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A Randomized Controlled Trial of the Collaborative Assessment and Management of Suicidality versus Enhanced Care as Usual With Suicidal Soldiers

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Objective: This study describes a randomized controlled trial called "Operation Worth Living" (OWL) which compared the use of the Collaborative Assessment and Management of Suicidality (CAMS) to enhanced care as usual (E-CAU). We hypothesized that CAMS would be more effective than E-CAU for reducing suicidal ideation (SI) and suicide attempts (SA), along with secondary behavioral health and health care utilization markers for U.S. Army Soldier outpatients with significant SI (i.e., > 13 on Beck's Scale for Suicide Ideation). *Method*: Study participants were 148 Soldiers who presented to a military outpatient behavioral health clinic. There were 73 Soldiers in the experimental arm of the trial who received adherent CAMS; 75 Soldiers received E-CAU. Nine a-priori treatment outcomes (SI, past year SA, suicide-related emergency department (ED) admits, behavioral health-related ED admits, suicide-related inpatient psychiatric unit

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(IPU) days, behavioral health-related IPU days, mental health, psychiatric distress, resiliency) were measured through assessments at Baseline and at 1, 3, 6, and 12 months post-Baseline (with a 78% retention of intent-to-treat participants at 12 months). *Results*: Soldiers in both arms of the trial responded to study treatments in terms of all primary and secondary outcomes (effect sizes ranged from 0.63 to 12.04). CAMS participants were significantly less likely to have any suicidal thoughts by 3 months in comparison to those in E-CAU (Cohen's d = 0.93, p=.028). *Conclusions*: Soldiers receiving CAMS and E-CAU significantly improved post-treatment. Those who received CAMS were less likely to report SI at 3 months; further group differences were not otherwise seen.

With 44,193 deaths per year in the United States, suicide is the 10th leading cause of death and poses a major public health issue (Xu, Murphy, Kochanek, & Arias, 2016). Among Americans, an estimated 1.3 million adults attempted suicide per year and 9.3 million adults reported suicidal thoughts per year (Centers for Disease Control and Prevention, 2015). The U.S. Army has recently been particularly plagued with dramatic increases in suicide rates since 2008 (Schoenbaum et al., 2014; Ursano et al., 2014).

Given these striking data, it is important to note that remarkably few clinical treatments have been proven through randomized controlled trials (RCTs) to be effective for suicide risk (Jobes, Au, & Siegelman, 2015). To date, *replicated* RCTs have shown only three major approaches to be effective for specifically treating suicide risk. These interventions include dialectical behavior therapy (DBT; Linehan, 1993, 2015), two forms of suicide-specific cognitive-behavioral therapy (CBT)—cognitive therapy for suicide prevention (CT-SP; Brown et al., 2005; Wenzel, Brown, & Beck, 2009) and brief cognitive behavior therapy (B-CBT; Rudd et al., 2015)—and the collaborative assessment and management of suicidality (CAMS; Jobes, 2006, 2016). CAMS is an evidence-based, suicide-specific therapeutic framework that targets and treats patient-defined "suicidal drivers" and has shown promise with suicidal military personnel (Jobes, Wong, Conrad, Drozd, & Neal-Walden, 2005). To date, CAMS has been shown through RCTs to be effective in rapidly reducing suicidal ideation (SI) and symptom distress while increasing hope (Comtois et al., 2011); CAMS appears to be promising for effectively treating self-harm and suicide attempts (SAs) as well (Andreasson et al., 2016). With eight nonrandomized published trials showing replicated effects for SI, overall symptom distress, depression, and cognitions related to suicide, there is increasingly robust evidence in support of CAMS (Jobes, 2006, 2016).

Considering the Joint Commission's (2016) recent *Sentinel Event Alert* titled "Detecting and Treating Suicide Ideation in All Settings," there is a significant and pressing need for easy-to-train suicide-specific care that is reliable, efficient, and effective for known high-risk populations. Consistent with this policy emphasis, the present randomized controlled clinical effectiveness trial comparing CAMS to enhanced care as usual (E-CAU; see Method section) as an outpatient treatment for SI in a U.S. Army treatment facility was pursued. We hypothesized that adherently used CAMS would be more effective than E-CAU for reducing SI and SAs, as well as a number of secondary behavioral health and health care utilization markers (e.g., suicide- and behavioral health–related emergency department admits and inpatient psychiatric unit days).

METHOD

Setting

This study was conducted in the Department of Behavioral Health at an Army Medical Center on an infantry military installation.

Behavioral health clinicians, clinic chiefs, and other medical staff referred suicidal Soldier participants. All study procedures were reviewed and approved by the Department of Defense's Institutional Review Board (IRB) and Human Research Protection Office (HRPO), as well as the University of Washington, The Catholic University of America, and the Denver Veterans Affairs IRBs. A data safety monitoring board (DSMB) oversaw the study.

Patient Participants

Active-duty U.S. Army Soldiers (N = 148) who spoke English, were at least 18 years of age, and had significant SI (defined as an index score of 13 or higher on the Scale for Suicidal Ideation–Current [SSI-C]; Beck, Brown, & Steer, 1997; Comtois et al., 2011) were included in this study. Exclusion criteria were (a) inability to understand, consent, or benefit from study procedures due to significant psychosis, paranoia, cognitive impairment, or where psychosocial therapeutic care was otherwise contraindicated; (b) a judicial order to treatment; or (c) separation, change of station, or deployment expected in the next 12 weeks. At the request of our military collaborators, the following individuals were also excluded: (a) Soldiers in the Warrior Transition Unit (WTU) and (b) pregnant Soldiers.

Therapist Participants

All eligible on-site clinicians were oriented to the study and invited to participate; 14 therapists (45% of those approached) consented to participate. All nine participating study clinicians were clinical social workers (9% of those approached). Of the 14 who consented two dropped out after consent without specifying a reason and three others left the clinic before a participant was referred. To assure sufficient staffing to support the study, two additional clinicians were hired by the study. They were recruited, hired, and managed by the same leadership as clinic therapists to maximize their equivalence to existing staff. Therapists were initially assigned to treatment conditions to maximize their allegiance to their current approach to treating suicidal patients (care as usual [CAU]). Therapists with lower allegiance were assigned to CAMS, so E-CAU clinicians had high allegiance to CAU. Selecting in this manner assured high allegiance of control clinicians to their existing approach, thereby maximizing expectancies and minimizing between-group contamination, thus leading to more generalizable results (Comtois et al., 2011).

Study Treatments

CAMS

Soldiers were offered clinical care guided by the CAMS approach (Jobes, 2016; Jobes, Comtois, Brenner, Gutierrez, & O'Connor, 2016). CAMS is a suicide-specific therapeutic framework that employs the use of a multipurpose assessment, treatment-planning, tracking, and outcome tool called the Suicide Status Form (SSF). Central to CAMS is an empathic and collaborative assessment and treatment-planning approach to suicide risk throughout care. Starting at the index session, CAMS uses the CAMS Stabilization Plan to reduce access to lethal means and increase coping strategies; CAMS also targets and treats patient-defined suicidal "drivers" using appropriate clinical interventions (e.g., exposure treatment for a posttraumatic stress disorder [PTSD]-related driver or couples therapy for a marriage-related driver). CAMS is concluded after three consecutive sessions when suicidal thoughts, feelings, and behaviors are successfully managed per CAMS resolution criteria (see Jobes, 2016). The principal investigator (PI) and his team reviewed digital recordings of CAMS sessions using the CAMS Rating Scale (CRS) to establish initial adherence and then spot-checked 10% of cases for any drift in CAMS adherence (Corona, 2016). There was no drift in the study.

E-CAU

Soldiers in the E-CAU group were offered typical treatment provided by on-site military

clinical social workers. These clinicians had a broad range of training experiences and approaches to working with the Soldiers, who were randomized to their care. Like the CAMS providers, the PI and his team monitored E-CAU recorded sessions using the CRS to ensure that control clinicians were *not* doing CAMS (i.e., scoring less than three on the CAMS Rating Scale—the measure used to determine CAMS adherence). E-CAU was considered resolved once the clinician was satisfied that the primary reason for the referral to E-CAU was resolved. To increase experimental internal validity, CAU in this study was "enhanced" (i.e., E-CAU) in three ways. First, all E-CAU therapists agreed to have all sessions recorded for potential checks (to verify they were not doing CAMS). Second, E-CAU providers offered participants at least one weekly treatment session and tried to ensure that treatment lasted at least four weeks to match the minimum amount of care provided in the CAMS arm. Third, E-CAU clinicians were offered the option of regular clinical consultation (above and beyond clinic supervision) comparable to CAMS. Thus, E-CAU was designed to balance and minimize threats to both the internal and external validity of the study.

Protocols Common to All Treatment Conditions

All study interventions were conducted at least until resolution of the problem (as defined by that treatment condition). After a study-related problem was resolved, therapists in both arms could continue to see the participant, refer the participant for treatment of other issues, or discharge the participant from treatment according to each provider's professional judgment and standard clinic policies and procedures. Medications were provided by the same psychiatrists or other prescribing clinicians in both arms (primarily within behavioral health but possibly through primary care or other medical services). Prescribing providers conducted pharmacotherapy according to standard policies and procedures in both treatment conditions.

Protocol to Prevent Cross-Contamination Between Conditions

No E-CAU provider had previous training in CAMS. CAMS therapists did not discuss their CAMS participants at the team meetings with E-CAU clinicians. Any issues of concern for CAMS providers were addressed in the CAMS group consultation that was part of this study (or, if medication related, with the participant's prescriber outside of the meetings). CAMS adherence ratings were conducted on therapist's initial sessions, and a 10% sample of ongoing sessions and confirmed they were using CAMS (experimental group) or not using CAMS (control group) across the duration of the study treatment.

Measures

Scale for Suicide Ideation–Current (SSI-C)

The SSI-C (Beck et al., 1997) is an interviewer-administered scale that measures a participant's SI at its worst point in the past two weeks. The SSI-C demonstrates strong reliability and validity in assessing current SI among psychiatric patients (Cronbach's alpha = .89; Beck et al., 1997; Beck, Kovacs, & Weissman, 1979). To reduce assessment burden, the first five SSI items were administered to all participants, but the remaining 14 items were not administered to participants with no SI on any of the first five items (i.e., if items 1 through 5 are all zero, items 6 through 19 are also coded zero, thus providing a total score of 0 for the measure). The responses were summed to create an index of SI ranging from 0 to 38, with higher scores reflecting greater ideation. This measure was used at all study time points.

Suicide Attempt Self-Injury Count (SASI-Count)

The SASI-Count (Linehan & Comtois, 1996; Linehan, Comtois, Brown, Heard, & Wagner, 2006) is a brief interview covering past self-inflicted injuries categorizing them

into suicide attempts (SAs) and nonsuicidal acts. The tool also creates counts of self-inflicted injuries by method, medical risk severity, and lethality. It has a Lifetime form and a Recent form, the latter of which covers a specific assessment period. The Lifetime and Recent version (for the past year) were conducted at baseline. Follow-up assessments were conducted with the Recent version (for the period since previous assessment). Interviewer ratings on the SASI-Count are the same as in the Suicide Attempt Self-Injury Interview (SASII), which has shown strong psychometrics (e.g., Cronbach's alpha reliability = .85; Linehan et al., 2006).

Structured Clinical Interview for DSM-*IV (SCID)*

The SCID (First, 1997b) is a diagnostic instrument based on diagnostic criteria for Axis I disorders found in the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (*DSM*-IV). The SCID has been demonstrated to have good reliability, with kappa values ranging from .40 to .84, with a mean of .61 for all disorders across a large number of samples (First, 1997b). Test-retest reliabilities for disorders in psychiatric patients range from .54 to .84 with a mean of .73. In addition, the Structured Clinical Interview for *DSM*-IV Axis II Borderline Personality Disorder (First, 1997a) was used to identify participants with borderline personality disorder given the suicide risk associated with this disorder. This interview was conducted after the baseline assessment and within one month of starting study treatment.

Treatment History Interview–Military (THI-M)

The THI-M (Linehan, 1996) is an interviewer-administered measure used to capture the participant's use of health and behavioral health services. The THI-M is a briefer version of the full Treatment History Interview (THI) adapted for a military health care system. The THI has high convergent validity with hospital records and psychotherapist reports. This measure was used at all time points throughout the study. At the baseline assessment, health and behavioral health services were assessed for the previous year. Subsequently, health and behavioral health services were assessed from the previous assessment. To improve data quality in this study, a review of the military electronic health record for the relevant time period was conducted prior to each assessment and used to prompt and clarify services with the participant during the interview.

Connor-Davidson Resilience Scale (CD-RISC)

The CD-RISC (Connor & Davidson, 2003) is a 25-item questionnaire regarding attitudes toward coping with adversity; it has high internal consistency (Cronbach's alpha = .89) and test-retest reliability (ICC = .87) as well as convergent and divergent validity (Connor & Davidson, 2003). The responses were summed to create an index of resiliency ranging from 0 to 100, with higher scores reflecting greater resiliency. This measure was used at all time points throughout the study.

Outcome Questionnaire-45 (OQ-45)

The OQ-45 (Lambert et al., 1996) is a 45-item questionnaire designed to measure key areas of mental health functioning. Subscales correlated between moderate to high ranges across scales: symptoms (r = .78, Cronbach's alpha = .91), interpersonal problems (r = .80, Cronbach's alpha = .74), and social role functioning (r = .82, Cronbach's alpha = .71; Lambert et al., 1996). The OQ-45 is a widely accepted tool for identifying, tracking, and measuring behavioral health treatment outcomes (Maruish, 2001) and possesses good overall psychometric properties across adults from a counseling center, community clinic, and psychiatric inpatient (Umphress, Lambert, Smart,

Barlow, & Clouse, 1997). The responses were summed to create an index of psychiatric distress ranging from 0 to 180, with higher scores reflecting greater distress. This measure was used at all time points throughout the study.

Medical Outcomes Study Short Form–36, version 2 (SF-36)

The Medical Outcomes Study SF-36 (Ware, Snow, Kosinski, Gandek, & New England Medical Center Hospital and Health Institute, 1993) contains 36 self-report items yielding a physical and a mental health summary score, as well as eight individual scales (Ware et al., 1993). In various populations, internal consistency for the scales has been shown to be at least .70, and the SF-36 has been widely used in veteran populations (Voelker et al., 2002). The present study focused on the mental health subscale scores, which range from 0 to 100; higher scores reflect better overall mental health. This measure was used only at the baseline assessment before randomization.

Procedures

Recruitment

Clinicians contacted the on-site research coordinator (RC) to arrange screening of interested suicidal Soldiers as soon as possible (i.e., appointments were scheduled as soon as possible given their mental status, clinical care, and release to come to the clinic). The RC described the study and conducted informed consent, and then confirmed that potential participants met the inclusion criteria. Eligible participants then completed the baseline assessments, were randomized, and were scheduled for their initial session of study treatment.

Randomization

Given the moderate sample size, a minimization strategy rather than stratification random strategy was used to assign Soldiers to conditions. This strategy for random assignment to condition was developed specifically for research studies where the number of matching criteria is large relative to the number of participants in a study (Freedman & White, 1976; Pocock & Simon, 1975; White & Freedman, 1978). Eligible participants were matched on four primary variables: (a) history of SA (0 versus 1 versus 2+); (b) polypharmacy as an indicator of psychiatric complexity (0–2 versus 3+ current medications); (c) severity of physical injury/disability defined as SF-36 physical functioning score indicating average to high functionality (≥ 41) versus below-average functionality (≤ 40); and (d) already enrolled in behavioral health outpatient treatment as defined by appointments attended at the clinic within the past eight weeks and an upcoming appointment scheduled (yes versus no).

Follow-up assessments

Outcome assessments were conducted one, three, six, and 12 months after baseline and consisted of three parts: (a) a "blind" assessment interview regarding SI (i.e., SSI-C), suicidal behavior (i.e., SASI-Count), and crisis services received by the participant (i.e., the crisis/medical section of the THI-M); (b) a "nonblind" assessment of outpatient services received (i.e., THI-M), including the study treatment (which could break the blind); and (c) an online survey of the questionnaires (i.e., CD-RISC and OQ-45). Independent assessors conducted the "blind" and "nonblind" assessments.

Remuneration

By regulation, it is not possible to pay active-duty Army personnel for their participation in research assessments. However, all study participants received a custom-made military coin at the three-month follow-up assessment to thank them for participation. If a participant separated from the U.S. Army

in the course of the study, that participant was paid $20 for each outcome assessment following separation. These separated participants were also given an additional incentive payment of $5 if they called to schedule their next appointment and $5 if they completed their assessment when originally scheduled (i.e., a total maximum of $30 if they called to schedule the assessment and completed when scheduled).

Data Analyses

To evaluate the impact of CAMS versus E-CAU, longitudinal regression analyses were conducted using generalized linear mixed modeling (GLMM). All study participants who were randomized and completed a baseline assessment were included in the primary outcome analyses (i.e., an intent-to-treat approach). The a priori study outcomes were (a) SI; (b) SAs; (c) suicide-related emergency department (ED) visits; (d) any behavioral health–related ED visits; (e) any suicide-related inpatient unit (IPU) admission; (f) any behavioral health–related IPU admission; (g) mental health (SF-36); (h) resiliency (CD-RISC); and (i) overall symptom distress (OQ-45). The ED and IPU visit variables were dichotomized into no visits versus one or more visits because of low postbaseline rates above 1. SAs were also combined from baseline through 12 months due to very low frequencies at each assessment point. Each outcome variable was regressed on treatment (CAMS versus E-CAU), time, and the treatment by time interaction in separate GLMM models. The time variable was divided into four planned contracts: (a) month one versus baseline; (b) month three versus baseline; (c) month six versus baseline; and (d) month 12 versus baseline. Logistic and Gaussian GLMMs were used for binary and relatively normally distributed variables, respectively.

The primary SI outcome (SSI) had a positively skewed distribution and many zeroes. For this outcome we used a two-part regression model known as a hurdle model (Atkins, Baldwin, Zheng, Gallop, & Neighbors, 2013), which assumes a threshold must be crossed from zero into positive values. The hurdle model approach effectively divides the SI outcome into two outcomes, each modeled in its own regression equation. One outcome is a dichotomous variable representing zero SI versus any SI and includes the entire sample. The second outcome represents the degree of SI when there is any SI. Thus, a hurdle model contains two submodels: (a) a logistic regression for zeroes versus not zeroes and (b) a zero-truncated overdispersed Poisson regression for the distribution of nonzero values. The hurdle model of the SI outcome provided two sets of results corresponding to the impact of treatment on (a) likelihood of any SI (i.e., logit model) and (b) average SI given any SI (i.e., zero-truncated count model). Another characteristic of the SI outcome was that the study inclusion criterion required all participants to have nonzero SI at baseline, resulting in a problem known as complete separation (Albert & Anderson, 1984), due to no variation in SI at one of the time points, which produces extreme and biased regression estimates. To accommodate this feature of the data, we used a Bayesian approach to GLMM, in which Cauchy prior distributions with scale 2.5 were specified where appropriate to restrict regression coefficients away from extreme values, as recommended by Gleman, Jakulin, Pittau, and Su (2008).

We also conducted planned secondary analyses evaluating the association between CAMS adherence and postbaseline outcomes. Due to a low base rate of SA and the reduced sample size, these secondary analyses focused only on (a) SI and (b) psychosocial outcomes. Postbaseline measurements of each outcome were regressed on the baseline measurement of the outcome, therapist, treatment (CAMS versus E-CAU), and adherence in separate models.

RESULTS

Flow of Participants

As shown in Figure 1 depicting the Operation Worth Living (OWL) Consort

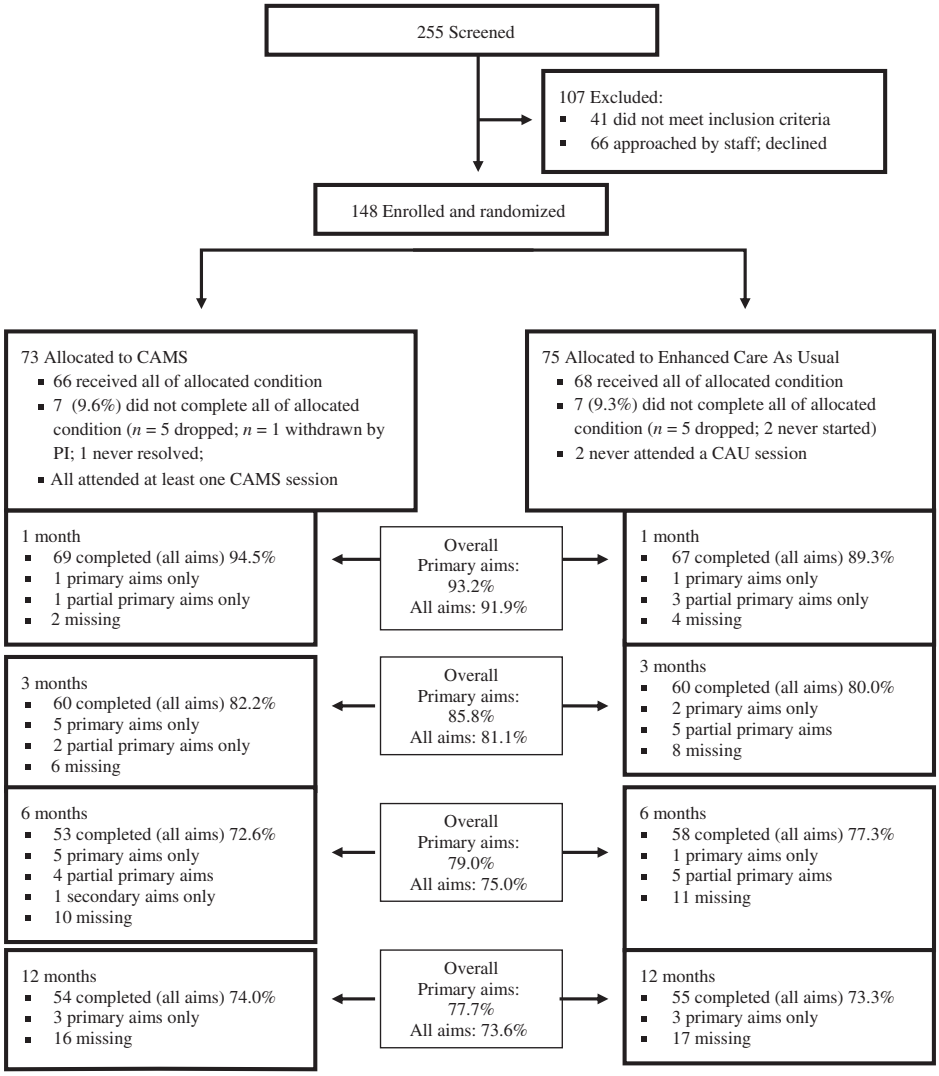

FIGURE 1. OWL Consort Chart: Intent-to-Treat Phase. Primary aims = blind assessments only; all aims = blind, nonblind assessments, and online questionnaires characteristics: Overall and by Treatment Condition.

Chart, a total of 255 individuals were screened for eligibility; the final sample consisted of the 148 who completed a baseline assessment and were randomized, 73 in the CAMS arm and 75 in the E-CAU arm.

Participants

The final sample of 148 participants ranged in age from 18 to 48 years (M = 26.8, SD = 5.9). Other characteristics of the sample are shown in Table 1. As expected with a military sample, participants were mostly male (80%). Half (53%) were white, 24% African American, 11% Asian or Pacific Islander, and the remaining 11% other ethnicities. The majority was junior enlisted (70%), a sizable portion (42%) had never deployed, and 14% had deployed three or more times. Half of the participants

reported at least one lifetime SA, with over one-quarter of participants (27%) reporting multiple attempts. There were no statistically significant differences in sociodemographic characteristics or Axis I clinical diagnosis rates between treatment conditions, indicating that randomization was successful (see Table 1).

Missing Data

Across the nine primary study outcomes, the overall rate of missing data over the five assessments was 13% and comparable to the 9% median rate (range = [0, 70%]) of missing data found in a recent review of clinical trials by Bell, Fiero, Horton, and Hsu (2014). Just under half of the participants had complete data from all five assessments (44%, n = 65), 25% (n = 37) were missing a single assessment, and 31% were missing multiple assessments (n = 46). Each sociodemographic characteristic and Axis I clinical diagnosis was regressed on an indicator for complete versus partial data in separate generalized linear models. There were no statistically significant differences between participants with complete versus incomplete data, with respect to gender, ethnicity, marital status, sexual orientation, education level, rank, number of combat deployments, lifetime SAs, bipolar diagnosis, depressive disorder diagnosis, anxiety disorder diagnosis excluding PTSD, PTSD diagnosis, or drug abuse/dependence diagnosis. At baseline, participants with incomplete data had 3.6-fold greater odds of an alcohol abuse or dependence diagnosis (OR = 3.58, 95% CI = [1.24, 10.34], p = .019). However, there was no statistically significant difference between treatment conditions in the rates of missing data. Since the GLMM approach utilizes all available data, including from participants with both complete and partial data, missing data should not bias outcome analyses as the rate of missing data was comparable across treatment conditions.

Intervention Participation

As described in the Method section, there was no fixed number of sessions in the CAMS or E-CAU conditions; 93% of participants in the CAMS condition and 92% of participants in the E-CAU condition completed the planned minimum of four sessions. Participants in the CAMS condition completed from one to 26 treatment sessions, with a median of five (M = 6.2, SD = 3.9) sessions. E-CAU participants received 0 to 21 treatment sessions, with a median of five (M = 6.4, SD = 3.5) sessions.

In addition, 44% of participants in the CAMS condition and 41% of participants in the E-CAU condition also received posttreatment sessions. Participants in the CAMS condition completed from 0 to 35 posttreatment sessions, with a median of 0 sessions (M = 2.6, SD = 5.7). E-CAU participants received from 0 to 22 posttreatment sessions, with a median of 0 sessions (M = 1.9, SD = 3.7). Wilcoxon signed-rank tests did not indicate any statistically significant difference between arms in the number of treatment (z = 0.69, p = .490) or posttreatment sessions (z = –0.40, p = .689).

Descriptive Data on Study Outcomes

As shown in Table 2, all participants reported moderate to severe SI at baseline, consistent with the inclusion criteria. At one month, the percentage of any SI among participants who completed an assessment dropped by more than one-quarter in both conditions, to 73% in the CAMS condition and 69% in the E-CAU condition. At three months, the percentage of any SI dropped further to 37% in the CAMS condition versus 61% in the E-CAU condition. By six months, the percentage of any SI dropped below 40% in both treatment conditions. In both the CAMS and E-CAU conditions, the intensity of SI when nonzero was highest at baseline and decreased by approximately half after one month and remained

TABLE 1. Baseline Sociodemographic and Clinical Characteristics: Overall and by Treatment Condition

	Overall		CAMS		E-CAU	
	N	%	*n*	%	*n*	%
Sociodemographics						
Gender						
Male	119	80.4	56	76.7	63	84.0
Female	29	19.6	17	23.3	12	16.0
Ethnicity						
White/Caucasian	75	53.2	37	51.4	38	55.1
Black/African American	34	24.1	17	23.6	17	24.6
Latino/a	15	3.6	12	16.7	3	4.3
Asian or Pacific Islander	5	10.6	2	2.8	3	4.3
Other	12	8.5	4	5.6	8	11.6
Marital status						
Single, never married	38	26.0	20	28.2	18	24.0
Married	74	50.7	35	49.3	39	52.0
Separated or divorced	33	22.6	16	22.5	17	22.7
Widowed	1	0.7	0	0.0	1	1.3
Sexual orientation						
Heterosexual	120	85.1	60	85.7	60	84.5
Bisexual	17	12.1	7	10.0	10	14.1
Homosexual	4	2.8	3	4.3	1	1.4
Education						
Some high school	1	0.7	1	1.4	0	0.0
High school graduate or GED	57	39.0	30	42.3	27	36.0
Some college, associate's degree, or technical training	77	52.7	33	46.5	44	58.7
Bachelor's or graduate degree	11	7.5	7	9.9	4	5.3
Rank						
Junior enlisted (E1–E4)	103	69.6	51	69.9	52	69.3
Noncommissioned officer (E5–E9)	41	27.7	21	28.8	20	26.7
Officer (W2–O3)	4	2.7	1	1.4	3	4.0
Number of combat deployments						
0	61	41.5	31	42.5	30	40.5
1	38	25.9	18	24.7	20	27.0
2	28	19.0	17	23.3	11	14.9
3 or more	20	13.6	7	9.6	13	17.6
Lifetime suicide attempts						
None	74	50.0	37	50.7	37	49.3
One	34	23.0	16	21.9	18	24.0
Multiple	40	27.0	20	27.4	20	26.7
*Axis I diagnoses (current)**						
Bipolar disorder						
No	134	96.4	68	95.8	66	97.1
Yes	5	3.6	3	4.2	2	2.9
Depressive disorder						
No	52	37.4	31	43.7	21	30.9
Yes	87	62.6	40	56.3	47	69.1
Anxiety disorder (excluding PTSD)						

(*Continued*)

TABLE 1. (*Continued*)

	Overall		CAMS		E-CAU	
	N	%	*n*	%	*n*	%
No	71	51.1	37	52.1	34	50.0
Yes	68	48.9	34	47.9	34	50.0
PTSD						
No	67	49.3	37	54.4	30	44.1
Yes	69	50.7	31	45.6	38	55.9
Alcohol abuse or dependence						
No	117	84.2	56	78.9	61	89.7
Yes	22	15.8	15	21.1	7	10.3
Drug abuse or dependence						
No	133	95.7	67	94.4	66	97.1
Yes	6	4.3	4	5.6	2	2.9
Borderline personality disorder						
No	100	72.5	49	70.0	51	75.0
Yes	38	27.5	21	30.0	17	25.0

Note. There were no statistically significant differences between treatment conditions with respect to the variables presented in Table 1. CAMS = collaborative assessment and management of suicidality; E-CAU = enhanced care as usual; PTSD = posttraumatic stress disorder; GED = general equivalency diploma.
*Axis I diagnoses determined by the Structured Clinical Interview for the *DSM*-IV Axis I Disorders (SCID-I).

stable through 12 months. Regarding SAs, approximately one-fifth of participants at baseline reported a past-year SA (CAMS 23%; E-CAU 22%). At 12 months, the percentage of participants reporting a past-year SA, among those with 12-month SA data (N = 111), dropped to 11% in the CAMS condition (n = 54) and 5% for E-CAU (n = 57).

Primary Intervention Outcome Analyses

GLMM analyses were used for all intervention outcome analyses, using the regression type appropriate to each outcome (e.g., logistic regression for binary outcomes). Due to a large number of zeroes in the SI (SSI) outcome, hurdle regression was utilized that divided the SSI outcome into (a) the probability of any SI and (b) the intensity of SI when nonzero. Across the study outcomes, the statistically significant intervention effect of CAMS versus E-CAU conditions was on the lower probability (but not intensity) of SI. Figure 2 summarizes the predicted probability and intensity of SI by time and treatment condition from the hurdle regression model. At three months, 37% of participants in the CAMS condition had any SI compared with 61% of participants in the E-CAU condition (Cohen's d = 0.93, p = .028). However, at six months, there was no longer a statistically significant advantage of CAMS over E-CAU (CAMS 33% versus E-CAU 36%; Cohen's d = 0.13, p = .769), nor at 12 months (CAMS 38% versus E-CAU 40%; Cohen's d = 0.06, p = .895).

Within each of the treatment conditions, there were consistently robust postbaseline improvements associated with both CAMS and E-CAU across all outcomes. Table 3 summarizes the within-condition effect sizes for all study outcomes in each arm of the study. The postbaseline improvements in outcomes ranged from 0.63 to 12.04, the majority of which

TABLE 2. Study Outcomes by Assessment Point and Treatment Condition

	Overall		CAMS		E-CAU	
	% Any	Mdn > 0 [95% CI]	% Any	Mdn > 0 [95% CI]	% Any	Mdn > 0 [95% CI]
Suicide ideation (SSI)						
Baseline	100	19.0 [12.0, 31.6]	100	20.0 [12.8, 33.0]	100	19.0 [12.0, 30.1]
1 month	71.0	11.5 [3.4, 22.6]	72.9	13.0 [3.5, 24.5]	69.1	11.0 [4.0, 20.0]
3 months	48.8	10.0 [3.0, 22.0]	36.9	12.5 [2.6, 21.9]	61.3	9.5 [3.9, 20.2]
6 months	36.8	9.0 [2.0, 21.8]	35.1	10.5 [2.0, 22.1]	38.3	9.0 [2.6, 20.3]
12 months	39.1	10.0 [1.0, 21.9]	38.6	10.5 [1.5, 25.8]	39.7	9.0 [1.0, 19.3]
Past-year suicide attempts (SASII)						
Baseline	22.4	1.0 [1.0, 31.4]	23.3	1.0 [1.0, 21.4]	21.6	1.0 [1.0, 20.1]
12 months	8.1	1.0 [1.0, 1.0]	11.1	1.0 [1.0, 1.0]	5.3	1.0 [1.0, 1.0]
Suicide-related ED admits						
Baseline	36.1	1.0 [1.0, 2.0]	38.4	1.0 [1.0, 2.0]	33.8	1.0 [1.0, 2.8]
1 month	5.6	1.0 [1.0, 1.0]	8.5	1.0 [1.0, 1.0]	2.8	1.0 [1.0, 1.0]
3 months	4.5	1.0 [1.0, 1.9]	3.0	1.0 [1.0, 1.0]	6.0	1.0 [1.0, 1.9]
6 months	7.1	1.0 [1.0, 1.8]	6.5	1.0 [1.0, 1.0]	7.8	1.0 [1.0, 1.9]
12 months	7.0	1.0 [1.0, 1.8]	5.3	1.0 [1.0, 2.0]	8.6	1.0 [1.0, 1.0]
Behavioral health–related ED admits						
Baseline	38.8	1.0 [1.0, 3.6]	39.7	1.0 [1.0, 2.6]	37.8	1.0 [1.0, 3.3]
1 month	8.5	1.0 [1.0, 2.0]	11.3	1.0 [1.0, 2.0]	5.6	1.0 [1.0, 1.0]
3 months	8.2	1.0 [1.0, 1.8]	6.0	1.0 [1.0, 1.0]	10.4	1.0 [1.0, 1.8]
6 months	10.3	1.0 [1.0, 1.7]	6.5	1.0 [1.0, 1.0]	14.1	1.0 [1.0, 1.8]
12 months	9.6	1.0 [1.0, 2.8]	7.0	1.0 [1.0, 1.9]	12.1	1.0 [1.0, 2.7]
Suicide-related IPU days						
Baseline	26.5	7.0 [3.0, 28.3]	31.5	6.0 [3.6, 15.7]	21.6	9.5 [3.8, 31.8]
1 month	4.9	7.0 [4.3, 19.2]	7.0	14.0 [4.2, 19.5]	2.8	6.5 [6.0, 7.0]
3 months	4.5	8.0 [3.5, 18.6]	3.0	6.0 [3.1, 8.8]	6.0	8.0 [7.0, 19.2]
6 months	6.3	5.5 [4.0, 28.9]	4.8	7.0 [4.2, 13.7]	7.8	5.0 [4.1, 29.4]
12 months	7	17.5 [1.2, 33.8]	7.0	16.0 [2.2, 34.5]	6.9	17.5 [1.5, 28.0]
Behavioral health–related IPU days						
Baseline	27.2	7.0 [3.0, 28.1]	31.5	6.0 [3.6, 15.7]	23.0	10.0 [3.8, 31.6]
1 month	4.9	7.0 [4.3, 19.2]	7.0	14.0 [4.2, 19.5]	2.8	6.5 [6.0, 7.0]
3 months	5.2	7.0 [3.0, 18.3]	4.5	3.0 [3.0, 8.7]	6.0	8.0 [7.0, 19.2]
6 months	6.3	5.5 [4.0, 28.9]	4.8	7.0 [4.2, 13.7]	7.8	5.0 [4.1, 29.4]
12 months	7.0	17.5 [1.2, 33.8]	7.0	16.0 [2.2, 34.5]	6.9	17.5 [1.5, 28.0]

	M	95% CI	*M*	95% CI	*M*	95% CI
Mental health (SF-36)						
Baseline	26.1	[24.8, 27.3]	26	[24.4, 27.8]	26.1	[24.2, 28.1]
1 month	34.9	[32.9, 37.1]	34.2	[31.5, 37.0]	35.7	[32.9, 38.4]
3 months	38.6	[36.3, 40.9]	40.2	[36.6, 43.6]	36.9	[34.2, 39.9]
6 months	39.8	[37.5, 41.9]	40.0	[36.4, 43.7]	39.6	[36.4, 42.7]
12 months	40.0	[37.6, 42.3]	40.6	[37.1, 44.2]	39.4	[36.5, 42.4]
Psychiatric distress (OQ-45)						
Baseline	97.6	[93.4, 101.3]	96.1	[89.9, 102.6]	99.0	[93.9, 104.5]

(*Continued*)

TABLE 2. (*Continued*)

	Overall		CAMS		E-CAU	
	% Any	Mdn > 0 [95% CI]	% Any	Mdn > 0 [95% CI]	% Any	Mdn > 0 [95% CI]
1 month	81.9	[77.0, 87.0]	80.4	[72.6, 87.9]	83.3	[75.5, 90.8]
3 months	76.5	[70.5, 82.8]	72.9	[63.7, 82.8]	80.2	[72.1, 88.1]
6 months	74.5	[67.6, 81.3]	72.4	[62.5, 82.0]	76.3	[67.9, 84.7]
12 months	71.1	[64.7, 78.1]	70	[60.5, 80.2]	72.2	[63.1, 81.7]
Resiliency (CD-RISC)						
Baseline	51.9	[49.1, 54.5]	52.0	[48.2, 56.1]	51.8	[48.0, 55.6]
1 month	55.8	[53.1, 58.4]	54.2	[50.3, 58.2]	57.5	[53.7, 61.1]
3 months	60.1	[56.9, 63.1]	58.4	[53.8, 62.8]	61.9	[57.7, 66.2]
6 months	61.8	[57.7, 65.5]	59.3	[53.5, 64.9]	64.3	[59.4, 69.4]
12 months	64.7	[61.2, 68.0]	64.5	[59.9, 69.3]	64.8	[60.0, 69.6]

Notes. Mdn > 0 = median of values greater than zero. CAMS = collaborative assessment and management of suicidality; E-CAU = enhanced care as usual; *M* = mean; CI = confidence interval; ED = emergency department; IPU = inpatient unit; SSI = Scale for SI; SASII = Suicide Attempt Self-Injury Interview; SF-36 = Medical Outcomes Study Short Form–36, version 2; OQ-45 = Outcome Questionnaire 45; CD-RISC = Connor-Davidson Resilience Scale.

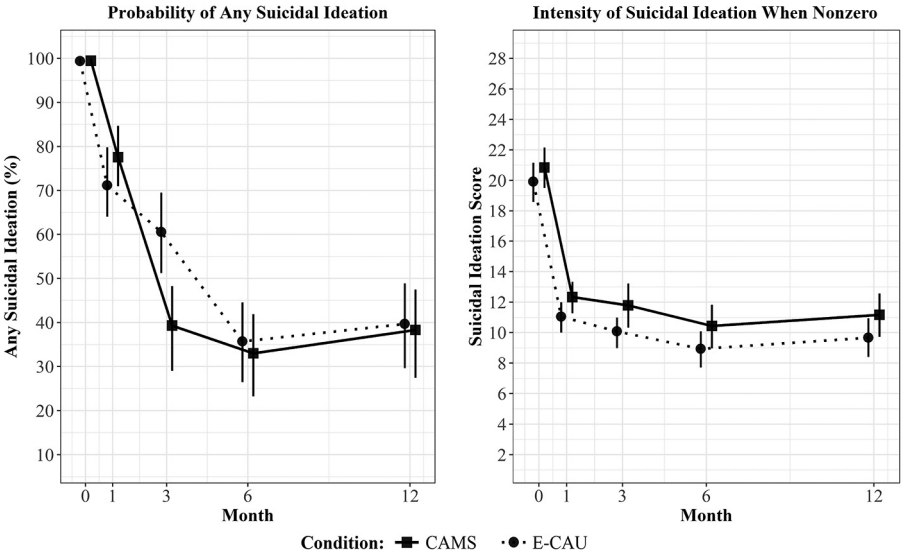

FIGURE 2. Experimental Main Effect on Suicidal Ideation (SI). Predicted probability and intensity of SI (SSI) at baseline, one, three, six, and 12 months by treatment condition (CAMS [collaborative assessment and management of suicidality] versus E-CAU [enhanced care as usual]). Nonoverlapping confidence intervals (CIs) correspond with a statistically significant difference at $p < .05$.

exceeded Cohen's (1988) $d = 0.80$ threshold for a large effect size. All postbaseline improvements in study outcomes within CAMS or E-CAU were statistically significant. There was no evidence of greater improvements over time in the CAMS condition compared with E-CAU (i.e., no statistically significant treatment

TABLE 3. Within-Condition Study Outcome Effect Sizes From Baseline (BL) to One, Three, Six, and 12 Months

	CAMS (n = 73)		E-CAU (n = 75)	
	d	*p*	*d*	*p*
Past-year suicide attempts (any)				
BL to 12 months	0.63	.066	1.17	.004
Suicide-related ED admits (any)				
BL to 1 month	1.94	< .001	1.29	< .001
BL to 3 months	1.39	< .001	2.04	< .001
BL to 6 months	1.21	< .001	1.48	< .001
BL to 12 months	1.14	.001	1.64	< .001
Behavioral health–related ED admits (any)				
BL to 1 month	1.60	< .001	1.15	< .001
BL to 3 months	1.16	< .001	1.61	< .001
BL to 6 months	0.93	< .001	1.57	< .001
BL to 12 months	1.05	.001	1.52	< .001
Suicide-related IPU days (any)				
BL to 1 month	1.56	< .001	1.27	< .001
BL to 3 months	1.02	< .001	1.89	< .001
BL to 6 months	0.82	.001	1.54	< .001
BL to 12 months	0.92	< .001	1.28	< .001
Behavioral health–related IPU days (any)				
BL to 1 month	1.63	< .001	1.27	< .001
BL to 3 months	1.08	.003	1.59	< .001
BL to 6 months	0.88	.017	1.54	< .001
BL to 12 months	0.98	.008	1.28	< .001
Mental health (SF-36)				
BL to 1 month	6.25	< .001	7.45	< .001
BL to 3 months	11.00	< .001	8.45	< .001
BL to 6 months	11.58	< .001	10.95	< .001
BL to 12 months	12.04	< .001	10.74	< .001
Psychiatric distress (OQ-45)				
BL to 1 month	4.08	< .001	3.66	< .001
BL to 3 months	5.17	.002	5.75	< .001
BL to 6 months	7.13	.008	7.36	< .001
BL to 12 months	7.69	.004	7.42	< .001
Resiliency (CD-RISC)				
BL to 1 month	2.52	< .001	1.31	.156
BL to 3 months	4.77	< .001	3.41	< .001
BL to 6 months	5.63	< .001	4.12	< .001
BL to 12 months	5.86	< .001	6.03	< .001

Notes. All Cohen's d effect size estimates were in the direction of improvement for all outcomes across all postbaseline assessment points. CAMS = collaborative assessment and management of suicidality; E-CAU = enhanced care as usual; ED = emergency department; IPU = inpatient unit; SF-36 = Medical Outcomes Study Short Form–36, version 2; OQ-45 = Outcome Questionnaire-45; CD-RISC = Connor-Davidson Resilience Scale.

by time effects) for intensity of SI, past-year SAs, suicide- or behavioral health–related ED admissions, suicide- or behavioral health–related IPU stays, mental health, resiliency, or overall psychiatric distress.

Secondary Intervention Adherence Analyses

A total of 29 participants in the CAMS condition had at least one therapy session that was rated for therapist adherence to the CAMS intervention. Adherence to CAMS ranged from 3.8 to 6, with an average adherence of 4.8 (SD = 0.4) on the 0 (*Poor*) to 6 (*Excellent*) scale (acceptable adherence = 3.0). There were no statistically significant associations between the degree of adherence to CAMS and the probability or intensity of SI or any other psychosocial outcomes.

DISCUSSION

Generally speaking, the experimental results of this RCT treating 148 suicidal active-duty Soldiers were largely unexpected, as *both* arms of the study demonstrated mostly comparable improvements over time across all outcome measures (i.e., generally large effects as per Cohen, 1988). There were significant and sustained postbaseline reductions in SI and SA behaviors across all follow-up assessments. Notably, CAMS reduced the probability of SI at three-month follow-up in comparision to E-CAU by 21 percentage points (Figure 2); however, this difference was not maintained at future time points. Nevertheless, these data replicate reductions in suicidal ideation seen in a previous military sample (Jobes et al., 2005) and underscore the virtue of focusing treatment on suicidal risk.

Beyond the greater reduction in SI likelihood by three months associated with CAMS, the within-group improvements from baseline to one-, three-, six-, and 12-month assessments were nearly all statistically significant with respect to SAs, suicide-related ED visits, behavioral heath–related ED visits, suicide-related IPU days, behavioral health–related IPU days, mental health, overall psychiatric symptom distress, and resiliency. In other words, Soldier-participants in this study reporting relatively high levels of SI at baseline improved and sustained their improvments across the board on all measures within both arms of the trial. Consequently, a rather stark floor effect emerged within some of the study outcomes (e.g., SAs), which made it difficult to detect significant differences. For example, there were nine recorded SAs among 148 suicidal participants, 114 of whom were followed across the entire follow-up period. Six of the nine SAs were in the CAMS condition, versus three of the nine in the E-CAU arm, a difference that was not statistically significant. This remarkably low incidence of SAs is in marked contrast to the number of attempts otherwise seen in comparable suicide RCT research of an Army sample (compare Rudd et al., 2015).

In addition, we saw no impact of adherence to CAMS having any differential treatment effect. This may be largely due to limited variability between the CAMS providers on the CRS (Corona, 2016). Indeed, we observed that each CAMS provider achieved adherence with their first Soldier within four sessions, and they remained adherent throughout the study with no drift. In addition, fidelity reviews of recordings of E-CAU providers did not suggest that key elements of the CAMS framework were implemented in the control arm.

Finally, we would like to address the limitations of the current study. As noted, participants improved within this trial regardless of the condition in which they were enrolled. After due consideration, we wonder if our efforts to increase the internal validity of this RCT may have inadvertently resulted in E-CAU being *too* enhanced. In hindsight, the care provided in E-CAU was perhaps influenced by the fact that all sessions were digitally recorded and potentially observed by the research team. In other words, it is possible that E-CAU was not truly "typical" clinical care that might otherwise be

routinely performed in the majority of military treatment facilities (e.g., a mental disorder focus versus a suicide-specific focus; refer to Department of Defense Task Force, 2010). While it is impossible to know whether this explantion for our findings is true, we nevertheless do know that this RCT was conducted with experimental rigor and high retention to follow-up. However, it should be noted that, in comparison to other suicide-specific treatment studies (e.g., Brown et al., 2005; Rudd et al., 2015), a 12-month follow-up period might have been simply too short of an assessment window to ascertain any potential impact on SA behaviors. Perhaps relying on a relatively high level of self-reported SI instead of recruiting those with a recent SA decreased our ability to detect SAs as a study-related outcome variable.

In conclusion, suicide is a major public health issue that affects the larger population and disproportionally impacts men and women who serve in our military. With few proven clinical treatments, it is vital that we continue to study suicide-specific care through rigorous RCTs. The OWL study endeavored to do so, and our findings, while mixed, make a case for CAMS to be further considered as an effective treatment for suicidal risk in military treatment faciliities.

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