Journal of Anxiety Disorders 50 (2017) 23–32

Contents lists available at ScienceDirect

Journal of Anxiety Disorders

journal homepage: www.elsevier.com/locate/janxdis

The efficacy of Trauma Management Therapy: A controlled pilot investigation of a three-week intensive outpatient program for combat-related PTSD☆

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ARTICLE INFO

Keywords:
PTSD
Combat-trauma
Exposure therapy
Skills training
Virtual reality

ABSTRACT

Despite the 8–18.5% of returning Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF) and Operation New Dawn (OND) veterans who are suffering from posttraumatic stress disorder (PTSD), few receive empirically supported treatments. Among those that do, the dropout rate is high and more than 50% retain their diagnosis after treatment. This study evaluated the efficacy of Trauma Management Therapy (TMT), delivered in a 3-week intensive outpatient (IOP) format. TMT combines virtual-reality augmented individual exposure therapy with a group intervention to address social isolation, anger, and depression. One hundred twelve (112) OIF/OEF/OND veterans and active duty personnel participated. Assessment included measures of PTSD, sleep, depression, anger, guilt, and social isolation, administered at post-treatment, 3-month, and 6-month follow-up. The effect size for TMT delivered in an IOP format was 2.06, with 65.9% no longer meeting diagnostic criteria for PTSD. There were similar positive effects in other domains and treatment gains were maintained at 6-month follow-up. The results are discussed regarding the need for efficacious, multi-component interventions that can be delivered safely and rapidly, and the potential of this approach towards that end.

1. Introduction

It is estimated that between 8% and 18.5% of veterans returning from Operation Iraqi Freedom/Operation Enduring Freedom/Operation New Dawn (OIF/OEF/OND) have been diagnosed with posttraumatic stress disorder (PTSD) (Richardson, Frueh, & Acierno, 2010; Smith et al., 2008; Tanielian & Jaycox, 2008). Given this prevalence, providing empirically supported treatments for the nation's veterans and active duty personnel who have served in these conflicts remains a national imperative.

The US Department of Veterans Affairs (VA) has designated prolonged exposure therapy (PE) and cognitive processing therapy (CPT) as empirically supported and first-line psychological treatments for PTSD in the VA settings. The published clinical trial literature on the treatment of PTSD among civilians (e.g., rape victims) shows substantial treatment gains across virtually all studies, with about 50% of patients showing full remission from the disorder; in stark contrast, the published literature on treatment of PTSD in combat veterans shows almost no treatment benefits, with very few in full remission (see review by Bradley, Greene, Russ, Dutra, & Westen, 2005). A recent meta-analysis has found this unfortunate pattern remains in effect (Watts et al., 2013). Among randomized controlled trials for OIF/OEF veterans with combat-related PTSD (Monson et al., 2006; Morland et al., 2014; Rauch et al., 2015; Reger et al., 2016; Resick et al., 2015, 2017; Yehuda et al., 2014; Yuen et al., 2015), significant reductions in symptoms occur but with few exceptions (Reger et al., 2016; Resick et al., 2017) sample sizes were small and approximately half to two thirds still met diagnostic criteria for PTSD (Steenkamp, 2016). In an assessment of the status of current psychological treatments, Hoge, Lee, and Castro (2016) describe an "ongoing crisis" in PTSD care for active duty personnel and veterans, reiterating the challenge of high treatment attrition (averaging 28% and up to 40% in recent RCTs) and the substantial number who retain their PTSD diagnosis after a full course of treatment. They conclude that there is still considerable room for

☆ This study was supported by the U.S. Army Medical Research & Materiel Command-Military Operational Medicine Research Program (USAMRMC-MOMRP; contract W81XWH-11-2-0038) to the first and second author. The study had both MRCM HRPO and local IRB approval and does not necessarily reflect the policy/position of the government. The funding source had no involvement with the design, collection, analysis or interpretation of the data, or the writing of the report or the decision to submit the article for publication.

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http://dx.doi.org/10.1016/j.janxdis.2017.05.001
Received 1 January 2017; Received in revised form 25 April 2017; Accepted 3 May 2017
Available online 11 May 2017

improving treatment efficacy, "particularly interventions that enhance treatment engagement or retention" (Hoge et al., 2016, p. E2).

Surveys of returning veterans (Crawford et al., 2015), active duty personnel (Hoge et al., 2004) and active duty personnel and National Guard (Kim, Thomas, Wilk, Castro, & Hoge, 2010) list the barriers that these personnel perceive with respect to accessing empirically supported treatments. These barriers include difficulties in scheduling appointments (due to lack of services in their area or difficulty in getting time off from work (Hoge et al., 2004; Kim et al., 2010)), perceived stigma of requesting or receiving services (Crawford et al., 2015; Hoge et al., 2004; Kim et al., 2010) and a disconnect between the services desired and the services offered (Crawford et al., 2015). With respect to the latter barrier, veterans report a preference for treatment of mental health issues such as sleep disruption, anger and stress, which are not often an integral part of the first-line treatments for PTSD provided by the VA.

The concerns about stigma may be the most difficult to overcome. Although the military has continuously provided assurance that seeking psychological treatment will not affect career trajectories, many individuals do not believe this to be the case. Thus, to address personnel concerns, what may be needed is not reassurance, but an alternative conceptualization of PTSD and how to treat it. For example, physical injuries because of military service typically require an intensive period of treatment and rehabilitation, after which the warfighter returns to active duty. If PTSD were re-conceptualized as a *psychological* injury, the same treatment approach could apply. That is, rather than a series of weekly outpatient appointments, where treatment stretches over several months (and dropout rates are high), treatment would be delivered intensively within a shorter time frame. Within the psychiatric treatment literature, such models exist, the most common of which is the intensive outpatient program (IOP).

An alternative to traditional outpatient therapy and less restrictive than inpatient hospitalization, IOPs are designed to (a) deliver treatment in a more rapid fashion, (b) establish psychosocial supports for participants, and (c) address relapse and enhance coping skills (McCarty et al., 2014). The IOP "…allowed acute patients to be treated in an outpatient setting and also provided clinicians the opportunity to work intensively with patients on a daily basis for an extended period of time" (Wise, 2005, p. 887). Furthermore, the IOP model is consistent with the extant literature that exposure therapy is most efficacious when delivered in "massed" versus "spaced" fashion (Foa, Jameson, Turner, & Payne, 1980; Gutner, Suvak, Sloan, & Resick, 2016). IOPs have been used with a variety of patient populations including individuals with mood and anxiety disorders (Ritschel, Cheavens, & Nelson, 2012), obsessive-compulsive disorders (Shikatani et al., 2016), eating disorders (Schaffner & Buchanan, 2008), and substance abuse (McCarty et al., 2014). Successfully implemented in private practice settings to treat individuals with severe depression (see Wise, 2005 for a review), IOPs have also been used to treat small samples of veterans and active duty personnel with PTSD (Dretsch et al., 2016; Humphreys, Westerink, Giarratano, & Brooks, 1999; Lande, Williams, Francis, Gragnani, & Morin, 2017; Meyers et al., 2017), with program length ranging from 3 to 12 weeks. The results of these investigations suggest some decrease in PTSD symptoms but individuals remain impaired (Lande et al., 2011). Other limitations of these investigations include small sample sizes, lack of clarity in the samples with respect to the triggering traumatic event (combat, sexual trauma), outcome assessment restricted to symptoms of PTSD and depression, and except for Humphreys et al. (1999), minimal follow-up.

IOPs hold significant promise in addressing some of the identified treatment barriers relevant to OIF/OEF service personnel. For example, providing empirically-supported treatments in this intensive fashion may help address the high drop-out rates (up to 40%) of programs that offer treatment once or twice per week (Imel, Laska, Jakupcak, & Simpson, 2013; Steenkamp, Litz, Hoge, & Marmar, 2015). An IOP could be particularly advantageous for active duty personnel who may be forced to drop out of traditional outpatient treatment programs because of orders to deploy or a change in duty station (e.g., Reger et al., 2016). Finally, recalling that one of the major barriers to treatment acceptance was that offered treatments were not always consistent with services that veterans most desired, an IOP model could combine current efficacious interventions and include additional desired services. "Including treatment components that veterans felt necessary could enhance treatment engagement or retention" (Hoge et al., 2016, p. E2). In a synergistic fashion, an IOP could be a service delivery model that has the promise to treat severe psychological disorders (Wise, 2005). However, further research is needed to determine the feasibility/efficacy of this treatment model.

Given the extensive limitations in the extant combat-related PTSD treatment literature and the promising nature of IOPs for treating severe psychological disorders, the next logical step is a well-controlled pilot investigation of an IOP format for the treatment of combat-related PTSD. Such an investigation should include a sufficient sample size, a manualized intervention and a multi-component assessment battery designed to assess not simply core PTSD symptoms but the feasibility/acceptability of this format as well as assessment of the myriad of behavioral and emotional symptoms that are part of this disorder. Trauma Management Therapy (TMT; Frueh, Turner, Beidel, Mirabella, & Jones, 1996; Turner, Beidel, & Frueh, 2005) was developed in the mid-1990s to address what were perceived as the limitations of standard exposure therapy for Vietnam veterans, who continued to exhibit anger, social isolation, depression, and guilt. TMT includes intensive individual exposure therapy plus a group intervention that addressed these additional behaviors and emotions. An initial randomized controlled trial with Vietnam veterans (Beidel, Frueh, Uhde, Wong, & Mentrikoski, 2011) and a recent randomized controlled trial with OIF/OEF veterans (Beidel et al., under review) both indicate statistically significant decreases on core PTSD symptoms as well as significant decreases for depression, anger, and social isolation. Given (a) the current status of treatments for combat-related PTSD, (b) the desire to provide interventions that enhance treatment engagement and retention (thereby reducing dropout rates), and (c) the potential of the IOP format to provide treatment rapidly and in a manner consistent with how physical injuries are treated, the next logical step is a controlled pilot investigation of TMT adapted for an IOP format.

Therefore, this study had two specific aims. The first aim was to deliver TMT using an IOP format, evaluating the acceptability and feasibility of this intervention when delivered in this format (drop-out rate, iatrogenic effects). The second specific aim was to examine TMT's efficacy in this format not only on core symptoms but also on associated emotions/behaviors in an OIF/OEF/OND sample.

2. Method

2.1. Study overview

We conducted a controlled pilot study, adapting TMT to an IOP format treatment in a sample of OIF/OEF/OND veterans and active duty military personnel (n = 112). Specifically, we adapted TMT, a 29-session intervention originally administered across of 17 weeks, to be delivered in three weeks. Clinical and process outcomes representing multiple symptom domains were assessed at pre-treatment, post-treatment, 3-month, and 6-month follow-up.

2.2. Participants

The study was approved by the US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office and from the University of Central Florida IRB and informed consent was obtained from each participant. Participants were recruited nationwide through Yellow Ribbon events, presentations to (a) veteran's support groups, (b) veteran related public

events, and (c) staff at military installations, as well as radio and television ads, and social media. Housing in the Orlando area was provided by the research grant; however, participants provided their own transportation to Orlando.

This study was initiated prior to the publication of the Diagnostic and Statistical Manual-5th Edition (APA, 2013), thus, diagnoses were assigned using DSM-IV-TR criteria. To establish the diagnosis, participants were assessed with the Clinician—Administered PTSD Scale (see below). Only participants who were confirmed by the CAPS assessment to have a primary DSM-IV diagnosis of combat-related PTSD were included in the study. Twenty percent of the interviews were audio/videotaped and rated by a second clinician to calculate inter-rater reliability. Following the CAPS interview, participants were interviewed with the Structured Clinical Interview for DSM-IV (SCID; First, Gibbon, Spitzer, Williams, & Benjamin, 1997) and the Structured Clinical Interview for DSM-IV (SCID-II; First, Spitzer, Gibbon, & Williams, 1997) to assess presence/absence of other Axis I and II disorders.

Specific inclusion and exclusion criteria were as follows:

- Individuals who reported acute cardiac difficulties (angina, myocardial infarction, and severe hypertension) were initially excluded because intensive exposure therapy, which is often accompanied by temporary increases in heart rate and blood pressure, could pose risks of exacerbating cardiac status. They were included only after their physician cleared their participation.
- Participants with comorbid psychotic disorders or antisocial personality disorder were excluded. Participants with acute substance abuse disorder were excluded until their substance abuse was under control for at least two weeks.
- Patients with comorbid depressive disorders, anxiety disorders, and personality disorders other than Antisocial Personality Disorder were included. Participants with comorbid mild Traumatic Brain Injury were included.
- Participants on benzodiazepines were excluded until they had discontinued use of benzodiazepines (under physician supervision). This exclusion was based on the empirical evidence to suggest that the efficacy of exposure therapy may be attenuated by benzodiazepines (Gray, 1987; Wardle, 1990). Patients on SSRI antidepressant medications were included after their medication regimen was stabilized for at least 2 weeks; this interval was chosen because it allowed for the establishment of a stable therapeutic dose. However, because psychotropic medications alone have not been demonstrated to be efficacious for combat-related PTSD (e.g., Friedman, Marmer, Baker, Sikes, & Farfel, 2007) this period provided an adequate interval prior to initiating the behavioral intervention. The study protocol required that medication was to remain stable throughout treatment.

One hundred twenty-two (122) veterans and active duty personnel were formally screened for the program (see Chart 1). Recruitment occurred from May 2012 through May 2016. Follow-up was completed December 2016. Ten participants declined to participate in the study. Of the 112 participants who began treatment, 10 were removed for administrative reasons as follows. Four (4) were removed for malingering – participants openly admitted in group treatment that they were deliberately planning to 'fail' the treatment to secure disability compensation or be dismissed from the military for medical reasons. Three (3) were excluded because further assessment after randomization revealed a primary diagnosis of depression, not PTSD. Three were removed because of protocol violations – participants decided to stop their medication against medical advice.

Only 2 participants dropped out of the study during treatment (although we were able to capture posttreatment data on 1 of those participants). Thus, a total of 100 participants completed the treatment program (Table 1).

2.3. Assessment

Clinician—Administered PTSD Scale (CAPS; Blake et al., 1990; Weathers & Litz, 1994; Weathers, Ruscio, & Keane, 1999). The CAPS is a 30-item semi-structured interview. In addition to assessing severity of each of 17 diagnostic criteria, the CAPS quantifies the impact of symptoms on social and occupational functioning. We used the "1, 2" rule be used to determine a diagnosis; that is, a frequency score of 1 (scale 0 = "none of the time" to 4 = "most or all of the time") and an intensity score of 2 (scale 0 = "none" to 4 = "extreme") is required for a particular symptom to meet criterion (Weathers et al., 1999). The diagnosis is then made according to the DSM-IV algorithm: (a) Criterion A is met, (experienced event and response involved intense fear, horror or helplessness); (b) At least one Criterion B symptom, (re-experiencing); (c) At least three Criterion C symptoms, (avoidance); (d) At least 2 Criterion D symptoms, (arousal); (e) Criterion E is met, (duration greater than one month) and (f) Criterion F is met (distress or impairment).

The CAPS was designated a priori as the primary outcome measure. In addition, the information on the CAPS was used to determine whether participants still met diagnostic criteria for PTSD at posttreatment and at all follow-up assessments. Licensed clinical psychologists or doctoral students in clinical psychology conducted the interviews. CAPS interviews were videotaped and 20% (across all assessment points) were rated by a second clinician for the purpose of determining inter-rater reliability. The resultant intra-class correlation was .993.

PTSD Checklist – Military Version (PCL-M; Weathers, Huska, & Keane, 1991). The 17-item self-report military-specific version of the PCL was used to assess PTSD symptom severity at pre and post-treatment as well as 3 and 6-month follow-up. Test-retest reliability is high (r = .97; Weathers, Herman, Huska, & Keane, 1993) and there is good convergent validity with other measures of trauma (r = .90; Weathers et al., 1993). Because this investigation used an intensive outpatient (3 week) format, participants were asked to assess the severity of their symptoms "over the past week" rather than over the past month. This was necessary to determine that assessment of post-treatment PTSD symptoms was not confounded by pre-treatment clinical status. Cronbach's alpha for this sample was 0.87.

Structured Clinical Interview for DSM-IV (SCID I and II; First, Gibbon et al., 1997; First, Spitzer et al., 1997) was used at pre-treatment to assess other Axis I and II disorders.

Quality of Life Inventory (QoLI; Frisch, 1994). The QoLI is a 192-item self-report questionnaire that assesses patients' perception of their quality of life across 15 different domains, including dimensions of interpersonal relationships (marital, parent-child, extended family, extramarital, and occupational) and social activities (altruistic behavior, political behavior, creative-aesthetic behavior, sports activity, and vacation behavior). The QoLI has good test-retest reliability (r = 0.79), and good convergent validity (r = 0.56) with other measures of life satisfaction (Frisch, 1994). The QoLI was administered at all 4 assessment points. Cronbach's alpha for this sample was 0.85.

Health-Related Functioning: Medical Outcome Study Short Form-36 Health Survey (SF-36; Ware & Sherbourne, 1992). The SF-36 is a 36-item self-report questionnaire that assesses health status and functioning along 8 dimensions covering (a) Functional Status; (b) Well-Being; and (c) Overall Evaluation of Health. The SF-36 has good test-retest reliability (r = 0.75) as well as sensitivity to change in health status (Beaton, Hogg-Johnson, & Bombardier, 1997; Brazier et al., 1992). The SF-36 was administered at all 4 assessment intervals. Cronbach's alpha for this sample was 0.92 for physical health and 0.90 for mental health.

The Behavior Rating Inventory of Executive Function – Adult Version (BRIEF-A; Roth, Isquith, & Gioia, 2005) The BRIEF-A assesses an individual's perception of their executive functions in nine areas and provides an overall summary score, the Global Executive Composite (GEC). Test-retest reliability ranges from 0.82 to 0.93 over a 4-week

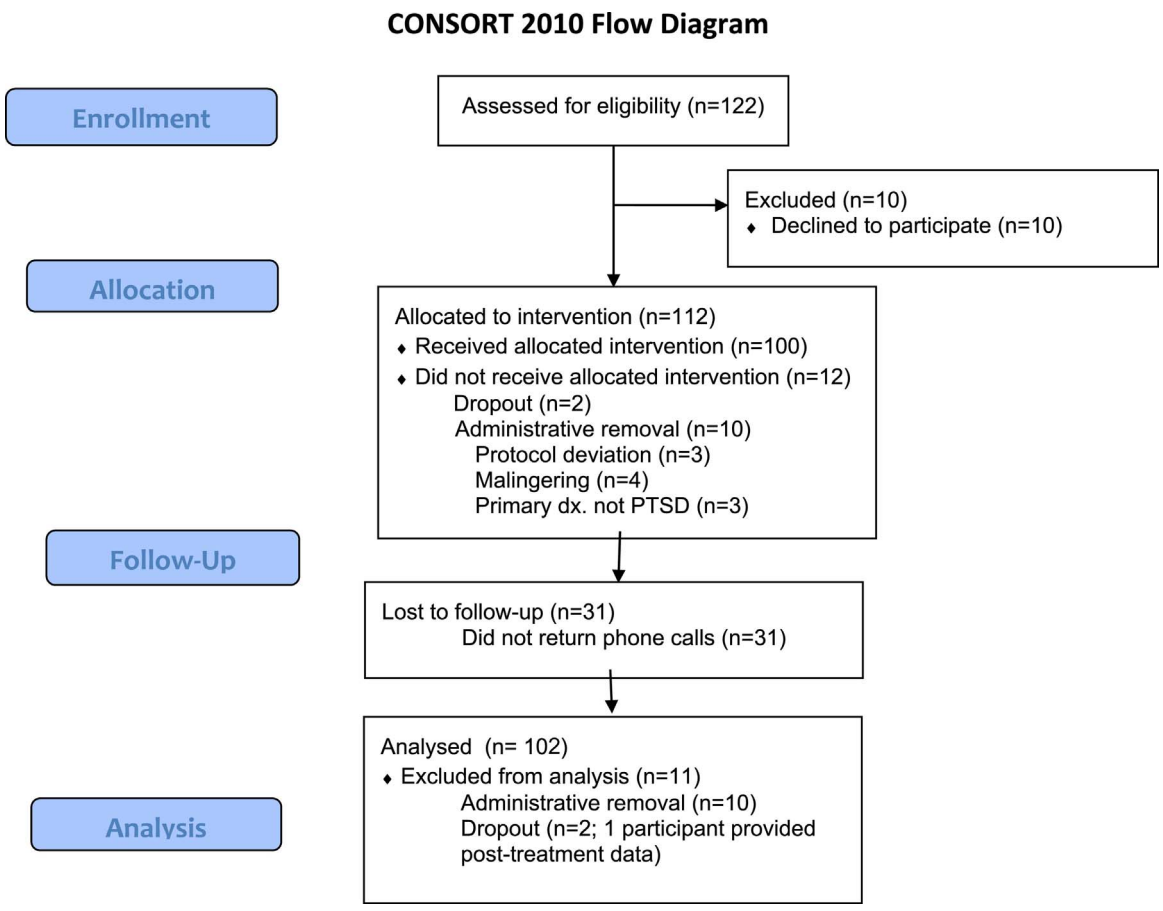

Chart 1. CONSORT diagram.

period and correlates significantly with other measures of executive functioning (r = 0.67 to r = 0.74; Roth et al., 2005). The BRIEF-A also includes assessment of behaviors that are related to poor executive functioning, such as anger. For this investigation, the anger item was used as part of the anger construct developed for the efficacy evaluation. The BRIEF-A was administered at each assessment point. Cronbach's alpha for this sample was 0.96.

Trauma-Related Guilt Inventory (TRGI; Kubany et al., 1996). The TRGI is a 32-item measure assessing 3 domains of trauma related guilt cognitions (Global Guilt, Distress, and Guilt Cognitions). Coefficients alpha computed for the Global Guilt, Guilt Cognitions, and Distress scales were 0.90, 0.86, and 0.86, respectively. The Global Guilt scale was correlated .48 with the Modified PTSD Symptom scale and 0.60 with the Beck Depression Inventory (both $p < .01$). The TRGI was added after study initiation but was administered at pre, post, and follow-up assessments. Cronbach's alpha for this sample was 0.95 for global guilt.

Clinical Global Impressions Scale (CGI; Guy, 1976). The Severity and Global Improvement Subscales are each 7-point scales that were used to assess overall severity and improvement at all assessment points as well as weekly during treatment. Inter-rater reliability was 0.95 for the CGI severity scale.

Hamilton Rating Scale for Depression (HAMD; Hamilton, 1960). This well-known clinical rating scale was used to assess depression. Inter-rater reliability was 0.93.

Clinician Administered Rating Form of Functional Indicators. Data were collected at each assessment point via a clinician-administered checklist regarding objective indicators of social functioning, such as changes in marital status, employment status, residential status, legal involvement, psychiatric hospitalization, and utilization of medical care.

Self-Monitoring. Throughout treatment patients kept a log of daily behavioral ratings to monitor the frequency and severity (on a 10-point scale) of PTSD symptoms, including nightmares, flashbacks, total hours of sleep, anger, physical rage episodes, verbal rage episodes, and anxiety.

2.4. Treatment credibility

To assess for outcome expectancy, treatment credibility scales developed by Borkovec and Nau (1972) were used. Three of the questions were used for this study, with 10-point Likert scales. These include questions regarding how logical the treatment seems, how confident participants are about treatment, and their expectancy of success. Treatment credibility was administered at Session 3, and participants were instructed to make their ratings based on their evaluation of all treatment components.

2.5. Treatment

2.5.1. Overview of the TMT Intensive Outpatient Program (IOP)

Referrals to the program were national in scope; therefore, individuals referred to the program completed a telephone screen to determine whether they met study exclusion/inclusion criteria. Following general screening questions, the CAPS was administered to determine a diagnosis of PTSD. After confirmation and before the first day of the IOP, the participant completed all other diagnostic interviews, self-report measures and a week of self-monitoring as described above. TMT was conducted as a closed cohort, which was composed of 4 to 7 participants depending upon the number seeking treatment at any one time. Participants were housed in the same local hotel, close to the location of the clinic (see Beidel, Stout, Neer, Frueh, & Lejuez, in

Table 1
Demographics.

Demographic Characteristics	Mean (sd)
Age	37.1 (9.1)
	N (%)
Sex	
Male	97 (95%)
Female	5 (5%)
Race	
Caucasian	67 (65.7%)
Hispanic	15 (14.7%)
Black	12 (11.8%)
Other	8 (7.8%)
Education	
High School Diploma	17 (16.7%)
Some College	61 (59.8%)
Bachelors	16 (15.7%)
Graduate	8 (7.8%)
Marital Status	
Single	17 (16.7%)
Married	55 (53.9%)
Separated	10 (9.8%)
Divorced	20 (19.6%)
Military Branch	
Army	74 (72.5%)
Marines	11 (10.8%)
Navy	7 (6.9%)
Airforce	9 (8.8%)
Coast Guard	1 (≈1%)
Active Duty	
Yes	37 (36.3%)
No	65 (63.7%)
Service Connected Disability	
Service Connected	51 (50%)
None/Not Applicable	51 (50%)
Average Disability%	74.5%
Comorbidity	
Mood Disorder	66%
Substance Use Disorder	15%
Panic Disorder	12%
Specific Phobia	5%
Generalized Anx. Dis.	3%
Social Anxiety Disorder	1%
Adjustment Disorder	1%
Obsessive-Compulsive Disorder	1%

press for logistical details of the IOP format). At the end of the IOP, participants returned home. The therapist scheduled a phone assessment one week post treatment to complete the CAPS, so that their clinical status could be assessed in their home environment. The validity of the CAPS administration over the telephone has been repeatedly demonstrated (e.g., Magruder et al., 2005). The other assessment measures were completed at that time and mailed back to the therapist. Follow-up assessments occurred three and six months post-treatment.

2.6. Elements of the TMT Program

2.6.1. Exposure therapy

Individual exposure therapy was conducted each morning and consisted of imaginal exposure augmented by virtual reality (*Virtual Iraq/Afghanistan System;* Rizzo, Reger, Gahm, Difede, & Rothbaum, 2009). The first exposure session consisted of a review of the information collected on the CAPS and the development of the imaginal scene. This session also included a "test" of the virtual reality elements (sights, sounds, smells) to accurately reproduce the individualized traumatic event. The imaginal scene was then written and approved by the first or third author. Beginning in session 2, baseline level of distress was assessed and then the imaginal scene (augmented by VR) was presented. At 10 min intervals, the therapist assessed the individual's level of distress, using a 9 point (0–8) SUDS Likert scale, where 0 equaled no distress and 8 was extreme distress. Sessions were conducted until within session habituation (a minimum of 50% reduction from in session "peak SUDS") occurred. Thus, a patient who had a peak anxiety of "8" would continue exposure until reporting a level of 4 or lower. Session SUDS levels were tracked and reviewed at weekly supervisory sessions. If the patient achieved between session habituation (no increase is SUDS upon presentation of exposure scene), patients initiated in vivo exposure, using environments related to their traumatic scene (crowded places, sitting with one's back to a doorway, driving on roads resembling the location of the IED explosion, etc.). On average, patients had 9.5 imaginal sessions and 3.9 in vivo sessions.

2.6.2. Programmed Practice

Programmed practice consisted of therapist–unaccompanied in-vivo exposure assignments. Consistent with the individual's unique traumatic event, assignments included watching movies (e.g., Black Hawk Down, Restrepo), visiting crowded places, or engaging with others in crowded social settings. Programmed practice was introduced at session 8 and assignments were given during the final 7 exposure sessions.

2.6.3. Social and emotional rehabilitation (SER)

Each afternoon, patients participated in a highly-structured group therapy program (SER). Three interventions were included in this protocol; social reintegration, anger management/problem solving training, and brief behavioral activation for depression (See Table 2). Led by two therapists, the goal of the group sessions was skill acquisition, which included discussion, modeling, behavioral rehearsal, and feedback. Group sessions were 90 minutes in length. The components of SER are described below:

2.6.4. Social reintegration

The goal of social reintegration is to establish/re-establish and maintain relationships with family members, friends, and co-workers and to engage in/maintain diverse social activities. Specific attention is given to assertiveness skills and requesting behavior change.

2.6.5. Anger management

This element focuses on reducing temper outbursts and problematic expression of anger. Skills are broken down into specific components, which include identifying high risk situations and planning ahead, taking a break during a heated moment, reevaluating the situation, problem solving, and using assertive communication. Problem solving skills include defining the problem, brainstorming, evaluating solutions, and selecting/implementing a solution.

2.6.6. Brief behavioral activation

In brief behavioral activation (Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011), veterans learn skills to deal with depression and guilt. Treatment involves identifying areas of functioning where the individual would like to make changes and examining the values held within those areas. The patient identified, planned, and

Table 2
Structure of the TMT Group Therapy.

WEEK	Monday	Tuesday	Wednesday	Thursday	Friday
Week 1	Behavioral Activation	Social Skills	Anger Management	Social Skills	Anger Management
Week 2	Behavioral Activation	Social Skills	Anger Management	Social Skills	Anger Management
Week 3	Behavioral Activation	Social Skills	Anger Management	Behavioral Activation	Participants Go Home

carried out daily activities that were consistent with the values identified as important.

2.7. Treatment fidelity

Therapists were licensed clinical psychologists or advanced clinical psychology doctoral students who received didactic training in the theory and implementation of all treatment components. This training was followed by conducting the treatment on a non-protocol patient, with close supervision by the first or third author. After demonstrating mastery of the treatment components, therapists were assigned protocol patients. Therapists received weekly supervision from the first and third author. Twenty percent of the treatment sessions were randomly selected for treatment fidelity. Raters listened to each session and, using a form that included all the treatment elements, indicated which treatment components were included in that session. Furthermore, interventions that were not part of the overall treatment strategy (such as relaxation training) were also included on the rating form to identify whether there were extraneous elements included in the treatment session. There were no protocol deviations.

3. Results

3.1. Treatment feasibility and acceptability

With respect to feasibility, there were no instances of increased suicidal ideation, no suicidal attempts, and no participants were removed due to worsening symptomatology. Similarly, there were no instances of increased substance use, suggesting that the intensive nature of the treatment program does not produce iatrogenic effects. Similarly, there were only two participants who dropped out during treatment resulting in a treatment drop-out rate of 2%. However, we collected exit data on one of the drop-outs.

With respect to treatment acceptability/credibility, the average rating was 8.1 (on the 10-point scale) for the item “How logical does the treatment seem to you.” For the item “How confident are you that this treatment will be successful in eliminating PTSD?”, the average rating was 6.8. For the item, “How confident would you be in recommending this treatment to a friend who had PTSD,” the average rating was 8.6. Thus, the treatment had high credibility and acceptability.

3.2. Treatment efficacy

3.2.1. Data analytic strategy

As noted above, posttreatment assessment was conducted 1 week following the end of treatment, when the participants had returned home. Nine patients completed all treatment sessions but did not complete the post-treatment assessment. Thus, the final posttreatment sample with complete post-treatment data consisted of 93 participants. The intent to treat analysis was conducted after multiple imputation was used to account for missing data. Analyses were conducted using the entire sample (n = 102) and the sample with full-posttreatment assessment (n = 93). The proportion of missing data was so low that inclusion of the imputed variables added negligible variation, with most mean scores moving 1 point or less when compared to the completer sample. Because outcome did not change with the inclusion of imputed data, results presented here are for the sample with completed posttreatment data as they do not rely on estimation.

Treatment outcome was determined by comparing pre-vs post-treatment scores. Stability of treatment outcome was determined by comparing pre-treatment data to post-treatment, 3-month, and 6-month follow-up data.

Table 3
TMT IOP Pre and Post Outcome Measures on PTSD Symptoms.

Measure	Pretreatment (M and sd)	Posttreatment (M and sd)	t
CAPS	95.2 (15.6)	42.6 (25.7)	19.82***
PCL-M	64.1 (10.3)	44.1 (15.8)	13.09***
CGI- Severity	5.4 (0.7)	3.2 (1.2)	W = 3570***
CGI-Improvement		1.77	

*p < 0.05, **p < 0.01, ***p < 0.001.

3.2.2. PTSD symptoms

3.2.2.1. CAPS. A t test was used to examine changes on the CAPS from pre to posttreatment (see Table 3) and the results revealed a statistically significant decrease in CAPS score (t = 19.82, df = 92, p < 0.001), resulting in a large effect size (d = 2.06 ± 0.36).

3.2.2.2. PCL-M. Consistent with the outcome for the CAPS, at test revealed a statistically significant decrease in PCL-M scores (see Table 3) from pre to posttreatment (t = 13.09, df = 92, p < 0.001), again resulting in a large effect size (d = 1.4 ± 0.28).

3.2.2.3. CGI severity and improvement. At pre-treatment, the average CGI Severity score was 5.4, indicating that the participants were rated as markedly to severely ill. At post treatment, the average rating was 3.2, indicating mild illness. Because the CGI-Severity ratings were not normally distributed, a Wilcoxon Signed Rank Test was used to examine pre vs post-treatment scores. The results indicated a statistically significant decrease in illness severity (W = 3570, p < .001). Consistently, the average improvement as assessed by the CGI Improvement scale was 1.77, indicating that the average participant was “much” to “very much” improved.

3.3. Other behavioral and emotional symptoms

Given PTSD’s multi-dimensional nature, demonstrating efficacy should include assessment of impact on anger, guilt, sleep, depression and social isolation, as well as core symptomatology. However, at the time the study was initiated, there were few specific measures that were validated for veterans and active duty personnel (except for depression). Other investigations have used a single item approach, such as a specific item on the CAPS. Although a single CAPS item has been used to assess constructs such as sleep (Pruiksma et al., 2016), such an approach is less than optimal. Questions of reliability arise for single item measures. Consistent with a multi-trait, multi-method approach to measurement, collecting information from multiple informants and/or multiple indices can reduce bias found by a single informant or a single instrument. Thus, just as investigators use both the CAPS and the PCL-M to assess changes in symptomatology, we constructed latent variables to assess sleep, anger, guilt, depression, and social interaction using data from self-report, clinician interviews and the daily diary. Specifically, four clinicians independently identified items from the entire assessment battery that addressed each of the five behavioral/emotional constructs. Using confirmatory factor analysis (CFA), various models (combinations of items) were tested to determine the factors that best fit the construct, using various indices of fit (CFI, RMSE, and SRMR).[1] For each CFA, we set criteria for CFI > 0.9, RMSE < 0.05, SRMR < 0.09 as suggested by Hu and Bentler (1999). Additional checks included verifying lack of multicollinearity, sampling adequacy (Kaiser-Meyer-Olkin test), and sphericity (Bartlett’s.). All our latent scores met the KMO cut-off value of 0.6 or higher except for Social, which was 0.58. These KMO’s confirm the existence of the latent variables, and thus warrant the choice of constructing the composite scores. For each

[1] All items included in the original analyses as well as all analyses conducted available from the first author upon request.

Table 4
TMT IOP Pre and Post Outcome Measures on Other Behavioral and Emotional Symptoms on Composite Measures.

Construct	Pretreatment (M and sd)	Posttreatment (M and sd)	T	Cohen's *d*
Sleep Disturbance	7.6 (1.4)	6.2 (2.3)	6.21***	0.63
Anger	6.2 (1.9)	3.9 (2.5)	9.73***	1.01
Guilt	5.8 (3.3)	2.2 (2.1)	6.11***	1.22
Depression	7.2 (1.5)	4.8 (1.9)	10.96***	1.26
Social Interaction[a]	3.0 (1.5)	4.0 (2.1)	4.36***	0.50

[a] Higher score on this variable represents better social functioning.
*** $p < 0.001$.

construct, all scores were scaled based on their ranges and weighted equally. The resultant composite score ranged from 0 to 10. Treatment efficacy data for sleep disturbance, anger, guilt, depression, and social isolation are presented below and in Table 4.

3.3.1. Sleep disturbance

The CFA resulted in a four-item sleep disturbance construct that included (1) the Pittsburgh Sleep Quality Index Addendum for PTSD (PSQIA) total score, (2) CAPS item 13 (difficulty falling or staying asleep), (3) PCL-M item 13 (trouble falling or staying asleep), and (4) average duration of sleep from the daily diary ratings; higher scores indicate lower sleep quality. The resultant *t*-test indicated a significant decrease in sleep disturbance from pre to post-treatment ($t = 6.21$, $df = 92$, $p < 0.001$).

3.3.2. Anger

The CFA resulted in a four-item construct that included (1) daily diary general anger rating, (2) PCL item 14 (feeling irritable or having angry outbursts), (3) CAPS item 14 (irritability or outbursts of anger), and (4) BRIEF-A item 1 (I have angry outbursts). The results indicated a significant decrease in anger from pre to post-treatment ($t = 9.733$, $df = 92$, $p < 0.001$).

3.3.3. Guilt

The CFA resulted in a three-item construct consisting of (1) TRGI Global Guilt score, (2) CAPS item 26 (guilt over acts of commission or omission), and (3) CAPS item 27 (survivor guilt). Because the TRGI was added to the assessment battery in year 3 of the study, there were only 25 participants included in this analysis. Nevertheless, there was still a statistically significant decrease in guilt because of the treatment ($t = 6.115$, $df = 24$, $p < 0.001$).

3.3.4. Depression

The CFA resulted in a six item construct consisting of (1) a reconstructed Hamilton depression scale score (collapsed according to published guidelines as follows: 0–7 no depression, 8–13 mild depression, 14–18 moderate depression, 19–22 severe depression, ≥23 very severe depression), (2) Clinician Checklist item 5 (presence of suicidal ideation), (3) SF-36 item 9c (have you felt so down in the dumps that nothing could cheer you up), (4) SF-36 item 9f (have you felt downhearted and depressed), (5) SF-36 item 9g (did you feel worn out), and (6) SF-36 item 9h (have you been happy). Due to some missing data, there were 76 participants who had pre and post data on this measure. The results indicated that there was a significant decrease in depression from pre to post-treatment ($t = 10.96$, $df = 75$, p-value: < 0.001).

3.3.5. Social interaction

The CFA resulted in a four item construct consisting of (1) QoLI item 22 (satisfaction with friends), (2) CARFFI item 23 (number of identified social affiliations; this item was capped at 3 – a spiritual group, a hobby group, and a work group) so the range was from 0 to 3; 92% of our participants reported 3 or fewer group affiliations), (3) SF-36 item 6 (the extent to which your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups), and (4) SF-36 item 10 (how much of the time has your physical health or emotional problems interfered with your social activities). The results indicated a statistically significant increase in social interaction from pre to posttreatment ($t = 4.365$, $df = 76$, p-value: < 0.001).

Table 5
Reliable and Clinically Significant Change.

CAPS	CAPS n = 93	
	N	%
Deteriorated	0	0%
No reliable change	2	2%
Reliable change, but not clinically significant	24	26%
Reliable and clinically significant change	67	72%

Clinical significant threshold for CAPS = 65.80.

3.3.5.1. Responder criteria. A priori, we defined responder criteria as individuals who showed improvement at the end of the active intervention phase (immediate post-treatment) of at least 1 rating category on both the CGI improvement and severity ratings. Based on these criteria, 90.3% of the participants responded to the IOP.

Another method of determining treatment response is by examining the reliable and clinically significant change on primary outcome measures. The percentage of the group that deteriorated, did not deteriorate but did not show reliable change, achieved reliable but not clinically significant change, and achieved reliable and clinically significant change on the CAPS is depicted in Table 5. To do so, we used the methods described by Hageman and Arrindell (1999). The reliability of time-specific scores is calculate as: (st2 − SE2)/st2, in which st is the time-specific standard deviation, and SE is the standard error of measurement (SEM) derived from the standard deviation and the internal consistency of the baseline population. The threshold for clinically significant change is defined as the baseline mean minus twice the reliable standard deviation of the baseline score.

3.3.5.2. Diagnosis at post-treatment. Another way to assess treatment response is to determine the number of participants who no longer meet diagnostic criteria for PTSD. At post-treatment, 65.9% of the participants no longer met DSM-IV-TR criteria for PTSD.

3.4. Three and six month follow-up

Analyses were conducted for both the sample for whom we had complete follow-up data and intent to treat analyses using multiple imputation for individuals lost to follow-up. Both approaches yielded identical results. As depicted below in Table 6, all treatment gains were maintained at three and six-month follow-up.

3.5. Relapse rate

A priori, relapse was defined as among those who responded during active treatment phase, at follow-up, the participant had (1) exacerbation or return of symptoms such that all CGI and CAPS ratings return to or are above (worse than) baseline levels; or (2) the functioning deteriorates to the point where acute psychiatric hospitalization is necessary to ensure patient safety. Only one participant met criteria, for a relapse rate of 1%.

4. Discussion

We conducted a large controlled pilot investigation trial of TMT for

Table 6
Post-treatment and follow-up data for TMT IOP program.

Measure	Pretreatment (M and sd)	Posttreatment (M and sd)	3 Month Follow-up (M and sd)	6 Month Follow-up (M and sd)	*F*	*p*[a]
CAPS	95.2 (15.6)	42.6 (25.7)	47.2 (25.0)	44.7 (26.6)	102.8	0.001
PCL-M	63.9 (10.4)	44.1 (15.8)	47.0 (13.8)	44.7 (16.5)	39.3	0.001
% without PTSD dx.	0%	66.3%	61.4%	60%		
CGI Severity	5.47 (0.7)	3.2 (1.2)	3.1 (1.3)	3.0 (1.2)	89.6	0.001
CGI Improvement		1.8 (0.9)	1.9 (1.1)	1.6 (0.7)	0.6	
Sleep Disturbance	7.6 (1.4)	6.2 (2.3)	6.3 (2.0)	5.6 (2.4)	7.9	0.001
Anger	6.3 (1.9)	3.9 (2.5)	3.9 (2.4)	3.5 (2.6)	21.4	0.001
Guilt	5.6 (3.2)	2.2 (2.1)	1.4 (1.8)	1.2 (1.8)	12.6	0.082
Depression	7.0 (1.7)	4.8 (1.9)	4.0 (2.0)	4.1 (1.9)	19.98	0.001
Social Interaction	3.3 (1.8)	4.0 (2.1)	4.2 (2.0)	4.4 (1.9)	3.7	0.016

[a] For all significant differences, pretreatment variables were all significantly different from posttreatment, three month and six-month follow-up, with no significant differences among the latter three time points.

combat-related PTSD, implementing it in an intensive outpatient (IOP) setting and delivering it in a three-week time frame. Patients were military veterans and active duty military personnel who served in OIF/OEF/OND with combat-related PTSD who attended two therapy sessions a day (morning, afternoon) five days per week for a three-week period, and then were evaluated at post-treatment, 3- and 6-months follow-up. Outcome variables included the acceptability and feasibility of an IOP model for treatment of combat-related PTSD as well as standard assessment of efficacy.

This study is the first attempt that we know of to evaluate the efficacy, safety, and feasibility of using an IOP approach to deliver a manualized evidence-based psychotherapy for combat-related PTSD. It provides early evidence to support the safety and efficacy of condensing a treatment that typically takes three months to deliver via traditional outpatient services into a three-week program. Process outcomes also confirm the acceptability and safety of this IOP. Patients reported high levels of treatment credibility and satisfaction with care. Importantly, the dropout rate during treatment was 2%, which is lower than rates reported when treatment is provided by standard outpatient programs (Imel et al., 2013; Reger et al., 2016; Resick et al., 2017). Finally, there were no instances of suicide attempts or adverse events during the active treatment or 6-month follow-up phase.

Providing treatment in this rapid and intense format offers several potential benefits. One, it brings quicker symptom relief – and thereby reduces a window of time during which a wide range of negative outcomes might occur (e.g., suicide, substance abuse, interpersonal violence, relationship disruption). Two, it allows active duty personnel or employed veterans to feasibly take a medical leave of absence from their work duties to receive treatment and may address stigma concerns, in that IOPs replicate a physical rehabilitation model. Moreover, while speculative, it is possible that a 3-week program may be superior to a 3-month program by massing sessions of exposure therapy close together and by inducing an intensive focus and shorter time frame that together reduce treatment dropout. Of course, there are limitations as well. Some individuals may not need this level of intensive treatment, some may not be able to arrange for 3 weeks off from work, single-parents may not be able to arrange alternative child care and travel costs may prevent some veterans from seeking a site where such services are available. This last concern would be less of an issue for active duty personnel, who in many cases were sent to the program on temporary duty (TDY) status. It is important to note that although these limitations are possible, they were rarely mentioned in our recruitment for this investigation. It is important however, that future investigations examine whether IOPs offered in one's own town result in similar outcomes.

IOPs have a history of use for treatment of substance abuse or dually diagnosed (substance abuse and mental health) populations but more recently there has been adaptation of this model for patients with solely psychiatric disorders. Typically, individuals treated in an IOP setting have symptom scores that are higher than scores for individuals treated in traditional outpatient settings (Wise, 2005) and that was true for this investigation as well. The average CAPS pretreatment score in this sample was higher than for other recently reported outpatient trials (Reger et al., 2016; Rothbaum et al., 2014). Although approximately half of our veteran participants came from therapists/programs where traditional outpatient treatment had not been successful, an equivalent number came from therapists or individuals themselves who did not have access to evidence-based treatments in their community. In the case of active duty personnel, the 3 week IOP was an important factor in their decision to refer individuals. Thus, whereas IOPs may be better equipped to serve individuals with severe psychopathology, that is not the only reason that some individuals choose this intervention.

In contrast to traditional outpatient treatment for PTSD, the treatment dropout rate for this study was 2%. Many factors may have contributed to this reduced dropout rate. For example, the closed cohort nature of this IOP format appeared (based on our clinical observation) to foster a group cohesiveness and functioned to provide informal peer support for the participants. Additionally, TMT includes interventions specifically addressing anger and stress, services that veterans desired (Crawford et al., 2015). The better match between services desired and provided may have been a contributing factor to treatment retention. At this time, it is difficult to disentangle the treatment delivery format from the inclusion of these desired treatment components. However, the low drop-out rate, lack of iatrogenic effects and the potential to re-conceptualize PTSD treatment in the same manner as treatment of physical injuries suggests that further examination of IOP formats is necessary.

The second specific aim was to determine the efficacy of TMT when delivered in this intensive fashion. Results indicated that the delivery format did not affect treatment outcome. TMT was efficacious, with 65.9% of the sample no longer meeting diagnostic criteria for PTSD at post-treatment. There were similar decreases across other domains (e.g., anger, guilt, depression, sleep, social interactions) and improvements were maintained at follow-up. In addition to statistical significance, the CAPS post-treatment score was also clinically significant, suggesting that this intervention resulted in impactful changes in functioning. The average decrease for CAPS scores was 52.4 points, resulting in a 54% decrease in scores from pre- to post-treatment. Using the VA's designation of a 10-point decrease on the CAPS as indicative of clinically significant improvement, 94.6% of this sample decreased by at least that amount. Moreover, using the VA's definition of clinically significant change, the average decrease on the PCL-M was 20.1 points, and 70.3% of patients had a decrease greater than 10 points.

These results stand in contrast to the conclusions of one recent meta-analysis that has called into question the efficacy of exposure based interventions (Steenkamp et al., 2015). Where similar outcome variables (CAPS or PCL-M decrease, percent no longer meeting diagnostic criteria) were presented in that analysis, the outcome presented here exceeded published rates for those interventions. Potential reasons for these differences may be the more intensive nature of the exposure

therapy used in this investigation, including the use of virtual reality to enhance the immersive experience of the imaginal exposure sessions, the use of massed (daily) exposure, and the inclusion of a group component. The decrease in PTSD symptoms was larger than, but consistent with other studies of virtual reality assisted prolonged exposure therapy (Reger et al., 2016; Rothbaum et al., 2014). The same virtual reality program was used in all these investigations. Thus, differences may be due to the manner in which exposure therapy was implemented. Whereas in some exposure-based interventions, session length is dictated by time (30–45 min), in this study, exposure therapy continued until measures of distress indicated that within-session habituation had occurred. Although the need for within-session habituation has been questioned (e.g., Craske et al., 2008), much of the data discounting its need is based on studies with specific phobias, panic disorder with agoraphobia, or obsessive-compulsive disorder and relevance to combat-related PTSD, a distinctly different disorder, is not clear. Future investigations testing the importance of within-session habituation for exposure therapy with PTSD are necessary.

Another difference that may have contributed to the different outcome was the intensity of IOP treatment sessions. Delivering exposure therapy in a massed fashion (massed defined as exposure sessions conducted in a daily or almost daily fashion, not one single "massed" session) may be more efficacious for PTSD (Gutner et al., 2016). The possibility of iatrogenic effects, such as increased suicidal ideation or substance abuse, were assessed daily but did not occur, despite the intensity of the treatment program. Thus, minimizing time between treatment sessions may maximize therapeutic outcome.

Although other interventions may indirectly impact symptoms such as anger or depression, the inclusion of a group component to directly address these additional dimensions might also contribute to its efficacy. Given the design of this IOP, it is not possible to determine if the group treatment enhanced treatment outcome over and above exposure therapy. However, an RCT specifically addressing this component has just been completed (Beidel et al., under review).

Because individuals left their home environment to attend the IOP, it is valid to ask if the efficacy of the intervention was simply the result of a change in environment. Although this is a reasonable concern, the post-treatment assessment was not conducted until participants were home for one week. Thus, the post-treatment data were reflective of any stressors existing in their home environment. A follow-up relapse rate of 1% further supports the idea that the outcome was not the result of simple removal from their home environment.

As a pilot investigation, this study has several limitations. It was not a randomized controlled trial and masking of independent evaluators was not possible. Although our assessment of primary PTSD symptoms used standard outcome measures, the lack of standard, validated measures of other behaviors/emotions for combat PTSD resulted in our need to construct some latent construct variables. Finally, the clear majority of participants were male and served in the Army. Despite these limitations, study implementation was rigorous, including use of a manualized evidenced-based intervention, use of structured diagnostic interviews, careful monitoring of therapist fidelity, follow-up assessments of 6-months, and high participant adherence and retention rates in a difficult-to-treat clinical sample. Broad study inclusion criteria allowed for high rates of psychiatric comorbidity, and therefore participants were representative of the diverse patient population with combat-related PTSD. This study also provided further evidence for the effectiveness of Trauma Management Therapy, a multicomponent cognitive-behavioral intervention that includes exposure therapy as well as other treatment elements to address the full range of symptoms and functional impairment seen in those with combat-related PTSD. In fact, this study becomes one of the few effectiveness studies where 50–100% of the sample (in this sample, 100%) consists of OIF/OEF/OND veterans with combat-related PTSD, thus adding to the literature for this younger generation of veterans and military personnel.

This study suggests that providing TMT using an IOP format is a feasible and efficacious means of delivering evidence-based psychotherapy for combat-related PTSD. Future research should assess the efficacy of this treatment delivery strategy in a randomized clinical trial, including comparison to the same treatment delivered over a longer period of outpatient care, as well as to other interventions (e.g., exposure therapy alone) delivered in an intensive fashion. These studies should include longer periods of post-treatment outcome follow-up and measurement of outcome domains directly related to employment functioning and cost-benefit analyses.

Acknowledgements

We wish to thank Rachel Ruffin, Ph.D., Ashley Arens, Ph.D., Shawn Carter, Ph.D., Franklin Mesa, Ph.D., Maryann Owens, Ph.D., Jeremy Stout, Benson Munyan, An Le, Michael Gramlich, Emily Kitsmiller, Krystal Morrison, and Jenny Scheurich for serving as individual or group therapists. We also wish to thank Rebecca Knapp, Ph.D. and Vu Nguyen, M.S. for their assistance with the statistical analysis.

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