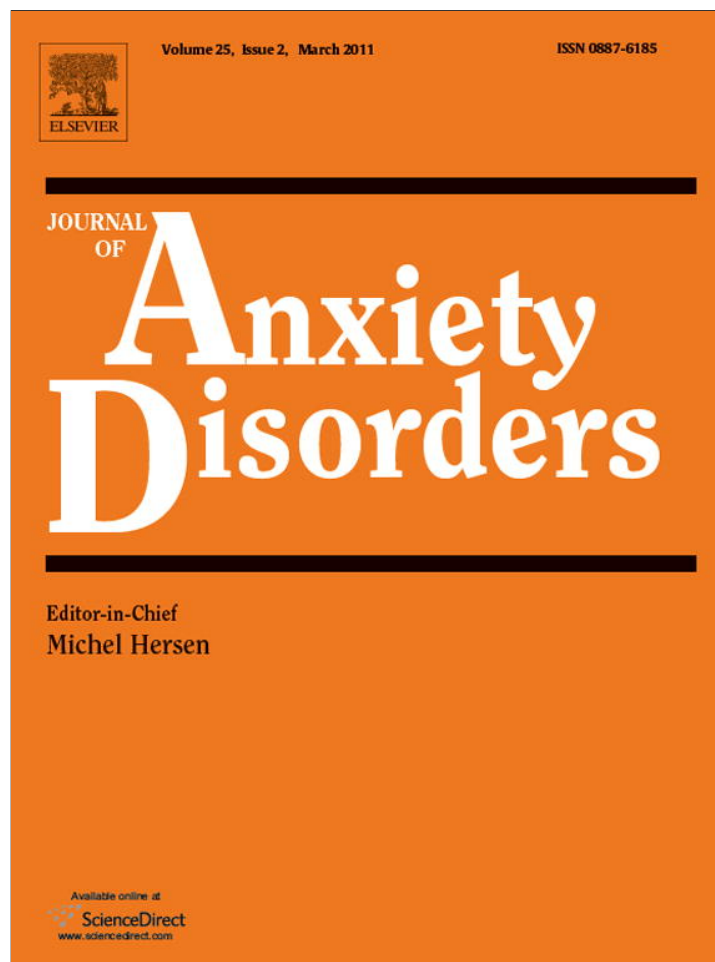


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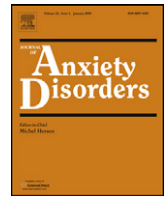
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## Multicomponent behavioral treatment for chronic combat-related posttraumatic stress disorder: A randomized controlled trial

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### ABSTRACT

This study examined the efficacy of a multicomponent cognitive-behavioral therapy, Trauma Management Therapy, which combines exposure therapy and social emotional rehabilitation, to exposure therapy only in a group of male combat veterans with chronic posttraumatic stress disorder (PTSD). Thirty-five male Vietnam veterans with PTSD were randomly assigned to receive either Trauma Management Therapy (TMT) or Exposure Therapy Only (EXP). Participants were assessed at pre-treatment, mid-treatment, and post-treatment. Primary clinical outcomes were reduction of PTSD symptoms and improved social emotional functioning. Results indicated that veterans in both conditions showed statistically significant and clinically meaningful reductions in PTSD symptoms from pre- to post-treatment, though consistent with *a priori* hypotheses there were no group differences on PTSD variables. However, compared to the EXP group, participants in the TMT group showed increased frequency in social activities and greater time spent in social activities. These changes occurred from mid-treatment (after completion of exposure therapy) to post-treatment (after completion of the social emotional rehabilitation component); supporting the hypothesis that TMT alone would result in improved social functioning. Although the TMT group also had a significant decrease in episodes of physical rage, that change occurred prior to introduction of the social emotional component of TMT. This study demonstrates efficacy of exposure therapy for treating the core symptoms of PTSD among combat veterans with a severe and chronic form of this disorder. Moreover, multi-component CBT shows promise for improving social functioning beyond that provided by exposure therapy alone, particularly by increasing social engagement/interpersonal functioning in a cohort of veterans with severe and chronic PTSD.

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The Department of Veterans Affairs (VA) is responsible for providing access to evidence-based treatment for combat veterans with posttraumatic stress disorder (PTSD). Epidemiological studies show that combat veterans across war eras evidence significant rates of PTSD (Richardson, Frueh, & Acierno, 2010; Sundin, Fear, Iversen, Rona, & Wessely, 2010), including veterans of wars in Vietnam (9%; Dohrenwend, Turner, Turse, Adams, Koenen, & Marshall, 2006) and Iraq and Afghanistan (4–13%; Grieger et al., 2006; Hoge, Auchterlonie, & Milliken, 2006; Hotopf et al., 2006; Seal, Bertenthal, Miner, Sen, & Marmar, 2007; Smith, Ryan, Wingard, Slymen, Sallis, & Kritz-Silverstein, 2008). Furthermore, 11% of all veterans treated in VA primary care clinics meet criteria for PTSD (Magruder et al., 2005). The disorder is generally associated with

significant clinical distress, social and occupational impairment, reduced quality of life, and medical and psychiatric comorbidity (Dohrenwend et al., 2006; Elhai, Kashdan, Snyder, North, Heaney, & Frueh, 2007; Frueh, Turner, Beidel, & Cahill, 2001; Schnurr, Spiro, & Paris, 2000). Anger management problems in particular are a significant source of distress and impairment (Chemtob, Hamada, Roitbla, & Muraoka, 1994; Frueh et al., 2001; Taft et al., 2007), affecting individual veterans as well as their spouses and families (Teten et al., 2010). While there is a strong evidence base to support psychiatric interventions for treatment of PTSD in civilians (Foa, Rothbaum, Riggs, & Murdock, 1991; Foa, 2006), there are very few data to support efficacy of treatments for veterans with PTSD (Bradley, Greene, Russ, Dutra, & Westen, 2005; Frueh, Grubaugh, Elhai, & Buckley, 2007; Institute of Medicine and National Research Council, 2007). Thus, it is imperative that we develop and implement effective strategies to increase access to efficacious treatments for these returning service members.

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There is excellent empirical support for efficacy of cognitive behavioral therapy (CBT), especially exposure therapy, for treating PTSD (Echeburua, de Corral, Zubizarreta, & Sarasua, 1997; Foa et al., 1991; Tarrrier et al., 1999). In addition to efficaciously treating PTSD among general adult populations, exposure therapy for PTSD has also shown promise for adults suffering from schizophrenia (Frueh, Grubaugh, Cusak, Kimble, Elhai, & Knapp, 2009), comorbid drug dependence (Brady, Dansky, Back, Foa, & Carroll, 2001), adults treated within community clinics (Foa et al., 2005), and for female veterans treated within Veterans Affairs Medical Centers (Schnurr et al., 2007). Data strongly indicate that exposure therapy alleviates the hallmark features of PTSD, notably maladaptive physiological arousal, fear, and re-experiencing symptoms (Foa, 2006). According to the Consensus Statement on PTSD by the *International Consensus Group on Depression and Anxiety* (Ballenger et al., 2000) and a recent report by the *Institute of Medicine* (IOM, 2007), the psychotherapy with the strongest empirical support for treating PTSD is exposure therapy.

Extant data do not indicate that exposure has a significant effect on certain debilitating symptoms of PTSD, such as behavioral avoidance, impaired social functioning, anger management, or social skill deficits (Frueh, Turner, & Beidel, 1995). Thus, a multi-component program targeting specific areas of dysfunction may be necessary to address the complex symptoms associated with this syndrome in veterans (Frueh, Turner, Beidel, Mirabella, & Jones, 1996). The purpose of this paper is to present results of a randomized controlled trial (RCT) examining the efficacy of a multi-component cognitive-behavioral intervention, Trauma Management Therapy, incorporating exposure therapy (Turner, Frueh, & Beidel, 2005), to reduce PTSD symptoms in combat veterans with PTSD. It was hypothesized *a priori* that veterans with PTSD receiving the multi-component intervention (including exposure therapy) would show greater clinical improvements across relevant social and emotional functioning domains than those veterans receiving exposure therapy only. Components of the intervention in this study were derived, developed, and adapted based on literature reviews (Frueh, Mirabella, & Turner, 1995; Frueh, Turner, et al., 1995), multi-component intervention models for other psychiatric populations (Turner, Beidel, Cooley, Woody, & Messer, 1994), and our own prior pilot data supporting efficacy of the treatment program in an open trial conducted with male combat veterans (Frueh et al., 1996).

## 1. Method

### 1.1. Study design

A randomized controlled trial was conducted with male combat veterans with PTSD to compare clinical efficacy of two cognitive-behavioral interventions: Trauma Management Therapy with exposure therapy (TMT), and Exposure Therapy Only (EXP). Recruitment and treatment took place between August 2005 and December 2007. The Institutional Review Board (IRB) at the Penn State College of Medicine/Milton S. Hershey Medical Center and the IRB at the Lebanon VA Medical Center approved the protocol; all participants provided written informed consent prior to study enrollment.

### 1.2. Participants

Forty-nine ( $n = 49$ ) male veterans were screened for study participation. All veterans were referred from a VA Medical Center and a Vet Center in the northeastern United States. To participate in the study, all participants were required to have a primary diagnosis of chronic PTSD. Specific inclusion/exclusion criteria followed

the guidelines suggested elsewhere (Frueh, Mirabella, et al., 1995) to ensure that the treatment would be broadly applicable to combat veterans with chronic PTSD (Stirman, 2008). Participants were excluded if they had a comorbid diagnosis of substance abuse or dependence, antisocial personality disorder, psychosis, cognitive impairment, severe depression or significant cardiac conditions. Five participants were eliminated during the diagnostic evaluation due to the presence of other disorders including severe depression with suicidality ( $n = 2$ ), antisocial personality disorder ( $n = 2$ ) and a criminal history of sexual assault ( $n = 1$ ). Additionally six veterans who were interviewed refused to participate in the treatment, indicating that they were simply in need of an updated evaluation for their disability benefits. Another 3 veterans who were interviewed refused study participation citing distance between the home and the clinic ( $n = 1$ ) or inability to make time commitment ( $n = 2$ ) as the reason for non-participation. Among the 35 veterans who were randomly assigned and began treatment, 5 participants had to be removed/dropped out during treatment for the following reasons: worsening substance abuse ( $n = 1$ ), worsening depression requiring inpatient hospitalization ( $n = 1$ ), onset of cancer diagnosis ( $n = 1$ ), heart attack ( $n = 1$ ), and death due to sudden cardiac arrest ( $n = 1$ ), resulting in a 14.3% drop out rate for those who attended at least one treatment session. Thus, of the 35 randomized participants, 30 completed the treatment: 14 completed the TMT group, and 16 completed the EXP group (see Fig. 1).

All of the participants were Caucasian. There were no differences between participants assigned to TMT or EXP Only conditions on age (58.93 years vs. 59.76 years, respectively), marital status (85.7% vs. 73.3%, married respectively), educational status (61.5% vs. 60.0%, respectively had achieved a high school diploma) or branch of military service (69.2% vs. 86.7%, respectively served in the Army). All veterans were honorably discharged and had served in either the Vietnam War ( $n = 34$ ) or the first Gulf War ( $n = 1$ ).

### 1.3. Diagnostic interviews

After referral to the program, veterans were interviewed with the Clinician-Administered PTSD Scale (CAPS-1; Blake et al., 1990) to confirm the PTSD diagnosis. Additionally, the Structured Clinical Interview for DSM-IV (SCID; First, Spitzer, Gibbon, & Williams, 1997) and the Structured Clinical Interview for DSM-IV Axis II (SCID-II; First, Gibbon, Spitzer, Williams, & Benjamin, 1997) were administered to determine the presence of comorbid Axis I and II disorders. Only veterans confirmed by the CAPS interview to have a primary Axis I diagnosis of PTSD were included in the study. Twenty percent (20%) of the interviews for the structured interviews were videotaped and rated by the first author to determine inter-rater reliability, which was  $\kappa = 1.0$  for the diagnosis of PTSD.

### 1.4. Assessment measures

The battery assessed symptoms in three distinct categories: primary PTSD symptoms, social and emotional functioning, and assessment of comorbid (secondary) psychological symptoms. Specific assessment measures are listed below. All clinician ratings were assigned by a masters or doctoral level psychologist. In addition, we assessed patient satisfaction with treatment and treatment credibility ratings.

#### 1.4.1. PTSD symptoms

*Clinician-Administered PTSD Scale.* In addition to its use as a diagnostic tool, the 17-item CAPS assesses the frequency and severity of PTSD symptoms. The scale has robust psychometric properties. The CAPS was administered at pre- and post-treatment to assess change in PTSD symptom severity.

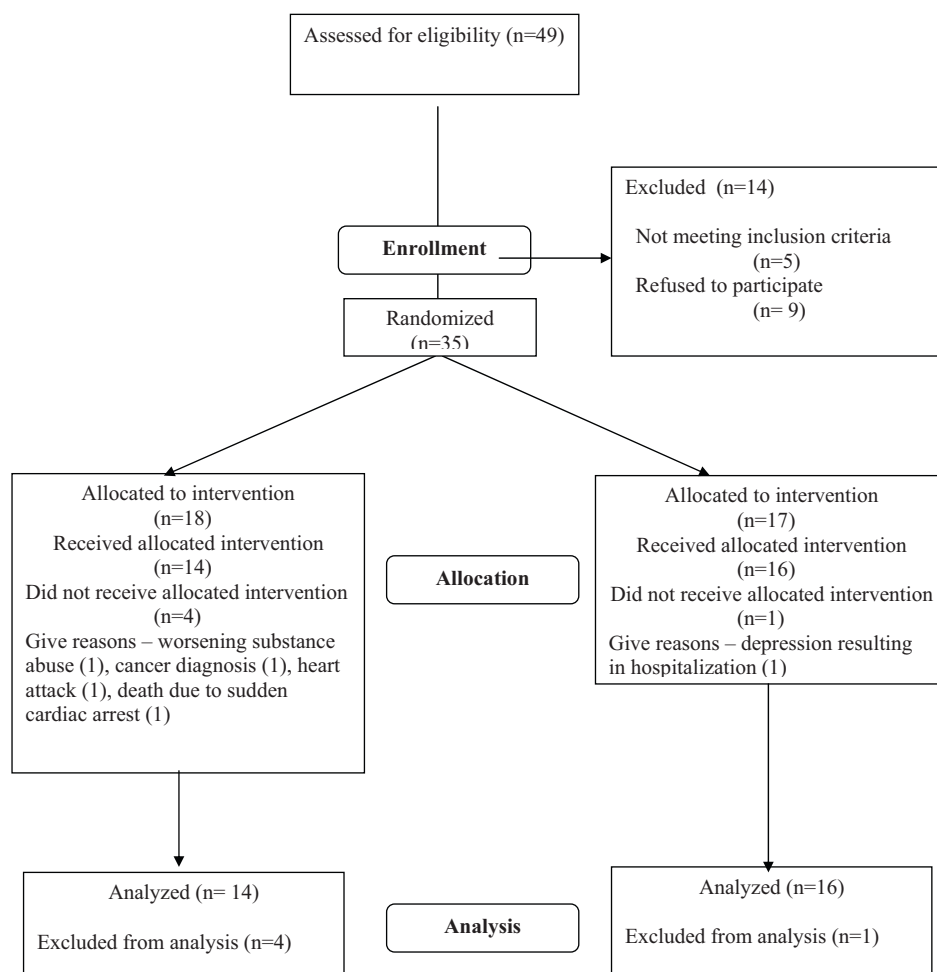
**Consort E-Flowchart**

Fig. 1. Consort flowchart.

**Clinician Rating of Behavioral Avoidance.** A 9-point Likert scale was used to rate the extent of the veteran's avoidance of situations associated with PTSD symptoms.

**PTSD Checklist – Military Version (PCL-M; Weathers, Keane, & Davison, 2001).** The PCL-M is a 17-item self-report measure of PTSD symptoms based on DSM-IV criteria, with a 5-point Likert scale response format. It is highly correlated with the CAPS ( $r = .929$ ), has good diagnostic efficiency ( $> .70$ ), and robust psychometric properties with a variety of trauma populations (Blanchard, Jones, Buckley, & Forneris, 1996). The PCL-M was administered at pre- and post-treatment.

**Patient Ratings.** For a 1-week period at pre-treatment, mid-treatment and post-treatment, veterans kept a log of daily behavioral ratings to monitor the frequency or severity of PTSD symptoms including number of nightmares, number of flashbacks, and total hours of sleep.

#### 1.4.2. Social and emotional functioning

**Clinician-Administered PTSD Scale.** To assess social and emotional functioning, a subset of four items (interest in activities, social detachment, range of affect, anger control) was examined separately, using frequency and intensity ratings on four items. These items were independently rated by the first and

second authors as being representative of social/emotional functioning.

**Quality of Life Questionnaire (QLQ; Evans & Cope, 1989).** The QLQ is a 192-item self-report questionnaire that assesses patients' perception of quality of life across 15 different domains. In this investigation, the total score was used. Preliminary data show that veterans with PTSD (QLQ Total mean = 47.2,  $SD = 19.4$ ,  $T$ -score = 17) report extreme dysfunction across dimensions on this measure relative to the original normative group (QLQ Total mean = 113.2,  $SD = 20.4$ ,  $T$ -score = 50; Frueh et al., 2001). The QOL was administered at pre- and post-treatment.

**Patient Ratings.** For a 1-week period at pre-treatment, mid-treatment, and post-treatment, veterans recorded social activities (frequency and time in minutes), number of rage episodes, and severity of anger and anxiety (the two latter measures were rated on 8-point Likert scales).

#### 1.4.3. Symptoms of other psychiatric conditions

Independent evaluators, blinded to treatment condition, completed the following rates at pre- and post-treatment.

**Clinical Global Impressions Scale (CGI; Guy, 1976).** Overall severity of psychological distress and extent of improvement were assessed using the severity and global improvement subscales using 7-point Likert scales.

*Hamilton Rating Scale for Anxiety* (HAMA; Hamilton, 1959) and *Hamilton Rating Scale for Depression* (HAM-D; Hamilton, 1960) were used to assess general levels of anxiety and depression.

**Treatment Responder Status.** In order to compare the outcome of this investigation to other pharmacological or psychosocial treatments for chronic combat-related PTSD, ratings on the CGI Global Improvement Scale were categorized to determine status as a treatment responder or non-responder. Treatment responders were defined as veterans who were rated as “1” very much improved or “2” much improved. Non-responders were veterans who were judged to be minimally improved, unchanged, or became worse.

#### 1.4.4. Treatment credibility and treatment satisfaction

**Treatment Credibility.** To assess for differences in outcome expectancy, four questions from the treatment credibility scales (Borkovec & Nau, 1972) were used. The four questions included how logical the treatment appears, how confident veterans were about the treatment, their expectancy of success, and how successful the veterans perceived that the treatment would be in decreasing another fear. Patients completed these 10-point rating scales after 3 weeks of treatment.

**Patient Satisfaction.** Veteran satisfaction with treatment outcome was assessed with the Charleston Outpatient Satisfaction Questionnaire (Pellegrin, Stuart, Mare, Frueh, & Ballenger, 2001), a 15-item scale designed to assess patient satisfaction with services in outpatient psychiatric settings. Although some of the items were not relevant for the VA research setting in which this study was conducted, the following items were analyzed “Matching treatment plan to my individual needs”, “Overall quality of care provided”, “Would you recommend this program to a friend or family member.” The first two items are rated on a 5-point scale ranging from 1 = poor to 5 = excellent. The third item is rated on a 4-point scale ranging from 1 = definitely not to 4 = yes, definitely.

#### 1.5. The treatment conditions

All treatment sessions were conducted by masters or doctoral level therapists who were trained in the behavioral interventions by the first two authors. All therapists conducted individual exposure sessions and both of the group treatment sessions. Therapists were supervised weekly by the first author. All treatment sessions were audio or videotaped. To determine treatment fidelity, 20% of the sessions were randomly selected for review by the first author. There were no protocol violations.

**Trauma Management Therapy** (TMT; Turner et al., 2005) is a multicomponent behavioral treatment that begins with individualized imaginal and in vivo exposure therapy (EXP) followed by group social skills training designed specifically for veterans with PTSD. Known as social and emotional rehabilitation (SER), this latter component combines general social skills training with anger management skills training and communication issues identified as problematic for veterans with chronic PTSD. Therefore, TMT consists of several interrelated components: intensive EXP, programmed practice (homework assignments) and social and emotional rehabilitation.

Following pretreatment assessment and one session of psychoeducation/treatment orientation, veterans participated in 14 EXP sessions, conducted three times per week over 5 weeks. Initially, veterans participated in imaginal exposure, using a scene designed to specifically address the core fear. The scene centered on a traumatic memory from their time in combat and included not just the physical characteristics but also their emotional responses of helplessness or feeling out of control. During these imaginal sessions, if any additional traumatic material or memories emerged, that material also was incorporated into the imaginal scene. Because of the horrific nature of many of the imaginal scenes, imaginal expo-

sure was conducted only within clinic sessions and was not given as a homework assignment. Beginning with session 9, the mode of exposure was changed to therapist-accompanied in vivo exposure, using tasks designed to address situations currently avoided by veterans as a result of their PTSD. In vivo exposure tasks included visits to airports and helicopter pads, being in the middle of crowds, or being in a place where people would pass behind the veteran without being able to monitor the person's identity. Also at session 9, programmed practice (homework) was introduced. Veterans were given specific assignments to complete between clinic exposure sessions. Examples included watching war movies (e.g., *Platoon* or *Hamburger Hill*), visiting war memorials or museums, speaking with other veterans or loved ones about war experiences, and visiting airfields or helicopter pads.

Upon completion of the 14 exposure sessions, veterans participated in the social and emotional rehabilitation (SER) phase of the treatment. SER was conducted in small groups (4–5 veterans) that were lead by the therapist. The groups met twice per week for the first 2 weeks and then once per week for the last 10 weeks (14 sessions total). All treatment sessions were 90 min in duration. Perhaps due to their long history of social isolation, many veterans were awkward in their social interactions. The first element of SER involved instruction and practice in basic conversational skills, particularly skills necessary for expanding social networks. Many of the veterans had not had contact with siblings or offspring for many years, thus re-establishing family contact was the focus of this component. The second component of SER was training in anger management and appropriate problem solving. This element was designed to reduce temper outbursts by teaching veterans a range of strategies for expressing their anger, problem solving, improving their emotional modulation, and communicating assertively with others. The third component, Veteran's Issues Management, taught veterans to improve communication regarding combat trauma and military issues with non-veterans, so as to increase the understanding of significant others. They were also taught how to assertively communicate when they are unable/unwilling to talk to others about certain issues and to identify and challenge negative and dichotomous thinking patterns (e.g., the belief that all civilians must be distrusted because they have not been to war), which limit their quality of life by reducing their involvement with others.

**Exposure Therapy Only (EXP).** Veterans randomized to this condition received 1 session of psychoeducation/treatment orientation and 14 sessions of EXP, using the identical format as described above. However, they did not receive SER. Instead, they participated in a therapist-led group intervention similar to that administered in most VA settings. Specifically, they participated in eight sessions of psychoeducation focused on various aspects of PTSD including DSM-IV criteria of PTSD, prevalence of PTSD, risk factors for PTSD, biological and conditioning models of PTSD, PTSD comorbidity, pharmacological treatment of PTSD, the impact of substance abuse, impairment in interpersonal functioning among veterans with PTSD, and issues related to anger control problems and suggested coping strategies. The final six sessions were structured as traditional “rap” group sessions, to provide veterans the opportunity to share experiences and to garner support from other group members. As with SER, the group sessions were 90 min in length. For both treatment conditions, participants who completed all of the individual exposure sessions and 75% of group sessions were considered treatment completers.

## 2. Results

Assessment of treatment credibility did not indicate any differences between groups. Indeed both groups indicated that treatment appeared highly logical ( $M = 7.8$  for TMT and  $M = 7.5$  for



**Table 1**  
Pre- and post-treatment data for TMT and Exp groups.

	TMT			EXP			p
	Pre-Tx	Mid-Tx	Post-Tx	Pre-Tx	Mid-Tx	Post-Tx	
PTSD symptoms							
CAPS Total Score	84.9 (14.3)		69.0 (24.0)	90.6 (14.4)		65.5 (20.2)	.001 (T)
PCL-M	67.0 (11.1)		60.9 (11.6)	68.2 (8.3)		63.6 (11.9)	.01 (T)
Self-Monitoring							
Nightmares	7.1 (6.7)	4.7 (3.7)	4.9 (6.9)	9.4 (6.4)	8.5 (4.7)	4.5 (4.7)	.01 (T)
Flashbacks	10.0 (21.0)	6.2 (6.3)	5.4 (7.3)	6.5 (5.1)	7.9 (7.9)	5.1 (6.5)	.025 (T)
Hours of Sleep	4.7 (1.2)	5.1 (1.6)	5.1 (1.3)	5.0 (1.5)	4.3 (1.2)	5.0 (1.2)	
Avoidance Rating	3.1 (1.8)		2.7 (1.2)	2.3 (1.9)		2.1 (1.5)	
Social and Emotional Functioning							
CAPS Social & Emot. Scale	22.6 (5.3)		17.9 (8.0)	22.4 (3.8)		17.6 (5.1)	.001 (T)
Quality of Life Questionnaire	68.0 (29.0)		72.7 (29.9)	61.0 (20.5)		57.0 (32.8)	
Self-Monitoring							
Social Activities (# per wk)	3.2 (3.3)	3.8 (4.1)	8.2 (7.7)	2.5 (2.8)	1.2 (1.5)	2.0 (1.4)	.025 (TxG)
Social Activities (min/day)	38.5 (51.4)	60.4 (57.1)	94.6 (81.4)	46.4 (61.3)	24.7 (50.6)	32.6 (38.6)	.05 (TxG)
Rage Episodes – Verbal	6.4 (4.8)	2.7 (2.5)	2.4 (2.1)	6.7 (6.7)	7.1 (6.4)	3.2 (6.6)	.05 (T)
Rage Episodes – Physical	2.1 (3.3)	0.2 (0.4)	0.0 (0.6)	0.5 (0.9)	1.6 (3.6)	0.2 (3.1)	.05 (TxG)
Global Anger	4.4 (2.1)	4.0 (2.4)	3.4 (1.7)	4.1 (2.2)	4.3 (2.0)	3.3 (2.0)	
Global Anx <sup>a</sup>	4.9 (2.2)	4.1 (2.6)	3.8 (2.0)	5.1 (2.5)	5.1 (1.8)	3.1 (2.6)	.05 (TxG)
Symptoms of Other Psychiatric Disorders							
CGI – Severity	5.3 (0.9)		3.7 (1.1)	4.8 (0.8)		3.8 (0.9)	.001 (T)
CGI-Improvement			2.6 (1.0)			2.8 (1.0)	
HAMA	27.0 (11.0)		18.6 (10.1)	27.5 (9.2)		20.4 (8.1)	.001 (T)
HAMD	22.7 (6.7)		14.1 (8.1)	22.1 (5.4)		16.0 (6.4)	.001 (T)

<sup>a</sup> Rated on an 8-point scale.

EXP), that veterans were moderately confident about the treatment ( $M=5.6$  for TMT and  $M=6.4$  for EXP), they had moderate to high expectancy of success ( $M=7.9$  for TMT and  $M=6.8$  for EXP), and were highly confident that the treatment would be successful in decreasing another fear ( $M=7.8$  for TMT and  $M=7.5$  for EXP). There were no significant group differences on the satisfaction measure, with both groups indicating that there was a very good match of the treatment to their needs ( $M=4.1$  for TMT and  $M=4.3$  for EXP), that there was a very good quality of care ( $M=4.8$  for TMT and  $M=4.5$  for EXP), and that they would definitely recommend the treatment to a friend ( $M=3.9$  for TMT and  $M=3.8$  for EXP). Five veterans (3 in TMT, 2 in EXP) participated in the post-treatment assessment but refused to complete the CAPS or the PCL-M, voicing concern that the data could be used to change their disability status. For those veterans, we used last observation carried forward (LOCF), carrying forward their pretreatment scores on these variables. These five veterans also were not consistently compliant with completing self-monitoring data. Thus, for the self-report data analysis, we excluded their data, analyzing 11 participants in the TMT group and 13 participants in the EXP group.

Group differences were analyzed with a 2 (group)  $\times$  2 (time; pre vs. post) repeated measures ANOVA for all clinical ratings and self-report questionnaire data. Group differences were analyzed with a 2 (group)  $\times$  3 (time; pre vs. mid vs. post) repeated measures ANOVA for self-monitoring data. Results are presented according to the three categories of outcome data described above: PTSD symptoms, social and emotional functioning, and symptoms of other psychiatric disorders. Means and standard deviations are presented in Table 1.

**PTSD Symptoms.** There were significant main effects for time for the CAPS Total Score ( $F(df=1,28)=34.08, p<.001$ ) and the PCL-M ( $F(df=1,28)=6.72, p<.01$ ). In each case, scores for both groups were significantly lower at post-treatment compared to pretreatment, indicating decreased PTSD primary symptoms. Similarly, there were significant main effects for time for the number of nightmares per week ( $F(df=2,44)=5.30, p<.01$ ) and number of flashbacks per week ( $F(df=2,42)=3.55, p<.05$ ). In each case, nightmares decreased from pre-treatment to post-treatment. There were no significant main or interaction effects for the number of

hours of sleep per night or the clinician's rating of behavioral avoidance.

**Social and Emotional Functioning.** There was a significant main effect for time on the CAPS social and emotional functioning subscale ( $F(df=1,27), p<.001$ ), indicating that both groups reported improved social and emotional functioning at post-treatment. There were significant time  $\times$  group interaction effects for two of the self-monitoring variables: number of social activities per week ( $F(df=2,44)=4.47, p<.025$ ), and the number of minutes per day engaged in social activities ( $F(df=2,44)=4.23, p<.025$ ). In each case, post hoc analyses indicated that only the TMT group had a significant increase in frequency and duration of social activities, and only after the introduction of the SER component (e.g., significant change occurred from mid- to post-treatment [ $p<.05$ ], corresponding with the introduction of the SER component of TMT).

There was also a significant time  $\times$  group interaction effect for the global rating of anxiety ( $F(df=2,44)=5.30, p<.01$ ) and physical rage episodes ( $F(df=2,44)=4.23, p<.025$ ). Post hoc analyses indicated that anxiety decreased significantly from pre- to mid-treatment for the TMT group and from mid- to post-treatment for the EXP group. With respect to physical rage episodes, the TMT group reported a significant decrease between pre- and mid-treatment, prior to the introduction of the SER component. There was a significant main effect for time for verbal rage episodes ( $F(df=2,44)=5.63, p<.01$ ). There were no significant main or interaction effects for global anger, or the total score on the Quality of Life Questionnaire.

**Symptoms of Other Psychiatric Disorders.** There were significant main effects for time for the CGI rating of severity ( $F(df=1,28)=41.35, p<.001$ ), the Hamilton Rating Scale for Anxiety ( $F(df=1,28)=17.49, p<.001$ ), and the Hamilton Rating Scale for Depression ( $F(df=1,28)=28.62, p<.001$ ). At post-treatment, overall clinical status was rated as between mild and moderately ill on the CGI Severity of Illness Scale, significantly lower than at pretreatment. Consistently, although improved with respect to pretreatment, scores on the HAMA and HAMD indicted minimal to moderate levels of depression and anxiety were still present.

Because ratings of improvement only occurred at post-treatment, an independent samples *t* test was used to examine CGI

ratings of improvement. These results did not indicate a differential improvement rate for the groups. On average, improvement fell between minimally and much improved for each group.

**Treatment Responder.** A chi square analysis indicated no significant difference in the percentage of veterans in each group who were rated as a treatment responder (43% in the TMT group vs. 44% in the EXP group).

### 3. Discussion

This is one of the first clinical trials to demonstrate efficacy of exposure therapy for treating the core symptoms of PTSD among combat veterans with a very chronic form (40 years) of this disorder. Veterans in both conditions, TMT and EXP, showed statistically significant and clinically meaningful reductions in global PTSD symptoms from pre- to post-treatment as rated by both structured interview (CAPS) and self-report (PCL). Participants in both conditions also demonstrated significant reductions in nightmares, flashbacks, and weekly episodes of verbal rage though there were no group differences on these variables. There were no statistical improvements on hours of sleep or behavioral avoidance variables for either group. Further, veterans in both conditions demonstrated statistically significant and clinically meaningful improvements on a global index of social and emotional functioning, though not on one related to quality of life. Compared to the EXP group, those participants in the TMT group showed increased weekly social activities and greater time spent in weekly social activities. Importantly, these changes occurred from mid-treatment (after completion of exposure therapy) to post-treatment (after completion of the SER component), supporting the hypothesis that TMT would lead to improved social functioning across a number of domains. There were also fewer weekly episodes of physical rage (although the latter decrease occurred from pre- to mid-treatment and cannot be directly attributed to the SER component of TMT). Unfortunately, and contrary to expectation, neither group showed improvements on global ratings of anger or scores on the Quality of Life Questionnaire. Finally, there was significant improvement on global assessments of illness severity, anxiety, and depression for veterans in both conditions, and just under half (44% TMT, 43% EXP) were classified as “treatment responders.” However, there were no differences between condition on any of these domains.

Taken together, these results show that participants in both conditions tolerated and benefitted from exposure therapy, contributing to the growing literature attesting to its treatment benefits for reducing core PTSD symptoms in combat veterans with the disorder. Among the five veterans who dropped out of the treatment study (14.3% drop out rate), two (6% of those who started treatment) dropped out as a result of worsening psychopathology. One veteran died as a result of heart disease and two others were diagnosed with serious medical conditions (not uncommon given the average age of the population). In fact, treatment drop out (14.3%) was lower than the 20–35% often reported in clinical trials with veterans or PTSD patients (IOM, 2007), and is comparable to at least one other recent RCT for veterans with PTSD (Morland et al., 2010). Among those who did complete treatment, participants in both conditions reported high levels of treatment credibility and satisfaction with their course of treatment.

It should be noted that 20% of the recruited sample agreed to the assessment but then declined treatment participation. In the majority of cases, this was the result of a lack of desire for treatment – potential participants noted that they were just in need of an updated disability evaluation. Therefore, although our results provide further support for use of cognitive-behavioral interventions, including exposure therapy (Becker, Darius, & Schaumberg, 2007), with this population, it should be noted that there is still a

substantial subset that are not benefitting from the treatment as they decline participation.

This study has several important and novel aspects. First, it is one of only a very small number of methodologically rigorous RCTs of interventions for combat veterans with PTSD. Study implementation was rigorously controlled, including randomized assignment, careful a priori analyses, use of an evidenced-based manualized intervention, careful therapist fidelity monitoring, and high participant adherence and retention rate in a difficult to treat clinical sample. Second, the cognitive-behavioral interventions, including exposure therapy, were well received and tolerated by the veterans and were clinically efficacious. Third, the SER component shows promise for improving social and emotional functioning beyond that provided by exposure therapy alone, by increasing social engagement. Fourth, there is good reason to believe that study participants are representative of the broader population of combat veterans with PTSD, given inclusion/exclusion criteria (Stirman, 2008), which allowed for high rates of psychiatric comorbidity, illness severity, and functional impairment.

Despite its merits, the current study has several important limitations. First, we did not fully evaluate changes in many important domains of functional impairment, such as marital/family relationships, and we did not use more traditional psychometric measures to evaluate domains related to anger (e.g., the Novaco Anger Scale; Novaco, 1975), patient satisfaction, etc. Second, although we collected follow-up data on 10 of the 30 participants, a number of patients declined to return to the clinic simply for assessments, coupled with the move of the first author to a different university, did not allow collection of follow-up data on the majority of participants. Third, the SER component did not successfully accomplish all that we initially envisioned. In particular it did not appear to have had a meaningful impact on general quality of life. However, this was a very chronic sample, many of whom had a 40-year history of unemployment, social isolation and family estrangement. It may have been optimistic to expect comprehensive changes in such a short period of time for such a chronic sample; given this level of chronicity, a more extensive intervention may be necessary. In contrast, for those veterans more recently exposed to trauma who have not yet suffered the extensive long-term effects of this disorder, the treatment length used in this study may be sufficient.

Although self-report measures of anger improved over the course of treatment, the change was not specifically linked to the SER component of TMT. Finally, global reductions in PTSD symptoms for veterans in both conditions, while clinically meaningful and statistically significant, did not decrease. Unfortunately, this pattern of only modest treatment success actually represents an improvement over most prior treatment studies with male combat veterans suffering PTSD (Bradley et al., 2005). As noted elsewhere (Frueh et al., 2007), most veterans evaluated and treated for PTSD within the VA are applying for and/or already receiving disability payments for their psychiatric symptoms, which represents a significant disincentive to recover or acknowledge clinical improvements. In fact, many participants in the current study expressed concerns about losing their disability benefits if their hospital records reflected significant improvement in PTSD symptoms. This represents an important area for VA policy reform and also a clinical challenge that current VA clinicians and future clinical studies with this population need to address in some way.

#### 3.1. Future directions

In addition to addressing all of the weaknesses noted above, future efforts might benefit from trying to tighten the focus of the social and emotional component, so as to more effectively target specific domains of interest. For example, elements of Behavioral

Activation (Lejuez, Hopko, & Hopko, 2001) have recently been used with veterans and may offer hope for addressing social isolation and depressive symptoms. Efforts to simplify or shorten the intervention might also be useful. Cost analyses are also necessary to improve our understanding of the relative costs and cost-benefits of the interventions, as well as other relevant systemic and economic implications of increasing access to mental healthcare for veterans. Finally, dissemination and implementation research are needed on how to most effectively translate evidence-based practices for populations with PTSD and integrate with existing models of care within the VA (Cahill, Foa, Hembree, Marshall, & Nacash, 2006; Cook, Schnurr, & Foa, 2004; Foa, 2006; Frueh, Grubaugh, Cusack, & Elhai, 2009).

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