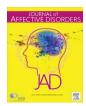


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Research paper

Effect of crisis response planning vs. contracts for safety on suicide risk in U.S. Army Soldiers: A randomized clinical trial[⋆]



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ABSTRACT

Objective: To evaluate the effectiveness of crisis response planning for the prevention of suicide attempts. Method: Randomized clinical trial of active duty Army Soldiers (N=97) at Fort Carson, Colorado, presenting for an emergency behavioral health appointment. Participants were randomly assigned to receive a contract for safety, a standard crisis response plan, or an enhanced crisis response plan. Incidence of suicide attempts during follow-up was assessed with the Suicide Attempt Self-Injury Interview. Inclusion criteria were the presence of suicidal ideation during the past week and/or a lifetime history of suicide attempt. Exclusion criteria were the presence of a medical condition that precluded informed consent (e.g., active psychosis, mania). Survival curve analyses were used to determine efficacy on time to first suicide attempt. Longitudinal mixed effects models were used to determine efficacy on severity of suicide ideation and follow-up mental health care utilization. Results: From baseline to the 6-month follow-up, 3 participants receiving a crisis response plan (estimated proportion: 5%) and 5 participants receiving a contract for safety (estimated proportion: 19%) attempted suicide (log-rank $\chi^2(1)$ =4.85, p=0.028; hazard ratio=0.24, 95% CI=0.06-0.96), suggesting a 76% reduction in suicide attempts. Crisis response planning was associated with significantly faster decline in suicide ideation (F(3,195)=18.64, p < 0.001) and fewer inpatient hospitalization days (F(1,82)=7.41, p < 0.001). There were no differences between the enhanced and standard crisis response plan conditions.

Conclusion: Crisis response planning was more effective than a contract for safety in preventing suicide attempts, resolving suicide ideation, and reducing inpatient hospitalization among high-risk active duty Soldiers.

1. Introduction

Due to the rapid rise in U.S. Army suicides (Schoenbaum et al., 2014), interest in developing effective strategies to prevent suicidal behavior in the military has increased. Recent findings indicate that brief cognitive behavioral therapy (CBT), a 12-session outpatient psychotherapy, reduced suicide attempts by 60% in a sample of active duty Soldiers Rudd et al., 2015). Unfortunately, during the month preceding their deaths, Soldiers who die by suicide are much less likely to visit a mental health clinic as they are to visit nonpsychiatric clinical settings (e.g., primary care, family medicine, emergency medicine) (Trofimovich et al., 2012), suggesting the majority of at-risk Soldiers

are unlikely to receive such treatments. Suicide rates in the U.S. general population have also risen during the past decade, prompting the Joint Commission to release an updated Sentinel Event Alert focused on the assessment and treatment of suicidal patients across all health care settings (The Joint Commission, 2016). Effective, highly transportable risk management strategies that can be easily implemented are therefore needed.

One widely-used strategy is the contract for safety, also known as the no-suicide contract, which entails eliciting a commitment from the suicidal patient to avoid engaging in suicidal behavior (Simon, 1999; Weiss, 2001; Range et al., 2002; Assey, 1985; Callahan, 1996; Kelly and Knudson, 2000; Kroll, 2000). Despite widespread use across

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medical disciplines, accumulating consensus is that contracting for safety may be ineffective (Kelly and Knudson, 2000; Reid, 1998; Shaffer and Pfeffer, 2001; Stanford et al., 1994) or potentially even harmful (Shaffer and Pfeffer, 2001; Rudd et al., 2006). The Joint Commission has therefore recommended (The Joint Commission, 2016) alternative strategies such as crisis response planning (Rudd et al., 2006; Bryan, 2010) and the related safety planning intervention (Stanley and Brown, 2012). Written on a small card, crisis response planning outlines steps for identifying one's personal warning signs, using coping strategies, activating social support, and accessing professional services (Rudd et al., 2006; Bryan, 2010; Stanley and Brown, 2012). The crisis response plan therefore outlines what to do during a crisis (i.e., use a range of coping strategies), an approach that sharply contrasts with the contract for safety, which outlines what not to do during a crisis (i.e., engage in suicidal behavior). Like the contract for safety, however, use of crisis response plans is largely based on clinicians' beliefs about effectiveness rather than actual empirical data (Kelly and Knudson, 2000; Hogan, 2016). Its adoption across psychiatric and nonspsychiatric health care settings (e.g., emergency departments, primary care clinics, inpatient psychiatric units, outpatient psychotherapy) has therefore occurred in the absence of explicit empirical testing.

The primary aim of the current study was to compare the effectiveness of crisis response planning on suicidal thoughts and behaviors during a 6-month follow-up period among active duty Soldiers as compared to supportive counseling with a verbal contract for safety. To this end, our first hypothesis was that crisis response planning would be significantly better than the contract for safety in reducing suicide attempts and suicide ideation. Recent evidence suggests that one mechanism of action contributing to reductions in suicide attempts in brief CBT is the strengthening of the patient's desire to live (Bryan et al., 2016). As such, we additionally sought to determine if the crisis response plan's effects could be enhanced by adding a component designed to clarify the patient's reasons for living. Our second hypothesis was that the enhanced crisis response plan would be significantly better than the standard crisis response plan and the contract for safety.

2. Methods

2.1. Participants and procedures

Participants were 97 active duty U.S. Army personnel (78% male) aged 19–53 years (M=26.1, SD=6.4) with active suicide ideation and/or a lifetime history of suicide attempt who voluntarily presented to a military medical clinic for an emergency behavioral health evaluation at Fort Carson, Colorado, from January to December 2013 and January 2015 to February 2016. There was a one-year gap in enrollment from January to December 2014 due to a temporary administrative closure of the study by the Madigan Army Medical Center's Institutional Review Board following staffing changes among collaborating Army personnel. The impact of this one-year delay on study outcomes is discussed below in the Data Analysis section.

Participants were recruited from the emergency department (n=8, 8.2%), the outpatient behavioral health clinic (n=55, 56.7%), and embedded behavioral health clinics (n=34, 35.1%) located at Fort Carson, Colorado. To maximize generalizability, the only exclusion criterion was an inability to provide informed consent due to impaired mental status (e.g., acute intoxication, psychosis, mania). Baseline characteristics of the sample are reported in Table 1. Inclusion criteria were the presence of suicide ideation during the past week and/or a lifetime history of suicide attempt; active duty military status; age 18 years or older; ability to speak English; and ability to understand and complete informed consent procedures. Soldiers were excluded if they had a medical or psychiatric condition that would preclude informed consent (e.g., active psychosis or mania).

Table 1Baseline demographic and diagnostic characteristics.

		Treatment Condition				
Variable	All (n=97)	TAU (n=32)	CRP (n=32)	E-CRP (n=33)		
Age, M (SD), y	26.1 (6.4)	25.4 (5.3)	27.0 (6.9)	26.0 (6.8)		
Deployments, M (SD)	1.2 (1.2)	1.2(1.1)	1.2 (1.2)	1.2 (1.4)		
Military service, M (SD), y	5.4 (5.2)	5.3 (4.1)	5.9 (6.4)	4.9 (4.9)		
Male gender, n (%)	76 (78)	24 (75)	24 (73)	28 (88)		
Rank, n (%)						
E1-E4	73 (75)	22 (69)	24 (75)	27 (82)		
E5-E6	15 (16)	5 (16)	4 (13)	6 (18)		
E7-E9	4 (4)	2 (6)	2 (6)	0 (0)		
Officer	5 (5)	3 (9)	2 (6)	0 (0)		
Race, n (%)						
White	71 (74)	25 (78)	20 (65)	26 (79)		
Black	17 (18)	6 (19)	7 (23)	4 (12)		
Asian	4 (4)	1(3)	1(3)	2 (6)		
Pacific Island	3 (3)	1(3)	2 (7)	0 (0)		
Native Amer.	8 (8)	2 (6)	1(3)	5 (15)		
Other	2(2)	0 (0)	1(3)	1(3)		
Hispanic ethnicity, n (%)	7 (7)	2 (6)	2 (7)	3 (9)		
Psychiatric diagnosis, n (%)						
Any adjustment disorder	43 (44)	13 (41)	15 (47)	15 (46)		
Any depressive disorder	38 (39)	16 (50)	9 (28)	13 (39)		
Any bipolar disorder	15 (16)	6 (19)	5 (15)	4 (13)		
Any anxiety disorder	19 (20)	6 (19)	7 (22)	6 (18)		
Any stressor disorder	12 (12)	4 (13)	5 (16)	3 (9)		
Any personality disorder	8 (8)	4 (13)	3 (9)	1(3)		
Any psychotic disorder	2 (2)	0 (0)	1 (3)	1 (3)		
Suicide attempt history, n (%)						
0	43 (44)	11 (34)	15 (47)	17 (52)		
1	24 (25)	8 (25)	8 (25)	8 (24)		
2+	30 (31)	13 (41)	9 (28)	8 (24)		
Referral location, n (%)						
Emergency department	7 (7)	2 (6)	2 (6)	3 (9)		
Specialty behavioral health	56 (58)	16 (50)	20 (63)	20 (61)		
Embedded behavioral health team	34 (35)	14 (44)	10 (31)	10 (30)		

Soldiers who presented to the emergency department or a behavioral health clinic for a voluntary emergency behavioral health appointment were referred to a research therapist if they reported recent suicide ideation and/or a lifetime history of suicide attempt on clinic paperwork. Research therapists conducted a suicide risk assessment using the Beck Scale for Suicide Ideation (described below) to determine eligibility. Soldiers meeting eligibility criteria were then informed about study procedures. To preserve participant blinding, Soldiers were informed that they would be assigned to "one of three interventions that are commonly used by health care providers." The three interventions were referred to by number only (i.e., crisis response plan 1, 2, or 3). Soldiers were informed that all three interventions included some combination of supportive counseling, strategies to manage emotional distress, education about crisis services, and referrals to treatment services, and differed only with respect to how much of each element was included. After signing the informed consent document, research therapists administered a structured clinical interview focused on suicide attempt history. Upon completion, the participant completed self-report measures via laptop computer, after which the research therapist executed a computerized simple randomization procedure. Intervention group was designated by color (red. green, or blue) to prevent inadvertent breaking of blinding. The therapist selected the appropriate color-coded manual and administered the assigned intervention, which was audio recorded for fidelity

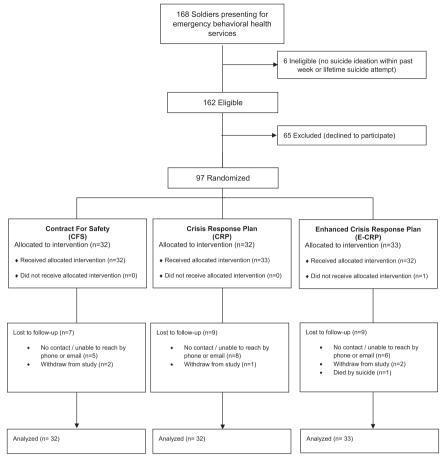


Fig. 1. Participant flow through a randomized clinical trial to prevent suicidal behavior in a sample of active duty U.S. Army Soldiers reporting recent suicide ideation or a history of suicide attempts.

monitoring. After the intervention was complete, participants completed several more self-report measures via laptop while the case was staffed with an on-call licensed Army mental health clinician in a separate room. Treatment assignment was not revealed to the on-call clinician, who made a disposition determination regarding psychiatric hospitalization.

2.2. Randomization

Participants were randomized to either the contract for safety (n=32), standard crisis response plan (n=32), or enhanced crisis response plan (n=33) group using a computerized randomization program created based on the RANUNI function available in the SAS software, constrained to produce equal numbers across groups. The flow of subjects through the study is shown in Fig. 1. Participants were allowed to continue all other forms of mental health and substance abuse treatment during the follow-up period across all three treatment groups. Treatment groups did not significantly differ with respect to any baseline variable.

2.3. Assessments

Research therapists were trained to conduct structured assessments by members of the investigative team who were clinical psychologists and had several years' experience administering and supervising the assessment interviews within the context of clinical trials (CJB and TAC). All interviews were recorded and reviewed by one of the trainers to ensure reliability and fidelity. Posttreatment assessments were conducted 1, 3, and 6 months after enrollment by a blinded independent evaluator who completed the assessments via phone interview

from a location separate from the treatment administration site. The evaluator's assessments were recorded and monitored for fidelity.

2.3.1. Outcome measures

The primary outcome was the occurrence of suicide attempts during the follow-up period. Suicide attempts were defined as behavior that is self-directed and deliberately results in injury or the potential for injury to oneself for which there is evidence, whether implicit or explicit, of suicidal intent (Crosby et al., 2011), and was assessed with the Suicide Attempt Self-Injury Interview (SASII) (Linehan et al., 2006a). The SASII is a structured clinical interview designed to assess the factors involved in nonfatal suicide attempts and nonsuicidal self-injury (e.g., method, lethality, impulsivity, subjective versus objective intent, reasons for the attempt, and consequences of the attempt). The SASII has high interrater reliability across the assessor-related items (median=0.96), and high consistency between retrospective report of suicide attempts as compared to weekly reports (ICC=0.91). Comparison of reports on the SASII relative to medical record verification has additionally supported the instrument's validity in assessing medical lethality and outcome.

The secondary outcomes were severity of suicide ideation and use of mental health services. Severity of suicide ideation was assessed with the Beck Scale for Suicide Ideation (BSSI) (Beck and Steer, 1991), a 19-item interviewer-administered scale that assesses the intensity of respondents' attitudes, behaviors, and plans to make a suicide attempt. Each item is scored on a 3-point scale, with higher scores indicating greater suicide risk. Items are summed to provide a metric of suicide risk severity. The BSSI has very good internal consistency (>0.89) and interrater reliability (0.83) (Beck et al., 1979), and is associated with eventual death by suicide (Brown et al., 2000). Use of mental health

Table 2Components of the three treatment conditions.

Component	Description	TAU	CRP	E-CRP
Suicide risk assessment	Therapist conducts a semi-structured interview of recent suicide ideation and lifetime history of suicide attempts	/	/	1
Supportive listening	Therapist and patient have unstructured conversation about recent stressors and current complaints; therapist expresses concern and support without discussing coping strategies or tips	1	1	✓
Warning signs	Therapist and patient collaboratively identify "clear signs that you're in a crisis or are really stressed out," whether behavioral, cognitive, affective, or physical	-	✓	✓
Self-management skills	Therapist and patient collaboratively identify "some things you can do on your own that will help to distract you or to feel less stressed"	-	1	✓
Reasons for living	Therapist and patient collaboratively identify "positive things in in our lives, or what is worth living for"; therapist directs patient to "tell me a story about these reasons for living"	-	-	✓
Social support	Therapist and patient collaboratively identify friends and family members who have "helped you during times of stress in the past, and who you feel comfortable contacting now when in crisis"	-	✓	✓
Crisis resources	Therapist provides phone numbers of medical providers and other professional sources of help, including the Military Crisis Hotline	✓	1	✓
Referral to treatment	Therapist staffs case with on-call provider, schedules follow-up appointment with mental health care provider, and makes referrals to other professional resources	1	1	✓
Contract for safety	Therapist asks patient, "If you were to go home today, do you think you would be able to keep yourself safe?"	✓	-	-

Abbreviations: TAU, treatment as usual; CRP, crisis response plan; E-CRP, enhanced crisis response plan

services was assessed via medical record review and a modified version of the Cornell Services Index (CSI) (Sirey et al., 2005), an interviewer-administered scale that assesses the type and amount of medical visits accessed by respondents during the assessment period. The CSI has demonstrated good interrater reliability (ICC=0.83), especially for outpatient psychiatric visits (ICC=0.98) and inpatient psychiatric admissions (ICC=1.00).

2.4. Treatment Conditions

Descriptions of each treatment condition are summarized in Table 2. A fidelity monitoring scale (available upon request) was used to rate therapist adherence to the three interventions. The fidelity checklist entailed assessing the presence or absence of each component listed in Table 1. Fidelity was therefore determined by the inclusion of correct components as well as the exclusion of incorrect components. All intervention administrations were reviewed, scored, and discussed during individual weekly supervision with each therapist. A random selection of 15 cases were rated independently by two separate investigators, which yielded high interrater reliability estimates for each component (0.84–1.00). Overall fidelity ratings also correlated strongly with each other (r=0.95).

2.4.1. Contract for safety

The contract for safety was selected as the treatment as usual condition based on interviews with clinical providers prior to the start of the study, and was comprised of several commonly-used components when interacting with high-risk patients: suicide risk assessment, supportive listening, provision of crisis resources, referral to a mental health professional, and a verbal contract for safety. Crisis resources were written on an index card by the therapist and handed to the patient. Specific to the verbal contract for safety, therapists asked patients the following question: "If you were to go home today, do you think you would be able to keep yourself safe?"

2.4.2. Standard crisis response plan

The standard crisis response plan was comprised of the same components as the contract for safety, with the exception of the verbal contract for safety. The standard crisis response plan additionally included a collaborative process in which the patient and therapist identified the patient's personal warning signs for an emotional crisis, self-management coping skills, and sources of social support. These components were written on an index card by the patient.

2.4.3. Enhanced crisis response plan

The enhanced crisis response plan was comprised of the same components as the standard crisis response plan, but additionally included an explicit discussion of the patient's reasons for living. The patient's reasons were living were written on the back side of the index card containing the written crisis response plan.

2.5. Therapists

A total of four female clinical social workers delivered the three interventions. Two therapists were licensed, one was unlicensed, and one achieved licensure during the course of the study. Clinical experience ranged from 1 to over 15 years. Therapists were trained and monitored by two of the investigators who were experts in each condition (CJB and TAC). In order to maximize generalizability, research therapists conducted all procedures within the military medical system and followed all military and local requirements for patient care, to include documenting the clinical encounter in the military's electronic medical record.

3. Statistical analysis

All analyses were conducted using an intent-to-treat approach. Primary analyses focused on the effect of treatment group on suicide attempt rates, severity of suicide ideation, and mental health care utilization during follow-up. Estimated proportions of participants in each treatment group who attempted suicide during follow-up were calculated using the Kaplan-Meier method. The log-rank statistic was used for the test of group differences in suicide attempt rates. Hazard ratios were calculated using the Cox proportional hazards model with censoring for participants who were lost to follow-up or did not attempt suicide. For suicide ideation, longitudinal generalized mixed models for Poisson and negative binomial distributions with a variance components covariance matrix were used. Fixed effects included treatment condition, time, and their interaction, and a random intercept was specified. Post-hoc pairwise contrasts were used to evaluate betweengroup differences at each time point. For post-intervention mental health utilization, generalized linear models for Poisson distributions was used.

Because the components comprising the two crisis response plans were additive in nature (i.e., the enhanced crisis response plan contained all of the elements as the standard crisis response plan, but added one unique component intended to enhance its effect), the data analytic approach reflected ordered effects (i.e., enhanced crisis response plan > standard crisis response plan > contract for safety).

Table 3Number and proportion of suicide attempts during follow-up across treatment groups, by study phase, with between-group comparisons.

				Log-rank χ^2				
	E-CRP	CRP	CFS	E-CRP vs. CRP	E-CRP vs. CFS	CRP vs. CFS	CRP _{comb} vs. CVS	
Phase 1	1/20 (5%)	0/15 (0%)	3/20 (20%)	0.12	2.45	4.21**	4.51**	
Phase 2	1/13 (8%)	1/17 (6%)	2/12 (18%)	0.05	0.58	0.91	1.05	
Aggregate	2/33 (5%)	1/32 (3%)	5/32 (19%)	0.14	2.70*	4.22**	4.78**	

^{*} p < 0.10.
** p < 0.05.

To determine the comparative effectiveness of crisis response planning to the contract for safety, we first compared the two crisis response plans, combined together, to the contract for safety. Next, to determine if the additional component in the enhanced crisis response plan provided incremental benefit, we compared each crisis response plan group (i.e., enhanced and standard) to each other and to the contract for safety group.

3.1. Effect of study closure on outcomes

Staffing changes at the research site resulted in a one year suspension of recruitment by the IRB and, ultimately, the inability to meet planned recruitment goals. In all, 97 participants were enrolled (54 and 43 during the first and second phases, respectively), approximately one-quarter the size of the original goal (N=360). Participants enrolled during the second phase reported significantly less severe baseline suicide ideation (t(94)=2.85, p=0.005) but did not differ on any other baseline variable. With regards to outcomes, suicide attempt rates during follow-up did not differ between study phases ($\chi^2(1)$ =0.11, p=0.736), but trajectories of suicide ideation significantly differed between phases (F(6184)=4.89, p < 0.001). Analyses were therefore conducted separately for each study phase and then conducted in the aggregate with baseline suicide ideation entered as a covariate to

determine if different patterns existed.

3.2. Power analysis

Our initial power analysis was based on previously published suicide attempt rates among treament-seeking active duty Soldiers with similar inclusion criteria (Rudd et al., 2015). We assumed a 50% difference in suicide attempts between crisis response planning and the contract for safety (i.e., hypothesis 1). Assuming 20% attrition and a 2:1 allocation ratio (due to the inclusion of two crisis response plan groups), a minimium sample size of 96 (64 in crisis response planning, 32 in contract for safety) was sufficient to provide 80% power. We expected a much smaller difference between the enhanced and standard crisis response plan conditions, however, due to the fact that both were both active and similar treatments. In order to achieve 80% power to detect a 50% difference in suicide attempt rates between these two conditions (i.e., hypothesis 2), a minimum sample size of 360 participants (120 per arm) was required. Following the one-year study closure, this recruitment goal was determined to be unachievable, but the recruitment of 96 participants was achievable. As such, we focused on reaching this recruitment goal instead of altering our study design or power assumptions.

3.3. Treatment dropout and missing data

There were no differences between groups with respect to dropout rates from follow-up assessments ($\chi^2(2)$ =0.26, p=0.880): enhanced crisis response plan, n=9 (27%); standard crisis response plan, n=9 (28%); contract for safety, n=7 (22%). The combined dropout rate for crisis response planning was n=18, (28%). Results of pattern mixture model analyses indicated that findings were not biased by dropouts or missing data.

4. Results

4.1. Suicide attempts

A total of 8 suicide attempts occurred across all treatment groups during the 6-month follow-up, to include one death by suicide in enhanced crisis response plan: enhanced crisis response plan, n=2

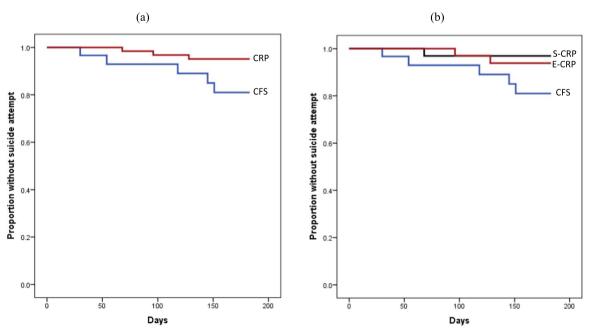


Fig. 2. Survival curves for time to first suicide attempt or end of study among suicidal active duty Soldiers receiving (a) the contract for safety (CFS) or a crisis response plan (CRP); and (b) the contract for safety (CFS), standard crisis response plan (s-CRP), or enhanced crisis response plan (E-CRP).

(estimated proportion: 6.2%); standard crisis response plan n=1 (estimated proportion: 3.1%); and contract for safety, n=5 (estimated proportion: 19.0%). The number and proportion of follow-up suicide attempts by treatment group and study phase were similar across both phases of treatment (see Table 3). Survival curves are plotted in Fig. 2a. Results indicated there was a statistically significant difference between crisis response planning and the contract for safety (estimated proportions: 4.9% vs. 19.0%; log-rank $\chi^2(1)$ =4.85, p=0.028). The hazard ratio from this analysis was 0.24 (95% CI=0.06-0.96), indicating that participants with a crisis response plan were approximately 76% less likely to attempt suicide during follow-up than participants with a contract for safety. When controlling for baseline suicide ideation severity, the adjusted hazard ratio fell shy of statistical significance (hazard ratio=0.29, 95% confidence interval [CI]=0.06-1.18, p=0.068), but was only 5% smaller in magnitude than the unadjusted hazard ratio.

We next examined the effects of each crisis response plan separately (see Fig. 2b). Results indicate there was no difference between the enhanced and the standard crisis response plan (log-rank $\chi^2(1)=0.158$, p=0.691) or the enhanced crisis response plan and the contract for safety (log-rank $\chi^2(1)=2.70$, p=0.100). There was a statistically significant difference between the standard crisis response plan and the contract for safety (log-rank $\chi^2(1)$ =4.31, p=0.038), however. The hazard ratio for this latter analysis was 0.15 (95% confidence interval [CI]=0.02-1.29), indicating that participants in the standard crisis response plan were approximately 85% less likely to attempt suicide than participants in the contract for safety. The 95% confidence interval for this analysis included the value of 1, however, suggesting this risk reduction fell short of statistical significance.

4.2. Suicide ideation

When comparing crisis response planning to the contract for safety, the treatment-by-time interaction was statistically significant for both the first (F(3,111)=19.69, p<0.001) and second (F(3,78)=4.20,p=0.008) phases of the study. Patterns of change in suicide ideation

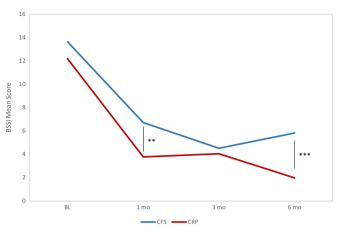


Fig. 3. Mean Beck Scale for Suicide Ideation (BSSI) scores over time among suicidal active duty Soldiers receiving a crisis response plan (CRP) versus the contract for safety (CFS). **p < 0.01, ***p < 0.001.

both within and between groups were similar across both phases (see Table 4). Both phases were therefore combined together and study phase was entered as a covariate. The treatment-by-time interaction remained statistically significant (F(3,195)=18.64, p < 0.001), indicating that suicide ideation declined at different rates across the three treatment groups. Post-hoc comparison of slopes indicated that suicide ideation declined significantly faster for crisis response planning than for contract for safety (t(195)=4.46, p < 0.001; see Fig. 3).

When examining the effects of each crisis response plan separately, results yielded a statistically significant treatment-by-time interaction for both the first (F(6,108)=13.12, p<0.001) and second (F(6,75)=2.37, p=0.038) phases of the study, with similar patterns in both within- and between-group change. The rate of decline in suicide ideation was significantly faster in the enhanced (t(192)=4.31, p < 0.001) and standard crisis response plan (t(192)=2.96, p < 0.001) as compared to the contract for safety. There was no difference between the enhanced and the standard crisis response plan (t(192)=1.41,

Change in suicide ideation mean scores and within- and between- group effect sizes over time, by treatment group and study phase.

	M (SD)		T		Test _{between} d		$d_{within}\ (95\%\ CI)^d$			d _{between} (95% CI) ^e		
	CFS	S-CRP	E-CRP	F	p	CFS	S-CRP	E-CRP	CFS vs. S-CRP	CFS vs. E-CRP	S-CRP vs. E-CRP	
Phase I												
BL	18.5 (6.6)	16.1 (5.0)	15.8 (6.9)	0.04	0.965	_	_	_	-0.4	-0.4	-0.1	
1 mo	8.0 (10.7) ^{a,b}	$4.9 (6.6)^{a,c}$	$2.6 (5.2)^{b,c}$	10.36	< 0.001	-1.2	-1.9	-2.1	-0.3	-0.6	-0.4	
3 mos	$3.6 (6.8)^a$	$3.7 (6.4)^{c}$	$0.9 (3.2)^{a,c}$	7.36	0.001	-2.2	-2.2	-2.5	0.0	-0.5	-0.5	
6 mos	5.1 (7.9) ^{a,b}	1.0 (2.5) ^a	0.7 (1.9) ^b	18.53	< 0.001	-1.9	-3.6	-2.7	-0.7	-0.7	-0.1	
Phase II												
BL	14.6 (7.2)	13.3 (8.4)	11.2 (4.7)	0.10	0.907	_	_	_	-0.2	-0.6	-0.3	
1 mo	8.0 (10.2)	5.7 (7.2)	5.1 (6.3)	0.49	0.612	-0.7	-0.9	-1.1	-0.3	-0.3	-0.1	
3 mos	7.6 (8.1)	9.9 (9.8)	6.7 (7.9)	0.03	0.970	-0.9	-0.4	-0.7	0.3	-0.1	-0.4	
6 mos	9.2 (9.3) ^b	6.7 (9.2)	3.8 (7.6) ^b	2.52	0.087	-0.6	-0.7	-1.2	-0.3	-0.6	-0.3	
Combined 1	Phases											
BL	17.0 (7.0)	14.7 (6.9)	13.9 (6.5)	0.18	0.834	_	_	_	-0.3	-0.5	-0.1	
1 mo	8.0 (10.3) ^{a,b}	5.3 (6.8) ^a	$3.6 (5.7)^{b}$	5.36	0.006	-1.0	-1.4	-1.7	-0.3	-0.5	-0.3	
3 mos	5.3 (7.5)	$6.8 (8.7)^{c}$	3.4 (6.2) ^c	4.82	0.009	-1.6	-1.0	-1.6	0.2	-0.3	-0.5	
6 mos	6.7 (8.5) ^{a,b}	$2.9 (6.0)^a$	$2.0 (5.1)^{b}$	17.37	< 0.001	-1.3	-1.8	-2.0	-0.5	-0.7	-0.2	

CFS=Contract For Safety; S-CRP=Standard Crisis Response Plan; E-CRP=Enhanced Crisis Response Plan.

CFS and CRP values significantly differ at unadjusted p < 0.05. $^{\rm b}$ CFS and E-CRP values significantly differ at unadjusted p < 0.05.

^c CRP and E-CRP values significantly differ at unadjusted p < 0.05.</p>

d For within-group effect sizes, positive coefficients indicate an increase in suicide ideation severity whereas negative coefficients indicate a decrease in suicide ideation severity relative to baseline

For between-group effect sizes, positive coefficients indicate the first listed group has a higher mean score whereas negative coefficients indicate the second listed group has a higher mean score.

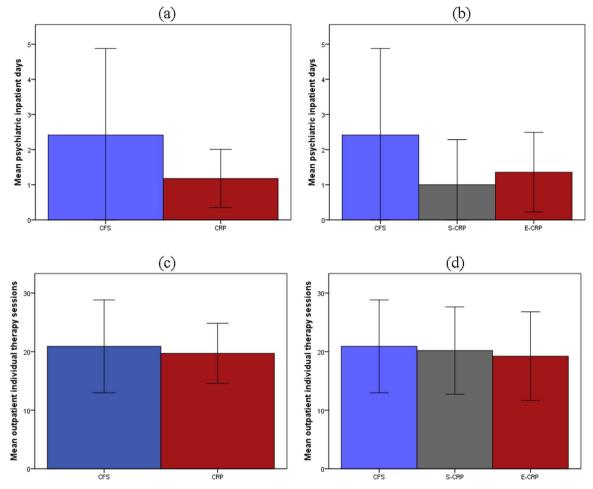


Fig. 4. Mental health care utilization during follow-up by treatment group: (a) mean psychiatric inpatient hospitalization days among contract for safety (CFS) and crisis response plan (CRP) participants; (b) mean psychiatric inpatient hospitalization days among CFS, standard CRP, and enhanced CRP participants; (c) mean outpatient individual therapy sessions among CFS and CRP participants; and (d) mean outpatient individual therapy sessions among CFS, standard CRP, and enhanced CRP participants.

p=0.161; (see Table 4).

4.3. Mental health service utilization

In terms of inpatient psychiatric hospitalization, crisis response planning was associated with significantly fewer inpatient days than the contract for safety (F(1,82)=7.41, p < 0.001; see Fig. 4a). The enhanced (t(81)=3.58, p < 0.001) and standard crisis response plans (t(81)=2.74, p < 0.001) each had significantly fewer inpatient days than the contract for safety, but the two crisis response plans did not differ from each other (t(81)=1.01, p=0.313; see Fig. 4b). There was no difference in mean number of outpatient individual therapy sessions between crisis response planning and the contract for safety (F(1,82)=0.52, p=0.472; see Fig. 4c). The enhanced crisis response plan, standard crisis response plan, and contract for safety similarly did not differ from each other (F(2,81)=0.27, p=0.767; see Fig. 4d).

5. Discussion

The focus of this randomized clinical trial was to compare the effectiveness of crisis response planning on the risk for follow-up suicide attempt and suicide ideation among active duty Soldiers presenting to military medical clinics for an emergency behavioral health appointment. Though commonly used across medical settings, the crisis response plan (and the related safety planning intervention) had not yet been definitely tested until now (Hogan, 2016). Consistent with our expectations, Soldiers who received a crisis response plan

were significantly less likely to make a suicide attempt during follow-up than Soldiers who received the contract for safety. Soldiers receiving a crisis response plan also experienced significantly faster reductions in suicide ideation. Contrary to our second prediction, however, there were no differences between the enhanced and the standard crisis response plans, suggesting that asking Soldiers about their reasons for living during a crisis response plan does not improve outcomes relative to a standard crisis response plan. This latter conclusion is made cautiously, however, in light of limited statistical power resulting from the IRB's temporary closure of the study, which hindered our ability to achieve our planned recruitment goal. As a result, there was insufficient power to detect differences between the two crisis response plan conditions. Additional studies with larger samples are needed to further test the effects of the crisis response plan's various components and to determine if enhancements can increase the intervention's magnitude of effect.

From a clinical perspective, these findings suggest that a Soldier's risk for suicidal behavior can be reduced for up to six months with a relatively simple intervention that emphasizes concrete steps to follow during an emotional crises. Because of its brevity and simplicity, the enhanced or standard crisis response plan could be feasibly implemented in a wide range of medical settings by a diverse range of health care professionals (e.g., physicians, nurses, mental health professionals). The observed effect in the present study (i.e., 75% decrease in suicide attempts) suggests that crisis response planning may be an especially potent component of treatments such as dialectical behavior therapy and CBT, each of which have been shown to reduce follow-up

suicide attempts by 50% or more (Rudd et al., 2015; Linehan et al., 2006a, 2015; Brown et al., 2005). Large reductions in suicide attempts have also been reported subsequent to a three-session outpatient psychotherapy that emphasizes crisis response planning (Gysin-Maillart et al., 2016). A recent component analysis of dialectical behavior therapy further suggests that skills training in self-monitoring of warning signs, self-management, and effective use of social support accounts for a larger portion of the treatment's overall effect than the individual therapy component (Linehan et al., 2015). The reductions in suicide attempts and ideation associated with crisis response planning in the present study were achieved concurrent with a reduction in inpatient hospitalization days, a pattern that also mirrors findings from dialectical behavior therapy and CBT (Rudd et al., 2015; Linehan et al., 2006b; Brown et al., 2005).

As noted previously, the crisis response plan shares many components with the safety planning intervention (i.e., identification of warning signs, self-management skills, social support, and crisis resources), although the safety planning intervention also includes a mean restriction counseling component (Stanley and Brown, 2012). To that end, the safety planning intervention is, in many respects, akin to an (alternative) enhanced crisis response plan. As noted by Hogan (Hogan, 2016), safety planning has not yet been definitely tested. However, preliminary data from an unrandomized cohort comparison study conducted in Department of Veterans Affairs (VA) emergency departments indicate the safety planning intervention is associated with reductions in suicide behavior reports, an administrative tool used by the VA to document known instances of suicide ideation, attempt, or death. In that study, the safety planning intervention was combined with weekly follow-up phone calls that continued until the patient initiated outpatient mental health care (mean=3.7 phone calls), resulting in a much higher "dose" of intervention than the singlesession crisis response plan tested in the present study. In light of the present findings supporting the crisis response plan's efficacy, additional research is warranted to further clarify which components of the crisis response plan (and the safety planning intervention) contribute most directly to reductions in risk for suicidal thoughts and behaviors.

In addition to the aforementioned limitations related to statistical power, conclusions may have limited generalizability beyond active duty Army personnel. Due to the present study's small sample size, we were also unable to shed light on how clinical context might influence outcomes. Because the contextual demands of emergency departments differ from those of outpatient behavioral health clinics and primary care clinics, for example, future studies aimed at determining if the effects of crisis response planning are moderated by clinical context would be of benefit. Relatedly, additional research is needed to determine if the crisis response plan can be reliably implemented as a suicide prevention strategy outside of the health care system (e.g., schools, families, military units). Despite these limitations, the present study provides the first empirical evidence supporting the value of crisis response planning as a brief intervention to mitigate short-term risk of suicidal behavior among Soldiers presenting to emergency settings with acute suicidal crises.

Previous Presentations

European Symposium for Suicide and Suicidal Behavior, Oviedo, Spain, Sep 8-10, 2016.

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