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Rationale and study protocol for a two-part intervention: Safety planning and structured follow-up among veterans at risk for suicide and discharged from the emergency department

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ABSTRACT

There are no evidence-based, brief interventions to reduce suicide risk in Veterans. Death by suicide is a major public health problem. This article describes a protocol, Suicide Assessment and Follow-up Engagement: Veteran Emergency Treatment [SAFE VET], developed for testing the effectiveness of a brief intervention combining a Safety Planning Intervention with structured follow-up (SPI–SFU) to reduce near-term suicide risk and increase outpatient behavioral health treatment engagement among Veterans seeking treatment at Veteran Affairs Medical Center (VAMC) emergency departments (EDs) who are at risk for suicide. In addition to describing study procedures, outcome measures, primary and secondary hypotheses, and human subjects' protection issues, the rationale for the selection of SPI–SFU as the intervention is detailed, as are safety considerations for the unique study setting and sample.

1. Introduction

Suicide is the 10th leading cause of death in the United States. In 2012, suicide claimed over 40,000 lives [1]. For two decades (from the mid- to late 1980s to the mid- to late 2000s), suicide rates among Veterans were higher than rates among their same aged and sex civilian peers [2–4]. In subsequent years, with the implementation of additional Department of Veterans Affairs (VA) initiatives to prevent suicide among Veterans, decreasing proportions of Veterans among U.S. suicide victims have been observed [5]. Nonetheless, suicide is still a major public health problem among U.S. Veterans. In 2010, suicide claimed an estimated 22 Veteran lives each day [5]. Non-fatal suicide attempts and serious suicidal ideation occur much more frequently [6] and confer particular risk for subsequent suicide in both U.S. civilian and Veteran populations [7].

Emergency departments (EDs), both within Veterans Health Administration (VHA) and other healthcare systems nationally, are assuming an increasingly important role in the care of suicidal individuals. In fact, suicide-related ED visits increased nearly 50% from 1992 to 2001 [8]. In 2010 and 2011, there were an estimated 2.5 million suicide-related ED-visits annually in the U.S. [9]. Given limits to outpatient treatment engagement among populations at risk for suicide [10,11], EDs often function as the primary or sole point of contact within the health care system for such individuals [12]. This contact often occurs either immediately following a suicide attempt or when suicidal thoughts escalate, and the individual feels in danger of acting on them.

Although American Psychiatric Association Clinical Practice Guidelines have been established for conducting suicide risk assessments [13], there are no widely adopted best practices for treating suicidal

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patients within emergency settings [14]. In practice, when suicidal patients are evaluated in the ED and hospitalization is not clinically indicated, they are generally discharged with referrals for outpatient mental health treatment [15]. Unfortunately, between 40% and 90% of suicidal patients assessed and then discharged from the ED do not attend even 1 follow-up outpatient mental health care appointment [16–19]. Of those who do attend some treatment, lags between ED discharge and first outpatient visit, as well as premature termination of outpatient treatment, are common and concerning. Only between 10% and 40% of suicidal ED patients discharged with a referral for outpatient mental health treatment are compliant with recommended treatment over a 3 to 12 month follow-up [17–19]. In the 6-month period following discharge from an ED visit for self-harm (suicide intent unknown) suicide rates are 562 per 100,000 individuals [20], whereas the suicide rate in the general U.S. population is 12.6 per 100,000 [21]. Because many patients will not seek or remain in treatment following an emergency evaluation or receive services in a timely manner, and given the increased suicide risk associated with the period following ED presentation for self-directed violence, provision of a brief, targeted psychosocial intervention to prevent suicide delivered in the ED is critical.

Thus, a multi-faceted approach combining the Safety Planning Intervention [19] and structured follow-up (SPI–SFU) was selected for implementation as a suicide prevention intervention for all patients presenting for clinical care in five different VAMC EDs in a project named Suicide Assessment and Follow-up Engagement: Veteran Emergency Treatment [SAFE VET]. The associated clinical demonstration project is described elsewhere [22]. Interpretation of outcomes from the clinical demonstration project was limited by a lack of a control condition. Patient reported outcomes were also not extensively tracked after ED discharge. However, the introduction of the SAFE VET intervention in some, but not all, VAMC EDs provided an opportunity for a quasi-experimental cohort comparison design. Since patient-level randomization was not feasible within the intervention sites where all eligible patients were receiving the SPI, we took advantage of the staggered roll-out of ED involvement to compare four of the intervention sites with four other VAMC EDs with similar patient flow characteristics and where the SAFE VET intervention was not provided. An adapted version of this intervention is also being tested in a concurrent randomized controlled trial that is ongoing in a military cohort who is being treated in an inpatient psychiatric setting [23].

The SPI is a brief intervention in which the patient and provider collaboratively develop a written, individualized list of coping skills to use, and professional and social supports to contact in suicidal crisis. SPI has been successfully implemented in a variety of settings including acute care, inpatient units, and suicide hotline service centers. The SFU portion of the intervention is designed specifically for SAFE VET and provides post-ED-discharge telephone contact between the patient and a clinician working for the project, usually the one who completed the safety plan with the patient.

1.1. Study aims and hypotheses

The primary aim of this study is to determine the effectiveness of SPI–SFU compared to usual ED clinical care, augmented by additional assessment (E-CARE), for decreasing suicide behaviors, suicide ideation and increasing treatment engagement and suicide-related coping strategies in Veterans seen in the ED for a suicide-related concern (i.e., significant suicide ideation or behavior) who do not require an inpatient hospitalization. We hypothesize that Veterans receiving SPI–SFU versus E-CARE will: 1) be less likely to attempt suicide within 6 months of the index ED visit; 2) have less severe suicidal ideation at 6 months post-index ED visit; 3) have greater suicide-related coping abilities at 6-months post-index ED visit, and 4) be more likely to attend 1 or more outpatient mental health or substance abuse treatment appointments within 6 months following the index ED visit.

2. Methods

2.1. Design

The study uses a quasi-experimental design to assess the effectiveness of SPI–SFU to E-CARE by comparing outcomes from 4 VAMC EDs where SPI–SFU is routinely carried out to outcomes from 4 similar EDs where the intervention is never employed. Eligible patients who present for ED care during day and evening shifts are invited to participate. Research assessments are administered at baseline and at 1, 3, and 6 months after the index ED visit (see Fig. 1). The trial is registered with ClinicalTrials.gov (identifier: NCT01334541).

2.2. Setting

Four VAMC EDs where SPI–SFU is already implemented as part of standard care for suicidal patients serve as the intervention sites: Portland, Denver, Manhattan, and Philadelphia VAMCs. Four matched control sites where SPI–SFU components are not provided are also participating. Matching criteria include urban/suburban versus rural setting, similar number of psychiatric ED evaluations provided per year, and presence of a psychiatric inpatient unit within the same VAMC. The control sites are Long Beach, Bronx, Milwaukee, and San Diego VAMCs. The eight participating VAMC EDs each treat an average of approximately 10,000 patients per year, of which about 10% present for mental health or substance abuse treatment purposes.

2.3. Recruitment and informed consent

Eligible Veterans, who appear to meet study criteria (see Section 2.4.1) and are deemed to be appropriate for the study by the treating ED physician, are referred to research staff for enrollment. Patients are considered appropriate for inclusion if the treating clinician does not consider it clinically contra-indicated. Study staff then meet with patients in the ED to determine eligibility, explain the study purpose, risks and benefits, and procedures, answer any questions about the study, and sign the VA Institutional Review Board (IRB)-approved study consent form and the Health Insurance Portability and Accountability Act (HIPAA) authorization form. All research team members hold a Bachelor's degree or higher in Psychology or a related field. The information for consented patients is tracked based on the guidance provided by the Consolidated Standards of Reporting Trials (CONSORT) statement [www.consort-statement.org].

2.4. Participants

Based on a power analysis (see Section 2.11.4) a minimum of 300 Veterans per treatment condition are expected to be recruited for this study. Study inclusion and exclusion criteria are provided below.

2.4.1. Inclusion and exclusion criteria

Inclusion criteria are as follows: 1) Veteran receives the Safety Planning Intervention at VA SAFE VET EDs or receives treatment-as-usual at VA control site EDs; 2) aged 18 years or older; 3) identified as being at risk for suicide based upon presenting complaints and/or the assessment of an ED clinician; 4) able to provide 2 collateral contacts with telephone numbers for tracking purposes; 5) in a stable living situation (i.e., able to provide a residential, domiciliary or shelter address at study entry); and, 6) able to provide a home, cellular, or other telephone number where the participant can be reached.

Exclusion criteria are as follows: 1) unable to read and understand English; 2) unable or unwilling to give informed consent as determined either by ED clinical staff or study staff; and/or 3) admitted to the VAMC inpatient psychiatric unit from the ED. All patients who meet study entry criteria are offered participation in the study.