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Adaptive disclosure, a combat-specific PTSD treatment, versus cognitive-processing therapy, in deployed marines and sailors: A randomized controlled non-inferiority trial

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ABSTRACT

Adaptive Disclosure (AD) is a new emotion-focused psychotherapy for combat-related PTSD. As a second step in the evaluation process, we conducted a non-inferiority (NI) trial of AD, relative to *Cognitive Processing Therapy – Cognitive Therapy* version (CPT-C), an established first-line psychotherapy. Participants were 122 U.S. Marines and Sailors. The primary endpoint was PTSD symptom severity change from pre- to posttreatment, using the Clinician Administered PTSD Scale for DSM-IV. Secondary endpoints were depression (Patient Health Questionnaire-9; PHQ-9) and functioning (Veterans Rand Health Survey-12; VR-12). For cases with complete data, the mean difference in CAPS-IV change scores was 0.33 and the confidence interval (CI) did not include the predefined NI margin (95% CI =-10.10, 9.44). The mean difference in PHQ-9 change scores was -1.01 and the CI did not include the predefined margin (95% CI = -3.31, 1.28), as was the case for the VR-12 Physical Component and VR-12 Mental Component subscale scores (0.27; 95% CI = -4.50, 3.95, and -2.10; 95% CI = -7.03, 2.83, respectively). A series of intent-to-treat sensitivity analyses confirmed these results. The differential effect size for CAPS-IV was $d = 0.01$ (nonsignificant). As predicted, Adaptive Disclosure was found to be no less effective than a first-line psychotherapy.

1. Introduction

Military-related PTSD can be uniquely and lastingly impairing (Kulka et al., 1990; Rodriguez et al., 2012; Thomas et al., 2010). In clinical efficacy trials, first-line exposure and cognitive psychotherapies have been shown to be less efficacious for military-related PTSD compared to other types of civilian trauma (chiefly trials of women with sexual assault-related PTSD; Kitchiner et al., 2019; Steenkamp et al., 2015, 2020; Watts et al., 2013), and their usage rates in routine care are low in the VA and the military (Rosen et al., 2016; Wilk et al., 2013), each arguably due to inadequately addressing the unique occupational/cultural context of the military and warzone exposure, and the multifarious and complex nature of combat-related PTSD. The psychotherapy we evaluated herein, *Adaptive Disclosure* (*AD*; Litz et al., 2017) was designed based on the clinical need for additional therapeutic options for military-related PTSD, featuring alternative change strategies and emphasizing the warrior ethos and the military culture.

Cultural relevance is a consideration in any psychotherapy, and the military should not be an exception. The military attracts people who typically want to serve, mandates an ethical code of conduct, and fosters intensely interdependent bonds and a shared warrior identity (Hoge, 2011; Litz et al., 2014; Nash and Figley, 2007; Nash and Litz, 2013). In

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the military, the personal life-threats and dangers that are the focus of existing psychotherapies are in many contexts occupational hazards and may be less harming than traumatic losses, and transgressive acts, otherwise known as *moral injury* (Litz et al., 2009). Failures to be responsible for others' safety, regardless of the circumstances, and high stakes transgressive acts evoke guilt and shame (Pivar and Field, 2004). Grief over fallen comrades is akin to losing a close family member and often leads to survivor guilt and complicated grief (Papa et al., 2008). The two most widely disseminated first-line treatments, prolonged exposure (PE; Foa et al., 2007) and cognitive-processing therapy (CPT; Resick et al., 2017), typically assume that because trauma-related beliefs are distressing, they are faulty or distorted constructions and the veracity of these beliefs needs to be challenged or contextualized (e.g., the fog of war; see Smith et al., 2013). Although this can be true and targeting overgeneralized inferences can be effective (e.g., self-blame associated with sexual assault in the military; see Wachen et al., 2017), this framework can be problematic because in the context of warzone loss and moral injury, there are instances in which culpability, responsibility-taking, and blame are not errant, but are intrinsically valid given the culture and the context (Gray et al., 2017; Papa et al., 2008; Steenkamp et al., 2013).

AD is a manualized psychotherapy that trains clinicians about the military culture and the warrior ethos and uses different experiential strategies to target danger- loss- and moral injury-related trauma, respectively (Litz et al., 2017). The latter feature is predicated on the foundational assumption that traumatic loss and moral injury are distinguishable from each other and from danger and personal victimization traumas (Litz et al., 2018), and each require a unique framework, understanding, and clinical approach. In collaboration with the Navy/Marine Corps, AD was also originally designed to be very brief (six sessions) to accommodate operational time-constraints. An open trial showed that AD was well-received, well-tolerated, and led to large effect size reductions in PTSD (Gray et al., 2012; Steenkamp et al., 2011).

Because of the wide-spread popularity and dissemination of existing first-line psychotherapies for PTSD in the military and in the VA, as a second step in the process of evaluating AD (culminating in future studies of its incremental validity), we sought to ensure that AD was not inferior to an existing evidence-based treatment for PTSD. In this paper, we describe a randomized non-inferiority (NI) trial of AD compared to an established first-line psychotherapy for PTSD, *Cognitive Processing*

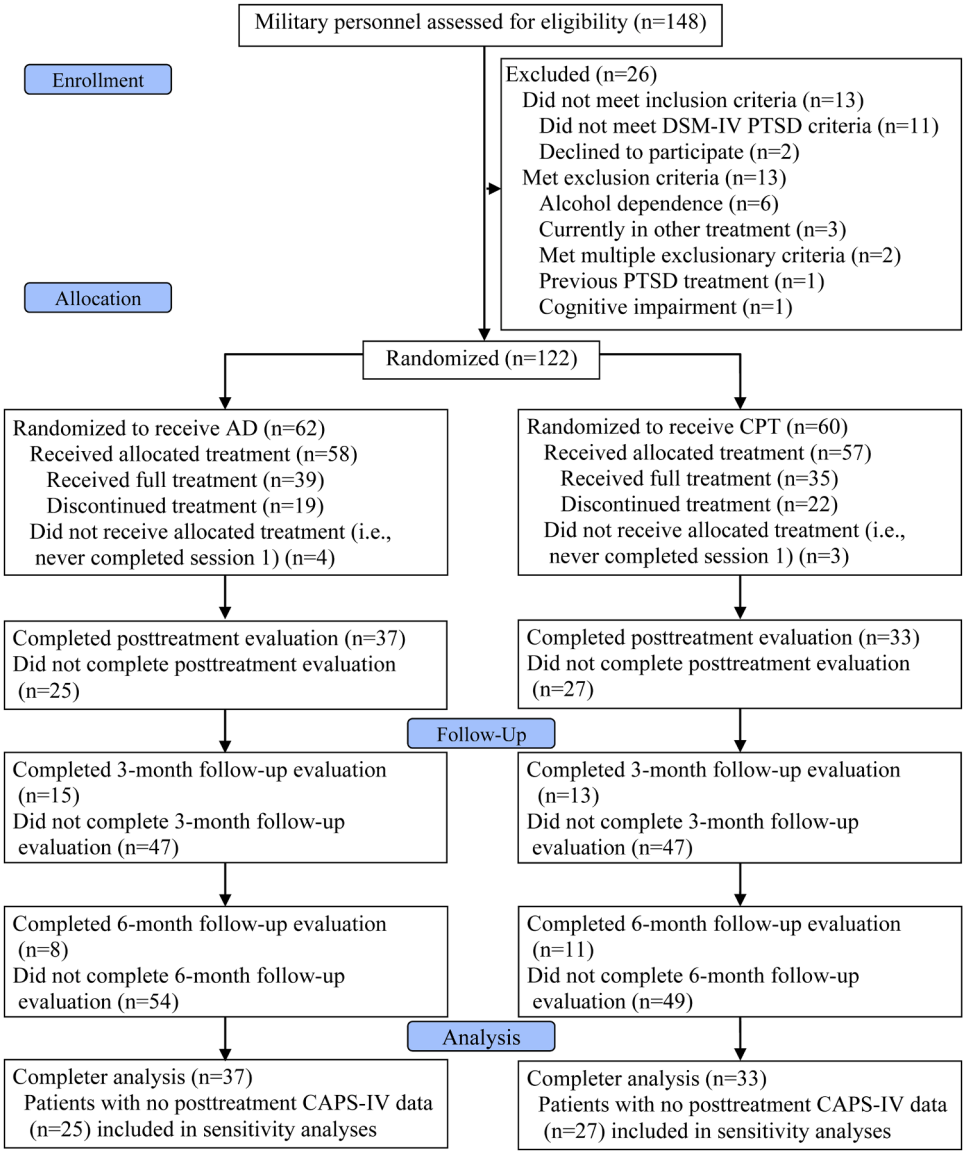

Fig. 1. Patient Flow Through Enrollment, Randomization, and Treatment
Note. We were not able to contact participants who have dropped out to determine reasons for doing so.

Therapy (Resick et al., 2017) – *Cognitive Therapy* version (CPT-C; Walter et al., 2014). We chose CPT-C after consulting with the developer of CPT/CPT-C, and because CPT-C is used in practice in the VA (e.g., Chard et al., 2011), and both AD and CPT-C attempt to address the meaning of trauma, but via distinctly contrasting means. The hypothesis was that AD would not be less efficacious than CPT-C. The primary endpoint was PTSD symptom change from pre- to posttreatment. Secondary endpoints were depression and functioning.

2. Methods

2.1. Participants

122 U.S. Marines/Sailors were randomized to receive AD or CPT-C (Fig. 1). Eligibility criteria were current DSM-IV PTSD (this trial occurred before DSM-5), active-duty status, and willingness to be treated for 8 or 12 weeks. Participants were screened with the Mini-International Neuropsychiatric Interview for DSM-IV (MINI; Sheehan et al., 1998) and they were administered a short battery of neuropsychological tests by a neuropsychologist (see supplemental document). Exclusion criteria were serious suicidality/homicidality, substance use disorder (patients who could demonstrate that they were recently or actively engaged in treatment for substance use and, in the judgment of a licensed clinician, could meaningfully engage in treatment and be sober for sessions and with respect to assigned homework tasks, were included), cognitive impairment (if a participant did not pass the neuropsychological screening battery, an experienced licensed neuropsychologist met with the patient to evaluate his or her ability to participate and whether there was a need for additional evaluation/intervention), current trauma-focused therapy, and past CPT. This study was approved by the IRBs at VA Boston and San Diego, which followed the Common Rule. Participants provided written and oral informed consent. Randomization/assignment (via a 1:1 sequence generated by blocks of six; three per arm) was generated by a technician and concealed from investigators, evaluators, and therapists.

This was the first trial conducted in the Marine Corps and the research faced recruitment, retention, and regulatory challenges common to psychotherapy trials conducted in military garrison settings. The trial was originally funded at the end of 2010, which meant that we were assessing and treating the DSM-IV iteration of PTSD. The trial faced long periods of military regulatory and performance site-related delays, which were unavoidable and out of our control (described in detail in the supplementary materials). Patients were not randomized into the study until the 3rd year of a 4-year grant. We were first granted no-cost extensions to continue the trial and then received new funding to complete the trial (the second grant period ended in early 2019).

2.2. Procedure

We followed consensus guidelines for PTSD trials (U.S. Department of Veterans Affairs Office of Research and Development, National Institute of Mental Health, and U.S. Department of Defense, 2008). This study had three therapists and each participant was assigned a therapist based on their treatment arm (therapists provided only one type of treatment; treatments were delivered face-to-face). Study therapists were post-doctoral psychologists without extensive experience treating war-related trauma and PTSD. Each therapist received weekly hourly clinical supervision by experts in the two therapies (see supplemental document for fidelity ratings).

Participants were referred by mental health providers, and following consent, completed a battery of questionnaires to determine eligibility. Eligible participants completed a baseline assessment and a clinician-rated assessment of their PTSD symptoms with an independent evaluator, and these assessments were audio-recorded. CPT-C was delivered in 12 h-long weekly sessions; to equilibrate the number of treatment hours, we expanded AD from six to eight 90-minute weekly sessions. At baseline and at posttreatment, the CAPS-IV was audio recorded. Before treatment sessions, participants completed an abbreviated assessment battery to monitor symptoms. The full assessment battery was repeated at post-treatment. Three- and six-month follow-up assessments were attempted, but few service members were available for follow-up. To reduce burden, these follow-ups included only the paper and pencil measures.

2.3. Treatments

AD employs emotion-focused, experiential change-agents designed to target the unique sequelae of life-threat, traumatic loss, and moral injury. The manual includes sections on the military culture and warrior ethos, and how and why traumatic loss and moral injury are uniquely harmful. AD uses an imaginal narrative of a focal trauma, not as a means of extinguishing conditioned fear, but as a vehicle to uncover and disclose previously unacknowledged aspects of a trauma and its meaning and implication. Modification via experience of these "hot cognitions" is the main change agent for danger-based traumas. AD employs Gestalt therapy techniques (Paivio and Greenberg, 1995) to help service members experience and process traumatic loss and moral injury, and to help find paths to healing and repair. For traumatic loss, the patient has evocative real-time dialogues (in imagination) with the lost service member. Emphasis is placed on moving forward or carrying on in a manner that honors and commemorates the fallen. A typical theme that arises for loss is the mandate to live a good life is the best way to honor the lost person. For moral injury, patients engage in an imaginal dialog with a compassionate and forgiving moral authority. Patients are also asked to share what the other's reaction is to what they just heard. In subsequent sessions, the experiential dialog is used as an opportunity for the patient to articulate what the other would say if they could about how the patient should proceed in their life. For personal moral transgressions, a common theme is the expression of alarm and disappointment but a mandate to make amends, repair damage done, and contextualize the event in the scope of a life that includes goodness. For betrayal-based moral injury, a common theme entails expressions of anger and solidarity but also a wish for the patient to move on by allowing goodness to occur around him or her. These experiential dialogues are akin to secular confessions, aiming to challenge guilt, shame, and self- and other-condemnation. Homework is assigned to engage in corrective healing and repairing life experiences (e.g., giving back, amends-making).

CPT-C omits the written trauma narrative utilized in CPT. CPT-C helps patients identify how their trauma has changed their thoughts and beliefs, particularly about safety, trust, intimacy, power and self-esteem. CPT-C addresses ways of thinking that keep individuals symptomatic and suffering ("stuck points") and that interfere with recovery. In addition to Socratic dialogues, CPT-C uses homework to help patients learn the connection between thoughts and emotions and to work on modifying appraisals (Walter et al., 2014).

2.4. Measures

Demographic and military service characteristics information were collected with a standardized self-report form.

2.4.1. Primary endpoint: PTSD

This trial began before DSM-5. The Clinician-Administered PTSD Scale for DSM-IV (CAPS-IV; Blake et al., 1995) is the gold standard semi-structured interview that assesses frequency and intensity of the 17 PTSD symptoms over the past month. The CAPS-IV yields a diagnostic and a total severity score (the sum of frequency and intensity ratings). The CAPS-IV has demonstrated strong psychometric properties (Weathers et al., 2001). The internal consistency reliability in our sample was 0.85.

The PTSD Checklist, Military Version (PCL-M; Weathers et al., 1993)

was used to cross-validate the interview findings. It is a 17-item self-report measure of DSM-IV PTSD symptoms over the past month. The PCL-M was administered at baseline, at every session, and at follow-up assessments. The PCL-M has excellent psychometric characteristics (Bliese et al., 2008). The internal consistency reliability in our sample was 0.89.

2.4.2. Secondary endpoint: Depression

The Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001) is a 9-item self-report measure of the severity of depressive symptoms over the past 2 weeks, with higher scores indicating greater depression severity. Items were rated on a 4-point Likert scale from 0 to 3, and the PHQ-9 was administered at baseline, every session, and follow-up. The PHQ-9 has excellent test-retest reliability, internal consistency, and construct validity (Kroenke et al., 2001). The internal consistency reliability in our sample was 0.86.

2.4.3. Secondary endpoint: Functioning

The Veterans RAND 12-Item Health Survey (VR-12; Kazis et al., 2006) was used to index the impact of physical and mental health on functioning. The VR-12 consists of Physical Component (PCS) and Mental Component (MCS) subscales. Of the 12 items, 10 are rated on a 5-point Likert scale, and two are rated on a 3-point Likert scale. It includes fewer items for seven of the eight scales, relative to the SF-36 but provides 90% of the reliable variance in the two component summary measures (Selim et al., 2009). The internal consistency reliability of the PC and MC subscales in this trial were 0.85 and 0.79, respectively.

2.4.4. Credibility and expectancy

We used a modified version of the original 6-item Credibility and Expectancy Questionnaire (CEQ), which is comprised of questions that assess participants expectancy that the treatment could help them and how credible the treatment is in their minds (Devilly and Borkovec, 2000). Our shortened (4-item) scale was administered only at baseline and was modified slightly so that the language would fit the military culture. The internal consistency reliability in our sample was 0.91.

2.5. Power calculation and data analysis plan

2.5.1. Sample size

For the sample size calculation, we used the Study Size program, Version 2.0.4 and a standard deviation of 25 on the CAPS-IV, based on a CPT trial with veterans (Monson et al., 2006). If the true difference between AD and CPT is 0 points, then we needed 99 participants per group, or roughly 200 participants, to ensure power = 0.80.

2.5.2. Non-inferiority tests

We examined the predicted difference in mean change between AD and CPT-C. If the 95% confidence interval (CI) around the estimate does not contain the NI margin, we can reject the null hypothesis (that AD is inferior to CPT-C). The NI margin for CAPS-IV scores was established a priori, based on a calculation of a reliable difference from baseline to posttreatment CAPS-IV scores from a previous trial (10 points [Monson et al., 2006]; the same margin was also used in a recent NI trial of a psychotherapy for PTSD [Sloan et al., 2018]). The NI margins for other outcomes were generated using the *Reliable Change Index* (RCI; Jacobson and Truax, 1991; see Supplemental document for a detailed explanation of the RCI). Although the RCI threshold for CAPS-IV in this trial was 22 points, we appealed to precedent and used the 10-point differential, which is a more conservative NI test. The RCI-based NI margins for the PCL-M and the PHQ-9 was 12 and 7 points, respectively. The NI margins for the VR-12 PC and MC was 12 points and 8 points, respectively.

Consistent with standard recommendations for NI trials, we first conducted linear regression analyses (SAS Software version 9.4) to predict the effects of treatment on mean change score (one-tailed 0.05 alpha), controlling for baseline scores, using participants with complete post-treatment data (Fleming et al., 2011). We also modeled time (days) since the start of the trial. Although the study was powered for pre- to posttreatment change, we conducted exploratory analyses of available follow-up data.

A significant proportion of participants did not complete the post-treatment evaluation (see Fig. 1). We performed a series of post-hoc intent-to-treat sensitivity analyses to assess the robustness of the results (National Research Council Panel on Handling Missing Data in Clinical Trials, 2010). For the CAPS-IV, the first analysis multiply imputed CAPS-IV scores based on participants' last PCL-M score if they attended at least half of the sessions (*Final PCL-M Score* in Fig. 2). The second analysis employed a series of preemptive imputations of all missing within treatment PCL-M scores (*Sequential PCL-M Score*), which were then used to multiple impute the CAPS-IV scores. In the third analysis, multiple imputation was used to simulate posttreatment CAPS-IV scores based on baseline covariates (age, race, CEQ scores, highest level of education, and baseline CAPS-IV scores; *Full Imputation*). Because completers in the CPT-C arm had lower mean baseline CAPS-IV scores than non-completers (72 vs. 81, Cohen's $d = 0.49$), a fourth imputation analysis imputed conditional posttreatment CAPS-IV scores for the CPT-C arm to reflect the higher propensity for dropout (*CPT-C Conditioned*).

For the PCL-M, we first calculated the change score as the final PCL-M score minus the baseline assessment score for the subset of participants that attended at least half the therapy sessions. The first sensitivity analysis used multiple imputation to obtain a plausible set of values for the participants missing final PCL-M scores that also did not attend at least half the sessions. We also predicted the missing final PCL-M change scores with baseline PCL-M scores, using the same set of variables. Because there is inherent variability in creating a change value from the final recorded PCL-M score of each participant given differing number of total sessions attended, we also performed a multiple imputation analysis that incorporated sequential imputations of missing PCL-M scores prior to imputing a score. We performed a series of regressions that predicted missing PCL-M scores per session as a function of the scores of the previous two measurements, as well as the characteristics used in the previous model. The final regression produced an imputed change score

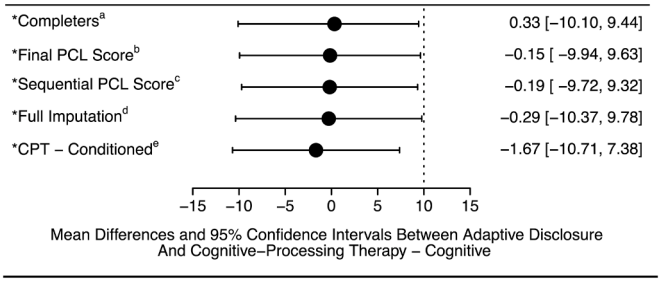

Fig. 2. Non-inferiority Results Between Treatment Arms for CAPS-IV Change Scores from Baseline and Posttreatment

[a]The analysis results comprised of study completers with non-missing baseline and posttreatment CAPS-IV scores.

[b]The analysis results inferred from posttreatment CAPS-IV imputation based on the Final PCL-M scores of subjects who attended at least half of total therapy sessions.

[c]The analysis results inferred from posttreatment CAPS-IV imputation based on final PCL-M scores sequentially imputed from the previous session scores.

[d]The analysis results inferred from posttreatment CAPS-IV imputation based on baseline CAPS-IV scores, Expectancy and Credibility score, age, educational attainment, and race.

[e]The analysis results inferred from posttreatment CAPS-IV imputation from the baseline and demographic characteristics conditioned upon the scores of the CPT-C cohort.

*Indicates the analyses that comprise the sensitivity analysis testing the robustness of the results of the completers analysis.

using the intent-to-treat sample.

For the PHQ-9, the completer analysis used the final PHQ-9 score as the final session's measurement for those participants that attended at least half of their respective cohort's total sessions. The sensitivity analyses mirrored those of the PCL-M. For the two VR-12 subscales, completer analyses used participants with posttreatment scores. A multiple imputation sensitivity analysis simulated missing posttreatment PC and MC scores from the same set of variables described above.

2.5.3. Benchmarking clinical significance

Consistent with recent PTSD trials of service members (Litz et al., 2019), we categorized the clinical significance of CAPS-IV change and endpoint scores *for each participant* in each arm (Jacobson and Truax, 1991, see Supplemental materials for further explanation). Participants that exceeded the RCI threshold (≥ 22-point change from baseline) were categorized as "improved." Participants who exceeded the RCI *and* whose posttreatment end-state score was two SD below the mean baseline score for the trial were categorized as "recovered" (see Supplemental document). If change did not exceed the RCI, participants were categorized as "no-change." Posttreatment scores that were higher and outside the RCI were categorized as "deteriorated." We also generated *intent-to-treat* benchmarks using these criteria by assigning patients who had missing posttreatment scores to the "no-change" category.

3. Results

3.1. Participant characteristics

Table 1 shows the demographic characteristics of the study group. Participants were mostly male (91.7%) and Caucasian (63.11%) with a mean age of 29.80 (SD = 6.39). There were no differences between the arms on any demographic characteristic (see Table 1), nor baseline or post-treatment CAPS-IV scores (see Table 2 for a summary of all baseline and posttreatment results).

3.2. Non-inferiority findings

If service members were available to be interviewed at posttreatment (completers), they attended all the requisite sessions in each arm of the trial. Fig. 2 shows the results of the NI analyses of CAPS-IV change scores from pre- to posttreatment. The Figure shows that the 95% confidence interval (CI) around the estimate of the predicted difference in mean CAPS-IV total severity score change between AD and CPT-C does not contain the NI margin. This signifies that AD is non-inferior to CPT-C, as predicted. Fig. 2 also shows the results of the sensitivity analyses, which confirmed the robustness of the completer analysis. Moreover, the PCL-M findings replicated the CAPS-IV findings. The estimated mean difference in PCL-M score change between AD and CPT-C was 3.88 [95% CI = −1.56, 8.32] (t_{85} = *2.90, p-value = 0.002)*. The confidence interval did not contain the NI margin. The test-statistics associated with the NI analysis (corresponding to the NI margin) were (t_{85}, p-value = 0.002), indicating statistically significant NI findings. The imputation of posttreatment PCL-M scores resulted in an estimated mean difference of 3.79 [95% CI = −1.37, 8.95]. The estimated mean difference in PCL-M change scores based on sequential PCL-M imputations of missing session values (in addition to baseline score and demographic characteristics) was 2.85 [95% CI = −2.62, 8.31].

The estimated mean difference in PHQ-9 scores was −1.01 [95% CI = −3.31, 1.28] (t_{83} = *5.36, p-value <0.001)*. The imputation of posttreatment PHQ-9 scores resulted in an estimated mean difference of −0.41 [95% CI = −2.61, 1.79]. Imputing posttreatment PHQ-9 scores from sequential imputations of missing session values (in addition to baseline score and demographic characteristics) resulted in an estimated mean difference of −1.23 [95% CI = −3.70, 1.24]. Each result satisfied the conditions of NI.

The estimated mean difference in VR-12 PC change scores was −0.27 [95% CI = −4.50, 3.95] (t_{61} = *4.74, p-value < 0.001)*. The imputation of posttreatment VR-12 PC from baseline score and demographic characteristics resulted in an estimated mean difference of 0.18 [95% CI = −3.74, 4.10]. The estimated mean difference in VR-12 MC was −2.10 [95% = −7.03, 2.83] (t_{61} = *2.45, p-value = 0.009)*. The imputation of posttreatment VR-12 MC from baseline scores and demographic characteristics resulted in an estimated mean difference of 0.31 [95% CI =

Table 1
Comparison of Demographic Characteristics Between Therapy Arms (N = 122).

Demographic Characteristic	Total Sample % (n)	AD (N = 62) % (n)	CPT-C (N = 60) % (n)		*t, χ2*	*DF*	*p-value*
Gender							
	Male	91.7 (110)	91.8 (56)	91.5 (54)	0.003	1	1.00[a]
Age[b]							
		29.80 (6.39)	30.30 (6.43)	29.29 (6.38)	−0.860	120	.39
Education							
	Some High School/High School Diploma/GED	38.52 (47)	38.71 (24)	38.33 (23)	0.001	1	97[a]
	Some Higher Education	61.48 (75)	61.29 (38)	61.67 (37)			
Race							
	White	63.11 (77)	66.13 (41)	60.00 (36)	0.492	1	.48[a]
	Nonwhite	36.89 (45)	33.87 (21)	40.00 (24)			
Marital Status							
	Currently/Previously Married	71.31 (87)	64.52 (40)	78.33 (47)	2.855	1	.09[a]
	Never Married	28.69 (35)	35.48 (22)	21.67 (13)			
Income							
	<$50,000	68.00 (83)	63.33 (38)	72.58 (45)	1.199	1	.27[a]
	$50,000+	32.00 (39)	36.67 (22)	27.40 (17)			
Military Rank							
	Enlisted	97.54 (119)	98.38 (61)	96.67 (58)	0.376	1	.53[a]
	Officer	2.45 (2)	0.08 (1)	3.33 (2)			
Number of previous deployments							
	0–2	59.02 (72)	58.06 (36)	60.00 (36)	0.047	1	.83[a]
	3+	40.98 (50)	41.94 (26)	40.00 (24)			

Note. AD = Adaptive Disclosure. CPT-*C* = Cognitive Processing Therapy, Cognitive Only.

[a] P-value represents the result from chi-square tests.

[b] Values reported are means and standard deviations (instead of percentages and n's, respectively). P-value represents the result from independent samples *t*-test. Otherwise, p-values represent the results from chi-square tests.

Table 2
Treatment Arm Comparisons at Baseline and Posttreatment.

Measure	AD		CPT-C		Independent Samples *t*-test			
	M	SD	M	SD	*Est.*	*t-value*	*DF*	*p-value*
Pre-treatment								
Primary Endpoints								
CAPS-IV	74.58	19.25	76.53	18.43	−1.96	0.57	120	0.57
PCL-M	63.00	11.45	62.47	11.06	0.53	−0.26	120	0.79
Secondary Endpoints								
PHQ-9	15.42	5.86	16.16	7.11	−0.73	0.62	118	0.54
VR-12 Mental Health Scale	28.61	11.45	30.63	12.23	−2.01	0.91	112	0.37
VR-12 Physical Health Scale	48.05	12.49	46.36	12.07	1.70	−0.74	112	0.46
Covariates								
CEQ	23.72	5.35	22.74	7.67	0.98	0.28	67	0.44
Post-treatment								
Primary Endpoints								
CAPS-IV	56.89	28.12	53.33	31.68	−3.56	−0.50	68	0.62
PCL-M	56.49	15.98	50.08	18.56	−6.40	−1.60	73	0.11
Secondary Endpoints								
PHQ-9	12.90	6.56	13.39	8.10	0.49	0.29	73	0.77
VR-12 Mental Health Scale	33.08	12.89	37.07	12.04	3.99	1.28	63	0.21
VR-12 Physical Health Scale	44.82	14.05	43.92	12.04	−0.90	−0.27	63	0.79
Covariates								
CEQ	24.58	3.57	24.84	4.10	0.26	0.28	67	0.78

Note. AD = Adaptive Disclosure. CAPS = Clinician Administered PTSD Scale. CEQ = Credibility and Expectancy Questionnaire. CPT-*C* = Cognitive Processing Therapy, Cognitive only. *M* = mean. PCL-*M* = PTSD Checklist Military Version. PHQ = Patient Health Questionnaire. SD = standard deviation. VR-12 = Veterans RAND 12-item Health Survey.

−4.36, 4.97]. Each result satisfied the conditions of NI.

3.2.1. Exploratory follow-up results

Attempts were made to follow-up with service members once per month (with questionnaires) for six months until it became clear that this was untenable due to compliance and availability. Using the PCL-M, we examined NI for the three- and six-month follow-up sessions to attempt to replicate the pre-post results with the service members who could be followed (the per arm N for the three month follow-up was CPT = 17, AD = 8; the per arm N for the six month follow-up was CPT = 13, AD = 5). The estimated difference in mean PCL-M change from baseline to the three-month follow-up was approximately −1.63 [95% CI = −14.7188, 11.4587] (t_{21} = *2.59, p-value = 0.009)*. The estimated difference from baseline to the six-month follow-up was approximately 1.55 [95% CI = −8.8970, 11.9896] (t_{21} = *2.45, p-value = 0.010)*, each supporting NI. Given the small sample size at each follow-up, sensitivity analyses could not be conducted.

3.2.2. Clinical significance

The effect size for the difference in CAPS-IV change scores between the two treatment arms was $d = 0.01$ [95% CI = −0.46, 0.48]. The effect size for the magnitude of CAPS-IV change, between baseline and post-treatment, for the entire sample was $d = 0.91$ [95% CI = 0.59, 1.22]. The rates of recovered, improved, no-change, and worsened are presented in Table 3. For the intent-to-treat sample, 24% of participants in the AD arm and 25% of the participants in the CPT-C arm improved or recovered. For completers, these rates were 41% and 45%, for AD and CPT-C, respectively.

3.2.3. Attendance and dropout

We defined dropout as missing the last treatment session (Applied Clinical Trials Editors, 2011). 37% of patients in the AD arm and 40% of patients in the CPT-C arm dropped out (χ^2= *0.10, p-value = 0.741*). Patients in the AD arm attended a mean of 75% of the eight sessions and patients in the CPT-C arm attended a mean of 71% of the twelve sessions (t_{120}= *−0.61, p-value = 0.543*).

3.2.4. Adverse events

Serious adverse events were rare and due to psychiatric emergencies (AD=2; CPT-*C* = 1). There was a total of 18 adverse events (11 in the AD arm and 7 in the CPT-C arm). Of these, increased psychiatric symptoms appeared to be study related (AD=5; CPT-*C* = 1).

Table 3
Benchmarks for Clinical Significance of CAPS Scores.

	Intent to treat (*N* = 122)			
	Recovered% (*n*)	Improved% (*n*)	No Change% (*n*)	Deteriorated% (*n*)
AD (*N* = 62)	17.74 (11)	6.45 (4)	75.80 (47)	0 (0)
CPT (*N* = 60)	13.33 (8)	11.67 (7)	75.00 (45)	0 (0)
	Completers (*N* = 70)			
	Recovered% (*n*)	Improved% (*n*)	No Change% (*n*)	Deteriorated% (*n*)
AD (*N* = 37)	29.73 (11)	10.80 (4)	59.45 (22)	0 (0)
CPT (*N* = 33)	24.24 (8)	21.21 (7)	54.54 (18)	0 (0)

Note: See Supplemental document that describes the Reliable Change Index (RCI; which if met, defines *Improved*), the 2SD threshold for endpoint scores, which if met along with the RCI, defines *Recovered. No-change* is defined as not meeting the RCI threshold. *Deteriorated* is defined as change scores that show worsening, exceeding measurement error (the absolute value of RCI).

4. Discussion

We conducted a randomized controlled trial in the Navy and Marine Corps, treating Sailors and Marines with PTSD, to determine if AD, a new emotion-focused psychotherapy for combat-related PTSD, was not less efficacious than CPT-C, a well-studied first-line evidence-based cognitive therapy for PTSD. The trial results supported our prediction that AD is not inferior to CPT-C. Across the primary endpoints (PTSD, as assessed by CAPS-IV and PCL-M severity scores) and two secondary endpoints (depression and functioning), AD was found to be non-inferior to CPT-C. The per-protocol results were confirmed with a series of post-hoc intent-to-treat sensitivity analyses.

The benchmark analyses showed that the percentage of completers that recovered or improved in AD and CPT-C were impressive. In comparison to the only other randomized controlled trials conducted in the military to date, the rates of clinically significant change among completers in this trial (Mean across arms = 43%) were higher than the percent of completers who improved or recovered in the *South Texas*

Research Organizational Network Guiding Studies on Trauma And Resilience (STRONG STAR) trials, which tested the efficacy of PE and CPT in three separate trials, treating soldiers with PTSD at Ft. Hood (the combined rate of recovery or improvement among completers across the three STRONG STAR trials was 31%; Litz et al., 2019). The percent of the intent-to-treat samples who either improved or recovered in each arm in this trial (Mean = 25%) also appear to be slightly higher than the intent-to-treat results for the STRONG STAR trials (21%; Litz et al., 2019). Our completer-based indices of clinically significant change appear to be comparable to a VA cooperative study of PE (which was 39%; Schnurr et al., 2007), yet, our rates of recovery or improvement for the intent-to-treat samples was lower than the VA cooperative study (which was 32%).

There are several noteworthy limitations to this trial. The power of the study was lower than planned. This means that the standard errors estimated in the models tested with 122 participants are likely larger than in a theoretical study with the original N estimated to power the trial ($N = 200$). However, this does not change the interpretation of the results. In particular, with a larger sample size, we would expect tighter confidence intervals around the estimated differences between outcomes in the AD and CPT-C arms, and therefore, stronger evidence supporting non-inferiority of AD to CPT-C. The trial was powered to test differences between AD and CPT-C with posttreatment endpoints only because we assumed that a variety of logistical and motivational limitations would make it difficult for service members to attend follow-ups. As anticipated, only a small percentage of Marines/Sailors were available for follow-up. We conducted post-hoc tests of the hypotheses with the available follow-up data and these confirmed that AD was non-inferior to CPT-C but these results require replication with a higher percentage of completers. We also encountered a significant problem with missing posttreatment data, yet all the intent-to-treat sensitivity analyses validated the completer findings. Recent clinical trials testing PTSD therapies among service members treated in garrison have also struggled with dropout and low follow-up rates. In the three STRONG STAR trials, 31% of soldiers dropped out of treatment (81% of therapy sessions were attended; Berke et al., 2019); the percentages of soldiers with missing posttreatment data were: 9%, 27%, and 29%, and the percentages missing six-month follow-up data in the three trials were 30%, 47%, and 50%. It appears that treating service members with demanding multisession psychotherapies entails difficulties getting service members to commit to or to be available for follow-ups. Future trials should account for the reasons for dropout and generate solutions (e.g., telehealth) that will increase the validity of results. Furthermore, these trial results may not generalize to service members in other branches or veterans.

Finally, there were a greater number of study-related psychiatric symptom exacerbation adverse events in the AD arm (5), relative to CPT-C (1). Although each of these adverse events occurred in less than 1% of Marines and Sailors treated in each arm and these results need to be replicated, the raw tallies suggest that AD may be associated with symptom worsening in some patients, relative to cognitive therapy. Relative to CPT-C, AD is an uncovering, experiential, and emotion-focused treatment and consequently these divergent symptom exacerbation findings are to some extent expected. In one study that examined symptom exacerbations associated with PE, also an emotion-focused treatment, Foa et al. (2002) found that 10% of women sexual assault survivors had significant exacerbation of PTSD symptoms. In this trial, the AD therapists prepared patients for the treatment in part by providing accurate expectations about the possibility that because the treatment entails focusing on painful content, sometimes patients can feel worse before they get better (and therapists collaborated with their patients in being vigilant about monitoring symptoms over the course of treatment). Yet, notwithstanding the good clinical practices in place with respect to potentially terminating a patient's participation in the trial and getting him or her the help they need to address very concerning symptom exacerbations, unlike in clinical practice, therapists in clinical trials do not have the latitude to shift gears to another approach or treatment target when patients symptoms significantly worsen (nor when there is no sign of clinically significant change). *In practice*, therapists who treat PTSD patients with AD should conduct measurement-based care by assessing PTSD and Depression (at a minimum) before each session and use shared decision-making to discuss the need to shift focus and target a potentially pressing matter that is principally causing clinically significant symptom exacerbation.

Notwithstanding the limitations noted above, the results suggest that AD, which required a smaller number of weekly sessions (8), is not inferior to CPT-C, which entailed 12 sessions. Yet, both therapies led to equally clinically significant changes in symptoms of PTSD and Depression over the course of treatment. Whether AD is attractive as a treatment option will depend on clinician and patient judgment about the length, approach, scope, and fit of the treatment. A superiority trial is needed to test whether AD is more efficacious than other treatments (we have a trial that is underway; Yeterian et al., 2017). Ultimately, because the field needs to move to a personalized care approach (Litz et al., 2019), future research is also needed to determine which patients may benefit most from AD, relative to existing first-line treatments.

The data analysis for this paper was generated using SAS software. Copyright © 2013 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

Data availability

Deidentified data that support the findings of this study are available on request from the corresponding author.

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Author statement

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Declarations of Competing Interest

none.

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Supplementary materials

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