Title
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Journal
Psychological Trauma Theory Research Practice and Policy, 13(8)

ISSN
1942-9681

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Publication Date
2021-11-01

DOI
10.1037/tra0000634

Peer reviewed

Published in final edited form as:
Psychol Trauma. 2021 November ; 13(8): 920–928. doi:10.1037/tra0000634.

Does Exposure Exacerbate Symptoms in Veterans with PTSD and Alcohol Use Disorder?

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Abstract

Objective: Patients with posttraumatic stress disorder (PTSD) and alcohol use disorder (AUD) are often not offered exposure therapy for PTSD due to concerns that symptoms may worsen. This study examined whether initiating exposure would cause exacerbation of PTSD, alcohol use, depression, or suicidal ideation (SI) among patients with PTSD/AUD participating in exposure therapy for PTSD.

Method: Veterans were randomized to either Concurrent Treatment of PTSD and Substance Use Disorders Using Prolonged Exposure (COPE) or Seeking Safety (SS), a non-exposure intervention, and were included in this study if they had data to at least session 5 available (n=81). They completed measures of PTSD, alcohol use, and depression/SI symptom severity throughout treatment and posttreatment. The reliable exacerbation method examined the number of participants who demonstrated clinically meaningful symptom exacerbation from session 3 to 5 (capturing the pre-post window for the start of exposure in COPE). Hierarchical/logistic

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regressions examined whether treatment condition predicted exacerbation of symptoms. T-tests/chi-square analyses examined whether clinical exacerbation led to worse posttreatment outcomes.

Results: Few participants endorsed exacerbation in symptoms of PTSD (15.8%), alcohol use (5.1%), depression (10.2%), or SI (12.8%). No significant treatment condition differences existed. Participants who experienced symptom exacerbation had higher rates of depression posttreatment compared to those who did not experience symptom exacerbation, but there were no differences in PTSD, alcohol use, or SI.

Conclusions: Exposure therapy did not lead to more clinical exacerbation than non-exposure therapy during the course of treatment, providing support that exposure therapy should not be withheld from patients with PTSD/AUD. This was a secondary analysis and future studies that are sufficiently powered may demonstrate different results.

Keywords

Posttraumatic stress disorder; Alcohol use disorder; Prolonged Exposure; Clinical Worsening; Symptom Exacerbation

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Although prolonged exposure (PE; Foa, Hembree, & Rothbaum, 2007) is one of the most efficacious and effective treatments for posttraumatic stress disorder (PTSD; Kline, Cooper, Rytwinksi, & Feeny, 2018; Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010), PE has what some call a “public relations problem” (Larsen, Stirman, Smith, & Resick, 2016). Even in settings like the Veterans Administration (VA) where extensive resources have been spent on training providers in PE, implementation is low. One study found that within six different VA specialty PTSD clinics, only 6.3% of new patients received either PE or cognitive-processing therapy (CPT), another evidence-based trauma-focused treatment (Shiner et al., 2013). Despite its effectiveness, one reason for poor implementation of PE is that providers may be wary of trauma-focused treatments, particularly exposure, due to concerns that it may exacerbate symptoms, cause patients to decompensate, or lead patients to dropout of treatment (Cook et al., 2013; Ruzek et al., 2017).

Studies that have tested such clinician concerns regarding PE have not found them to be accurate. Indeed, findings suggest that when PE is implemented in an outpatient setting, symptom exacerbation is rare and not associated with worse treatment outcomes or treatment dropout in patients with PTSD. One study of women who had experienced assault found that imaginal exposures led to an increase in PTSD, general anxiety, and depression symptoms in only a small number of participants who engaged in imaginal exposures (10.5%, 21.1%, and 9.2%, respectively); however, those who experienced an increase in symptoms showed similar benefit from treatment and symptom increase was unrelated to dropout from treatment (Foa, Zoellner, Feeny, Hembree, & Alvarez-Conrad, 2002). Specifically, 15% of those who showed an exacerbation in symptoms dropped out prior to session 9 compared to 16.7% of those who did not show exacerbation. Larsen and colleagues (2016) found no significant differences in PTSD symptom exacerbation among women completing PE, CPT with written trauma narrative, or CPT without the written trauma narrative (20.0%, 28.6%, and 14.7%, respectively). Additionally, no treatment condition differences existed in those who dropped out of treatment prior to session 4

(13% in CPT without written trauma narrative; 16% in CPT with written trauma narrative; 19% in PE). Those who experienced symptom exacerbation had higher posttreatment PTSD symptoms and were more likely to retain a PTSD diagnosis than those without symptom exacerbation (with small effects), although they still showed clinically significant improvement of PTSD symptoms by posttreatment. A recent study examined reliable exacerbations in PTSD, SUD, and depression symptoms between veterans receiving COPE or relapse prevention (RP; Lancaster et al., 2019). Symptom worsening was minimal and equally likely to occur in either COPE or RP at each of the 12 sessions. Of those who completed treatment, individuals in RP experienced slightly more exacerbations of PTSD symptoms throughout treatment. Additionally, of those who attended at least one treatment session, condition differences did not exist between COPE and RP in dropout prior to completing all 12 sessions.

Concerns about suicidal ideation (SI) and attempts may also act as a barrier to offering trauma-focused treatments such as PE. One study found that 45% of clinicians with experience and 75% without experience using PE endorsed suicidality as a likely complication to arise from using PE (Becker, Zayfert, & Anderson, 2004). However, empirical studies exist that dispute this claim. In a study of veterans receiving PE within PTSD specialty clinics across several VA medical centers, SI decreased over the course of treatment (Cox et al., 2016). Bryan and colleagues (2016) found that completing either group CPT or group present-centered therapy led to significant decreases in SI for active duty military personnel, and those improvements were maintained for up to 12 months posttreatment. Additionally, worsening of preexisting SI and presence of new-onset SI was rare and occurred similarly in both treatments.

Given the extent of clinician concerns about PE, it is not surprising that clinicians may be even more wary of offering PE to patients with comorbid substance use disorders (SUDs; Becker et al., 2004). One common concern is that asking patients with this comorbidity to engage in exposure when they are still using or recently abstinent may make them increase use, relapse, or otherwise exacerbate clinically (Becker et al., 2004; Riggs et al., 2003). Potentially further adding to clinician concerns is that comorbid PTSD/SUDs are associated with more severe symptoms of PTSD and alcohol dependence, greater likelihood of SI and past suicide attempts, worse treatment outcomes, and more comorbid disorders than having only one disorder (Blanco et al., 2013; Ilgen et al., 2010; Lee et al., 2018; Norman, Haller, Hamblen, Southwick, & Pietrzak, 2018).

However, a growing body of research shows that integrated exposure and SUD treatment, such as concurrent treatment of PTSD and substance use disorders using prolonged exposure (COPE; Back et al., 2015), is more effective than treatment without exposure for reducing PTSD symptoms, does not lead to worse substance use, and may lead to better long-term SUD outcomes even when implemented in an outpatient setting (Mills et al., 2012; Norman et al., 2019; Roberts et al., 2015). In light of this research, current clinical practice guidelines recommend that clinicians treat PTSD and SUD concurrently using evidence-based trauma-focused treatment such as PE (Department of Veterans Affairs/Department of Defense, 2017). Despite this recommendation, concerns regarding implementing PE in comorbid populations have persisted (Back, Waldrop, & Brady, 2009). Because comorbid PTSD/SUD

is extremely common (e.g., 46.4% of individuals with lifetime PTSD report a lifetime SUD; Pietrzak et al., 2011) and highly impairing, it is critical to better understand whether PE leads to symptom exacerbation in this vulnerable population.

Given the evidence that exposure therapy with SUD treatment is more effective than other treatments for PTSD/SUD (Roberts et al., 2015), it is important to understand whether initiating exposure exacerbates PTSD, alcohol use, depression, or SI during the course of PTSD/SUD treatment. This information is needed to assuage clinician concerns about initiating exposure and ultimately making PE more broadly available to patients with PTSD/SUD. Given that AUD commonly co-occurs with PTSD and that the majority of research examining COPE has utilized samples with various comorbid SUDs, it is also critical to examine worsening in a PTSD/AUD sample. Utilizing data from a randomized clinical trial comparing an exposure-based integrated treatment, COPE, to a present-focused integrated coping skills therapy without exposure (seeking safety; SS) for the treatment of PTSD and alcohol use disorder (AUD; Norman et al., 2019), we examined whether participants undergoing PTSD/AUD treatment experienced symptom exacerbation in PTSD, alcohol use, depression, or SI when first initiating exposure, and whether early symptom exacerbation affected posttreatment outcomes or treatment attendance. For those in the COPE condition, in vivo exposure to avoided situations was initiated after session 3 and imaginal exposure to the trauma memory was initiated during session 4. We hypothesized that participants in COPE would not experience an increase in PTSD, alcohol use, depression, or SI relative to those receiving SS between session 3 and session 5, when exposures were first introduced in COPE. We also predicted that those who experienced symptom exacerbation would not demonstrate worse posttreatment outcomes compared to those who did not experience symptom exacerbation. This is the first study to our knowledge to compare COPE to an active comparator treatment, SS, and to examine whether exposure leads to increases in SI.

Method

Participants and Procedures

Participants were 81 veterans recruited from a large urban VA hospital (see Table 1 for full descriptive information). Veterans who potentially had PTSD/AUD diagnoses were referred by mental health providers, and veterans also responded to flyers posted at the VA. Inclusion criteria included having experienced a previous traumatic event in childhood or adulthood and meeting DSM-5 criteria for current PTSD and DSM-IV criteria for alcohol abuse or dependence (AUD), with at least 20 days of alcohol use in the last 90 days. Most participants (97.5%) included in the current study met current criteria for alcohol dependence at baseline (the remainder met criteria for alcohol abuse). The majority of participants (88.9%) in the current study had deployed to a combat zone at least once. Exclusion criteria for the parent study included moderate or severe cognitive impairment, acute suicidality, intravenous drug use, and unmanaged current psychosis or mania independent of substance use.

Participants gave written informed consent prior to enrollment by the study coordinator. Although 119 participants were randomized to treatment, participants were excluded from these analyses if they did not initiate treatment ($n = 2$; COPE $n = 1$; 1.6% within COPE;

SS n = 1; 1.8% within SS), discontinued treatment at or prior to session 5 (n = 20; COPE n = 14, 22.6% within COPE; SS n = 6, 10.7% within SS), or were missing data of interest (n = 16; COPE n = 8, 12.9% within COPE; SS n = 8, 14.3% within SS). The study design was approved by the local IRB and registered with ClinicalTrials.gov (NCT01601067). For the full description of recruitment methods, sample, treatment arms, and procedures, see Norman et al. (2018). Primary findings can be found in Norman et al. (2019).

Measures

Unless otherwise indicated, the following measures were obtained by therapists at the beginning of every other treatment session.

PTSD Symptoms.—The PTSD Checklist for DSM-5 (PCL-5; Weathers, Litz, et al., 2013) is a 20-item self-report measure that assesses past-month symptoms of PTSD. It corresponds to each of the DSM-5 PTSD symptoms (*Diagnostic and Statistical Manual of Mental Disorders* (DSM–5; American Psychiatric Association, 2013). Scores on the PCL-5 range from 0 to 80, and scores of 33 or higher indicate a potential diagnosis of PTSD (Wortmann et al., 2016). The PCL-5 has shown good temporal stability over the course of three months in a sample of veterans with combat exposure (Keane et al., 2014). Cronbach's alpha for this sample at session 3 was .94.

Posttreatment PTSD symptoms were assessed with the Clinician Administered PTSD Scale for DSM-5 (CAPS-5; Weathers, Blake, et al., 2013), a 30-item structured interview considered to be the gold-standard for PTSD assessment. The CAPS-5 has demonstrated strong psychometric properties in a sample of military veterans, including strong interrater reliability and test-retest reliability, high internal consistency, and good convergent validity with other measures of PTSD including the PCL-5 (Weathers et al., 2018). Cronbach's alpha for this sample at posttreatment was .90.

Alcohol Use.—The Substance Use Inventory (SUI; Weiss, Hufford, Najavits, & Shaw, 1995) measured the number of days alcohol was used and number of standard drinks consumed each day during approximately the past week (for session 3: M_{days} = 8.66; SD = 4.63). A variable was calculated based on the percentage of days participants drank multiplied by the average number of drinks consumed each day they drank (to index frequency by quantity of alcohol use). The Timeline Follow-back (TLFB; Sobell & Sobell, 1992) assessed posttreatment alcohol use, and a similar variable was created that indicated frequency by quantity of alcohol use in the follow-up timeframe posttreatment (M_{days} = 94.47; SD = 22.33).

Depression and Suicidal Ideation.—Depression severity was measured with the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) that includes nine items about depression over the past two weeks. However, we used only eight items assessing depression (PHQ-8; Corson, Gerrity, & Dobscha, 2004), as the ninth item regarding suicidal ideation (SI) was examined separately. Scores on the PHQ-8 range from 0 to 24, and a score of 10 or higher indicates a potential depressive disorder (Kroenke et al. 2009). The PHQ-8 has strong psychometric properties, including excellent internal

reliability and test-retest reliability and good specificity. Cronbach's alpha for this sample at session 3 was .89.

SI was measured with the Patient Health Questionnaire-9 item 9. This question asks, "How often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some ways?", with responses ranging from 0 (*not at all*) to 3 (*nearly every day*). As the majority of participants at session 3 endorsed no SI (70.5%) or a 1 (21.8%), we dichotomized the SI variable to indicate SI versus no SI. The PHQ-9 item 9 was associated with increased risk of future suicide in a large sample of veterans utilizing VA healthcare (Louzon, Bossarte, McCarthy, & Katz, 2016).

Treatments

The COPE (Back et al., 2015) protocol is an individual evidence-based treatment that integrates prolonged exposure therapy for PTSD (Foa, Hembree, & Rothbaum, 2007) with cognitive-behavioral therapy relapse prevention techniques for SUD (Carroll, 1998). COPE includes three key elements: in vivo (real life) exposure to trauma-associated stimuli for PTSD (sessions 3–12); imaginal exposure (repetitive oral discussion of the traumatic event; sessions 4–12); and relapse prevention for SUD.

Seeking safety (SS) is a present-focused therapy that focuses on establishing safety (e.g. reducing substance use, ending harmful relationships) as the primary clinical need for individuals with comorbid PTSD/SUD (Najavits, 2002). Past trauma is discussed regarding how it is currently affecting the participant's life. Overarching themes of SS include interpersonal topics, cognitive topics, behavioral topics, and combination topics. SS was implemented in a standardized way in the present study such that all participants received the same content for sessions 1–12. The present study focuses on examining symptom change from sessions 3–5. The topics for sessions 3–5 were "PTSD—taking back your power," "detaching from emotional pain," and "when substances control you," respectively.

Both treatments occurred in 90-minute, individual sessions once or twice weekly (depending on participants' preferences). Both treatments included 12 sessions with the option of continuing to 16 sessions if participants had not met their treatment goals. Participants were given up to six months to complete therapy if needed.

Data Analytic Approach

All analyses for the current study were conducted using SPSS 25. To understand whether and how many participants experienced a clinically meaningful exacerbation in PTSD, alcohol use, depression, and SI from session 3 to 5 (spanning the period before and after in vivo and imaginal exposures were introduced in COPE), we used the reliable deterioration calculation as described in Devilly and Foa (2001). This calculates symptom exacerbation using the measure's test-retest score, standard deviations (*SD*s), and the standard error of measurement (Devilly & Foa, 2001). The standard error is calculated by multiplying the *SD* by the square root of one minus test-retest reliability (r_{xx}): $SE = SD\sqrt{1 - r_{xx}}$. The standard error of the difference between two administrations of a scale, or reliable exacerbation, is calculated by using $\sqrt{2(SE^2)}$. Standard deviations from psychiatric or non-clinical samples

may be used, with the latter indicating smaller standard deviations and therefore producing lower cutoff scores, which would lead to a larger number classified as significantly worsened. We used values derived from non-clinical samples when available.

Chi-square analyses determined whether there was a significant difference in number of participants who reported exacerbation of symptoms by treatment condition. Pearson's coefficient of contingency, *C*, was used as a measure of effect size for chi-square analyses (Cohen, 1988).

A series of separate hierarchical regressions tested whether treatment condition (COPE vs. SS) predicted symptoms of PTSD, alcohol use, or depression at session 5 while adjusting for session 3 (pre-exposure session) symptoms. A logistic regression tested whether treatment condition (COPE vs. SS) predicted the presence of SI at session 5 while adjusting for session 3 SI. For example, Step 1 included session 3 PTSD symptoms as a covariate, Step 2 included the treatment condition (COPE or SS), and the dependent variable was session 5 PTSD symptoms. We examined session 5 as a dependent variable to determine whether there were effects of beginning exposure for the COPE participants and adjusted for session 3 as it was the most recent data point we had for participants prior to beginning exposures. Amount of time between sessions 3 and 5 was considered as an additional covariate, but as results were unchanged with this covariate it was not included in the final models.

Analyses of variance (ANOVAs) and a chi-square determined whether there were posttreatment differences in PTSD, alcohol use, depression, or presence of SI between those who experienced symptom exacerbation versus those who did not in both COPE and SS. All analyses used available data, which resulted in slight variations in sample sizes for different analyses.

Results

At session 1, the average PCL-5 score was 47.18 (SD = 15.19), the average PHQ-8 score was 13.44 (SD = 5.60), and 29.5% (n = 23) endorsed SI on the PHQ-9. Participants reported heavy use of alcohol (5 or more drinks for men; 4 or more drinks per women) on 47.48% (SD = 24.84) of the 100 days prior to starting the study; they used other substances 13.83% (SD = 27.05) of those days. Participants completed an average of 11.42 (SD = 3.49) sessions total, with those in SS completing significantly more sessions (12.61 sessions) than COPE (10.20 sessions; $t[79] = 3.29$, $p = .001$). Participants spent an average of 15.07 (SD = 5.27) weeks in treatment, with no significant group differences between COPE (13.95 weeks; SD = 5.51) and SS (16.18; SD = 4.83; $t[79] = 1.93$, $p = .057$). As noted in Norman et al. (2019), no participants were discharged from either treatment condition due to serious adverse events throughout the study.

Evaluating frequency of dropout prior to session 5

Fourteen participants in COPE (22.6% of those randomized to COPE) and six in SS (10.7% within SS; OR = 2.43; 95% CI = 0.86–6.84; p = .09) discontinued treatment prior to session 5. Reasons for dropping were obtained from a questionnaire completed by therapists at the end of treatment. Eight participants in COPE (57.1% of those who dropped prior to session

5) discontinued due to logistical reasons such as moving or schedule changes compared to one participant in SS (16.7%). Six participants in COPE (42.9% of those who dropped before session 5) dropped due to concerns related to treatment or no showed and did not respond to follow-up calls versus five participants in SS (83.3%; X^2 [1, N = 20] = 2.78, p = .10).

Evaluating frequency of meaningful exacerbation in symptoms between COPE and SS

The reliable symptom exacerbation method examined whether there were treatment condition differences in frequencies of participants who experienced a meaningful exacerbation of PTSD, alcohol use, depression, and SI from session 3 to session 5 using methods similar to Foa et al. (2002; see Table 2). Twelve of 78 participants (15.3%) exhibited clinically meaningful exacerbation (based on a reliable exacerbation of 6.11 points in PTSD symptoms on the PCL-5). Eight individuals in COPE exhibited clinically meaningful exacerbation in PTSD symptoms (20.5% within COPE) versus four individuals in SS (10.3% within SS; OR = 2.26; 95% CI = .62 – 8.24; p = .22). Eight out of 78 participants (10.2%) exhibited clinically meaningful exacerbation (based on a reliable exacerbation of 3.26 points in depression on the PHQ-8). Ten out of 78 participants (12.8%) exhibited clinically meaningful exacerbation (based on a reliable exacerbation of .52 points in SI on the PHQ-9 item 9). Four out of 78 participants (5.1%) exhibited clinically meaningful exacerbation (based on a reliable exacerbation of 1.75 points in alcohol use on the SUI). There were no significant differences between treatments in number of participants who exhibited clinical exacerbation in PTSD, depression, alcohol use, or SI: X^2 (N = 78) = .01–1.58, p's > .05, C's = .01–.14.

Evaluating change in PTSD, depression, alcohol use, and SI within treatment

Several hierarchical linear regressions and a logistic regression examined whether treatment condition predicted session 5 symptoms (PTSD, alcohol use, depression, or SI) after controlling for session 3 symptoms. For each of the analyses, we found that session 3 symptoms predicted session 5 symptoms, but treatment condition did not predict session 5 symptoms (see Table 3).

Associations between within-treatment symptom exacerbation, posttreatment outcomes, and session attendance

Twenty-four out of 81 participants (29.6%) exhibited reliable exacerbation of PTSD, alcohol use, depression, or SI. We examined posttreatment PTSD, depression, alcohol use (using the TLFB), and SI for four groups of participants (those who experienced exacerbation versus those who did not within COPE and SS). No significant group differences existed in posttreatment PTSD severity [F(3, 60) = 2.02, p = .12], alcohol use [F(3, 59) = .29, p = .83], or SI (X^2 (N = 63) = 2.94, p = .40, C = .21). Groups differed in posttreatment PHQ-8 scores [F(3, 59) = 6.34, p = .001], with those who exhibited exacerbation in COPE (M = 11.90; SD = 5.48) or SS (M = 12.09; SD = 6.33) endorsing higher rates of depression than those who did not experience exacerbation in COPE (M = 4.89; SD = 3.27) or SS (M = 9.04; SD = 5.41). A Bonferroni test indicated that participants in COPE who did not experience exacerbation endorsed non-statistically significant lower PHQ-8 scores compared to participants in SS who did not experience exacerbation (p = .07).

Participants who experienced exacerbation in treatment attended a non-significant higher number of treatment sessions (M = 12.46 sessions) compared to those who did not experience exacerbation (M = 10.98 sessions), $t(79) = -1.76$, $p = .08$.

Discussion

Previous studies showed that only a small number of people exhibit clinical exacerbation when initiating exposure in trauma-focused treatment and that this early exacerbation is not associated with treatment outcome or dropout (Foa et al., 2002; Lancaster et al., 2019; Larsen et al., 2016). We extended previous work by Lancaster and colleagues by comparing COPE to an active comparator trauma-focused treatment, seeking safety, and also examined whether COPE may lead to increases in SI. Our findings that few people worsened and that exacerbation in PTSD, alcohol use, depression, and SI did not differ between treatment conditions add to a growing body of literature that indicates that trauma-focused treatments are in fact safe even for complicated PTSD patients, including those with comorbidities (Bryan et al., 2016; Foa et al., 2002; Lancaster et al., 2019; Larsen et al., 2016). These findings are also consistent with clinical practice guidelines that recommend evidence-based treatments such as PE for individuals with PTSD/SUD (Department of Veterans Affairs/ Department of Defense, 2017). It should be noted that there were very low rates of reliable symptom exacerbation in our study; these low rates (e.g., there were 4 more participants who experienced exacerbation in PTSD symptoms in COPE than SS) made it difficult to make definitive conclusions about whether symptom exacerbation differed by treatment conditions. Although COPE showed a non-significant higher likelihood of dropping out of treatment prior to session 5 compared to SS, we examined reasons for dropping and found that those in COPE were not more likely to drop out due to treatment concerns or unknown reasons.

Our study complements recent research by Jarnecke and colleagues (2019), who found that for participants receiving COPE, within session substance craving and subjective units of distress related to exposure did not predict the future week's substance use or PTSD symptom severity. The study also adds important information regarding within treatment changes, as the majority of treatment research examines pretreatment versus posttreatment symptom change. Understanding what happens *during* treatment will encourage clinicians who may be skeptical of implementing PE that engagement will likely not lead to decompensation when exposures are introduced.

Participants in both treatment conditions who demonstrated any clinical exacerbation from session 3 to 5 still showed improvements at posttreatment in PTSD, alcohol use, and SI. However, participants in both COPE and SS who exhibited symptom exacerbation endorsed higher depression at posttreatment compared to those who did not exhibit exacerbation. This speaks to the importance of clinicians assessing depression throughout treatment and offering additional interventions for depression if needed. Behavioral activation (BA), is an effective treatment for depression (Mazzucchelli, Kane, & Rees, 2009) that focuses on encouraging patients to re-engage in activities they have given up due to their depression by scheduling pleasant activities and rating their mastery/pleasure in activities. BA may be integrated into in vivo exposures by including assignments with the goal of engaging in

activities that the patient previously found enjoyable or meaningful (Back et al., 2015). It is important to note that these analyses may have been impacted by those who dropped out of treatment prior to session 5 and should be interpreted with caution.

These results, together with the primary findings of this study that participants receiving COPE had greater PTSD symptom reduction than those in SS and that no participants were discharged from the study due to serious adverse events (Norman et al., 2019), emphasize the importance of making trauma-focused treatment available to patients with PTSD even if they have an active AUD. *The Prolonged Exposure Therapist Guide* (Foa, Hembree, & Rothbaum, 2007) discusses that patients may experience an exacerbation of symptoms before they improve; however, our study, like other recent studies of PTSD without AUD (Foa et al., 2002; Larsen et al., 2016), found that this may be true for only about 15% of individuals. Additionally, we found that symptom exacerbation was no more likely to occur in exposure therapy than in therapy without exposure. We did not have a no-treatment control condition, but it is likely that some people may have worsened even if they did not receive any treatment as PTSD symptom severity tends to fluctuate over time (Doron-LaMarca et al., 2015). Communicating to patients that only about 15% of people may experience a clinically meaningful symptom exacerbation during treatment can be a powerful intervention in itself.

These results should be interpreted in light of several limitations. First, SS was delivered in a longer session format than typical (90 versus 45–60 minute sessions). Generalizability may be limited as our sample was mostly comprised of men and all were veterans; however, our findings are similar to Foa and colleague's (2002) study, which was conducted in civilian female survivors of sexual and nonsexual assault. Additionally, the current study and previous research in this area has focused on adult samples only, and it is unclear whether these findings would generalize to younger populations. On average, participants in the larger trial completed 8.4 sessions of COPE while those in SS completed 11.4 sessions (Norman et al., 2019), and we do not know whether those who dropped out prior to session 5 may have worsened. We found that a greater percentage of individuals in COPE discontinued treatment prior to session 5, and while it is possible that the anticipation of future exposure may have led to this, it is an important area for future study. Unfortunately, a limitation of this and previous studies is the lack of understanding whether exacerbation may have occurred in participants who dropped out of treatment early, which is a common issue in outpatient therapy randomized clinical trials (Sagarin et al., 2014). In this study we found that participants who experienced symptom exacerbation attended a non-significant higher number of sessions compared to those who did not experience exacerbation (across both conditions). Additionally, previous studies show that higher dropout is not associated with worse patient outcomes (Simpson et al., 2017).

In terms of strengths, this study had few exclusion criteria, which expands the generalizability of our findings to a broad population. This is the first study to our knowledge that examined exacerbation of suicidal ideation during exposure therapy for those with comorbid PTSD/AUD. Because AUD is a common comorbidity with PTSD (Pietrzak et al., 2011), understanding the best treatment approaches for both disorders is

crucial. Findings highlight that exposure treatment may be considered safe and effective for PTSD/AUD populations.

Acknowledgments:

This material is the result of work supported with resources and the use of facilities at the National Center for PTSD, the VA San Diego Healthcare System, and the Center for Excellence for Stress and Mental Health.

Funding:

Funding for this work was made possible by a Veterans Affairs Clinical Science Research and Development Merit Grant 1I01CX000756 (PI: Sonya Norman).

Conflicts of Interest:

Dr. Norman reported receiving funding from the Department of Veterans Affairs, Department of Defense, National Institute of Health, and royalties from Elsevier Press. No other disclosures were reported. For the remaining authors, no conflicts of interest were declared.

Appendix

The data reported in this manuscript have been previously published and were part of a larger data collection (at one or more points in time). Findings from the data collection have been reported in separate manuscripts. Norman et al. (2019) focused on PTSD symptoms/remittance and alcohol use changes from pre to posttreatment and through six-month follow-up. The current manuscript focused on change in PTSD symptoms, alcohol use, depression, and suicide ideation mid-treatment (sessions 3 to 5) after exposures were introduced in COPE. Curry, Malaktaris, Lyons, Herbert, and Norman (2019) examined pretreatment trauma-related cognitions and their association with chronic pain, while adjusting for the effects of PTSD symptoms and frequency of alcohol use. Lyons, Haller, Curry, and Norman (2019) examined pretreatment trauma-related cognitions and their association with poorer psychosocial functioning after adjusting for PTSD and alcohol use disorder symptom severity. Capone et al. (2020) focused on treatment condition differences in global guilt at pretreatment, posttreatment, 3-month, and 6-month follow-ups. Tripp et al. (2020) examined residual symptoms of PTSD and alcohol abuse/dependence posttreatment by treatment condition and those who retained versus remitted a diagnosis of PTSD or alcohol abuse/dependence. Tripp et al. (2020) examined whether alcohol use is associated with subsequent PTSD symptom severity (and vice versa) throughout treatment, and whether these patterns differed by treatment condition (COPE vs. SS). Straus et al. (submitted for publication) are examining attendance patterns in both treatment conditions (COPE and SS) and how these patterns may influence posttreatment PTSD and alcohol use outcomes. The previously published and submitted manuscripts did not focus on potential symptom worsening due to exposure therapy as the current one did.

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Clinical Impact Statement:

Although clinicians may have concerns that offering exposure therapy to patients with comorbid PTSD and alcohol use disorder will lead to clinical exacerbation, Concurrent Treatment of PTSD and Substance Use Disorders Using Prolonged Exposure did not lead to more symptom (PTSD, alcohol use, depression, suicidal ideation) exacerbation than a present-focused treatment that does not include exposure. Clinicians should not refrain from offering exposure treatment for patients with PTSD/AUD due to concerns of symptom exacerbation.

Table 1

Descriptive Statistics for the Full Sample

Variable	*N (%)*	*M*	*SD*
Age		41.66	38.38
Number of prior trauma types directly experienced		8.18	2.62
Sex			
Men	69 (85.2)		
Women	12 (14.8)		
Race			
White	55 (67.9)		
Bi- or multi-racial	10 (12.3)		
Black or African American	7 (8.6)		
Asian	6 (7.4)		
American Indian/Alaska Native	2 (2.5)		
Pacific Islander/Hawaiian Native	1 (12)		
Military Branch			
Army	31 (38.3)		
Navy	26 (32.1)		
Marine Corps	23 (28.4)		
Reserve/National Guard	1 (12)		
Marital Status			
Divorced	32 (39.5)		
Never Married	18 (22.2)		
Married	16 (19.8)		
Separated	11 (13.6)		
Widowed	3 (3.7)		
Remarried	1 (12)		
Living Conditions			
House/Apartment	60 (74.1)		
Living in a controlled environment	16 (19.8)		
No stable housing arrangements	5 (6.2)		
Deployment Status			
Deployed to combat zone	72 (88.9)		
Never deployed to a combat zone	9 (11.1)		
Prior suicide attempts			
Endorsed previous suicide attempts	20 (24.7)		
Denied previous suicide attempts	61 (75.3)		

Table 2

Test-Retest and Standard Deviations Used for Reliable Exacerbation Index; Reliable Exacerbation Values, Numbers, Percentages, and Average Values of Participants who Experienced Exacerbation in Treatment.

Measure	Test-Retest	Standard Deviation	Reliable exacerbation	*n* (% in treatment) exacerbated in COPE	*n* (% in treatment) exacerbated in SS	Average increase in those who exacerbated	OR (95% CI)
PCL-5[a]	.82	14.72	6.11	8 (20.5)	4 (10.3)	10.83	2.26 (.62–8.24)
PHQ-8[b]	.84	5.76	3.26	4 (10.5)	4 (10.0)	6.25	1.05 (.24–4.57)
PHQ-9 SI	.75	.74	.52	4 (10.5)	6 (15.0)	1.00	0.66 (.17–2.58)
SUI Alcohol	.86	3.33	1.75	3 (7.5)	1 (2.6)	3.00	3.00 (.30–30.18)

Note. PCL-5 = PTSD Checklist for DSM-5; PHQ-8 = Patient Health Questionnaire-8; PHQ-9 SI = Patient Health Questionnaire-9 Suicidal Ideation; SUI = Substance Use Inventory; OR = Odds Ratio; CI = Confidence Interval;

[a]Test-retest and standard deviations for PCL-5 taken from Blevins et al., 2015 and test-retest for

[b]PHQ-8 taken from Kroenke, Spitzer, & Williams, 2001.

Table 3

Hierarchical/Logistic Regressions with Treatment Condition Predicting PCL-5, SUI Alcohol Use, PHQ-8 Depression, and PHQ-9 Suicidal ideation After Adjusting for Previous Session Symptom

Dependent Variable (DV) & Predictors	β	*SE*	ΔR^2	*F*	Δ*F*
DV: Session 5 PCL-5 score					
Step 1: Session 3 PCL-5	.70*	.09	.49	71.64*	71.64*
Step 2: Treatment Condition	−.02	2.72	.00	35.38*	.03
DV: Session 5 SUI alcohol					
Step 1: Session 3 SUI alcohol	.86*	.05	.74	218.13*	218.13*
Step 2: Treatment Condition	.11	.31	.01	114.34*	3.47
DV: Session 5 PHQ-8					
Step 1: Session 3 PHQ-8	.65*	.09	.43	56.60*	56.60*
Step 2: Treatment Condition	−1.00	.97	.01	29.00*	1.23
	β	*SE*	*Wald* X^2	*OR*	95% CI
DV: Session 5 PHQ-9 SI[a]					
Step 1: Session 3 PHQ-9 SI	−2.54	.61	17.48*	.08	[.02, .26]
Step 2: Treatment Condition	.43	.61	.48	1.53	[.46, 5.16]

Note.

*$p < .05$; SS = 0; COPE = 1; $n = 78$ for all of the above analyses; PCL-5 = PTSD Checklist for DSM-5; SUI = Substance Use Inventory; PHQ-8 = Patient Health Questionnaire-8; PHQ-9 SI = Patient Health Questionnaire-9;

[a]as this item was dichotomous, a logistic regression was conducted.