Additionally, Veterans must have been receiving care at the VA and have had an available, consenting, and qualifying supporting partner to participate. Supporting partners needed to meet at least three (two for nonrelatives) of five criteria inclusion criteria established by (Pollak & Perlick, 1991): 1) is a spouse, co-habiting significant other or parent; 2) has more frequent contact than any other caregiver; 3) helps to support the patient financially; 4) is contacted by treatment staff for emergencies; 5) has been involved in the patient's treatment.

Veterans and supporting partners were excluded if: 1) history of suicide attempt in the past 3 months; 2) they presented with untreated or un-medicated active psychosis; 3) they presented with alcohol or drug abuse or dependence within the past month; 4) they presented with medical condition or life event (e.g., an upcoming move to another state) that would compromise participation; 5) they recently (past 6-months) participated in another family-based psychosocial intervention trial ; 6) had limited English proficiency; 7) and if they were participating with a romantic partner and endorsed recent, "severe" intimate-partner violence. Participants were screened for inclusion/exclusion with measures described below immediately after consent.

To determine inclusion/exclusion the Patient Health Questionnaire (PHQ; Spitzer, Kroenke, & Williams, 1999) was used to screen for alcohol or drug abuse or dependence within

the past month, defined by criteria met on the PHQ's modules of alcohol and drug abuse or dependence. For romantic couples, to determine recent, "severe" intimate-partner violence, the revised 20-item Conflict Tactics Scale Short Form (CTS2S; Straus & Douglas, 2004) was used.

The study aimed to recruit, consent, and randomize 40 Veterans at risk for suicide and 40 corresponding supporting partners over a 30-month period from a large VA medical center in a major metropolitan area in the North East. Recruitment sources included VA suicide prevention coordinators, a Veteran's primary clinician from the VAMC's psychiatric inpatient unit or outpatient care center, or through community outreach (e.g., Vet Centers and higher education institutions).

Procedure

Assessments

After screening and consent, Veterans and supporting partners completed separate in-person baseline assessments which included demographic data, Veteran and supporting partner assessments to assess inclusion/exclusion, and measures including the final study outcomes. Each Veteran-supporting partner dyad was then randomly assigned to participate in either I-SPI or SAFER with a one to one ratio using a block randomization scheme. Regardless of randomization, Veterans were allowed to continue with all other VA care, as needed. Outcomes were re-assessed immediately post-intervention and then again through a follow-up assessment at least 3-months post-intervention. To minimize attrition in this difficult to obtain and track sample, participants were initially contacted at the end of their intervention and then re-contacted until one or both provided the post-treatment assessment (Range=0.30-7.47 months from baseline; *M*=2.84 months) and then the follow-up was timed three months from that point or up

until one year from enrollment (Range=3.10-11.43 months from participants' baseline; *M*=6.32 months).

Attrition. Of the 78 participants in the study, 57 gave at least one wave of follow-up (30 Veterans; 27 Supporting Partners). Examination of demographic predictors of attrition found that participants who provided follow-up did not significantly different from participants who did not with respect to assigned condition, years of education, gender, ethnicity, race, employment status, nature of caregiving relationship, Veteran status of the non-Veteran partner, or any of the baseline levels of the outcome measures. However, age did significantly predict attrition ($t(76)= -2.36$; $p<.02$), with those providing follow-up being generally older (M=51.37 years) than those who did not (M=42.76 years).

Individual Suicide-Safety Planning (Control)

As noted above, all participants were able to continue in standard VHA care based on their own determined needs (psychiatry; psychotherapy; and case management by the suicide prevention coordinator). Veterans in the control group were able to update and review their safety plan with a study clinician. Veterans created a full SPI with a study clinician if they did not already have one.

SAFER Intervention (Treatment)

The SAFER intervention is a novel, manualized, 90-minute dyad-based intervention that typically includes a joining session, two treatment sessions, and a booster. SAFER follows standard skills training session format and include: 1) brief check-in with brief assessment of mood, current level of suicidality and use of safety plan; 2) homework review; 3) teaching of new material and skill; 4) in-class practice of the skill; and assignment of homework/outside practice of skill /development of safety plan. Session content includes the use of psychoeducation,

communication skills training and revision and development of both the Veteran and a complementary supporting partner SPI. The SAFER treatment goal is to provide the tools and structure to support social support involvement in Safety Planning Intervention for Veterans at moderate risk for suicide (**Table 1**).

Treatment Fidelity. A fidelity scale was developed during the prior open trial plot testing to assess core features of SAFER's structure, contents and treatment principles, along with general clinical competence (e.g., building rapport, crisis management, etc.). This 14-17 item scale (13 general competence items and 1-4 session-specific items) was rated on a 4-point Likert scale (where 0 = unacceptable and 3 = excellent). were made by one trained rater. The rater was trained by the Principal Investigator and research staff. It was a one-day training to review components of the treatment manual, instruction in group therapy principles and group didactics, and suicide risk assessment. Additionally, the rater read the 51-page manual inclusive of session handouts and worksheets. All intervention sessions were recorded, and a randomization scheme was generated to have seven sessions randomly selected for review. Clinicians are required to maintain a total score of 80% or above on each session to demonstrate acceptable adherence to the intervention. Clinicians whose ratings fall below this criterion were given additional supervision and their adherence was monitored until satisfactory adherence was regained. The average percentages on the adherence scale ranged from 82 to 100 with the mean score being 90.7. No interventionists ever dropped below the 80% adherent threshold and therefore no re-training was required throughout the trial.

Measures

Primary Outcome Measure (Hypothesis 1)

Veteran suicidal ideation. Moderate suicidality was measured to determine eligibility

using the Columbia Suicide Severity Rating Scale (C-SSRS). Posner and colleagues (2011) found the C-SSRS to have divergent validity, predictive validity, sensitivity, specificity, sensitivity to change, and internal consistency in a multisite study (Posner, et al., 2011). The C-SSRS was also used across time points to record level of ideation, lifetime suicide attempts, and recent suicide attempts. Research staff was trained by Dr. Barbara Stanley and Dr. Ainsley Burke, two of the developers of the assessment. Additionally, staff had weekly meetings in which the C-SSRS was discussed to ascertain consensus when scenarios warranted further discussion.

Suicide-Specific Coping (Hypothesis 2)

Veteran suicide-related coping. Suicide-related coping was evaluated by the Suicide-related Coping Scale (SRCS), a 17-item self-report measure assessing one's ability to cope with suicidal ideation and urges (Stanley, Green, Ghahramanlou-Holloway, Brenner, & Brown, 2017). The scale demonstrated good internal consistency (α=.85) at baseline; scores were summed so that higher scores represent greater confidence and breadth of approaches to coping with suicidal thoughts and feelings.

Partner's support of suicide-related coping. Supporting partners also completed five items adapted from the SRCS that assessed their confidence in their ability to support the Veteran through their suicidal urges. The five items were, "I know the nearest hospital or urgent care facility where my loved one can go if I cannot handle the crisis on my own," "When my loved one is feeling suicidal or showing signs of suicidal thinking/behavior, there are places we can go to help take his/her mind off the problems," "I have several things I can do to help my loved one get through a suicidal crisis," "I am able to put aside my own fears and focus on taking appropriate actions when my loved one is feeling suicidal or showing signs of suicidal

thinking/behavior," and "Seeking help from health care professionals is a good way to keep my loved one safe when he/she is feeling suicidal or showing signs of suicidal thinking/behavior." Items were rated on a 0 (*Strongly Disagree)* to 4 (*Strongly Agree*) and were summed so that higher scores indicated greater self-efficacy when supporting the Veteran through suicidal crises, In addition to face validity, the scale showed acceptable internal consistency in the sample (α=.78).

Suicide-promoting appraisals (Hypothesis 3)

Veteran perceptions of burdensomeness and thwarted belongingness. Perceived burdensomeness and thwarted belongingness were evaluated by the Interpersonal Needs Questionnaire (INQ-15; Van Orden, Cukrowicz, Witte, & Joiner, 2012). Scores on each subscale are summed so that higher scores represent a greater degree of Perceived Burdensomeness (α= .95) and Thwarted Belongingness (α =.79).

Supporting partner's experience of caregiver burden. Caregiver burden was evaluated using the Caregiver Burden Inventory (CBI; Novak & Guest, 1989), a 24-item scale assessing caregiver burden in five areas: time, physical, social, developmental and emotional burden. Items were summed to create an overall measure of caregiver burden (α =.94).

Analytic Strategy

We examined predicted trajectories on the outcomes of interest using slope-intercept trajectories based on Hierarchical Linear Modeling (HLM; Raudenbush & Bryk, 2002). We specifically created a two-level model in which repeated measurements over time were modeled at Level 1 (within-person change) and differences between participants/dyads were modeled at Level 2 (between-person change, including difference in condition).

Level 1 Outcome = $\pi_0 + \pi_1$ * (months since baseline) + *E*

The Level 1 equation represents a slope-intercept model predicting each participants' estimated score on an outcome baseline (π_0) and then calculating linear change in that outcome each month across the study (π_1). Slope-intercept trajectories are ideal for the present data given the variable assessment windows across all participants and the ability of HLM to use all available information from each participant to estimate these slopes using restricted maximum likelihood estimation.

Level 2 $\pi_0 = \beta_{00} + \beta_{01}$*(Condition) + β_{02}*(Veteran History of Attempt) + β_{03}*(Relationship with Supporting Partner) + β_{04}*(Age) + r_0

$\pi_1 = \beta_{10} + \beta_{11}$*(Condition) + β_{12}*(Veteran History of Attempt) + β_{13}*(Relationship with Supporting Partner) + β_{14}*(Age)

The Level 2 equation models respondents' trajectories based on condition (SAFER=1; I-SPI=0). Due to limited power, we were sparing with our controls and limited them to those considered most relevant to Veteran risk (history of attempt; 0= No attempts; 1=Has 1+ attempts), ability to collaborate with the supporting partner (nature of relationship between partners; 1=Romantic; 0=All others), and attrition (age). The treatment effect of SAFER is modeled as the effect of condition on change in functioning over time (β_{11}) after controlling for differences between conditions at baseline (β_{01}) and demographic controls (all other βs).

As Veterans and supporting partners were assessed on separate outcomes that in many cases were assessed weeks to months apart from one another, we estimated separate trajectories for each outcome without needing to account for dyadic dependence.

Results

Descriptives

Participant characteristics at baseline can be found on Table 3. Consistent with the Veteran population in the recruitment region, the sample was generally middle-aged, more likely to be black, somewhat more likely to be Hispanic/Latino and somewhat more likely to be unemployed than the general population. The final sample of 39 Veteran-supporting partner dyads included a range of supports including 14 romantic partners, 13 family members of Veterans, and 12 close friends. Although supporting partners were not required to be Veterans, a third of supporting partner (n=13) identified as Veterans themselves. 19 Veterans reported a history of one or more suicide attempts. As can be seen on Table 3, participants were generally similar across both conditions with respect to demographics characteristics as well as all outcomes. This highlights the effectiveness of random assignment in our small sample and suggests the groups are roughly comparable for treatment analyses.

Impact of Treatment Condition on Change in Outcomes over Time

The full model examining change in C-SSRS rated severity of suicidal ideation can be found in **Table 4**. As can be seen in the top half of **Table 4**, Veteran suicidal ideation did not significantly differ at baseline by condition or demographic controls. However, there was a significant effect of treatment condition on their trajectories over the course of the study. Specifically, Veterans in the active SAFER condition were predicted to see sharper declines in suicide ideation than those in the control group (B= -0.37; *p*=.032). In order to clarify the impact of treatment on trajectory over time, we then calculated the slope-intercept trajectory within each condition. Veterans in the SAFER condition experienced significant declines in severity of suicidal ideation while there was little change over time in the control condition.

This pattern of findings was replicated when examining the impact of treatment participation on coping strategies (Hypothesis 2). Specifically, a significant treatment-by-time

interaction emerged when predicting Veteran suicide-related coping (B=1.40; *p*=.028). Examination of simple slopes highlights that Veterans in SAFER reported marginal increases in suicide-related coping (Simple Slope= 0.88; *p*=.080) while Veterans in I-SPI reported non-significant declines in coping. Similarly, a treatment effect emerged for supporting partners support of Veteran coping (B=0.79; *p*=.034). Specifically, while supporting partners in I-SPI provided marginally less support over time, caregivers in SAFER maintained their efforts to support Veteran coping.

Contrary to expectations, self-reported appraisals of relational factors and self-efficacy were not impacted by condition for either Veterans or supporting partners. In fact, modeling trajectories across both conditions highlight that most appraisal variables are expected to be stable across the length of the study.

Impact of Controls

Although not part of our primary hypotheses, we examined significant effects of controls on the outcomes of interest. Notably, romantic partners of Veterans reported substantially higher overall levels of caregiver burden at baseline (B=17.66; *p*=.01) that remained relatively stable over the study. Veterans with romantic partners showed corresponding increases in suicide ideation severity (B=0.49; *p*=.02; Table 2) and decreases in suicide-related coping (B=-1.52; *p*=.04). In contrast, Veteran history of suicide attempt was associated with only somewhat elevated caregiver burden on baseline (B=7.22; *p*=.28) that were offset greater declines in caregiver burden over the study (B=-2.38; *p*=.03). Taken together, this indicates that caregivers of Veterans with a history of attempt showed general adaptation as the crisis subsided while romantic partners of Veterans experienced stable high levels of burden that were then followed by worsening functioning for the Veteran over time.