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The PRImary care Screening Methods (PRISM) study: Rationale and design considerations

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ABSTRACT

Background: Primary care is the most frequently visited clinic type immediately prior to suicidal behavior, with nearly half of suicide decedents visiting a primary care provider within a month of their death. Data supporting the efficacy of suicide risk screening in this setting is lacking, however. Improved suicide risk screening in primary care could lead to earlier intervention and treatment.

Purpose: The PRImary care Screening Methods (PRISM) study is designed to develop and evaluate the efficacy of an alert algorithm that can be used by military primary care providers to accurately identify high-risk patients, to improve the identification of high-risk patients who deny suicidal thoughts, and to quantify patient subgroups who are more likely to be missed by existing screening methods (i.e., false negatives).

Methods: The rationale of the PRISM study is discussed, along with ethical and design considerations related to the conduct of suicide prevention research. The PRISM study enrolled 2690 patients from six primary care clinics across the U.S. Patients were enrolled during routine visits to a primary care clinic, and completed a battery of self-report scales in clinic waiting rooms. Follow-up phone interviews are conducted 1, 6, and 12 months after enrollment. The primary outcome is suicide attempt.

Conclusions: PRISM is the first study to prospectively examine multiple suicide risk screening methods in "real-world" military primary care clinics. Ethical and design issues were considered to ensure that human participants, especially suicidal patients, were adequately protected while minimizing the potential confounding effect of risk management protocols.

1. Background

From 2000 to 2017, the U.S. suicide rate increased by 33% [1]; during this period, suicide rates increased more quickly among individuals who have served in the U.S. military [2]. Primary care has been identified as a critical component of comprehensive suicide prevention efforts [3] because approximately half of suicide decedents visit primary care but only 20% visit a mental health professional in the month prior to death [4]. Military data further indicate that primary care is clinic type visited most frequently immediately prior to suicide deaths and attempts [5].

In primary care, suicide prevention screening commonly uses an indicated approach, meaning that patients are screened for suicide risk only if they first screen positive for depression [6]. This approach assumes that suicide risk is a symptom or outcome of depression. However, suicidal thoughts and behaviors are actually transdiagnostic phenomena [7,8], and epidemiological data indicate that approximately half of suicide decedents do not have a known psychiatric condition [1]. For these reasons, indicated screening approaches based on positive screens for psychiatric disorders is inherently limited. Universal suicide risk screening could potentially address these issues, but current suicide risk screening methods do not demonstrate

Abbreviations: CRP, crisis response plan; DoD, Department of Defense; PHQ, Patient Health Questionnaire; PRISM, PRImary care Screening Methods; SCS, Suicide Cognitions Scale; SDVCS, Self-Directed Violence Classification System; SIS, Suicide Intent Scale; SITBI, Self-Injurious Thoughts and Behaviors Interview

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sufficient accuracy or precision in prospectively identifying individuals at risk of suicidal behavior to be of practical utility [9]. For example, in a large study of patients enrolled in an integrated health system, higher scores on a suicide risk screening item were associated with significantly increased risk for suicide attempt and death during the following year, but over 96% of patients who screened positive did not attempt or die by suicide (i.e., false positives), and approximately 20% of those who attempted or died by suicide in the following year had screened negative (i.e., false negatives) [10]. False negatives can be reduced by increasing a screening tool's sensitivity, but this comes at the cost of increased false positives, which can strain clinic resources. Newer, more effective methods for suicide prevention screening that balance accuracy with efficiency are therefore needed for primary care settings.

The PRImary care Screening Methods (PRISM) study was designed to address this knowledge gap. The PRISM study has three primary objectives: (1) to test the efficacy and prospective validity of the Suicide Cognitions Scale (SCS) as an indicator of increased risk for suicide attempts among primary care patients; (2) to improve the accuracy of universal suicide prevention screening methods for identifying patients with increased risk of future suicidal behaviors through the reduction of false negatives; and (3) to develop an alert algorithm that can be used by primary care providers to accurately identify high-risk patients. To achieve these objectives, the PRISM study seeks to examine the prospective validity of multiple suicide risk screening tools. In addition to existing screening tools, PRISM will also examine the prospective validity of the SCS, a new scale that has accumulated preliminary empirical support as an indicator of current and future suicide risk [11–15]. The purpose of this paper is to summarize PRISM methodology.

2. Study design and procedures

Patients were recruited from waiting rooms in six primary care clinics located at five military installations across the U.S., either before or after routine medical visits, between July 2015 and August 2018. Clinics were selected to represent all branches of the U.S. military and to represent a range of clinic types and sizes, from relatively small community clinics to very large medical centers (Table 1). One researcher was assigned to each clinic and was positioned in the waiting room at a table visible to all patients. The researcher approached patients who were seated in the waiting room to inform them about the study. Patients interested in learning more about the study were provided with information about PRISM, including the study's purpose and procedures, possible risks and benefits, and confidentiality protections. Patients agreeing to participate in the study were asked to sign an informed consent document, after which they were asked to complete an online, web-based survey containing a battery of self-report measures using a study tablet or laptop computer with wireless internet capabilities. After completing the survey, patients returned the tablet or laptop to the researcher and were allowed to select a small token of appreciation for their participation (e.g., T-shirt, military challenge coin, $5 gift card to a local coffee shop).

Participants are contacted 1, 6, and 12 months post-baseline via phone, email, or text message (depending on their indicated preference) to schedule a phone interview with a research evaluator. All evaluators are licensed clinical social workers or advanced graduate students in psychology and social work who have been thoroughly trained in study procedures and administration of study measures. During each interview, evaluators administer the Self-Injurious Thoughts and Behaviors Interview (SITBI) [16], an empirically supported, clinician-administered assessment focused on the incidence and timing of suicidal thoughts, suicidal behaviors, and other types of self-injurious behaviors at any point during their life (for the 1-month assessment) or since baseline or the last assessment interview (for the 6- and 12-month assessments). At the conclusion of the study (anticipated to be September 2019), a medical record review will be conducted to extract data that will be linked with survey data from the baseline and follow-up assessments. Regulatory oversight for the study is provided by the Institutional Review Board at Naval Health Research Center.

2.1. Participants

Inclusion and exclusion criteria were selected to maximize the representativeness of the sample and the generalizability of results to other military primary care clinics. Patients were eligible to participate in the PRISM study if they were a TRICARE beneficiary (i.e., eligible to receive medical services from the Department of Defense [DoD]), 18 years of age or older, able to understand and read the English language, and able to complete the informed consent process. The only exclusion criterion was the presence of an acute psychiatric and/or medical condition that diminished capacity for providing informed consent (e.g., psychosis, mania, cognitive impairment, acute intoxication). Although this study was funded by DoD, we decided to recruit all DoD beneficiaries (i.e., members of military families and retirees) rather than restrict enrollment to current military personnel for two primary reasons. First, using broader eligibility criteria was expected to result in a larger sample size, thereby yielding greater statistical power to examine associations between possible risk factors and a low base rate outcome (i.e., suicide attempts). Second, we enrolled a more heterogeneous sample to afford us the ability to examine results across multiple subgroups, thereby increasing the generalizability of findings and enabling us to consider whether suicide risk screening methods are equally valid and reliable across patient subgroups.

2.2. Baseline assessments

Baseline assessment were selected to assess a range of empirically supported domains and factors associated with suicide risk while also maintaining brevity, a critical consideration for studies implemented in primary care settings. A list of the 17 baseline assessment measures are presented in Table 2. The primary independent variable of interest in the present study, suicide risk, was assessed by two measures: the 9-item Patient Health Questionnaire depression subscale (PHQ-9) [17] and the 18-item SCS [11]. The PHQ-9 was the first measure completed by all study participants. We decided to administer this scale first to mirror existing suicide risk screening practices (i.e., this measure was already in use as a suicide screener within participating clinics) and to minimize missing data on this particular scale, thereby facilitating our primary analyses. The SITBI was presented after the central scales to

Table 1
PRISM research site characteristics.

Site	Location	Population	Approximate enrollment
Fort Carson	Colorado Springs, CO	Army	70,000
Hill Air Force Base	Ogden, UT	Air Force	16,500
McConnell Air Force Base	Wichita, KS	Air Force	11,000
Naval Medical Center Portsmouth[a]	Portsmouth, VA	Navy	180,000
Naval Medical Center Camp Lejeune	Jacksonville, NC	Marines	150,000

[a] Naval Medical Center Portsmouth included two separate primary care clinics.

Table 2
Assessment measures administered at baseline.

Measure	Construct(s) measured
Presented first	
1. Demographics	Age, gender, race/ethnicity, sexual orientation, military status, branch of service
2. Patient Health Questionnaire-9	Depression (includes single-item suicide risk screener)
Presented in random order	
3. Brief College Student Hassles Scale	Nontraumatic life stressors
4. Brief Reasons for Living Inventory	Reasons for living
5. CAGE screener	Alcohol abuse
6. Differential Emotions Scale	Guilt, shame, and self-hatred
7. Entrapment Scale	Perceptions of feeling trapped
8. Household safety questionnaire	Firearm ownership and storage practices
9. Insomnia Severity Index	Subjective sleep quality
10. Interpersonal Support Evaluation List-Short Form	Social support
11. Life Events Checklist	Lifetime trauma exposure
12. Nightmare disorder checklist	Nightmare frequency and intensity
13. Positive and Negative Affect Scale	Current mood state (positive and negative)
14. Primary Care PTSD Screen	Posttraumatic stress disorder
15. Suicide Cognitions Scale	Suicide risk
Presented last	
16. Self-Injurious Thoughts and Behaviors Interview (self-report version)	Suicide ideation and planning, nonsuicidal self-injury, and suicide attempts (lifetime and recent)
17. Moral Injury Events Scale	Exposure to morally injurious events
18. Acquired Capability for Suicide Scale	Fearlessness about death

Table 3
Suicide Cognitions Scale (SCS) Items.[a]

1.	The world would be better off without me.
2.	Suicide is the only way to solve my problems.
3.	I can't stand this pain anymore.
4.	I've never been successful at anything
5.	I can't tolerate being this upset any longer.
6.	I can never be forgiven for the mistakes I have made.
7.	No one can help solve my problems.
8.	It is unbearable when I get this upset.
9.	I am completely unworthy of love.
10.	Nothing can help solve my problems.
11.	It is impossible to describe how badly I feel.
12.	I can't cope with my problems any longer.
13.	I can't imagine anyone being able to withstand this kind of pain.
14.	There is nothing redeeming about me.
15.	Suicide is the only way to end this pain.
16.	I don't deserve to live another moment.
17.	I would rather die now than feel this unbearable pain.
18.	No one is as loathsome as me.

[a] In the PRISM study, items 2 and 15 were omitted because of their explicit use of the word "suicide," to reduce the possibility of motivated responding among participants seeking to minimize or conceal suicidal intent.

minimize priming of suicide-related constructs. All other scales (including the SCS) were presented to participants in a randomized order to control for order effects. Two additional scales, the Moral Injury Events Scale and the Acquired Capability for Suicide Scale, were added to the very end of the survey because they were not central to the study's aims but were of scientific interest to the investigative team. The entire baseline survey was completed in a median of 22.1 min.

2.2.1. Patient health questionnaire depression subscale (PHQ-9)

The PHQ-9 is an empirically supported and widely used self-report scale that assesses the frequency with which patients have experienced each of the nine symptoms of major depressive disorder, as defined in the fourth and fifth editions of the Diagnostic and Statistical Manual [18], within the past 2 weeks. Each item is rated on a 4-point scale ranging from 0 (*not at all*) to 3 (*nearly every day*). As discussed previously, in military primary care settings, a two-stage screening approach is commonly used. Patients first receive the first two items of the PHQ-9, which assess anhedonia and depressed mood (PHQ-2). Only patients who screen positive for likely depression (by attaining a summed score of 3 or higher across these two items) are asked to complete the remaining seven PHQ-9 items. The ninth item, which assesses the frequency of "thoughts that you would be better off dead, or of hurting yourself" is often used as a suicide risk screener. A non-zero score is typically used to denote elevated suicide risk.

2.2.2. Suicide cognitions scale (SCS)

The SCS is an 18-item self-report scale designed to assess thought processes, assumptions, and beliefs commonly reported and/or verbalized by suicidal individuals (see Table 3 for SCS item content). Items are rated using a Likert-type scale (1 = *strongly disagree*, 5 = *strongly agree*), and ratings are summed to compute a total score, with higher scores representing increased suicide risk. The SCS has excellent internal consistency, correlates strongly with measures of suicide risk, differentiates patients who have attempted suicide from those who have thought about but not attempted suicide, and prospectively predicts[1] suicide attempts [11–15]. The original SCS includes two items that explicitly use the word "suicide." Because these items could elicit motivated responding among patients seeking to conceal or minimize their suicide risk, they were omitted from the present study. Previous research indicates the removal of these two items does not affect the scale's psychometric properties or validity [12].

2.3. Outcomes assessment

Because suicide death is expected to occur very infrequently, the primary study outcome was suicide attempt, which was defined as a nonfatal, self-directed, potentially injurious behavior with any intent to die as a result of the behavior. If any occur, suicide deaths will be counted as suicide attempts with fatal outcome. Suicide attempt was distinguished from other suicidal behaviors including interrupted and

[1] In this paper, we use the term "predict" (and various derivatives of the term) solely in their statistical sense to describe prospective associations between constructs assessed at baseline and subsequent risk of suicide attempts during the follow-up period.

Table 4
Self-injurious thoughts and behaviors interview questions used to differentiate suicide attempts (primary outcome) from other self-injurious behaviors.

Variable	Interview question
Suicide attempt	Since your last assessment, have you made an actual attempt to kill yourself in which had at least some intent to die?
Aborted suicide attempt	Since your last assessment, have you been close to killing yourself and at the last minute decide not to kill yourself?
Interrupted suicide attempt	Since your last assessment, have you been very close to killing yourself and at the last minute someone or something else stopped you?
Nonsuicidal self-injury	Since your last assessment, have you actually purposely hurt yourself without wanting to die?

aborted suicide attempts, which are defined as initiating a suicide attempt but being stopped by an external force or by oneself, respectively, before the potential for injury has occurred. We distinguished suicide attempt from other suicidal behaviors because suicide attempts entail actions that are potentially injurious whereas interrupted and aborted attempts fall short of potential injury. We also distinguished suicide attempt from nonsuicidal self-injury, which entails actions that are potentially injurious but do not include any intent to die as a result of the behavior. Suicide attempt was selected as the primary outcome and distinguished from these other behaviors because it represents the closest approximation of death by suicide. The SITBI [16], an empirically supported clinician-administered assessment that is included as a recommended measure within the National Institute of Mental Health's PhenX Toolkit (available at www.phenxtoolkit.org/collections/mhr), was used to distinguish between each of these types of behaviors. The specific SITBI items used to distinguish suicide attempts from other suicidal behaviors and nonsuicidal self-injury are provided in Table 4. Participants who endorsed any of these items were then asked a series of follow-up questions to obtain further information about the behavior (s), including frequency, method, motivations, and extent of physical injury.

Secondary outcomes assessed included severity of suicidal intent and medical lethality associated with each suicide attempt. Suicidal intent was assessed using the Suicide Intent Scale (SIS) [19], an interviewer-administered assessment that measures the participant's wish to die at the time of a given suicide attempt. The SIS measures subjective intent (e.g., desire and motivation to die) and objective intent (e.g., steps taken to prevent rescue, preparatory behaviors and/or rehearsal) present at the time of the suicide attempt. The medical severity of each suicide attempt was assessed using the Beck Lethality Scales [20], an interviewer-rated series of scales that assess the potential for death associated with each attempt. Separate scales are used to rate the lethality of suicide attempts using different methods. Suicidal intent and medical lethality were selected as secondary outcomes to examine the possibility that suicide risk screening methods are more sensitive for identifying more (or less) dangerous suicide attempts.

2.4. Training and supervision of research evaluators

Research evaluators conducting follow-up assessments participated in training workshops focused on the Self-Directed Violence Classification System (SDVCS) and crisis response planning. SDVCS training was conducted to ensure consistency of coding and classification of suicide attempts, interrupted and aborted attempts, and nonsuicidal self-injury across multiple evaluators, and to ensure consistency with the recommendations of the Centers for Disease Control and Prevention [21]. Training materials included curriculum, case vignettes, and a decision-making tool developed by the Rocky Mountain MIRECC for Veteran Suicide Prevention (available online at https://www.mirecc.va.gov/visn19/). Research evaluators also completed a full-day training workshop focused on crisis response planning, which included video demonstrations and multiple role plays with feedback. To monitor fidelity of interview administration, classification of behaviors, and consistency in coding, research evaluators participate in group consultation and supervision meetings twice per month, during which time cases are reviewed and discrepancies in coding are resolved.

2.5. Medical record data extraction and de-identification

After completion of data collection, electronic medical record data, including but not limited to appointment dates, clinic type, problem and diagnosis codes, and procedures performed, were extracted and linked with self-report and interview data. After the data were merged and quality assurance checks were completed, the dataset was de-identified by assigning each participant a unique identification code that contained no information about his or her identity.

3. Risk management procedures

Because PRISM included patients at elevated risk for suicidal thoughts and behaviors, suicide risk management protocols were developed for both baseline and follow-up assessments. At baseline, the primary concern was responding appropriately to participants who endorsed elevated thoughts of death or self-harm on the PHQ-9 during the baseline assessment. The risk management protocol for this stage of the study took into consideration the fact that (1) participants were being recruited and enrolled during routine visits to a primary care clinic and (2) suicide risk management protocols already existed at each clinic. Because the purpose of the study was to test various suicide risk screening methods in “real-world” clinics under conditions of routine operations, we determined that the baseline study suicide risk management protocol should mirror each clinic's existing protocol. Although each clinic had somewhat different procedures, all of the clinic protocols included a review of the patient's PHQ-9 responses by a primary care provider or nurse and, if thoughts of death or self-harm were endorsed, a referral to an integrated behavioral health provider (either a clinical psychologist or clinical social worker) for further risk assessment and treatment planning. To implement a similar protocol for study participants, we programmed an automated alert system within the electronic survey system that flagged participants reporting thoughts of death and self-harm on the PHQ-9. This alert process was designed to be discrete enough to protect participant privacy while easily recognizable by the researcher to minimize missed cases. To balance these two requirements, we designed the final page of the survey to provide a “thank you” message to participants with instructions to return the tablet or laptop computer to the research associate. If a participant endorsed thoughts of death or self-harm on the PHQ-9, this message was displayed with red instead of black font, and the message directed participants to speak with the research associate for further guidance. This enabled research associates to ask follow-up questions about the nature of the participant's thoughts (e.g., frequency, intensity, planning) and, if indicated, to facilitate a referral to the integrated behavioral health provider.

For follow-up assessment interviews, our primary concern is being able to effectively respond to participants reporting elevated suicide risk during the interview. The risk management protocol for this stage of the study was developed with consideration of the fact that (1) participants were being interviewed over the phone instead of face to face, and (2) participants were typically located in another state, geographically separated from the research evaluators. Because these factors mirror the context within which many crisis hotlines (including the Military Crisis Line operated by the Department of Veterans Affairs) operate, we integrated procedures and strategies used by many crisis

hotlines into our risk management protocol. At the outset of each call, research evaluators asked participants to report their current location and asked whether anyone was around who could hear their responses. These questions served the dual purpose of enabling research evaluators to gauge the relative privacy of the interview and to obtain information necessary to facilitate an emergency rescue in the event of imminent suicide risk. Research evaluators next asked participants how they were doing and engaged them in a brief discussion to build rapport and to assess the participant's mental status before starting the SITBI. Participants who endorsed suicide ideation, suicide planning, non-suicidal self-injury, or suicidal behaviors were asked a series of standardized follow-up questions that assessed the frequency, timing, duration, and severity of endorsed thoughts and behaviors. Each of these variables are recommended components of suicide risk assessments conducted within clinical practice [22], and can be used for suicide risk stratification, to include possible evaluation for hospitalization and/or the need to activate emergency response services within the participant's locality.

If the participant's SITBI responses and/or demeanor are judged by the research evaluator to reflect elevated suicide risk, the evaluator works collaboratively with the participant to develop a crisis response plan (CRP). The CRP is a tool designed to promote self-monitoring and self-regulation during periods of heightened emotional distress, when suicidal behaviors are more likely to occur [23]. The CRP can typically be developed in less than 30 min, and comprises several components that involve identifying personal indicators or warning signs of an emerging crisis, self-management strategies that reduce or distract from emotional distress, reasons for living that foster positive emotions and hope, sources of social support, and sources of professional support and/or emergency services. The CRP and other related interventions (e.g., the safety planning intervention) are empirically supported for the reduction of suicidal behaviors among high-risk individuals [24–26]. Finally, research evaluators provide information for local mental health resources both on and off base, and use motivational enhancement strategies to encourage follow-up with these resources. The resources provided were obtained from collaborators at each research site, thereby ensuring their relevance and alignment with local preferences and procedures.

4. Analysis plan

Our first hypothesis is that the SCS will improve the accuracy of detection of primary care patients who will make a suicide attempt during the 12-month follow-up period, beyond the predictive efficacy of the PHQ-2 and PHQ-9. Our second hypothesis is that, among patients who screen negative for depression and/or suicide risk using the PHQ-2 and PHQ-9, the SCS will significantly differentiate patients who attempt suicide during the 12-month follow-up period. To test these hypotheses, we will use a combination of multilevel (i.e., participants nested within clinics) logistic regression, generalized linear modeling, and Cox regression modeling with maximum likelihood estimation. Finally, we will conduct exploratory analyses to identify the optimal combination of items from all baseline assessment measures for identifying those patients who attempt suicide during follow-up.

4.1. Assessing for potential confounding of the risk management protocol

As described above, our risk management protocol for follow-up assessment interviews included the collaborative development of a CRP, a method that has been shown to reduce the risk of suicidal behaviors [24–26]. The CRP could therefore influence the likelihood that a participant engages in suicidal behavior during the follow-up assessment period. Although the CRP is known to influence the subsequent likelihood of suicidal behaviors, the CRP is not a causal factor inherent to the emergence of suicidal behavior itself. Development of a CRP might also be correlated with baseline scores on the SCS, PHQ-2, and PHQ-9, the primary predictor variables because participants scoring higher on these scales may report higher levels of suicide risk during a follow-up assessment. In light of these possible relationships, we will track which participants develop a CRP during the 1- and 6-month follow-up assessments. We are primarily concerned with the impact of the 1- and 6-month assessments because the development of a CRP at either of these points, partway through the follow-up period, could reduce the likelihood of suicidal behavior during the latter portion of the follow-up period. Developing a CRP at the 12-month assessment, by comparison, would not impact outcomes since the participant would be finished with all research activities at this point.

To assess the potential impact of the risk management protocol on our analyses, we will conduct a series of logistic regression models before conducting our main analyses. In these logistic regression models, the outcome will be a dummy code variable representing the receipt of a CRP at the 1- or 6-month assessment (either received or not received). This will enable us to determine whether participants who received a CRP during the first half of the follow-up period systematically differ from participants who did not in terms of our primary predictor variables (i.e., SCS, PHQ-2, and PHQ-9). If systematic differences are identified, we will stratify the sample according to receipt of CRP and conduct our primary analyses on each group separately in addition to analyzing data from the full sample.

4.2. Primary analyses

To test the first hypothesis, we plan to use logistic regression to determine whether scores on the SCS differentiate participants who subsequently attempt suicide from those who do not. The SCS total score will be entered as a continuous predictor variable, with follow-up suicide attempt serving as the outcome. A series of models will be constructed with the PHQ-2 total score, the PHQ-9 total score, and item 9 of PHQ-9 entered as separate covariates, along other relevant demographic variables (e.g., gender, age, race, prior history of suicide attempts). To determine whether the relationships among follow-up suicide attempts and the PHQ-2, PHQ-9, and the SCS are similar across demographic groups (e.g., gender, race, military status), additional models will include interaction effects between these scale score and demographic characteristics. We will supplement these analyses with Cox regression analyses to determine whether PHQ-2, PHQ-9, item 9 of PHQ-9, and SCS scores predict time to first suicide attempt. Time will be calculated as the number of days from baseline to the first suicide attempt, with right censoring used for those who do not attempt suicide. To examine the scale's practical performance as an indicator of short-term versus long-term risk, analyses will be repeated with follow-up constrained to different timeframes of interest (e.g., 1 month, 3 months, 6 months). In addition to conducting standard tests of significance, we will assess the practical importance of each effect through interpretation of obtained effect sizes (e.g., odds ratios, hazard ratios, sensitivity, specificity). Finally, analyses will be repeated to determine the sensitivity of the observed effects when adjusting for a range of covariates (e.g., demographic variables, baseline clinical variables, medical diagnosis, reason for clinic visit).

For our secondary outcomes (i.e., suicidal intent, medical lethality of attempts), our approach will mirror the primary analyses, except that analyses will be conducted using multilevel generalized linear modeling for continuous and ordinal outcomes. Generalized linear modeling can be flexibly used for outcomes characterized by a range of distributions (e.g., normal, Poisson, zero inflated). To determine which model specification is most appropriate, we will compare Bayesian information criterion values from each model, with smaller values indicating better fit.

4.3. Statistical power

Power for the planned analyses was estimated using the large-sample approximation of the Wald test method [27,28]. The estimated

probability of a suicide attempt during the 12-month follow-up (0.01) was based on the annual prevalence rate of suicide attempts (0.6%) among U.S. adults [29]. Our estimated attrition rate,defined as failure to complete either follow-up interview, was 20%, based on studies utilizing similar designs previously conducted by our team; other sources of missing data were expected to be negligible. We assumed conservative effect sizes (odds ratio = 2.0) with a one-tailed $\alpha = 0.05$. Given these assumptions, a sample size of at least 1265 participants and 1786 participants were required to test hypotheses 1 and 2, respectively.

4.4. Additional planned analyses

In addition to our primary analyses, we will also conduct a series of analyses designed to identify a small subset of items that yield the greatest ability to identify those individuals who will attempt suicide within the next 1, 3, 6, and 12 months. First, we will use graded response modeling to identify the SCS items that provide the most information about the latent construct (suicide risk) and that best discriminate between individuals with varying levels of suicide risk. These items will then be tested as predictors of suicide risk, both in isolation and in combination with other baseline assessments. Second, we will randomly assign participants to one of two subgroups of approximately equal size. In the first subgroup, we will use machine learning methods to identify optimal combinations and scoring of items from the SCS, the PHQ-9, and all other baseline measures. The obtained algorithm will then be cross-validated in the second subgroup.

5. Discussion and conclusion

PRISM represents the first large-scale empirical effort to test the prospective validity of multiple suicide risk screening tools within military primary care medical settings, to improve the accuracy of universal suicide prevention screening by reducing false negatives, and to develop an algorithm that can be used by primary care providers to identify high-risk patients. Study results will help to evaluate the feasibility, effectiveness, and efficiency of existing suicide risk screening tools, as well as identify optimal combinations of suicide risk screening methods that are practical for use within a primary care setting. The development and testing of new suicide risk screening tools that can be easily used in primary care settings could lead to much-needed advances in suicide prevention.

A potential limitation of PRISM is the use of self-report screening methods, an approach that is vulnerable to motivated or biased responding due to concerns about the potential negative impact of disclosing emotional distress and elevated suicide risk. This issue could be heightened by the non-anonymous response format. Another possible limitation involves the recruitment and collection of data in clinic waiting rooms instead of private rooms. In combination, these design features may reduce the accuracy of self-disclosure, especially as they are related to suicide risk and other sensitive topics. Although these design features could limit conclusions, they mirror routine practice in primary care (i.e., administering self-report tools in the clinic waiting room for review by a healthcare professional). Ecological validity and potential generalizability of results are therefore expected to be high. A final limitation involves the low base rate of suicidal behavior, which restricts the predictive accuracy of all suicide risk screening methods. Conclusions based on PRISM's results will therefore need to be considered accordingly within the context of this issue. In light of the continued expansion of suicide risk screening despite this limitation, the present study should provide an empirical basis for determining which suicide risk screening methods most effectively balance pragmatism with clinical utility.

Disclaimer

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