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14. ABSTRACT Symptoms of PTSD appear to affect 15 - 30% of OIF / OEF servicemen and women (Hoge et al, 2004; Hoge et al., 2006; Seal et al., 2007; Kang et al., 2003; Iversen et al., 2005), and often effectively end their military careers at great cost to (1) the servicemen and women themselves, in terms of psychological suffering, (2) the DoD in terms of the loss of trained, skilled personnel who must be replaced by individuals who will require new investment in the training, and (3) the VAMCs in terms of providing many years of treatment for an often intractable condition. The present project used a randomized controlled design to compare in-person VS. <i>home</i> -telehealth delivery of evidence based treatments for depression and PTSD (behavioral activation and therapeutic exposure) in terms of each modality's ability to reduce symptoms in post-deployed OIF / OEF personnel and Veterans of Vietnam and Persian Gulf conflicts. Post-treatment, 3 month and 12 month data were available from 196 participants. Results revealed non-inferiority of either modality in terms of reducing symptoms of PTSD, depression, anxiety, substance abuse, and attrition. However, preliminary cost analyses revealed savings were realized for the telemedicine group, when considering VA sponsored beneficiary travel costs, and among those not completing treatment, higher numbers of sessions were received in the telemedicine group than the in person group prior to dropout.					
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1. INTRODUCTION:

Overview: Post-Traumatic Stress Disorder (PTSD) and its Treatment: Symptoms of PTSD appear to affect 15 - 30% of OIF / OEF servicemen and women (Hoge et al, 2004; Hoge et al., 2006; Seal et al., 2007; Kang et al., 2003; Iversen et al., 2005), and often effectively end their military careers at great cost to (1) the servicemen and women themselves, in terms of psychological suffering, (2) the DoD in terms of the loss of trained, skilled personnel who must be replaced by individuals who will require new investment in the training, and (3) the VAMCs in terms of providing many years of treatment for an often intractable condition.

The most effective treatments for post-traumatic stress disorder (PTSD) were developed in the last twenty-five years (Powers et al., 2010; Watts et al., 2013), and routinely feature exposure to discriminative conditioned fear stimuli as central components (see Prolonged Exposure (PE) (Foa et al., 1991). Although initially designed to treat PTSD related to sexual violence, exposure based treatments have also been tested with combat Veterans following widespread awareness of psychological suffering of Vietnam, Persian Gulf, Afghanistan, and Iraq war service men and women (Eftekhari et al, 2013; Goodson et al., 2013; Rauch et al., 2012). Exposure based treatments such as PE have the most consistent support for their efficacy (Foa et al., 1999; 2005; 2013; Institute of Medicine, 2007; Powers et al., 2010), and also appear to decrease other traumatic stress-related problems such as depression, anger, and guilt (Cahill et al., 2003; Foa et al., 1991; 1999; 2004, 2005; Stapelton et al., 2006)

A particularly common comorbid mental health diagnosis often presenting with PTSD is depression (Kessler et al., 2005). As such, many clinicians treating PTSD also include strategies that target depression. One such strategy that is very complementary to exposure based treatments is Behavioral Activation (BA). BA is a relatively straightforward, action oriented treatment with good support for its efficacy, and its 'action oriented' emphasis on behavioral change often resonates with military and Veteran populations. Learning theory (Lewinson, 1973) forms the basis upon which BA is conceptualized. Specifically, BA is hypothesized to induce states incompatible with depression by increasing the frequency of positively reinforcing and/or less enjoyable, albeit functional (negatively reinforcing) activities (e.g., chores). Where possible, activities are given a social aspect (e.g., reading at a bookstore, rather than reading alone at home). This shift in balance of activities (and subsequent reinforcement density) has long been posited to facilitate increased positive mood and cognitions (see Lewinson, 1973, Lejuez, Hopko, Acierno, Daughters, & Pagoto (2011)). The present research project used a combination of exposure and behavioral activation to treat PTSD and related depression symptoms in Veterans.

Telemedicine: A Potential Means to Overcome Barriers to Delivering Evidence Based Care Such As Stigma or Geographic Distance?

As defined by the American Telemedicine Association, telemedicine refers to medical information exchanged from one site to another via electronic mediums to improve a patient's health status (Van den Berg et al., 2012). Other popular terms include telehealth, telepsychology, telepsychiatry, and telemental health, and common features include remote audio-video conferencing between provider and patient, either to remote clinics, or even directly into patients' homes. Although telemental health services are still growing in terms of their application nationwide relative to traditional treatment delivery modalities (Spinsante et al., 2012), and intra and inter-state licensing issues have not been fully resolved (Fleisher & Dechene, 2006), the

potential of these methods to export treatments to patients who otherwise would not receive them is great. In addition, telemedicine, particularly when delivered directly into the home, may also help to address treatment dropout due to logistical factors such as travel time or cost (Frueh et al., 2000; Sha et al, 2013).

As such, telemedicine may both enhance VA goals (VHA, 2012) of disseminating evidence based mental health treatment for PTSD to all Veterans who need these services, as well as enhance treatment retention by overcoming logistical barriers such as travel time and cost (Morland et al., 2008, 2013; Strachan et al., 2012). However, as McLean and Foa (2013) noted, it is essential that fidelity to evidence based PTSD treatment protocols be maintained when using telemedicine services, and the relative non-inferiority of delivering exposure-based treatments for PTSD in person vs. Telemedicine is not yet established. The present study was conducted to establish such non-inferiority.

The Present Study:

The present project used a randomized controlled non-inferiority design to determine whether an intervention to address the functional impairment associated with PTSD symptoms in post-deployed OIF/OEF service men and women (Behavioral Activation and Therapeutic Exposure (BA-TE) could be delivered with comparable effectiveness via either in person or home based telemedicine mediums. BA-TE is an 8-session, manualized treatment program. Using a between-groups, repeated measures design, study participants were randomized to BA-TE delivered via telepsychology, or BA-TE delivered in-person. Participants were assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

2. KEYWORDS:

Veteran, OIF, OEF, Persian Gulf, Vietnam, Telemedicine, telepsychiatry, telepsychology, telemental health, televideo, PTSD, post-traumatic stress disorder, prolonged exposure, behavioral activation, cognitive behavior therapy, psychotherapy, learning theory, extinction, conditioning, PCL, depression, randomized controlled trial, non-inferiority design.

3. OVERALL PROJECT SUMMARY:

Major tasks of the SOW. included (1) **recruit** 250 active duty or Veteran participants with PTSD or Sub-Threshold PTSD and randomly **assign** to either in person or televideo based treatment for PTSD; (2) collect measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and follow-up. (3) report analyses to demonstrate or fail to demonstrate non-inferiority of home based televideo delivery of evidence based treatment. Note that our S.O.W. has been amended and approved to address the more prevalent problem of chronic PTSD by including Vietnam Veterans, in addition to OIF/OEF and Persian Gulf Veterans.

Primary Dependent Measures:

PTSD Checklist-Military (PCL): The PCL is a 17-item self-report measure of PTSD symptoms based on DSM-IV criteria. The instrument is highly correlated with the Clinician Administered PTSD Scale ($r = .93$), has good diagnostic efficiency ($> .70$), and robust psychometrics with a variety of trauma populations.

Beck Depression Inventory-II (BDI): The BDI-II is a 21-item, 4-point Likert self-report scale, and is among the most widely used instruments to measure depression. Beck, Steer, Ball, and Ranieri [47] demonstrated that the BDI-II has high internal consistency ($\alpha = .91$).

Beck Anxiety Inventory (BAI): The BAI (Beck & Steer, 1990) is a 21-item self rating scale of anxiety symptomatology. Specific symptom clusters have been identified by Beck and Steer (1991; 1993) reflecting neurophysiological, subjective, panic, and autonomic dimensions

Medical Outcome Study Social Support Module (WHO, 2008) is a 19 item scale assessing three domains of social support: emotional, instrumental, and appraisal.

Drug Abuse Screen Test – 10 item (DAST-10) (derived from Skinner, 1982) is a 10-item, yes/no self-report instrument that has been condensed from the 28-item DAST and is one of the selected Common Data Elements. The DAST-10 was designed to provide a brief instrument for clinical screening and treatment evaluation.

Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993) was developed from a six-country WHO collaborative project as a screening instrument for hazardous and harmful alcohol consumption. It is a 10-item questionnaire which covers the domains of alcohol consumption, drinking behavior, and alcohol-related problems.. Responses to each question are scored from 0 to 4, giving a maximum possible score of 40. Among those diagnosed as having hazardous or harmful alcohol use, 92% had an AUDIT score of 8 or more, and 94% of those with non-hazardous consumption had a score of less than 8.

Sample Description:

Over 1,000 potential participants were screened and 280 were enrolled for this project. 265 were recruited, consented and randomized, and 234 completed at least 1 treatment session. 171 appeared for post treatment assessment, 166 for 3 month followup, and 164 for 12 month followup. Many participants who missed 3 month followup were available for 12 month followup and vice versa, allowing us to use interpolation methods to address missing data and yielding a sample for which over 215 participants provided data or interpolated data for all 4 time periods, and 196 participants completed 4 or more sessions (defined as the per protocol sub sample).

Considering the total sample of recruited participants, 51.3% were OIF/OEF Veterans; 23.3% were Persian Gulf War Veterans and 25.5% were Vietnam War Veterans. Over 92% were male, and 7% female. Most were married (65%), with 15% never married, 18% separated or divorced, and 1.5% widowed. The average age of participants was 46 years. Service Branches were proportionally represented, with 14% Air Force, 54% Army, 9% Navy, 12% Marine Corp, and the remainder primarily Coast Guard. Immediately prior to deployment, 63% were active duty, with the remainder being largely Guard and Reserves. Race was primarily Black (48%) or White (50%), with the remainder self-reporting as Hispanic. Fully 43% were service connected at the 50% level or greater, with 18.8% reporting being 100% service connected and 45% being classified as disabled. Clearly, this was a sample evincing significant functional impairment.

Rationale for “Per Protocol” over “Intent to Treat” Definitions for Primary Analyses and Handling of Missing Data:

In standard ‘head to head’ trials where the objective is to determine which treatment is better than the other, conservative approaches to data analysis include (a) use of ‘intent to treat’ rather than per protocol treatment samples, (b) imputed data (c) across the sample conditions (sharing the variance) as opposed to mean substitution within conditions (which amplifies between group differences while at the same time reducing within group variance). These techniques minimize the likelihood of Type I error: finding a difference between conditions when in reality, there is none. *The case is precisely reversed in non-inferiority studies like the present experiment.* That is, we designed and powered this study to be able to answer the question: “are results of evidence based treatment for PTSD and Depression delivered by home-based telemedicine no worse than when delivered via the traditional, in person, office based medium.” As such, that which is typically

conservative becomes liberal, and vice versa; and so a conservative approach is one that maximizes the likelihood that between group differences would be found. If they are not, despite these decisions, then one can reasonably state that “treatment A is non-inferior to treatment B.”

Therefore, in order to adopt a *maximally conservative* approach for primary outcome analyses, we used the sample of per protocol completers (completed at least 4 sessions of the protocol 8) rather than intent to treat; mean substitution (which reduces variance, making it ‘easier’ to reach statistically significant differences...exactly what we do not ‘want’ in non-inferiority studies), and substitution within experimental conditions (to maximize between group differences, again, exactly what we do not ‘want’ to see). Thus we have set the stage against our hypothesis of non-inferiority for the telemedicine condition so that our confidence in statements of equivalence, if demonstrated, is very high.

Per Protocol Sample:

The per protocol sample very closely matched the afore-described total recruited and consented intent to treat sample: 49.5% (were OIF/OEF Veterans; 24.5% were Persian Gulf War Veterans and 26.0% were Vietnam War Veterans. 94% were male. Most were married (63%), with 14% never married, 18% separated or divorced, and 2% widowed. The average age was 45.9 years, and Race was primarily Black (46%), White (51%), with the remainder self-reporting as Hispanic. Service Branches were again proportionally represented in this subsample, with 16% Air Force, 60% Army, 10% Navy, 14% Marine Corp, and the remainder primarily Coast Guard. Fully 40% were service connected at the 50% level or greater, with 17% reporting being 100% service connected and 42% being classified as disabled. As with the total sample, the per protocol sample experienced significant functional impairment.

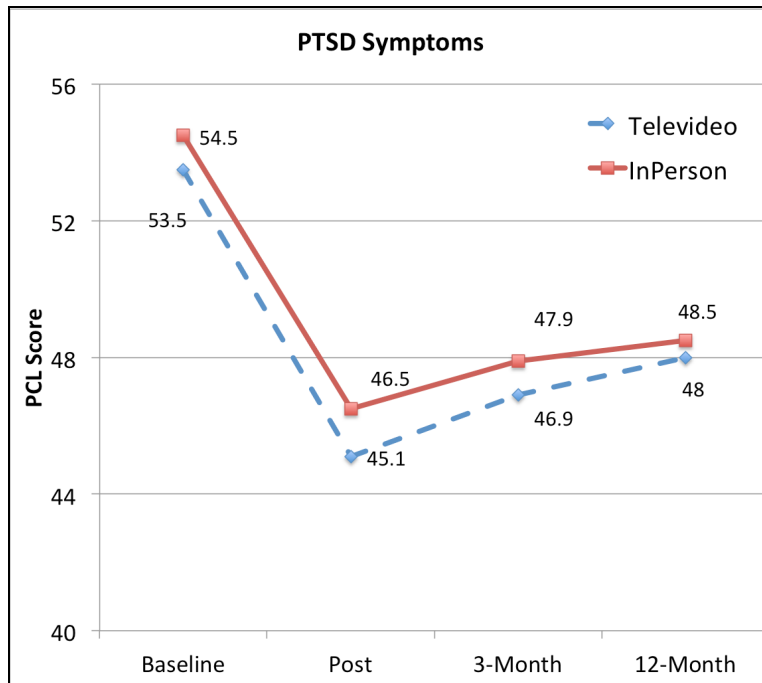
Table 1 gives means and confidence interval information with respect to key demographics and study measures in terms of Treatment Condition, age, service connection, disability status, baseline measures of PTSD (PCL), depression (BDI), alcohol problem use (AUDIT), drug problem use (DAST), social support (MOS).

Results:

Baseline analyses indicated no differences with respect to aforementioned key study variables; nor were there group differences in terms of number of sessions completed (7.5 for both groups) (see Table 2). For psychological outcome variables related to PTSD (PCL), depression (BDI), anxiety (BAI), within group improvement was noted for both conditions between baseline and posttreatment, with gains largely maintained (e.g., treatment worked in both delivery modalities). *With respect to the primary study analysis of non-inferiority of home televideo delivered behavioral activation and therapeutic exposure for PTSD and depression: we did not detect any difference between groups at any time points for any dependent variable.*

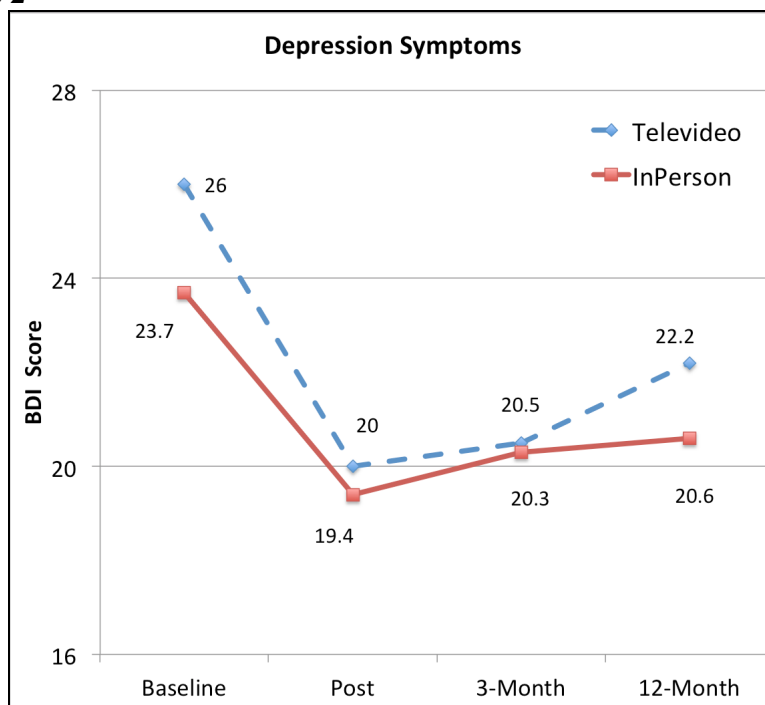
Specifically, considering PTSD (PCL), baseline, post-test, 3 month followup, and 12 month followup mean scores for the in person condition (54.5, 46.5, 47.9, and 48.0 respectively) were not statistically significantly different than mean scores in the televideo condition at any time point (53.5, 45.1, 46.9, and 48.5 respectively) ($F_{1,194} = 0.10$ $p = .754$); however improvement over time was evident for both conditions ($F_{3,194} = 26.7$ $p < .001$), with no significant interaction effect (see Figure 1).

Figure 1



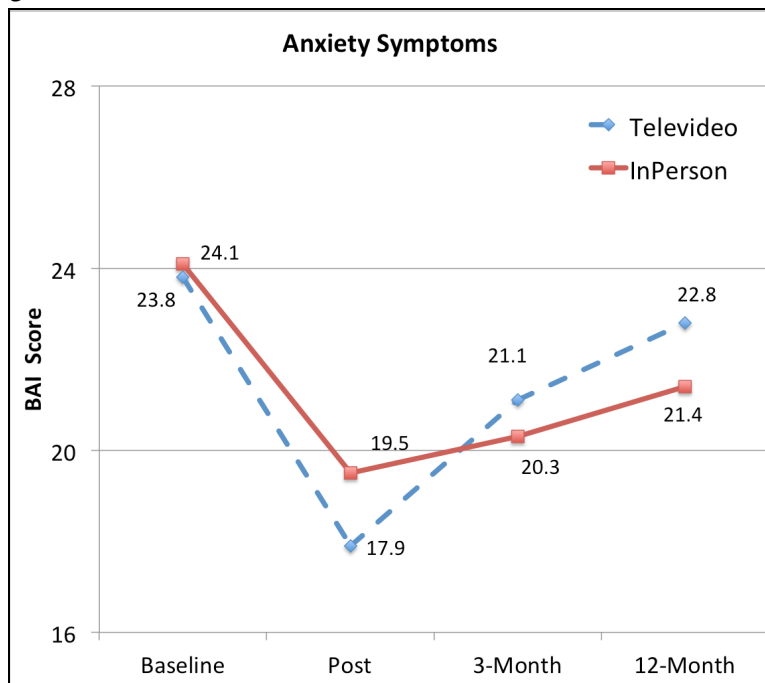
Considering depression (BDI), mean scores for in person participants at each time point (23.7, 19.4, 20.3, and 20.6) were not significantly different from televideo participants at any time point (26.0, 20.0, 20.5, 22.2) ($F_{1,194} = 0.84$ $p = .361$), and there was no significant interaction effect, but both groups improved from baseline to post-treatment ($F_{3,194} = 18.13$ $p < .001$) (see Figure 2).

Figure 2



Considering anxiety and panic like symptoms (BAI), in person mean scores at baseline, post-treatment, 3 and 12 month followup were (24.1, 19.5, 20.3, 21.4, respectively), which were not statistically different than those of televideo participants (23.8, 17.9, 21.1, 22.8, respectively) ($F_{1,194} = 0.00$ $p = .967$). However, pre-posttreatment improvement was evident for both groups with no significant interaction effect ($F_{3,194} = 12.88$ $p < .001$) (see Figure 3).

Figure 3



Very slight improvement over time was noted for alcohol (AUDIT) (mean of 6.4 at baseline compared to 5.1 at 12 month followup across groups) ($F_{3,194} = 3.43$ $p < .05$) but not drug use (DAST) ($F_{3,194} = 2.01$ $p < .117$), which is not surprising as use of both of these types of substances was at low levels, and the interventions did not specifically target use. There were also no between group differences for either the alcohol ($F_{3,194} = 0.80$ $p = .373$) or drug ($F_{3,194} = 0.06$ $p = .814$) measures.

One aspect of treatment we were interested to explore was social support, as there was some initial trepidation that the televideo condition, by its very nature, would reduce access to social support naturally found in treatment centers. However, this was not the case. Average social support scores for the in person group at baseline, post treatment and 3 month followup (79.7, 79.4, 79.2) were not different than the televideo group (79.1, 79.6, 83.1) ($F_{1,194} = 0.09$ $p = .768$) which actually had an increase over time, albeit this did not reach statistical significance in that there was no effect for time, nor was there an interaction effect (interaction $F_{2,194} = 1.04$ $p = .356$).

Interesting Process Findings within the Subsample of Participants who Dropped Out from this Department of Defense Study and an Ongoing Prolonged Exposure for PTSD Sister Study, also under PI Acierno:

Drop out analyses are rarely conducted beyond the descriptive level, because overall numbers are typically prohibitively small for any one study. However, we were fortunate to conduct two concurrent telemedicine studies with two variations of exposure therapy for PTSD (BA-TE and PE). As such, we had a large sample of treatment dropouts available. We recontacted participants

who dropped out from either of two concurrent telemedicine studies prior to completing 8 sessions (the minimum generally accepted ‘dose’ of exposure treatment) by telephone and inquired about subjective reasons for treatment withdrawal in order to identify differences between in-person and telemedicine formats using the following scales:

Barriers to Exposure Therapy Participation Scale: The BTPS (Kazdin et al., 1997) consists of 68 items (45 items rated on a 5-point-likert scale, and 23 items in a yes/no format; higher scores correspond to greater perceived barriers to treatment), asking participants to rate how often they experienced a variety of barriers that may have interfered with treatment. Items are divided into four general categories, with sum scores derived for each category: Stressors and Obstacles to Obtaining Treatment, Treatment Demands, Perceived Relevance of Treatment, and Problems in Relationship with Therapist. With the present sample of veterans, reliability was comparable to that of Kazdin et al., with Cronbach $\alpha = 0.84$.

Telehealth Attitudes Questionnaire (TAQ): The TAQ (Grubaugh et al., 2008) is a 23-item self-report measure that asks participants to rate opinions toward telemedicine-delivered mental health care on a 5-point Likert scale (e.g. 1 “Not at all” to 5 “Extremely”). Areas of assessment include comfort with the medium of care, concerns, and general perceptions. Preference for using face-to-face services also was assessed. The authors report that TAQ has a good internal consistency ($\alpha = 0.88$) and was validated with a sample of rural and urban patients with or without PTSD ($N=194$).

Procedure:

All participants who completed fewer than 8 sessions of treatment from both the DoD CDMRP study for which this Final Report is produced, and the sister VA study were asked to continue to allow contact for study assessments.

Combined Study Dropout Participants: Demographic and Baseline Psychopathology Across Conditions

All participants met DSM-IV criteria for PTSD. At the time of dropout analyses, 258 participants had been randomized to either telemedicine or in person conditions and received at least one exposure treatment session, 69 (26.7%) withdrew from treatment. All were male, 13 (27.7%) were Vietnam Veterans, 13 (27.7%) were Persian Gulf Veterans, and 21 (44.7%) were OIF/OEF Veterans, with no significant differences in theatre in terms of treatment condition. Rate of dropout from telemedicine (28.7%, $n = 35$) was not significantly different from that of in person treatment (25.0%, $n = 34$) ($\chi^2=0.45$, $p = 0.30$). Forty-seven of the 69 (68.1%) treatment dropouts (27 telemedicine; 20 in person) agreed to provide data for either or both the TAQ and the BTPS. Age ranged from 21-70 years ($\bar{x} = 46.5$, $SD = 14.5$), and was not significantly different between conditions (in person $\bar{x} = 41.8$, $SD = 14.1$ vs. telemedicine $\bar{x} = 49.9$, $SD = 14.1$, $F_{(1, 43)} = 3.66$, $p = .06$). A significantly greater proportion of participants in the telemedicine condition were: white; earned less than \$20,000 annually. There were no significant differences in terms of education, employment, or marital status between conditions, nor were there differences in terms of baseline psychopathology (PTSD: PCL in person $\bar{x} = 55.3$, vs. telemedicine $\bar{x} = 58.5$, $F_{(1, 45)} = 0.96$, $p = 0.41$; Depression: BDI in person $\bar{x} = 27.0$, vs. telemedicine $\bar{x} = 28.6$, $F_{(1, 45)} = 1.15$, $p = 0.33$).

Dropout Characteristics Between Conditions

As mentioned, rate of dropout from telemedicine (28.7%, $n = 35$) was not significantly different from that of in person treatment (25.0%, $n = 34$) ($\chi^2=0.45$, $p = 0.30$). Dropout occurred relatively later in the telemedicine condition as compared to in person treatment (see Figure 7), with the majority of in person dropouts occurring by session 3 (63%), compared to telemedicine

dropouts (only 50% had dropped out by session 4). Telemedicine participants were relatively evenly distributed in terms of how many sessions were completed prior to dropping out. Forty-seven of the 69 (68.1%) treatment dropouts (27 telemedicine; 20 in person) agreed to provide data for either or both the TAQ and the BTPS (Below).

Overall BTPS Comparisons of Reasons For Dropout: ANOVAs:

Considering the Stressors and Obstacles factor, one-way ANOVA indicated a significant difference between in person and telemedicine participants, with in person participants reporting more problems with bad weather, parking, transportation, and work/family obligations ($\bar{x} = 22.5$) compared to telemedicine participants ($\bar{x} = 19.6$) ($F_{(1,45)} = 5.20, p = 0.027$). No other significant differences were noted for any other factor, including Treatment Demands (in person $\bar{x} = 16.2$, vs. telemedicine $\bar{x} = 15.6$; $F_{(1,45)} = 0.34, p = .560$); Perceived Relevance of Treatment (in person $\bar{x} = 20.9$, vs. telemedicine $\bar{x} = 20.7$; $F_{(1,45)} = 0.01, p = 0.906$), or Relationship with Therapist (in person $\bar{x} = 9.1$; telemedicine $\bar{x} = 9.0$; $F_{(1,45)} = 0.04, p = 0.847$).

Significant differences were found between groups with respect to reporting that they would feel comfortable using telemedicine at a local church, with a greater proportion of in person (72.2%) vs. telemedicine participants (41.7%) reporting comfort. Similarly, 55.6% of in person participants felt comfortable receiving telemedicine services at a local clinic, compared to only 25% of those who actually were in the telemedicine condition. Interestingly, majorities of both groups indicated that telemedicine would not be as effective as, or preferable to in person treatment.

Notably, our hypothesis that telemedicine delivered exposure therapy would result in fewer dropouts from treatment was not supported, and differential dropout rates from in person vs. telemedicine delivered exposure therapy were not observed. *However, participants receiving exposure therapy via telemedicine tended to complete more sessions prior to dropping out.* While the therapeutic difference of receiving 5 sessions instead of 3 (out of a recommended 8-12, per protocol) may not be significant *statistically*, it does appear that this modality permitted a slight increase in ‘dose received’. Given the tremendous resources the VA and DoD are investing in telemedicine-delivered mental health care (Tuerk et al., 2010) even this small advantage is worth noting.

Though overall rates of dropout were the same across treatment modalities, we found some differences with respect to specific reasons for dropout given in each condition. Not surprisingly, and largely consistent with hypothesis and prior research (Spinsante et al, 2012), participants receiving in person treatment reported relatively greater difficulties with logistical obstacles, such as parking or transportation. Moreover, work related issues that could be considered logistical in nature (e.g., too tired to attend sessions after work, work got in the way of making it in to treatment) affected twice the proportion of in person participants than telemedicine participants. Additionally, differences in reported problems with other logistical factors associated with travel and childcare, which were reported by nearly twice the proportion of participants receiving in person treatment may have been even larger if participants receiving telemedicine therapy were not asked to come in person to the VA research site for all assessments, and if individuals living greater distances from the clinic were included in the randomization to condition (i.e., prior to randomization, all participants had to agree to accept whichever condition assignment they received. As such, individuals who lived far away and faced potential randomization into in person conditions opted out of the study).

Although no statistically significant differences in exposure therapy treatment demands (i.e.,

engaging in intense imaginal exposure and homework assignments to confront avoided situations) were observed across conditions, a clear trend was noted across items and is worthy of mention. Specifically, large proportionate differences on most of the items related to ability to tolerate aspects of exposure therapy were observed, indicative of relatively greater problems in the telemedicine condition. For example, 11.8% of in person vs. 21.1% of telemedicine participants reported imaginal exposures made them feel bad. Similarly, 20.0% of in person vs. 41.2% of telemedicine participants reported that they worried about losing control during exposure trials; and 40.0% of in person vs. 58.3% of telemedicine participants indicated that they could not tolerate assignments to go out in public.

An important study finding is that patient-provider relationship does not seem to be negatively affected by telemedicine. This is consistent with the majority of reports on the matter (Richardson et al., 2009), with the exception of Rees and Stone (2005) In the present study, dropouts from both telemedicine and in person conditions overwhelmingly liked and were confident in their therapists, felt that they could share personal information with them, and felt that their therapists were supportive and understood them. Dropping out of treatment despite a good therapeutic relationship is consistent with literature noting that one's relationship with a therapist seems independent of the decision to dropout from treatment (Munley et al., 1994). This is not to say that the relationship is unimportant. Indeed as Imel, Laska, Jakupcak and Simpson (2013) have stated, poor therapist training and low motivation to use exposure therapy for patients may be related to dropout. Rather, in this case, therapists in both modalities were equally able to convey and sustain positive relationships, and patients in both conditions understood the importance of treatment.

Figure 4

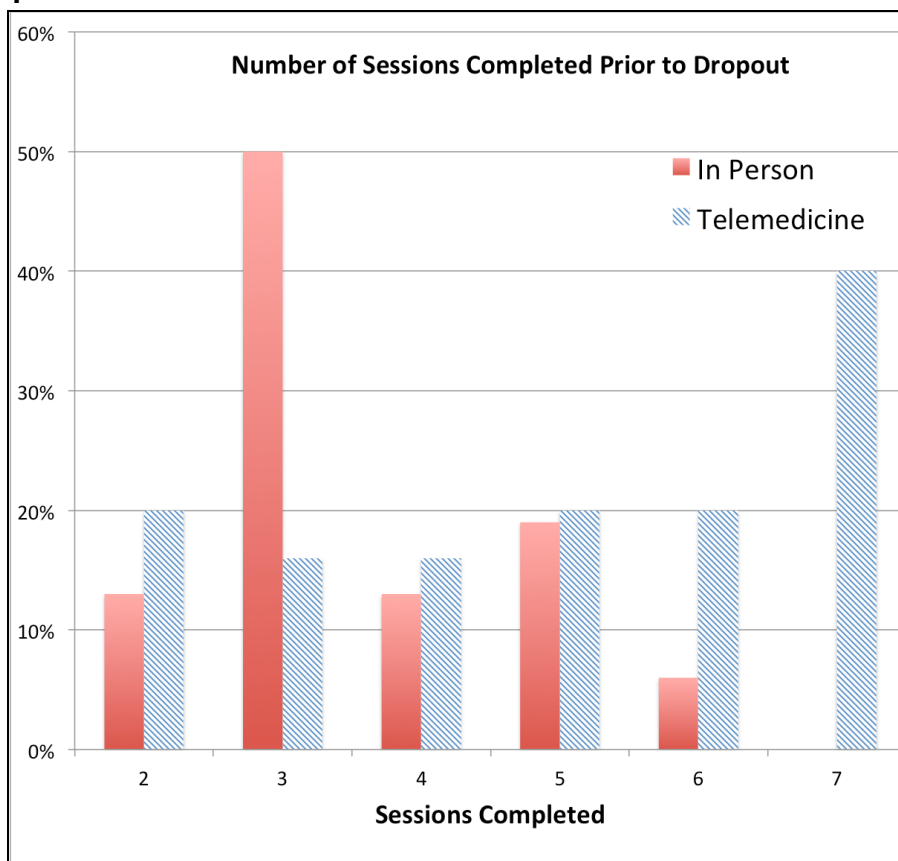


Table 1: Descriptive Baseline Data for Per Protocol Sample

		95% Confidence Interval for Mean							
		N	Mean	Std. Deviation	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum
Age	In Person	101	45.0	15.0	1.4	42.0	47.9	23.0	77.0
	Televideo	95	47.0	14.5	1.4	44.0	49.9	23.0	71.0
PCL Score	In Person	101	54.5	13.0	1.2	51.9	57.1	25.0	80.0
	Televideo	95	53.5	11.6	1.1	51.1	55.9	28.0	80.0
BDI Score	In Person	101	23.7	12.3	1.2	21.2	26.	1.0	55.0
	Televideo	95	26.0	9.0	.9	24.1	27.8	8.0	53.0
BAI Score	In Person	101	24.1	13.0	1.2	21.5	26.6	.0	63.0
	Televideo	95	23.8	12.4	1.2	21.2	26.3	.0	56.0
DAST Score	In Person	97	.9	.6	.0	.7	1.0	.0	5.0
	Televideo	93	.9	.7	.0	.7	1.0	.0	4.0
Audit Score	In Person	98	7.1	5	.5	6.0	8.2	2.0	23.
	Televideo	92	6.1	5.3	.5	5.0	7.2	2.0	29.00
MOS Social Support Score	In Person	76	80.5	22.9	2.6	75.2	85.7	33.0	114.0
	Televideo	81	77.4	22.9	2.5	72.4	82.5	25.0	114.0
Number of Sessions Completed	In Person	101	7.5	1.1	.1	7.	7.7	4	8
	Televideo	95	7.6	.9	.0	7.5	7.8	4	8
Percentage Service Connected	In Person	80	45.8	39	4.4	37.0	54.6	.0	150.0
	Televideo	68	46.2	37.5	4.5	37.1	55.3	.0	100.0
Classified as Disabled	In Person	87	1.6	.4		1.5	1.7	1.0	2.0
	Televideo	84	1.5	.5	.0	1.4	1.6	1.0	2.0

Table 2: ANOVAs for Baseline Measures

		SS	<i>df</i>	MS	<i>F</i>	<i>p</i>
Age	Between Groups	191.9	1	191.9	.8	.351
	Within Groups	42573.9	194	219.4		
Base PCL Score	Between Groups	47.9	1	47.9	.3	.576
	Within Groups	29728.1	194	153.2		
Base BDI Score	Between Groups	257.3	1	257.3	2.1	.141
	Within Groups	22873.8	194	117.9		
Base BAI Score	Between Groups	5.0	1	5.0	.0	.860
	Within Groups	31574.8	194	162.7		
DAST Score	Between Groups	.0	1	.0	.0	.783
	Within Groups	93.7	188	.4		
AUDIT Score	Between Groups	46.6	1	46.6	1.5	.214
	Within Groups	5650.4	188	30.0		
MOS Social Support Score	Between Groups	363.7	1	363.7	.6	.407
	Within Groups	81619.1	155	526.5		
Number of sessions completed	Between Groups	1.2	1	1.2	1.0	.300
	Within Groups	225.2	194	1.1		
Percentage Service Connected	Between Groups	8.0	1	8.0	.0	.942
	Within Groups	218209.8	146	1494.5		
Classified as Disabled	Between Groups	.7	1	.7	3.0	.082
	Within Groups	40.9	169	.2		

4. KEY RESEARCH ACCOMPLISHMENTS:

- *Recruitment Goals of over 100 participants in each condition were met.*
- *Behavioral Activation and Therapeutic Exposure (BA-TE) was associated with reduced PTSD, Depression, and Anxiety Scores over time from pre to post treatment, and gains were largely maintained at followup.*
- *Non-inferiority of Telemedicine delivered BA-TE compared to In Person BA-TE was demonstrated, despite an exceptionally conservative analysis plan*
- *The concurrent running of a second VA study under the PI allowed pooling of dropouts for analysis in terms of in person and telemedicine conditions and demonstrated that telemedicine participants receive more sessions prior to dropout.*

5. LIST OF PERSONNEL:

Name:	Role:
Ronald Acierno, PhD	Principal Investigator
Leonard Egede, MD, MS	Co-Investigator (MUSC)
Ken Ruggiero, PhD	Co-Investigator (MUSC)
Clara Dismuke, PhD	Co-Investigator (MUSC)
Becky Knapp, PhD	Co-Investigator (MUSC)
Christopher Freuh, PhD	Consultant
Carl Lejuez, PhD	Consultant
Peter Tuerk, PhD	Consultant
Sheila Rauch, PhD	Consultant
Wendy Muzzy, MRA, MLIS	Project Coordinator
Martha Strachan, PhD	Project Coordinator
Kimberly Veronne, MA	Project Therapist
Kyleen Welsh, BS	Research Assistant
Julie Rossi, MA	Project Therapist
Katina Kuhlmann, MA	Research Clinician
Karen May, RN	Research Clinician
Alicia Meyer, MS	Research Clinician
Samantha Rodman, MS	Research Clinician
Jessica Parker, PsyD	Co-Investigator
Michael Kofher, MS	Research Clinician
Stephanie Zeigler, BS	Research Assistant
Erica Yuen, PhD	Research Coordinator
Tracey Rosenlieb, MA	Research Clinician
Martina Radic, MA	Research Clinician
Raquel Vining	Research Assistant

6. CONCLUSION:

Overall, this study supports the massive expenditures on the parts of the DoD and DoVA with respect to telemedicine delivered evidence based therapy for PTSD. Specifically, this study extended current research by using HOME based telemedicine to demonstrate non-inferiority of the medium. This is significant because tremendous cost savings (one office instead of provider office at site 1 and patient in office at site 2) and logistical simplification (patients do not have to

travel to either major medical centers or satellite clinics, which may be hours away), as well as virtual elimination of publically perceived stigma associated with receiving mental health care (i.e., presenting at a mental health facility). As such, it is clear that telemedicine in general, and home based telemedicine in particular is a useful treatment modality. The finding that, even dropouts from treatment completed more sessions prior to dropping out if they received telemedicine delivered BA-TE was also particularly supportive of the medium.

7. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

1. Acierno, R., Gros, D.F, Strachan, M., Frueh, BF (in press). The Next Step: Moving Combat-Related PTSD Care out of the Clinic and into the Home (or Boat, or Hotel, or Car [Parked]). Clinicians Research Digest.
2. Gros, D. F., Price, M., Yuen, E. K., & Acierno, R. (under review). Predictors of Completion of Exposure Therapy in OEF/OIF Veterans with Posttraumatic Stress Disorder.
3. Gros, D. F., Gros, K. S., Acierno, R., Frueh, B. C., & Morland, L. A. (2013). Relation Between Treatment Satisfaction and Treatment Outcome in Veterans with Posttraumatic Stress Disorder. *Journal of Psychopathology and Behavioral Assessment*, 35(4), 522-530.
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11. Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., & Acierno, R. (2013). The role of social support in exposure therapy for Operation Iraqi Freedom/Operation Enduring Freedom veterans: A preliminary investigation. *Psychological Trauma: Theory, Research, Practice, and Policy*, 5(1): 93-100. PMID: 23869250.
12. Strachan, M.K., Gros, D.F., Ruggiero, K.J., Lejuez, C.W., & Acierno, R. (2012). An integrated approach to delivering exposure-based treatment for symptoms of PTSD and depression in OIF/OEF Veterans: Preliminary findings. *Behavior Therapy*, 43, 560-569. doi: 10.1016/j.beth.2011.03.003. Epub 2011 May 24. PMID: 22697444.
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PRESENTATIONS

1. Acierno, R. Tuerk, P. (2010, September). Psychotherapy for post-traumatic stress disorder. Presented at MUSC's Update in Psychiatry Conference in Charleston, SC.
2. Acierno, R. (2011, March). Treatment where it counts: Home-based telemedicine for PTSD and Depression in Veterans. Presented at The Citadel Honorary Patrick Leverett Lecture, Charleston, SC.
3. Acierno, R. (2011, May). Emerging technologies and new applications for telemental health. Paper presented at the 2011 American Telemedicine Association in Tampa, FL.
4. Acierno, R. (2012, March). UPDATE: Secondary prevention of PTSD in at risk OIF-OEF service men and women: BA-TE via HOME based telemedicine. Paper presented at the MOMRP/CDMRP PTSD IPR Meeting, Bethesda, MD.
5. Acierno, R. (February 2011). Secondary prevention of PTSD in at risk OIF-OEF service men and women: BA-TE via HOME based telemedicine. Paper presented at the MOMRP/CDMRP PTSD IPR Meeting.
6. Acierno, R. (November 2010). Two home based telemedicine treatments of PTSD. Symposium paper presented at the ABCT 44th Annual Convention in San Francisco, CA.
7. Acierno, R., Tuerk, P., Yoder, M., & Yuen, E. (2012, September). Home-based telemedicine delivery of evidence based psychotehrapy for comorbid ptsd and depression: Results from an ongoing large scale radomized controlled trial. Paper presented at the Annual Conference of the Society for the Study of Anxiety and Stress, Valencia, Spain.
8. Gros, D.F., Strachan, M., Ruggiero, K.J., Tuerk, P.W., Lejuez, C.W., & Acierno, R. (November 2010). Predictors of treatment completion in OEF/OIF Veterans with posttraumatic stress disorder. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
9. Price, M., Gros, D. F., Strachan, M., Ruggerio, K. J., Acierno, R. (2011, November). The role of social support in the treatment of PTSD in OEF/OIF veterans. Poster presented for the Disaster & Trauma Special Interest Group at the 45th annual meeting of the Association for Behavior and Cognitive Therapy, Toronto, Canada.
10. Price, M., Gros, D. F., Strachan, M., Ruggiero, K. J., & Acierno, R. (2012, November). The interactive effect of increased combat exposure and pre-deployment training on

exposure therapy outcomes in PTSD for Operation Enduring Freedom/Operation Iraqi Freedom Veterans. In D. Grasso (Chair) Processes of Interpersonal Traumatic Stress. Paper presented at the 28th meeting of the International Society for Traumatic Stress Studies, Los Angeles, CA.

11. Price, M., Gros, D. F., Strachan, M., Tuerk, P. W., Yoder, M., Ruggiero, K. J., Egede, L. E., Lejuez, C.W., Acierno, R. (February 2011). Comparison of general health outcomes for African Americans and Caucasians after outpatient treatment for PTSD. Poster presented at the VA HSR&D 2011 National Meeting, Baltimore, MD.
12. Price, M., Gros, D. F., Strachan, M., West, J. S., Ruggiero, K. J., Acierno, R. (2011, October). Enhancing behavioral interventions for PTSD in Operation Enduring Freedom/Operation Iraqi Freedom Veterans: Influence of personal and environmental factors. Poster presented at the Perry V. Halushka Student Research Day, Charleston, SC.
13. Price, M., Strachan, M., Gros, D., Ruggiero, K., Acierno, R. Combat Experiences, Pre-deployment Training, and Outcome of Exposure Therapy for PTSD in Operation Enduring Freedom/Operation Iraqi Freedom Veterans. (2011, November). Poster presented for the Disaster & Trauma Special Interest Group at the 45th annual meeting of for the Association for Behavior and Cognitive Therapy, Toronto, Canada.
14. Price, M., Strachan, M., Gros, D.F., Ruggiero, K.J., Acierno, R. (November 2010). Examination of PTSD and depression treatment response for Behavioral Activation and Therapeutic Exposure. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
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17. Strachan, M. & Acierno, R. (2009, August). Innovative service delivery for the secondary prevention of PTSD in OIF/OEF service men and women. Paper presented at Military Health Research Forum (MHRF), Kansas City, KS.
18. Strachan, M., Brown, C., Veronee, K., Welsh, K., Price, M., Gros, D.F., & Acierno, R. (March 2011). Legal issues relevant to the diagnosis and treatment of PTSD in OIF/OEF populations. Poster presented at the International Congress of Psychology and Law, Miami, FL.
19. Strachan, M., Gros, D. F., Welsh, K., Lejuez, C. W., & Acierno, R. (2010, June) An Evaluation of Behavioral Activation and Therapeutic Exposure for PTSD: Preliminary Results. Poster presented at the 6th Annual Conference of the World Congress of Behavior and Cognitive Therapies Convention (WCBCT), Boston, MA.
20. Strachan, M., Gros, D.F., Ruggiero, K.J., Lejuez, C.W., Tuerk, P.W., & Acierno, R. (November 2010). Predictors of patient satisfaction in OEF/OIF Veterans with posttraumatic stress disorder. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.

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22. Strachan, M., Parker, J., Warner, C., Welsh, K., Muzzy, W., Boswell, J., Lejuez, C., & Acierno, R. (March 2011). Building a Collaborative Infrastructure for Research: Lessons Learned. Paper presented at the 13th Annual Armed Forces Public Health Conference, Hampton Roads, VA.
23. Strachan, M., Price, M., Gros, D.F., Ruggiero, K.J., Acierno, R. (November, 2011). Combat experiences, pre-deployment training, and outcome of exposure therapy for PTSD in OIF/OEF veterans. Poster presentation at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, Toronto, ON.
24. Tuerk, P. W., Yoder, M., Myrick, D. H., Acierno, R., & Hembree, E. (2010, November). Expanding the use of Prolonged Exposure Therapy for PTSD to diverse patient populations and clinical settings. Symposium presented at the ABCT 44th Annual Convention in San Francisco, CA.
25. Veronee, K., Gros, D.F., Strachan, M., Price, M., Ruggiero, K.J., & Acierno, R. (November 2010). Managing suicidality in home-based telehealth exposure therapy for combat-related PTSD: A case presentation of an OEF Veteran. Poster presented at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, San Francisco, CA.
26. Yoder, M., Tuerk, P., Ruggiero, K., & Acierno, R. (2009, November). Prolonged exposure for Combat-Related PTSD: Differences in live vs. telehealth treatment delivery. Paper presented at the 25th Annual Meeting for the International Society for Traumatic Stress Studies, Atlanta, GA.
27. Zeigler, S., Welsh, K., Yuen, E., Strachan, M., Gros, D.F., M., Price, M., Acierno, R. (November, 2011). Home-based telehealth delivery of exposure therapy to veterans with PTSD living in federally designated rural areas. Poster presentation at the Annual Meeting of the Association for Behavioral and Cognitive Therapies, Toronto, ON.

8. INVENTIONS, PATENTS AND LICENSES:

None

9. REPORTABLE OUTCOMES:

Home based delivery of evidence based treatment for PTSD is not inferior to delivering the same treatment in traditional office based settings.

10. OTHER ACHIEVEMENTS:

Based on these study findings, the VA now offers home based telemedicine for evidence based psychotherapy for PTSD in over 15 clinics across the country.

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12. APPENDICES:

Articles

(See Next Pages)

The Next Step: Moving Combat-Related PTSD Care out of the Clinic and into the Home (or Boat, or Hotel, or Car [Parked])

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Editor's Note: This is the eighth in a recurring series of bulletins, from individual clinicians' and clinical researchers' perspectives, on research-informed accounts of day-to-day practice in various clinical settings.

Ron Acierno, Daniel F. Gros, Martha Strachan, and Chris Frueh are clinical research psychologists in the areas of trauma and PTSD in both civilian and military populations. They have worked together on office and home-based telemedicine demonstration projects in both Veterans Affairs and university hospitals as part of the Veterans Integrated Service Network (VISN) 7.

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Technology now brings health and mental health care service delivery full circle, with house calls, albeit virtual, poised to once again become the norm. While patient convenience and cost savings are two major driving forces in this movement, another equally, if not more, important factor supporting telemedicine expansion involves the nature of the treated disorders themselves, for example, when ambulation is affected, or in the psychopathological realm, when systems factors, stigma, and avoidance symptoms combine to preclude even initiation of evidence-based treatment. The latter scenario is often the case for Post-Traumatic Stress Disorder (PTSD) in combat veterans, for whom social

and professional stigmas surrounding mental health problems are particularly salient (Pietrzak, Johnson, Goldstein, Malley, & Southwick, 2009) and contribute to failure to obtain needed effective treatments.

The Department of Veterans Affairs (VA) is currently the largest provider of telemedicine services in the world, and this presence is a fortuitous advantage in meeting Evidence-Based Psychotherapy (EBP) dissemination goals to treat PTSD. VA telemedicine technology connects patients receiving care in rural, community-based outpatient satellite clinics with larger VA medical centers that offer specialty mental health services. Preliminary research suggests that this form of telehealth is associated with high levels of patient satisfaction and clinical outcomes that are comparable to

in-person service delivery (Richardson et al., 2009).

Despite these successes, this treatment delivery medium still requires patients to travel to office-based treatment sites; thus, it is unclear how this model can circumvent the pathology- and system-level barriers previously described, particularly for PTSD. Indeed, these satellite clinic-based telemedicine services solve only the problem of distance from the central provider facility. By contrast, Home-Based Telehealth (HBT) may enhance retention in EBPs such as Prolonged Exposure (PE; Foa, Hembree, & Rothbaum, 2007) by directly circumventing this and other barriers.

The Charleston Consortium (i.e., Ralph H. Johnson VA Medical Center—Medical University of South Carolina) has been studying HBT for psychological problems to overcome aforementioned barriers (e.g., stigma, avoidance) to office-based care in military personnel for the past 5 years, first with depression in geriatric veterans (Egede et al., 2009), and currently with PTSD. We predict that changing the service delivery medium from satellite clinics to HBT will actually result in better outcomes insofar as completion rates for evidence-based treatment will be higher. Indeed, Dr. Peter Shore at the Portland, OR, VA reports fewer than 5% missed sessions with HBT compared over 15% with traditional satellite clinic-based telemedicine (Shore, 2011). Reduced attrition is particularly important for those suffering from combat-related PTSD (Bradley, Greene, Russ, Dutra, & Westen, 2005).

Home-Based Telehealth

Historically used to enhance management of chronic diseases such as diabetes, obstructive pulmonary disease, and congestive heart failure, prelimi-

nary research suggests HBT service delivery is associated with high patient satisfaction, reduced frequency and duration of inpatient hospital stays, and overall symptom improvement (DelliFraine & Dansky, 2008; Shore, 2011). Although these preliminary data are promising, administrators and clinical providers have been reluctant to apply HBT service models to mental health interventions, citing concerns that HBT via video-conferencing may compromise therapeutic alliance, patient safety, and (Bauer, 2001).

Despite this skepticism, HBT for mental health treatment offers several advantages over conventional, satellite clinic-based telehealth models. First, HBT service delivery circumvents stigma-related avoidance of office-based mental health care; second, HBT removes many logistical barriers related to travel time and transportation; and third, HBT service delivery circumvents system-level barriers including space constraints (satellite clinic-based telehealth requires 2 offices for each appointment). Moreover, we have found that all procedures common to CBT in general and PE in particular can be accomplished via HBT, including homework review, audio recording of exposure scenes, completion of rating scales, visual monitoring of patient distress and facial signals, and the like.

Safety Considerations

The question of suicide risk is universally among the first and most frequent concerns when evaluating whether or not a site should adopt HBT. Our position is that HBT represents incremental *increase* in, rather than a threat to, patient safety for 2 distinct reasons. First, if a suicidal patient abruptly leaves one's facility or office, providers have little idea where to send police or Emergency Medical Services. By contrast, HBT providers know exactly where to send help if a suicidal patient cannot guarantee self-safety. In fact, we have just published a case presentation illustrating the safe and effective use of HBT in managing acute suicidality with a veteran being treated for PTSD (Gros, Veronee, Strachan, Ruggiero, & Acierno, in press).

The second reason we view HBT as a suicide safety enhancement is that many

patients in extremely depressed or actively suicidal states are less motivated to travel to their mental health treatment center for their appointment. In other words, these truly at-risk patients often do not show up for their office-based appointment. Thus, providers would not even know or have the opportunity to know the extent of suicidal risk *in situ* because the patient never would have entered their office or the telemedicine suite at the satellite clinic. However, with HBT, the effort required to connect to the therapist standing by for their session is dramatically reduced; indeed, "no-show" patients are simply called on the telephone and asked to turn on their computer (and more recently, the tele-video application on their smart phone) and thus are more likely to receive care. In other words, with HBT, we are more likely to be in contact with suicidal patients, and we are more likely to be able to intervene, and we are more likely to dispatch resources to the necessary site of intervention while safely maintaining contact with both the patient and the emergency responders.

HIPPA Licensure

There are 2 general approaches to maintaining HIPPA compliance/confidentiality with HBT and telehealth: third-party HIPPA compliant server hosting and recording of all transmitted data (i.e., Intel's PHS6000) versus real-time encryption/transfer, without recording (e.g., AK Summit). Issues regarding licensure and privileging are complicated in telemedicine and more so in HBT. The federal government has proposed national standards outlining many of these parameters. Typically, medical records must reside where the patient is receiving services, whereas privileging processes are based on standards of the site from which the provider practices. Moreover, in the absence of interstate agreements, cross-state telehealth is prohibited in many states. The exception to this rule is when the provider and patient are both in federal facilities, such as the VA or DoD centers. However, while this exception clearly includes the hub and spoke (main facility to satellite facility) model of telehealth, it leaves unaddressed the issue of HBT, where treatment originates from a central federal facility, but

is received across state lines in the patient's *home*.

Future Directions

Overall, issues and problems confronting telehealth in general and HBT in particular are relatively easily resolved, as demonstrated by the aforementioned recent research in the area. Issues do remain, not the least of which are interstate and international licensing standards, but these are not insurmountable. On almost a monthly basis, technology-driven options are expanding for service delivery. Tablets and smart phones seem to be the most likely landing place for HBT. We predict expansion of the HBT model will proceed at a tremendous pace, with services offered at the time and place patients choose. Of course, providers should be vigilant that cars be parked and turned off prior to any session initiation.

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Behavioral Activation and Therapeutic Exposure for Bereavement in Older Adults

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Abstract

The development and clinical trial of a 5-session behavioral intervention for complicated bereavement (CB) is presented. We conceptualized CB in terms of Major Depression (MDD) and Post-traumatic Stress Disorder (PTSD) and consequently applied treatment components of Behavioral Activation and Therapeutic Exposure (BA-TE). In order to assure standardization of treatment, control costs, and engage patients, a multi-media, multi-context format was adopted to address avoidance and withdrawal behaviors conceptualized as central pathogenic responses in CB. Participants (N = 26) were assessed before and after BA-TE treatment via structured clinical interview and standardized questionnaires in terms of PTSD, MDD, CB, and health concerns. The number of days since the death of the loved one was widely variable and served as a covariate for all outcome analyses. ANCOVAS revealed statistically significant improvement, irrespective of how many days since death had elapsed prior to initiation of intervention, on structured interviews and self-report measures for most outcome variables.

Keywords

complicated bereavement, behavioral activation, therapeutic exposure, major depression, posttraumatic stress disorder, older adults

Over three decades ago, participants in a landmark study by Holmes and Rahe¹ identified spousal death as the most stressful life event experienced, a finding more recently supported by Stroebe and Stroebe.² Not only is loss of a loved one among the most stressful life events, it is also among the most common for older adults. Almost 1 million individuals become widowed in this country each year, and almost 75% are 65 years of age or older.³ According to the US Census Bureau, in 2003 approximately 14% of men and 45% of women 65 years and older were widowed. Among those of age 85 and older, this increased to 43% of men and 80% of women. About 33% of surviving older adult spouses will experience a “complicated bereavement” (CB),^{4,5} placing them at significantly increased risk of health problems, psychological illness, and mortality (for men).⁶⁻⁹ These concerns are increased in older adults who are also experiencing reduced social and economic opportunities by virtue of their age. Indeed, impact of spousal loss is very often overwhelming for older adults; failure to provide effective services for these individuals at the time of their spouses’ death represents a missed opportunity to reduce suffering, control health care costs, and improve quality of life for older adults.

Outcomes of Death in Terms of CB

Complicated bereavement, variously labeled traumatic bereavement, traumatic grief, or prolonged grief disorder,

refers to a syndrome characterized by symptoms of anxiety and distress that is distinct from both normal grief and major depressive disorder (MDD).^{10,11} Findings from a psychometric validation study of CB criteria reveal that core aspects of the syndrome included yearning, diminished sense of self, difficulty accepting the loss, avoidance of reminders of loss, inability to trust others, anger, numbness, feeling life has no meaning, feeling dazed/shocked by loss.¹² Overall, there is a general anxious tone to the symptom picture, complemented by emotional numbing and an inability to accept the death of the spouse or loved one. Conceptualizing CB as an anxiety-based disorder is not entirely new, however. Kavanagh¹³ likened bereavement to phobic responses and reasoned further that the treatment for phobic responses (ie, exposure to feared or avoided stimuli) may be appropriate for CB.

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Differences Between CB and MDD

Complicated bereavement appears to be distinct from MDD.^{10,14-17} Previously, CB was conceptualized as a form of “agitated depression.” However, initial work by Prigerson et al.^{16,17} identified a second factor in addition to depression in bereaved individuals. The first factor, depression, was primarily evident in the form of somatic complaints, apathy, guilt, suicidality and psychomotor retardation. The second factor, complicated grief, was characterized by the symptoms outlined above (yearning, preoccupation with thoughts of the deceased, disbelief about the death). Additional evidence that the disorders are distinct comes from a study by Pasternak et al.¹⁸ in which changes in depression accounted for only 12% of the variance in bereavement. Specifically, even when depression was reduced in their study sample, scores on the Texas Revised Inventory of Grief remained high. This was supported by findings from a controlled study of bereavement-related depression with nortriptyline and interpersonal therapy where the combination therapy and antidepressant medication had a remission rate of 69% but did not reduce symptoms of CB relative to placebo.¹⁹ Similarly, Prigerson et al.^{16,17} found that depression was reduced but symptoms specific to CB were not.

Commonalities Between Posttraumatic Stress Disorder and CB

While data support conceptualizing CB as distinct from MDD, several studies offer converging evidence that CB share some similarities to posttraumatic stress disorder (PTSD). Indeed, as early as 1985, Windholz, Marmar, and Horowitz²⁰ outlined CB in terms of PTSD. Frank, Prigerson, Shear, and Reynolds²¹ also conceptualized CB as a form of PTSD and outlined a treatment based directly on Foa et al.’s²² exposure-based treatment of PTSD for interpersonal violence victims (see Shear et al.²³). Specific similarities include the disorders’ presentations, courses, risk factors, and perhaps, responses to treatment. For example, the core symptoms of CB include numbness, denial, preoccupation with thoughts of the deceased (ie, intrusive ideation), anger, and an altered sense of the future. *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition [DSM-IV]) defined symptoms of PTSD include “recurrent and intrusive distressing recollections of the event; recurring dreams of the event; intense distress at exposure to . . . cues that . . . resemble an aspect of the event; diminished interest or participation in significant activities; feeling detachment or estrangement from others; sense of foreshortened future; difficulty concentrating.” Lastly, and most relevant to treatment planning, both disorders share a very potent risk factor: low social support.^{4,20,24-28}

Existing Outpatient Treatment Options

Treatment is most commonly offered in the form of support groups for surviving spouses. These groups are typically run by nonprofessional peers and offered by hospice centers, larger

funeral homes, and other social service venues that interact with older adults. Unfortunately, there is limited evidence for the efficacy of these types of bereavement-focused treatments (see reviews by Jordan and Neimeyer²⁹ and Schut et al.³⁰). Alternately, Shear and colleagues³¹ examined a manualized psychotherapy for CB in a randomized controlled trial of 95 adults experiencing CB. Participants who were at least 3 months post loss and who met criteria for CB were randomly assigned to a CB treatment package or interpersonal psychotherapy. The treatment protocol was a highly structured 16-session individual counseling by a trained clinician, which included psychoeducation about grief and CB, grief theory, motivational enhancement techniques, behavioral activation (BA) components, imagined conversations with the deceased, and retelling of death scene. Findings indicated greater improvement in CB symptoms among those who received the CB treatment (51% response rate) than those in the interpersonal therapy (28% response rate).³¹ This study gives promises to focusing therapeutic interventions on CB symptomatology, but these strengths should be balanced by feasibility issues including the length of the treatment and the need for a skilled, trained clinician to implement.

An Alternative, Paraprofessional-Led Treatment: BA and Therapeutic Exposure

Empirically validated exposure methods for treating symptoms of PTSD and anxiety noted in CB are based on learning theory models of psychopathology and have consistent empirical support for their efficacy. According to learning theory, the death of a spouse or close loved one serves as the original event that naturally leads to responses characteristic of the PTSD-related aspects of CB (ie, avoidance, hyperarousal, and intrusive ideation). Initial responses typically also include symptoms of depression and even panic. As with other anxiety responses, these responses become associated with salient stimuli present in the environment during the time of death (eg, hospitals, disinfectant smells), as well as stimuli that remind the bereaved of the lost one (eg, pictures, mementos) that themselves begin to elicit learned bereavement responses in the future. Thus, when a bereaved individual is exposed to one of these stimuli or finds herself or himself in situation similar to the one in which she or he lost her or his loved one, a negative emotional response identical or very similar to the original emotional response occurs.

To reduce or eliminate extreme aversiveness of this learned anxiety response, individuals will escape from and subsequently avoid things or people or places that remind them of the event. This avoidance behavior naturally results in diminution of negative emotions (ie, it “works” to reduce discomfort) and is thus more likely to occur in the future. Unfortunately, this avoidance also perpetuates the PTSD-like CB symptoms in that individuals never “learn” not to become distressed in the presence of these cues because they always avoid them. In addition, this avoidance or withdrawal reduces the number of positive activities with which the individual is engaged. Withdrawal naturally leads to depression and further withdrawal. Indeed,

according to Lewinsohn's theory of depression,³² negative affect resulting from reduced activity is actually a product of reduced reinforcement density. That is, individuals who interact less with their social environment are less likely to receive reinforcement simply because they are doing fewer things that they might find enjoyable. Hence, the agitated anxiety symptoms of CB exacerbate depressive symptoms associated with the loss of a loved one by causing avoidance, which leads to reduced activity, and following, reduced reinforcement. This vicious cycle endures and does not resolve without altering behaviors, namely avoidance and withdrawal that perpetuate symptoms.

Effective treatment for the anxiety or "PTSD component" of CB will involve behavioral change in which individuals expose themselves to avoided stimuli and activities until the initial discomfort is extinguished and they become relatively less uncomfortable in these situations.²² At the same time, this exposure is a form of BA that ameliorates depressive symptoms produced by withdrawal.³³ Thus, by teaching individuals to confront activities and situations that they have avoided because they remind them of their loved one's death, levels of discomfort will naturally be reduced. Many times, however, bereaved individuals are not affectively engaged with exposure activities or in bereavement counseling sessions, discuss their loss in a distanced, less intense, and hence less therapeutically useful way. Thus, the goal of exposure treatment delivered in the context of BA is to use ecologically valid, behaviors characterized by real-world relevance and manifest in specific daily activities. For example, if a husband and wife used to attend religious services together, and the wife now avoids these services because they remind her of her lost husband and make her distressed, sad, and uncomfortable, repeatedly going to services and exposing herself to similar situations would comprise the targeted exposure-based behavior and will eventually result in a reduction (ie, desensitization) of symptoms. This is complemented by the natural reinforcement derived by engaging in previously rewarding activities and thus reduces depressive affect. Although this conceptualization is based upon the empirical literature for PTSD and MDD, findings of several investigators support its applicability to CB. For example, Kavanaugh¹³ and Sireling et al³⁴ noted that increasing pleasurable activities is an important aspect of treatment for CB. Moreover, other investigators reported that people who quickly resume social roles and activities recover from bereavement-related distress more rapidly.^{35,36} Of note, Shear and colleagues^{23,31} tested this model with traumatic grief victims and their findings supported this conceptualization.

Given the significant overlap between CB with MDD and PTSD, as well as the lack of effective treatments for CB (and effective treatments for MDD and PTSD), we designed a componential treatment consisting of BA (MDD) and therapeutic exposure (TE) strategies to reduce symptoms in each of these areas. A major design goal was to create an intervention (1) that was highly exportable and affordable to those agencies providing bereavement services, such as hospice organizations staffed by paraprofessionals, (2) but that maintained standardization and treatment quality. Thus, a multicontext (in-person and

telephone) format was adopted to limit costs associated with in-person home-based treatment while maintaining the "dosage" at 5 sessions, the minimum conceptualized as necessary for BA treatments. The multimedia intervention featured a video in which core treatment components were featured, and an accompanying brochure which used images from the video and restated core treatment components. The video and brochure allowed review of treatment components and assured some degree of consistency of treatment delivery across therapists over time. The treatment itself was designed to address the avoidance and withdrawal behaviors conceptualized as central pathogenic responses in CB. We hypothesized that individuals receiving the intervention would improve on measures of MDD, PTSD, and CB, and we predicted that these improvements would be independent of the length of time that had elapsed since the loved one's death.

Methods

Treatment

Behavioral activation and therapeutic exposure treatment included 2 components designed to assure its relevance to hospital- and community-based service agencies across the country while maintaining its standardization and cost-effectiveness when delivered by peer counselors, who provide the majority of this type of service. The first component was a video-based intervention illustrating BA and TE and was designed to treat those symptoms of CB that resembled PTSD and MDD. This video outlined essential treatment strategies and their rationale and thus served the dual purpose of (1) educating participants and (2) "centering" bereavement counselors on treatment components so that a significant focus of their therapeutic work was standardized, consistent with the intervention as specified. This video was complemented an active therapy component, based on the principles of BA for MDD and TE for PTSD, which used daily planners and worksheets to identify and rate positively and negatively reinforcing behaviors, as well as the lists of stimuli avoided since the death of the loved one (eg, going to religious services, looking at pictures of the deceased). For the present study, a list of community activities and resources for older adults was generated. Each participant used this list as a prompt to generate 10 to 20 highly defined activities that were either fun (positively reinforcing) or, if not fun, at least functional (negatively reinforcing), in that an aversive but necessary task was completed. Each activity was rated in terms of desirability and difficulty, with relatively easier and more desirable activities used before equally desirable, but more difficult activities. A second list of behaviors was also generated that focused on the often subtle avoidance responses of most individuals with CB. Next, these 2 lists were used to generate activities for the next 2 days. A daily planner was used to guide behaviors and was kept by patients throughout the day so that planned activities were known and any changes to activities recorded. In this way, activities that were ineffective in altering mood, or that were routinely not accomplished despite

being scheduled, were removed or modified. Treatment was delivered in 5 sessions over 5 weeks (2 in-person, followed by 2 via telephone, followed by a final in-person session), consistent with the following general outline:

Session 1: In the first session, the rationales for BA and TE are given in the video and again in the accompanying brochure. The core points made are (1) what one does often plays a role in how they feel and (2) if one develops patterns of avoidance, specifically as it relates to the memories of loved ones, the pain of loss may endure longer and more intensely than it has to. After playing the video, this rationale is restated and any questions answered. Participants are asked to describe the rationales in their own words. Therapists then proceed to identify 3 types of specific behaviors that are positively reinforcing (ie, enjoyable behaviors), negatively reinforcing (eg, behaviors such as chores that, when completed, result in reduction of stress or aversiveness), or incompatible with bereavement-related avoidance. Each reinforcing behavior is rated in terms of its reinforcing potential and difficulty to complete. Whenever possible, behaviors are framed in a social context (eg, if a participant endorses reading a book, we will ask them to consider reading a book at a library or book store, where the potential exists, however low, to meet someone and have a pleasant exchange). Participants are then given a daily planning calendar with sections allocated to list and rate behaviors as described above. Behaviors that are reinforcing and relatively easily accomplished are then planned each day, with the objective of at least 3 hours of reinforcing activities and 30 minutes of exposure behaviors planned for the following 2 days. Participants are instructed to plan 1 additional day each night at the same time, thereby always maintaining 2 days of planning in the future. Note that many bereaved individuals state that they do not want to “heal” and that they equate lessening of negative affect related to the loss with “forgetting” their loved one. We are very careful to validate feelings of loss and assure patients that “getting better” is not the same as forgetting, with focus placed on what their partner would have wanted for them, which is probably fond memories, rather than painful memories.

Session 2: This session begins with a review of homework and verbal reinforcement of completed planners, completed behaviors, restatement of the rationale, and problem solving. Behaviors that were consistently planned but not completed are removed and alternative behaviors suggested. A discussion of avoidance behaviors related to bereavement is held and exposure activities derived from this. The next day’s activities are planned.

Session 3-4: These sessions are conducted over the telephone and begin with a review of homework, followed by asking the participant to state, in their own words, their interpretation of the rationale for BA and TE. Obstacles to completing behaviors are discussed and additional

exposure-based and reinforcing behaviors are generated. The next day’s activities are planned.

Session 5: A final discussion of the rationale and treatment gains obtained thus far is conducted. Discussion is also centered on the need to continue planning activities and using a daily planner for at least 6 months. Relapse prevention strategies are reviewed.

Project therapists and treatment fidelity. A major goal of this project was to develop an intervention of sufficient exportability that any bereavement service agency in the country, even those with minimal resources and staff with varied training backgrounds, could acquire, learn, and implement all major treatment components. Thus, the entire study manual was condensed to its essential elements and comprised only 1 page, and the intervention video, while designed to instruct patients in therapeutic behaviors, also served to reinforce intervention components and their implementation for therapists on an ongoing basis. In order to demonstrate the simplicity of the intervention, therapists in this study ranged in skill and experience, from novices with no therapy experience who had recently completed their BA in psychology to predoctoral psychology interns to social workers who had been engaged in hospice activities for some time. Therapy cases were evenly distributed across therapists.

The first author conducted weekly supervision meetings with all treating therapists, during which behavioral planning and recording forms were reviewed. In order to make such review possible, all participants’ BA planning weekly calendars consisted of “carbon copy sheets” in which planned behavioral events (ie, positively reinforcing behaviors, negatively reinforcing behaviors, exposure or avoidance-incompatible behaviors) were recorded and subsequently reviewed to assure that events took place. For telephone sessions, therapists entered the previous 3 days’ events and the next 2 days’ planned events for review. In this manner, therapists and the supervisor could ascertain both that BA events were being planned and executed.

Dependent Measures

All measures were administered by trained interviewers, supervised by the project director, at pretreatment and again at 1 week posttreatment. The assessment battery required approximately 1 hour to complete and included the following:

Complicated Grief Assessment Interview (CGA-I). This semi-structured interview is based on the Inventory of Complicated Grief¹⁷ and permits both diagnosis of complicated grief and a total intensity score (ranging from 9: *no symptoms*, to 45: *extreme symptoms*). Assessed are criterion A (separation distress); criterion B (other symptoms such as difficulty with the following: accepting the death, trusting others, experiencing feelings other than numbness, moving on; as well as feeling: bitter, as though life were meaningless, as though the future holds

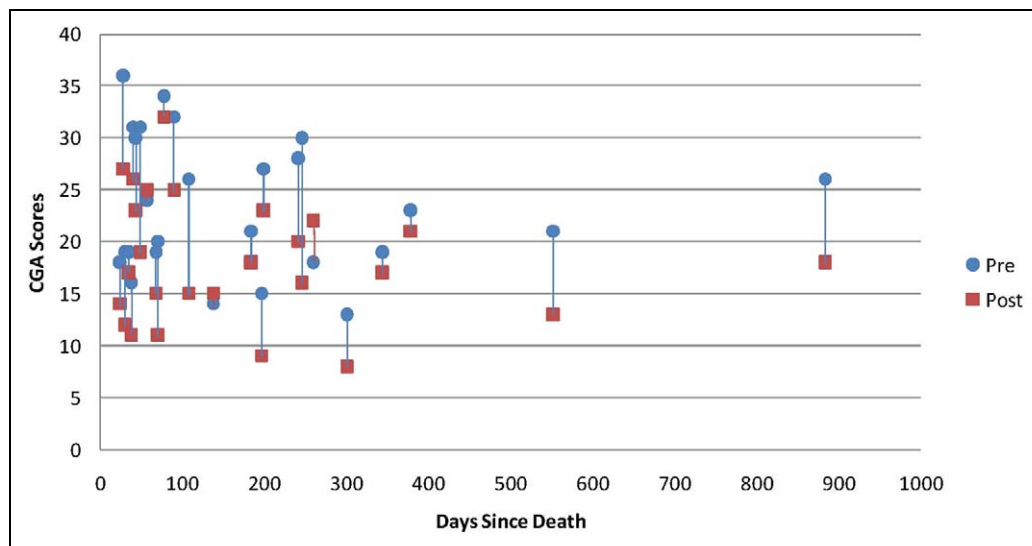


Figure 1. Scatter plot of pre-post CGA-I scores. CGA-I indicates Complicated Grief Assessment Interview.

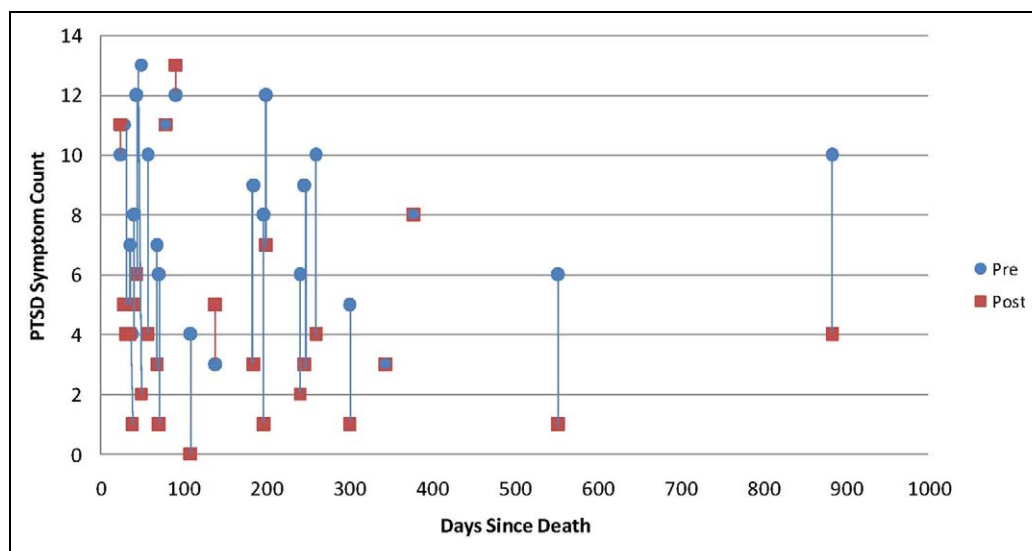


Figure 2. Scatter plot of pre-post PTSD symptom count scores. PTSD indicates posttraumatic stress disorder.

no purpose, and on edge); and criterion C (impairment in functioning).

Structured Clinical Interview for DSM-IV (SCID-IV).³⁷ Symptoms of MDD and PTSD were measured via structured clinical interview based directly on the *DSM-IV* (SCID-IV). The SCID-IV is one of the most used interviews to assess a full range of psychiatric syndromes in adults. Ventura et al³⁸ found excellent interrater reliability on assessments of symptoms across a variety of disorders (overall $\kappa = .85$). Structured interview questions were read verbatim and yielded symptom count scores for MDD and PTSD.

Beck Depression Inventory (BDI).³⁹ The BDI, a 21-item self-report scale, is among the most widely used instruments to measure depression. Each item contains 4

statements reflecting current manifestations of depression in increasing intensity, from neutral (eg, “I am not particularly discouraged about the future.”) to severe (eg, “I feel that the future is hopeless and that things cannot improve.”). Each item is scored 0 to 3 and the total scores range from 0 to 63, with higher scores indicating greater depressive severity. Of the 21 items on the scale, 13 assess depressive symptoms that are primarily psychological in nature, while 8 measure symptoms that are somatically oriented. Beck and Steer⁴⁰ and Gallagher et al⁴¹ demonstrated that the BDI has high internal consistency ($\alpha = .86$ and $\alpha = .91$, respectively).

*Health-Related Functioning: Medical Outcome Study Short Form-36 Health Survey (SF-36).*⁴² This is a 36-item questionnaire that measures health status and functioning

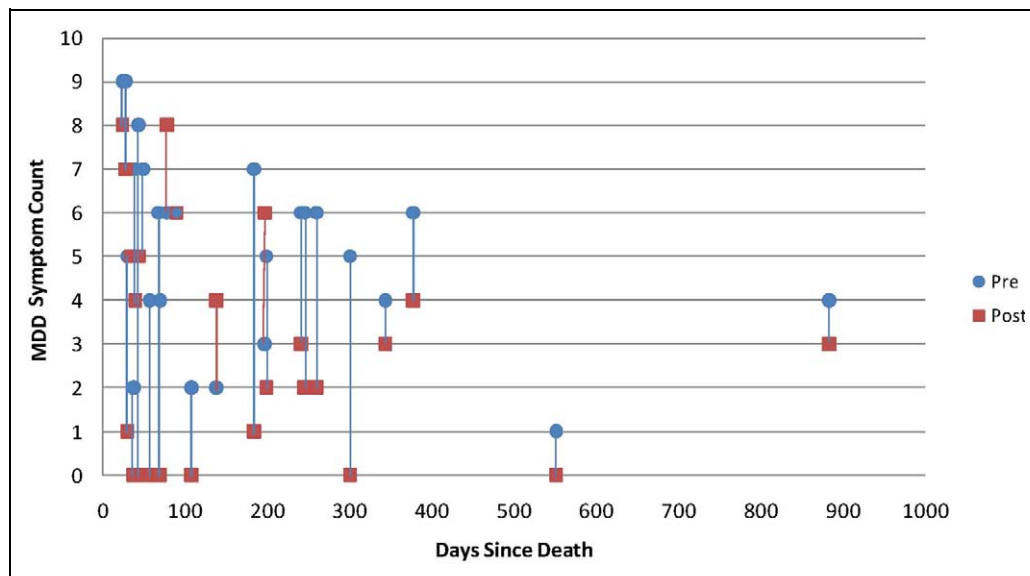


Figure 3. Scatter plot of pre-post MDD symptom count scores. MDD indicates major depressive disorder.

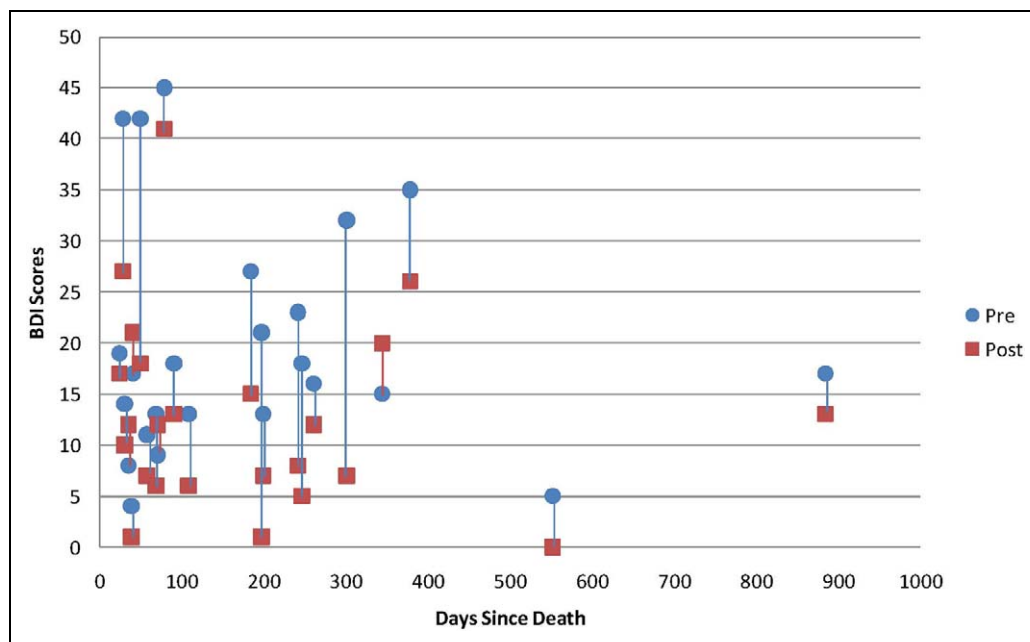


Figure 4. Scatter plot of pre-post BDI scores. BDI indicates Beck Depression Inventory.

over the past 4 weeks. The items vary from dichotomous (yes/no) responses, to ratings on a 6-point Likert scale. Responses are compiled into 8 dimensions covering physical functioning, role limitations due to physical causes, role limitations due to emotional causes, energy-fatigue, emotional well-being, social functioning, pain, and general health. The SF-36 has good test-retest reliability as well as sensitivity to change in health status.^{43,44} Lin and Ward⁴⁵ found the SF-36 to have high internal consistency (Cronbach $\alpha > .87$) and found the subscales reliability coefficients ranged from .59 to .89. Furthermore, Weinberg

et al⁴⁶ examined the validity and feasibility of the SF-36 in an elderly population.

Research Participants

Participants (N = 26) who had lost a loved one and were seeking counseling services for bereavement issues and had at least 1 risk factor for CB were enrolled in the study, and all 26 completed the posttreatment assessment. One participant declined to engage in the study after initially consenting. Participants who completed both pre- and posttreatment assessments were 22 women and 4 men (mean age 65.6 years, SD = 10.5, range 47-83; 90%

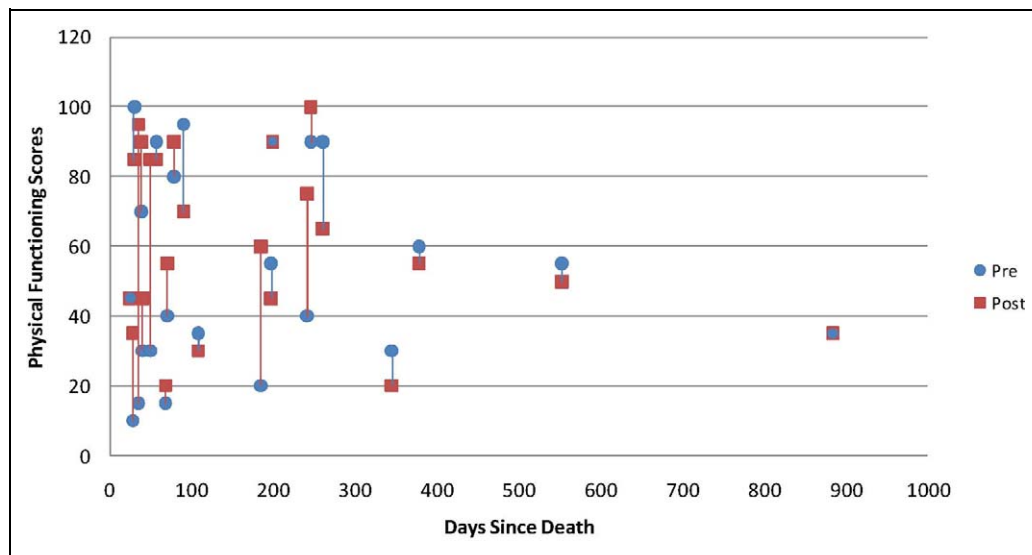


Figure 5. Scatter plot of pre-post SF-36 subscale of physical functioning scores.

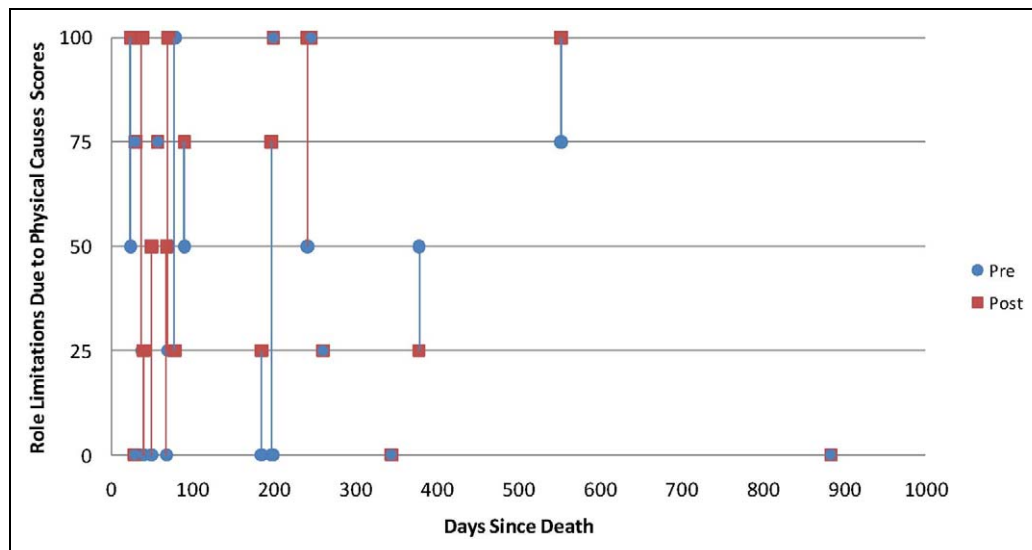


Figure 6. Scatter plot of pre-post SF-36 subscale of role limitations due to physical causes scores.

Caucasian) without significant dementia or psychosis, who lost a spouse or romantic partner and were identified by hospice workers, hospital staff, or mental health care providers as in need of psychological intervention for bereavement. Approximately 11% did not complete high school, 16% completed high school, 38% completed some college, and 35% received a college degree. Seventy-six percent rated their relationship with their deceased partner as well above average, 16% rated the relationship as slightly above average or average, and 8% indicated that the relationship was below average. The number of days since death upon study enrollment averaged 180 (SD = 196.1) and ranged from 24 to 884 days.

Procedures

Participants were referred by local hospice agencies, other agencies that served bereaved individuals, university hospital nurse

supervisors, or self-referred in response to posted brochures. Participants completed informed consent documents and study measures and were included if they reported significant distress on CGA interview scores (CGA score greater than 13) and at least 1 risk factor for CB. Dependent measures were collected prior to treatment initiation and again at posttreatment (approximately 6 weeks later). One week following completion of the assessment battery with the study interviewer, participants met with a study therapist in person for 60 to 90 minutes, reviewed the video that described BA-TE for bereavement, and completed study checklists and rating forms for reinforcing behaviors and exposure situations. Finally, participants completed the daily planners for the next 2 days, wherein each day was planned to include positively reinforcing (eg, going to dinner with friends) and or negatively reinforcing (eg, chores) behaviors and exposure-based behaviors (eg, looking at pictures of the deceased when they were

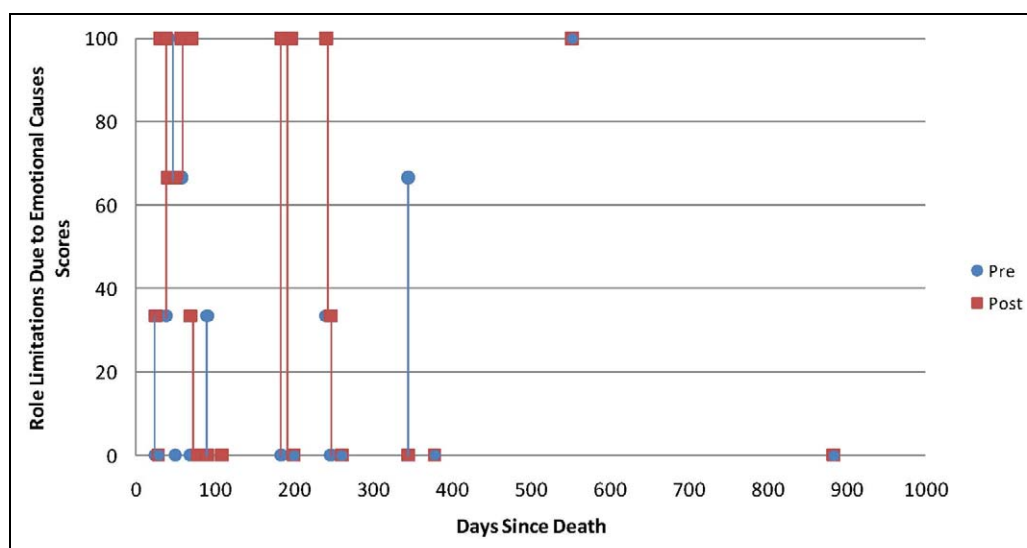


Figure 7. Scatter plot of pre-post SF-36 subscale of role limitations due to emotional causes scores.

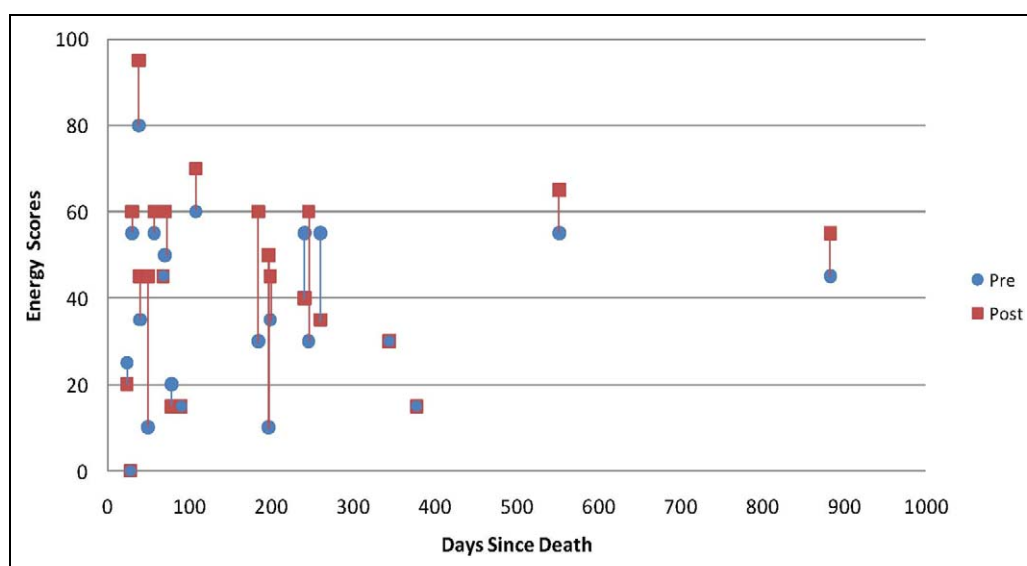


Figure 8. Scatter plot of pre-post SF-36 subscale of energy-fatigue scores.

alive). Each night the participants were instructed to plan for the next unscheduled day, thereby keeping 2 days advanced in their daily planners. The next session reviewed the study homework, restated the rationale, and resolved difficulties, culminating in planning the following 2 days. Sessions 3 and 4 were similar to the first 2 but were conducted over the telephone, and the fifth and final session was conducted in person, consisted of a review of all study procedures and advice to continue with the BA-TE procedures after treatment termination.

Results

Considering the diagnostic status, at pretreatment, 34.6% met full criteria for CB (not considering the 6-month post-death requirement) and 7.7% met criteria at posttreatment.

Participants were contacted at 3 months posttreatment and invited to complete follow-up measures, but fewer than 30% participated in this and follow-up data are not considered here. Figures 1 to 12 provide pre- and posttreatment overlaid scatter plots for each continuous dependent measure illustrated in terms of the number of days post-death, which served as the covariate in all analyses. Note that each participant's pre- and posttreatment scores are joined by a vertical line illustrating the change after treatment. Table 1 provides the overall analysis of covariance (ANCOVA) results for all structured clinical interview-based dependent variables, and Table 2 provides the overall ANCOVA results for self-report measures.

Considering the interview data first, and controlling for the number of days post-death prior to intervention initiation, neither the covariate (days since death) nor its

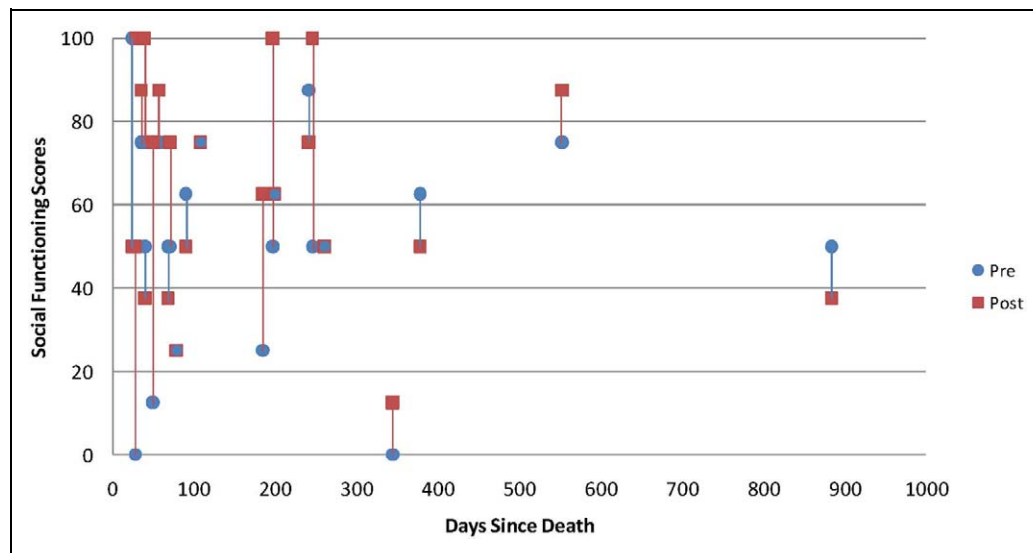


Figure 9. Scatter plot of pre-post SF-36 subscale of social functioning scores.

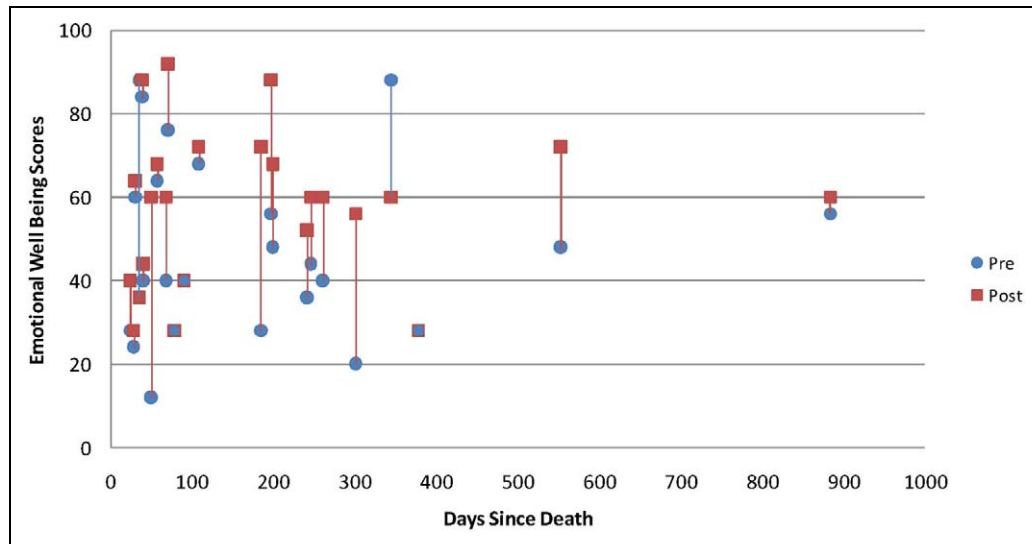


Figure 10. Scatter plot of pre-post SF-36 subscale of emotional well-being scores.

interaction with the independent variable (pre- and posttreatment) was significant. Therefore, focus is turned to the main effect of time (pre- and posttreatment change). Complicated Grief Assessment Interview scores were reduced from a mean of 23.4 (standard error [SE] = 1.3) to a mean of 18.2 (SE = 1.2) $P < .001$, effect size (range 0-1) partial $\eta^2 = .46$; PTSD symptom count scores were reduced from 8.0 (SE = 0.6) to 4.3 (SE = 0.7) $P < .001$, $\eta^2 = .41$; MDD symptom count scores were reduced from 5.2 (SE = 0.4) to 2.8 (SE = 0.5), $P < .01$, $\eta^2 = .38$.

Considering the self-report questionnaires, the BDI scores were reduced from 19.9 (SE = 2.4) to 12.7 (SE = 2.0) $P < .01$, $\eta^2 = .27$; the SF-36 subscale physical functioning evidenced improvement from 53.0 (SE = 6.3) to 62.0 (SE = 5.1), $P < .05$, $\eta^2 = .17$; scores on the role limitations

due to physical causes subscale were improved from 33.3 (SE = 8.0) to 58.3 (SE = 8.3) $P < .05$, $\eta^2 = .27$; role limitations due to emotional causes improved from 22.2 (SE = 7.6) to 49.2 (SE = 9.9) $P < .05$, $\eta^2 = .30$; energy-fatigue scores were improved from 36.5 (SE = 4.2) to 45.9 (SE = 4.8) $P < .05$, $\eta^2 = .19$. The social functioning scale was significant, with improvement from 52.7 (SE = 5.6) to 64.7 (SE = 5.4) $P < .05$, $\eta^2 = .17$. However, the change in pre- to posttreatment scores were not significantly different for the SF-36 subtests emotional well-being, pain, and general health.

Discussion

The intervention developed and pilot tested in this study was designed around the techniques of BA and TE, wherein focused

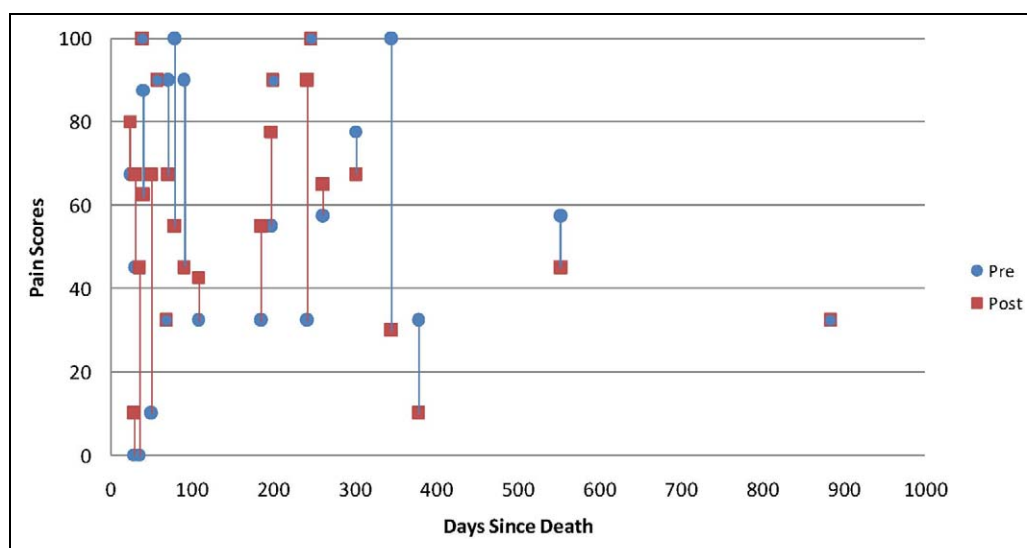


Figure 11. Scatter plot of pre-post SF-36 subscale of pain scores.

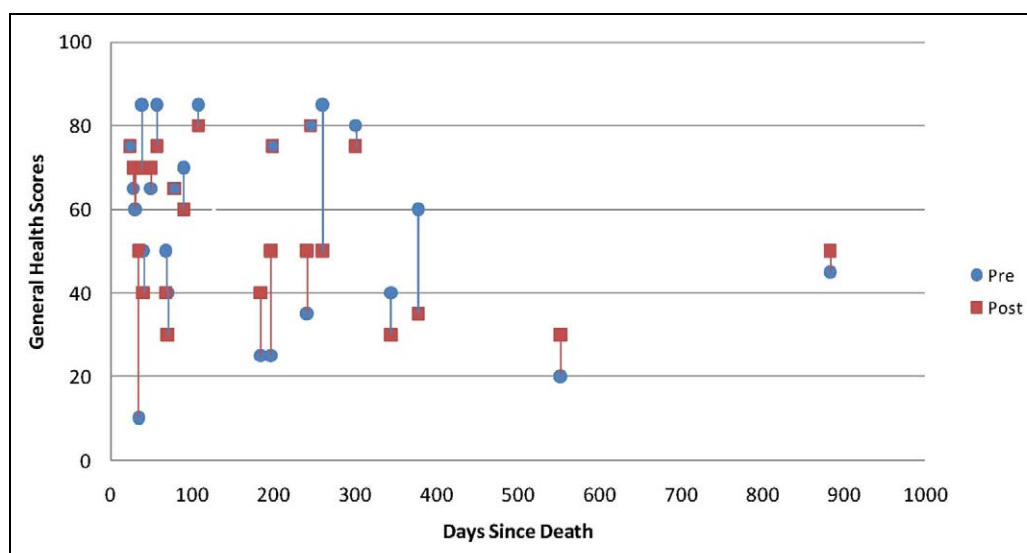


Figure 12. Scatter plot of pre-post SF-36 subscale of general health scores.

attempts are made to consistently and repeatedly engage the bereaved older adult in socially based events in the community. We view this community connection and reintegration, via planned scheduled BA techniques, as central to the treatment. We consider the trial highly successful in that we produced an easily exportable, multimedia intervention and subjected it to initial pilot testing with positive results. The intervention, consisting of a 1-page manual and a video, was designed to be delivered through 3 in-person and 2 telephone sessions by relatively novice therapists. Moreover, the treatment appears to have produced effects in excess of those typically achieved by more formal and complex interventions. The intervention, as intended, is sufficiently inexpensive and user-friendly to be successfully adopted by hospice centers and others who assist the bereaved across the country.

Despite promising results, this was not a controlled trial, and statements of causality cannot be supported beyond initial inference. Nonetheless, we did examine outcomes in terms of the number of days since the spouse or partner died, and our effects were sustained across a variety of post-death time frames. Controlling for the number of days since death, which was quite variable across patients, allowed some inferential support for the conclusion that improvement following the intervention was a consequence of treatment. In other words, participants in this study appeared to improve significantly after they received the treatment, no matter how much time had elapsed since the death of their loved one. This “naturalistic multiple baseline” provides partial, albeit weak experimental control for the effects of “time” and indicates that further randomized controlled trials are probably justified.

Table 1. Analysis of Covariance for Interview Symptom Count Scores: CGA-I, SCID PTSD, and SCID MDD

Source	SS	df	MS	F	p
CGA-I					
Between participants					
Days since death (D)	32.98	1	32.98	0.46	.506
Error	1735.10	24	72.97		
Within participants					
Time (T)	181.14	1	181.14	20.20 ^a	.000
T × D	0.56	1	0.56	0.06	.805
Error	215.21	24	8.97		
PTSD					
Between participants					
Days since death (D)	8.61	1	8.61	0.54	.468
Error	379.34	24	15.81		
Within participants					
Time (T)	81.39	1	81.39	16.96 ^a	.000
T × D	1.36	1	1.36	0.28	.599
Error	115.2	24	4.8		
MDD					
Between participants					
Days since death (D)	15.23	1	15.23	1.88	.183
Error	194.25	24	8.09		
Within participants					
Time (T)	47.93	1	47.93	14.99 ^a	.001
T × D	1.2	1	1.2	0.38	.546
Error	76.74	24	3.2		

Abbreviations: CGA-I, Complicated Grief Assessment Interview; SCID, Structured Clinical Interview; PTSD, posttraumatic stress disorder; MDD, major depressive disorder; SS, sum squares; MS, mean squares.

^a $p < .05$.

With respect to specific areas of assessment: the treatment was associated with improvement in complicated grief symptoms, as well as symptoms of PTSD and MDD. Importantly, this intervention targeted both symptoms of avoidance and reexperiencing, as well as the more prototypic symptoms of depression. The impact of this dual focus appears to have been realized. This statement is supported both by interview outcome measures of CB, PTSD, and MDD and self-report measures of depression. An unexpected but welcome finding was that of improved self-reported health status across dimensions of physical functioning, role limitations due to physical causes, role limitations due to emotional causes, and energy-fatigue scores, with social functioning also improving. These findings are heartening in that bereavement is associated with increased morbidity, and the fact that this health-related outcome was potentially affected by this mental health intervention is of key importance.

In evaluating the benefits of the current work and considering future directions, several limitations should be considered. First and most important, this was not a randomized controlled trial, and no firm statements of causality can be made with respect to the intervention and the positive outcomes noted in this study. Moreover, while follow-up interviews were attempted, fewer than 30% of participants completed these assessments, and the enduring effects of the treatment or incidence of relapse are unknown. Finally,

Table 2. Analysis of Covariance for Self-Report Scores (BDI & SF-36 Subscales)

Source	SS	df	MS	F	p
BDI					
Between participants					
Days since death (D)	51.99	1	51.99	0.26	.613
Error	4337.93	22	197.18		
Within participants					
Time (T)	289.02	1	289.02	8.20 ^a	.009
T × D	2.19	1	2.19	0.06	.805
Error	775.47	22	35.25		
Physical functioning					
Between participants					
Days since death (D)	692.67	1	692.67	0.58	.456
Error	36865.00	19	1940.26		
Within participants					
Time (T)	1366.13	1	1366.13	4.43 ^a	.048
T × D	470.94	1	470.94	1.53	.230
Error	15635.41	19	822.92		
Role limitations due to physical causes					
Between participants					
Days since death (D)	1468.33	1	1468.33	0.76	.395
Error	36865.00	19	1940.26		
Within participants					
Time (T)	5792.19	1	5792.19	7.04 ^a	.016
T × D	614.59	1	614.59	0.75	.398
Error	15635.41	19	822.92		
Role limitations due to emotional causes					
Between participants					
Days since death (D)	740.90	1	740.90	0.34	.569
Error	41798.78	19	2199.94		
Within participants					
Time (T)	8412.55	1	8412.55	7.94 ^a	.011
T × D	1662.72	1	1622.72	1.57	.226
Error	20136.22	19	1059.80		
Energy-Fatigue					
Between participants					
Days since death (D)	101.76	1	101.76	0.13	.725
Error	16819.98	21	800.95		
Within participants					
Time (T)	675.80	1	675.80	4.95 ^a	.037
T × D	14.35	1	14.35	0.11	.749
Error	2868.26	21	136.58		
Social functioning					
Between participants					
Days since death (D)	279.78	1	279.78	0.29	.599
Error	20616.96	21	981.76		
Within participants					
Time (T)	1695.18	1	1695.18	4.24	.052
T × D	276.08	1	276.08	0.69	.415
Error	8392.40	21	399.64		
Emotional well-being					
Between participants					
Days since death (D)	28.91	1	28.91	0.05	.831
Error	13618.75	22	619.03		
Within participants					
Time (T)	533.04	1	533.04	2.31	.143
T × D	23.20	1	23.20	0.1	.754
Error	5077.80	22	230.81		

(continued)

Table 2 (continued)

Source	SS	df	MS	F	p
Pain					
Between participants					
Days since death (D)	909.20	1	909.20	0.68	.417
Error	29276.21	22	1330.74		
Within participants					
Time (T)	189.92	1	189.92	0.40	.532
T × D	315.06	1	315.06	0.67	.423
Error	10386.51	22	472.11		
General health					
Between participants					
Days since death (D)	1544.76	1	1544.76	2.32	.142
Error	14654.72	22	666.12		
Within participants					
Time (T)	0.5	1	0.5	0.01	.951
T × D	1.57	1	1.57	0.01	.913
Error	2831.24	22	128.69		

Abbreviations: BDI, Beck Depression Inventory; SS, sum squares; MS, mean squares.

^a $p < .05$.

comprehensive health and mental health outcomes were not assessed, and more thorough measurement, for example, of specific daily activities, resources, physical status and disease states, mode of death, and so on, may shed light on potential “active ingredients” in the treatment.

A central goal of the project was to develop an intervention that could be used, at extremely low cost, by hospice centers and their existing staff. To that end, we developed a video and brief manual that complement each other such that information in the video trains both the bereaved and the therapist in the core treatment components of BA and TE. These strategies are often counterintuitive to the bereaved, who may feel that withdrawal, isolation, and cessation of activities is the most easily followed course of action. Using daily planners, community resource lists, and avoided behavior lists, therapists and bereaved individuals planned their days and weeks to be filled with activities that were either positively or negatively reinforcing, or therapeutically exposure based. As often as possible, BA assignments were given a “social angle” (eg, if a participant indicated that he or she enjoyed reading, we encouraged him or her to make this solitary activity more potentially social in nature, by scheduling a trip to one of the large-chain bookstores with café). This seemed to have achieved the desired effects of reconnection with social and community resources to the extent that individuals receiving the treatment of only 5 sessions, 2 of which were on the telephone, evinced significant improvement in a variety of measures.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Research Article

PREDICTORS OF COMPLETION OF EXPOSURE THERAPY IN OEF/OIF VETERANS WITH POSTTRAUMATIC STRESS DISORDER

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Background: Despite large-scale dissemination and implementation efforts of evidence-based psychotherapy to veterans from Operation Enduring/Iraqi Freedom (OEF/OIF), little is known regarding the factors that contribute to the successful completion of these treatments in this high-risk population. The present study investigated predictors of treatment completion during a standardized exposure-based psychotherapy for PTSD. **Methods:** Ninety-two OEF/OIF combat veterans enrolled in a randomized controlled trial for an eight session exposure-based psychotherapy for PTSD. All participants completed structured clinical interviews and several background and symptom questionnaires. Of the initial 92 participants, 28% of the sample ($n = 26$) discontinued treatment prior to completion of the trial. **Results:** Predictors of discontinuation of treatment were assessed with a hierarchical logistic regression. Disability status was positively associated with treatment discontinuation, and postdeployment social support was negatively associated with discontinuation. In contrast to previous findings, other factors, such as age and PTSD symptomatology, were not identified as significant predictors. **Conclusions:** The present study suggested that disability status at the start of treatment increases the risk for treatment discontinuation whereas increased social support buffers against discontinuation. Together, these findings highlight the importance of increased assessment and early intervention when these factors are present to potentially reduce treatment discontinuation and improve treatment outcomes in OEF/OIF veterans with PTSD. *Depression and Anxiety 30:1107–1113, 2013. Published 2013. This article is a U.S. Government work and is in the public domain in the USA.*

Key words: Operation Enduring Freedom; Operation Iraqi Freedom; posttraumatic stress disorder; exposure therapy; dropout; social support; disability

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INTRODUCTION

Between 2001 and 2010, nearly 1.9 million U.S. service members were deployed in Operations Enduring/Iraqi Freedom (OEF/OIF),^[1] with as many as 15% returning with psychiatric disorders such as posttraumatic stress disorder (PTSD).^[2,3] Given the high prevalence of psychiatric symptomatology and severe impairment associated with the disorder, emphasis has been placed on the identification and evidence-based treatment of OEF/OIF veterans with PTSD within the Veteran Affairs Medical Centers (VAMCs), as well as in treatment facilities within the Department of Defense.^[4] Fortunately, several evidence-based psychotherapies are effective in treating PTSD in veterans and military personnel, including treatments such as *Prolonged Exposure Therapy for PTSD* and *Cognitive Processing Therapy for PTSD in Veterans and Military Personnel*.^[5] These psychotherapeutic interventions are administered by highly trained providers for 12–16 weekly sessions, guided by a treatment protocol that includes specific session-by-session psychoeducation, skills training, and between session practices. The two primary mechanisms of these treatments are exposure techniques/exercises, involving both situational and imaginal exposures, and cognitive restructuring.^[5]

Although these treatments were rigorously developed for victims of trauma, and evaluated in, and disseminated through VAMCs, the majority of veterans with PTSD do not receive and/or complete an adequate trial of psychotherapy within the VAMCs.^[6] Based on data from VAMCs in 2004, 64% of veterans with PTSD did not receive any sessions of psychotherapy after their initial diagnosis, and of those veterans with PTSD receiving psychotherapy, only 21.4% received an adequate dose, defined as at least eight sessions.^[6] Across all veterans that attended at least one session of psychotherapy within the study, the average number of sessions attended was small ($M = 5.4$; $SD = 8.7$; median = 2.0; mode = 1; range = 1–180). Although several initiatives have been implemented throughout the VAMCs over the past several years that likely have resulted in significant improvements in the number of veterans with PTSD receiving evidence-based psychotherapy, including national VAMC provider training programs^[7] as well as using telehealth technologies to increase VAMC providers' service areas,^[8] these findings suggest that additional understanding is needed on service use of veterans with PTSD.

Questions of particular interest for OEF/OIF veterans with PTSD are: (1) what factors are associated with utilization of services within the VAMC?, (2) what types of services are used?, and (3) what factors are associated with successful completion of these services? Several studies have attempted to address the first two research questions over the past several years.^[9–12] These studies have used large VAMC national databases to track service utilization and *International Classification of Diseases* diagnostic codes, VAMC clinic and procedural

codes, and veterans' demographic information. Findings indicate widescale use of primary care services (94.3%) as well as mental health outpatient services (95.5%) by OEF/OIF veterans with PTSD.^[10] Mental health inpatient services also are used by a significant minority of OEF/OIF veterans with PTSD (12.4%).^[11] Veterans living in rural settings were less likely to utilize outpatient services whereas the number of comorbid conditions was associated with increased service utilization.^[9]

The investigation of the factors associated with successful completion of VAMC services, namely, evidence-based psychotherapy, by OEF/OIF veterans with PTSD has received less attention in the literature.^[13–15] Unlike the studies listed above, evidence-based psychotherapeutic services do not receive distinct procedural codes, nor are all types of psychotherapy necessarily evidence-based, limiting researchers' ability use of large national databases to address this question. Rather, to date, research has focused on investigating predictors within existing trials of evidence-based psychotherapy and has identified a few preliminary findings thus far. When compared to Vietnam Era veterans, OEF/OIF veterans with PTSD attended fewer sessions and were less likely to complete treatment,^[13,14] but these differences were not accounted for by differences in symptomatology. In the only study of predictors of treatment discontinuation in OEF/OIF veterans with PTSD, younger veteran age (but not employment status or ethnicity), more severe pretreatment PTSD symptom severity, and higher pretreatment negative treatment indicators on the Minnesota Multiphasic Personality Inventory-2 (MMPI-2) differed between veterans that did and did not complete treatment.^[15] However, this study had several limitations. In particular, evidence-based psychotherapy, labeled cognitive behavioral therapy in the study, was not standardized across all participants, with variations noted in individual versus group sessions, inclusion of exposure therapy, and the number and frequency of sessions provided. In addition, the predictors included in the analyses were limited to three demographic variables and two self-report questionnaires.

The present study sought to address these gaps in the treatment completion literature in OEF/OIF veterans with PTSD. Specifically, this study investigated predictors of treatment completion during a standardized evidence-based psychotherapy for PTSD. Hypothesized predictors were based on two primary sources from the existing literature. First, the present study included predictors identified from the preliminary findings described earlier.^[13–15] Second, the present study also included factors identified in the general literature to influence treatment outcome of evidence-based psychotherapy for PTSD, due to the relation between treatment discontinuation and symptomatology.^[15] For example, research has demonstrated that increased social support is positively associated to increased treatment response in OEF/OIF veterans with PTSD.^[16] Although treatment discontinuation was not investigated in the study, it is reasonable to hypothesize that increased

social support also may lead to improved treatment retention, due to improved symptomatology. Similar findings and related predictions exist for stress, combat exposure, and comorbidity in the existing literature.^[17–19] Together, the predictors in the present study included demographic variables (ethnicity, marital status, disability status, employment, age), treatment modality (in-person vs. telehealth), factors from deployment (combat exposure, perceived threat), postdeployment factors (social support, stressors), PTSD symptoms, and comorbid symptoms of depression. Based on the previous literature on treatment completion,^[13–15] younger age, deployment factors,^[16,17] PTSD symptom severity, and comorbid depression symptom severity^[18,19] were hypothesized predictors of increased treatment discontinuation, whereas increased postdeployment social support was hypothesized to be associated with decreased treatment discontinuation.^[16]

MATERIALS AND METHODS

PARTICIPANTS

Combat veterans ($N = 92$) of OEF/OIF were recruited through PTSD clinic referrals at a large Southeastern VAMC. Eligible participants were required to meet diagnostic criteria for combat-related PTSD or subthreshold PTSD, defined as fulfillment of Criteria A (traumatic event) and Criteria B (re-experiencing), and either Criteria C (avoidance) or Criteria D (hyperarousal).^[20] To determine eligibility, a masters-level clinician administered the Clinician Administered PTSD Scale (CAPS)^[21] to assess PTSD symptoms and the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (SCID-IV)^[22] to assess psychiatric comorbidities. Individuals who were actively psychotic, acutely suicidal, or met criteria for substance dependence on the SCID were excluded from participation. To enhance generalizability of study findings, participants receiving psychotropic medication were not excluded from participation, nor were participants with comorbid mood or anxiety disorders. Consented participants were predominantly male (93.5%), African-American (40.2%) or Caucasian (55.4%), employed (52.2%), married (50.0%), served in the Army (64.1%), and had a mean age of 33.2 years ($SD = 9.0$) and an average of 13.0 years ($SD = 3.3$) of education. A significant percentage of participants reported being disabled (37.0%) and met diagnostic criteria for major depressive disorder (MDD; 34.8%) or panic disorder (20.7%) on the SCID. Participants reported an average of 54.7 months ($SD = 25.2$) between their index trauma and their intake assessment and an average of 2.0 ($SD = 1.8$) deployments to OEF/OIF.

PROCEDURES

A full description of the larger study methodology involving a complete list of assessment measures, treatment protocols, and the randomization process can be found in a previously published article.^[23] An abbreviated presentation of the methodology that is most pertinent to the current study is presented below. All participants were offered eight, 90-min sessions of Behavioral Activation and Therapeutic Exposure (BA-TE), a transdiagnostic exposure-based psychotherapy designed specifically to improve treatment outcome in patients with comorbid symptoms of PTSD and depression.^[24,25] The active treatment components of BA-TE include behavioral activation, situational exposure, and imaginal exposure techniques/exercises.^[24] All participants were randomized into either in-person treatment ($n = 49$) or

treatment via home-based telehealth technologies ($n = 35$). Masters-level therapists administered BA-TE and met weekly with the principal investigator for supervision throughout the duration of the study. Sessions were audio-recorded and monitored by an independent rater to ensure treatment fidelity. Several assessments were completed at baseline, including a brief demographic questionnaire, select SCID modules, CAPS, Deployment Risk and Resiliency Inventory (DRRI),^[26] Beck Depression Inventory-Second Edition (BDI-II),^[27] and PTSD Checklist (PCL).^[28] Disability status was assessed by a self-report demographic question, “are you currently classified as disabled?”, which was completed by all participants. No independent verification was completed for the demographic variables (e.g., disability, marital, or employment status).

Of note, the preliminary findings from the larger trial were consistent with our initial hypotheses.^[25] More specifically, significant pre- to posttreatment symptom improvements were demonstrated on the PCL and BDI-II across all participants. In addition, no differences were observed in symptom improvements between the two treatment conditions (telehealth vs. in-person).

MEASURES

Deployment Risk and Resiliency Inventory. The DRRI consists of 13 subscales to assess predeployment, active duty, and postdeployment factors in recently returning combat veterans.^[26] For the present study, four subscales were of interest: deployment concerns (e.g., “I thought I would never survive.”), combat experience (e.g., “I went on combat patrols or missions.”), postdeployment support (e.g., “I have problems that I can’t discuss with family or friends.”), and postdeployment life events (e.g., “Since returning home, I have lost my job.”). Work with veterans has shown the DRRI to demonstrate acceptable internal consistency for the subscales ($\alpha s > .81$) and convergent and discriminative validity.^[26]

BDI-II. The BDI-II is a 21-item measure designed to assess the cognitive, affective, behavioral, motivational, and somatic symptoms of depression in adults and adolescents.^[27] The BDI-II has demonstrated excellent test-retest reliability over a 1-week interval ($r = .93$), excellent internal consistency ($\alpha s < .92$), and convergent and discriminant validity in multiple samples.^[27]

PTSD Checklist-Military. The PCL is a 17-item measure designed to assess PTSD symptom severity.^[28] The PCL has been shown to have excellent internal consistency ($\alpha s > .94$), test-retest reliability in veterans ($r = .96$), and convergent validity with alternative measures of PTSD ($r s$ range from .77 to .93).^[28]

TELECOMMUNICATIONS TECHNOLOGY

Treatment sessions for the telehealth participants were conducted using in-home videoconferencing technology as part of the larger study. Either an internet-based instant video service (e.g., a “Skype” type program) or an analog videophone (Viterion 500; Elmsford, NY) was used at the participant’s discretion. Prior research demonstrates that exposure therapy can be delivered effectively to individuals with PTSD via telehealth technologies.^[8,12,29]

DATA ANALYTIC PLAN

Treatment discontinuation was defined as discontinuing treatment prior to the completion of all eight sessions of the BA-TE treatment protocol. Participants that missed scheduled appointments were rescheduled, sometimes repeatedly, until all eight sessions were completed and posttreatment assessments were administered (treatment complete: M sessions attended = 8.0; $SD = 0.0$). However, a significant minority of participants did not ultimately reschedule and/or attend all sessions and discontinued treatment without completion of follow-up assessments (treatment discontinued: M sessions

attended = 3.2; $SD = 1.7$; range = 1–6). Predictors of treatment discontinuation were assessed with a hierarchical logistic regression. Discontinuation served as the outcome variable such that 0 = completed treatment and 1 = discontinued treatment. Predictors were entered into the model across two steps with demographic variables (ethnicity, disability status, marital status, employment status, age) and treatment condition (in-person or telehealth) entered in step 1 and symptom measures (BDI-II, PCL) and deployment factors (DRRI subscales) in step 2. Demographic variables were included in the first step to control for their effects given prior work that has suggested age, ethnicity, and marital status are associated with discontinuation of treatment. Missing data on at least one continuous variable was observed on 16% ($n = 15$) of the cases. Missing data was handled with multiple imputation such that final estimates were obtained by pooling the estimates of 25 complete datasets.^[30] Complete datasets were created with imputation models that used all variables used in the current analyses. All analyses were performed with SPSS 20 (Chicago, IL). An a priori power analysis indicated that with $\alpha = 0.05$ and power of 0.80, the current sample size could detect an odds ratio (OR) > 1.74 or an OR < 0.57 .

RESULTS

Findings evidenced that 28.3% of the sample ($n = 26$) discontinued treatment. Descriptive statistics for discontinuers ($n = 26$) and treatment completers ($n = 66$) are presented in Table 1. In comparison to normative data from veterans, participants endorsed higher symptoms of PTSD on the PCL and depression on the BDI-II, as well as higher combat exposure, higher deployment concerns, higher postdeployment stressors, and lower postdeployment social support on the DRRI.^[26]

Fit statistics for the first step of the logistic regression that included demographic variables and treatment condition suggested that the model demonstrated good fit ($P = .71$). However, treatment condition, ethnicity, marital status, age, and employment status were unrelated to treatment discontinuation (Table 2). Disability status was positively associated with discontinuation, OR = 3.38, $P = .04$, 95% CI: 1.05–10.81. The total model, which included measures of mental health symptoms and deployment factors, demonstrated good fit ($P = .82$). Postdeployment support was negatively associated with discontinuation of treatment as well, OR = 0.89, $P = .01$, 95% CI: 0.82–0.97. These findings suggest that disability status at the start of treatment increases the risk for treatment discontinuation whereas increased social support buffers against discontinuation. Correlations among the predictor variables do not support evidence of multicollinearity of suppression (Table 3).

DISCUSSION

The present study investigated predictors associated with treatment discontinuation of evidence-based psychotherapy in OEF/OIF veterans with PTSD. Prior to this study, little research on treatment discontinuation had been completed with this high-risk patient population. Strengths of the study include its standardization of evidence-based psychotherapy for PTSD, as

well as the number of investigated predictors for treatment discontinuation, which were selected based on prior studies.^[13–19] The present findings provided reliable support for two predictors of treatment discontinuation, namely, disability status and postdeployment social support. The lack of a relation for age and PTSD symptom severity, as well as marital status and employment status in this sample were also of note, as these factors have been identified as predictors in the previous literature and/or are typically discussed as facilitators/barriers to participation in evidence-based psychotherapy.^[13,15] In addition, the lack of differences in discontinuation rates between the telehealth and in-person treatment conditions also is of note, as improved attendance and adherence are frequently cited as primary rationale for the shift to treatment delivery via telehealth.^[8] Together, these aforementioned factors associated with treatment discontinuation may provide additional areas for consideration to improve treatment completion and related outcome in OEF/OIF veterans with PTSD.

The two primary predictors of treatment discontinuation identified in the present study yield important implications regarding treatment of OEF/OIF veterans with PTSD. Lack of social support has been consistently identified as a risk factor for developing and maintaining PTSD, as well as influencing pretreatment presentation and posttreatment outcomes.^[16] Complicating these findings, OEF/OIF veterans must make a substantial transition from surviving the war-zone experience abroad to reintegrating with friends and family at postdeployment,^[31] which may in turn diminish their social support and exacerbate PTSD symptomatology. The present findings extend the literature by suggesting that OEF/OIF veterans with poorer social support are more likely to discontinue evidence-based psychotherapy for PTSD. Interestingly, a new development in the evidence-based psychotherapies for PTSD, *Cognitive-Behavioral Conjoint Therapy for PTSD* (CBCT), simultaneously addresses symptoms of PTSD and enhances relationship satisfaction,^[32] and has evidenced promising initial outcome findings.^[33] In addition, CBCT has been revised to specifically address symptoms in OEF/OIF veterans with PTSD.^[34] Together, these findings may suggest that additional psychotherapeutic practices, such as CBCT and/or a review of available social resources, should be considered in OEF/OIF veterans that are identified to have poor social support prior to treatment to investigate potential influence on rates of treatment discontinuation. Although pretreatment social support, rather than changes in social support, was found to be predictive of treatment discontinuation, it is reasonable to expect that improved social support may improve treatment completion.

The second reliable predictor of treatment discontinuation was disability status, in that disabled OEF/OIF veterans were more likely to discontinue treatment than OEF/OIF veterans that were not disabled. There are two primary interpretations for these findings. The first interpretation is consistent with the previous findings

TABLE 1. Descriptive statistics

Scale	Complete (<i>n</i> = 66)	Discontinuation (<i>n</i> = 26)	Total sample (<i>n</i> = 92)
In-person treatment	34 (52%)	15 (58%)	49 (53%)
Nonwhite	31 (47%)	10 (39%)	41 (45%)
Disabled	22 (33%)	13 (50%)	35 (38%)
Married	34 (52%)	12 (46%)	46 (50%)
Employed	35 (53%)	13 (50%)	48 (52%)
Age	34.0 (9.3)	32.3 (9.5)	33.8 (9.3)
Deployment concerns (DDRI-H)	51.3 (8.9)	48.6 (11.7)	50.6 (9.7)
Combat experiences (DDRI-I)	8.7 (4.4)	10.1 (3.5)	9.1 (4.2)
Postdeployment support (DDRI-L)	52.4 (8.2)	48.7 (9.0)	51.4 (8.5)
Postdeployment life events (DRRI-M)	4.4 (3.1)	4.0 (3.7)	4.3 (3.3)
PTSD (PCL)	56.4 (13.7)	56.5 (15.6)	56.4 (14.1)
Depression (BDI-II)	22.7 (10.4)	26.7 (13.1)	23.7 (11.3)

Note. The first five rows represent categorical variables (yes/no) with sample size and percentages presented in the group columns. The final seven rows represent continuous variables with means (standard deviations) in the group columns.

DRRI, Deployment Risk and Resiliency Inventory; PCL, PTSD Checklist; BDI-II, Beck Depression Inventory II.

regarding symptom severity and impairment;^[15] that is, disability status is associated with more severity symptoms (PTSD and MDD), and more severe symptoms are associated with treatment discontinuation. This interpretation is limited somewhat by the marginal find-

ings for the symptoms of PTSD and depression. However, it also is possible that the overlap between disability and symptomatology and variance accounted for by disability may have contributed to the marginal findings for the symptoms PTSD and depression. A second

TABLE 2. Logistic regression predicting treatment discontinuation

Variable	<i>b</i>	SE	OR	95% CI	<i>P</i>
Step 1					
In-person treatment	0.25	0.54	1.28	0.45–3.67	.65
Nonwhite	– 0.15	0.58	0.86	0.28–2.66	.79
Disabled	1.22	0.59	3.38	1.05–10.81	.04
Married	0.42	0.56	1.52	0.51–4.53	.47
Employed	0.63	0.59	1.87	0.59–5.49	.29
Age	– 0.05	0.03	0.95	0.89–1.01	.11
Step 2					
Deployment concerns (DRRI-H)	– 0.04	0.03	0.96	0.90–1.02	.17
Combat experiences (DRRI-I)	0.08	0.08	1.09	0.89–1.01	.28
Postdeployment support (DRRI-L)	– 0.12	0.04	0.89	0.82–0.97	.01
Postdeployment life events (DRRI-M)	– 0.03	0.09	0.97	0.91–1.16	.73
PTSD (PCL)	– 0.05	0.03	0.95	0.89–1.01	.11
Depression (BDI-II)	0.07	0.04	1.07	0.99–1.16	.11

Note. DRRI, Deployment Risk and Resiliency Inventory; PCL, PTSD Checklist; BDI-II, Beck Depression Inventory II.

TABLE 3. Correlations of continuous variables

	1	2	3	4	5
1. Combat Experiences (DRRI-I)	1.00				
2. Deployment Concerns (DRRI-H)	0.15	1.00			
3. Postdeployment support (DRRI-L)	0.15	– 0.10	1.00		
4. Postdeployment life events (DRRI-M)	.27*	0.12	– .28*	1.00	
5. PTSD (PCL)	0.09	0.15	– .33**	.31**	1.00
6. Depression (BDI-II)	0.07	0.06	– .43**	.35**	.79**

Note. DRRI, Deployment Risk and Resiliency Inventory; PCL, PTSD Checklist; BDI-II, Beck Depression Inventory II.

**P* < .05.

***P* < .01.

interpretation is related to the potential unintentional influence of disability on full participation in treatment programs,^[35] and therefore result in higher rates of treatment discontinuation. Although controversial and still largely lacking rigorous investigation, some researchers have suggested that disability status may have iatrogenic effects on the treatment of PTSD in veterans, due to reduced motivation to complete treatment.^[35] This second interpretation may suggest that motivation building techniques, such as Motivational Interviewing (MI),^[36] could be incorporated into evidence-based psychotherapy protocols to improve treatment completion. In fact, there is preliminary support for the use of telephone MI to enhance treatment engagement in OEF/OIF veterans.^[37] Together, whether either interpretation is correct regarding disability status, disabled OEF/OIF veterans may be at greater risk for discontinuing evidence-based psychotherapy for PTSD, suggesting increased recognition, assessment, and motivational interventions may be needed.

Surprisingly, symptoms of PTSD were not identified as a reliable predictor of treatment discontinuation in the present study in contrast to previous findings.^[15] Rather, both the symptoms of PTSD and MDD were found to be marginal predictors of treatment discontinuation. There are a couple possible interpretations of these contrasting findings for PTSD symptoms. In comparison to previous studies in which fewer predictors were investigated,^[15] the effects for the symptoms PTSD may have been attenuated by other related predictors, such as disability status and social support. The inclusion of the highly overlapping symptoms of MDD also may have lessened the effects for the symptoms of PTSD.^[18,19] Another possibility is that the use of a standardized evidence-based psychotherapy for PTSD in the present study, in comparison to unstandardized treatment approaches across participants in previous research,^[15] reduced the influence of the symptoms of PTSD on treatment discontinuation. However, despite these marginal findings, the symptoms of PTSD and MDD still should be assessed, and potentially addressed, as a possible risk for treatment discontinuation. Additional brief treatment components for consideration include MI^[36,37] and behavioral activation psychotherapy.^[38,39]

There were several limitations within the present study that should be addressed in future studies on this topic. First, the evidence-based psychotherapy used in the present study was only eight sessions, suggesting similar research may be warranted for psychotherapy protocols with a greater number of sessions.^[13] Second, treatment discontinuation was coded as a dichotomous variable due the available sample size and related power analyses, rather than investigating the range of sessions completed, suggesting future research on the time/session of discontinuation is needed to investigate potential differences between discontinuing earlier versus later in treatment. Third, not all of the previously identified predictors of treatment discontinuation (e.g., negative treatment indicators on the

MMPI) were included in the present study due in part to the length of the existing assessment materials. Fourth, the present study was completed within a randomized controlled trial,^[23] suggesting that similar investigations are needed in purely clinical settings as well. These methods may have contributed to the lower than expected discontinuation rates and diagnostic comorbidity in the present study, compared to previous effectiveness studies.^[13–15,18,19] Finally, the present study was underpowered to accurately detect the significance of the smaller effects that were observed in this sample. Thus, it is unclear if these findings were misclassified as Type II errors. A power analysis suggested that unusually large samples ($N > 1,000$) would be needed to detect such small effects.

CONCLUSION

The present study represents the first investigation of treatment discontinuation in OEF/OIF veterans with PTSD during a course of standardized evidence-based psychotherapy for PTSD. The present findings identified disability status and social support as the most significant predictors of treatment discontinuation. Although included in the analyses, age and PTSD symptom severity were not shown to be reliable predictors, in contrast to previous findings.^[15] Together, these findings may highlight the necessity of early identification and intervention in disabled OEF/OIF veterans and/or those with poor postdeployment social support in order to potentially reduce treatment discontinuation and improve treatment outcomes in this particularly high risk patient population.

There are no conflicts of interest to disclose.

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Relation Between Treatment Satisfaction and Treatment Outcome in Veterans with Posttraumatic Stress Disorder

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Abstract Existing measures of patient treatment satisfaction are largely characterized by a lack of psychometric evaluation, varied definitions across studies, and small numbers of items. The present study evaluated a patient treatment satisfaction questionnaire specifically designed for psychiatric outpatient treatment satisfaction, the Charleston Psychiatric Outpatient Satisfaction Scale (CPOSS), to extend previous findings by examining: 1) the psychometric properties of the CPOSS and the common domains within patient treatment satisfaction, and 2) the preliminary relations between the CPOSS and treatment outcome during exposure therapy in patients with posttraumatic stress disorder (PTSD). The present investigation included two studies. The first involved 170 combat veterans with PTSD who completed brief psychotherapy, and whose post-treatment CPOSS scores were used for the factor analytic investigations. The second study involved 63 combat veterans with PTSD who received a course of brief exposure-based psychotherapy and

completed pre- and post-treatment assessments to investigate the relations between the CPOSS and treatment outcome. The first study supported the psychometric properties of the CPOSS, including identifying four psychometrically-sound subscales for: respectful care, appearance of facility, convenience of facility, and recommendation to friends/family. The second study demonstrated that the CPOSS was a significant predictor of post-treatment PTSD symptoms, relative to demographics and pre-treatment symptoms. Together, these findings support the use of the CPOSS as a valuable addition in psychiatric outpatient settings to both assess and potentially improve patient treatment satisfaction.

Keywords Charleston Psychiatric Outpatient Satisfaction Scale · CPOSS · Treatment satisfaction · PTSD · Psychometrics

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Social validity of treatment with respect to patient perceptions may play a pivotal role in treatment outcome and subsequent dissemination efforts (Anttkisson and Zwick 1982; Burnett-Zeigler et al. 2011; Cone 2002; Fontana et al. 2003; Frueh et al. 2002; Lebow 1983). Specifically, acceptability of proposed interventions and satisfaction with the interventions implemented have been indicated as core factors in external validity and successful dissemination. Patient treatment satisfaction is a key therapy variable in treatment completion, treatment compliance, clinical improvement, and patient's recommendation of the treatment approach (Cone 2002). Patient satisfaction has been defined as the patient's subjective evaluation of the provider, the treatment process/tasks they have experienced, and the results of the treatment (Foster and Mash 1999). However, there is considerable variability in what, when, and how the variable of satisfaction has been assessed. In addition, operationalization of patient satisfaction has varied considerably across studies (Burnett-Zeigler et al. 2011; Hermann et al. 1998; Howard et al. 2007; Naples et al. 2009). The resulting confusion has led to a call for researchers

to shift to multi-question and multi-dimension assessments of patient treatment satisfaction (Burnett-Zeigler et al. 2011; Kaltenthaler et al. 2008), rather than relying on frequently used, but often variable, single item predictors (Fontana et al. 2003). Despite this clear need, measures of patient treatment satisfaction have continued to vary in definition across treatment studies and systematic reviews of psychometric properties have not been conducted.

As a result of the limitations of current assessment practices, several questions still remain unaddressed in the literature on psychiatric treatment satisfaction. In particular, there have been few investigations of treatment satisfaction with evidence-based psychotherapy (EBP) for the psychiatric disorders. This omission is likely due in part to the age of the literature, with many patient satisfaction articles being published prior to large-scale cognitive-behavioral therapy dissemination efforts. However, EBPs also have been largely neglected in more recent studies on patient treatment satisfaction (Burnett-Zeigler et al. 2011). In addition, the few studies that have investigated EBPs have lacked rigor in their assessment of treatment satisfaction. For example, in one of the few investigations of treatment satisfaction, a single item measure was administered at 4- (short-term satisfaction) and 12-months (long-term satisfaction) during EBPs involving a variety of modalities (Fontana et al. 2003). These findings further reinforce the potential limitations in both the measurement (e.g., reliability of single item predictor) and treatment procedures (e.g., non-standardized protocols) in the patient treatment satisfaction literature. Upon development and evaluation of evidence-based assessments for treatment satisfaction, predictors of patient treatment satisfaction and their relations to patient treatment outcome could be investigated to inform and potentially improve the delivery of EBPs.

The present investigation involved two separate studies using the Charleston Psychiatric Outpatient Satisfaction Scale (CPOSS), a brief and user-friendly treatment satisfaction questionnaire designed for psychiatric outpatient populations (Frueh et al. 2002; Pellegrin et al. 2001). The CPOSS covers key clinical (e.g., helpfulness of the services you have received), administrative (e.g., helpfulness of the secretary), and environmental (e.g., location of outpatient service) factors that are important to psychiatric outpatients (Pellegrin et al. 2001). The investigation extends previous findings by examining the psychometric properties and factor structure of the CPOSS in order to identify common domains within patient treatment satisfaction. In addition, the investigation also examined the relations between patient treatment satisfaction and treatment outcome in EBP for patients with posttraumatic stress disorder (PTSD). Based on the limited research on patient treatment satisfaction (Burnett-Zeigler

et al. 2011; Howard et al. 2007), we hypothesized that both tangible (e.g., accessibility and environment) and subjective (e.g., goal attainment and self-actualization aspects) domains will be identified within the CPOSS and that these domains will be related to treatment outcome at varying strengths.

Study 1: Factor Structure and Psychometric Properties of CPOSS

Study 1 aimed to investigate the factor structure of the CPOSS, investigate the psychometric properties of the measure, and identify subtypes or scales contributing to patient treatment satisfaction. A large sample of veterans that completed an EBP for PTSD was used for the factor analytic investigations.

Method

Participants Participants were recruited for one of two clinical trials within a large Western Veterans Affairs Medical Center (VAMC) and its associated clinic sites (outpatient clinics and Vet Centers) from August 2005 to December 2011 (Morland et al. 2009, 2010). Both clinical trials recruited male veterans diagnosed with combat-related PTSD, as assessed by the Clinician Administered PTSD Scale (Blake et al. 1995). In the first clinical trial, 160 veterans were consented and assessed, with 53 participants later excluded, declined to participate before the initiation of treatment, discontinued prior to treatment completion, or had significant missing data on the CPOSS. In the second clinical trial, 126 veterans were consented and assessed, with 63 participants later excluded, declined to participate before the initiation of treatment, discontinued prior to treatment completion, or had significant missing data on the CPOSS. Eligible participants were excluded for active psychotic symptoms, active homicidal or suicidal ideation, significant cognitive impairment, current substance dependence, or unwillingness to refrain from substance use during treatment. After providing complete description of the study to the participants, written informed consent was obtained. The final combined sample of 170 participants were male, predominantly middle-aged (54.9 years old; $SD=10.4$), married (60.9 %), Caucasian (29.2 %) or Native Hawaiian (26.2 %), completers of high school (35.2 %) or some college (41.9 %), and veterans of the Vietnam War (72.0 %).

Intervention and Assessment Procedures All procedures were approved by the local institution review board. A full description of the larger study methodology involving a

complete list of assessment measures, treatment protocols, and the randomization process is published elsewhere (Morland et al. 2009, 2010). The methodology pertinent to the current study is presented below.

Each of the two clinical trials focused on a different treatment. The first clinical trial involved a 12-session manual-based cognitive behavioral intervention for anger management that was developed by the National Institute on Drug Abuse Behavioral Therapies Development Program (Reilly and Shopshire 2002). The second clinical trial involved 12-session of Cognitive Processing Therapy for PTSD (Resick et al. 2007). Both treatments were delivered in a group format, with treatment sessions occurring twice weekly. Symptom assessments were completed at baseline, at mid-treatment (3 weeks), and immediately at post-treatment (6 weeks). The CPOSS also was administered at post-treatment to assess patient treatment satisfaction.

Measures. *Charleston Psychiatric Outpatient Satisfaction Scale – Veteran Affairs Version* The CPOSS is a sixteen-item measure designed to assess patient treatment satisfaction in psychiatric outpatient settings (Frueh et al. 2002; Pellegrin et al. 2001). The first fifteen items are rated on a five-point Likert scale ranging from “excellent - 5” to “poor - 1.” The final item assesses the likelihood that patients would recommend the treatment to others, and is rated on a four-point Likert scale ranging from “yes, definitely - 4” to “no, definitely not - 1.” The CPOSS has excellent internal consistency in previous research ($\alpha=.96$) (Frueh et al. 2002). A copy of the CPOSS is included in Appendix 1.

Clinician Administered PTSD Scale The CAPS is a clinician-rated structured interview designed to diagnose PTSD (Blake et al. 1995). The CAPS targets the 17 specific PTSD symptoms from the *DSM-IV*, and assesses the intensity and frequency of each symptom on a five-point Likert scale. The CAPS has adequate internal consistency, inter-rater reliability, and test-retest reliability (Orsillo 2002).

Data Analytic Plan Study 1 investigated the factor structure and related internal consistency of the CPOSS. The factor structure of the CPOSS was investigated through an exploratory factor analysis (EFA), involving several steps. First, parallel analyses were used to guide the number of factors to extract (Horn 1965). Second, separate EFAs were run with the squared multiple correlations as communality estimates for each factor model identified by the parallel analyses. Third, oblique rotations (Promax) were used to investigate factor loadings (Brown 2006). All factors with at least one loading above .40 were interpreted (Gros et al. 2011a, 2012b). Internal

consistency was investigated via calculating Cronbach’s alphas for each of the subscales identified by the EFAs.

Results

Factor Structure An item-by-item analysis of the CPOSS items is presented in Table 1. The findings from the parallel analysis of the eigenvalues suggested that no more than four factors should be retained; thus, the 1-, 2-, 3-, and 4-factor solutions were examined. The findings from the EFAs are summarized in Table 2. Based on the number of poorly loading items (i.e., all loadings < .40) and cross-loading items (i.e., loadings > .30 on multiple components), the one-factor and four-factor models represented the cleanest of the models. Although both models had one poorly loading item, the poorly loading item in the four-factor model (i.e., cross-loading item with .51 on one factor and .32 on second factor) fit the data slightly better than the poorly loading item in the one-factor model (i.e., one item with loading below .30). Thus, the four-factor model was deemed to represent the cleanest and most psychologically meaningful solution for the CPOSS. The four factors were interpreted to represent: (I) respectful care (CPOSS-RC), (II) appearance of facility (CPOSS-AF), (III) convenience of facility (CPOSS-CF), and (IV) recommendation to friends/family (CPOSS-R). The factor loadings from the four-factor model are presented in Table 3.

Reliability The internal consistency findings (α s ranged from .87 to .95) and the average inter-item correlations (r s ranged from .58 to .90) provided evidence of the reliability and relative narrowness of the CPOSS scales.

Study 2: Prediction of Treatment Outcome

The goal of Study 2 was to investigate the relations between four subscales of the CPOSS and treatment outcome. A sample of combat veterans with PTSD received a course of brief exposure-based psychotherapy and completed pre- and post-treatment assessments, including the CPOSS. There were no overlapping participants between the samples from Study 1 and 2.

Method

Participants Participants were recruited for one clinical trial within a large Southeastern VAMC and its associated clinic

Table 1 Item-by-item statistics for CPOSS

Items	Mean	SD	Range	Skewness	Kurtosis
1. Helpfulness of the secretary.	4.25	0.86	3.00	−0.76	−0.58
2. Information provided about services	4.17	0.93	4.00	−0.99	0.54
3. Amount of time waiting to be seen.	3.91	1.11	4.00	−0.72	−0.45
4. Amount of information given about your problem.	3.99	1.02	4.00	−0.87	0.10
5. Respect shown for your opinions about treatment.	4.15	0.96	4.00	−0.88	−0.12
6. Matching of treatment plan to your individual needs	3.96	0.97	4.00	−0.72	−0.03
7. Helpfulness of the services you have received	4.23	0.88	3.00	−0.90	−0.06
8. Overall quality of care provided	4.30	0.87	3.00	−1.00	0.04
9. Appearance of the waiting area	4.10	0.85	3.00	−0.62	−0.50
10. Appearance of the office.	4.15	0.89	4.00	−0.86	0.21
11. Office hours	3.97	1.00	4.00	−0.63	−0.55
12. Location of this outpatient service.	4.01	1.02	4.00	−0.93	0.38
13. Parking.	3.10	1.34	4.00	−0.02	−1.24
14. Clear documentation of problems in medical record.	3.69	1.08	4.00	−0.37	−0.76
15. Time between your first request and first appointment.	3.67	1.13	4.00	−0.53	−0.50
16. Would you recommend this clinic?	4.28	0.68	3.00	−0.55	−0.26

Some of the item descriptors were summarized from the original item content as a function of the allocated space

SD standard deviation

sites (outpatient clinics) from November 2008 to September 2011 (Gros et al. 2011b). In this clinical trial, 113 veterans were consented and assessed, with 50 participants later excluded, declined to participate before the initiation of treatment, discontinued prior to treatment completion, or had significant missing data on the CPOSS. Eligible participants were required to meet diagnostic criteria for PTSD or sub-threshold PTSD (Blanchard et al. 1994), as assessed on the CAPS (Blake et al. 1995). Individuals who were actively psychotic, acutely suicidal, or met criteria for substance dependence were excluded from participation. The 63 participants in the final sample were predominantly male

(92.5 %), 37.7 years old ($SD=11.8$), married (47.2 %), Caucasian (50.9 %) or African-American (43.4 %), completed high school (35.8 %) or some college (30.2 %), veterans of Operation Enduring Freedom/Operation Iraqi Freedom (79.2 %), and had either PTSD (66.7 %) or subthreshold PTSD (33.3 %).

Intervention and Assessment Procedures All procedures were approved by the local institution review board. A full description of the larger study methodology involving a complete list of assessment measures, treatment protocols, and the randomization process is published elsewhere

Table 2 Summary statistics for exploratory factor analyses for CPOSS

Number of clean items							
Model	F1	F2	F3	F4	<.40	CLs	% PI
1-Factor	15	—	—	—	1	0	6.3 %
2-Factor	6	3	—	—	2	5	43.8 %
3-Factor	6	3	2	—	1	4	31.3 %
4-Factor	8	4	2	1	0	1	6.3 %

Clean items were defined as those having a loading $>.40$ on only one factor and having cross-loadings $<.30$ on all other factors. F1-F4=factors 1 to 4. $<.40$ =number of items with all loadings below $.40$; CLs=number of cross-loading items with components loadings of greater than $.40$ on one component and greater than $.30$ on at least one more component; %PI=total percent of problematic items as categorized as $<.40$ and CLs

Table 3 Standardized factor loadings for the four-factor model for the CPOSS

Items	RC	CF	AF	R
1. Helpfulness of the secretary.	.53	.	.	.
2. Information provided about services	.76	.	.	.
3. Amount of time waiting to be seen.	.56	.	.	.
4. Amount of information given about your problem.	.86	.	.	.
5. Respect shown for your opinions about treatment.	.85	.	.	.
6. Matching of treatment plan to your individual needs	.69	.	.	.
7. Helpfulness of the services you have received	.69	.	.	.
8. Overall quality of care provided	.64	.	.	.
9. Appearance of the waiting area	.	.	.80	.
10. Appearance of the office.	.	.	.88	.
11. Office hours	.	.72	.	.
12. Location of this outpatient service.	.	.43	.	.
13. Parking.	.	.40	.	.
14. Clear documentation of problems in medical record.	.	.74	.	.
15. Time between your first request and first appointment.	.32	.51	.	.
16. Would you recommend this clinic?	.	.	.	.58

Some of the item descriptors were summarized from the original item content as a function of the allocated space. Only factor loadings above .30 were provided to improve presentation of findings

RC respectful care; CF convenience of facility; AF appearance of facility; R recommendation to friends/family

(Gros et al. 2011b). The methodology pertinent to the current study is presented below.

The treatment involved eight weekly 1.5 h individual sessions of exposure therapy (Gros et al. 2012a; Strachan et al. 2012). The one-week pre-treatment and immediate post-treatment assessments involved a series of clinician-rated and self-reported measures, including the PTSD Checklist – Military Version (PCL-M) to assess treatment outcome (Weathers et al. 1993). The CPOSS also was administered at post-treatment to assess patient treatment satisfaction. The treatment was largely consistent with the treatment model described by Foa and colleagues (Foa et al. 2007; Riggs et al. 2006; van Millen et al. 2002) in which the primary components were situational and imaginal exposure trials.

Measures. PTSD Checklist-Military Version The PCL-M is a 17-item measure designed to assess PTSD symptom severity (Weathers et al. 1993). Respondents are presented with 17 specific symptoms of PTSD and asked to rate “how much you have been bothered by that problem in the last month” on a 5-point Likert scale, ranging from 1 (not at all) to 5 (extremely). The PCL-M has been shown to have excellent internal consistency, test-retest reliability, and convergent validity with alternative measures of PTSD (Orsillo 2002).

Data Analysis Zero-order correlations were investigated between each of the measures. The CPOSS total scale also was investigated across demographic and diagnostic variables through a series of analysis of variance (ANOVAs). In addition, hierarchical regression analysis was conducted to identify the unique predictive effect of the CPOSS on treatment outcome. In the first step, demographic variables and pre-treatment symptoms (baseline PCL-M) were entered as covariates to investigate and control for their potential influences on treatment outcome. Only demographic variables previously found to potentially influence treatment outcome were included (van Millen et al. 2002). The CPOSS total scale was entered as a covariate in the second step, with post-treatment PTSD symptoms (post-treatment PCL-M) as the dependent variable. The CPOSS total scale, rather than the four subscales, was used in the regression analyses due to the potential instability of the factors (e.g., small number of items in CPOSS-CF and CPOSS-R) and intercorrelations among the subscales (Table 4).

Results

Zero-Order Correlations All of the correlations between the CPOSS subscales, CPOSS total scale, and pre- and post-treatment PCL-M are presented in Table 4. In general, the

Table 4 Correlations of the scales of the CPOSS and post-treatment PCL-M

Scale	1	2	3	4	5	6	
1. CPOSS-RC	(.95)						
2. CPOSS-AF	.51*	(.95)					
3. CPOSS-CF	.71*	.59*	(.82)				
4. CPOSS-R	.72*	.25	.54*	(n/a)			
5. CPOSS-Total Scale	.93	.68	.89	.71	(.94)		
6. Pre-Treatment PCL-M	.18	.05	.23	.09	.19	(.91)	
7. Post-Treatment PCL-M	-.16	-.13	-.05	-.19	-.14	.56	(.96)

Cronbach's alphas are presented in parentheses on the diagonal. Alpha was not provided for CPOSS-recommendations to friends/family (1 item scale). * $p < .01$

CPOSS scales demonstrated moderate to strong intercorrelations (r s ranged from .51 to .72, $ps < .01$), with one exception. The correlation between CPOSS-AF and CPOSS-R was small and non-significant ($r = .25$; $p > .05$). Although all in the expected directions (i.e., small positive correlations between CPOSS and pre-treatment PCL-M scores and small negative correlations between the CPOSS and post-treatment PCL-M scores), none of the correlations between the CPOSS scales and pre- and post-treatment PCL-M were significant (pre-treatment: r s ranged from .05 to .23; $ps > .05$; post-treatment: r s ranged from -.19 to -.05; $ps > .05$).

Influence of Demographic and Diagnostic Variables on CPOSS Scores A series of one way ANOVAs was computed to investigate the influence of demographic and diagnostic variables on CPOSS total scores. Demographic variables included sex, age, race, combat theatre, marital status, and education. The diagnostic variable was diagnosis (subthreshold versus full diagnosis of PTSD). Together, no significant findings were observed across the demographic and diagnostic variables (F s < 1.7 ; $ps > .05$).

Hierarchical Regression Analysis The regression analysis used the CPOSS total scale as predictors of post-treatment

PTSD symptoms on the PCL-M above and beyond demographic variables and pre-treatment PCL-M PTSD symptoms. The findings from this analysis are presented in Table 5. The first step (age, race, and pre-treatment PCL-M scores) was significant in the model ($F = 12.1$; $p < .001$). The significant predictors in the first step included race ($t = -2.3$; $p < .05$), and pre-treatment PCL-M ($t = 5.3$; $p < .001$), such that Caucasian race and higher pre-treatment symptoms were associated with greater post-treatment symptomatology. The second step added the CPOSS total as a predictor and significantly increased the variance explained in the model ($F_{\text{change}} = 4.2$; $p < .05$). The model continued to be significant in the second step ($F = 10.7$; $p < .001$), with the CPOSS total scale being a significant predictor of post-treatment PCL-M in the model ($t = -2.0$; $p < .05$).

General Discussion

Despite the clear call for multi-dimensional and psychometrically valid measures of patient satisfaction (Cone 2002; Lebow 1983; Kaltenthaler et al. 2008), there have been few studies on the properties of these measures. This investigation is one of the first to explore both psychometrics and predictive utility of a patient treatment

Table 5 Hierarchical regression analysis testing treatment satisfaction predicting treatment outcome

Step	Variable	<i>B</i>	<i>SE</i>	β	<i>t</i>	<i>F</i>	ΔR^2
1	Age	0.27	0.16	0.18	1.64	12.10**	0.41
	Race	-5.77	2.53	-0.25	-2.28*		
	Pre-Treatment PCL-M	0.82	0.15	0.57	5.35**		
2	CPOSS-Total Scale	-0.37	0.18	-0.23	-2.04*	10.66**	0.04

** = $p < .01$; * = $p < .05$

satisfaction measure in understanding EBTs treatment outcome. The first study provided support for the psychometric properties of the CPOSS, and identified four distinct factors related to patient satisfaction: respectful care, appearance of facility, convenience of facility, and recommendation to a friend or family member. Although convergent validity studies of the CPOSS are still necessary and objective measures of treatment satisfaction are still needed (Cone 2002; Kaltenthaler et al. 2008), the present research represents an important step in improving the assessment of patient treatment satisfaction.

In the second study, the CPOSS total scale was a significant predictor of post-exposure therapy PTSD symptoms, relative to demographic variables and pre-treatment PTSD symptoms. These findings suggested that patient treatment satisfaction across several domains (respectful care, appearance of facility, convenience of facility, and recommendation to a friend or family member) was particularly related to treatment outcome. Interestingly, Caucasian race also emerged as significant predictors of treatment outcome and merits future investigation. Previous research demonstrated that characteristics of the trauma (e.g., personal trauma and childhood trauma), higher age, less control over anger, benzodiazepine-use, chronicity of complaints, feelings of shame, and higher pre-treatment PTSD symptoms are all associated with less positive symptom outcomes at post-treatment; however, only a few of these predictors have been reported across studies (van Millen et al. 2002). Interesting, although several of these potential predictors were investigated in the present study (e.g., pre-treatment PTSD symptoms, race, age), patient treatment satisfaction still was identified as a significant predictor of treatment outcome. Together, these findings highlight patient treatment satisfaction as a particularly important influence in patient symptom outcomes in PTSD treatment.

Despite advancing our understanding of the relation of patient treatment satisfaction and treatment outcome, considerable work still needs to be done. This investigation did not examine how patient satisfaction changes across treatment length or how satisfaction may ebb and flow with longer-term treatment gains. In addition, the present studies did not investigate the influence of process variables associated with treatment (e.g., homework completion, session attendance, and study attrition), pre-treatment hostility, or social desirability, suggesting possible alternative explanations and additional influences on patient treatment satisfaction that merit consideration in future research on the CPOSS. As some prior literature has suggested, the relation between treatment acceptability or satisfaction and treatment outcome over

time is likely to be a complex pattern highly dependent on measurement timing (Kaltenthaler et al. 2008; McCord 1978). Further, the current studies focused on predominantly male veteran samples and treatment completers within a single treatment facility, suggesting that additional research and replication is needed in alternative samples across treatment settings before assuming these findings hold across all outpatient clinical populations. Although the CPOSS was adapted from a general outpatient measure to address patient treatment satisfaction in veterans in VAMC settings (Frueh et al. 2002), it is possible that the CPOSS also could be useful in other settings as well upon further investigation. The investigation also was limited to the single EBP for a specific disorder, suggesting that replication studies are needed across EBPs and diagnoses. And finally, the factor analytic investigation relied only on EFA methods and resulted to two subscales with small numbers of items (i.e., CPOSS-CF and CPOSS-R), suggesting the confirmatory factor analyses should be used to further investigate the fit of the identified factor structure (e.g., compare one-factor and four-factor models). Similarly, the removal of item 16 also should be considered in future factor analytic investigations due to its use of a different Likert scale and related loading onto its own factor.

However, despite these limitations, findings supported the CPOSS as a psychometrically-sound, multi-dimensional measure of patient treatment satisfaction, addressing gaps in the existing literature that largely utilized single-item predictors for satisfaction (Cone 2002; Lebow 1983; Kaltenthaler et al. 2008). The present findings also highlighted the influence of patient treatment satisfaction on treatment outcome, suggesting that these characteristics of respectful care, appearance of facility, and convenience of facility should be a focus in psychiatric outpatient settings to ensure and/or improve patient treatment outcomes. Although additional research is needed to further support these initial findings, together, these findings suggest that the administration of the CPOSS could be a valuable addition in psychiatric outpatient settings to both assess and potentially improve patient treatment satisfaction.

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Appendix 1

Charleston Psychiatric Outpatient Satisfaction Scale

(Veterans Affairs Version)

Your opinions about us are very important. Please **give your honest opinions on each question, but do not give your name.**

Please rate each item on the following scale: EXCELLENT, VERY GOOD, GOOD, FAIR, or POOR.

	EXCELLENT	GOOD	VERY GOOD	FAIR	POOR
1. Helpfulness of the secretary	5	4	3	2	1
2. Information provided about what services you will receive here	5	4	3	2	1
3. Amount of time waiting to be seen	5	4	3	2	1
4. Amount of information given to you about your problem	5	4	3	2	1
5. Respect shown for your opinions about treatment	5	4	3	2	1
6. Matching of treatment plan to your individual needs	5	4	3	2	1
7. Helpfulness of the services you have received	5	4	3	2	1
8. Overall quality of care provided	5	4	3	2	1
9. Appearance of the waiting area	5	4	3	2	1
10. Appearance of the office	5	4	3	2	1
11. Office hours	5	4	3	2	1
12. Location of this outpatient service	5	4	3	2	1
13. Parking	5	4	3	2	1
14. Clear and correct documentation of problems in your medical record	5	4	3	2	1
15. Amount of time between your first request for an appointment and your first appointment	5	4	3	2	1
16. Would you recommend this clinic to a friend or family member? (circle one)	YES, DEFINITELY	YES, PROBABLY	NO, PROBABLY NOT	NO, DEFINITELY NOT	
How could we improve our services?					
THANK YOU VERY MUCH!					

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Behavioral Activation and Therapeutic Exposure: An Investigation of Relative Symptom Changes in PTSD and Depression During the Course of Integrated Behavioral Activation, Situational Exposure, and Imaginal Exposure Techniques

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Abstract

Effectiveness of exposure therapy for posttraumatic stress disorder (PTSD) may be adversely influenced by comorbid disorders. The present study investigated behavioral activation and therapeutic exposure (BA-TE), a new integrated treatment designed specifically for comorbid symptoms of PTSD and depression. Combat veterans with PTSD ($N = 117$) completed eight sessions of BA-TE that included two phases of treatment: (a) behavioral activation (BA) in which some activities involved situational exposures and (b)

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BA and situational exposures with imaginal exposures. Findings supported improvements in symptoms of PTSD, and overlapping symptoms of PTSD and depression, but not in nonoverlapping symptoms of depression. The findings also demonstrated a relatively consistent rate of change in PTSD and depression symptoms during BA-TE, despite the addition of imaginal exposures midway through the treatment. Together, these findings provide preliminary support for BA-TE as a treatment for PTSD and depression, and highlight the utility of transdiagnostic treatments in addressing comorbidity and symptom overlap.

Keywords

behavioral activation and therapeutic exposure, BA-TE, depression, PTSD, comorbidity, transdiagnostic

Posttraumatic stress disorder (PTSD) is a severe mental health condition secondary to exposure to a traumatic event. Untreated PTSD is unlikely to remit without intervention (Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995). Exposure-based therapies are the most thoroughly investigated forms of treatment for PTSD (Gros, Tuerk, Yoder, & Acierno, 2011; Keane & Barlow, 2002), with all highly effective interventions involving therapeutic strategies that attempt to counter behavioral and cognitive avoidance, such as prolonged exposure (PE; Foa, Hembree, & Rothbaum, 2007) as well as several others (Kilpatrick & Amick, 1985; Shapiro, 1989).

Exposure treatments typically involve two primary components: situational (in vivo) exposures and imaginal exposures (Gros, Tuerk, et al., 2011; Keane & Barlow, 2002). The goal of both types of exposure is to reduce avoidance, disconfirm false beliefs, increase mastery, and promote inhibitory learning with respect to fear responding. Situational exposure refers to prolonged, repeated, and controlled encounters with avoided fear conditioned stimuli, including people, places, and things that are associated with the traumatic event or its direct sequelae. Imaginal exposure involves encouraging patients to provide repeated accounts of their traumatic experience in great detail, followed by imaginal recreations of these experiences in vivid detail. These exposure trials typically involve creating a narrative of the traumatic event (via audio recording or written story) and then revisiting the narrative repeatedly. The effectiveness of exposure therapy across a variety of trauma populations is well established (Cahill, Hembree, & Foa, 2006), with

outcomes maintained at follow-up (Resick, Nishith, Weaver, Astin, & Feuer, 2002).

Despite considerable research supporting positive treatment outcomes, the effectiveness of exposure therapy in treating PTSD may be diminished by the presence of comorbid disorders (Foa et al., 2007). This is somewhat disconcerting given the considerable rate of comorbidity in those with PTSD, with estimates ranging between 62% and 92% in population-based surveys (Keane, Brief, Pratt, & Miller, 2007; Perkonig, Kessler, Storz, & Wittchen, 2000). However, the high degree of comorbidity between PTSD and other disorders such as depression may be a result of symptom overlap between the diagnoses (Frueh, Elhai, & Acierno, 2010; Resick & Miller, 2009; Rosen et al., 2008). Indeed, recent investigations demonstrate that the majority of veterans with PTSD also met criteria for major depressive disorder (MDD; Gros, Price, Magruder, & Frueh, 2012; Gros, Simms, & Acierno, 2010). Together, these findings suggest that treatments for PTSD should be more transdiagnostic in their scope to address symptoms of not only PTSD but also its common comorbidities, such as MDD (Gros et al., 2010).

Several large-scale clinical trials for exposure therapy for PTSD have assessed treatment response across PTSD and depression symptoms (Foa et al., 1999; Foa et al., 2005; Resick et al., 2002). Although exposure therapies for PTSD can reduce depression symptoms in addition to symptoms of PTSD (Foa et al., 1999; Foa et al., 2005; Resick et al., 2002), it is common for depression symptoms to persist even after the completion of treatment, indicating that there are some symptoms unique to MDD. More specifically, treatment studies delivering exposure therapy for PTSD have reported pre- to posttreatment reductions in Beck Depression Inventory–Second Edition (BDI-II; Beck, Steer, & Brown, 1996) mean scores ranging from 32% to 67% (Foa et al., 1999; Foa et al., 2005; Resick et al., 2002). However, many participants with comorbid MDD at pretreatment continue to meet diagnostic criteria for MDD after treatment completion (Resick et al., 2002). Furthermore, depression symptoms have been shown to be positively associated with PTSD symptoms and thus may negatively affect PTSD treatment response or endurance of treatment gains (Scott & Stradling, 1997; Shalev et al., 1998). Therefore, the effectiveness of exposure therapies may be enhanced by integrating transdiagnostic interventions that target symptoms of PTSD and depression.

Behavioral activation (BA) is a treatment showing some promise in addressing comorbid symptoms of depression in individuals with PTSD (Acierno et al., 2012; Nixon & Nearmy, 2011; Strachan, Gros, Ruggiero,

Lejuez, & Acierno, in press). BA involves identifying and scheduling values-based activities that reinforce and promote enjoyment (i.e., associated with positively reinforcing activities, such as a hobby) or reduce stress (i.e., associated with negatively reinforcing activities, such as chores; Lejuez, Hopko, LePage, Hopko, & McNeil, 2001). As mentioned, not only is BA an evidence-based treatment for reducing depression symptoms (Dimidjian et al., 2006; Gros & Haren, 2011; Lejuez et al., 2001), but preliminary findings also demonstrate that BA is effective in reducing PTSD symptoms in patients with PTSD (Jakupcak et al., 2006; Mulick & Naugle, 2004). Furthermore, BA is highly compatible with therapies that use situational exposure (Acierno et al., 2012; Nixon & Narmy, 2011; Strachan et al., in press). Both techniques engage patients in increased activity to reduce isolation. However, limited research to date has examined the effect of a transdiagnostic treatment that combines exposure and BA for PTSD and depression symptoms.

The present study investigates a new integrated treatment, behavioral activation and therapeutic exposure (BA-TE). BA-TE is designed specifically as a transdiagnostic approach to improve treatment outcome in patients with comorbid symptoms of PTSD and depression (Strachan et al., in press). The protocol was designed with two primary phases. The first involves daily behavioral practices that incorporate BA and situational exposure strategies (e.g., to reduce situational avoidance and to increase likelihood of reinforcement). The second phase adds daily imaginal exposures to the initial behavioral practices (BA and situational exposures) to target-specific PTSD symptoms, such as trauma-related reexperiencing and intrusions. Although preliminary findings are supportive of BA-TE in reducing symptoms in participants with PTSD (Strachan et al., in press), additional research is needed to (a) investigate the effect of BA-TE on symptoms of PTSD and depression and (b) better determine whether treatment response varies across the two phases of treatment (e.g., addition of imaginal exposures to BA and situational exposure practices).

Participants in the present study were part of a larger randomized controlled trial comparing BA-TE treatment delivery via telehealth versus in-person methods (Gros, Strachan, et al., 2011). Data collected thus far revealed no significant difference on PTSD or MDD measures in terms of delivery modality (Strachan et al., in press), and patients in both treatment conditions were included in the analyses, with treatment modality investigated as a potential moderator. In the present study, we hypothesized that the second component of treatment (imaginal exposure) would lead to increased symptom improvement for PTSD, as compared with the first component of treatment (BA and

situational exposure trials). We also hypothesized that all patients receiving BA-TE would demonstrate significant improvements in symptoms of PTSD and depression.

Method

Participants

Combat veterans ($N = 117$) of Operation Iraqi Freedom, Operation Enduring Freedom, Persian Gulf War, and/or Vietnam War were recruited through referrals at a large southeastern Veterans Affairs (VA) Medical Center. Eligible participants were required to meet diagnostic criteria for combat-related PTSD ($n = 37$) or subthreshold PTSD ($n = 80$), defined as fulfillment of Criteria A (traumatic event) and Criteria B (reexperiencing), and either Criteria C (avoidance) or Criteria D (hyperarousal; Blanchard et al., 1994; Grubaugh et al., 2005). To determine eligibility, a registered psychiatric nurse administered structured psychiatric interviews for PTSD (Clinician Administered PTSD Scale [CAPS]; Blake et al., 1995) and psychiatric comorbidities (Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders* [4th ed., text rev.; *DSM-IV*; American Psychiatric Association (APA), 2000]; SCID-IV; First, Spitzer, Gibbon, & Williams, 1996). Individuals who were actively psychotic, acutely suicidal, or met criteria for substance and/or alcohol dependence on the SCID were excluded from participation. To enhance generalizability of study findings, participants receiving psychotropic medication treatment were not excluded from participation. Consented participants were predominantly male (90.0%), African American (38.6%) or Caucasian (41.9%), veterans of Operation Enduring Freedom/Operation Iraqi Freedom (71.8%), Persian Gulf War (18.0%), or Vietnam War (10.3%), and had a mean age of 37.7 years ($SD = 12.9$). The majority of participants reported they were married (55.1%), followed by divorced or separated (18.9%), followed by never married (18.1%). A significant percentage of participants reported VA service connection/disability (79.1%) and met diagnostic criteria for MDD on the SCID (27.6%).

Over the duration of the study period, 35 participants withdrew from the study due to redeployment, employment, loss of transportation, or lack of interest in continuing to participate in the study (29.9% dropout rate). As such, the final treatment sample consisted of 82 participants. There was no significant difference in rates of dropout from the initial phase of treatment and the second phase of treatment, $\chi^2(1) = 0.15, p = .70$. The primary outcome analyses were conducted using the entire “intent-to-treat” sample. To justify

collapsing in-person and telehealth conditions into one condition for analyses, attrition and outcome were examined, and attrition rates were comparable across treatment delivery mediums. Two-variable chi-square tests revealed no group differences between completers and dropouts in sex, race, marital status, work status, treatment condition (telehealth and in-person; Gros, Strachan, et al., 2011), and disability status (χ^2 s < 5.81, ps > .05). In addition, one-way ANOVAs failed to reveal any group differences in age, $F(5, 112) = 0.71$, p > .05, or any measures of baseline symptomatology (F s < 0.15, ps > .05).

Procedures

A full description of the larger study methodology involving a complete list of assessment measures, treatment protocols, and the randomization process can be found in Gros, Strachan, et al. (2011). An abbreviated presentation of the methodology that is most pertinent to the current study is presented below.

All participants received eight 90-min sessions of BA-TE administered by masters-level therapists. All therapists completed a training program on BA-TE with the BA training component led by an expert in brief behavioral activation treatment for depression (Lejuez et al., 2001), the exposure training components led by an expert in PE (Foa et al., 2007), and the integration training of the two components led by the principal investigator. All therapists were also required to shadow a senior level clinician throughout a complete course of treatment before administering BA-TE independently. Therapists met weekly with the principal investigator for supervision throughout the duration of the study. Sessions were audio-recorded and monitored by an independent rater to ensure treatment fidelity. Assessments of PTSD (PTSD Checklist [PCL]; Weathers, Litz, Herman, Huska, & Keane, 1993) and depression (BDI-II; Beck et al., 1996) were completed at baseline, midtreatment (beginning of Session 4), and posttreatment (1 week following Session 8). The assessments of PTSD symptomatology (PCL) were focused on current symptoms of combat-related PTSD. As described below in more detail, the first phase of treatment focused on BA and situational exposures (Sessions 1-3). The second phase of treatment added imaginal exposures to the BA and situational exposures (Sessions 4-8).

Telecommunications Technology

Treatment sessions for the telehealth participants were conducted using in-home videoconferencing technology as part of a larger study. Either an Internet-based instant video service (e.g., a “Skype” type program) or an analogue videophone (Viterion 500) was used at the participant’s discretion.

Exposure therapy can be delivered effectively to individuals with PTSD via telehealth technologies (Germain, Marchand, Bouchard, Drouin, & Guay, 2009; Gros, Yoder, Tuerk, Lozano, & Acierno, 2011; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010).

BA-TE

BA-TE consists of eight 90-min sessions that include BA and situational exposure practices during Sessions 1 to 3, and BA and situational exposure practices with imaginal exposure practices during Sessions 4 to 8. Prior to beginning treatment, participants were given an agenda book specifically created for use in the study. The agenda book, used to record homework exercises and plan future days according to BA and exposure principals, was small and discrete, resembling typical planners found at office supply stores; this inconspicuous format was used to assuage potential participant concerns regarding confidentiality and improve portability of skills posttreatment. Furthermore, all worksheets required to complete treatment were included in the appendices of the planner reducing the number of extraneous forms necessary for psychoeducation, skills training, and between-session exercises. For more thorough descriptions of the theory, rationale, and practices involved in BA-TE, please see Acierno et al. (2012) and Strachan et al. (in press).

Sessions 1 to 3. The first phase of BA-TE began with the introduction of psychoeducation on common reactions to traumatic events, development of PTSD and MDD, and how avoidance operates to maintain and worsen symptoms of depression, anxiety, and fear. BA and situational exposure techniques were introduced as a primary method for reducing avoidance due to PTSD and depression. In brief, these techniques focused on increasing the planning of activities that were consistent with personal values and that had the potential for reinforcement. These activities frequently were combined with planning activities that involved exposing participants to avoided/feared situations. Taken together, these activities were designed to promote reduction in symptoms of depression, anxiety, and fear, which are common in PTSD and MDD. Unlike the lighter versions of BA described in existing exposure treatments (Foa et al., 2007), BA assignments in BA-TE were not limited to activities that changed/reduced avoidance due to the trauma; rather, these assignments were more consistent with stand-alone versions of BA for depression (Lejuez et al., 2001). In addition, activities were given a “social” aspect whenever possible. For example, if a participant endorsed “reading” as an enjoyable activity, we might suggest “reading at the bookstore” as a social addition to this activity. For homework, participants scheduled multiple, daily practices

in their planners, and progress was assessed by the therapist at the beginning of each session. Examples of these assignments involved specific hour-by-hour planning of a wide range of activities, such as walking each day with one's spouse, going to a crowded setting (e.g., shopping mall), eating dinner with friends and family either at home or a crowded setting (e.g., busy restaurant), or getting together with family and friends to watch the big game at home or a crowded setting (e.g., sports bar or stadium).

Sessions 4 to 8. The second phase of BA-TE incorporated imaginal exposure practices into the existing BA and situational exposure practices. Participants created a detailed narrative (audio and/or written) of the traumatic event, consistent with imaginal exposure practices from existing exposure therapy for PTSD (Foa et al., 2007). These additional activities were designed to address recurrent intrusive and distressing traumatic memories, commonly reported in PTSD. For homework, participants added daily imaginal exposure practices to their multiple, daily practices of BA and situational exposure practices.

Measures

BDI-II. The BDI-II is a 21-item measure designed to assess the cognitive, affective, behavioral, motivational, and somatic symptoms of depression in adults and adolescents (Beck et al., 1996). Each item is rated on a 0 to 3 scale with different responses based on the targeted symptom content. The BDI-II has demonstrated excellent test-retest reliability over a 1-week interval ($r = .93$), excellent internal consistency ($\alpha < .92$), and convergent and discriminant validity in multiple samples (Beck et al., 1996).

CAPS. The CAPS is a clinician-rated scale designed to diagnose current and lifetime PTSD (Blake et al., 1995). The CAPS targets the 17 specific PTSD symptoms from the *DSM-IV* (APA, 2000) to assess the intensity and frequency of each symptom on a 5-point Likert-type scale. Although a full assessment of past trauma was completed, active combat-related PTSD was the focus of the symptom assessments and related diagnosis. The CAPS has been shown to have adequate internal consistency (α s ranged from .73 to .95), interrater reliability on the same interview (r s ranged from .92 to .99), and test-retest reliability over a 2- to 3-day period across different interviewers (r s ranged from .77 to .98; for review, see Orsillo, 2002).

PCL-Military. The PCL is a 17-item measure designed to assess PTSD symptom severity related to military-/combat-related trauma. Respondents were presented with 17 specific symptoms of PTSD and asked to rate "how much you have been bothered by that problem in the last month" on a 5-point Likert-type scale, ranging from 1 = *not at all* to 5 = *extremely*. The PCL has

been shown to have excellent internal consistency in veterans, victims of motor vehicle accidents, and sexual assault survivors ($\alpha s > .94$), and excellent test–retest reliability in veterans ($r = .96$). In addition, the PCL has demonstrated excellent convergent validity with alternative measures of PTSD ($r s = .77$ to $.93$; Orsillo, 2002).

SCID-IV. The SCID-IV (First et al., 1996) is a semistructured diagnostic interview designed to assess the *DSM-IV* diagnostic criteria for Axis I disorders (APA, 2000). The SCID has shown adequate interrater reliability for all disorders ($r s = .69$ – 1.0) and adequate test–retest reliability over a 1- to 3-week interval in patient samples ($r s = .40$ – 1.0 ; Zanarini & Frankenburg, 2001).

Data Analysis

The current hypotheses were assessed using multilevel modeling (MLM). MLM accounts for autocorrected residuals for repeated measurements and has a superior method for handling missing data than other general linear modeling procedures (Singer & Willett, 2003). MLM divides variation across multiple levels. For the present study, Level 1 contained variation attributed to intraindividual changes (i.e., change in PTSD and depression during treatment) and Level 2 contained variation attributed to interindividual differences (i.e., demographic factors, PTSD diagnosis vs. subthreshold PTSD, and treatment condition). Missing data were handled with maximum likelihood estimation (MLE), a method that has been highly recommended in the literature (Graham, 2009; Kwok et al., 2008) and has shown to provide more accurate estimates when handling missing data (Raudenbush, 1995). This approach allowed for information from all participants ($N = 117$) to be included in the subsequent analyses.

A series of hierarchical linear change models were fitted to the data to test the hypotheses for the current study. First, a single linear change model and a piecewise model were examined to determine which best approximated the data. Piecewise models allow for separate rates of change across distinct periods. For the current study, separate rates of change were hypothesized for the first phase of BA-TE (Sessions 1–3), in which BA and situational exposure practices were primarily used, and the second phase of BA-TE (Sessions 4–8), in which imaginal exposure practices were added. Random effects were included to assess residual repeated measures variation (Level 1) and residual individual level variation (Level 2) in pretreatment values (intercept) and the rate of change (slope).

On selecting the model that best approximated the data, a fixed effect for comorbid symptoms (PTSD/depression) was included. Such an effect

Table 1. Descriptive Statistics for PTSD and Depression Symptoms During Treatment

Variable	Baseline	Session 2	Session 4	Session 6	Posttreatment
PCL-M	58.72 (14.18)	56.73 (13.81)	53.24 (15.77)	49.39 (16.45)	49.20 (17.38)
BDI-II	25.42 (11.59)	23.52 (10.47)	21.71 (10.48)	20.38 (11.90)	21.27 (14.17)

Note: PTSD = posttraumatic stress disorder; PCL-M = Posttraumatic Checklist–Military Version; BDI-II = Beck Depression Inventory–Second Edition.
* $p < .05$. ** $p < .01$.

determines the extent to which symptoms were related during the course of treatment, controlling for improvement in the dependent variable. Finally, a fixed effect for the interaction between the rate of change and PTSD/depression scores was included. A significant interaction provides support for the conditional effect of the co-occurring disorder on the rate of change in the dependent variable. For example, a significant Rate of change $\times$ Depression interaction would suggest that the rate of change in PTSD symptoms is conditional on levels of depression.

Results

Descriptive statistics for the current sample are presented in Table 1. Separate piecewise models were used to examine the rate of change in PTSD and depression scores during treatment. For PTSD symptoms, initial status was significantly elevated, $\beta_{00} = 59.21$. The rate of change from baseline to Session 3 was $\beta_{10} = -1.21$ and from Sessions 4 to 8 was $\beta_{20} = -1.39$. Both rates of change were significant ($ps < .01$). By comparison, the fixed effect for a single rate of change was $\beta_{10} = -1.30$, $p < .01$. The single rate model was selected because of (a) the small difference in rate magnitude (0.18) across both pieces as compared with prior work with piecewise models (Price, Anderson, Henrich, & Rothbaum, 2008), (b) both components were highly significant, and (c) a single slope model is more parsimonious.

For depression symptoms, initial status was significantly elevated, $\beta_{00} = 25.49$. The rates of change from the first and second portions of treatment were $\beta_{10} = -0.75$, $p < .01$, and $\beta_{20} = -0.60$, $p = .03$, respectively. Alternatively, the rate of change for the linear model was $\beta_{10} = -0.68$, $p < .01$. Following a similar rationale to that of the previous model, a single rate model was selected.

Symptoms for the co-occurring disorder (depression or PTSD) were then included as time varying predictors for the linear change models (Table 2).

Table 2. Linear Change Models for PTSD and Depression During Treatment

Fixed effect	Linear change model	Model with additional symptoms	Conditional change model
PCL-M as dependent variable			
Intercept (β_{00})	59.21** (1.25)	57.41** (0.86)	40.28** (1.97)
Slope (β_{10})	-1.30** (0.23)	-0.72** (0.14)	-1.09** (0.30)
BDI-II (β_{20})	—	0.81** (0.06)	0.76** (0.08)
BDI-II $\times$ Slope interaction ($\beta_{10} \times \beta_{20}$)	—	—	0.02 (0.01)
BDI-II as dependent variable			
Intercept (β_{00})	25.50** (1.01)	22.51** (0.63)	22.61** (0.63)
Slope (β_{10})	-0.68** (0.15)	-0.05 (0.11)	-0.54 (0.30)
PCL-M (β_{20})	—	0.52** (0.03)	0.49** (0.04)
PCL-M $\times$ Slope Interaction ($\beta_{10} \times \beta_{20}$)	—	—	0.01 (0.01)

Note: PTSD = posttraumatic stress disorder; PCL-M = Posttraumatic Checklist–Military Version; BDI-II = Beck Depression Inventory–Second Edition.

* $p < .05$. ** $p < .01$.

For the PTSD linear model, depression symptoms were positively related to PTSD symptoms when controlling for time, $\beta_{20} = 0.81$, $p < .01$. Furthermore, the rate of change in PTSD symptoms was significant while controlling for depression symptoms, $\beta_{10} = -0.72$, $p < .01$. These findings suggest that PTSD symptoms and depression symptoms were positively associated during the course of treatment. In addition, PTSD symptoms declined during treatment, even after accounting for depression symptoms during the course of treatment.

For the second model, PTSD symptoms were significantly related to depression symptoms after controlling for time, $\beta_{20} = 0.52$, $p < .01$. However, the rate of change for depression was no longer significant after controlling for PTSD symptoms, $\beta_{10} = -0.05$, $p = .67$. This suggested that after controlling for PTSD symptoms, depression symptoms did not change as a result of treatment.

Finally, an interaction between the symptoms of the co-occurring disorder and the rate of change ($\beta_{10} \times \beta_{20}$) was included in the linear models for PTSD and depression. For the PTSD model, the interaction between the rate of change and depression was not significant, $\beta_{10} \times \beta_{20} = 0.01$, $p = .12$. Similar findings were obtained for the depression change model. The interaction between rate of change and PTSD symptoms was not significant, $\beta_{10} \times \beta_{20} = 0.02$, $p = .28$. These findings suggested that, although PTSD and depression

symptoms were positively related during the course of treatment, the rate of symptom improvement for each disorder was not conditional on levels of other disorders. That is, the rate of change in PTSD was independent of the levels of depression during treatment. Furthermore, the rate of change in depression was independent of levels of PTSD during the treatment.

Discussion

The present study investigated symptoms of depression and PTSD during the course of an eight-session treatment involving integrated BA, situational exposure, and imaginal exposure practices. Contrary to our hypotheses, a linear model best fit the data, suggesting that symptom improvements for PTSD and depression were roughly consistent across the two phases of treatment and that the addition of imaginal exposure to BA and situational exposures did not increase the rate of decline in PTSD symptoms. In addition, although significant improvements were observed in the symptoms of PTSD when controlling for symptoms of depression, symptoms of depression failed to demonstrate significant improvements when controlling for the symptoms of PTSD. Together, these findings have several implications for integrated and/or transdiagnostic treatments of PTSD and MDD.

First, findings supported a linear rate of change across the two primary phases of treatment, suggesting that BA and situational exposure practices alone appear to provide sufficient treatment for PTSD. Despite substantial literature suggesting that imaginal exposure is very effective in the treatment of PTSD symptoms (Cahill et al., 2006; Foa et al., 2007), the findings of the present study suggest that imaginal exposure did not substantially accelerate PTSD treatment response beyond that of BA and situational exposure practices (of course, there is no way to know whether, in the absence of imaginal exposure, observed gains would have tapered off). Furthermore, the rate of response for the initial portion of treatment was comparable with that found in participants receiving manualized PE (e.g., Yoder et al., 2012). Recent meta-analytic investigations of “bona fide” psychotherapies for PTSD have reported similar findings across treatments, suggesting that BA, situational exposures, imaginal exposures, and several other evidence-based practices produce similar outcomes (Benish, Imel, & Wampold, 2008). Together, these findings call into question existing beliefs that specific evidence-based treatment components (e.g., imaginal exposure) are needed to effectively treat specific disorders (e.g., PTSD). Additional comparative research is needed in which outcomes in participants receiving only BA and situational exposure are compared with those of participants receiving treatment that involves

imaginal exposure to determine whether imaginal exposure practice aided in maintaining treatment effects in the second phase of BA-TE. The findings would help clarify the role of imaginal exposure in the treatment of PTSD.

The present findings also investigated the relations between the symptoms of PTSD, depression, and overlapping PTSD and depression during the course of BA-TE. Although these findings demonstrated significant improvements in the symptoms of PTSD and overlapping PTSD/depression, the residual variation of depression did not improve with BA-TE. The overlapping symptoms of PTSD and MDD have received much attention in the recent literature, especially in preparation for the revision of the *DSM* (Frueh et al., 2010; Gros et al., 2010; Gros et al., 2012; Resick & Miller, 2009; Rosen et al., 2008). These studies have highlighted the problematic boundaries between PTSD and MDD, with a particular emphasis of the symptoms of dysphoria and numbing (Gros et al., 2010) and the significance of how traumatic events are defined (Frueh et al., 2010; Gros et al., 2012). Additional research is needed to improve our understanding regarding the match between specific treatments (e.g., BA, situational exposures, imaginal exposures) and specific symptoms of PTSD (e.g., intrusions, avoidance, dysphoria, numbing, and arousal) and depression. Together, the present findings may suggest that additional treatment components may be needed in exposure therapy to address nonoverlapping symptoms of MDD, potentially with other treatment components common in MDD treatments, such as cognitive treatments or acceptance-based therapy.

Although the BA-TE findings are only preliminary and require replication, they contribute to the growing literature in support of integrating BA techniques into exposure therapy to potentially improve the ability of PTSD treatments to address comorbidity (Acierno et al., 2012; Nixon & Nearing, 2011). However, unfortunately, comorbidity and symptom overlap are not limited to PTSD and depression, as similar concerns have been raised for panic disorder and other anxiety disorders (Gros, Frueh, & Magruder, 2011). Thus, fully transdiagnostic approaches to psychotherapy may be needed to better address these comorbidities by simultaneously addressing the symptoms common among various mood and anxiety disorders (Barlow, Allen, & Choate, 2004; Barlow et al., 2010; Norton, 2009). Transdiagnostic treatments for mood and anxiety disorders include various evidence-based treatment components and focus on treating overall symptom impairment, rather than requiring specific sets of treatments for specific disorders. Recently, several examples of transdiagnostic treatments have been supported in the literature (Farchione et al., in press; Norton, in press; Schmidt et al., in press). With

continued support and replication, these transdiagnostic approaches may represent an important step in addressing comorbidity and symptom overlap in the mood and anxiety disorders.

The present study included several limitations. The sample was restricted to veterans with combat-related PTSD or subthreshold PTSD, which may limit the generalizability of these findings. To further investigate the transdiagnostic nature of BA-TE, future studies should include patients with various mood and anxiety disorder diagnoses in veteran and nonveteran samples. In addition, the rate of treatment discontinuation was higher than expected in trials for exposure therapy for PTSD. Another limitation of the study was the short duration of BA-TE. Although significant improvements were observed in both outcome measures, these improvements were small. It is possible that more sessions of BA-TE, as typical of several evidence-based psychotherapies (e.g., Foa et al., 2007), could have influenced the present findings. A lack of a comparison group(s) and/or randomization of medication use also limited the interpretation of the findings. Finally, the study did not include measures of unique and common symptoms of PTSD and depression and relied solely on self-report outcome measures.

The present study investigated the efficacy of BA-TE in the treatment of the symptoms of PTSD and depression in veterans with PTSD. These preliminary findings supported improvements in the symptoms of PTSD, and overlapping PTSD and depression, but not in nonoverlapping symptoms of depression. The findings also demonstrated a relatively consistent rate of change in these symptoms during the course of BA-TE, despite the addition of imaginal exposure practices midway through the treatment. Together, these preliminary findings support the use of BA-TE as a treatment for PTSD and related symptoms of depression. These findings also provide support for the growing literature of integrated behavior therapies of PTSD and depression (Acierno et al., 2012; Nixon & Nearing, 2011) and more fully transdiagnostic therapies for the mood and anxiety disorders (Farchione et al., in press; Norton, in press; Schmidt et al., in press).

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Bios

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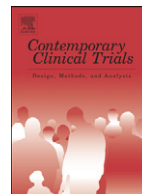
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Innovative service delivery for secondary prevention of PTSD in at-risk OIF–OEF service men and women

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ABSTRACT

Service personnel involved in Operation Enduring Freedom/Operation Iraqi Freedom are at high risk for trauma-related physical injury and emotional problems, including posttraumatic stress disorder (PTSD) and major depression. Although evidence-based psychotherapies are increasingly available and effective in treating symptoms of PTSD, a large number of service personnel are reluctant to seek mental health treatments due to both perceived stigma associated with these treatments and geographically-based barriers to care at specialized treatment facilities. The present investigation evaluates an innovation in service delivery designed to address these concerns. Specifically, we are comparing exposure-based therapy for PTSD delivered via traditional, in-person settings to the same exposure-based treatment delivered via telehealth technology. The proposed project is a prospective, randomized repeated measures design with two treatment groups (telehealth and in-person) assessed at pre-treatment, mid-treatment, post-treatment and 3- and 12-month follow-up points. Outcome measures ascertain longer-term effects of the treatments on three domains: clinical, process, and economic. Non-inferiority and superiority analyses will be conducted to determine symptom changes between pre-treatment, post-treatment, and follow-up time points between the two treatment conditions. The study will determine whether an exposure therapy for PTSD delivered via telehealth is at least as successful as the same exposure-based therapy delivered in-person in treating the symptoms of PTSD in both subthreshold and fully diagnosed cases.

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1. Introduction

Service men and women involved in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) are at high risk for exposure to combat-related trauma [1,2]. In addition to the initial physical injury and/or emotional distress associated with

exposure to these events, a broad range of long-term negative outcomes, impairments, psychiatric disorders, and physical health problems also appear prevalent. One particularly impairing sequela of trauma is posttraumatic stress disorder (PTSD) and its subthreshold, albeit functionally impairing, presentations [3–5]. For example, in the National Vietnam Veterans Readjustment Study, PTSD prevalence was 9–15% of Veterans with an additional 8–11% reporting significant subthreshold symptomatology [6,7]. Similar rates of PTSD and subthreshold PTSD have been reported in OEF/OIF Veterans [4,8,9], in addition to high rates of comorbid major depressive

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disorder, generalized anxiety disorder, and substance use disorder [4,8,10,11]. Both PTSD and subthreshold PTSD contribute to significant functional impairment including relationship, legal, and employment problems as well as disproportionately high rates of health care utilization [12,13].

Numerous evidence-based psychotherapies exist to address symptoms of PTSD [14,15]. In particular, research has supported using exposure-based interventions that are derived from models of learning theory and involve altering patients' problematic patterns of behavioral and cognitive avoidance that appear to maintain symptoms [16,17]. Although these interventions are available, service personnel are often reluctant to seek mental health treatment, both while in service and after leaving the military [18]. A recent study of OEF/OIF Veterans found that 42% indicated that they were interested in receiving help for their symptoms of PTSD, but only 25% actually receive services [8]. Several potential barriers to treatment have been identified in the literature, including person-based barriers (e.g., perceived stigma associated with mental health treatments), documentation concerns (e.g., fears that certain diagnoses will have adverse effects on advancement in the military), and geographically-based barriers (e.g., disparities of access associated with physical and personal environmental constraints) [4].

In order to address these barriers to obtaining effective mental health treatments, the application of non-conventional models of service delivery to military and Veteran populations has been advocated [19,20]. In particular, new modalities for evidence-based treatments need to be broadened to make them sensitive and responsive to changes in severity and symptom presentation over the course of service delivery. One method proposed was using telehealth to overcome barriers to treatment delivery. Telehealth has several advantages for patients over traditional treatment approaches, including lower cost of transportation, travel time, and missed work [21–23]. In addition, telehealth may be useful in overcoming several of the other barriers to treatment outlined above by providing services directly to Veterans in their home. Preliminary findings for PTSD treatments delivered via telehealth are promising [24]; however, additional research is needed to understand the comparable efficacy of telehealth and in-person treatment modalities [25].

1.1. Research aims

The proposed project aims to compare in-person and telehealth delivery of exposure therapy in post-deployed, active duty OEF/OIF personnel presenting with significant functionally impairing symptoms of PTSD and, typically depression, to determine whether the relatively less stigmatizing telehealth medium is equally effective in terms of symptom reduction to more expensive, traditional in-person treatment medium. Such a finding would provide support for a treatment that could, potentially, reduce attrition from the military due to mental health causes and reduce eventual mental health costs for the Veteran Administration Medical Center (VAMC) system, thereby benefiting service men and women, the Department of Defense (DoD) and the Veteran Affairs (VA).

1.2. Hypotheses

There are several hypotheses related to the research aims described above. First, exposure therapy delivered via telehealth will be as effective as in-person exposure therapy in reducing PTSD symptoms and related psychopathology at post-treatment and these findings will be maintained at the 12 month follow-up points. Second, participants in the telehealth treatment condition will report greater satisfaction with treatment, greater rates of treatment attendance, and reduced attrition compared to participants in the traditional in-person treatment condition at the end of treatment. Third, the telehealth treatment condition will be relatively more cost effective than treatment delivered in-person.

2. Methods

2.1. Design

The study is funded by the DoD's Congressionally Directed Medical Research Programs within the Psychological Health and Traumatic Brain Injury Program as an Intramural PTSD Investigator-Initiated Research Award. The vision of the program is “to prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for service members as well as their caregivers and family” [26]. The proposed project will use a between groups, random assignment repeated measures design powered appropriately for non-inferiority conclusions. Superiority analyses (e.g., cost) also are intended.

Individual therapy sessions will be administered over an eight-week period; outcome measures will ascertain longer-term effects of the treatments on three outcome domains: clinical, process, and economic. Participants will be assessed at pre-treatment, mid-treatment, post-treatment, 3 month and 12 month follow-up. All participants will be randomly assigned (1:1) to one of the two individual exposure therapy treatment conditions: telehealth or in-person (see Fig. 1).

A non-inferiority design was chosen for the clinical outcome variables for several reasons. Based on previous findings for PTSD and telehealth [24], no differences are expected between conditions on the outcome measures of PTSD and related symptomatology and functional impairment. In addition, the identical treatment protocol will be delivered in both treatment conditions. In contrast, superiority analyses will focus on the process and economic variables that are predicted to differ between groups and provide support for greater satisfaction with treatment, greater rates of treatment attendance, reduced attrition, and reduced costs associated with the telehealth condition compared to participants in the traditional in-person treatment condition. Together, if supported by the analyses, this study will suggest that telehealth technologies represent a more desirable and cost effective alternative to in-person treatments with equal efficacy on clinical outcomes.

2.2. Participants

Patients will be male and female OIF/OEF Veterans, age 21 and above, with significant symptoms of PTSD. Thus, patients may present with either diagnosable PTSD or subthreshold PTSD. Subthreshold PTSD was defined as endorsement of Criterion A

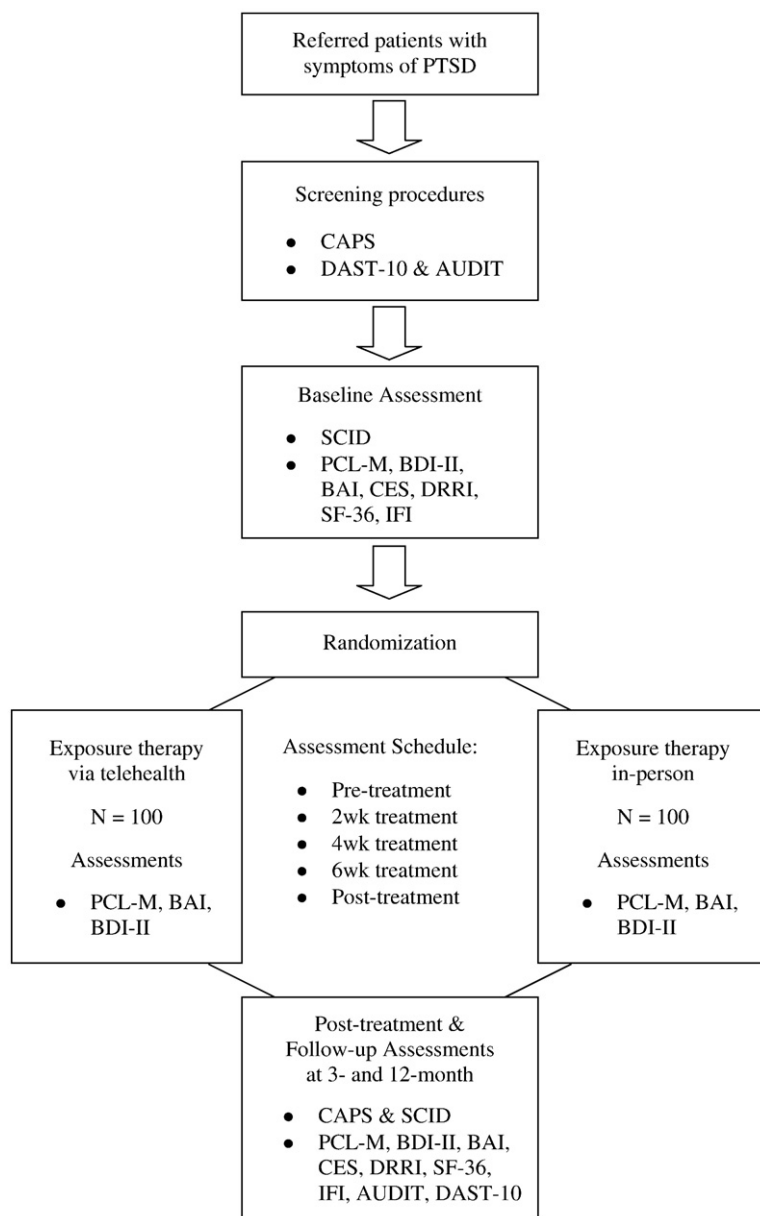


Fig. 1. Flowchart depicting the stages involved in the study design.

(history of trauma), and B (reexperiencing symptom of the trauma) for PTSD, and either the Criterion C (avoidance symptoms) or D symptom cluster (arousal symptoms) as defined by the Diagnostic and Statistical Manual-IV [5,27]. Actively psychotic or demented persons, individuals with both suicidal ideation and clear intent, or substance dependence are excluded from participation; however, to maximize generalization of results, the presence of other forms of psychopathology is not a basis for exclusion. Inclusion/exclusion criteria are evaluated via a diagnostic intake, involving the Clinician Administered PTSD

Scale (CAPS) [28], Drug Abuse Screening Test (DAST-10) [29], and Alcohol Use Disorders Identification Test (AUDIT) [30]. In addition, those patients meeting inclusion criteria are asked to maintain medications at current dosages where medically possible. A final sample of 200 OEF/OIF service members, either active duty or retired Veterans, is targeted.

The inclusion of minorities in PTSD research is recognized as being of critical importance [31]. Based on our previous VA data [32], we estimate that approximately 38.3% of the sample will be comprised of minority groups and 7.1% of the

sample will be comprised of female participants. No additional recruitment strategies are planned to target and/or oversample these populations in the present study.

2.3. Recruitment

The study is taking place at three sites, a large VAMC, university hospital, and Army Medical Center, all of which are located within the southeastern United States. This multi-site structure increases the representativeness of our sample by maximizing opportunities to recruit and enroll: (1) OIF/OEF Veterans who use the VA healthcare system; (2) active duty service men and women who are recently post-deployed and face re-deployment; and (3) Veterans and active duty personnel living in the community who utilize civilian healthcare.

Project staff works closely with administrators from all three hospitals to develop recruitment strategies that are consistent with the routine clinical practices at that particular facility. At the VAMC and Army Medical Center, health care providers will refer patients endorsing symptoms of PTSD to each facility's designated behavioral health clinic for an evaluation and treatment. Per standard of care at both facilities, patients receive a comprehensive diagnostic evaluation conducted by mental health staff. Following the evaluation, staff informs patients about clinic-based treatment options as well as opportunities to participate in military-sponsored, PTSD research. Patients who are interested in participating in research meet with the site coordinator to initiate consent and eligibility procedures. Recruitment at the university hospital involves posting descriptive flyers about the study in prominent areas around the hospital, utilizing the hospital-associated research podcast system, and speaking with healthcare providers as to how to refer patients to the study.

2.4. Exposure therapy

Both the in-person and telehealth treatment conditions will utilize exposure therapy as described below. The exposure-based treatment will be comprised of eight, 1.5 hour sessions. The treatment provided was most consistent with the treatment model described by Foa and colleagues [33]. Thus, the primary treatment component will be in vivo and imaginal exposure trials. Exposure trials will be completed in-session as well as scheduled for between-session periods. A daily planner is used for this in order to maximize treatment participation and homework completion. As a secondary component, patients also will be asked to schedule and track the completion of personal values-based (i.e., meaningful), positive activities in their daily planner throughout treatment, following the overarching guidelines of behavioral activation. This planning of reinforcing activities is rather basic in behavior therapy and does not interfere with frequent exposure practice, and therefore serve to complement the exposure and fill the patient's weekly schedule. In session 1, the therapist provides psychoeducation about common reactions to traumatic events, development of PTSD and depression, and how avoidance and withdrawal operate to maintain PTSD and symptoms of depression. Patients will be instructed to monitor their activities and avoidance and corresponding mood using the daily planner provided at the start of treatment. Session 2 involves identifying patterns of behavioral avoidance and withdrawal and defining sets of behaviors to

promote recovery. Patients will be instructed to begin scheduling value-based activities in the daily planner. In session 3, both in vivo and imaginal exposure hierarchies and detailed exposure narratives (audio and/or written) of the traumatic event will be developed and both within- and between-session in vivo and imaginal exposures are scheduled in the daily planner, as well as continued value-based activities, for the remainder of treatment (sessions 3–8). The primary role of the therapist during these sessions is to emphasize the relation between symptoms and behaviors, identify continued patterns of avoidance, and prescribe activities based on patient self-reports of symptomatology. The final session will emphasize relapse prevention strategies. Specifically, the therapist and patient identify the behavioral warning signs that signal possible re-emergence of symptoms and troubleshoot strategies to sustain treatment gains.

2.5. Telecommunications technology

Treatment sessions for the telehealth condition are conducted using in-home videoconferencing technology. We use either an internet-based instant video service (e.g., "Skype") or, at the participant's discretion, an analogue videophone (Viterion 500) that operates via traditional telephone service. Apart from the video screen, this equipment appears and functions much like a basic touch-tone telephone. It is a "plug-and-use" product, with built-in camera, full duplex speakerphone, 4-inch LCD color screen (270K pixels) with real-time motion display (18 frames/s), and oversized touch-tone buttons for easy use by patients. Because many younger OIF/OEF Veterans do not have traditional telephone service and may rely on cell phones, we permit patients to use internet-based videoconferencing technology such as "SKYPE" if this is their preference, given the following caveats. First, we inform these patients that all methods of internet-based communication, including Skype and email, carry a slight risk of breach of confidentiality by a third party. Because of this risk, we recommend that patients use the videophone equipment provided. Second, patients who choose internet-based videoconferencing technology instead of the recommended equipment are required to initiate contact with the therapist at each session; this ensures that using internet-based communication is *their* choice.

2.6. Intervention and assessment procedures

The treatment phase involves eight weekly 1.5 hour individual sessions of exposure therapy. The assessment schedule is as follows: one week pre-treatment, mid-treatment (sessions 2, 4, 6, and 8), immediately post-treatment, and three and twelve month follow-up points. The pre-treatment, post-treatment, three and twelve month follow-up assessments will involve a series of clinician-rated and self-reported measures (detailed below) and will be administered by a trained clinical technician in psychology. The administrator will be blind to the treatment condition (all assessments completed in-person), will not be a provider of therapy to assessed patients, and will complete thorough trainings to administer the clinical interviews (e.g., didactic training DVDs, two observations of reliable assessors, and two administrations under observation by reliable assessor). Brief self-report questionnaires will be administered by the treating clinicians at sessions 2, 4, 6, and 8.

Master's-level clinicians underwent a 12 hour treatment-specific training program focused on Prolonged Exposure for PTSD [31], in addition to 6 months of trainings in exposure therapy with Veterans with PTSD (average total clinical experience 2.75 years). Clinicians conduct the treatment for both the telehealth and in-person conditions. During the project, clinicians follow the treatment manual, and undergo weekly supervision. In addition, the present study will obtain a quantitative measure of protocol adherence through a checklist of the specific procedures scheduled to be followed in the treatments outlined above. In order to ensure that treatments are competently administered in accordance with the guidelines, all sessions will be audiotaped, and 20% of these will be rated for competence and adherence by co-investigators.

2.7. Measures

2.7.1. Clinical descriptive and outcome measures

The following measures have been widely used in the clinical evaluation of adults with PTSD, and will be used in the present study, including both clinical interviews (CAPS [28] and Structured Clinical Interview for DSM-IV [34]) and self-reported measures (PTSD Checklist-Military (PCL-M) [35], Beck Depression Inventory-2nd Edition (BDI-II) [36], Beck Anxiety Inventory (BAI) [37], Combat Exposure Scale [38], Deployment Risk and Resiliency Inventory [39], Health-Related Functioning: The Medical Outcomes Study Social Support Survey Form and Short Form-36 Health Survey (SF-36) [40], DAST-10 [29], and the AUDIT [30]). In addition, each of these measures has received thorough investigation and support for their psychometric properties in the literature.

The Index of Functional Impairment will be used as the primary measure of functional status, which assesses seven domains of functional impairment on a self-reported 7-point Likert scale. Data also will be collected via a self-report format regarding objective indicators of social functioning, such as changes in marital status, employment status, residential status, legal involvement, and health care use. We have successfully used this strategy to assess change [41].

2.7.2. Process variables

Several measures were included to assess process variables associated with treatment (e.g., treatment satisfaction, adherence, and credibility). These variables were measured by the Charleston Psychiatric Outpatient Satisfaction Scale (CPOSS) [41], Treatment Credibility [42], and the Service Delivery Perceptions Questionnaire. Indices of treatment adherence also will be recorded, such as homework completion, session attendance, and study attrition. An additional questionnaire, Prior Experience with Computer and Audiovisual Technology, will be included to learn more about participants' prior experiences and comfort level with computers and audiovisual technology as these data may serve as relevant covariates in subsequent analyses of the telehealth condition.

2.7.3. Economic and utilization variables

Several cost-related measures will be recorded and investigated for telehealth-related capital expenditures (e.g., hardware, software, and telecommunications equipment) and resource utilization at months zero and 12 (e.g., hospitalizations, physician/professional visits, employment information,

and personal patient costs). In combination with the clinical outcome and process variable findings, analyses of the cost-related measures will help to inform whether the investment of new equipment and additional variable costs (clinician time, training of staff, and cost of down-time) are offset by the benefits of telehealth and reducing the associated costs of treatment. Depreciation and annualization will be incorporated into the analyses. Analyses of the resource utilization will investigate changes in overall healthcare utilization in the 12 months prior to and following the initiation of treatment in both treatment conditions as a proxy variable of general improvement.

2.8. Power

The sample size determination was based on the non-inferiority analyses. The primary response variable for sample size calculation relating to non-inferiority of exposure therapy delivered via telehealth versus in-person is treatment response, defined as at least a 50% improvement from baseline to post-treatment level on the PCL-M. For the one-sided non-inferiority comparison between telehealth and in-person, with $n_1 = n_2 = 100$ subjects per condition, power is 85% for detecting a non-inferiority effect size, Δ , of 0.15. The conclusion that telehealth is non-inferior to in-person in clinical efficacy requires that the response proportion (% responders) for in-person cannot exceed by more than $\Delta = 0.15$ the response proportion for telehealth.

2.9. Hypothesis testing

Separate analyses will be investigated for the per-protocol and intent-to-treat samples. For non-inferiority analyses, per-protocol samples are more conservative; the opposite is true of superiority analyses, for which intent-to-treat samples provide the most conservative estimates. The primary clinical response variable is the proportion (%) of patients who respond to treatment. Secondary continuous clinical outcomes are PCL-M, BDI-II, BAI, SF-36. The primary process outcome is CPOSS total score (continuous); secondary process outcomes are treatment credibility, Service Delivery Perceptions, treatment adherence (as measured by percent of returned, completed homework assignment forms), session attendance/attrition (as measured by % of missed sessions, and drop-out status).

2.10. Non-inferiority analyses

Testing the non-inferiority of telehealth versus in-person will be carried out using a confidence interval approach [43,44], with primary reference given to the per-protocol sample. With this approach, the upper limit of the one-sided 90% confidence limit for the difference in % responders between the two comparison groups must be 0.15 (Δ , the pre-specified non-inferiority effect size) or less to accept the hypothesis of a non-inferior telehealth. A second set of analyses to compare % responders, adjusted for putative confounding variables, will be carried out using a multivariable logistic regression model to obtain estimates of covariate-adjusted % responding for each treatment delivery condition for the covariables of interest. The one-sided confidence intervals approach will then be applied, using the covariate-adjusted response proportions, to evaluate

non-inferiority of the two interventions. For secondary continuous outcomes, the one-sided non-inferiority 90% confidence interval approach using the difference in change from baseline mean scores for each variable will be used. The magnitude of the difference in the means (effect sizes), as estimated by the confidence intervals will provide useful clinical information and will allow a clinical judgment relative to the clinical non-inferiority of the two modes of delivery.

2.11. Superiority analyses

Unadjusted proportions (dichotomous clinical and process outcomes) for *a priori* specified pairwise comparisons (in-person vs. telehealth) will be compared using a z-test for proportions with primary reference given to the intent-to-treat sample. Multivariable logistic regression analyses will be used to model the association between the dichotomous outcomes and treatment modality and to evaluate the effect of putative moderating variables on this relation and the possible effect modification (interaction) of these variables on the relation between treatment status (delivery mode) and clinical outcome. Covariates to be considered include age, race baseline PTSD severity, number/type of comorbidities, use of psychiatric medication, and others if identified in preliminary descriptive analyses. Interaction between treatment status and covariates will be evaluated by inclusion of treatment by covariate interaction terms in the model. Single end of study continuous clinical and process outcomes (e.g. change from baseline scores) will be compared across treatment modalities using a general linear model approach similar to that described above for multivariable logistic regression. Analyses will be repeated for each of the outcome measures, both with and without a Bonferroni correction for the multiple outcome variables.

3. Discussion

The primary objective of the present study is to evaluate the effectiveness of exposure therapy in treating the symptoms of PTSD and related conditions in post-deployed OEF/OIF service men and women across two treatment modalities: telehealth and in-person. Particular focus will be paid to the telehealth condition as it represents an innovative medium that may overcome specific barriers to treatment in OEF/OIF service members such as stigma associated with mental health treatments, as well as limited access to care in rural communities. The results of this study will inform future mental health developments and practices within the VA and DoD in regards to treating OEF/OIF service members and using telehealth technologies to deliver mental health treatments. The study has several strengths and limitations.

3.1. Strengths

There are several strengths of the present study design. First, the same clinicians provide the intervention across the two treatment conditions (telehealth and in-person), controlling for potential therapist effects. Second, the study involves careful assessment of treatment fidelity. Third, the assessments are conducted by interviewers who are blind to the treatment conditions. And fourth, the study uses an adequate sample size to

detect even small effects and investigate most subgroup differences.

3.2. Limitations

The study design also contains a few limitations. First, due to funding limitations and ethical concerns associated with using control treatments with Veterans with PTSD, the study lacks a third group of participants receiving an alternative intervention to compare exposure therapy via telehealth with a standard control-group treatment (e.g., supportive counseling). Second, the focus of the experimental/telehealth condition is on one specific treatment protocol; generalizability of these data to other treatments for anxiety and depression will be uncertain. Third, the study design is unable to discern between the effects attributable to the method of delivery (telehealth vs. in-person) relative to the setting (office vs. home). Forth, due to the expected demographics of the sample, subgroup analyses for sex may be difficult in the present study.

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► Managing suicidality in home-based telehealth

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Summary

We describe the case of a US veteran from the war in Afghanistan with post-traumatic stress disorder (PTSD). The patient was undergoing treatment at home via telehealth as part of a research trial. In week six, he presented with severe suicidal ideation and required emergency hospitalization. Through a series of immediate enhanced communications (i.e. by videoconference) between the patient, patient's family, treatment team and local resources, the patient's symptoms were assessed to identify suicidality and an intervention was successfully carried out, involving the development of a safety plan and eventual transportation to an inpatient unit at the local Veterans Administration Medical Center, where he was hospitalized for three days. This demonstrates the value of telehealth in identifying and treating severe psychiatric symptoms in addition to supporting the safety of these procedures to address suicidality.

Introduction

Telepsychiatry has been employed in a number of settings, including patients in rural areas, older adults, racial/ethnic minorities, patients adjudicated by the courts and military veterans.¹ In addition, there is strong evidence for both high patient and moderately high provider satisfaction with mental health services delivered via telehealth.² Recent studies support the effectiveness of telehealth for delivering evidence-based psychotherapies to rural veterans with post-traumatic stress disorder (PTSD).^{3–5} Similar beneficial effects of mental health care delivered via telehealth have been demonstrated for other psychiatric conditions, including panic disorder,⁶ obsessive compulsive disorder⁷ and social phobia.⁸

Little is known regarding the safety of providing telehealth-delivered treatment to high-risk patients. Traditionally, telehealth services have been provided to patients at community-based outpatient clinics where local services are immediately available.^{4,5} However, as these technologies improve, telehealth is shifting to in-home services to further improve patient outcomes and cost savings, but potentially raising additional concerns that are associated with the absence of an on-site health-care provider. The present case report concerns a US veteran of the Afghanistan war with PTSD, who developed severe suicidal ideation.

Case report

Mr B was a 45-year-old African-American male veteran living in a rural county in the south-east United States (population about 40,000 in 2005). Mr B lived in a trailer with his 21-year-old son and 20-year-old daughter, while his home was being repaired. Mr B and his wife were divorced and lived apart. Mr B served in an Army Reserve unit and completed two deployments in Afghanistan. While in Afghanistan in 2007, Mr B witnessed a suicide bombing at the rear of a convoy entering the base. The force of the explosion pushed Mr B into a wall. Afterwards, Mr B inspected the scene of the explosions and was ordered to gather the scattered body parts of the suicide bomber. After returning from his deployment, Mr B reported constant, unrelenting intrusive thoughts and images related to his service in Afghanistan and the suicide bombing, including nearly daily nightmares associated with the event (e.g. seeing dead bodies). Mr B also reported moderate situational avoidance of crowded locations (e.g. shops and restaurants), extreme hypervigilance, exaggerated startle and sleep disruption. Mr B also had several other health complaints, including chronic lower back pain and diabetes.

All study procedures described below were approved by the appropriate ethics committees. At baseline assessment, Mr B met the diagnostic criteria for PTSD on the Clinician Administered PTSD Scale and major depressive disorder (MDD) on the Structured Clinical Interview for DSM-IV.^{9,10} Mr B reported mild alcohol use (2–4 times a month) on the Alcohol Use Disorders Identification Test and denied drug use in the past month on the Drug Abuse Screening Test.^{11,12} Mr B's self-reported drug and alcohol use was consistent with drug tests and blood work completed as part

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of his hospitalization. Three months prior to beginning psychotherapy, Mr B was prescribed citalopram hydrobromide (50 mg daily) for his mood, risperidone (1 mg daily) for his sleep, and morphine sulphate SR (30 mg daily) for his back pain. However, Mr B initially reported inconsistent use of his mood and sleep medications.

Home telehealth

Mr B was participating in a large randomized controlled trial of home-based telehealth in veterans with PTSD.¹³ Telehealth treatment sessions were conducted using videoconferencing to his home. An analogue videophone (Viterion 500, Viterion TeleHealthcare, NY, USA) was used that operated via a conventional telephone line. The videophone had a 10-cm LCD colour screen displaying video at 18 frames per second.

Treatment

The treatment provided was consistent with the treatment model described by Foa and colleagues.^{14,15} Thus, the primary treatment components were in vivo and imaginal exposure trials. There were 10 treatment sessions, all conducted by telehealth.

In session 1, the therapist provided psycho-education about common reactions to traumatic events, development of PTSD and depression, and how avoidance and withdrawal operate to maintain PTSD and symptoms of depression. Mr B was instructed to monitor his activities and avoidance and corresponding mood using the daily planner provided at the start of treatment. Session 2 involved identifying patterns of behavioural avoidance and withdrawal, and defining sets of behaviours to promote recovery. Mr B was instructed to begin scheduling value-based activities in his daily planner. In session 3, both in vivo and imaginal exposure hierarchies and detailed exposure narratives (audio and/or written) of the traumatic event were developed, and both within- and between-session in vivo and imaginal exposures, as well as continued value-based activities, were scheduled in Mr B's daily planner. This was repeated for the remainder of treatment (sessions 3–8). The primary role of the therapist during these sessions was to emphasize the relation between symptom maintenance and avoidance behaviours, identify continued patterns of avoidance, and prescribe activities based on Mr B's self-reports of symptomatology. The final session emphasized relapse prevention strategies.

Mr B completed the first five weekly sessions of exposure therapy. During the sixth session, Mr B reported suicidal ideation and emergency procedures were used (see below). Mr B was hospitalized for three days at the Veterans Administration Medical Center (VAMC). During his hospitalization, Mr B's medication regiment was evaluated and altered to better address his physical and mental health concerns (e.g. diabetes medications were added). Upon symptom stabilization and subsequent discharge, Mr B

completed a brief stabilization psychotherapy session via telehealth and the final three sessions of exposure therapy via telehealth per protocol. Upon completion of the telehealth treatment, Mr B was referred to the VAMC for continuation of care.

Suicide intervention via home-based telehealth

Mr B reported mild suicidal ideation during the first five sessions of exposure therapy, but denied having intent and/or plan of action. However in week six, Mr B reported a 3 ('I would kill myself if I had the chance') on the Beck Depression Inventory (BDI-2).¹⁶ Mr B stated that he would hang himself on further assessment. Mr B said that he felt more and more like hurting himself and could not guarantee his own safety.

The following steps were taken to address Mr B's suicidality. First, the therapist contacted another therapist (therapist 2) to provide consultation and co-ordination with local services in Mr B's rural area. Second, the therapist developed a safety plan with Mr B via telehealth and was able to incorporate Mr B's family in the planning (e.g. his son was at home). The safety plan included identifying warning signs, coping skills, social contacts, family support and emergency contacts. The plan also created a safe environment, by removing any potentially harmful objects. Once again, Mr B could not guarantee his safety and required hospitalization, but lacked transportation to facilitate his hospitalization. Third, therapist 2 contacted Mr B's local emergency dispatcher to co-ordinate hospitalization while therapist 1 remained connected with Mr B and his family via telehealth. Mr B's information (e.g. medical history, risks, treatment programme, suicidality, and his address and telephone number) was communicated to the first responders via therapist 2. Unfortunately, the local officials in Mr B's rural area could only transport Mr B to a local hospital, rather than the VAMC located 80 km away. Fourth, after the police arrived, therapist 1 contacted the local hospital to arrange transfer to the VAMC and therapist 2 contacted the VAMC to arrange hospitalization. Each step was communicated to Mr B by therapist 1 and therapist 2 via telehealth in the home.

The home-based telehealth equipment provided several benefits to the provider and patient during this emergency. First, the telehealth equipment provided a secondary route of communication for the provider, allowing for continual communication and observation of Mr B while co-ordinating care with outside facilities and providers. Second, Mr B's behavioural information (facial cues and body language), as viewed through the telehealth equipment, presented an additional assessment of Mr B's level of distress. Third, the telehealth equipment also allowed for the behavioural observation of Mr B's actions, reducing the likelihood that Mr B would engage in any risky (e.g. leaving the home) or self-injurious (e.g. swallowing pills) behaviours while viewed on the telehealth monitor. Thus, the use of telehealth in this case probably assisted in the successful management of Mr B's suicidality.

Response to therapy

Mr B's scores on the BDI-2, Beck Anxiety Inventory (BAI), and PTSD Checklist – Military Version (PCL-M) are shown in Figure 1.^{17,18} In addition to these assessments, Mr B completed regular telephone check-ins and appointments with his new providers at the VAMC, following his final session of exposure therapy. The BDI-2 was the only measure administered during the crisis week due to Mr B's response to item 9 (suicidal thoughts and wishes). Mr B showed a steady improvement in the BDI-2, BAI, and PCL-M scores from baseline to week 10. A small elevation was observed on the BDI-2 on the crisis week. After the completion of exposure therapy, Mr B reported an increase in symptoms at the 30-day follow-up assessment, which was probably related to a hospitalization for a physical health concern on the week prior to the assessment.

Discussion

We used telehealth to treat a patient with PTSD and MDD, and co-ordinate care to address acute suicidality. These telehealth services were provided from a VAMC in an urban area directly into the home of a veteran patient living in a rural area. Through a series of immediate enhanced communications (i.e. by videoconference) between the patient, patient's family, treatment team and local resources, the patient's symptoms were assessed to identify suicidality and an intervention was successfully carried out, involving the development of a safety plan and eventual transportation to an inpatient unit at the local VAMC. This demonstrates the value of telehealth in identifying and treating severe psychiatric symptoms in addition to supporting the safety of these procedures to address suicidality.

The present case report raises several important matters for future providers of home-based telehealth for at-risk patients

in rural settings. First, telehealth services rely on telecommunication lines, such as ordinary telephone lines or broadband connections. These services may tie up the only line of communication between patient and provider. Thus, providers must have a backup communication method (e.g. mobile phone or second telephone line) in case of emergencies. This includes arranging for a health-care provider to be accessible in the event of an emergency. Second, knowledge of the local services and facilities is necessary for emergency situations. This includes contact information for the local emergency services (e.g. police department), transportation services and local hospitals with emergency mental health services. Providers must be able to communicate quickly any emergency needs to local services. Providers may want to prepare local services for emergency situations (e.g. suicidality) to familiarize them with the telehealth procedures and develop a local action plan. Third, although the present case was complicated by barriers (e.g. lack of transportation) that were successfully overcome via telehealth communications, the successful management of the case hinged on the willingness of the patient to maintain communication throughout the process. Had the patient disconnected the telehealth unit, a different protocol would have been required to address his suicidality, including immediately contacting local emergency services. Note that the likelihood of patient contact with clinicians is significantly higher in telehealth, since patients who might otherwise fail to attend a clinic for treatment because they are suicidal or very depressed are more likely to participate in home-based telehealth on these particularly dangerous days. Clinicians therefore have a better opportunity to intervene and help suicidal patients. In other words, for patients such as Mr B, safety is enhanced via telehealth.

The benefits of telehealth services have been emphasized in the literature.^{1,2,19} Recent studies have focused on the delivery of evidence-based psychotherapies and have reported promising results.^{3–5} The present case report may represent a useful direction for future clinical interventions. Our patient lived in a rural area with severe psychiatric symptoms. He had limited transportation available and would have been unlikely to have received services without the aid of home-based telehealth, and certainly would not have made the effort to travel to the clinic on the day he was overtly suicidal. In addition to the promotion of telehealth in the treatment of psychiatric disorders, home telehealth could also be utilized to assess, track and prevent suicidality in at-risk patients. It may be both feasible and highly beneficial to provide frequent telehealth check-ins with patients identified as high risk for suicidality. Although this form of home-based telehealth may not have the same cost-saving benefits as transferring standard in-person treatments to telehealth services (as described above), the use of home-based telehealth to assess suicidality would probably improve outcomes in at-risk patients for little extra cost.

In summary, the preliminary findings in the present case support the use of telehealth in the identification and intervention of suicidality at home.

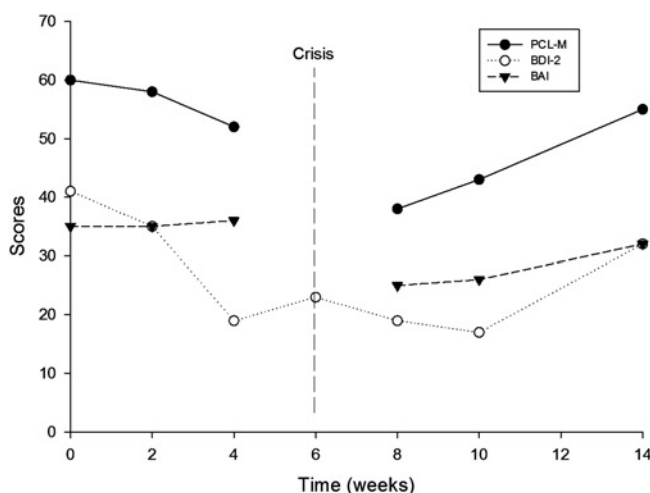


Figure 1 Symptoms of PTSD, depression and anxiety from baseline, during treatment sessions, crisis week and at 30-day follow-up. Crisis = crisis week in which hospitalization occurred; PCL-M = PTSD Checklist; BDI-2 = Beck Depression Inventory – Version II; BAI = Beck Anxiety Inventory

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Research Highlight

Telehealth Technologies for the Delivery of Mental Health Services

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Over the past decade, rural health disparities and access to quality health care in rural settings have been major priority areas in both Veteran and civilian populations. Persons in rural settings generally have fewer health care options and face a number of barriers to care, such as limited financial resources and long travel distances relative to their urban counterparts. Disparities in rural communities are particularly problematic with regard to the receipt of mental health care services. Recent research demonstrates that, relative to those in rural areas, residents in metropolitan areas are 47 percent more likely to receive general mental health services and 72 percent more likely to receive specialized services (Richardson et al., 2009). In response to these and similar data, a number of initiatives have been launched within the VA and other large health care agencies to address disparities in access to mental health care.

Use of Telehealth Technology to Overcome Barriers to Treatment

One proposed method to overcome barriers to mental health care access in rural settings is with the use of telehealth technologies to provide assessment and treatment services from metropolitan areas to patients in underserved rural or geographically remote areas. Telehealth has several advantages for patients over traditional treatment approaches, including decreased patient cost (e.g., lower cost of transportation, travel time, and missed work), decreased provider costs, and increased system coverage area. In addition, telehealth may be useful in overcoming several other barriers to mental health treatments, such as perceived stigma associated with mental health care in active military service personnel and Veterans, by providing services directly in patients' homes.

Preliminary Findings

Telehealth has received preliminary support in a number of treatment settings and with a range of patient populations, including patients in rural areas, older adults, racial/ethnic minorities, patients adjudicated by the courts, and Veterans (for review, see Richardson et al., 2009). In addition, there is strong evidence for both high patient and moderately high provider satisfaction with mental health services delivered via telehealth. Of particular relevance to mental health services in the VA, recent studies support the effectiveness of telehealth for delivering evidence-based psychotherapies to rural Veterans with post-traumatic stress disorder (PTSD) (Tuerk et al., 2010). Similar beneficial effects of mental health care delivered via telehealth also have been demonstrated for other psychiatric conditions (e.g., obsessive compulsive disorder, panic disorder, and anger management).

Ongoing Research

To better understand the effectiveness of mental health services delivered via telehealth to rural Veterans, HSR&D, the U.S. Department of Defense (DoD), and other agencies have recently funded several treatment outcome studies within the Charleston Veterans Affairs Medical Center (VAMC) and its associated VA Health Services Research and Development Research Enhancement Award Program (REAP). These studies include: 1) a randomized controlled trial (RCT) of Behavioral Activation for depression delivered via telehealth or in-person in elderly Veterans (n=224) (Egede et al., 2009); 2) a RCT of Behavioral Activation and Therapeutic Exposure delivered via telehealth or in-person in OEF/OIF Veterans with PTSD (n=220); and 3) a RCT of Prolonged Exposure delivered via telehealth or in-person in OEF/OIF Veterans

with PTSD (n=226). In addition to the above, the Charleston VAMC recently received funding from the Office of Rural Health to initiate a two-year clinical treatment program to provide evidence-based psychotherapies and pharmacotherapies to rural VAMCs and their associated community-based outpatient clinics across three states. The program provided funding for five psychiatrists, five psychologists, and two support staff in addition to telehealth equipment. Together, these projects will greatly improve and

“...there is strong evidence for both high patient and moderately high provider satisfaction with mental health services delivered via telehealth.”

expand our understanding of use of telehealth services in the treatment of a wide range of mental health conditions for rural Veterans or Veterans who may simply prefer telehealth services over face-to-face care.

Conclusions

Telehealth services can overcome many of the current obstacles to quality mental health care in rural settings, including lack of local providers, transportation barriers, lost time from work, and stigma. Preliminary findings suggest that telehealth services are both effective and are received favorably by patients and providers alike. Together with ongoing research and clinical initiatives of the VA, telehealth services stand to bridge longstanding gaps in access and mental health care delivery to rural and underserved Veterans, ultimately resulting in improved mental health outcomes, health care-related costs, and overall quality of life in our nation's Veterans.

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**EARLY TREATMENT WITHDRAWAL FROM
EVIDENCE-BASED PSYCHOTHERAPY FOR PTSD:
TELEMEDICINE AND IN-PERSON PARAMETERS***

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ABSTRACT

Objective: To determine differences in reported barriers to treatment completion associated with telemedicine vs. in-person delivery of evidence-based treatment for PTSD in combat veterans. *Method:* The present study was derived from two ongoing randomized controlled trials (RCTs) comparing

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in-person vs. telemedicine delivery of exposure therapy for PTSD. A one-time telephone assessment of participants who dropped out from the treatment phase of these two studies was conducted, with measures focusing on reported reasons for dropout, and perceived comfort and efficacy of the treatment modality. Dichotomous data were analyzed via chi-square and logistic regression; continuous data via ANOVA. *Results*: Forty-seven of 69 total dropouts participated. There was no difference in rate of dropout between modalities. A greater proportion of participants receiving in-person exposure therapy reported difficulties with logistical aspects of care (e.g., parking), whereas a greater proportion of participants receiving telemedicine therapy reported difficulty tolerating certain stressful aspects of treatment; however, those receiving telemedicine delivered treatment completed more sessions before dropping out. Participants in both conditions reported that they liked and were confident in their therapist. *Conclusions*: Dropout reasons varied according to type of treatment delivery. Recommendations for future research are given in terms of modification of treatment protocol according to delivery modality.

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Key Words: attrition, telemedicine, psychotherapy, PTSD

INTRODUCTION

The most effective treatments for post-traumatic stress disorder (PTSD) were developed in the last 25 years [1, 2] and include Prolonged Exposure (PE) [3] and Cognitive Processing Therapy (CPT) [4]. Both treatments involve self-directed exposure to traumatic memories, and PE also emphasizes exposure to situations and reminders of the traumatic event. Although initially designed to treat PTSD related to sexual violence, PE and CPT have also been tested with combat veterans following widespread awareness of psychological suffering of Vietnam, Persian Gulf, Afghanistan, and Iraq war service men and women [5-7]. Exposure-based treatments such as PE have the most consistent support for their efficacy [1, 3, 8-12], and also appear to decrease other traumatic stress-related problems such as depression [3, 8, 9, 13], anger [14], and guilt [15, 16]. Moreover, Meyers et al. [17] reported that veterans receiving PE and CPT for PTSD use significantly fewer mental health services following treatment. However, Tuerk et al. [18] suggested that this finding may not generalize to those who drop out of treatment.

The Department of Veterans Affairs (VA) has undertaken an unprecedented effort to offer PE or CPT to all veterans with PTSD, and to meet this demand by training all PTSD specialist psychologists and social workers in formal PE and CPT multi-day workshops, followed by 6 months of active consultation [19, 20]. It is therefore disconcerting that, despite the effectiveness of and training resources allocated to these treatments, 25-30% of veterans who begin the 10-15

week course of either PE or CPT fail to complete these interventions [5, 21, 22]. Limited research has been done on reasons for discontinuing treatment. Some studies [e.g., 23] identify differences in dropout between veterans of different conflicts, indicating that age or other factors may play a role in the reason for dropout. Relatively little information, beyond dropout rates for different groups, is available in veteran samples.

Some studies with non-veterans have outlined factors associated with dropout or non-completion of PE or CPT treatments for PTSD, such as greater trauma exposure intensity, lack of engagement between patient/provider [24], high PTSD symptom intensity, alcohol consumption at pretreatment [25], and comorbid personality disorder [26]. Based upon their meta-analysis examining dropout from PTSD psychotherapies, Imel, Laska, Jakupcak, and Simpson [22] concluded that attrition was not due to specific aspects of a given treatment. Rather, they posited that therapist and patient characteristics (e.g., therapist training, appropriate screening regarding patient motivation), and, most importantly, basic logistics such as time and cost to attend treatment, were most likely contributing factors to treatment dropout. This is a particularly important area of study because, if untreated, PTSD symptoms endure for decades and increase likelihood of developing additional complicating mental health problems including substance abuse, depression, and suicide [27, 28].

Telemedicine: A Potential Solution to Dropout from Evidence-Based Treatment for PTSD in Veterans?

As defined by the American Telemedicine Association, telemedicine refers medical information exchanged from one site to another via electronic mediums to improve a patient's health status [29]. Other popular terms include telehealth, telepsychology, telepsychiatry, and telemental health, and common features include remote audio-video conferencing between provider and patient, either to remote clinics, or even directly into patients' homes. Although telemental health services are still growing in terms of their application nationwide relative to traditional treatment delivery modalities [30], and intra- and inter-state licensing issues have not been fully resolved [31], the potential of these methods to export treatments to patients who otherwise would not receive them is great. In addition, telemedicine, particularly when delivered directly into the home, may also help to address treatment dropout due to logistical factors such as travel time or cost [32, 33].

As such, telemedicine may both enhance VA goals [34] of disseminating evidence-based mental health treatment for PTSD to all veterans who need these services, as well as enhance treatment retention by overcoming logistical barriers such as travel time and cost [35-37]. However, as McLean and Foa [38] noted, it is essential that fidelity to evidence-based PTSD treatment protocols be maintained when using telemedicine services, and the relative equivalence of

delivering exposure-based treatments for PTSD in-person vs. Telemedicine is not yet established. To that end, the VA and Department of Defense (DoD) have funded two studies comparing the same exposure-based treatment delivered via in-person vs. telemedicine modalities. Surprisingly, initial data indicate that, although gains are similar for both modalities, predicted advantages for telemedicine in terms of treatment adherence, dosing (e.g., session attendance), and reduced attrition have not been realized, indicating that barriers for completion of treatment via telemedicine may be different than barriers for completion of in-person treatment. For example, barriers associated with telemedicine may center on weaker therapeutic alliance, as the clinicians in a study by Rees and Stone [39] reported, whereas barriers associated with telemedicine may be more logistical in nature (i.e., relative time and travel burden).

The Present Study

We originally predicted that telemedicine would reduce or eliminate logistical barriers to receiving evidence-based treatment for PTSD, such as travel time and cost, and would thus result in reduced dropout from exposure therapy.

However, initial data from these home-based telemedicine vs. office-based PE treatment studies reveals that treatment dropout rates are not statistically different across conditions [40]. Nonetheless, reasons for dropout may vary by treatment delivery modality, and specifying these differences is the first step in adapting treatments to modalities to reduce dropout. Given that tremendous resources are being invested nationwide by VA and DoD to export evidence-based treatments for PTSD via telemedicine and home-based telemedicine [41], it is essential that the unexpectedly high rate of dropout from this modality be studied, and potential factors associated with dropout identified.

Thus, the central goal of the present study is to determine specific parameters and barriers to treatment completion for veterans receiving exposure therapies such as PE in traditional office-based in-person formats compared to those receiving PE via home-based telemedicine.

Hypotheses

We predict that reasons for dropout/barriers to treatment completion will vary in terms of treatment delivery format, with reasons for in-person exposure therapy dropout centering around logistical barriers, and reasons for telemedicine dropout centered around therapeutic relationship factors. Thus, the following hypotheses are made:

1. Considering the entire sample, patients in the telemedicine condition will be less likely to drop out of treatment than those in in-person treatment.
2. Dropouts from in-person delivered treatment will report more problems with stressors and obstacles to obtaining treatment, while dropouts from

telemedicine delivered treatment will report more problems in terms of relationship with therapist. No differences between groups will be observed with respect to treatment demands or perceived relevance of treatment.

3. Perceptions about and comfort with the telemedicine modality of delivering mental healthcare will be higher in dropouts from telemedicine, who had received experience with the modality prior to dropping out, compared to in-person participants.
4. Dropout rate from both treatment conditions will be positively associated with initial severity of symptoms as indicated by baseline scores on scales of Depression (BDI) and PTSD (PCL).

METHODS

Study Design

The present study was derived from two ongoing randomized controlled trials (RCTs) comparing exposure therapy for PTSD delivered via in-person vs. telemedicine methods. A one-time telephone assessment of participants who dropped out from either of these two studies prior to completing eight sessions (the minimum generally accepted “dose” of exposure treatment) was conducted. This assessment measured factors and subjective reasons for treatment withdrawal in order to identify differences between in-person and telemedicine formats.

Dependent Variables

Demographics

Demographic variables were collected at baseline assessment in the parent studies, and include race, gender, age, marital status, employment status, and war theater (Vietnam, Persian Gulf, OIF/OEF).

Barriers to Exposure Therapy Participation Scale

The BTPS [42] items were derived from focus groups of providers and then validated with an outpatient sample of families. For this study, wording of some BTPS items were modified so that they were logically applicable to exposure therapy for PTSD. The scale consists of 68 items (45 items rated on a 5-point Likert scale, and 23 items in a yes/no format; higher scores correspond to greater perceived barriers to treatment), asking participants to rate how often they experienced a variety of barriers that may have interfered with treatment. Items are divided into four general categories, with sum scores derived for each category: Stressors and Obstacles to Obtaining Treatment (item numbers: 1, 8, 16, 17, 31, 37, 38, 40, 42, 49, 50, 59, 64), Treatment Demands (item numbers: 10, 19, 21, 22, 23, 33, 34, 43, 44, 63, 64, 65, 66, 67), Perceived Relevance of Treatment (item

numbers: 4, 5, 6, 9, 11, 13, 21, 24, 25, 30), and Problems in Relationship with Therapist (item numbers: 7, 18, 26, 27, 32, 68). The BTPS demonstrated high levels of internal consistency ($\alpha = .86$) in the first study conducted by Kazdin while researching reasons of therapy non-completion in children with psychopathology (guardians were the responders). With the present sample of veterans, reliability was comparable to that of Kazdin et al. [42], with Cronbach $\alpha = 0.84$.

Telehealth Attitudes Questionnaire (TAQ)

The TAQ [43] is a 23-item self-report measure that asks participants to rate opinions toward telemedicine-delivered mental health care on a 5-point Likert scale (e.g., 1 “Not at all” to 5 = “Extremely”). Areas of assessment include comfort with the medium of care, concerns, and general perceptions. Preference for using face-to-face services also was assessed. The authors report that TAQ has a good internal consistency ($\alpha = 0.88$) and was validated with a sample of rural and urban patients with or without PTSD ($N = 194$).

In addition to the aforementioned measures, baseline data from two symptom intensity rating scales—the PTSD Checklist (PCL) and Beck Depression Inventory (BDI)—were used as covariates in statistical analyses because symptom intensity may play a role in treatment non-completion.

PTSD Checklist-Military (PCL-M) [44]

The PCL is a 17-item self-report measure of PTSD symptoms based on DSM-IV criteria. The PCL uses a 5-point Likert scale response format ranging from “not at all” to “extremely.” Total scores on the PCL range from 17 to 85. The instrument is highly correlated with the Clinician Administered PTSD Scale ($r = .93$), has good diagnostic efficiency ($> .70$), and robust psychometrics with a variety of trauma populations [45].

Beck Depression Inventory-II (BDI) [46]

The BDI-II is a 21-item, 4-point Likert self-report scale, and is among the most widely used instruments to measure depression. Beck, Steer, Ball, and Ranieri [47] demonstrated that the BDI-II has high internal consistency ($\alpha = .91$).

Independent Variable

The independent variable was the delivery modality of exposure therapy: telemedicine to participants’ homes vs. standard, in-person office-based sessions.

Procedure

All participants, including those who withdrew from treatment prior to achieving the minimum “dose” of eight sessions, were asked to continue to allow contact

for study assessments for use in intent to treat analyses. Under the supervision of the Principal Investigator of the parent studies, trained research assistants contacted those participants identified as treatment non-completers (from both in-person and telemedicine conditions) via telephone and asked if they were willing to respond to questions regarding their reasons for treatment dropout so that we might offer better service in the future.

RESULTS

Participants: Demographic and Baseline Psychopathology Across Conditions

All participants met DSM-IV criteria for PTSD. Of the 258 participants who were randomized to either telemedicine or in-person conditions and received at least one exposure treatment session, 69 (26.7%) withdrew from treatment. All were male, 13 (27.7%) were Vietnam Veterans, 13 (27.7%) were Persian Gulf Veterans, and 21 (44.7%) were OIF/OEF Veterans, with no significant differences in theater in terms of treatment condition. Rate of dropout from telemedicine (28.7%, $n = 35$) was not significantly different from that of in-person treatment (25.0%, $n = 34$; $\chi^2 = 0.45$, $p = 0.30$). Forty-seven of the 69 (68.1%) treatment dropouts (27 telemedicine; 20 in-person) agreed to provide data for either or both the TAQ and the BTPS. Age ranged from 21-70 years ($\bar{x} = 46.5$, $SD = 14.5$), and was not significantly different between conditions (in-person $\bar{x} = 41.8$, $SD = 14.1$ vs. telemedicine $\bar{x} = 49.9$, $SD = 14.1$, $F_{(1, 43)} = 3.66$, $p = .06$). A significantly greater proportion of participants in the telemedicine condition were: white; earned less than \$20,000 annually. There were no significant differences in terms of education, employment, or marital status between conditions (see Table 1), nor were there differences in terms of baseline psychopathology (PTSD: PCL in-person $\bar{x} = 55.3$, vs. telemedicine $\bar{x} = 58.5$, $F_{(1, 45)} = 0.96$, $p = 0.41$; Depression: BDI in-person $\bar{x} = 27.0$, vs. telemedicine $\bar{x} = 28.6$, $F_{(1, 45)} = 1.15$, $p = 0.33$).

Data Analytic Plan

First, overall rates of dropout between conditions were examined in the total sample of 258 participants from the parent studies via chi-square. Next, responses from the 47 dropouts who provided data were examined and aggregate subscale scores were derived for each of the four thematic areas of the BTPS related to dropout (i.e., Stressors and Obstacles to Obtaining Treatment; Treatment Demands; Relevance of Treatment; and Relationship Problems with Therapist), and these subscale scores were compared between groups using ANOVA. Next, individual items of the BTPS were dichotomously coded with “never” or “rarely a problem” = 0 and “sometimes,” “often,” and “very often a problem” = 1. These

Table 1. Descriptive Characteristics of Dropout Sample

Demographic	% Total	<i>n</i>	% In-person	% Telemed	χ^2	<i>p</i>
Race						
White	57.8	26	40.0	72.0	4.66	.031
Other	42.2	19				
Marital status						
Single	37.2	16	38.9	36.0	0.04	.548
Married	62.8	27				
Education						
< High school	7.9	3	6.7	8.7	0.75	.660
=> High school	92.1	35				
Employment						
Yes	38.5	15	35.3	40.9	0.13	.491
No	61.5	24				
Income						
Below \$20k	29.7	11	12.5	42.9	4.01	.048
Above \$20k	70.3	26				

items were then examined individually via chi-square for differences between conditions. Similarly, individual items of the TAQ relating to perceptions of and comfort with telemedicine were dichotomously coded with “not at all” and “a little bit” = 0, and “moderately,” “quite a bit,” or “extremely” = 1. Finally, data from the entire parent study (treatment completers and dropouts) were examined via logistic regression to identify relative impact of demographic, baseline PTSD and depression symptom severity, war theater, and treatment condition on likelihood of dropping out from treatment.

Dropout Rates between Conditions

Dropout occurred relatively later in the telemedicine condition as compared to in-person treatment (see Figure 1), with the majority of in-person dropouts occurring by session 3 (63%), compared to telemedicine dropouts (only 50% had dropped out by session 4). Telemedicine participants were relatively evenly distributed in terms of how many sessions were completed prior to dropping out.

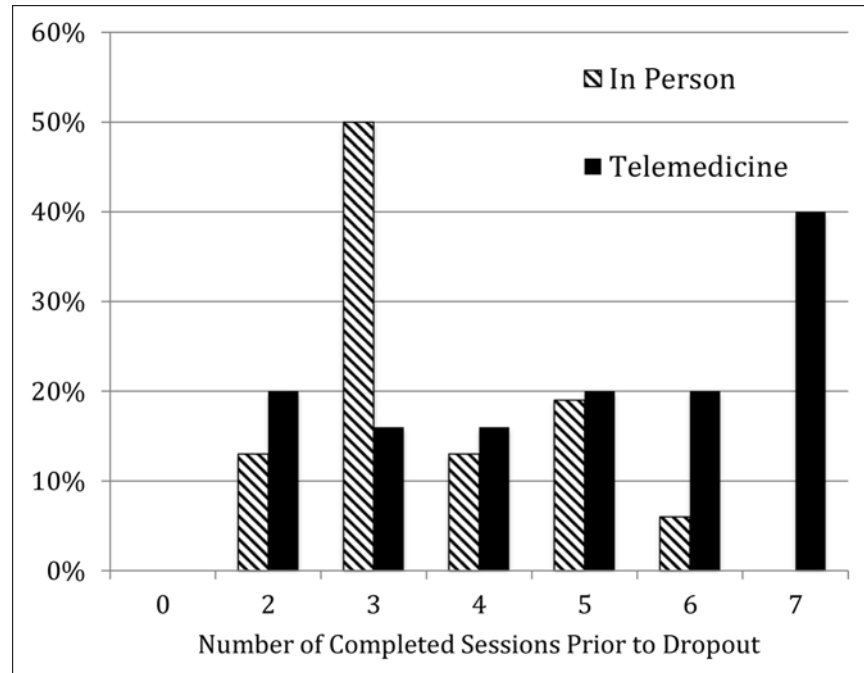


Figure 1. Session number at which corresponding proportions of participants in each condition dropped out of treatment.

Overall BTPS Comparisons of Reasons for Dropout: ANOVAs

Considering the Stressors and Obstacles factor, one-way ANOVA indicated a significant difference between in-person and telemedicine participants, with in-person participants reporting more problems with bad weather, parking, transportation, and work/family obligations ($\bar{x} = 22.5$) compared to telemedicine participants ($\bar{x} = 19.6$; $F_{(1, 45)} = 5.20, p = 0.027$). No other significant differences were noted for any other factor, including Treatment Demands (in-person $\bar{x} = 16.2$, vs. telemedicine $\bar{x} = 15.6$; $F_{(1, 45)} = 0.34, p = .560$); Perceived Relevance of Treatment (in-person $\bar{x} = 20.9$, vs. telemedicine $\bar{x} = 20.7$; $F_{(1, 45)} = 0.01, p = 0.906$), or Relationship with Therapist (in-person $\bar{x} = 9.1$; telemedicine $\bar{x} = 9.0$; $F_{(1, 45)} = 0.04, p = 0.847$).

Focused BTPS Comparisons of Reasons for Dropout: Chi-Squares

Table 2 provides chi-square analyses of items concerning the therapeutic relationship and perceived improvement at the time of dropout. There were no

Table 2. Chi-Square Analyses: BTPS Items Related to Patient-Provider Relationship/Perceived Improvement

Predictive factor	%	<i>n</i>	χ^2	OR	CI	<i>p</i>
<i>I like my therapist</i>			0.79	1.04	0.96-1.12	0.565
In-person	100.0	20				
Telemedicine	96.2	25				
<i>I had a problem sharing personal info with therapist</i>			0.02	1.67	0.52-5.40	0.575
In-person	25.0	5				
Telemedicine	23.1	15				
<i>My therapist was confident treatment would work for me</i>			0.06	0.79	0.10-6.11	0.606
In-person	90.0	18				
Telemedicine	92.0	23				
<i>My therapist was confident in my ability to carry out homework</i>			1.49	2.84	0.51-15.96	0.206
In-person	90.0	18				
Telemedicine	76.0	19				
<i>My therapist was supportive</i>			0.73	0.44	0.07-2.97	0.350
In-person	84.2	16				
Telemedicine	92.3	24				
<i>My therapist was not a veteran, and did not understand</i>			0.09	1.31	0.23-7.57	0.554
In-person	18.8	3				
Telemedicine	15.0	3				
<i>Patient felt better and that tx no longer necessary</i>			4.18	3.51	1.03-11.9	0.040
In-person	65.0	13				
Telemedicine	34.6	9				

differences across all relationship parameters; however, a significantly greater proportion of in-person dropout participants, 65%, reported that they did not perceive the need to continue treatment, compared to only 34.6% of telemedicine participants.

Table 3 provides chi-square analyses of the items related to perceived inability to tolerate treatment, for which there were no significant differences between conditions.

Table 4 provides chi-square analyses in terms of logistical and cost issues related to obtaining treatment. Though not significantly different, transportation problems affected 35% of in-person participants compared to 16% of telemedicine participants (who had to attend study assessments in-person, if possible). Parking was particularly problematic for 75% of in-person participants, compared to 42.3% of those in the telemedicine condition. Because participants were engaged in a research study, there was no cost of treatment per se, but they did incur costs related to other aspects of obtaining treatment. However, despite twice the proportion of in-person participants reporting that childcare and lost employment affected treatment participation, these differences were not statistically significant.

Table 5 offers chi-square analyses of employment-related challenges for participants. Fatigue after work and work precluding having a session were relatively greater problems for those in-person conditions at the borderline levels of significance (50% for in-person condition and 23.1% for telemedicine condition).

Perceptions of and Comfort with Telemedicine: TAQ Findings

Table 6 shows results of chi-square analyses for personal impressions about treatment modalities after having experienced treatment either in-person or telemedicine condition. Significant differences were found between groups with respect to reporting that they would feel comfortable using telemedicine at a local church, with a greater proportion of in-person (72.2%) vs. telemedicine participants (41.7%) reporting comfort. Similarly, 55.6% of in-person participants felt comfortable receiving telemedicine services at a local clinic, compared to only 25% of those who actually were in the telemedicine condition. Interestingly, majorities of both groups indicated that telemedicine would not be as effective as, or preferable to in-person treatment.

Logistic Regression

Logistic regression (Table 7) was conducted on the entire parent data set, including dropouts, to identify baseline predictors for dropout. Results indicated no independent predictors of dropout with respect to demographic factors (i.e., race, gender, age, marital status, employment status, or income), war theater (i.e., Vietnam, Persian Gulf, OIF/OEF), baseline symptomatology (i.e., PTSD or depression), or treatment modality.

Table 3. Chi-Square Analyses: BTPS Items Related to Inability to Tolerate Treatment

Predictive factor	%	<i>n</i>	χ^2	OR	CI	<i>p</i>
<i>Tx added stress to my life</i>			0.73	1.67	0.52-5.40	0.289
In-person	45.0	9				
Telemedicine	57.7	15				
<i>Tx was more work than expected</i>			0.49	1.59	0.44-5.80	0.355
In-person	25.0	5				
Telemedicine	34.6	9				
<i>Atmosphere of sessions was uncomfortable</i>			0.12	0.74	0.13-4.12	0.532
In-person	15.0	3				
Telemedicine	11.5	3				
<i>Could not tolerate thinking about trauma</i>			0.51	0.55	0.11-2.86	0.382
In-person	20.0	3				
Telemedicine	31.1	5				
<i>Could not tolerate assignments to go out in public</i>			0.90	0.50	0.08-3.16	0.386
In-person	40.0	6				
Telemedicine	58.3	7				
<i>Imaginal exposures made me feel bad</i>			0.56	0.48	0.10-2.23	0.288
In-person	11.8	2				
Telemedicine	21.1	4				
<i>I worried about losing control during exposures</i>			1.66	0.36	0.07-1.75	0.183
In-person	20.0	3				
Telemedicine	41.2	7				

Table 4. Chi-Square Analyses: BTPS Items Related to Logistical Issues and Cost

Predictive factor	%	<i>n</i>	χ^2	OR	CI	<i>p</i>
<i>Problems with transportation to session</i>			2.17	0.35	0.09-1.45	0.131
In-person	35.0	7				
Telemedicine	16.0	4				
<i>Bad weather</i>			0.08	0.75	0.10-5.84	0.590
In-person	10.0	2				
Telemedicine	7.7	2				
<i>Parking</i>			4.92	0.24	0.07-0.88	0.027
In-person	75.0	15				
Telemedicine	42.3	11				
<i>Getting childcare to participate in sessions</i>			0.70	0.36	0.03-4.28	0.401
In-person	10.0	2				
Telemedicine	3.8	1				
<i>Lost job or change in income</i>			1.02	0.24	0.07-2.35	0.274
In-person	11.1	2				
Telemedicine	23.1	6				

DISCUSSION

To our knowledge, this is the largest study of treatment dropout comparing different delivery modalities in PTSD treatment. It is extraordinarily difficult to study participants who have dropped out (e.g., terminated prior to completing eight sessions of treatment) of the treatment phase of a randomized controlled trial because their motivation for continued assessment is typically reduced. This is particularly the case for those individuals withdrawing from treatment of an avoidance-based disorder such as PTSD. The aggregate treatment dropout rate from the parent studies for this article, 26.7%, is directly in line with that of prior exposure therapy treatment outcome investigations, and other therapies in general [5, 20, 48]. This means that only one in four recruited participants from parent studies is typically potentially available for assessment as to their stated reasons for withdrawal. As treatment outcome studies are generally powered to control Type II error for primary dependent variables, statistical power for dropout analyses such as those offered here is routinely low. Thus, very few investigations

Table 5. Chi-Square Analyses: BTPS Items Related to Employment

Predictive factor	%	<i>n</i>	χ^2	OR	CI	<i>p</i>
<i>Crises at work made difficult to attend tx</i>			0.12	0.74	0.13-4.12	0.532
In-person	15.0	3				
Telemedicine	11.5	3				
<i>Too tired after work to participate in tx</i>			3.61	0.30	0.09-1.06	0.056
In-person	50.0	10				
Telemedicine	23.1	6				
<i>Job got in the way of having a session</i>			3.61	0.30	0.09-1.06	0.056
In-person	50.0	10				
Telemedicine	23.1	6				

of the reasons for dropout, and even fewer investigations of the reasons for differential dropout with respect to treatment conditions, exist. We were fortunate to have access to two extremely large parent studies with a relatively large subsample of 69 dropouts, 47 of whom (68.1%) provided additional information regarding the reasons for their withdrawal from treatment.

Notably, our hypothesis that telemedicine delivered exposure therapy would result in fewer dropouts from treatment was not supported, and differential dropout rates from in-person vs. telemedicine delivered exposure therapy were not observed. However, participants receiving exposure therapy via telemedicine tended to complete more sessions prior to dropping out. While the therapeutic difference of receiving five sessions instead of three (out of a recommended 8-12, per protocol) may not be significant *statistically*, it does appear that this modality permitted a slight increase in “dose received.” Given the tremendous resources the VA and DoD are investing in telemedicine-delivered mental health care [see 41], even this small advantage is worth noting.

Though overall rates of dropout were the same across treatment modalities, we found some differences with respect to specific reasons for dropout given in each condition. Not surprisingly, and largely consistent with hypothesis and prior research [30], participants receiving in-person treatment reported relatively greater difficulties with logistical obstacles, such as parking or transportation. Moreover, work related issues that could be considered logistical in nature (e.g., too tired to attend sessions after work, work got in the way of making it in to treatment) affected twice the proportion of in-person participants than

Table 6. Chi-Square Analyses: TAQ Items Related to Impressions of and Comfort with Telemedicine

Predictive factor	%	<i>n</i>	χ^2	OR	CI	<i>p</i>
<i>Would feel comfortable using telemedicine at a local church</i>			3.88	0.28	0.07-1.02	0.048
In-person	72.2	13				
Telemedicine	41.7	10				
<i>Would feel comfortable using telemedicine at a local clinic</i>			4.07	0.27	0.07-0.99	0.045
In-person	55.6	10				
Telemedicine	25.0	6				
<i>Would feel comfortable using telemedicine at home</i>			0.30	0.70	0.20-2.50	0.411
In-person	66.7	12				
Telemedicine	58.3	14				
<i>Technology is too sophisticated</i>			0.00	1.00	0.27-3.66	0.631
In-person	33.3	6				
Telemedicine	33.3	8				
<i>Do not think telemedicine would help my problems</i>			0.03	0.89	0.26-3.10	0.555
In-person	38.9	7				
Telemedicine	41.7	10				
<i>Fear what others might think</i>			0.62	0.57	0.14-2.31	0.331
In-person	22.2	4				
Telemedicine	33.3	8				
<i>I prefer telemedicine over in-person tx</i>			0.14	0.79	0.22-2.80	0.480
In-person	38.9	7				
Telemedicine	33.3	8				
<i>Not as effective as in-person</i>			1.48	2.50	0.56-11.23	0.196
In-person	83.3	15				
Telemedicine	66.7	16				

Table 7. Logistic Regression: Demographic Factors, War Theater, and Treatment Condition Predicting Dropout, Controlling for One Another

	B	S.E.	Wald	<i>p</i>	OR	95% C.I. OR	
						Lower	Upper
Race	.229	.34	.45	.502	1.26	.65	2.45
Gender	1.255	1.10	1.30	.254	3.51	.41	30.28
Age	-.053	.61	.01	.930	.95	.29	3.10
Marital status	.041	.36	.01	.910	1.04	.52	2.11
Employment	-.225	.37	.37	.543	.80	.39	1.65
Income	-.011	.42	.00	.980	.99	.44	2.25
Theater	-.019	.29	.01	.946	.98	.56	1.73
BDI	-.023	.02	1.15	.284	.98	.94	1.02
PCL	-.001	.02	.00	.953	1.00	.96	1.04
Tx condition	-.228	.33	.48	.490	.80	.42	1.52
Constant	.951	1.93	.24	.622	2.59		

Note: *N* = 258; War Theater: Vietnam = 0, Persian Gulf = 1, OIF/OEF = 2; BDI: Beck Depression Inventory; PCL: Post-traumatic Stress Disorder Symptom Scale.

telemedicine participants. Additionally, differences in reported problems with other logistical factors associated with travel and childcare, which were reported by nearly twice the proportion of participants receiving in-person treatment may have been even larger if participants receiving telemedicine therapy were not asked to come in-person to the VA research site for all assessments, and if individuals living greater distances from the clinic were included in the randomization to condition (i.e., prior to randomization, all participants had to agree to accept whichever condition assignment they received. As such, individuals who lived far away and faced potential randomization into in-person conditions opted out of the study).

An important study finding is that patient-provider relationship does not seem to be negatively affected by telemedicine. This is consistent with the majority of reports on the matter [see 49] with the exception of Rees and Stone [39]. In the present study, dropouts from both telemedicine and in-person conditions overwhelmingly liked and were confident in their therapists, felt that they could share personal information with them, and felt that their therapists were supportive and understood them. Dropping out of treatment despite a good therapeutic relationship is consistent with literature noting that one's relationship with a

therapist seems independent of the decision to dropout from treatment [50]. This is not to say that the relationship is unimportant. Indeed, as Imel, Laska, Jakupcak, and Simpson [22] and Schnurr and Friedman [51] have stated, poor therapist training and low motivation to use exposure therapy for patients may be related to dropout. Rather, in this case, therapists in both modalities were equally able to convey and sustain positive relationships, and patients in both conditions understood the importance of treatment.

Although no statistically significant differences in exposure therapy treatment demands (i.e., engaging in intense imaginal exposure and homework assignments to confront avoided situations) were observed across conditions, a clear trend was noted across items and is worthy of mention. Specifically, large proportionate differences on most of the items related to ability to tolerate aspects of exposure therapy were observed, indicative of relatively greater problems in the telemedicine condition. For example, 11.8% of in-person vs. 21.1% of telemedicine participants reported imaginal exposures made them feel bad. Similarly, 20.0% of in-person vs. 41.2% of telemedicine participants reported that they worried about losing control during exposure trials; and 40.0% of in-person vs. 58.3% of telemedicine participants indicated that they could not tolerate assignments to go out in public.

Overall, considering the general trend indicated in Table 3, data suggest that participants in the telemedicine condition who dropped out of treatment were having more difficulty with specific aspects of exposure therapy compared to those receiving exposure therapy in-person. This is in keeping with cautions by Morland, Greene, Ruzek, and Godleski [36], and consistent with findings of Tuerk, Ruggiero, Yoder, Gros, and Acierno [52] who noted that a proportion of patients receiving exposure therapy via telemedicine evinced extreme hypervigilance relative to those receiving the same treatment via in-person condition. These findings across samples are somewhat worrisome, as some had feared that dropouts from the telemedicine condition would report fewer logistical issues, but more problems related to dealing with stressful treatment components. Therefore, it may be the case that exposure therapies delivered via telemedicine should proceed more slowly in order to retain participants who would otherwise dropout from therapy. If this modification were successful, telemedicine delivered exposure therapy would actually have a *lower* rate of dropout than in-person exposure therapy, rather than equal rates as observed here.

Some interesting findings with respect to patient perceptions of treatment modalities were in direct contrast to study hypotheses and included the fact that those in the telemedicine condition were *less* likely than those receiving in-person treatment (i.e., those who had never used telemedicine), to report feeling comfortable using telemedicine to receive treatment at a church or clinic. Additionally, both groups perceived that telemedicine would not be as effective as in-person treatment, and only about a third of both groups indicated that they preferred telemedicine over in-person treatment, despite increased convenience of the

former. Finally, a great majority of dropouts from in-person treatment reported that they felt no clinical need to continue treatment compared with the participants in telemedicine condition. However, as all of these participants met full criteria for PTSD upon study entry, and as virtually all received far less than a therapeutic dose of exposure therapy, it is unlikely that these participants were actually asymptomatic.

Limitations

This study was not without limitations. Most notable were the small cell sizes of some chi-square calculations, due to small overall dropout sample size. Moreover, despite attempts to query participants immediately upon dropout, some questionnaires were complete several months later. Ideally, these questions would be asked immediately after dropout to identify the most salient reasons for withdrawal. Further information regarding reasons for dropout may have been gleaned from a review of case notes, but this was beyond the scope of the current study. Finally, as studies of treatment dropout are so rare, questionnaires used to identify reasons for premature treatment withdrawal lack standardization or widespread use. Indeed, it was necessary to use an adapted version of one of the few available scales with any history of use.

Conclusion and Future Directions

Exposure therapy is an effective treatment for PTSD, and its successful completion reduces future utilization of mental health services by veterans [19, 38, 53]. As such, identifying and resolving barriers to effective treatment completion is important. This study identified several barriers that may have contributed to dropout, and these barriers differed in terms of treatment delivery modality. Not unexpectedly, veterans receiving treatment in-person reported more problems with logistic and work- or time-related factors that could be resolved by telemedicine. These problems probably contributed to earlier termination compared to the telemedicine condition (i.e., after completing fewer sessions than telemedicine). Of concern, however, was the finding that veterans receiving treatment via telemedicine reported higher levels of discomfort with aspects of exposure therapy. This, combined with evidence from prior studies [36, 52] that found increased hyper-vigilance symptoms in telemedicine vs. in-person PTSD treatment groups, may suggest a need for clinical and administrative modifications to the standard exposure therapy protocol when delivered via telemedicine. Specifically, when treating PTSD via telemedicine, treatment should probably proceed more slowly, with gradual introduction of intense exposure exercises and a concomitant increase in the overall number of sessions by 3-5. Second, offering a hybrid, in-person + telemedicine option may be useful, and would empower patients to match the modality of treatment delivery to the stage of treatment they are completing. Perhaps, earlier treatment sessions where exposure therapy

assignments are first implemented could be offered in-person, followed by an option to continue treatment via telemedicine. Third, other health specialties (e.g., organ transplant [54]; and cancer [55]) have effectively incorporated “peer navigators” into treatment and treatment retention procedures, and these individuals may be useful in helping patients to accomplish difficult aspects of treatment, such as in vivo exposure assignments. Indeed, this is directly in line with the recent DoD and VA implementation of “Peer Support Programs” [56], and may serve to address the dropout issues associated with telemedicine-delivered exposure therapy so that, eventually, those Veterans in need of care receive it in full measure.

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Ten Year Revision of the Brief Behavioral Activation Treatment for Depression: Revised Treatment Manual

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Abstract

Following from the seminal work of Ferster, Lewinsohn, and Jacobson, as well as theory and research on the Matching Law, Lejuez, Hopko, LePage, Hopko, and McNeil developed a reinforcement-based depression treatment that was brief, uncomplicated, and tied closely to behavioral theory. They called this treatment the brief behavioral activation treatment for depression (BATD), and the original manual was published in this journal. The current manuscript is a revised manual (BATD-R), reflecting key modifications that simplify and clarify key treatment elements, procedures, and treatment forms. Specific modifications include (a) greater emphasis on treatment rationale, including therapeutic alliance; (b) greater clarity regarding life areas, values, and activities; (c) simplified (and fewer) treatment forms;

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(d) enhanced procedural details, including troubleshooting and concept reviews; and (e) availability of a modified Daily Monitoring Form to accommodate low literacy patients. Following the presentation of the manual, the authors conclude with a discussion of the key barriers in greater depth, including strategies for addressing these barriers.

Keywords

depression, reinforcement, activation, matching law

Following from the seminal work of Ferster (1973) and Lewinsohn (1974), as well as theory and research on the matching law (Herrnstein, 1970; McDowell, 1982), Jacobson et al. (1996) found that the behavioral components of cognitive behavior therapy (CBT) for depression (Beck, Rush, Shaw, & Emery, 1979) performed as well as the full CBT package. Jacobson et al. referred to the behavioral component of CBT as behavioral activation (BA), and it included a wide range of behavioral strategies across 20 sessions, including (a) monitoring of daily activities, (b) assessment of the pleasure and mastery that is achieved by engaging in a variety of activities, (c) the assignment of increasingly difficult tasks that have the prospect of engendering a sense of pleasure or mastery, (d) cognitive rehearsal of scheduled activities in which participants imagine themselves engaging in various activities with the intent of finding obstacles to the imagined pleasure or mastery expected from those events, (e) discussion of specific problems (e.g., difficulty in falling asleep) and the prescription of behavior therapy techniques for dealing with them, and (f) interventions to ameliorate social skills deficits (e.g., assertiveness and communication skills).

From Jacobson et al. (1996), Martell, Addis, and Jacobson (2001) and then Martell, Dimidjian, and Hermann-Dunn (2010) provided a more comprehensive BA treatment manual that was expanded to include a primary focus on targeting behavioral avoidance as well as a variety of other related strategies more indirectly related to BA (e.g., periodic distraction from problems or unpleasant events, mindfulness training, and self-reinforcement). Lejuez, Hopko, and Hopko (2001) developed a compact 12 session protocol limited to components directly related to BA, including a focus on activity monitoring and scheduling with an idiographic, values-driven¹ framework supporting this approach. In recognition of the findings of Jacobson et al., Lejuez and colleagues (2001) named their approach brief behavioral

activation treatment for depression (BATD), with the original version of the manual published in this journal.

Hopko, Lejuez, Ruggiero, and Eifert (2003) provided a thorough comparison of the treatment components of BA and BATD, including strengths and weaknesses, as well as a review of the supportive literature for the two approaches. Comparative effectiveness studies have not been conducted to determine the superiority of either approach or for which patient's each version would be best suited. However, some have hypothesized that BA may be the treatment of choice in cases of more complicated depression, whereas BATD may be more appropriate in cases where a more straightforward and brief approach is desirable (Kanter, Manos, Busch, & Rusch, 2008; Sturmey, 2009). In addition to conceptual pieces (e.g., Hopko et al., 2003; Jacobson, Martell, & Dimidjian, 2001; Sturmey, 2009), specialized books (Kanter, Busch, & Rusch, 2009), and meta-analyses (Cuijpers, van Straten, & Warmerdam, 2007; Ekers, Richards, & Gilbody, 2008; Mazzucchelli, Kane, & Rees, 2009), recent recommendations from clinical guidelines have indicated that BA is efficacious for treating depression (National Institute of Health and Clinical Excellence [NICE], 2009).

Several key large-scale, randomized clinical trials (RCTs) have indicated that BA is a cost-effective and efficacious alternative to cognitive therapy and antidepressant medication (Dimidjian et al., 2006; Dobson et al., 2008). Several trials provide support specific to BATD. Hopko, Lejuez, LePage, Hopko, and McNeil (2003) showed improved depressive symptoms for patients within an inpatient psychiatric hospital as compared with the treatment as usual at the hospital in a small-scale RCT. In a second study highlighting the brief nature of BATD, Gawrysiak, Nicholas, and Hopko (2009) showed that a structured single-session of BATD resulted in significant reductions in depression as compared with a nontreatment control for university students with moderate depression symptoms. Several studies also have demonstrated efficacy for BATD for depression in the context of other comorbid conditions. In addition to case-controlled studies of individuals with depression comorbid with obesity (Pagoto et al., 2008) and cancer (Hopko, Bell, Armento, Hunt, & Lejuez, 2005), two RCTs support BATD, one among a community-based sample of smokers attempting cessation (MacPherson et al., 2010) and the other among individuals in residential drug treatment (Daughters et al., 2008). In the context of our clinical and research experience with the treatment combined with extensive manual development efforts (including the key informant interviews with patients, counselors, and supervisors), useful modifications to the manual have been made. These fit

well within the framework of Rounsaville, Carroll, and Onkin (2001) on the stage model of behavior therapies research development. Specifically, evidence for BATD has been provided for each part of Stage I, including (a) pilot/feasibility testing, (b) manual writing, (c) training program development, and (d) adherence/competence measure development. Good progress has been made in Stage II requirements of RCTs to evaluate efficacy as noted above, with the more recent studies using revised BATD (BATD-R) manual (Daughters et al., 2008; Gawrysiak et al., 2009; MacPherson et al., 2010). Moreover, although these studies have not explored mediation, they have shown significant changes compared with a control group in activation and reinforcement-based variables hypothesized as mediators, with future work planned to formally test mediation. On the basis of this progress, Stage III work is being conducted, which centers on systematically answering the key questions of transportability (e.g., generalizability, implementation, and cost effectiveness) in unique settings, including residential drug treatment centers for adults and adolescents, a college-orientation program, a junior high school summer scholars program for low-income youth, a hospital-based cancer treatment program as well as international settings, including a community health center with Spanish-speaking patients and a torture survivors recovery program in the Kurdistan region of Iraq.

In considering the development of BATD, it is important to address the role of functional analysis. Although a comprehensive functional analysis is not included in BATD because of the brevity of this treatment approach (Hopko et al., 2003), several treatment components fit well within a functional analytic framework. This is most evident in the selection of activities tied closely to values given the dual focus on (a) identifying positive and negative reinforcers that maintain or strengthen depressive behavior and (b) identifying positive reinforcers that maintain or strengthen healthy behavior across multiple life areas. Establishing values prior to identifying activities helps ensure that selected activities (healthy behaviors) will be positively reinforced over time, by virtue of being connected to values as opposed to being arbitrarily selected. Patients are asked to consider multiple life areas when identifying values and activities to ensure that they increase their access to positive reinforcement in several areas of life rather than in one or two, the latter of which can narrow the opportunities for success. The review of monitoring with planned activities at the start of each session also tied it closely to the principles of functional analysis. Specifically, the patient and therapist consider planned activities that were not completed and develop a plan for successfully completing these activities in the coming week. Similar to what might be done in a more formal functional analysis, this plan could include

selecting smaller, more attainable activities in line with the process of shaping or using contracts to address environmental barriers in completing activities by soliciting social support to provide a more supportive environment. Alternatively, this plan could include dropping activities (and possibly values) for which the potential positive consequences of completion do not outweigh the negative consequences or where the environmental barriers to completion are not modifiable.

Presentation of BATD-R

The purpose of this article is to provide a revised manual of BATD that reflects modifications over the past 10 years, largely focused on simplifying and clarifying the key treatment elements, procedures, and treatment forms for both research and clinical settings. These changes in no way alter the theoretical underpinnings of the approach but instead are structural in nature to improve delivery and patient acceptability. As a result of these efforts to streamline the protocol, this revised manual (i.e., BATD-R)² provides the treatment in five unique sessions and includes five additional sessions to allow for concept review and termination/posttreatment planning. Although there has yet to be systematic work comparing different lengths of treatment, this 10-session protocol serves as a useful standard recommendation because it presents the manual in the fewest number of sessions needed to provide all unique material and concept reviews as indicated above. However, additional sessions are certainly not contraindicated, and BATD-R can be modified to include fewer sessions when needed, with studies indicating significant reductions in depression from 6 to 8 sessions (e.g., Daughters et al., 2008; MacPherson et al., 2010) and one study even showing some benefits of BATD-R with a single session (Gawrysiak et al., 2009). It is notable that although research protocols require a preset number of sessions, BATD-R also can be used very flexibly in clinical settings with the treatment shortened or extended on a case by case basis given the unique characteristics of the patient and the setting. BATD-R is also quite amenable to be used in conjunction with other approaches in the case of comorbidity, patient preference, or as supported by clinical judgment. Taken together, BATD-R can be provided in a manualized packaged program with evidence providing support across a range of sessions, it also used flexibly where strict adherence to a manualized protocol is not a requirement.

Although streamlining the protocol is a clear goal in BATD-R, the revised manual also was developed with the goal of including (a) greater emphasis on treatment rationale including therapeutic alliance, (b) greater clarity

regarding life areas, values, and activities, (c) simplified (and fewer) treatment forms, (d) enhanced procedural details including troubleshooting and concept reviews, and (e) the availability of a revised daily monitoring (with activity planning) form to accommodate low literacy. We also provide a sample treatment adherence checklist in Appendix A. As with the original manual, the revised manual is written to be used by both the therapist and patient. As an important procedural note, we recommend that the patient keep the manual and copies of all treatment forms and homework, including completed monitoring forms from previous weeks over the course of treatment. This allows patients the opportunity out of session to reflect on their values, associated activities, and changes in daily activities over time. We also recommend that the therapist make copies of all completed forms and retain them for treatment planning to provide a back up if the patients do not bring their manual to session. Before presenting the revised manual, we provide a discussion of each change and the associated rationale.

Greater Attention to the Treatment Rationale, Including Therapeutic Relationship

To move expeditiously to therapeutic content, the original manual provided only limited guidance on how to provide patients with the treatment rationale. Because the patient's understanding of the treatment rationale is an essential first step of treatment that sets the framework for all sessions, we now provide therapists with more clear and comprehensive detail on the treatment rationale. Our experience indicates that a greater level of attention to the treatment rationale also has important implications for developing a strong therapeutic alliance (see Daughters, Magidson, Schuster, & Safren, 2010; Lejuez, Hopko, Levine, Gholkar, & Collins, 2006), and facilitates therapist training and treatment fidelity. In presenting the rationale, it is important to note that while the treatment is manualized and sessions are structured, BATD-R allows for ample flexibility toward the particular background, goals, and skills of the patient. This latter point is addressed in further detail throughout the manual and in the discussion.

Greater Clarity Regarding Life Areas, Values, and Activities

The revised manual provides greater clarification for the relationship and distinction between life areas, values, and activities as well as the manner in which they are integrated in treatment. For each life area, the patient is asked

to identify their values, which are broad descriptions of how they would like to live within that particular life area. Activities are the most reducible and concrete manifestations of these values. Activities are specific behaviors that can be accomplished on a daily basis and are within the patient's current ability and resources. For example, for the life area of relationships, a mother might identify the value of "being a good parent," with activities, including "taking a walk with my daughter each Tuesday evening" and "telling my daughter that I love her once each day."

The current manual has been simplified to include a single form that links life areas, values, and activities that provides greater clarity in the distinction between these three concepts and how they are connected to one another in treatment. Activities are derived from values, and once selected, they become the work of therapy. Patients with depression often have the tendency to select activities that are aversive, difficult to complete, not closely linked with their values, and/or associated with delayed as opposed to immediate reinforcement. For example, a patient who identifies the value of "physical fitness" might select activities that are motivated by the desire to lose a large amount of weight (e.g., jog 3 miles 5 times a week), which initially may be aversive, difficult to accomplish, and have low levels of immediate reinforcement. As a result, it is unlikely that the activities will be sustained, increasing likelihood of failure. The revised manual more strongly emphasizes that activities are directly tied to values, are small manageable steps that can occur on a daily basis, and are identified as enjoyable and/or important by the patient so that they have the capacity to be immediately reinforcing. Thus, the patient who values fitness might instead consider smaller and less aversive activities that are also healthy and meaningful such as taking the stairs instead of the elevator; preparing healthy recipes; light intensity, enjoyable exercise such as walking with a friend; and/or joining a health-related Internet chat group to garner social support for their lifestyle changes. As depressed behavior often is largely maintained by negative reinforcement that is immediate and certain, selected activities that provide positive reinforcement that is also immediate and certain are important for displacing depressed behavior and ultimately leading one to a life consistent with one's values.

Although patients must maintain their daily focus on activities throughout treatment, a common problem is when patients attempt to move directly from the life area to the activity without considering their values in that life area. For example, in the life area of education/career, a patient may immediately suggest returning to school in his or her previous area of study. Although this ultimately may be a good choice for this patient, it is important for the patient to first understand their values in this life area that will guide the selection of

activities. Thus, the patient first should consider what they value about education, such as the opportunity to learn or to provide improved employment opportunities and then select the most relevant activities. This consideration might suggest not only returning to the same area of study but also a slightly different focus of study or taking a different path altogether. Using values as a starting point to select meaningful activities will increase the likelihood that the activities will be a match to the values and that they ultimately will be accomplished.

Taking a closer focus on activities, a patient might at times select an activity that cannot feasibly be completed because it requires several intermediary steps. In this case, the patient and therapist can identify the smaller intermediary activities and plan these at first. For example, if the life area is education/career and a value is obtaining advanced education, an activity might be to attend a class at a local community college. However, the patient may first need to identify local schools with relevant programs, obtain a list of courses, and set up an appointment to talk to a school advisor about the available courses as initial steps. In cases where patients are repeatedly unable to complete an activity they strongly report valuing, efforts to find intermediary smaller activities may be a useful strategy to provide the support and momentum the patient needs to make progress. Those activities are broken into the smallest, most manageable steps that are essential in maximizing the patient's weekly success experiences and minimizing failure experiences.

Simplified (and Fewer) Treatment Forms

In addition to the development of the Life Areas, Activities, and Values Inventory, several important changes were made to the treatment forms in the original BATD manual. The life areas checklist, rewards, baseline assessment of depressive symptoms, and the progress graphs are four forms that were omitted from the original manual. The life areas checklist held some value in terms of providing ideas about possible activities but was removed because it could be viewed as overly general or insensitive to cultural differences. Moreover, this checklist at times actually constrained patients from thinking more creatively about activities that are linked to their values and resulted in arbitrary selection of activities as opposed to values-driven activities. Rewards were removed because they often created confusion when the selected rewards were activities themselves (as opposed to tangible good etc.), obscuring the difference between rewards for progress and weekly activities as part of the treatment itself. In addition, the rewards process often was limited by the need for the patient to serve as the gatekeeper for their reward. The baseline assessment of depressive symptoms and the progress

graphs were removed for similar reasons. The collection of the key outcome data is a core feature of BA and behavior therapy in general, but this may be best left up to the therapist to provide the most appropriate, timely, and comprehensive assessment. In addition to the omitted forms, important changes also were made to the Daily Monitoring Form and contracts outlined below.

The Daily Monitoring Form. The original Daily Monitoring Form was used only for the first 3 weeks of treatment largely to allow patients to obtain a clearer understanding of their daily activity. This form is now used throughout the entire course of treatment. Hourly mood ratings were eliminated because many patients have difficulty in noticing and reporting subtle mood changes over such a short period of time. Instead, the patient is asked to rate the level of enjoyment and importance of each activity, and make a single overall mood rating for the day. This modification is in line with the concept of desynchrony, which suggests that cognitive and mood changes may be delayed even when tied to positive behavior change (Rachman, 1978). The new ratings may help the patients understand that doing enjoyable and important activities will lead to better mood over time, even if that association is not evident in the moment.

In the original BATD manual, the behavioral checkout and master activity log were used to assess activity planning and completion, but they were somewhat complex; in their place, the Daily Monitoring Form (see Form 1, available from <http://bmo.sagepub.com/supplemental>) also is now used for activity planning in later sessions. The goal of the new approach was to combine the function of these three forms into one simple highly intuitive form (i.e., Daily Monitoring Form) that is used throughout therapy.

Contracts. The purpose of contracts in the original manual was to address the unfortunate reality that the actions and statements of others can punish the patient's healthy behavior and possibly provide negative reinforcement for their unhealthy behavior. This goal fits with behavioral theory but was reported by many therapists and patients as being difficult to address in the context of BATD and as having the potential for unexpected negative effects. For example, some patients reported difficulty in understanding how to convey to a family member who is handling responsibilities for them that these efforts may be contributing to the patient's depression without making that family member feel blamed and the patient feel guilty or manipulative. As an alternative approach, the emphasis of contracts has been altered from a focus on the unhelpful behaviors of other people to concrete strategies for the patient to get assistance and social support for their activities. Specifically, contracts now involve the patient identifying (a) an activity that is difficult to accomplish, (b) up to three supportive individuals who might be able to assist/support, and (c) specifically how and when each person might do this. This

change in emphasis provides the patient with an opportunity to identify concrete needs and provides a specific plan on how to obtain the help needed. Although contracts no longer target the negative “enabling” behaviors of others, it is expected that if patients can request concrete ways for others to be more supportive of their healthy behavior, the unsupportive behaviors of those individuals also can be displaced by more supportive behaviors. Given that the content of contracts is now directly tied to support for activities, this component of treatment has been moved to occur after the introduction of activity planning (Session 5), as opposed to before activity planning in the previous manual.

Enhanced Procedural Details, Including Troubleshooting and Concept Reviews

In the revised manual, more structure and guidance are provided to the therapist for troubleshooting treatment challenges, including difficulty in identifying values and/or selecting and planning activities as well as noncompliance to daily monitoring. In addition, concept reviews have been added to later sessions. In addition to providing a refresher for the patient, reviewing core concepts at a point when depressive symptoms have begun to improve can deepen the patient’s understanding of the concepts and reinforce continued use of BA strategies after therapy. The concept review is also especially important if depressive symptoms have not improved because it provides the opportunity to reinforce the treatment rationale and for continued practice of treatment strategies. The revised manual also now offers more detailed material on posttreatment planning to encourage patients to continue monitoring and planning after treatment, thereby helping maintain the gains after therapy has ended. In addition to the material provided in the manual, the Discussion section following the presentation of the manual addresses key barriers in greater depth, including strategies for addressing these barriers.

Revised Daily Monitoring (With Activity Planning) Form for Low Literacy

Although a strength of BATD-R is its uncomplicated nature, the reliance on paper-and-pencil Daily Monitoring Forms presents some challenges to low-literacy applications. Enlisting a supportive family member to help with written assignments is one strategy; however, we now also provide a revised supplemental version of the daily monitoring and activity planning form that low literacy patients can complete without assistance from a literate other (Form 1 Supplement, available from <http://bmo.sagepub.com/supplemental>).

As indicated in the manual below, this modified monitoring form includes stickers with symbols that represent different activities that can be used in place of a written description of each activity. In the sample included here, we provide seven common activity stickers but acknowledge that the images may not be appropriate for all cultures and ages. Therapists and researchers are encouraged to develop unique forms with symbols that are most relevant culturally as well as age appropriate for a particular patient population. Although to date we have used these forms only with low-literacy adults, a similar approach would be useful when using the treatment with children or the elderly where the standard monitoring forms may be less developmentally appropriate and/or difficult to complete.

When using this revised supplemental version of Form 1, the text in the manual remains unchanged with the exception of adding the following text when daily monitoring is first introduced in Session 1.

At the top of the form you will see a series of pictures, each representing a common daily activity. We will now discuss what each picture means. For example, the first picture is a fork and knife, and this represents the activity of eating. The other activities indicate sleeping, exercising, watching TV, spending time with family, doing housework, and talking on the phone. We also can develop new pictures that fit with your daily activities. You can have up to 20 pictures. Whenever you complete an activity, write the number corresponding to the picture that best represents your activity.

For a patient with some ability to read and write, space is provided to write in any details to supplement the activity stickers. Information specific to the low-literacy form is not included in the manual as presented below to limit confusion, but the information in this current paragraph easily can be added in cases where the low-literacy monitoring form would be useful.

The Revised Treatment Manual for the BATD-R

Session 1

Session 1 Key Elements:

1. Discussion of Depression
2. Introduction to Treatment Rationale
 - What about stressful life events and loss in your life?

3. Introduction to Daily Monitoring (Form 1)
 - Enjoyment and importance ratings
 - When should you complete the Daily Monitoring Form?
4. Important Points About the Structure of This Treatment

Discussion of Depression. This treatment was designed to help you with depression, which is defined as an extended period of time of at least 2 weeks in which a person experiences a depressed mood or a loss of interest or pleasure in activities that were once enjoyed, along with several other symptoms. Many people will experience at least one episode of major depression in their lifetime and it can affect people of all ages, cultures, income, education, and marital status. Depression can have a major impact on your life, including decreased optimism or motivation, low self-esteem, trouble concentrating (paying attention), self-harm, and/or suicidal thoughts and behavior. Medical problems associated with depression include heart disease, chronic pain, type 2 diabetes, substance use, fatigue, and malnutrition. Individuals with depression often keep to themselves and avoid their normal activities. This isolation can cause additional problems, such as loneliness, relationship problems, decreased job satisfaction or unemployment, and educational failure. Given all these resulting problems, the identification and treatment of depression are critical.

The specific symptoms of depression may include the following:

- Feeling sad or down most of the time,
- Loss of interest in usual activities,
- Significant weight loss or weight gain,
- A decrease or increase in appetite,
- Difficulty sleeping or sleeping too much,
- Feelings of agitation or irritability,
- Feeling tired or loss of energy (fatigue),
- Feelings of worthlessness or excessive/inappropriate guilt,
- Difficulty thinking or concentrating or making decisions,
- Crying spells,
- Feeling hopeless,
- Suicidal thoughts and/or attempts.

Although most individuals experience some form of the above symptoms from time to time, a diagnosis of depression only is made if you feel strong feelings of distress, or you are having a lot of trouble with your day-to-day functioning. Some people can identify stressful life events including loss of

a loved one, financial difficulty, or job loss as a reason for their depression. However, the specific causes of depression are rarely known, and depression might start without warning. Regardless of the initial cause of depression, depression results in a specific pattern of behavior that leads to feelings of loneliness, sadness, isolation, lack of purpose, and/or hopelessness. The key to feeling better is not in identifying the root cause of depression because this is nearly impossible, but rather in understanding and changing your depressed patterns of behavior.

Introduction to Treatment Rationale for Behavioral Activation. Treatment will involve an approach called Behavioral Activation. According to this approach, the key to a depression-free life is to develop healthier patterns of behavior where each day contains important and/or enjoyable activities that help you feel fulfilled and as if your life has purpose. Once you have identified the areas of your life you want to focus on and your values within those areas, we will begin to identify and plan daily activities that help you to live according to the values that are most important to you. This is important because when you accomplish activities that are closely linked to what you value in life, you are more likely to have positive and enjoyable experiences, which will improve how you feel and think about your life. It is difficult to feel depressed and hopeless if you are regularly doing activities that you feel are valuable and worthwhile and that bring you a sense of pleasure and accomplishment.

This manual targets changing your behavior as a method for improving your thoughts, feelings, and overall quality of life. Many individuals with depression often feel tired and lack the motivation to do various activities; thinking that once they have more energy and think more positively, they will be able to do the activities they have ignored or have been unable to accomplish in the past. The opposite approach is taken in this treatment—behavior is changed first as a way to increase energy and motivation as well as positive thinking and feelings. The focus on behavior change, however, does not mean that we ignore thoughts and feelings. Instead, we suggest that negative thoughts and feelings will change only after you change your behavior and have more positive life experiences. Healthy behavior is defined as behavior that is directed toward improving your quality of life and attaining the values you have in your life. In contrast with healthy behavior, unhealthy (depressed) behavior generally is not directly related to improvements in the quality of your life and does not move you closer to living according to your values.

You should know that it is possible for you to be active, yet still be depressed. This can happen if you feel overwhelmed with activities that are

unfulfilling or forced by others. For example, although you may be busy at work and home, these activities may be focused only on helping others. Although it certainly is important to help others, it is never a good idea to focus so much on others that your own needs and feelings are completely neglected. Focusing entirely on the needs of others may result in feelings of emptiness and dissatisfaction, followed by confusion and guilt for having such feelings. Thus, it is important not only to have many activities in your life but also specifically to have activities that bring you some degree of pleasure and fulfillment.

What about stressful life events and loss in your life? Often people who have experienced stressful life events and loss end up having long-standing feelings of depression. After something very bad has happened or loved ones are lost, life can feel empty or meaningless. It can feel as if there is very little to live for and that all the support and happiness you once had is gone forever. Thoughts and bad dreams may keep coming back about the bad experience or about the loved one who has passed away. In this treatment, it is very important for the therapist to understand what happened to you, how you felt about it, and most importantly, how it affects your life now. At every session, we will spend some time talking about events in your life that have led to your depression. However, this treatment requires more than just talking about what has happened. In addition, we also will spend some time trying strategies that will help you to live a more fulfilling and meaningful life going forward. Nobody can change events of the past, but we can plan for a better future by what we do today. Often, when people have experienced stressful life events and loss, negative thoughts and feelings about the event come to mind all the time. It becomes hard not to think about it or feel terrible that it happened. We find that it is important to understand how these experiences affect your current behavior. Often after a loss or stressful life event, people change how they spend their time, and this can lead to depressed behavior patterns. For example, you might find it difficult to sleep at night, and so you spend a lot of time sleeping during the day. If you sleep during the day, you may be unable to perform important daily activities or lack the energy and desire to socialize with family and friends. This treatment will help you to identify activities that might be making your depression worse and can help you modify or change those activities so that you feel depressed less often. After a loss or stressful event, it can often take time and focus to decide how you want to live your life moving forward, and this treatment is designed to help you with that. The goal is to help you make the best life possible for yourself. This can be hard work, but if you trust the process you will find that good things will come from your effort. We will

work at a pace that is comfortable for you. Are you willing to work on this together?

Daily Monitoring Form (Form 1). Because the main focus of this treatment is increasing your healthy behavior, it is important to become aware of what you do each day. Although you probably have an idea of how you spend your time, we really need exact information about what you are doing each day. To that end, we would like you to spend the next week writing down all of your activities. This is useful for several reasons. First, it will help us to identify the pattern of your depressed behaviors and moods. Every person is different, so it is important for us to see how depression is affecting your daily activities. Being aware of your patterns might motivate you to increase your healthy activity level. Second, this will provide us a measure of your current activity level, which we will then be able to compare with your activity level later in treatment, after you use the treatment strategies. Finally, a close look at your daily routine might lead you to develop some ideas about where you might consider adding some healthy activities to each day. To monitor your current activities, you keep a detailed log (hour by hour) of all activities that you do, including those that seem insignificant, such as sleeping or watching television. You will use the Daily Monitoring Form (Form 1) to record your activities. You will need to complete one form for each day. For now, just do things as you normally would do them. Your only task is to write down your activities, trying to be as accurate and as thorough as you can.

Enjoyment and importance ratings. Once you have recorded the activity, you then rate the activity in terms of two things: (a) enjoyment and (b) importance. For the enjoyment rating, think about how much you enjoy the activity. In other words, think about how much fun or pleasure you have when you are doing the activity. You will use a scale from 0 to 10 to rate enjoyment. A rating of 0 will be for activities that you do not enjoy at all. A rating of 10 will be for activities that you enjoy very much. For example, going to a picnic might be considered a very enjoyable activity and be assigned a rating of 10, whereas washing the dishes might be considered no fun at all and be assigned a rating of 0.

For the importance rating, think about how important in your heart it is to have this activity in your life. On a scale from 0 to 10 rate each activity, with 0 meaning that the activity has no importance at all and 10 meaning that the activity is of the highest importance in your life. For example, going to work is probably a very important activity in your life because it is your source of income to support your family. You might give your work a rating of 10. However, watching television is probably a less important activity in your life. You might give watching TV a low rating such as a 2.

Consider for a moment that some activities might be very important but not very enjoyable, and other activities might be very enjoyable but not very important. For instance, washing clothes might be high in importance but not very enjoyable, whereas watching a favorite TV program might be very enjoyable but not very important. Meanwhile, some activities may be rated as high on both enjoyment and importance and others as low in enjoyment and importance. For example, eating dinner with family might get rated as a 9 in enjoyment and importance because it is both very enjoyable and important. However, lying in bed in the afternoon might be rated a 0 in both enjoyment and importance because it is neither important to your life nor very enjoyable. In addition to enjoyment and importance ratings for each activity, you also should provide a single rating for your overall mood for the day at the bottom of the form. The rating should be between 0 for the most negative mood and 10 for the most positive mood. You don't have to rate your mood for each hour of the day, just a general rating of your mood for the day.

When should you complete the Daily Monitoring Form? To complete your Daily Monitoring Form, you might choose to record your activities as you go through your day or you might prefer to wait until the end of the day to do so all at once. You may do whichever you prefer. However, it is best to record your activities on the day that they occurred, as opposed to several days later. For example, on Wednesday it will be difficult to remember the activities you did on Monday. We will spend a lot of time reviewing your Daily Monitoring Forms each week, so be sure to complete and bring the completed forms to each session.

Important Points About the Structure of This Treatment. Before we finish today, it is important to understand that this is a structured treatment. This means that the treatment involves a series of steps. Depression is a problem that builds over time, so it is not possible to overcome it in a few days or after just one or two visits. It takes some work and it is very important to practice all of the strategies we will review in this treatment. Although you may notice some immediate benefits in the first few sessions, only coming to a small number of sessions may not be helpful in the long term. Consider the example of cancer treatment. Attending regular chemotherapy sessions is essential to completely eliminating the cancer. Coming to only half of your chemotherapy sessions or just one or two might slow the cancer down temporarily but it is likely to come back unless the full course of treatment is delivered. Skipping several weeks between chemotherapy sessions could also slow the treatment effect, making you vulnerable to cancer returning or only partially remitting. The cancer would continue to grow between sessions

and only worsen. Although it might seem very different, the treatment for depression requires the same structure and consistent attention. For this reason, we ask that you commit to try to come to all scheduled sessions. We realize that sometimes unforeseen events can arise that might cause you to miss a session, and this is understandable, but we urge you not to cancel a session because you are feeling depressed, tired, or unmotivated. Most people find that even when they are feeling depressed before a session, they are likely to feel much better after the session. This idea of motivating yourself to take positive steps like attending treatment sessions even when you are feeling depressed, tired, or unmotivated is an approach that will help you tremendously in this treatment and in overcoming depression.

In addition to the importance of regular attendance, these sessions will include both assignments for you to complete during our session and assignments for you to work on at home. Completing the homework assignments is very important for progress as we find that people who regularly complete the homework assignments see the most improvement in their lives. If you find any homework assignments difficult or overwhelming, we can discuss this and come up with ways to make it easier for you to do. It is very important that we work together to make sure that this process feels comfortable and useful to allow you to complete these important assignments.

Assignments:

1. Complete Daily Monitoring Form

Session 2

Session 2 Key Elements:

1. Daily Monitoring: Review Assignment (Form 1)
 - Troubleshooting
2. Treatment Rationale: Review
3. Complete Life Areas, Values, and Activities Inventory (Form 2, available from <http://bmo.sagepub.com/supplemental>)

Daily Monitoring: Review Assignment (Form 1). We will begin this session by reviewing your Daily Monitoring Forms (Form 1) from the past week. Notice the types of activities you are doing and if they are enjoyable, important, both, or neither. Often people with depression find themselves spending very little time in activities that are enjoyable. They often will also withdraw from activities that are important to them. We should discuss your

level of activity and how often you are doing enjoyable and important activities. In the next few sessions, we will focus on making changes in your daily activities but right now do not try to change anything. Instead, just pay attention to what your life is like every day, what you are doing, and to what extent these activities are leading you to feel better or worse.

Troubleshooting. Some people find it difficult to complete the Daily Monitoring Forms. If you have not been able to complete this form in the past week, it first will be important to understand why. One reason it may be difficult to complete the monitoring is that you may feel you already have a good sense of how you spend your time and that it would not be useful to write activities down. You can probably recall a lot of things you have done in the past week, but there may be quite a few activities that you might have forgotten about by now. Having your daily activities recorded on paper for each day can be helpful for both me and you to identify those depressed patterns that we discussed in last session. Many people are very surprised by patterns they notice on the forms and begin to gain a real understanding of how certain patterns lead to more depressed feelings, whereas others lead to more positive feelings. Having these forms for the session allows our work to be more efficient by allowing us a clear sense of exactly how you are spending your time moment to moment without having you try to recall all of that information in the session.

A second reason it may be difficult to complete the monitoring is that you may feel like it is an overwhelming task. Writing down all of your activities of the day can feel like a lot of work, but in the end you are likely to find that what you learn is well worth the effort. One way to make this easier is to keep your recordings as brief as possible (e.g., “lunch,” “took kids to school,” and “cooked dinner”). Another way to keep this easier is to complete the form at the end of the day. Finally, if you find it extremely challenging to do the forms at all, you might consider initially doing the forms for 2 or 3 days of the week (being sure to include both week and weekend days) and then gradually increasing the number of days each week that you complete the forms. You are likely to find that once you get into the habit of doing the forms, it will seem less burdensome. People who have some difficulty in writing and/or reading also may find the forms difficult to complete. If this is the case, a modified form that does not require writing or reading is available.

If you were not able to complete any Daily Monitoring Forms for the past week, it is not recommended that you attempt to remember the entire week right before the session or in the session with your therapist. Remembering the necessary level of detail will be too difficult, and with so much information missing, it will be difficult to detect any consistent behavior patterns. Instead, you should complete a form right now in session for the past day or

two. You will likely be able to recall most of your activities from today and 1 or 2 days ago. Even though it is only 1 or 2 day's worth of activities, it is a starting point, and you and we can begin to look for behavior patterns. Completing the forms for each day of the coming week will increase the chances of making good progress.

Treatment Rationale: Review. Review treatment rationale as needed using content from Session 1.

Life Areas, Values, and Activities (Form 2)

Life areas. An important step in this treatment involves thinking about the most important areas of your life. Think for a moment about each of the following life areas:

1. **Relationships:** This life area refers to the part of your life that involves family, friends, and/or your romantic partner (for example, your spouse, boyfriend, or girlfriend).
2. **Education/career:** This life area refers to time spent in developing your education and your career. This can include formal education such as college or a trade school but could also be informal such as reading books on a particular topic. It also includes working at your current job or finding a new job.
3. **Recreation/interests:** This life area refers to leisure time, when you can have fun and/or relax. It also may include doing things for others such as volunteering.
4. **Mind/body/spirituality:** This life area refers to physical and mental health as well as religion and/or spirituality.
5. **Daily responsibilities:** This life area refers to your obligations and responsibilities to others and your belongings.

Values. Once we have considered these different life areas, we move to identify your values in each of these areas. A value is an ideal, quality, or strong belief in certain way of living.

In other words, what is important to you about each of these life areas? What are you striving to be in each life area? What are the qualities of that life area that are important to you? A value is something that is important to you, in your heart, about that life area. Be sure that the values you identify are very personal to you and not necessarily the values of other people in your life or society in general.

Activities. A primary goal of this session is to identify key values from each life area and translate them into activities. Life areas are the important parts of your life, values are how you want to live your life in each of those areas, and activities are things you can do to actually live according to the values. Becoming more aware of your values and using them as a guide to selecting your activities is the key to this treatment. However, without the activities that help you live according to your values, the values are just words and ideas, and not a reality. Please see the examples of life areas, values, and activities provided in Appendix B.

The Life Areas, Values, and Activities Inventory allow you to turn your values across the key areas of your life into reality. For each life area, you have space for both values and activities (you can add extra blank sheets for each life area to add additional values and activities). Each activity should be something that you might do to live consistently with the value that you identified. For example, if “being a good husband/wife” is something you value, list some activities that you think are consistent with being a good husband or wife. Possible activities might include planning a date with your husband or wife once a week or helping your husband or wife with a household chore he or she dislikes. When selecting activities, it is important to remember that the activity must have two specific characteristics: they should be both observable by others and measurable. Therefore, “feeling better” is not what we mean by activity but “eating dinner with my mother twice a week” would be appropriate. This latter activity could be observable and measurable in the sense that you could meet with her twice per week. The activity should also be broken into its smallest piece. For example, if an activity is going for a bike ride, consider that a number of intermediate steps are required before one can do this. Such steps might include bringing the bike up from the basement, checking the air in the tires, finding a tire pump, pumping the tires, and so on. So the first step in the activity of going for a bike ride might just include checking that the bike is in good shape, with later weeks including the actual ride. Activities are far easier to accomplish if they are broken into the smallest pieces possible. Thus, if these three conditions (observable, measurable, and smallest piece possible) are met, you have identified an acceptable activity.

Sometimes it is tempting to select very difficult activities for which the benefits are in the future and not a guarantee. For example, getting a college degree is a long-term goal that may take some time to achieve. It is important to have these types of goals, but it is even more important to be clear about the rewarding activities that are a part of achieving that long-term goal. This might include activities that get you to the goal but are important and/or

enjoyable on a daily basis such as studying a topic you enjoy or having a discussion about something you learned in a class. Therefore, you should select activities across a range of difficulty, with only a few being smaller steps toward more difficult long-term projects. To improve the likelihood of initial success and to help you start this program, some of the activities you choose should be activities you already are doing regularly but would like to increase in frequency or duration (see your Daily Monitoring Forms for assistance). We will now complete this form together, and you will continue adding to it and editing it for homework.

Assignments:

1. Complete Daily Monitoring Form (Form 1)
2. Review and edit Life Areas, Values, and Activities Inventory (Form 2)

Session 3

Session 3 Key Elements:

1. Daily Monitoring: Review Assignment (Form 1)
2. Life Areas, Values, and Activities Inventory: Review Assignment (Form 2)
3. Activity Selection and Ranking (Form 3, available from <http://bmo.sagepub.com/supplemental>)

Daily Monitoring: Review Assignment (Form 1). We will begin this session by reviewing your Daily Monitoring Forms (Form 1) from the past week. Notice the types of activities you are doing and if they are enjoyable, important, both, or neither. Often people with depression find themselves spending very little time in activities that are enjoyable. Some people withdraw from activities that are important to them and end up spending long periods of time during the day in activities that are neither enjoyable nor important. In this case, you may find it hard to find any activities that are rated high in either enjoyment or importance. However, some people with depression have many important activities in their week but very few that are enjoyable. These people often spend a lot of time working, taking care of others, and meeting various obligations to the exclusion of any time spent on self-care or pleasurable activities. For many people with depression, their important activities are not very enjoyable. How would you describe your activities? How often are you doing enjoyable and important activities? In the next few sessions, we will focus on making changes in your daily activities, and I know we have

already started identifying values and activities in various areas of your life but for now do not try to change anything. Instead, just pay attention to what your life is like every day, what you are doing, and to what extent these activities are leading you to feel better or worse. You might also find over time that recording your activities in this way becomes easier.

Life Areas, Values, and Activities Inventory: Review Assignment (Form 2).

From last session you have learned about life areas, values, and activities. For example, the life area of “education/career” and the related value of “getting a college education” might include specific actions such as identifying a school, speaking to an enrollment counselor, enrolling in classes, and so on. As another example, the life area of “family relationships” and the value of “developing a closer relationship with a particular family member” may include specific actions such as eating dinner together every Saturday, talking on the phone twice a week, or offering specific assistance (e.g., baby sitting). Although completing activities aimed at one specific life area and value can be satisfying, it is important to select activities across a wide range of life areas because depression is rarely the result of only one aspect of your life. For example, someone with depression might think that if they could only get a certain job, they would not be depressed anymore. As a result, all of their focus might be on would-be activities that have to do with getting that job. In this situation, it would certainly be helpful to work on activities related to the job, but it is just as important to work on activities tied to other life areas. Living a fulfilling life is not about getting a certain job, achieving a certain body weight, being with one particular person and no other, or having a specific amount of money. By narrowing your focus on one aspect of your life, you limit your opportunity to have positive experiences and feel fulfilled in other areas. Ultimately, this can worsen your depression, especially if the goals you have in mind require a long period of time or are extremely difficult to obtain. Finally, be sure that you have both “enjoyable” and “important” activities in your plan, with emphasis on the type of activity that is less frequent in your Daily Monitoring Forms. Throughout treatment, be sure to keep thinking about values in each life area and to generate new activities in line with these values.

Activity Selection and Ranking (Form 3). By now, you will have identified many activities for each of the values in your life areas. Today, we will pick 15 activities to use as a starting point. As you select an activity, add it to the left column of Form 3 (activity selection and ranking). Remember that the

activities should be observable, measurable, in their smallest pieces, and directly relevant to the values you listed in the Life Areas, Values, and Activities Inventory (Form 2). The more your daily activities are linked to your values, the more likely you will experience the activities as both pleasurable and meaningful, and the more you will feel that you are living the life you want to live. This is extremely important to pay attention to because there is no reason to busy yourself with activities that do not make you feel that you are living a richer, more meaningful life. Once you have your 15 activities listed on Form 3, rank them from 1 (*easiest to accomplish*) to 15 (*hardest to accomplish*) on the right column of Form 3. One way to do this is to first identify the easiest and assign it a 1 and then to identify the most difficult and assign it a 15. From there, try to fill in the others. In activity planning, you will start with the easiest activities and gradually work toward the more difficult ones. However, don't worry this week about starting any of these activities. We will use the next session to rereview your list and get you started with the activities.

Assignments:

1. Daily Monitoring (Form 1)
2. Continue to review and edit Life Areas, Values, and Activities Inventory (Form 2)
3. Review and edit activity selection and ranking

Session 4

Session 4 Key Elements:

1. Daily Monitoring: Review Assignment (Form 1)
2. Daily Monitoring With Planning (Form 1)

Daily Monitoring: Review Assignment (Form 1). We will begin this session by reviewing your Daily Monitoring Forms (Form 1) from the past week. Notice the types of activities you are doing and if they are enjoyable, important, both or neither. Be sure to take some time to think about and discuss your level of activity and how often you are doing enjoyable and important activities. At this point you might also think about if there are certain life areas in which you have very few important and/or enjoyable activities. This type of information will help us with activity selection and planning. Now that you have had some practice, you might find that recording your activities is becoming easier. If not, or if it is becoming more

difficult, we can come up with some strategies for making this an easier task for you.

Daily Monitoring With Activity Planning (Form 1). Once you have identified the 15 target activities, you will need a plan for how you will include these activities in your daily schedule and how you will monitor your progress. We will use your Daily Monitoring Forms for the upcoming week to help you plan your new activities. Your opinion will be critical in deciding how many activities to select, and it is important that you challenge yourself without becoming overwhelmed. The simplest approach is usually to start with 1 to 3 of the easiest activities. We will begin now by identifying activities for the coming week and entering these activities into the blank Daily Monitoring Forms for each day at the time that you plan to do them. For example, if your activity is “play with your daughter” you might enter that activity (Form 1) at 11 a.m. on Monday, 10 a.m. on Wednesday, and 9 a.m. on Thursday.

Be sure to seriously consider whether you are ready for a particular activity and consider barriers that you might encounter. If you are not ready, you may wait for another week to do it. If there are barriers to doing the activity, we should discuss steps you might take to first overcome those barriers. Remember in previous sessions when we discussed breaking activities down into the smallest pieces possible? When you run into difficulty with an activity, it can be useful to consider if you really have broken the activity down far enough. For example, if your activity is to go to the gym twice a week, you first might have to buy clothing, research gyms, find a partner to go to the gym with, or arrange for transportation. In this case, “going to the gym” may not be the smallest piece of this activity. You should add any additional activities to overcome these barriers on Form 2 (Life Areas, Values, and Activities Inventory). A key aspect of this treatment is to plan the specific day and time that you will do each activity. This will require you to really think through where you can realistically fit the activity into your schedule. By doing this, you will find that you are more likely to accomplish the activity.

During the upcoming week, you will complete the Daily Monitoring Form just as you have been doing each day. However, circle each planned activity in your form if you completed it. Be sure to give it an enjoyment and importance rating at this time too. This is important because it will allow us to see if you experienced the activity as more or less enjoyable or important than you originally thought. If you did not complete the activity at the scheduled time, put a line through it (but do not erase it) and write in the activity you did accomplish at that time. If possible, try to replan the missed activity

for another time that week (or even that day) and be sure to circle it if you complete it. We will review your Daily Monitoring Forms next week as usual, but this time we will look for the circled activities you planned, how enjoyable and important they were, and if you encountered any problems trying to accomplish them. We can work together to address whatever challenges arise.

When you begin to complete your activities, you will begin to move toward the values you have set out for yourself in important life areas and you will be living a fuller life and feeling less depressed. The key is to not focus too much on whether you have succeeded at accomplishing the values but instead it is to focus entirely on completing the daily activities that come directly from your values. Many values require a lifelong effort (e.g., being a good parent) where you constantly try to live in a way that is consistent with your values. For this reason, values are not considered an end-point of a process, but instead they are a guide throughout the process, providing information about how we want to live our lives and helping us to choose the activities that are the vehicles that help us move in the direction of our values.

Assignments:

1. Daily Monitoring with Activity Planning for upcoming week (Form 1)

Session 5

Session 5 Key Elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1)
2. Contracts (Form 4, available from <http://bmo.sagepub.com/supplemental>)
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1)

Daily Monitoring With Activity Planning: Review Assignment (Form 1).

Let's review your seven forms of daily monitoring with activity planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How enjoyable and important did you find them? How did you feel about having accomplished those activities? Would you like to continue those activities or select different

ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and could not complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities.

Contracts (Form 4). Your chances of overcoming depression are much improved when you have support from others for your healthy activities. Family and/or friends can be a great support in our lives, but sometimes they may be more likely to notice your depressed behavior than your healthy activities. Other times, supportive people would like to help but they either do not know how or they tend to do things that they think are helpful but are not actually helpful. For example, sometimes friends or family take over your responsibilities because they see what a hard time you are having now or instead they may nag or push you to do things you are not ready to do. In both cases, the support person wants to help, but is doing things that are not helpful.

Contracting will help you to ask support people for help for your healthy activities in the ways that you need it. To get you the help you need, let's begin with Form 4 (Contracts) by identifying activities from Form 3 that you could use some help to complete. Once you have done that, let's identify up to three people who could help you and the specific ways they could help. For example, you might find that going grocery shopping once per week is difficult because you don't have a car. In this case, you would list grocery shopping and then any person who might be able to give you a ride. In addition,

you might find grocery shopping really boring. In this case, you could add others who might go grocery shopping with you to make it more enjoyable. In this case, you might end up with the names of two people who might give you a ride and a third who might go shopping with you. Once you have identified the activity, identified one or more people who can help, and described exactly how each person might help, the next step is to tell each person what you are trying to accomplish and exactly how they can help. You might learn that involving others in your activities makes the activity not only more likely to occur but also more enjoyable. Involving others can also strengthen your relationships. All of these things will have a positive impact on the way you feel every day. You can either show the support person the actual contract or simply just have a discussion with the support person about the specific ways they can help with an activity.

In using contracts, it is important to note that you do not want to become dependent on those around you, especially if some people in your support network may be unreliable. Thus, you should use contracts to enhance your ability to do things that are enjoyable and important to you, but you should never rely entirely on others as well. As we develop contracts, we will consider how to ensure that we can gain support from others without becoming reliant on them.

Daily Monitoring With Activity Planning for the Upcoming Week (Form 1). On the basis of our discussion in this session, you should now plan your activities for the next week. If you are able, try to plan for one or more new activities for the upcoming week in addition to the activities you accomplished the previous week.

Assignments:

1. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)
2. Continue adding/editing contracts (Form 4)

Session 6

Session 6 Key Elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1)
2. Contracts: Review Assignment (Form 4)
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1)

Daily Monitoring With Activity Planning: Review Assignment. Let's review your seven forms of daily monitoring with activity planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How important and/or enjoyable were your planned activities? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and could not complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities. Finally, you might need help from others to complete scheduled activities. In this case, be sure to use contracts to secure the help you need from others.

Contracts: Review Assignment (Form 4). Were you able to accomplish at least one contract? If not, it might be helpful to discuss the challenges you encountered. What made it difficult? If you are finding it difficult to identify supportive people, we might discuss planning some activities that will help you build a more supportive network of friends. For example, are there people in your workplace, neighborhood, or community who are your age and have had similar experiences as you? Perhaps there are ways to get to know these people better. Another idea is to identify places you can go where you will meet people who are similar to you. Then you can plan activities around visiting these places. If you were able to complete a contract, how did it go? How important and/or enjoyable did the activity turn out to be?

You may find that some activities are more enjoyable when done with the help of a supportive person. This could be especially crucial for planning activities that are important but not very enjoyable. Thus, doing laundry or grocery shopping with a friend might be more tolerable than doing it alone. Alternatively, you may use contracts to schedule an enjoyable activity with a friend to occur immediately after a low-enjoyment activity you needed to do, almost as a reward for following through on the first activity. Finally, always remember that you are responsible for your activities even if a support person does not follow through on a contract. This may involve contracting with someone else and then rescheduling the activity or scheduling the activity again at another time alone. The important thing to remember is that contracts can be helpful but you are responsible for the activities you select. If you are still having trouble with any part of contracts, it might be useful to take some time in this session to further review contracts with your therapist.

Daily Monitoring With Activity Planning for the Upcoming Week (Form 1). On the basis of our discussion during this session, you should now plan your activities for next week. If you can, try to plan one or more new activities for the upcoming week, in addition to the activities you accomplished last week.

Assignments:

1. Daily Monitoring with activity planning for the upcoming week (Form 1)
2. Continue adding/editing contracts (Form 4)

Session 7

Session 7 Key Elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1)
2. Life Areas, Values, and Activities Inventory: Concept Review and Edit (Form 2)
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1)

Daily Monitoring With Activity Planning: Review Assignment. Let's review your seven forms of daily monitoring with activity planning for the week. How many of the planned activities did you accomplish? For those that

you accomplished, how easy or difficult were they? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned but did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and could not complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities. Finally, you might need help from others to complete scheduled activities. In this case, be sure to use contracts to secure the help you need from others.

Life Areas, Values, and Activities Inventory: Concept Review and Edit (Form 2). Today, we will review the concept of values to make sure that the activities that you are accomplishing still seem consistent with the values you mentioned earlier in treatment. Remember, an important step in this treatment approach involves determining the activities you would like to add to your life. Although becoming more active in life is important, we need to be sure that the activities that you select are ones that are enjoyable and/or important to you and that make you feel like you are living the life you want to live. One way to help identify activities that are important to you is to think about what you value in life. Let's revisit each of the life areas and the values you have in these areas. Remember, a value is something that is important to you in your heart about that life area. Review your values for the following: relationships, education/career, recreation/interests, mind/body/spirituality, and daily responsibilities. Think about how much the activities you have identified in the last few weeks fit into your values. Are there new values that

have come to mind? Are each of the activities consistent with the values you mentioned?

Daily Monitoring With Activity Planning for the Upcoming Week (Form 1). On the basis of our discussion in this session, you should now plan your activities for the next week. If you are able, try to plan for one or more new activities for the upcoming week in addition to the activities you accomplished the previous week.

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1)
2. Continue adding/editing contracts (Form 4)

Session 8

Session 8 Key Elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1)
2. Activity Selection and Ranking: Concept Review and Edit (Form 3)
3. Daily Monitoring with Activity Planning for the Upcoming Week (Form 1)

Daily Monitoring With Activity Planning: Review Assignment (Form 1). Let's review your seven forms of daily monitoring with activity planning for the last week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and could not complete this activity. We should revisit your monitoring forms and think about ways to fit new

activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help you fill your life with enjoyable and important activities. Finally, you might need help from others to complete scheduled activities. In this case, be sure to use contracts to get the help you need from others.

Activity Selection and Ranking: Concept Review and Edit (Form 3).

Throughout treatment, you may have added, subtracted, or changed activities in your Activity Selection and Ranking Form (Form 3). We can take some time to review how to go about selecting activities to add (as well as activities to remove or change) in Form 3. In general, if you believe that completing a particular activity would bring a sense of pleasure and/or accomplishment, then it probably would be good to include it. It is also important to decide which life area and value each activity is associated with. This is a good reminder to revisit the activities on your list and to think of the relevant life values. Also, when selecting activities, it is important to remember that they must be observable by others, measurable, and broken into the smallest piece. For example, “being a better daughter” is not an activity that you could plan but “offering to help mom make dinner twice a week” would be appropriate. If these conditions are met, you have identified an appropriate activity. Although it is sometimes tempting to select very difficult activities for which the benefits are very delayed or uncertain. For example, having your own home is a long-term goal. To address this potential problem without limiting your ambition, break activities into small steps and select activities across a range of difficulty, from easy activities you are currently doing to extremely difficult activities that will take some effort.

Daily Monitoring With Activity Planning for the Upcoming Week (Form 1).

At this point, you might find that you want to make changes to the 15 activities in Form 3 (activity selection and ranking). Often new activities come to mind or you change your mind about activities you originally put in Form 3. You should feel free to change Form 3 as you would like, adding new activities, changing them, breaking them into smaller steps if necessary, or removing some that you no longer want to include. Overcoming depression is a process, and as you begin to feel better, your plans for yourself may

change. You might find it easier to be more active and set increasingly difficult activity goals. However, you might feel that your original plan was too difficult and have new ideas on how to reduce the difficulty of your activities. Do not feel stuck with your original plan as it is always open to change. The important thing is that you are increasing your activity level, and as you do this, your depression is improving. It is impossible to live an active, fulfilling, and enjoyable life and be depressed at the same time. The idea is to increase the amount of time you spend in healthy, active, fulfilling, and enjoyable activities so that this is what your life is about instead of your life being about depression.

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1)
2. Continue adding/editing contracts (Form 4)

Session 9

Session 9 Key Elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1)
2. Contracts: Concept Review and Edit (Form 4)
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1)

Daily Monitoring With Activity Planning: Review Assignment (Form 1). Let's review your set of seven forms of daily monitoring with activity planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned but did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into

smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and could not complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities. Finally, you might need help from others to complete scheduled activities. In this case, be sure to use contracts to secure the help you need from others.

Contracts: Concept Review and Edit (Form 4). In Session 5, you began to use the contracts to help complete some of your activities (Form 4). It would be helpful to take some time to review how well the contracts have worked for you. At this point, have you used a contract to get help completing a difficult activity? Remember, getting supportive people to help you accomplish healthy activities will not only make the activities easier to accomplish but will also help to strengthen your support system. Contracts are a way to get your supportive people to help you overcome depression. As we discussed before, sometimes supportive people in our lives would like to help us, but they either do not know how or they tend to do things for us that they think are helpful but are not actually helpful. Contracting will help you to ask for the specific help you need. Again, it is not important that you show the support person the written contract, just that you have a discussion with the person about the specific ways they can help. If you have not yet tried a contract, now might be a good time to review the material from Session 5 and give it a try.

Daily Monitoring With Activity Planning for the Upcoming Week (Form 1). Once again, plan for one to two additional activities on Form 3 and write them on your Daily Monitoring Forms for the coming week.

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1)
2. Continue adding/editing contracts (Form 4)

Sessions 10 and Beyond

Session 10 and Beyond Key Elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1)
2. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1)
3. Preparing for the End of Treatment

Daily Monitoring With Activity Planning: Review Assignment (Form 1). Let's review your seven forms of daily monitoring with activity planning for the week. How many of the planned activities did you accomplish? For those that you accomplished, how easy or difficult were they? How did you feel about having accomplished those activities? Would you like to continue those activities or select different ones for next week? Are you finding that you feel better when you are more active? If so, this is good progress.

Were there activities that you planned that you did not accomplish? If so, what happened? Was it because you really do not find the activity to be enjoyable and/or important? If this is true, then one option is to select a different activity instead. If it is an activity that you want to keep trying to do, then there are a few other issues to consider. Was the activity more difficult to accomplish than what you originally had expected? If so, we can discuss breaking it into smaller steps as we have discussed previously. Alternatively, you might have felt you just ran out of time and could not complete this activity. We should revisit your monitoring forms and think about ways to fit new activities into your schedule. You might also have to seriously consider strategies for reducing your time spent in less valued current activities to make more time for these new more valued activities. This may include the difficult task of setting stricter boundaries around your time. In this case, we can discuss how to plan some activities to help set those boundaries and reclaim some time for yourself. Although these types of changes in your daily routine may be difficult, the planning and monitoring in this treatment can help reduce currently unfulfilling activities and to get you doing more enjoyable and important new activities. Finally, you might need help from others to complete scheduled activities. In this case, be sure to use contracts to secure the help you need from others.

Daily Monitoring With Activity Planning for the Upcoming Week (Form 1). Once again, plan for one to two additional activities on Form 3 and write them on your Daily Monitoring Forms for the coming week.

Preparing for the End of Treatment. We have done a lot of great work together throughout treatment and you have accomplished so much. When we look back at your Daily Monitoring (Form 1) from the first week of treatment and compare them to your Daily Monitoring with Activity Planning (Form 1) from the last week of treatment, what do you see? It is important to identify your patterns of behavior not only now but also at the start of treatment that will help you know what patterns to look out for in the future.

At this point, you have learned a number of skills that can help you feel better and live healthier when you begin to feel depressed again. You are strongly encouraged to consider continuing to use these forms to monitor and plan, especially in the next few weeks. In some cases you might find it useful to schedule booster sessions to review material and solve any difficulties you are having using this process on your own. Eventually, you may find you are living consistent with your values on a daily basis without having to use the forms to monitor and plan, but you might find it helpful to review this manual and practice all of the skills again should depressed feelings return.

Of course, it is possible that feelings of depression could return, but you should remain aware that depression is far less likely to persist when you live a healthy, meaningful, and fulfilling life. No matter what has happened in the past, it is possible to make changes to our lives, to make the best of circumstances, and spend time doing activities that fill your life with purpose and meaning.

Assignments:

1. Daily Monitoring with activity planning for the upcoming week (Form 1)
2. Continue adding/editing contracts (Form 4)

Discussion

In summary, BATD-R is a clear and straightforward treatment approach that can be used in the treatment of depression. However, as with all approaches, there are important areas for clarification and barriers for consideration in the use of the treatment. In this discussion, we will attempt to

highlight the relevant issues and provide supplemental material for using BATD-R.

First, it is important to consider the patient characteristics that seem to be associated with good response and treatment acceptability in BATD-R. Although to date there has been no systematic work aimed at identifying patient characteristics associated with treatment outcome, feedback from developers, clinicians, and patients suggest that BATD-R is well suited in patients who are open to change and amenable to the idea that therapy is an active process aided by efforts outside of the session. Patients with a more traditional view of talk therapy may initially be confused or frustrated by the focus on homework assignments, in particular the daily monitoring and activity planning. In this case, the therapist should spend extra time on the treatment rationale and engaging the patient's commitment to this approach in treating depression. Revisiting the treatment rationale throughout the course of therapy can help to reinforce the purpose of the activities and assignments. Taking time to develop the rationale will also facilitate a stronger therapeutic alliance that is necessary to help patients embark on a way of living that might seem quite overwhelming at first (see Lejuez et al., 2006).

Even after providing a clear treatment rationale, treatment resistance can sometimes occur. One common form of resistance is when the patient attempts to spend a large amount of the session "venting" or discussing frustrations and life stressors, both generally and with particular reference to events since the previous session. Unstructured discussion can thwart the session agenda, and to the extent that it exacerbates rather than relieves negative affect, it can slow progress. The therapist should work with the patient to determine whether such discussion is associated with feeling better or worse, and the therapist can work with the patient to allow some time in the session for such discussion as well as help the patient develop other social outlets for venting their frustrations, but in a manner that does not interfere with the goals of BATD-R. For example, Hopko, Sanchez, Hopko, Dvir, and Lejuez (2003; later continued in Lejuez et al., 2006) presented a case study of a patient presenting with comorbid depression and borderline personality disorder and being treated with a combination of BATD and dialectical behavior therapy (DBT; Linehan, 1993). In the early sessions, the patient struggled with the therapist to spend therapy time discussing stressful events of the week while the therapist attempted to bring the focus back to the tasks of therapy (e.g., Daily Monitoring Forms and progress on planned activities). Because neither the goals of the therapist nor the patient were being achieved, a plan was constructed where BATD and DBT strategies were addressed in the first half of the session, and on their completion, full attention was devoted

to discussing stressful events of the week in the last half of the session. BA strategies also were used to help the patient develop opportunities outside of the session to obtain social support. Even in cases where discussing daily frustrations helps to relieve negative affect in the short term, it is important to consider that this relief is immediate but not likely long lasting. BATD-R strategies can help patients work toward building a more fulfilling life in a way that has potential for long-lasting improvements in depression. To the extent that venting absorbs session time, the patient's opportunity to experience long-lasting benefits of therapy is lessened. In cases of treatment resistance, longer treatment duration may be necessary to complete BATD-R strategies. Occasionally, venting behavior can occur simply because it is what the patient expects is their role in therapy, it serves as an avoidance behavior, or it is reinforced by the therapist. Agreeing on a clear agenda at the beginning of each session and adhering to the agenda is essential to insure that the patient and therapists have the same expectations. Helping the patient seek out appropriate times to solicit social support in session and in their natural environments using activity planning and contracts can address otherwise problematic venting in a more productive manner for the patient.

Homework completion is another treatment challenge. From the first session, the therapist must establish the centrality of homework in the therapeutic process to help the patient understand the value of efforts that occurs outside of the therapy session. Reviewing the monitoring forms for the week at the beginning of each session helps to highlight the importance of homework, which is now simplified with the use of a single form that is used for both monitoring and planning in BATD-R. If a patient attends a session having not completed homework, the therapist should first determine whether the patient understood the assignment and has the skills to carry it out. The newly added Low-Literacy Behavior Monitoring Form in BATD-R may be useful when low literacy and/or comprehension is an issue. If homework was incomplete for other reasons, the therapist should troubleshoot the barriers to completion with the patient, while continuing to reinforce the importance of homework to treatment outcome. Incomplete homework should be worked on in session, but we do not recommend completing entire assignments in session because the treatment will have its optimal effect if the patient devotes time outside of session to the therapy.

Another treatment challenge in BATD-R is when the patient is focused on a single unchangeable event or condition as the root cause of depression. For example, a patient who has experienced the death of their spouse might believe that it is not possible to feel better now that they cannot go on in productive manner without this person. Alternatively, a patient might believe that they

will be depressed as long as they are overweight and the only chance for recovery is if they lose a large amount of weight. Strong resistance is often evident in such cases as the patient may be unwilling to acknowledge the utility of enjoyable and important activities, unless these activities have an immediate impact on this particular issue. For example, if the overweight person had an enjoyable time walking with friends, he or she might minimize the enjoyment because this activity alone cannot address the weight problem in that moment. It becomes the job of the therapist to not only acknowledge the long-term value of weight loss but also to encourage the patient to focus on their daily activities developed in BATD-R to experience happiness at their current weight, while considering other important values and activities that are unrelated to weight. The goal is to draw the patient's attention to the impact of activities related and unrelated to weight on their mood in the moment to help them realize that there are a broad range of experiences that can make them feel joy and happiness, regardless of their current weight. Working broadly to increase positive experiences across multiple life areas with such patients is important to help in the goal of creating a more rounded life.

Patients who have severely limited settings and/or resources can also present challenges when using BATD-R. For example, a patient who is in an inpatient treatment program for depression or a related condition may have little flexibility in how his or her time is allotted and might feel that there are no activities he or she could be doing that are important or enjoyable. Also, patients who have very little income, are homebound, or who work long hours might also feel like they have little ability to do anything different with their time. In these cases, it is important that the therapist work as creatively as possible to generate enjoyable and/or important activities within the patient's limitations. Much of our work within inpatient drug treatment settings (Daughters et al., 2008) has shown that patients can identify a large range of activities even in the most restricted settings if they start with values and creatively examine their daily life for opportunities where more value activities could be activated.

One strength of BATD-R is that it is highly flexible and extremely amenable to individual tailoring based on any range of patient characteristics, including symptom severity, functioning, socioeconomic status, health status, other comorbid conditions, age, intellectual functioning, social support, and cultural background. The focus on life areas, values, and the activities that embody those values remains the same across patients, but the values and activities selected will be unique to each patient and his or her circumstances. For example, values and activities selected by a patient who is HIV-positive and in an inpatient substance abuse recovery facility may be very different from those of a working mother of three children living in a suburban

neighborhood. For the first patient, the value of staying healthy might be pertinent and lead to activities such as taking medication on time each day and going for walks. The value of building a social support network might lead to activities such as attending the HIV-support group and writing a letter to an old friend. In the second patient, the value of achieving work/life balance might be pertinent and lead to activities such as asking her husband to assume a household chore and her saying no to staying late at work, whereas the value of being a good mom might lead to activities such as eating dinner as a family every night and taking the kids bowling. Using BATD-R, the therapist can help the patient to develop a values-driven life within the means, resources, and environments available to the patient, which can change in a dynamic manner over time.

Understanding the cultural values of the patient is essential to BATD-R because these values should be incorporated into treatment. For example, if family is an especially strong cultural value for the patient, the therapist can work with the patient to incorporate family into as many activities as possible, regardless of the life area. BATD-R is also applicable across the life span. When working with children or elderly patients, attention must be paid to the level of independence and participation of caregivers. Modifications can also be made to forms as was done for low-literacy patients in the revised Form 1. BATD can also be modified to fit patients with a high level of technological literacy. Such individuals may prefer electronic forms of self-monitoring using a computer or with mobile technology in line with advancements in ecological momentary assessment approaches. In addition to electronic self-monitoring in BATD-R, treatment delivery itself also can be conducted online to increase the dissemination of treatment to individuals for whom attending therapy regularly may be difficult (Egede et al., 2009). Finally, the focus of treatment and how BATD-R can be applied can vary greatly across patients. Although BATD-R is a manualized treatment, it is by design an idiographic approach to treating depression.

In conclusion, this revised manual (BATD-R) addresses practical issues and shortcomings of the original manual while still preserving the theoretical underpinnings of the original BATD manual. We present BATD-R as a stand-alone treatment, but we also recommend the use of BATD-R in combination with other treatment approaches. When done in a theory-driven manner and considering key contextual issues and patient characteristics, such a combined approach, may provide flexibility to therapists treating more complicated cases, including those where comorbid mental and/or physical health conditions are evident. In addition, although BATD-R is designed as a traditional therapy manual, it would be useful for future efforts to consider

technological advancements such as web-based or mobile phone platforms. Certainly, these efforts come with additional costs and unique challenges and also hold great potential for increasing treatment adherence, depth and immediacy of information and feedback, opportunity for more therapist–patient interaction outside of session, and scope of dissemination. In conclusion, we are excited about the contribution of BA strategies to the treatment of depression and comorbid conditions and we are optimistic that this 10 year revision of BATD will support further progress.

Appendix A

Adherence Checklist

Session 1 key elements:

1. Discussion of Depression ____
2. Introduction to Treatment Rationale ____
 - What about stressful life events and loss in your life? ____
3. Introduction to Daily Monitoring (Form 1) ____
 - Importance and enjoyment ratings ____
 - When should you complete the Daily Monitoring Form? ____
4. Important Points About the Structure of This Treatment ____

Assignments:

1. Complete Daily Monitoring Form ____

Session 2 key elements:

1. Daily Monitoring: Review Assignment (Form 1) ____
 - Troubleshooting ____
2. Treatment Rationale: Review ____
3. Complete Life Areas, Values, Activities Inventory (Form 2) ____

Assignments:

1. Complete Daily Monitoring (Form 1) ____
2. Review and edit Life Areas, Values, and Activities Inventory (Form 2) ____

(continued)

Appendix A (continued)

3. Review Appendix A: Moving from life areas and values to activities ____

Session 3 key elements:

1. Daily Monitoring: Review Assignment (Form 1) ____
2. Life Areas, Values, and Activities Inventory: Review assignment (Form 2) ____
3. Activity Selection and Ranking (Form 3) ____

Assignments:

1. Daily monitoring (Form 1) ____
2. Continue to review and edit Life Areas, Values, and Activities Inventory (Form 2) ____
3. Review and edit activity selection and ranking ____

Session 4 key elements:

1. Daily Monitoring: Review Assignment (Form 1) ____
2. Daily Monitoring with Activity Planning (Form 1) ____

Assignments:

1. Daily Monitoring with activity planning for upcoming week (Form 1) ____

Session 5 key elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1) ____
2. Contracts (Form 4) ____
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1) ____

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1) ____

Appendix A (continued)

2. Continue adding/editing contracts (Form 4) _____

Session 6 key elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1) _____
2. Contracts: Review Assignment (Form 4) _____
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1) _____

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1) _____
2. Continue adding/editing Contracts (Form 4) _____

Session 7 key elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1) _____
2. Life Areas, Values, and Activities Inventory: Concept Review and Edit (Form 2) _____
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1) _____

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1) _____
2. Continue adding/editing contracts (Form 4) _____

Session 8 key elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1) _____
2. Activity Selection and Ranking: Concept Review and Edit (Form 3)

(continued)

Appendix A (continued)

3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1) ____

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1) ____
2. Continue adding/editing contracts (Form 4) ____

Session 9 key elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1) ____
2. Contracts: Concept Review and Edit (Form 4) ____
3. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1) ____

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1) ____
2. Continue adding/editing contracts (Form 4) ____

Session 10 and beyond key elements:

1. Daily Monitoring With Activity Planning: Review Assignment (Form 1) ____
2. Daily Monitoring With Activity Planning for the Upcoming Week (Form 1) ____
3. Preparing for the End of Treatment ____

Assignments:

1. Daily monitoring with activity planning for the upcoming week (Form 1) ____
2. Continue adding/editing contracts (Form 4) ____

Appendix B

Moving From Life Areas and Values to Activities

Life area (1/5): Relationships

Value: Being a loving parent

Activity: Tell my child I love them every day

Activity: Make a special breakfast for my child on Saturday

Activity: Pick up my child from school promptly each day

Value: Being an attentive and caring friend

Activity: Call my friend once per week

Activity: Text my friend

Activity: Ask my friend about his or her week

Value: Caring for the needs of your spouse

Activity: Make special plans with spouse

Activity: Tell spouse I love them every day

Activity: Buy my partner a surprise gift

Life area (2/5): Education/career

Value: Get more formal education

Activity: Ask a friend for advice about school

Activity: Write out a plan for enrolling in school

Value: Learn new skills for work

Activity: Ask someone at work to teach me a new skill

Activity: Take a class

Value: Be knowledgeable about the world around you

Activity: Read the newspaper everyday

Activity: Talk about current events to a stranger

Value: Improve your job performance and satisfaction

Activity: Set a work-related goal

Activity: Read a book about my profession

Value: Find a new job that fits with your skills and interests

Activity: Look at job advertisements

Activity: Talk to someone who has a job available

Life area (3/5): Recreation/interests

Value: Being active

Activity: Go to the park with my son

Activity: Take a walk outside

Activity: Play football on Saturday

(continued)

Appendix B (continued)

Value: Being artistic and creative

Activity: Knit

Activity: Make crafts

Value: Making a sacrifice for something you believe in

Activity: Start a petition

Activity: Spend time helping at my place of worship

Value: Helping others less fortunate or who need help

Activity: Donate clothes

Activity: Spend 30 min helping an elderly person

Value: Showing a commitment to your country

Activity: Vote in an election

Activity: Volunteer for a campaign

Life area (4/5): Mind/body/spirituality

Value: Being physically healthy

Activity: Go to a doctor for a physical/check-up

Activity: Eat fruit everyday

Activity: Take my medication as prescribed

Value: Talking to someone about your problems and feelings

Activity: Ask someone to lunch to talk

Activity: Make an appointment with a therapist

Activity: Write in a journal

Value: Developing your religious/spiritual views

Activity: Talk with a religious figure

Activity: Talk to others with religious beliefs you are interested in

Value: Living a spiritual life

Activity: Pray everyday

Activity: Read my religious material

Activity: Attend a religious service

Value: Being tolerant, nonjudgmental, accepting of others differences

Activity: Talk to someone with a different background

Activity: Read a book about a different culture

Life area (5/5): Daily responsibilities

Value: Being someone others can depend on

Activity: Arrive at work on time

Activity: Offer to help someone who is very busy

Activity: Repay a debt

(continued)

Appendix B (continued)

Value: Taking care of your belongings

Activity: Complete a much-needed household repair

Activity: Wash your clothes and shoes

Activity: Clean the house

Value: Being organized

Activity: Review my days activities the night before

Activity: Use a calendar to record dates and meetings

Activity: Develop a filing system for important paperwork

Authors' Note

All forms and form supplements are available online at <http://bmo.sagepub.com/supplemental>. They can also be requested from the first author.

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Declaration of Conflicting Interests

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Notes

1. Acceptance and Commitment Therapy (ACT) provides a useful discussion of values that provided a useful starting point in use of life areas, values, and activities (Hayes, Strosahl, & Wilson, 1999).
2. In retrospect, it may have been more prudent to name the treatment BBATD instead of BATD, with the first B to highlight the brief nature of the treatment.

In this revision, we considered changing the name of the treatment to reflect this aspect. However, we decided a change at this point would produce more confusion than clarity, and therefore simply refer to the revised manual as BATD-R. A modifiable version of the manual, formatted for patient use, is available from Dr. Lejuez.

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Combat Experiences, Pre-Deployment Training, and Outcome of Exposure Therapy for Post-Traumatic Stress Disorder in Operation Enduring Freedom/Operation Iraqi Freedom Veterans

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Abstract

The association between exposure to multiple potentially traumatic events (PTEs) and subsequent increased risk of post-traumatic stress disorder (PTSD) is well established. However, less is known about the relation between exposure to numerous PTEs, as is typical with military service, and treatment outcome. Furthermore, there has been little research examining military specific protective factors, such as pre-deployment preparedness, on PTSD treatment response. The current study investigated combat exposure and potential moderators of treatment outcome for exposure therapy in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans with PTSD. One hundred and eleven OEF/OIF veterans diagnosed with PTSD participated in 8 weeks of exposure therapy. Results indicated that increased combat exposure was associated with a reduced rate of change in PTSD symptoms but not depression symptoms. These findings were consistent across two measures of combat exposure. There was preliminary support for the moderating effect of pre-deployment preparedness on the association between combat exposure and treatment response. Together, these findings suggest that increased combat exposure is associated with poor treatment response in veterans with PTSD; however, this can be reduced by elevated pre-deployment preparedness.

Keywords

PTSD; OEF/OIF; Veterans; Exposure Therapy; Combat Exposure; Pre-Deployment Preparedness

The cumulative effects of multiple potential traumatic events (PTEs) on the symptoms of post-traumatic stress disorder (PTSD) and response to treatment is an area of great interest (Cloitre *et al.*, 2009; Follette, Polusny, Bechtle, & Naugle, 1996; Kilpatrick, Resnick, & Acierno, 2009; Suliman *et al.*, 2009). On the basis of epidemiological findings, individuals rarely experience only a single PTE (Kessler, 2000; Kilpatrick, Acierno, Resnick, Saunders, & Best, 1997). Moreover, findings suggest that the effect of exposure to multiple PTEs is cumulative in that it is associated with increased symptoms of PTSD, anxiety and depression (Follette *et al.*, 1996; Hedtke *et al.*, 2008; Suliman *et al.*, 2009). In addition, these findings are consistent across civilian victims of rape, domestic violence and childhood sexual abuse (e.g., Follette *et al.*, 1996) as well as combat-exposed veterans (e.g., Hiley-Young, Blake,

Abueg, Rozyanko, & Gusman, 1995; Koenen, Stellman, Stellman, & Sommer, 2003; Owens *et al.*, 2009; Renshaw, 2011).

One area of particular concern is the influence of increased combat exposure on the severity and treatment of PTSD in veterans. Since 2001, nearly 1.5 million US service members have been deployed in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF; Committee on the Initial Assessment of Readjustment Needs of Military Personnel, Veterans and their Families, 2010), with many returning home with psychiatric disorders post-deployment (Hoge *et al.*, 2004). In addition, OEF/OIF veterans report increased combat exposure when compared with veterans of past military operations (Renshaw, Rodrigues, & Jones, 2009). Two recent studies demonstrated that increased exposure to combat has a curvilinear relation with PTSD symptoms during deployment in active duty soldiers (Lee, Goudarzi, Baldwin, Rosenfield, & Telch, 2011) and is linearly related to more severe post-deployment PTSD symptoms in a sample of recently returning veterans (Renshaw, 2011). Taken together, these findings indicate that OEF/OIF veterans may be at greater risk for negative mental health outcomes as a result of increased PTE exposure.

Interestingly, Renshaw (2011) provided preliminary evidence for the protective effect of pre-deployment training and preparation on the association between combat exposure and PTSD symptoms. The association between combat exposure and PTSD was diminished in those that reported higher levels of pre-deployment training. This finding is consistent with theoretical models of PTSD that suggest the disorder is associated with increased beliefs of a 'dangerous world' and an 'incompetent self' (Foa & Jaycox, 1999). Veterans who perceive greater pre-deployment training may view themselves as better able to deal with combat stress, view combat as less dangerous or both. As such, pre-deployment training may be a key protective factor in the development of PTSD in veterans who were exposed to greater combat. However, additional work on pre-deployment training is needed given the preliminary nature of these findings.

Considerable research suggests that exposure-based, cognitive behavioural interventions (e.g., prolonged exposure therapy; Foa, Hembree, & Rothbaum, 2007) and cognitive behavioural therapies (CBT) with significant exposure components (e.g., cognitive processing therapy; Resick & Schnicke, 1992) are effective treatments for PTSD (e.g., Foa, Rothbaum, Riggs, & Murdock, 1991; Schnurr *et al.*, 2007).

However, the impact of exposure to multiple PTEs on treatment response is unclear. In a review of the severity and characteristics of the event (Schottenbauer, Glass, Arnkoff, Tendick, & Gray, 2008), a mixed pattern of results was found for the impact of multiple PTEs on treatment outcome of exposure-based therapies. Childhood traumatic events were unrelated to treatment response for CBT in a large sample of sexual assault victims (Resick, Nishith, & Griffin, 2003). A history of childhood trauma was shown to be unrelated to treatment response in community samples with a broader presenting trauma history (Taylor, 2003; Van Minnen, Arntz, & Keijsers, 2002). The only study to examine the impact of aspects of the presenting trauma provided contradictory findings (Hembree, Street, Riggs, & Foa, 2004). Assault victims who were physically injured as a result of their trauma and had a history of childhood trauma responded poorer to treatment than those without such characteristics.

The findings of these studies suggest that historical PTEs such as childhood experiences may be unrelated to treatment response for a recent trauma. In contrast, findings from the only study to examine specific sequelae of the presenting traumatic event, injury, demonstrated that increased PTEs were associated with decreased treatment response. Given the mixed state of these findings and the consistent use of civilian samples, it is unclear how

these results generalize to combat veterans. All of these studies classified multiple PTEs as events from childhood as opposed to the multiple exposures to a recent trauma. The PTEs that are experienced by combat veterans occur within the relatively brief period of a deployment.

Furthermore, none of the prior studies assessed the impact that frequency of PTEs had on treatment response. Prior work demonstrates that an increased number of PTEs is associated with more severe initial PTSD symptoms (Filipas & Ullman, 2006; Lauterbach & Vrana, 2001; Schumm, Briggs-Phillips, & Hobfoll, 2006). Combat involves exposure to numerous PTEs in a brief period. Furthermore, the increased frequency of PTEs is associated with an increased likelihood of exposure to negative consequences (e.g., seeing dead bodies, being injured, seeing a fellow soldier harmed or killed). Frequent exposure to more severe trauma is hypothesized to be associated with poorer treatment response in this population. However, such conclusions cannot be drawn due to the lack of research on combat exposure's role in treatment response. All of the reviewed studies were completed with civilian victims of repeated sexual abuse/assault. Furthermore, no studies have examined the combined effect of exposure to multiple PTEs and the protective factor of perceived pre-deployment training on treatment response.

Thus, the present study investigated the influence of combat and perceived pre-deployment training on treatment response for exposure therapy in OEF/OIF veterans. Such work is consistent with recommendations to identify individual level variables that are indicative of treatment response (Krause, 2011; Thompson-Brenner, 2011). Identification of such variables allows researchers and clinicians to better tailor interventions to meet the needs of specific subgroups. For the current study, levels of combat exposure and perceived pre-deployment preparedness were identified as such variables. Participants for the current study were part of a larger randomized controlled trial comparing exposure therapy for PTSD delivered either via telehealth technologies or a traditional in-person settings (for an overview of the methods, refer to Gros *et al.*, 2011). The goal of the overall project is to provide support for telehealth treatments as a cost-effective, preferred and equally efficacious treatment for PTSD and related symptoms. For the purposes of the present study on combat exposure and treatment outcome, patients in both treatments conditions were considered in analyses and treatment modality was investigated as a potential moderator. We hypothesized that consistent with previous literature, increased combat exposure would be related to reduced treatment response in OEF/OIF veterans and that pre-deployment preparedness would moderate this relation such that increased perceived pre-deployment training would attenuate the association between combat exposure and treatment response.

METHOD

Participants

Participants were 111 OEF/OIF veterans diagnosed with PTSD ($n = 72$) or subthreshold PTSD ($n = 39$) according to the Clinician-Administered PTSD Scale (CAPS; Blake *et al.*, 1995) and recruited through referrals at a large Southeastern VA Medical Center. Diagnoses were made by trained research staff supervised by a licensed clinical psychologist. Subthreshold PTSD was defined as endorsement of Criterion A (history of PTE) and B (re-experiencing symptoms of the trauma) for PTSD and either the Criterion C (avoidance symptoms) or D symptom cluster (arousal symptoms) as defined by the Diagnostic and Statistical Manual of Mental Disorders (*DSM-IV*) (Blanchard, Hickling, Taylor, Loos, & Gerardi, 1994; Grubaugh *et al.*, 2005). Persons who are actively psychotic or demented, individuals with both suicidal ideation and clear intent, or persons with substance dependence were excluded. Participants on active medications were required to maintain medications at current dosages for the duration of treatment.

The sample was primarily male ($n = 101$; 91%), employed ($n = 67$; 60%), and married ($n = 57$; 52%). The mean age was 31.66 years (standard deviation = 8.37 years). The sample was representative of the surrounding area with most participants self-identifying as Caucasian ($n = 56$; 51%) or African American ($n = 49$; 44%).

Intervention and Assessment Procedures

A full description of the larger study methodology involving a complete list of assessment measures, treatment protocols and the randomization process can be found in Gros *et al.*, (2011). An abbreviated presentation of the methodology that is most pertinent to the current study is presented below.

The treatment involved eight weekly 1.5-hour individual sessions of exposure therapy. Assessments were completed at 1-week pre-treatment, sessions 2, 4, 6, and immediately post-treatment (session 8). The pre-treatment and post-treatment assessments involved a series of clinician-rated and self-reported measures. Self-reported measures of PTSD and depression were administered at sessions 2, 4 and 6 in addition to the pre-treatment and post-treatment (session 8) assessments.

Telecommunications Technology

Treatment sessions for the telehealth patients were conducted using in-home videoconferencing technology as part of a larger study. Either an Internet-based instant video service (e.g., 'Skype') or an analogue videophone (Viterion 500 [Viterion Telehealth Care, Tarrytown, NY]) was used at the participant's discretion. Research has demonstrated that exposure therapy can be delivered effectively to individuals with PTSD via telehealth technologies (Germain, Marchand, Bouchard, Drouin, & Guay, 2009; Gros, Yoder, Tuerk, Lozano, & Acierno, 2011; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010). After completing an initial assessment, participants were randomized to either receive treatment in-person ($n = 54$) or via telehealth ($n = 57$) as part of a larger study.

Exposure Therapy

The treatment was largely consistent with the treatment model described by Foa and colleagues (2007; Riggs, Cahill, & Foa, 2006) in which the primary components were *in vivo* and imaginal exposure trials. Exposure trials were completed in-session as well as scheduled for between session periods. A daily planner was used in order to maximize treatment participation and homework completion. As a secondary component, patients also were asked to schedule and track the completion of personally meaningful activities in their daily planner, consistent with the overarching guidelines of behavioural activation (Lejuez, Hopko, LePage, Hopko, & McNeil, 2001).

Measures

Beck Depression Inventory—2nd Edition (Beck, Steer, & Brown, 1996)—The Beck Depression Inventory—2nd Edition (BDI-II) is a 21-item measure designed to assess the cognitive, affective, behavioral, motivational and somatic symptoms of depression in adults and adolescents (Beck, Steer, & Brown, 1996). Each item is rated on a 0–3 scale with different responses based on the targeted symptom content. The BDI-II has demonstrated excellent test–retest reliability over a 1-week interval ($r = 0.93$), excellent internal consistency ($\alpha s < 0.92$) and convergent and discriminant validity in multiple samples (Beck *et al.*, 1996; Steer & Clark, 1997).

Clinician-Administered PTSD Scale (Blake et al., 1995)—The Clinician-Administered PTSD Scale (CAPS) is a clinician-rated scale designed to diagnose current

and lifetime PTSD (Blake *et al.*, 1995). The CAPS targets the 17 specific PTSD symptoms from the *DSM-IV* (APA, 2000) to assess the intensity and frequency of each symptom on a five-point Likert scale. The CAPS has been shown to have adequate internal consistency (α s ranged from 0.73 to 0.95), inter-rater reliability on the same interview (r s ranged from 0.92 to 0.99) and test–retest reliability over a 2-day to 3-day period across different interviewers (r s ranged from 0.77 to 0.98; for review, see Orsillo, 2002).

PTSD Checklist—Military (Weathers, Litz, Herman, Huska, & Keane, 1993)—

The PTSD Checklist—Military (PCL-M) is a 17-item measure designed to assess PTSD symptom severity. Respondents are presented with 17 specific symptoms of PTSD and asked to rate ‘how much you have been bothered by that problem in the last month’ on a five-point Likert scale, ranging from 1 (not at all) to 5 (extremely). The PCL has been shown to have excellent internal consistency in veterans, victims of motor vehicle accidents and sexual assault survivors (α s >0.94) and excellent test–retest reliability in veterans (r = 0.96). In addition, the PCL has demonstrated excellent convergent validity with alternative measures of PTSD (r s range from 0.77 to 0.93; Orsillo, 2002).

Combat Experiences Scale (Keane, Fairbank, Caddell, & Zimering, 1989)—

The Combat Experiences Scale (CES) is a seven-item scale designed to assess the frequency of combat exposure on a five-point Likert scale (Keane *et al.*, 1989). Sample items include ‘Were you ever under enemy fire?’ and ‘What percentage of soldiers in your unit were killed (KIA), wounded, or missing action (MIA)?’ The CES has demonstrated high internal consistency (α = 0.85) and test–retest reliability (r = 0.97) and is a consistent predictor of PTSD symptomatology in veterans (Keane *et al.*, 1989).

Deployment Risk and Resiliency Inventory (L. A. King, King, Vogt, Knight, & Samper, 2006)—

The Deployment Risk and Resiliency Inventory (DRRI) consists of 13 subscales to assess pre-deployment, active duty and post-deployment factors in recently returning combat veterans (L. A. King *et al.*, 2006). For the current study, two subscales were of interest—the DRRI-C (Training and Deployment Preparation; items include ‘I was accurately informed about what to expect from the enemy.’) and the DRRI-I (Combat Experiences; items include ‘I personally witnessed someone from my unit or an ally unit being seriously wounded or killed.’). Work with OEF/OIF veterans has shown the DRRI to demonstrate acceptable internal consistency for the subscales (α s >0.81) and convergent and discriminative validity (Vogt, Proctor, King, King, & Vasterling, 2008).

Data Analysis

The current hypotheses were assessed with multilevel modelling (MLM). MLM is considered a superior method for analyzing longitudinal data as opposed to ordinary least square regression approaches for several reasons including its improved mechanism for handling missing data and its ability to handle repeated measures (Singer & Willett, 2003). MLM divides variance across two levels. Level 1 contains variance attributed to intra-individual changes (i.e., change associated with treatment) and level 2 contains variation attributed to inter-individual differences (i.e., differences in combat exposure). Linear change models were fitted to the data that included a level 1 fixed effect for intercept (β_{00}), representing pre-treatment severity, and slope (β_{10}), representing the rate of change during treatment, and a random effect to capture residual variation. A level 2 model was fitted to the data that included measures of combat severity, pre-deployment preparedness, an interaction between these effects as predictors of intercept (β_{01}) and slope (β_{11}) and corresponding random effects to capture individual level residual variation. Data analyses were performed with SPSS 19 (SPSS Inc., Chicago, IL) and HLM 6.08 (Lincolnwood, IL).

RESULTS

Descriptive statistics are reported in Table 1. Bivariate relations amongst PCL-M, BDI-II, DRRI-I, CES and DRRI-C were conducted to assess for multicollinearity. CES and DRRI-I scores were positively related ($r = 0.67, p < 0.01$), and BDI-II and PCL-M scores were positively related ($r = 0.83, p < 0.01$). As such, these variables were included in separate analyses. MLM was used to assess the rate of change in PCL-M and BDI-II scores during the course of treatment. An unconditional change model that included subthreshold PTSD as a fixed effect for intercept and slope suggested that PCL-M scores ($\beta_{10} = -1.75, p < 0.01$) and BDI-II scores ($\beta_{10} = -0.91, p < 0.01$) declined during the course of treatment. The fixed effect for sub-threshold PTSD for the intercept was significant for the PCL-M ($\beta_{01} = -14.37, p < 0.01$) and BDI-II ($\beta_{01} = -10.83, p < 0.01$), but it was not significant for slope (PCL-M: $\beta_{11} < 0.01, p = 0.99$; BDI: $\beta_{11} = 0.17, p = 0.71$). As such, subthreshold PTSD diagnosis was retained as a fixed effect for the intercept but was removed as a fixed effect for slope. Prior to conducting the primary outcome analyses, potential covariates were examined including treatment type (in person or telehealth), age, self-reported ethnicity, sex and marital status. None of these variables were significantly associated with intercept or slope and were not included in the tested models.

Combat Exposure as Predictor of Treatment Response

Separate models were used for the CES and DRRI-I sub-scales to address potential multicollinearity issues due to a moderate correlation between the measures ($r = 0.67, p < 0.01$). The CES and DRRI-I were entered as level 2 fixed effects for intercept and slope for the PCL-M and BDI-II. For the PCL-M, CES scores were not significantly associated with intercept ($\beta_{01} = 0.35, p = 0.25$) but were positively associated with slope ($\beta_{11} = 0.08, p < 0.05$). Similar findings were obtained for the DRRI-I in that it was not significantly related to intercept ($\beta_{01} = 0.19, p = 0.67$) but was positively related to slope ($\beta_{11} = 0.18, p < 0.05$). CES and DRRI-I scores accounted for 11% and 12%, respectively, of the variance in slope for the PCL-M. These findings suggest that increased CES and DRRI-I scores, indicative of increased combat exposure, were associated with a lower rate of change in PCL-M scores, suggesting slower treatment response.

For the BDI-II, CES scores were not significantly associated with intercept ($\beta_{01} = 0.15, p = 0.46$) and slope ($\beta_{11} = 0.02, p = 0.34$). Similar findings were obtained for the DRRI-I in that it was not significantly related to intercept ($\beta_{01} = 0.19, p = 0.67$) and slope ($\beta_{11} = 0.07, p = 0.41$). Furthermore, the effect sizes were small with the CES and DRRI-I accounting for 4% and 2% respectively, of the variance in slope for the BDI-II. This suggests that combat exposure was unrelated to the rate of change in BDI-II scores.

Moderating Effect of Pre-Deployment Training on the Relation Between Combat Exposure and Treatment Response

The DRRI-C (Training and Deployment Preparation) and a DRRI-C x combat exposure (CES/DRRI-I) interaction were included as fixed effects for the slope of the PCL-M and BDI-II (Table 2). For the PCL-M, the DRRI-C had a significant fixed effect ($\beta_{12} = -0.05, p < 0.05$) and a significant interaction with the CES ($\beta_{13} = 0.01, p < 0.01$). Similar findings were obtained for the DRRI-I subscale such that the interaction term approached significance ($\beta_{13} = 0.01, p = 0.06$). The interaction term with the CES accounted for 13% of the variance in slope for the PCL-M. The interaction term for the DRRI-I accounted for 6% of the variance in slope for the PCL-M. Interaction effects typically have small effect sizes (Aiken & West, 1991) that can make them difficult to detect in smaller samples (Heo & Leon, 2010). Given that effects were found across two measures of combat exposure, prior research has supported an interaction between combat exposure and pre-deployment training

in a combat-exposed sample (Renshaw, 2011), and the limitations of the 0.05 criteria (Cohen, 1994; Nickerson, 2000; Van De Schoot, Hoijsink, & Romeijn, 2011), the interaction between the DRRI-C and the DRRI-I, was considered valid and was interpreted.

The interaction was probed at ± 1 standard deviation of the combat exposure measures (CES, DRRI-I) and the DRRI-C. The findings suggested that the relation between combat exposure (CES, DRRI-I) and treatment response for PTSD was attenuated by elevated pre-deployment training (DRRI-C) (Figure 1).

For the BDI-II, the DRRI-C was unrelated to treatment response ($\beta_{12} = -0.03$, $p = 0.54$). Furthermore, the interactions between the DRRI-C and CES ($\beta_{13} = 0.01$, $p = 0.87$) and DRRI-C and DRRI-I ($\beta_{13} = 0.01$, $p = 0.57$) were not significant (Table 2).

DISCUSSION

The present study investigated the relation between combat exposure and treatment response in OEF/OIF veterans with PTSD. Findings suggested that increased combat exposure was associated with a lower rate of change in PTSD symptoms but not depressive symptoms. Additionally, the findings provided partial support for pre-deployment preparedness as moderator of this relation such that increased pre-deployment preparedness reduced the strength of the association between combat exposure and treatment response for PTSD symptoms. Taken together, these findings suggest that although combat exposure is associated with poorer PTSD treatment response, this effect may be attenuated by increased pre-deployment preparedness.

The findings from the existing literature on the frequency of PTEs and treatment outcome are mixed and focused primarily on civilian samples with sexual abuse and assault histories (Schottenbauer *et al.*, 2008). In contrast to previous findings, the present study demonstrated a consistent negative influence of repeated PTEs (i.e., combat exposure) on treatment outcome across two measures. There are several possible explanations for this difference. First, the sample used in the current study, combat veterans, differed from those used in previous research (Hembree *et al.*, 2004; Resick *et al.*, 2003). The differences in qualitative (e.g., combat in a foreign country as opposed to assault in one's home) or quantitative (e.g., consistent exposure to ongoing combat as opposed to distinct periods of assault) aspects of the trauma could have impacted treatment response. Additional cross-trauma comparative research is needed to better understand the differences across populations of trauma-exposed individuals. Second, in contrast to previous research that used correlational and regression analyses, the present study utilized MLM, which may have been more sensitive in detecting differences. MLM provides estimates of rates of change as opposed to overall pre-treatment to post-treatment symptom changes (Singer & Willett, 2003). Additional research on veterans and other populations using MLM would be useful in providing additional support for the influence of multiple traumas on treatment outcome.

Another implication of the findings relates to the moderating effect of pre-deployment preparedness (i.e., perceived readiness for combat or resilience training) and preparation on the relation between combat exposure and treatment outcome. Pre-deployment training and combat readiness programs have gained in popularity in the US military (e.g., 'Battlemind training') (Castro & Hoge, 2005; Hall, Cipriano, & Bicknell, 1997; Sharpley, Fear, Greenberg, Jones, & Wessely, 2008). However, evidence regarding the impact that these programs have on those that go on to develop PTSD and subsequently enter treatment have yet to be reported. The present findings are the first to suggest that pre-deployment preparedness may serve to reduce the negative impact of increased combat exposure on treatment response for PTSD.

The present findings also identified a different pattern of results for the symptoms of PTSD and depression. Specifically, combat exposure was not statistically related to treatment response for symptoms of depression, and the effect sizes were also substantially smaller than those for the symptoms of PTSD. This finding was surprising given the highly overlapping nature of the symptoms of depression and PTSD (Gros, Simms, & Acierno, 2010; Kessler, Sonnega, Bromet, & Hughes, 1995; Perkonig, Kessler, Storz, & Wittchen, 2000). More specifically, recent research has demonstrated that specific symptoms of PTSD—referred to as symptoms of dysphoria (Simms, Watson, & Doebbell, 2002) or numbing (D. W. King, Leskin, King, & Weathers, 1998)—are more associated with depression than PTSD itself (Gros *et al.*, 2010). Given these findings, the present study may suggest that the influence of combat exposure is most strongly related to the PTSD-specific symptoms, namely re-experiencing, avoidance, and hyperarousal. Interestingly, these symptoms (re-experiencing, hyperarousal) are most commonly targeted using exposure therapy, potentially explaining the identified changes in treatment outcome in the present study. However, note that recent empirical research has suggested that the symptom overlap between depression and PTSD does not fully account for this comorbidity (van Emmerik & Kamphuis, 2011). Future work is needed to identify factors that are associated with the treatment of co-occurring depression in PTSD patients.

Several limitations of the present study require consideration. First, the present study relied on retrospective, self-reported measures of combat exposure and pre-deployment training and support. More formal documentation of the extent and content of pre-deployment training should follow in future studies, though accessing this information is somewhat difficult. Moreover, despite similar findings having been obtained for pretreatment levels of PTSD (Renshaw, 2011), implications of the findings of the current study should be interpreted with caution given the limitations of the methodology. Recently, Lee and colleagues (2011) developed the Combat Experience Log (CEL), a system by which combat experiences are reported by active duty service members while they are in theater. The CEL provides a method to assess exposure to PTEs that is less vulnerable to retrospective bias and could be used in prospective studies of PTSD development and treatment response. Furthermore, the CEL will be able to capture more relevant aspects of combat experience that may be associated with resilience and outcomes such as perceived threat during a combat experience. Second, although all patients endorsed significant Criteria A PTEs on the CAPS, the combat exposure questionnaires assessed the amount of combat exposure, rather than PTEs, limiting conclusions regarding multiple traumatic exposures. Third, the study involved single measures of self-reported PTSD and depression as the outcomes. Future studies should incorporate more thorough assessment procedures of these constructs to replicate and expand the findings of the present study. Finally, an extensive trauma history for each patient was not available and so the current study was unable to control for the effects of past traumas, including that of childhood traumatic events.

In conclusion, the present study is among the first to demonstrate a negative relation between increased combat exposure and treatment response for PTSD symptoms in OEF/OIF veterans. However, perceived pre-deployment training moderated this relation such that increased perceptions of pre-deployment training reduced the impact of combat exposure on treatment response. These findings highlight the important role of increased combat exposure in the treatment of PTSD symptoms and provide preliminary evidence as to the additive benefits of combat training on treatment response. Researchers are encouraged to replicate these findings in order to provide more substantial evidence as to the role of these variables with the goal of enhancing the treatment process.

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Key Practitioner Message

- Increased combat exposure is associated with poorer treatment response.
- Pre-deployment training is associated with improved treatment response.
- PTSD interventions should account for the frequency of combat in military personnel.

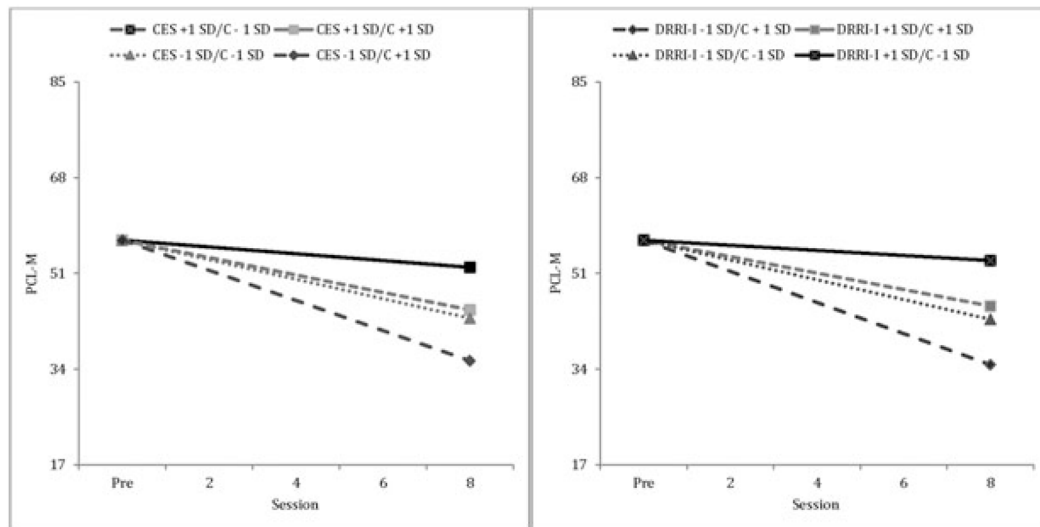


Figure 1.

Outcome trajectories for PCL-M at ± 1 standard deviation (SD) of the CES and ± 1 SD of the pre-deployment training sub-scale. CES = Combat Exposure Scale. DRRI-I = Deployment Risk and Resilience Inventory, I (Combat Exposure) subscale. PCL-M = PTSD Check List—Military Version. C = DRRI-C = pre-deployment training subscale

Table 1

Descriptive statistics for outcome and moderators of treatment response

	Pre-treatment	Session 2	Session 4	Session 6	Post-treatment (session 8)
Symptom variables					
PCL	56.70 (15.21)	55.21 (14.88)	49.54 (16.53)	45.47 (17.17)	44.64 (17.55)
BDI	23.64 (11.39)	21.62 (10.73)	18.13 (10.06)	17.00 (11.02)	17.09 (12.44)
CAPS	60.72 (18.50)	—	—	—	47.87 (25.02)
Combat exposure					
CES	20.45 (5.86)	—	—	—	—
DRRI-I	20.93 (4.05)	—	—	—	—
Moderators					
DRRI-C	51.32 (9.38)	—	—	—	—

PCL-M = PTSD Check List—Military Version. BDI-II = Beck Depression Inventory. CAPS = Clinician-Administered PTSD Scale. CES = Combat Exposure Scale. DRRI-I = Deployment Risk and Resilience Inventory, I (combat exposure) subscale. DRRI-C = Deployment Risk and Resilience Inventory, C (Pre-deployment training).

Table 2

Multilevel model examining combat exposure and pre-deployment training as moderators of treatment response for PTSD and depression symptoms

Combat exposure measure		PCL-M	
		CES	DRRI-I
Intercept	β_{00}	62.93 ** (2.11)	62.75 ** (2.20)
Subthreshold PTSD	β_{02}	-14.48 ** (3.31)	-14.10 ** (3.38)
Slope	β_{10}	-1.70 ** (0.33)	-1.62 ** (2.60)
Combat exposure	β_{11}	0.09 ** (0.02)	0.11 * (0.05)
Pre-deployment training	β_{12}	-0.05 ** (0.02)	-0.07 * (0.03)
Combat exposure $\times$ DRRI-C	β_{13}	0.01 ** (0.002)	0.01 ⁺ (0.004)
BDI-II			
		CES	DRRI-I
Intercept	β_{00}	27.96 ** (1.60)	27.85 ** (1.61)
Subthreshold PTSD	β_{01}	-10.64 ** (2.10)	-10.40 ** (2.10)
Slope	β_{10}	-0.90 ** (0.20)	-0.88 ** (0.20)
Combat exposure	β_{11}	0.03 (0.03)	0.04 (0.04)
Pre-deployment training	β_{12}	-0.03 (0.02)	-0.03 (0.02)
Combat exposure $\times$ DRRI-C	β_{13}	0.01 (0.01)	0.01 (0.003)

* $p < 0.05$.

** $p < 0.01$.

⁺ $p = 0.06$.

PCL-M = PTSD Check List—Military Version. CES = Combat Exposure Scale. DRRI-I = Deployment Risk and Resilience Inventory, I (combat exposure) subscale. DRRI-C = Deployment Risk and Resilience Inventory, C (Pre-deployment training). BDI-II = Beck Depression Inventory.

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The Role of Social Support in Exposure Therapy for Operation Iraqi Freedom/Operation Enduring Freedom Veterans: A Preliminary Investigation

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Abstract

The lack of social support has consistently been identified as a relevant factor in the development, maintenance, and treatment of posttraumatic stress disorder (PTSD). Prospective studies with combat veterans have supported the erosion model of social support in the development of PTSD. This model posits that increased PTSD symptoms lead to diminished social support over time. Additional epidemiological work that has investigated mental health and functional impairment in recently returning Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF) veterans has suggested that interpersonal problems coincide with the onset of PTSD. Despite research that suggests OIF/OEF veterans experience high rates of PTSD and associated interpersonal problems, no studies have examined social support in relation to treatment response in this group. The current study examined the role of four theorized functional aspects of social support— emotional/informational support, positive social interactions, affectionate support, and tangible support— on pretreatment PTSD symptom severity and treatment response in a sample of OIF/OEF veterans receiving exposure-based psychotherapy. Findings showed that positive social interactions were negatively correlated with pretreatment symptom severity, and emotional/informational support was positively related to increased treatment response. Together, these findings suggest that specific types of social support may have an important influence on the course of exposure treatment.

Keywords

PTSD; OEF/OIF; Veterans; social support; exposure therapy

Posttraumatic stress disorder (PTSD) is a chronic condition characterized by the reexperiencing of a traumatic event, avoidance of reminders of this event, and hyperarousal. A number of studies have examined potential risk and protective factors for PTSD with social support emerging as a key construct (Kilpatrick et al., 2007; Pietrzak, Goldstein, Malley, Rivers, & Southwick, 2010; Whealin, Ruzek, & Southwick, 2008; Wilcox, 2010; Zoellner, Foa, & Brigidi, 1999). A meta-analysis demonstrating that reduced social support was strongly associated with increased chronic PTSD symptoms, especially in high risk populations (Brewin, Andrews, & Valentine, 2000). Furthermore, theorists have identified social support as a key mechanism in the prevention and treatment of the disorder (Whealin et al., 2008). However, much of the research on social support and PTSD has focused on

disaster-affected samples, which may limit the generalizability of these findings to other high risk groups, such as combat veterans. Social support may be a particularly relevant construct in the study of combat veterans because the deployment cycle is characterized by considerable social upheaval. Young men and women deployed to the war zone experience considerable displacement as they adjust to military culture abroad. Further, they may feel alienated from loved ones with whom they have less direct contact. At postdeployment, soldiers must make a substantial transition, reintegrating with their families, friends, peers, and coworkers after having experienced life-changing traumas (Milliken, Auchterlonie, & Hoge, 2007).

The *erosion model* provides a theoretical framework for the association between PTSD and social support in combat veterans (King, Taft, King, Hammond, & Stone, 2006). This model posits that prolonged PTSD symptoms lead to a reduction in social support due to interpersonal difficulties, feelings of detachment, increased irritability, and increased avoidance of social stimuli. The erosion model is consistent with leading cognitive models of PTSD that suggest that those with the disorder adopt a perspective in which others are viewed as dangerous and the world is viewed as unsafe (Ehlers & Clark, 2000; Resick & Schnicke, 1992). Support networks are viewed with frustration, potential support members are perceived as threatening, and social interactions are thought to increase the risk for additional trauma exposure (Kaniasty & Norris, 1993; Keane, Scott, Chavoya, Lamparski, & Fairbank, 1985). Over time, those with PTSD avoid members of their support network in an effort to reduce perceived threat and increase perceived safety. Indeed, a recent study demonstrated that viewing support as inappropriate, useless, or dangerous, mediated the association between PTSD symptoms and reduced social support (Clapp & Beck, 2009).

Several longitudinal empirical studies provide support for the erosion model in combat veterans. One of the first examined a large sample of male Gulf War veterans assessed within 7 years of their deployment and then reassessed 5 years later (King et al., 2006). Findings suggested that initial PTSD symptoms predicted lower social support at 5-year follow-up; however, initial social support did not predict baseline PTSD symptoms. Similar findings were obtained in another study using Vietnam and Gulf War veterans (Laffaye, Cavella, Drescher, & Rosen, 2008), in which PTSD symptoms were predictive of lower levels of interpersonal support from nonveteran peers and partially associated with poorer support from veteran peers over a 6-month period. A third study demonstrated that Vietnam and Gulf War veterans with poorer social support had increased PTSD symptoms and were more likely to utilize Veterans Affairs (VA) PTSD treatment services than those with higher ratings of support (Fontana & Rosenheck, 2010). Furthermore, those who accessed treatment more than once demonstrated reduced social functioning over time. Additional support for the erosion hypothesis comes from longitudinal research with disaster victims. Kaniasty and Norris (2008) examined the association between PTSD and social support over the course of 2 years in survivors of a natural disaster. Increased PTSD symptoms at 1 year were highly predictive of reduced social support at 18-month follow-up. Similarly, increased PTSD symptoms at 18-month follow-up was associated with reduced social support at 2-year follow-up. Furthermore, social support at the 18-month follow-up did not predict PTSD symptoms at 2-year follow-up. These findings suggest that pervasive PTSD symptoms eroded social support over time.

The negative effect of PTSD on social support several months after exposure to a traumatic event is especially relevant to combat veterans. There is often a significant amount of time between exposure to a traumatic event and reconnection with the home social network. Evidence for a negative relation between PTSD and social support comes from research demonstrating that Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) veterans have prevalence estimates of PTSD ranging from 17% to 21% (Hoge et al., 2004;

Seal et al., 2009), and a fourfold increase in rates of self-reported interpersonal conflict in veterans within 6 months of returning from deployment (Laffaye, Cavella, Drescher, & Rosen, 2008). Only two studies have directly examined the association between social support and PTSD symptoms in this population. Pietrzak, Johnson et al. (2010) demonstrated that OIF/OEF Veterans with PTSD reported lower postdeployment social support than those without a diagnosis. A second study examined the relation between PTSD symptoms and social support from different sources (e.g., family members, peers, military peers; Wilcox, 2010). Results demonstrated that reduced overall social support was associated with increased PTSD symptom severity. Lack of support from significant others, family, and military peers was specifically associated with increased PTSD symptom severity, whereas support from nonmilitary peers was unrelated.

Interestingly, there have not been any studies evaluating the effects of social support during the treatment of PTSD in veterans. Exposure-based psychotherapies are successful at reducing symptoms of PTSD across a wide range of traumatized samples, including combat veterans (Institute of Medicine, 2007; Gros et al., 2010; Gros, Yoder, Tuerk, Lozano, & Aciermo, 2011; Tuerk et al., 2011). Exposure therapy is theorized to reduce PTSD symptoms through stimulus habituation that is secondary to emotional processing of fear memories. Emotional processing occurs through prolonged, controlled, and sustained exposure to a feared stimulus. In the treatment of PTSD, the feared stimuli include in vivo situations, as well as memories associated with the trauma that are typically avoided. Due to the nature of these exercises, exposure treatment components may also be interpreted as aversive and frequently avoided. Social support may facilitate engagement with these treatment practices, and thus, improve overall outcomes. For example, veterans with higher degrees of social support may bring support members to an in vivo exposure and/or discuss the content of an imaginal exposure with a support member. The support member would serve as a source of additional feedback about the safety of the situation, which would facilitate the development of extinction learning.

Given the emphasis placed on social support as a protective factor in the empirical and theoretical literature, further research on this construct in the treatment of PTSD in veterans is warranted. The majority of the research on this topic has been conducted with veterans from prior conflicts, and there is little data examining the association between social support and PTSD symptoms in veterans of the most recent OIF/OEF conflicts. Furthermore, few studies have examined the relation between perceived social support and response to exposure therapy among veterans with PTSD.

The current study attempts to build on this research in several ways. First, it assessed social support as a multidimensional construct as defined by its functional components (Cohen & Wills, 1985; House & Kahn, 1985; Vaux, 1988). The most commonly endorsed functions of social support include the following: (a) emotional support, which involves caring and empathy; (b) tangible support, which involves assistance in completing tasks; (c) affectionate support, which involves specific expression of positive emotions; and (d) social interaction, which involves a sense of social companionship or integration (Sherbourne & Stewart, 1991). It was predicted that lower levels of social support across all of the assessed domains would be associated with increased PTSD symptom severity. Second, the current study evaluated social support as a predictor of treatment response for exposure therapy, one of the most empirically supported methods of treating PTSD symptoms (Fontana & Rosenheck, 2010; King et al., 2006). The only study to demonstrate that self-reported social support was associated with improved PTSD treatment response was conducted with a civilian sample (Thrasher, Power, Morant, Marks, & Dalgleish, 2010). Although members of the social support network are not directly involved in treatment, it is expected that

increased support outside of treatment will enhance response due to the protective effect of social support on PTSD symptoms (Barrett & Mizes, 1988; Whealin et al., 2008).

Methods

Participants

Participants were 69 OIF/OEF veterans diagnosed with PTSD ($n=43$) or subthreshold PTSD ($n=26$) according to the Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995). Participants were treatment-seeking veterans who were referred to the study through a PTSD clinic in a large Southeastern VA Medical Center (VAMC). Upon consent, they were administered an assessment battery designed specifically for the study. Diagnoses were made by trained research staff who were supervised by a licensed clinical psychologist. Subthreshold PTSD was defined as meeting full criteria for Criteria A (history of PTE) and B (reexperiencing symptoms of the trauma) for PTSD, and either Criterion C (avoidance symptoms) or D (arousal symptoms), as defined by the *Diagnostic and Statistical Manual, Fourth Edition (DSM-IV)* (American Psychiatric Association, 1996; Blanchard, Hickling, Taylor, & Loos, 1994; Grubaugh et al., 2005). Veterans with actively psychotic or demented symptoms, including both suicidal ideation and clear intent, or substance dependence were excluded from the study. Participants on active medications were required to maintain current dosages for the duration of treatment. After completing an initial assessment, participants were randomized to either receive treatment via in-person exposure therapy ($n=36$) or via telehealth-based exposure therapy ($n=33$) as part of a larger study (Gros et al., 2010).

The sample was primarily male ($n=58$; 91%), employed ($n=40$; 58%), and married ($n=33$; 52%). The mean age was 31.66 ($SD=8.37$; Range = 21–56). The majority of the sample self-identified as either Caucasian ($n=32$; 46%) or African American ($n=28$; 41%).

Intervention and Assessment Procedures

The treatment involved eight weekly 1.5-hour individual sessions of exposure therapy. The pretreatment assessments involved a series of clinician-rated and self-reported measures, including the CAPS and Medical Outcomes Study Social Support Survey (MOSSS; Sherbourne & Stewart, 1991). The PTSD Checklist—Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993) was administered by the treating clinicians at pretreatment and treatment Sessions 2, 4, 6, and 8. A final posttreatment assessment was scheduled for all participants, including those who did not complete treatment, in order to obtain endpoint data.

Exposure Therapy

The treatment provided was most consistent with the model described by Foa, Hembree, and Rothbaum (2007). Thus, the primary treatment components were in vivo and imaginal exposure trials. Exposure trials were completed in-session, as well as scheduled between session periods. A daily planner was used for scheduling to maximize treatment participation and homework completion. As a secondary component, patients were also asked to schedule and track the completion of personal values-based (i.e., meaningful), positive activities in their daily planner throughout treatment, following the overarching guidelines of behavioral activation (Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011). This planning of reinforcing activities did not interfere with frequent exposure practice, and therefore, served to complement the exposure and fill the patient's weekly schedule. Social support was not explicitly addressed as part of the treatment protocol. All participants received eight 90-minute sessions administered by masters-level therapists. Therapists completed a week-long training program and were required to shadow a senior level

clinician throughout a complete course of treatment before administering the treatment independently. Therapists met weekly with the principal investigator (Ron Acierno, Ph.D.) for supervision throughout the duration of the study. Sessions were audio-taped and monitored by an independent rater to ensure treatment fidelity.

Telecommunications Technology

Treatment sessions for the telehealth patients were conducted using in-home videoconferencing technology as part of a larger study. Either an Internet-based instant video service (e.g., “Skype”) or an analogue videophone (Viterion 500) was used at the participant’s discretion. Research has demonstrated that exposure therapy can be delivered effectively to individuals with PTSD via telehealth technologies (Germain, Marchand, Bouchard, Drouin, & Guay, 2009; Gros et al., 2011; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010).

Measures

Clinician-administered PTSD scale—The CAPS is a clinician-rated scale designed to diagnose current and lifetime PTSD (Blake et al., 1995). The CAPS assesses the intensity and frequency of 17 specific PTSD symptoms on a five-point Likert scale. The CAPS has been shown to have adequate internal consistency (α s ranged from .73 to .95), interrater reliability on the same interview (r s ranged from .92 to .99), and test–retest reliability over a 2 to 3 day period across different interviewers (r s ranged from .77 to .98; for review, see Orsillo, Batten, & Hammond, 2001). In addition, the CAPS has demonstrated adequate convergent validity to alternative measures of PTSD (r s ranged from .77 to .91) and adequate discriminant validity to measures of depression (r s ranged from .69 to .74) and anxiety (r s ranged from .65 to .76). Finally, the diagnosis established by the CAPS has been found to be comparable to alternative structured interviews (Weathers, Ruscio, & Keane, 1999), including the Structured Clinical Interview for the *DSM-IV* (American Psychiatric Association, 2000; First, Spitzer, Gibbon, & Williams, 1996).

PTSD Checklist—Military—The PCL–M is a 17-item measure designed to assess PTSD symptom severity. Respondents are presented with 17 specific symptoms of PTSD and asked to rate “how much you have been bothered by that problem in the last month” on a five-point Likert scale, ranging from 1 (*not at all*) to 5 (*extremely*). The PCL has been shown to have excellent internal consistency in veterans, victims of motor vehicle accidents, and sexual assault survivors (α s > .94) and excellent test–retest reliability in veterans ($r = .96$; for review, see Orsillo et al., 2001). In addition, the PCL has demonstrated excellent convergent validity with alternative measures of PTSD (r s range from .77 to .93; Orsillo et al., 2001). Cronbach’s alphas for the current study were consistently in the excellent range (α s > .93).

Medical Outcomes Study Social Support Survey Form (MOSSS)—The MOSSS is a widely used 19-item, self-report measure designed to assess social support across four domains: emotional/information support (8 items; range: 8 – 48; e.g., “Someone you can count on to listen to you when you need to talk”), tangible support (4 items; range: 4–24; e.g., “Someone to help with daily chores if you were sick”), affectionate support (3 items; range: 3–18; e.g., “Someone who shows you love and affection”), positive social interaction (3 items; range: 3–18; e.g., “Someone to do something enjoyable with”), and an additional item that does not load on any other factor (1 item; range 1– 6; e.g. “Someone to do things with to help you get your mind off things.”). Responses are given on a 6-point Likert scale ranging from 1– 6 with greater scores indicating less support in the given domain. The measure was originally developed to examine the function and types of interpersonal support in chronically ill patients (Sherbourne & Stewart, 1991). A factor-analytic study

with a large clinical sample validated the subscales of the MOSSS (Sherbourne & Stewart, 1991), and additional work has validated the measure in mental health samples (Gjesfjeld, Greeno, & Kim, 2008). The MOSSS has been shown to be an accurate measure of social support in veteran samples with mental health issues (Cotten, Skinner, & Sullivan, 2000; Hart, 2002; Jakupcak et al., 2011; Kilbourne, McCarthy, Post, Welsh, & Blow, 2007). Internal consistency for the MOSSS subscales at pretreatment and posttreatment were consistently in the excellent range (α s > .95). For the current study, only the primary subscales (emotional information support, tangible support, affectionate support, and positive social interactions) were included in the analysis.

Data Analyses

Hypotheses were assessed with multilevel modeling (MLM). MLM is considered a stronger method for analyzing longitudinal data than ordinary least squares regression approaches such as because of its improved mechanism for handling missing data and its reliance on fewer assumptions, such as a need for measurements to be independent (Singer & Willett, 2003). MLM divides variance across two levels. Level 1 contains variance attributed to intraindividual changes (i.e., change associated with treatment), and Level 2 contains variance attributed to interindividual differences (i.e., differences in social support). Linear change models were fitted to the data that included a Level 1 fixed effect for intercept (β_{00}), representing pretreatment severity, and slope (β_{10}), representing the rate of change during treatment. A Level 2 model was fitted to the data that included measures of social support as predictors of intercept (β_{01-4}) and slope (β_{11-4}). Of the 69 participants that were enrolled in the study, posttreatment data was available for 45 of them. Restricted Maximum Likelihood (RML) was used with all available information included in the analyses. RML has shown to provide more accurate estimates for smaller samples (Singer & Willett, 2003).

Results

Preliminary Analyses

Descriptive statistics for all variables are presented (see Table 1). Preliminary analyses were conducted to assess potential differences across demographic variables on the PCL–M, as well across the MOSSS subscales. The results consistently suggested that there were no differences across these variables in terms of ethnicity, employment status, or branch of the military. Furthermore, PCL–M and MOSSS subscales were unrelated to age or education. Participants who were married, $M = 5.18$, $SD = 2.57$, reported significantly greater support on the affection subscale than those who were not married, $M = 8.52$, $SD = 6.07$; $F(2, 60) = 4.29$, $p < .01$. This variable (married or not married) was included in the analysis as a covariate. There were no significant differences in the primary variables of interest between treatment modality (in-person or telehealth). Additionally, a series of repeated measures t tests were conducted to determine if social support changed during the course of treatment. There were no significant differences for any measure, suggesting that emotional/information support, $t(68) = -0.97$, $p = .34$; tangible support, $t(68) = -0.33$, $p = .75$; affectionate support, $t(68) = 1.16$, $p = .27$; and positive social interactions, $t(68) = -0.15$, $p = .88$, did not change during the course of treatment. Finally, dropout status was not predictive of initial PTSD symptom severity and was unrelated to all social support subscales.

Social Support as a Predictor of Symptom Severity

An MLM was fitted to the data that included Level 1 fixed effects for pretreatment severity (intercept) and the rate of change (slope) and Level 2 fixed effects for emotional/informational support, tangible support, affectionate support, and positive social interactions for both slope intercept and slope. For symptoms of PTSD (PCL–M), the relation between

positive social support and pretreatment severity was significant such that decreased support was associated with greater symptom severity, $\beta_{01} = 0.45$, $p < .05$ (see Table 2). Emotional/information support, tangible support, and affectionate support were not related to pretreatment PTSD symptoms. The social support subscales accounted for 8% of the variance in PTSD symptom severity.

Social Support as a Predictor of Treatment Response

For treatment response, the findings suggested that PTSD symptoms, $\beta_{11} = -2.26$, $p < .01$, declined as a result of treatment. Emotional/information support was significantly related to the rate of change in PTSD symptoms such that increased emotional support was associated with better treatment response, $\beta_{14} = 0.11$, $p < .05$ (see Figure 1). However, affectionate support, tangible support, and positive social interaction were not associated with the rate of change in PTSD symptoms. The social support sub-scales explained 11% of the variance in treatment response.

Discussion

The present study examined the relation between the functional aspects of social support and PTSD symptom severity and treatment response in a sample of OIF/OEF veterans. The findings suggested that reduced positive social interactions were associated with increased PTSD symptoms at the start of treatment and increased emotional/informational support is associated with stronger treatment response. In contrast, affectionate and tangible support were unrelated to both symptom severity and treatment response. These associations were maintained after controlling for marital status.

The association between pretreatment PTSD symptom severity and positive social interactions is likely to be reciprocal in nature in OIF/OEF Veterans. That is, PTSD is defined by avoidance of cues related to the traumatic event, and these cues are often social in nature; the avoidance of these cues then reduces the opportunity for future social interactions. Consistent with prior work, increased isolation (Brewin et al., 2000; Herman, 1992) and reduced support from family, loved ones, and military peers (Wilcox, 2010) often maintains and can exacerbate symptoms of PTSD. The association between symptoms and the positive social interaction scale, which assesses level of companionship, provides added support for this hypothesis. Building upon the findings of Kaniasty and Norris (2008) and using the framework of the erosion model (King et al., 2006), this relation may be indicative of patients who have been struggling with PTSD for longer periods. The current study was unable to test this hypothesis due to the unavailability of data on the duration of symptoms and time since deployment. Additional longitudinal and prospective studies are needed to fully evaluate the likely complicated association between social support and PTSD symptom severity.

These findings are the first to suggest that increased emotional/informational support is associated with improved PTSD treatment response in exposure treatment. Cognitive models suggest that those with PTSD perceive the world as dangerous or threatening and view their social support network as a source of risk (Ehlers & Clark, 2000; Keane et al., 1985; King, King, Foy, Keane, & Fairbank, 1999; Resick & Schnicke, 1992). Sources of emotional/informational support express positive and empathetic affect, encourage expression of feelings and emotion, and offer advice, guidance, and feedback, which promote a sense of safety (Kessler, Price, & Wortman, 1985; Sherbourne & Stewart, 1991). Indeed, theorists have suggested that increased social support may increase feelings of safety for those with PTSD, which have also been highlighted as a critical component for conducting successful exposure therapy (Charuvastra & Cloitre, 2008). The perceived safety that comes from these sources of support is theorized to facilitate treatment response.

There are several potential mechanisms to explain how increased perceived safety enhances treatment response. First, those with greater emotional support may be more compliant with treatment, and thus, willing to engage in more exposures or more difficult exposures. Increased emotional support also may further reinforce treatment gains as successful exposures are met with positive, empathic, and supportive responses. These responses would strengthen the extinction learning that takes place during exposures. Alternatively, the perceived safety from sources of emotional support may improve the participant's inherent coping mechanisms, which may then facilitate greater extinction learning.

Prior research suggests that increased social support is associated with improved coping strategies (Besser, Neria, & Haynes, 2009). Emotional support may help one overcome the emotional numbing that is associated with PTSD such that the veteran would receive a positive empathic response when expressing emotions to others. This may be related to an improved therapeutic alliance as prior work has demonstrated that increased social support at the start of treatment is associated with more rapid acquisition of a therapeutic alliance in victims of child sexual abuse (Keller, Zoellner, & Feeny, 2010).

Finally, there has been evidence to suggest that increased social support helps to facilitate the natural recovery process in those that have experienced a trauma (Dunmore, Clark, & Ehlers, 2001). Theorists suggest that increased support helps to buffer against the pervasiveness of negative world views that are associated with PTSD (Charuvastra & Cloitre, 2008; Horowitz, 1986). It is therefore plausible that increased positive social support will facilitate the recovery process in combat veterans enrolled in exposure therapy by providing additional corrective experiences. Future research is needed to better understand the mechanism by which increased emotional support enhances PTSD treatment response for exposure-based interventions. Such research should also focus on examining the impact of social support across different symptoms clusters of PTSD in order to more fully examine the influence of social support on treatment response (King, Leskin, King, & Weathers, 1998; Simms, Watson, & Doebbeling, 2002).

Tangible support (e.g., having others who assist with or complete tasks), positive social interactions (e.g., having others to engage in pleasurable activities with), and affectionate support (e.g., receiving physical affection from others) were unrelated to treatment response for PTSD symptoms. Tangible support may be unrelated to treatment response to the extent that it reduces the therapeutic efficacy of in vivo exposures. More specifically, veterans who have high levels of tangible support may be less motivated to enter perceived dangerous situations because members of their support network complete tasks for them. For example, a veteran may be less willing to complete in vivo exposures associated with daily living activities, such as going to the grocery store, if they have members of their network who will complete such tasks for them. Future work should determine if higher levels of tangible support are associated with an increased sense of disability such that patients are less likely to engage in exposures that are paired with functional activities. Due to the preliminary nature of these findings, the lack of an association between such types of support and treatment response should be interpreted with caution until they are replicated in larger samples of veterans.

The current study had several limitations. First, the sample of veterans was relatively small as compared to other studies that have examined social support and PTSD (Forbes et al., 2008; Pietrzak, Johnson, et al., 2010; Wilcox, 2010). The findings of the current study should be replicated with larger military samples. The current sample consisted entirely of treatment-seeking veterans and may not generalize to veterans who do not seek treatment. Also, the sample was predominately male (91%), and so the findings may not generalize to female combat veterans. Additional research should be conducted to explore the associations

between support and PTSD symptoms in female combat veterans, especially victims of military sexual trauma. Third, the study relied exclusively on self-report measures of social support. Social support has been defined as a complex construct that may not be fully assessed with self-report measures (Cohen & Wills, 1985). Future work should replicate these findings using mixed method approaches that assess social support through responses from members of the veteran's social network, behavioral observations, and ecological assessments of support. Furthermore, the sources of social support were not considered. Prior work has demonstrated the association between social support and PTSD symptoms can vary across different sources, including family and friends (Wilcox, 2010). Additional research is needed to determine if the source of support moderates the association between the type of social support and treatment response. Furthermore, the current study was not sufficiently powered to fully assess potential moderators of the association between social support and treatment response including current living situation, family characteristics, and length of time since deployment. Length of time since deployment should be considered in future studies as this will provide an estimate of the duration of time since a traumatic event. Prior work with disaster victims has shown that the relation between PTSD and social support changes as time from the traumatic event increases (Kaniasty & Norris, 2008).

The findings of the current study are the first to demonstrate that social support is associated with treatment response for PTSD in returning combat veterans, and these results replicate findings that social support is associated with PTSD symptom severity. Furthermore, the functional components of social support have different roles in that social interactions are most strongly associated with pretreatment severity, and emotional/informational support was found to be the strongest predictor of treatment response. This suggests that incorporating sources of emotional support into the treatment process may enhance exposure-based interventions. Additional work is needed to more fully explore how this type of support results in more positive outcomes. Specifically, research should examine if social support is more strongly associated with certain components of treatment, such as in vivo and imaginal exposures.

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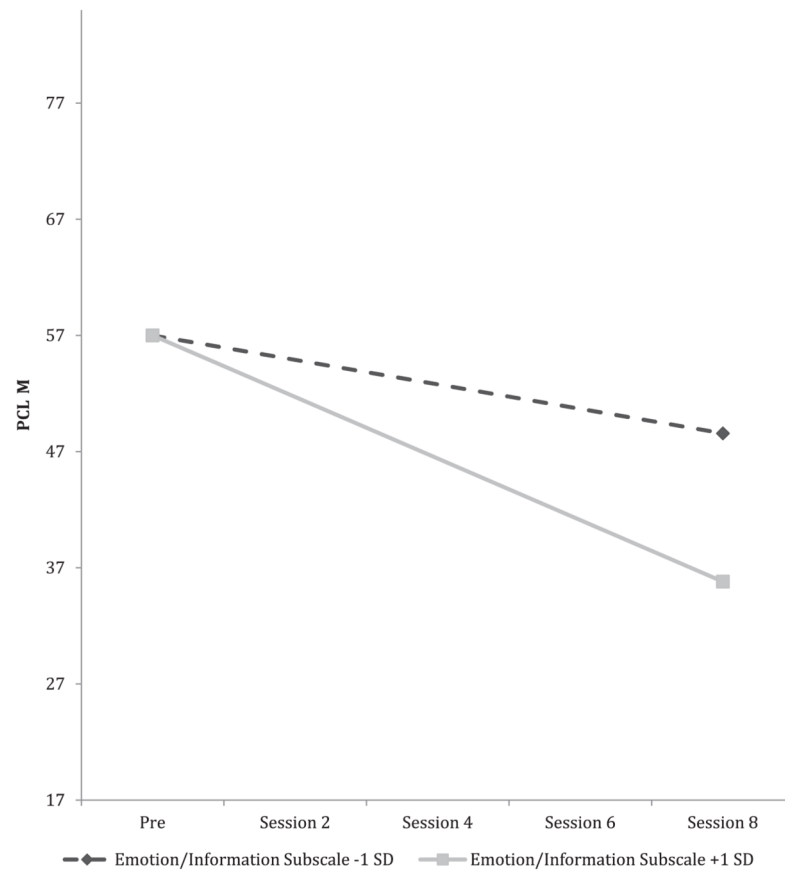


Figure 1. Outcome trajectories on PCL–M for ± 1 *SD* on the MOSSS Emotional/Informational Support subscale. Interaction probed at ± 1 *SD* according to the guidelines of Aiken and West (1991). The lowest possible score on the PCL–M is a 17.

Table 1

Descriptive Statistics for PCL-M and Medical Outcomes Social Support Subscales Across Treatment

Variables	Pretreatment	Session 2	Session 4	Session 6	Session 8
PCL-M	56.70 (15.21)	55.21 (14.88)	49.54 (16.53)	45.47 (17.17)	44.64 (17.55)
Subscales of MOSSS					
Positive social interactions	2.76 (1.65)	—	—	—	2.54 (1.59)
Emotional/informational support	2.98 (1.43)	—	—	—	2.67 (1.45)
Tangible support	2.32 (1.36)	—	—	—	2.24 (1.52)
Affectionate support	2.23 (1.58)	—	—	—	2.17 (1.51)

Note. PCL-M = Posttraumatic Checklist—Military; MOSSS = Medical Outcomes Social Support scale. Scores on the MOSSS reflect the mean item score. Higher scores on MOSSS subscales indicate lack of support. Values in parentheses are standard deviations.

Table 2

Fixed Effects for MOSSS Subscales as a Predictor of Treatment Response

Fixed Effect	Coefficient	PCL-M
Pretreatment severity (intercept)	β_{00}	57.47 ** (1.87)
Positive social interactions	β_{01}	0.45 * (0.21)
Emotional/informational support	β_{02}	-0.33 (0.46)
Tangible support	β_{03}	0.03 (0.59)
Affectionate support	β_{04}	-0.33 (0.60)
Married or not married	β_{05}	-0.42 (4.00)
Rate of change (slope)	β_{10}	-2.26 ** (0.47)
Positive social interactions	β_{11}	<0.01 (0.03)
Emotional/informational support	β_{12}	0.11 * (0.06)
Tangible support	β_{13}	0.10 (0.13)
Affectionate support	β_{14}	-0.21 (0.13)
Married or not married	β_{15}	0.83 (0.60)

Note. PCL-M = Posttraumatic Checklist—Military. Values in parentheses are standard errors.

*
 $p < .05$.

**
 $p < .01$.

An Integrated Approach to Delivering Exposure-Based Treatment for Symptoms of PTSD and Depression in OIF/OEF Veterans: Preliminary Findings

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Combat-exposed military personnel from the wars in Iraq and Afghanistan report high rates of PTSD and associated psychiatric problems. A formidable body of research supports exposure therapy as a front-line intervention for PTSD; however, relative to studies of civilians, fewer investigations have evaluated the effectiveness of exposure therapy using military samples. Specifically, barriers to care (e.g., stigma associated with receiving mental health services) may compromise utilization of evidence-based psychotherapy. As such, researchers have argued that veterans with PTSD may require an integrated and innovative approach to the delivery of exposure techniques. This paper presents the rationale for

and preliminary data from an ongoing clinical trial that compares the home-based telehealth (HBT) application of a brief, behavioral treatment (Behavioral Activation and Therapeutic Exposure; BA-TE) for veterans with PTSD to the standard, in-person application of the same treatment. Forty OIF/OEF veterans with PTSD and MDD were consented, enrolled, and randomized to condition (BA-TE in-person, or BA-TE HBT) and symptoms of anxiety and depression were assessed at pre- and posttreatment. Participants in both conditions experienced reductions in depression, anxiety, and PTSD symptoms between pre- and posttreatment, suggesting that HBT application of an integrated PTSD treatment may be feasible and effective.

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VETERANS OF OPERATION ENDURING/IRAQI FREEDOM (OEF/OIF) report high rates of mental health disorder and associated functional impairment. Prevalence estimates for PTSD among U.S. veterans and active-duty service members range between 4% and 17% (Hoge et al., 2004; Hoge, Auchterlonie,

& Milliken, 2006; Milliken, Auchterlonie, & Hoge, 2007; Richardson, Frueh, & Acierno, 2010), with a high percentage meeting criteria for comorbid depression and anxiety (e.g., Gros, Simms, & Acierno, 2010; Tanielian & Jaycox, 2008). Further, this cohort experiences significant functional and readjustment challenges, including high rates of unemployment, marital problems, problematic drinking, and anger control problems (Khaylis, Polusny, Erbes & Gewirtz, & Rath 2011; Sayer et al., 2010; Thomas et al., 2010).

Per federal directive, VA medical facilities must provide veterans with PTSD access to evidence-based treatments including exposure therapy (Department of Veterans Affairs, Veterans Health Administration, 2010). Although exposure therapies are consistently superior to supportive counseling interventions across clinical and psychosocial outcomes (e.g., Bradley, Greene, Russ, Dutra, & Westen, 2005; Foa, Rothbaum, Riggs, & Murdock, 1991; Powers, Halpern, Ferenschak, Gillihan, & Foa, 2010), a significant minority of patients do not respond, or respond less well to these interventions. For example, in a recent study comparing exposure therapy to present-centered therapy with female veterans and active-duty service members with PTSD, nearly 60% of participants in the exposure therapy condition continued to meet criteria for PTSD at posttreatment (Schnurr et al., 2007). Further, some studies report lower treatment response rates in veteran samples relative to civilian samples (Bradley et al., 2005; Johnson et al., 1996; Schnurr et al., 2007).

These data may speak to the limitations of conventional models of psychotherapeutic service delivery (i.e., protocol treatment delivered via office-based, in-person therapy over consecutive weeks) rather than to the effectiveness of exposure techniques per se. First, it is unclear whether a single intervention can address the complex needs of veterans with PTSD who present with significant comorbidity and functional impairment (Frueh, Turner, Beidel, Mirabella, & Jones, 1996; Prigerson, Maciejewski, & Rosenheck, 2001). Although studies suggest that exposure leads to significant reductions in depressive symptoms (e.g., Foa et al., 1999), the presence of major depressive disorder (MDD) may moderate the development and course of PTSD, potentially undermining responsiveness to treatment (Scott & Stradling, 1997; Shalev et al., 1998). Second, barriers to care (e.g., negative attitudes about mental health treatments and providers, living in rural areas that lack trained providers, lack of transportation, etc.) may reduce the likelihood that some veterans or active-duty service members will initiate and/or receive a therapeutic dose of services (Hoge et al., 2004; Vogt, 2011).

These limitations appear to have real and significant impact on rates of mental health service utilization among veterans with PTSD. Only about a third of veterans with recent PTSD diagnosis receive “minimally adequate treatment,” defined as taking a prescribed medication for the indicated duration and having at least four visits with a medical professional, or at least eight visits with a mental health provider over the past 12 months (Spoont, Murdock, Hodges, & Nugent, 2010). Furthermore, despite promising dissemination initiatives, relatively few providers regularly implement exposure protocols in clinical practice. This may be related to practitioner concerns that patients with complex symptom profiles will require flexible interventions comprised of multiple therapeutic techniques (Becker, Zayfert, & Anderson, 2004; Frueh, Cusack, Grubaugh, Sauvageot, & Wells, 2006; Karlin et al., 2010).

In sum, conventional service delivery of exposure therapy may provide “necessary” but “insufficient” treatment for combat veterans with PTSD and comorbid psychopathology. As such, some researchers have argued for integrated treatment approaches that maximize the benefits of exposure techniques for patients with complex symptom profiles (e.g., Back, 2010; Wagner, Rizvi, & Harned, 2007). Further, others have argued that innovative, technology-based service delivery modalities can enhance access to care for veterans with PTSD by circumventing common barriers (Tuerk et al., 2010).

Integration: Behavioral Activation Models

Traditionally used in the treatment of MDD (e.g., Dimidjian et al., 2006; Hopko, Lejuez, Ruggiero, & Eifert, 2003; Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2010; Lejuez, Hopko, LePage, Hopko, & McNeil, 2001), several recent studies suggest that behavioral activation (BA) provides effective treatment for veterans with PTSD (Jakupcak et al., 2006; Jakupcak, Wagner, Paulson, Varra, & McFall, 2010; Mulick & Naugle, 2004; Turner & Jakupcak, 2010). BA strategies (e.g., scheduling and participating in positively reinforcing and/or valued activities) may enhance exposure therapy for PTSD by directly targeting comorbid MDD symptoms and areas of functional impairment. By aligning daily behaviors and activities with core values, BA strategies may promote community readjustment among recently postdeployed veterans with trauma-related mental health symptoms. Second, although thematically consistent (i.e., both models highlight the relationship between stressful life events and the development of psychopathology, both emphasize the concepts of avoidance and engagement), BA strategies may target a broader range of symptoms and

psychosocial domains. Exposure techniques are typically trauma-focused; thus, these techniques may not ameliorate depressive symptoms that bear more direct relation to pre- and/or postdeployment readjustment stressors (i.e., as opposed to depressive symptoms maintained by the avoidance of stimuli that cue trauma-related distress). In contrast, BA strategies are designed to promote involvement in positively reinforcing, valued activities regardless of their relation to the trauma; thus, these strategies may broaden the therapeutic range of exposure. Third, functional analysis, a core element of BA models, provides an empirically validated process for the contextualization of treatment and selection of outcome parameters (Lejuez et al., 2001); thus, the integration of functional analytic techniques with exposure-based intervention may increase the relevance of protocol treatment to both patients and providers.

Innovation: Home-Based Telehealth

Telehealth, delivering medical or psychological care to patients via video-conferencing technology, may promote access to exposure therapy for veterans who are unable or unwilling to attend weekly, office-based psychotherapy (i.e., Darkins, Cruise, Armstrong, Peters, & Finn, 2008; Tuerk, Fortney, et al., 2010). The current VA telehealth infrastructure connects community outpatient clinics (CBOC) to larger VA medical centers where PTSD services are offered. Veterans who live in rural areas that are outside the range of larger VA medical centers attend the CBOC each week to utilize the telehealth network. Preliminary evidence suggests that telehealth application of exposure therapy is feasible and effective for OEF/OIF veterans with PTSD (Gros, Yoder, Tuerk, Lozano, & Acierno, 2011; Tuerk, Yoder, Ruggiero, Gros, & Acierno, 2010). Recently, researchers have advocated for the application of *home-based* telehealth to PTSD service delivery (Bensink, Hailey, & Wootton, 2006; Gros et al., 2011). Preliminary data suggest that cognitive-behavioral treatments can be safely and effectively delivered to military personnel via home-based telehealth (e.g., Egede et al., 2009; Gros et al., 2011); however, the efficacy of home-based telehealth applications for exposure interventions remains largely untested.

The Current Study

The current study presents preliminary data from an ongoing clinical trial that compares the home-based telehealth application of a brief behavioral treatment (Behavioral Activation and Therapeutic Exposure; BA-TE) for veterans with PTSD to the standard, in-person application of the same treat-

ment (Gros, Strachan, et al., 2011). Presentation of interim findings is warranted given the time-sensitive nature of the subject matter. Specifically, the Department of Defense (DoD) projects that as many as 300,000 new mental health cases will be diagnosed among returning OIF/OEF veterans over the next 5 years (Tanielian & Jaycox, 2008). Given DoD/VA imperatives to increase the quality and availability of mental health services for veterans and active-duty service members with PTSD, data are needed now to support the dissemination of effective treatments.

The current study represents the first investigation of the efficacy of BA and exposure therapy and the feasibility of a home-based telehealth service delivery model with veterans with PTSD. Between December 2008 and January 2010 we recruited and enrolled 40 OIF/OEF veterans and active-duty service members with PTSD symptoms, randomized them to eight weekly sessions of BA-TE in-person (BA-TE-IP) or BA-TE telehealth (BA-TE-T) treatment, and evaluated them on anxiety, depression, and PTSD symptom measures at pre- and posttreatment. We hypothesized that participants in both conditions would experience significant reductions in all symptoms from pre- and posttreatment and that these reductions would be comparable across the two treatment conditions (telehealth and in-person).

Method

PARTICIPANTS

The present study included 31 (out of 40 total participants who were consented and enrolled in the study) OIF/OEF military personnel with PTSD symptoms who completed the eight-session BA-TE treatment protocol. Eligible participants were veterans of OIF/OEF who met criteria for PTSD or subthreshold PTSD, defined as fulfillment of Criteria A (traumatic event) and B (reexperiencing), and either C (avoidance) or D (hyperarousal) (Blanchard, Hickling, Taylor, Loos, & Gerardi, 1994). Participants were recruited from a large Southeastern VA medical center and affiliated university via provider referral. To determine eligibility, a registered psychiatric nurse administered structured psychiatric interviews for PTSD via the Clinician Administered PTSD Scale (CAPS; Blake et al., 1995), MDD via Structured Clinical Interview for DSM-IV (SCID-IV; First, Spitzer, Gibbon, & Williams, 1996), and alcohol dependence and substance dependence via brief self-report screeners. Individuals who were actively psychotic, suicidal, or met criteria for substance and/or alcohol dependence were excluded from participation. To enhance generalizability of study findings, participants receiving psychotropic

medication treatment or case management services for PTSD, mental health treatment for other psychiatric disorders, and those who met criteria for alcohol or substance abuse were not excluded from participation.

Consented participants were predominantly male (92.5%), Caucasian (45.0%), married (40.0%), completed 12 years of schooling (35.0%), currently employed (57.5%), not disabled (55.0%), and had a mean age of 30.4 years ($SD=7.6$). All participants endorsed symptoms consistent with either PTSD (62.5%) or subthreshold PTSD (37.5%) on the CAPS. A minority of participants also reported symptoms consistent with comorbid MDD (22.5%) on the SCID. Participants reported an average of 55.0 ($SD=22.3$) months between their traumatic event and their intake interview for the study.

Over the duration of the study period, nine participants withdrew from the study for various reasons, including six moved away from the area (due to redeployment or relocation for employment), one lost transportation, and the remaining two participants did not provide a reason for withdrawal. Attrition rates were comparable across treatment delivery medium (5 BA-TE-IP, 4 BA-TE-T). Two-variable χ^2 tests revealed no group differences between completers and dropouts in sex, race, marital status, work status, and disability status (χ^2 s < 3.5; $ps > .05$). In addition, one-way ANOVAs failed to reveal any group differences in age, $F(1, 38)=3.3$, $p > .05$, or any measures of baseline symptomatology (F s < 3.4; $ps > .05$).

PROCEDURES

All study procedures were approved by the appropriate institutional review board and research and development committee. Consented participants were randomized to BA-TE-IP or BA-TE-T using a block randomization procedure. Participants randomized to the BA-TE-T were provided with in-home video-conferencing technology and were allowed to choose between internet- or landline-based equipment (3 chose landline-based equipment, 10 chose Internet-based equipment). All participants received eight, 90-minute sessions of BA-TE administered by master's-level therapists. Therapists completed a week-long training program and were required to shadow a senior-level clinician throughout a complete course of BA-TE before administering the treatment independently. Therapists met weekly with the Principal Investigator (Ron Acierno, Ph.D.) for supervision throughout the duration of the study. Sessions were audio-taped and monitored by an independent rater to ensure treatment fidelity. The PTSD Checklist–Military (PCL-M; Weathers, Litz, Herman, Huska, & Keane, 1993), Beck Anxiety

Inventory (BAI; Beck & Steer, 1993), and Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996) were administered at pre- and posttreatment assessments by raters blind to the treatment condition.

Prior to beginning treatment, participants were given a Behavioral Activation Agenda book specifically created for use in the study. The agenda book is small and discrete, resembling typical planners found at office supply stores. This inconspicuous format may reduce patient concerns regarding confidentiality and potentially enhances the portability of skills posttreatment (i.e., patients can use agenda planners purchased in office supply stores in a similar fashion). Further, all worksheets required to complete treatment are included in the appendices of the planner, reducing the number of extraneous forms necessary to conduct clinician trainings and for patients to complete homework assignments.

MEASURES

Beck Anxiety Inventory

The BAI is a 21-item measure designed to assess the severity of anxiety in psychiatric populations (Beck & Steer, 1993). The BAI has demonstrated adequate test-retest reliability over a one-week interval ($r=.75$), excellent internal consistency ($\alpha=.92$), and convergent and discriminant validity in multiple samples (Beck, Epstein, Brown, & Steer, 1988; Beck & Steer, 1993). Unfortunately, the BAI was missing from several of the initial pretreatment questionnaire packets in the present study, resulting in a smaller sample size ($N=23$).

Beck Depression Inventory—2nd Edition

The BDI-II is a 21-item measure designed to assess the cognitive, affective, behavioral, motivational, and somatic symptoms of depression in adults and adolescents (Beck, Steer, & Brown, 1996). The BDI-II has demonstrated excellent test-retest reliability over a 1-week interval ($r=.93$), excellent internal consistency ($\alpha < .92$), and convergent and discriminant validity in multiple samples (Beck et al., 1996; Steer & Clark, 1997).

Clinician-Administered PTSD Scale

The CAPS is a clinician-rated scale designed to diagnose current and lifetime PTSD (Blake et al., 1995). The CAPS has been shown to have adequate internal consistency (α s ranged from .73 to .95), inter-rater reliability on the same interview (r s ranged from .92 to .99), and test-retest reliability over a 2- to 3-day period across different interviewers (r s ranged from .77 to .98; for review, see Orsillo, Batten, & Hammond, 2001). In addition, the CAPS has demonstrated adequate convergent

validity to alternative measures of PTSD (r s ranged from .77 to .91) and adequate discriminant validity to measures of depression (r s ranged from .69 to .74) and anxiety (r s ranged from .65 to .76; Weathers & Litz, 1994). Finally, the diagnosis established by the CAPS has been found to be comparable to alternative structured interviews (Weathers, Ruscio, & Keane, 1999), including the SCID (First et al., 1996).

PTSD Checklist–Military

The PCL-M is a 17-item measure designed to assess PTSD symptom severity (Weathers et al., 1993). The PCL has been shown to have excellent internal consistency (α s > .94) and excellent test-retest reliability in various populations (r = .96; for review see, Orsillo et al., 2001). In addition, the PCL has demonstrated excellent convergent validity with alternative measures of PTSD (r s range from .77 to .93; Orsillo et al., 2001).

Structured Clinical Interview for DSM-IV (First et al., 1996)

The SCID-IV is a semistructured diagnostic interview designed to assess the DSM-IV diagnostic criteria for Axis I disorders. The SCID have shown adequate interrater reliability for all disorders (r s range: .69 to 1.0) and adequate test-retest reliability over a 1- to 3-week interval in patient samples (r s range: .40 to 1.0; Zanarini & Frankenburg, 2001). For the purposes of the present study, only the MDD module was used.

INTERVENTION

BA-TE

BA-TE is comprised of eight, 90-minute sessions that include exposure (situational and imaginal) and BA (activity monitoring and scheduling) strategies. Here, we describe the intervention highlighting the integrated BA components, including the treatment rationale, contextualized to military populations, and the addition of the valued behaviors component.

Treatment rationale. Providing a clearly defined, therapeutic rationale may enhance treatment credibility and adherence when offered to patients as a routine part of treatment (e.g., Addis & Jacobson, 2000; Kohlenberg, Kanter, Bolling, & Parker, 2002). Further, therapists may be more likely to administer treatments that are contextualized to their specific patient population. Conceptualized within a BA framework, the postdeployment transition represents the shift in the salience and availability of reinforcement and a reduction in value-driven behavior. These characteristics are

associated with mood disorders and are prescriptive of BA treatment components (Hopko et al., 2003; Lejuez et al., 2010).

The postdeployment transition may be characterized by a significant reduction in the salience and availability of reinforcement. In the war zone, reexperiencing, avoidance, and hyperarousal are adaptive behaviors that actually may elicit powerful proximal reinforcement, whether positive (e.g., sharing memories of combat events yields strong social support from fellow soldiers who experienced or witnessed the same events) or negative (e.g., escaping a potentially deadly IED blast is associated with sharp reductions in fear and corresponding increases in endorphins), and promote long-term functional outcomes (e.g., survival; facilitation of war-time objectives). In the context of civilian life, these same behaviors may fail to elicit proximal reinforcement and long-term functional outcomes commensurate with war zone contingencies. From the standpoint of proximal reinforcement, escaping a crowded movie theater because it cues trauma-related distress may engender less salient negative reinforcement than escaping an unmarked, slow-moving vehicle because it signals an IED. In parallel, from the standpoint of functionality, the benefits of sustained hyperarousal may outweigh the potential negative health effects only when the life threat is real.

Homecoming initially delays the manifestation of psychiatric symptoms. For recent veterans of OIF/OEF, the immediate weeks following homecoming may be marked by high levels of negative (e.g., relief experienced from returning home alive) and positive (e.g., praise and affection from family members) reinforcement; thus, homecoming serves as a short-lived protective factor that temporarily delays manifestation of psychiatric disorder. As the novelty of homecoming wanes, for veterans with PTSD, behavioral avoidance of traumatic stimuli and reintegration challenges increase the risk of developing MDD and related psychosocial impairment.

Reduced participation in routine, personal value-driven behavior increases risk of psychopathology.

From a BA perspective, daily routines are protective against the development of mood disorders because they (a) promote task completion in absence of proximal reinforcement, (b) reduce ambivalence associated with task selection and prioritization, and thus reduce procrastination or avoidance, (c) increase recognition of behaviors that warrant reinforcement, and (d) increase identification of feedback as “reinforcement.”

Active-duty deployment may be described as structured and routinized; military personnel perform duties that are assigned by rank, under a predictable reinforcement schedule prescribed by the chain of command, within the context of military values (e.g., loyalty, courage, camaraderie, valor, etc.). As such, tasks potentially characterized as trivial in the civilian sector (e.g., transporting supplies) are imbued with meaning in theater; expectations for feedback are consonant with the reinforcement schedule. In contrast, in the civilian sector, absence of ostensible value permeates daily life and routines tend to be self-imposed. Thus, roles are often poorly defined, schedules of reinforcement are often unpredictable; but the application of value-driven behavior requires direct, explicit, and sustained effort. Under this type of environmental contingency, individuals may select behavioral alternatives that elicit proximal reinforcement rather than those that elicit adaptive or valued outcomes. To the extent that these alternatives are mutually exclusive, the absence of routine and ostensible value serves as risk factors for psychopathology.

A key component of BA-TE is to assignment of military values (e.g., loyalty, commitment, courage, valor, etc.) to civilian goals. For example, applied to fatherhood, commitment may entail changing diapers and 4:00 A.M. feedings, tasks proximally experienced as thankless. Thus, value-driven behavior is prescribed as place-holder for affective behaviors (e.g., avoidance); assigning these tasks to the value of commitment to fatherhood increases the likelihood of completion, directing the individual's focus away from proximal reinforcement and towards long-term, meaningful outcomes.

Session 1. The therapist provides participants with psychoeducation about common reactions to traumatic events, development of PTSD and MDD, and how avoidance and withdrawal operate to maintain PTSD and MDD symptoms. Although the first session emphasizes BA techniques, the presentation of basic themes (i.e., avoidance, withdrawal, behavioral engagement) prepares patients for later participation in exposure activities. The therapist introduces the agenda planner which will become a focal point of treatment. For homework, participants are instructed to monitor their activities and corresponding mood using the agenda planner provided at the start of treatment.

Session 2. The therapist expands on the treatment rationale, identifying patterns of behavioral avoidance and withdrawal using the participant's homework. Participants complete the Life Values Worksheet located in the Appendix of the planner.

Directed by the therapist, participants define sets of behaviors as they relate to specific psychosocial domains (i.e., romantic relationships, employment, spirituality, etc.) and promote life values. Veterans generally have both positive and negative feelings regarding their deployment experiences. For many, the struggle to readjust to civilian life is related to loss of meaning. Thus, therapists use this session to demonstrate how military values (e.g., commitment, loyalty, courage, and honor) can translate to the civilian sector. For homework, participants schedule and complete valued behaviors and document corresponding consequences of these behaviors in the agenda planner.

Sessions 3 and 4. The therapist incorporates the rationale for in vivo and imaginal exposure exercises into the overall presentation of treatment rationale. Participants complete in vivo and imaginal exposure hierarchies (exposure worksheets are located in the Appendices of the agenda planner) and begin to create a detailed narrative (audio and/or written) of the traumatic event. During session, patients engage in repeated, prolonged imaginal exposure to the traumatic memory. For homework, the patient schedules and completes selected in vivo exposure exercises (i.e., attending a war memorial service, listening to session audiotapes) in addition to value-based behaviors.

Sessions 5 through 8. These sessions develop skills learned in Sessions 1 through 4. In session, activities focus on review of homework as well as continued repeated imaginal exposure to the traumatic memory. Patients continue to schedule and complete activities from the Life Values and Exposure Exercises worksheets. The primary role of the therapist during these sessions is to emphasize the relationship between symptoms and behaviors, identify continued patterns of avoidance, and prescribe activities (i.e., valued or exposure activities) based on psychosocial goals. The final session emphasizes relapse prevention. Specifically, the therapist and patient identify the behavioral warning signs that signal possible reemergence of symptoms and troubleshoot strategies to sustain treatment gains.

Results

BASELINE MEASURES

In order to assess whether differences existed between treatment delivery modalities, demographic characteristics and baseline symptomatology were investigated across the two treatment delivery mediums. Two-variable χ^2 tests revealed no group differences in sex, race, marital status, work status,

and disability status ($\chi^2s < 3.6$; $p > .05$). One-way analyses of variance (ANOVA) demonstrated no differences in patient age, $F > 1$. One-way ANOVAs also were used to investigate baseline symptomatology across the two treatment conditions. These analyses demonstrated no significant group differences on any of the self-report measures, including the PCL, BDI, and BAI ($Fs < 3.2$; $ps > .05$).

TREATMENT EFFECTS

To investigate the efficacy of the BA-TE, paired t -tests were run for each of the self-report measures in all patients. As presented in Table 1, these analyses revealed significant within subject pre- to posttreatment reductions on the primary symptom measures: PCL-M, BDI-II, and BAI ($ts > 2.7$; $ps < .05$; $ds > .40$).

A series of repeated measures ANOVAs were used to investigate the pre- to posttreatment changes in the two treatment conditions. As presented in Table 2, significant reductions in symptoms were evidenced on the PCL-M, BDI, and BAI ($Fs > 5.6$; $ps < .05$; $ds > .50$) in the telehealth patients. A similar pattern of findings was observed in the in-person sample on the PCL-M, BDI-II, and BAI; however, only the PCL-M was found to have a statistically significant change, $F(1, 29) = 7.9$, $p = .009$. As expected, there were no reliable differences between the pre- to posttreatment findings across the two treatment conditions on any of the self-report measures ($Fs < 2.8$; $ps > .05$).

Discussion

As hypothesized, results provide preliminary evidence for an integrated treatment approach—BA-TE—comprised of evidence-based treatment strategies to reduce symptoms of PTSD, depression, and anxiety in combat-exposed veterans. In addition, the present findings also demonstrated that home-based telehealth application of behavioral health treatments is a feasible treatment delivery method. Data are consistent with previous research supporting the use of BA strategies (e.g., Jakupcak

et al., 2006) and exposure strategies (e.g., Schnurr et al., 2007) to treat military populations with PTSD and MDD symptoms and with previous studies that indicate that behavioral treatments can be delivered via telehealth technology to veterans with PTSD (Gros, Yoder, et al., 2011; Tuerk, Yoder, et al., 2010).

The current study is not sufficiently powered for noninferiority analyses; thus, we cannot draw conclusions regarding the effectiveness of the telehealth relative to in-person treatment delivery. However, lack of significant difference between treatment modalities is a necessary first step (i.e., if we had found differences in this low power sample, then we would be more confident that one modality was better than the other). We were encouraged that both modalities resulted in symptom reductions. Results are particularly promising given the brief duration of treatment and the fact that approximately 40% of the sample received telehealth sessions that were conducted in the patient's home using lower-cost, lower-resolution, Internet- or landline-based video-conferencing equipment.

Reductions in PTSD symptoms were greater than for depressive symptoms in both conditions. Interestingly, this pattern of findings is similar to a previous study in which 16 sessions of BA-only treatment lead to greater reductions in PTSD symptoms relative to depressive symptoms (Jakupcak et al., 2006). To the extent that the PCL-M and BDI-II measure similar constructs, it may be that the PCL-M, which contextualizes symptoms to military involvement, has greater sensitivity to PTSD and MDD symptom change in this population.

LIMITATIONS, IMPLICATIONS, AND FUTURE DIRECTIONS

Several limitations are noteworthy. First, we did not evaluate BA-TE against treatment as usual or exposure-only arms; thus, conclusions regarding the superiority of BA-TE relative to comparison conditions or the additive benefit of BA cannot be drawn. Regarding the latter comparison (i.e., BA-TE versus exposure-only) while cross-study comparisons are premature, effect sizes for the current study are smaller than those reported in similar studies that investigated telehealth and in-person applications of exposure therapy (e.g., Tuerk, Yoder, et al., 2010), which may be due to important methodological differences. Unlike the current study, participants from Tuerk, Yoder, et al. (2010) were not randomized to condition, assessors were therapists who were neither blind to condition nor to the objectives of the study, and participants received a greater number of sessions. Thus, the larger effect sizes may be partially related to

Table 1
Efficacy of BA-TE Across All Patients

Scale	Pre-Tx	Post-Tx	t	p	d
PCL-M ($n=31$)	57.9 (14.6)	44.2 (17.9)	5.4	.000	.84
BDI-II ($n=31$)	23.2 (10.8)	17.1 (12.8)	3.2	.003	.52
BAI ($n=23$)	23.5 (16.5)	16.8 (16.1)	2.8	.010	.41

Note. Pre-Tx and Post-Tx columns are presented as means (standard deviations). Tx=treatment; PCL-M=PTSD Checklist – Military; BDI-II=Beck Depression Inventory – II; BAI=Beck Anxiety Inventory.

Table 2
Efficacy of BA-TE in Telehealth and in-Person Treatment Conditions

Scale	Telehealth						In-Person						Between Groups		
	Within Group Outcome						Within Group Outcome								
	Pre-Tx	Post-Tx	<i>F</i>	<i>p</i>	<i>d</i>		Pre-Tx	Post-Tx	<i>F</i>	<i>p</i>	<i>d</i>		<i>F</i>	<i>p</i>	<i>d</i>
PCL-M (<i>ns</i> = 18,13)	57.2 (16.2)	41.4 (16.1)	22.1	.000	.98		59.0 (12.7)	47.9 (20.1)	7.9	.009	.66		.8	.373	.33
BDI-II (<i>ns</i> = 18,13)	23.2 (11.9)	16.8 (13.3)	6.3	.018	.51		23.2 (9.5)	17.5 (12.6)	3.7	.065	.51		.0	.874	.06
BAI (<i>ns</i> = 12,11)	26.8 (16.8)	18.8 (13.8)	5.7	.027	.52		19.9 (16.1)	14.6 (18.7)	2.3	.141	.30		.3	.594	.23

Note. Pre-Tx and Post-Tx columns are presented as means (standard deviations). Tx=treatment; PCL-M=PTSD Checklist – Military; BDI=Beck Depression Inventory – II; BAI=Beck Anxiety Inventory.

experimenter demand and selection biases and to the greater number of therapy sessions. Still, considering results from the current study, post-treatment PCL-M and BDI-II scores for the entire sample were in the mild to moderate range. Research suggests that combined treatment approaches typically do not augment the effects of exposure on PTSD symptoms (e.g., Foa et al., 1999; Foa et al., 2005). However, combined treatments may differ from the integrated approach used in the current study in that the strategies that comprise combined approaches are presumably presented in a disparate fashion, diluting the potential effects of each strategy when presented alone. Further research will illustrate if BA strategies confer additional benefit to exposure therapies for veterans with PTSD, and the burden of proof will fall on the developers of integrated treatments to demonstrate if, how, when, and why an integrated approach should be used. Second, although BA treatments are hypothesized to have direct effects on psychosocial functioning, no assessment of functional impairment was included here; assessment of functional status is included in the 3-month and 1-year follow-up assessments in the ongoing, larger study comparing the effectiveness of BA-TE-IP to BA-TE-T. It is suspected that changes in functional status may not be evident until several months posttreatment as psychosocial outcomes (e.g., employment status, marital status) may require an extended duration to become manifest.

Basic principles of BA treatments are consistent with DoD/VA directives to enhance the quality, efficiency, and cost-effectiveness of mental health services for veterans with PTSD. BA paradigms emphasize idiographic assessment and treatment planning; thus, clinicians can calibrate the content and dose of treatment to meet the specific needs of individual patients, reducing potentially costly over- and underutilization of services. Furthermore, administered within the early months of postdeployment, brief, integrated treatments such as BA-TE

may serve as a preventive intervention, mitigating the development of traumatic stress disorders and subsequent functional impairment.

From the standpoint of clinical effectiveness, we believe the use of VA system-level standard operating procedures to design the methodology of the study enhances its clinical relevance. Per standard of care, all veterans who screen positive for PTSD symptoms are referred to the PTSD clinic; all referrals receive a diagnostic evaluation and are provided information about opportunities to participate in research. This created a seamless transition between clinic procedures and enrollment to the study. To further streamline current method with standard operating procedures, we employed liberal inclusion criteria: Veterans and active duty personnel with at least subthreshold PTSD, potential comorbid psychiatric problems, and who potentially were receiving concomitant psychological services (e.g., case management, medication treatment) were not excluded from participation. Thus, to the closest extent possible, BA-TE was evaluated within a “typical” VA setting with “typical” VA patients. Admittedly, there may be a potential trade-off for the liberal inclusion criteria in the present study: The inclusion of veterans with comorbid psychiatric disorders who may or may not have been receiving concomitant treatments may have introduced potential confounds when interpreting the results. The influence of these potential confounds should be investigated as larger samples become available.

In summary, results provide preliminary evidence that a brief therapeutic protocol, inclusive of BA and exposure components, may reduce symptoms of PTSD, depression, and anxiety in OIF/OEF military personnel and that this treatment may be effectively delivered via home-based telehealth. The ongoing trial will evaluate the efficacy of home-based telehealth relative to in-person delivery in a larger sample that includes active-duty participants across clinical, process, and functional outcomes.

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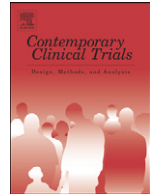
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Home-based telehealth to deliver evidence-based psychotherapy in veterans with PTSD[☆]

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ABSTRACT

Although medical service delivery via home-based telehealth technology (HBT) is gaining wider acceptance in managing chronic illnesses such as diabetes or chronic obstructive pulmonary disease, few studies have tested HBT applications of psychotherapy. Clinicians, administrators, and researchers question whether delivering psychotherapeutic services to patients in their homes via video-conferencing technology compromises patient safety, potency of treatment, or data security. Despite these concerns, HBT service delivery may increase access to evidence-based psychotherapies for veterans with posttraumatic stress disorder (PTSD), who may be less willing or less able to receive weekly treatment at a VA medical center or outpatient clinic due to symptom severity or other similar barriers to care. Indeed, although combat-exposed service members endorse high rates of psychiatric disorders, few appear to initiate mental health services or receive an adequate dose of treatment. Thus, using HBT technologies to administer evidence-based therapies remains uncharted territory in both the clinical and research arenas. This manuscript describes an ongoing four year randomized controlled trial comparing in-person Prolonged Exposure (PE) – a specialized evidence-based psychotherapy for PTSD – and PE delivered via HBT, with a particular focus on the selection, application, and strengths/weaknesses of HBT procedures.

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1. Introduction

Military personnel deployed to the war zone are at heightened risk of trauma exposure and development of subsequent posttraumatic stress disorder (PTSD), a debilitating psychiatric

illness with significant mental and physical health morbidity [1–4]. Despite impressive scientific and organizational support for exposure psychotherapies [5–8], veterans with PTSD underutilize these interventions. A recent study [9] suggested that less than 10% of veterans with new PTSD diagnoses received minimally adequate care (e.g., defined as at least 9 psychotherapy sessions in less than 15 weeks). Further, in the largest clinical trial of exposure therapy to date, nearly 40% of patients terminated treatment participation prior to completion [10]. Barriers to care (e.g., fear of stigmatization for receiving psychiatric services, living in rural or physician shortage areas that lack specialty mental health services, etc.) may reduce the likelihood that veterans will engage in evidence-based exposure therapies (e.g., Prolonged Exposure therapy [11]) that typically require 9 to 12 weekly, 90-minute sessions to complete.

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Home-based telehealth (HBT) may enhance enrollment and retention of veterans with PTSD in exposure therapy by extending service delivery to veterans in their own homes. Although HBT is routinely used by primary care providers to improve the management of chronic health conditions, mental health clinicians have traditionally been reluctant to use HBT when treating PTSD patients, citing concerns about patient safety, confidentiality, diluting the potency of imaginal exposure exercises, and/or compromising the therapeutic alliance [12]. To our knowledge, only one randomized controlled clinical trial (RCT) has tested HBT service delivery against in-person service delivery for veterans with PTSD symptoms, with only preliminary findings to date [13,14]. As such, methodologically rigorous studies (i.e., inclusion of a comparison or control condition, random assignment) that evaluate the feasibility, efficacy, safety, and clinical utility of HBT psychotherapeutic service delivery modalities are needed.

2. The current study

The proposed study involves a randomized controlled design powered for non-inferiority analyses to compare Prolonged Exposure (PE) [11] delivered via HBT (PE-HBT) and in-person (PE-IP). We will recruit 226 male and female veterans with PTSD in the catchment area of a large Veterans Affairs Medical Center (VAMC) in the Southeastern United States and randomize them to either the PE-HBT or PE-IP condition. All participants will receive 9 to 12 sessions of PE and be assessed at baseline, mid-treatment, one-week post-treatment, and at 3- and 6-month follow-up across clinical, process, and economic outcome variables. The design and method of the current study are consistent with recommendations suggested for the implementation of non-inferiority trials [15]. Specifically, we will test an innovative application (i.e., service delivery of PE via HBT video-conferencing technology) of an already established reference intervention for PTSD against the conventional application (i.e., in-person, office-based delivery of PE). We hypothesize that although the conditions will produce comparable clinical outcomes, barriers to care, such as lack of transportation, residence over 20 miles away from the VA facility and/or community-based outpatient clinic (CBOC), and stigma of receiving care at mental health facility, will moderate treatment and process outcomes across condition. Below we describe the basic method of the study, highlighting several innovations including: 1) the selection of HBT technology used in the study; 2) coordinating with VA information technology (IT) staff to establish the HBT capacity without overburdening the VA network; and 3) strategies used to troubleshoot the potential safety concerns that may arise when delivering PE via HBT.

3. Method

3.1. Participants

Participants will be 226 male and female veterans and military personnel, age 21 and over, with PTSD as assessed by the Clinician Administered PTSD Scale (CAPS) [16], who are enrolled in a program of VA healthcare. This may include active duty and reserve personnel who are enrolled in VA services via the TRICARE agreement which allows Department of

Defense (DoD) beneficiaries to receive treatment in VA medical facilities in some circumstances. Veterans with PTSD related to civilian and/or military traumas will be included. Veterans with active alcohol and/or substance dependence (as assessed by the Structured Clinical Interview for the DSM-IV [SCID-IV] [17] alcohol and substance dependence modules), those who are actively psychotic, and those who endorse severe suicidal ideation with plan and intent will be excluded from participation. To maximize generalizability of results, presence of other forms of psychopathology will not be a basis for exclusion. Further, veterans receiving psychopharmacological treatment for PTSD and/or associated symptoms or non-PTSD focused psychotherapy will not be excluded from participation; however, those who report recent changes in psychiatric medication use (i.e., changes in type or dose of medication) will be required to delay the first treatment session for a stabilization of three weeks. To minimize potential confounds to results, we will collect information about patient involvement in concurrent mental health treatments at the baseline, mid- and post-treatment assessments, and will co-vary these data in the final analyses.

3.2. Recruitment plan

Our prior experience conducting non-inferiority treatment outcome research in military health facilities has informed several key strategies designed to maximize recruitment and enrollment of eligible participants [18]. Our research team has established collaborative relationships with mental health teams at the core VAMC and the affiliated CBOCs. We will employ four primary recruitment paths: 1) VAMC PTSD clinic receives automated referrals derived from mandatory screening of all primary care patients. Each veteran referred to the clinic is offered an opportunity to participate in clinical research; 2) letters of invitation mailed to VAMC patients screening positive over the past year but not attending PTSD clinics for treatment identified from the VHA Decision Support System (DSS); and, 3) VA provider referral independent of PTSD screens, from VA physicians, other clinic staff such as nurses, or patients themselves in response to recruitment flyers displayed in prominent locations in the study clinics.

3.3. Strategies to maximize retention

Strategies described here are consistent with recommendations for maximizing participant retention in treatment outcome studies with trauma populations [18] and are informed by our previous experiences conducting clinical trials with veterans with PTSD [13,14]. First, all veterans who enroll in the study will attend a pre-treatment orientation session that provides general information and expectations and requirements regarding participation in this VA-sponsored treatment outcome research project. In our previous clinical trials, we have found that informing participants about routine procedures and expectations (i.e., completion of self-report measures every other session), and about important milestones associated with progression through the study (i.e., completion of post-treatment assessment and 6-month assessment) increases consistency of session attendance and the likelihood that patients will complete post-treatment assessments. Second, consistent with data that suggest family support is

associated with higher session attendance and completion rates, with the participant's permission, we meet with and answer questions from family members and significant others regarding the research project and the treatment itself. In addition, participants are given the opportunity to authorize family members or significant others as a secondary point of contact for the duration of the study. Third, we request participant permission to notify other providers (e.g., case manager, primary care physician, psychiatrist) when the participant has completed or missed an important study milestone (e.g., first therapy session, post-treatment assessment). In this way, study participation maintains the continuum of care found in good clinical practice. Fourth, to the best of our ability, we will schedule post-treatment and follow-up assessments so that they coincide with the participant's other medical appointments at the VAMC. Fifth, we will provide compensation to participants for attending the post-treatment assessments. Finally, we have designated one study representative to serve as the patient liaison. The patient liaison is primarily responsible for monitoring patient attendance across the duration of the study. Specific job related duties include: scheduling all therapy and follow-up assessment appointments, making reminder phone calls, and alerting the investigative team when patients have gone "missing in action" or appear to be at risk of dropping out of the study. We have found that having a familiar face monitor attendance across the entire duration of the study reduces risk of attrition during transition periods (i.e., enrollment to first treatment session, last session to post-treatment assessment, post-treatment assessment to 3-month follow-up, 3-month follow-up to 6-month follow-up).

3.4. Procedures

To determine eligibility, the CAPS and SCID will be administered to all referrals by a trained, masters-level clinician. All interviews will be audiotaped to calculate inter-rater reliability on a randomly selected 20%. Consented participants will be randomized to PE-IP or PE-HBT using a block randomization procedure. Participants randomized to the HBT condition will be provided with in-home video-conferencing technology, or they may choose to use their existing internet connection and computer. All participants will receive 9 to 12, 90-minute sessions of PE administered by masters-level therapists and will be assessed across primary outcome variables at baseline, one-week post-treatment, and at 3- and 6-month follow-up. Number of sessions required for each patient will be determined by therapist and patient agreement on treatment progress and termination.

Therapists completed a four-day training program with Dr. Edna Foa (lead developer of PE and co-investigator in present study) as well as a three-day refresher course provided by designated PE trainers within Dr. Foa's team. Further, clinicians were required to shadow a senior level clinician throughout a complete course of PE before administering the treatment independently. Therapists will meet weekly with the principal investigator (Dr. Ron Acerno) for supervision throughout the duration of the study. Consistent with the guidelines for the PE dissemination initiative, all sessions will be recorded and 20% will be monitored by an independent rater to ensure treatment fidelity.

3.5. Intervention

All participants will receive 9 to 12 sessions of manualized PE [11]. PE is based on emotional processing theory which suggests that traumatic events are incompletely and inaccurately encoded in memory as fear networks. Gradual exposure to corrective information via the confrontation of traumatic stimuli within a safe and therapeutic environment results in a competing and antithetical memory structure that inhibits the conditioned fear response. PE relies on two primary therapeutic tools: in vivo exposure and imaginal exposure. During in vivo exposure, the patient confronts feared, but safe, stimuli that cue trauma-related distress. Common examples of in vivo exposure exercises used in the treatment of war veterans may include driving alone at night, visiting a war memorial, or watching a movie in a dark theater alone. During imaginal exposure, patients "revisit" the traumatic event, providing a detailed verbal account that includes sensory information, thoughts, feelings, and reactions experienced during the traumatic event. PE includes the following components: 1) education about common reactions to trauma and presentation of the treatment rationale (sessions 1 and 2), 2) repeated in vivo exposure to traumatic stimuli (in vivo exercises are assigned as homework during sessions 2 through 11), 3) repeated, prolonged, imaginal exposure to traumatic memories (implemented during sessions 3 through 12), and 4) relapse prevention strategies and further treatment planning (session 12). Prior to beginning treatment, all participants will be provided with a digital audio recorder and a PE workbook that includes homework and supplemental forms required to complete the treatment. All sessions are audio recorded and patients will be instructed to listen to the session audio-recording (of the entire session) and imaginal exposure audio-recording (of the imaginal exposure) for between session homework.

3.6. Treatment conditions: home-based telehealth (HBT) versus in-person (IP) service delivery

Veterans randomized to PE-HBT will receive 9 to 12, 90-minute sessions of PE delivered via their choice of two videoconferencing modalities: (a) encrypted internet-based televideo software to their home computer, or (b) an analog "plug-and-use" videophone with built-in camera and video screen that operates using plain old telephone service (POTS line). The videophone looks like a standard telephone with the exception of having a 4-inch LCD color screen with real-time motion display. Both formats (i.e., encryption software, videophone) offer two-way videoconferencing capability and thus offer enhanced functionality over currently used telehealth audio and monitoring devices. Given significant advances in consumer-driven video-conferencing technology over the past 3 years, it is unlikely that the analog videophones will be used in future HBT clinical trials. Indeed, the VA is moving towards providing patients who receive HBT with televideo devices that look and function like laptop computers. Further, in our HBT clinical trial experience we have found that most patients – even older Vietnam veterans – have access to computers with videoconferencing capability and prefer this modality to the videophone. Additionally, fewer younger veterans have landline telephones, relying instead on cell phones. All operations are in compliance with the Health Insurance Portability and

Accountability Act (HIPAA) privacy requirements and protect personal health information.

Telehealth technology used in the current study was funded by our VA Health Services Research and Development (HSR&D) grant support (VA Merit Award: Prolonged Exposure (PE) for PTSD: Telemedicine vs. In Person). Patients who choose option (a) are provided with the software, a camera, and a microphone for use in the study. Patients who choose option (b) are provided a videophone for use in the study. All equipment is inventoried and patients sign a release acknowledging that they have received the equipment and that they will return it after completing the study.

Use of un-standardized equipment may introduce confounds to the results and we have taken precautions to improve interpretation of the data. Research staff records information about the type of network connection (e.g., cable, wireless, dial-up), computer hardware, and miscellaneous equipment (e.g., camera, microphone, etc.) used by each participant in the study. Further, the therapist records and describes technical problems that occur (e.g., loss of sound, loss of video, connection interrupted) during each telehealth session using a standardized form. We will co-vary this information (e.g., average number of technical disruptions per session, type of network connection) in the final analyses to determine if equipment and connection quality are associated with clinical and process outcomes.

Participants in the HBT condition will receive instruction in using the technology prior to starting treatment. If necessary, project staff or VAMC IT staff will be available to visit participants in their homes to help set up the equipment. However, preliminary investigations suggest that even computer “neophytes” navigate the technology easily [19]. Nonetheless, we will track the type and amount of assistance required across sessions in order to describe difficulties with in-home use and derive cost estimates.

3.7. Assessment of clinical, quality of life, and process outcomes

Participants will be assessed across clinical, quality of life, and process outcomes at baseline, mid-treatment (every other session), one-week post treatment, and three and six month follow-ups by blind raters.

3.7.1. Clinical descriptive and outcome measures

The following measures have been widely used in the clinical evaluation of adults with PTSD, and will be used in the present study: clinical interviews (CAPS [16] and SCID-IV [17] administered at baseline, post-treatment, and at 3- and 6-month follow-up) and self-report measures (PTSD Checklist-Military [PCL-M] [20], Beck Depression Inventory 2nd edition [BDI-II] [21]). Veterans who endorse non-military traumas as their index trauma during the CAPs are provided the non-military version of the PTSD Checklist (i.e., PCL) to complete at baseline, mid-treatment, post-treatment, and 3- and 6-month follow-up assessments. Participants must be enrolled in a program of VA healthcare to participate in the study. Veterans' SF-12 Health Survey (SF-12) [22,23], and Index of Functional Impairment (IFI) (administered at baseline, post-treatment, and at 3- and 6-month follow-up). Each of these measures has received thorough investigation and support for their psychometric properties in the literature.

3.7.2. Process outcome measures

Several measures are included to assess process variables associated with treatment (e.g., treatment satisfaction, adherence, credibility): Treatment Expectancy Scale [24] (baseline assessment), Charleston Psychiatric Outpatient Satisfaction Scale (CPOSS) (session 5 and post-treatment assessment) [25], and the Service Delivery Perceptions Questionnaire (baseline and session 5 assessment) [19]. Indices of treatment adherence also will be recorded, such as homework completion, session attendance, and study attrition.

3.7.3. Economic outcomes

To determine the relative cost-effectiveness of service delivery via HBT, capital costs of HBT technology will be estimated for both the central center and the HBT sites (homes). Further, incremental HBT-related variable costs per treatment session will be estimated for therapist and IT support staff time using the DSS National Dataset which provides estimates of hourly salaries and benefits for about 80 classes of employees. Staff training costs will also be estimated using the DSS National Data and included in sensitivity analyses. It is important to calculate costs and benefits with and without training costs since they are important initially but are likely to become nominal if the intervention is implemented on a wide scale basis. Finally, transportation costs will be estimated for those veterans who meet the criteria for travel reimbursement from the VA based on distance from the centroid of the zipcode of the veteran's residence to the VAMC or CBOC at prevailing mileage reimbursement rates. This is a potentially important cost off-set for the proposed HBT intervention. Finally, incremental benefits of the proposed intervention relative to the comparator will be measured in two ways. First, differences between the two conditions in reduced PTSD symptoms (severity) as measured by the CAPS scale. Second, differences in symptom reduced days and finally, monetary value based on an accepted value of individual willingness to pay for an additional symptom-reduced day [26].

3.7.4. Covariables

Participants will also complete the Deployment Risk and Resiliency Inventory (DRRI) and the Combat Exposure Scale (CES) at baseline [27]. The DRRI is collection of self-report measures assessing 14 key deployment-related risk and resilience factors with demonstrated implications for veterans' long-term health. The CES is a 7-item self-report measure that assesses the frequency and severity of combat-related events. Based on previous research on the factors that predispose trauma-exposed individuals to PTSD [28], we hypothesize that certain pre-deployment factors (e.g., childhood family environment), deployment factors (e.g., frequency and severity of combat exposure) and post-deployment stressors (e.g., perceived social support) measured by the DRRI will moderate the relation between warzone trauma exposure and the development of mental health symptoms.

3.8. Power

We posit that a maximum clinically unimportant difference in response proportion (Δ , the non-inferiority effect size) is 0.15 between PE-HBT and PE-IP groups (upper limit of one-sided 90% confidence interval must not be greater than

$\Delta = 0.15$ for HBT to be declared noninferior). We further assume that the response proportion for the standard in-person mode of delivery is 0.75. The primary response variable for sample size calculation is the proportion (%) of patients who respond to treatment, defined as having at least a 1.5 standard deviation pre- to post-treatment improvement on the PCL, and maintained over follow-ups. For detecting a non-inferiority effect size of $\Delta = .15$ between PE-HBT and PE-IP, power is 85%, with one-sided $\alpha = 0.10$, $P_{\text{in person}} = 0.75$, and $N = 226$ (assuming 20% dropout rate, with 90 completers per condition).

3.9. Data analyses

Treatment response, defined as a pre- to post-treatment improvement of at least 1.5 standard deviations, will be evaluated at the end of the active treatment phase and at each of the follow-up time points. To reflect the fact that, in a non-inferiority assessment, use of the intent-to-treat (ITT) sample will often increase the risk of falsely claiming noninferiority [29] we will consider equally the ITT and the per protocol samples. To investigate potential limits on generalizability, we will compare characteristics between the PE-HBT and PE-IP conditions of the premature exits/protocol non-adherent with those who were completers/protocol adherent, using an independent sample *t*-test or Wilcoxon rank sum test for continuous variables and a chi-square test for categorical variables.

To test the hypothesis that PE-HBT and PE-IP groups are similar in clinical outcomes, two approaches will be taken to compare outcomes for active and follow-up phases for dichotomous variables. The first approach will estimate the unadjusted proportion of responders (% responders) at the end of the active intervention course and at the end of the 6 month follow-up phase. With a one-sided non-inferiority confidence interval approach, the upper limit of the one-sided 90% confidence limit for the difference in % responders (unadjusted and adjusted) for the PE-HBT and the PE-IP groups must be 0.15 (Δ) or less to accept the hypothesis of a non-inferior novel treatment. The second approach will estimate % responders adjusted for putative confounding variables based on a multivariable modeling approach, and then will apply the methods described above (one-sided confidence intervals) to evaluate non-inferiority of the two interventions. Adjustment covariables include age, race, gender, baseline level of the variable of interest, initial disease severity, and use of psychiatric medication.

The analyses for continuous clinical outcome measures (clinical rating scales) will use the same basic non-inferiority confidence interval approach as described above for the dichotomous outcome variables. A general linear model (GLM) approach will be used to model the adjusted relationship between intervention modality and the continuous clinical outcomes at the immediate post intervention time point. For the GLM model, each continuous clinical outcome serves separately as the dependent variable, with intervention (PE-HBT and PE-IP) as the primary independent variable and additional covariates added to adjust for the effect of the putative confounding variables. The non-inferiority analyses for the dichotomous outcome and the continuous clinical outcomes

will be repeated for the 3- and 6-month naturalistic follow-up time points.

Mixed effects models (MEM) analyses (or equivalently, random regression models or hierarchical linear models) will be used on the weekly PCL data to compare the longitudinal trajectories of PTSD symptom severity for the PE-HBT and PE-IP conditions from pre-treatment to follow-up. Longitudinal methods for continuous, binary (e.g. response status) and categorical or ordinal outcomes [30–32] will be used as appropriate for a given clinical outcome variable. The possible effect modification (interaction) of the covariables on the relation between intervention status (delivery mode) and post-intervention clinical outcomes will be evaluated through inclusion of treatment by covariate interaction terms in the model. For the naturalistic follow-up period, we will carry out post hoc subgroup analyses considering participants' intervening events (e.g., grouped by amount/type of additional treatment). Where appropriate, we will include these events as covariables in the regression models. We will estimate the relapse proportions and differences in proportions for PE-HBT and PE-IP using confidence intervals (CIs) and non-inferiority analyses as described above. We will estimate the adjusted proportion of relapsers (and corresponding CIs) for the PE-HBT and PE-IP groups using a multivariable logistic regression approach (as described above). All analyses for the naturalistic follow-up period will be considered exploratory.

Process outcome variables include CPOSS total score, treatment credibility, Service Delivery Perceptions, treatment adherence (percent of returned, completed homework assignment forms; project therapist's subjective ratings of the completeness of and adherence to homework assignments (inclusive of reading assignments) for each session), session attendance/attrition (percent of missed sessions, and dropout status). The process outcomes will be analyzed using the unadjusted and adjusted (via GLM and MEM modeling for continuous outcomes, and logistic regression for dichotomous outcomes) noninferiority approaches as described above for clinical outcomes. In further exploratory analyses, we will repeat the multivariable methods to explore predictors of treatment satisfaction and treatment attrition.

Analyses to evaluate the cost-effectiveness of PE-HBT versus PE-IP will consist of both descriptive statistics and net benefit regression analysis. First, simple tabulations of treatment effect and cost-effectiveness data will be provided. For the proposed intervention and the comparator, means and standard deviations of effect size in symptom-reduced days will be provided as well as means and standard deviations of total costs and severity (measured by CAPS). We will then use regression analysis to estimate the effect of the proposed intervention (relative to the comparator) on extra effect and extra cost via ordinary least squares regression analysis estimation, and then estimate a model of net benefit. Cost-effectiveness (based on symptom reduced days and reduced severity) and cost-benefit ratios will be calculated varying values for training costs, discount rates and willingness to pay, to provide a range for VA managers and policy makers to examine when making decisions about recommendations regarding the proposed telehealth intervention.

To evaluate whether the effect of mode of treatment delivery (PE-HBT vs. PE-IP) on clinical and process outcomes

differs by race and sex, non-inferiority analyses (90% one-sided CI) will be repeated within race and sex strata to describe African-American versus Caucasian and male versus female participants' outcomes at immediate post-treatment and 6-month follow-up time points. GLM (for single end of study outcomes) and MEM (for longitudinal data), and logistic regression analyses (for the dichotomous outcomes, e.g., responder/nonresponder), as described above, will be used to evaluate whether the relations between intervention and outcomes (clinical and process) are different for African Americans and Caucasians or for males and females through inclusion of race/sex by treatment interaction terms in the multivariable models. Because sample sizes within strata are small, particularly for sex, these are exploratory analyses.

4. Discussion

To the extent that findings from the current study indicate that HBT service delivery is effective, safe, and feasible, HBT may enhance access to care for veterans who would otherwise go underserved. For some veterans with PTSD (e.g., those who lack consistent transportation, those who live in rural or physician shortage areas, those with impaired physical mobility due to ambulatory or physical health conditions, etc.), HBT may offer the only viable avenue to evidence-based care. For others, HBT may offer the flexibility and convenience necessary to maintain consistent attendance to therapy appointments (i.e., by eliminating travel time to and from the medical facility and thereby reducing the total amount of time needed to take off from work or childcare responsibilities due to travel). Despite these possible advantages, specific considerations should be made prior to implementing HBT in a particular facility. These include considerations of safety, informed consent and technology access, billing, practice privileges and licensure, and data protection and HIPAA compliance.

4.1. Special safety considerations for HBT condition

Providers are often concerned about whether a treatment that involves prolonged and repeated exposure to upsetting memories can be safely delivered to patients at heightened risk of suicide via HBT. However, a recent case report suggested that when managing suicidal patients remotely, many of the same principles of in-office management of at-risk patients apply (e.g., consult with professional colleagues, act consistently with facility-level guidelines for management of at-risk patients). Further, for severely depressed, suicidal patients, HBT may confer some advantages over in-person. For example, suicidal patients may lack motivation to travel to their mental health treatment center for their appointment. However, with HBT, the effort required to connect to the therapist who is standing by for their session is dramatically reduced, and thus at-risk patients may be more likely to attend session. Additionally, HBT therapists may have access to the patient's loved ones/family members who may be home at the time of the crisis. These individuals can help ensure the patient's safety.

4.2. Informed consent and technology access

While seemingly obvious that a patient is consenting to the process of telehealth by virtue of the steps one must take to engage in such treatment, consent also must entail the consideration of alternative approaches to receiving psychological care. Specifically, whenever possible, in-person treatment should be offered as an alternative to patients receiving telehealth, at least in the near future until this format is generally accepted, and more importantly, reliably demonstrated as equally effective with respect to treatment outcomes.

With respect to technology access, there appear to be a myriad of options, and in this case, more is better. At a most basic level, the provider will need a basic internet connection and webcam with microphone. The patient will require an internet connection, either DSL, Cable, or cellular broadband. In addition, a video monitor and audio device is necessary. These can range from a standard desktop or laptop, to a tablet with front facing camera, to a smart phone. The range of options is growing daily, and the important point to be considered is that the patient very likely has the required equipment in their possession, or can acquire it for relatively less expense than long distance travel and extended time off from work that in-person treatment would require.

4.3. Billing, practice privileges and licensure, and HIPAA requirements

Most coding standards and reimbursement rates are based on resource utilization. When telehealth is used according to the 'hub and spoke' model, where providers sitting in a central facility export services via telehealth to satellite facilities, two offices, an extremely large bandwidth channel, and remote office staff are required. Hence, hub and spoke services generally are billed at higher rates relative to standard in-person services. By contrast, HBT involves one therapist, one office, and one standard internet bandwidth channel. As such, billing is routinely the same as in-person services because the resources required are the same.

More controversial is the topic of licensure and privilege. The federal government has published national standards outlining many of these parameters, but these are being refined and are guidelines at this point. Typically, the medical records must reside where the patient is receiving services, whereas the privileging process and maintenance is based on the standards of the site from which the provider practices. Licensure currently does not restrict interstate practice of psychology and psychiatry; however, in the absence of interstate agreements, cross state telehealth is prohibited in many states. The exception to this rule is when the provider and patient are both in federal facilities, such as the VA or DoD facilities. However, while this exception clearly includes the hub and spoke (main facility to satellite facility) model of telehealth, it leaves unaddressed the issue of HBT, where treatment originates from a central federal facility (e.g., VAMC), but is received across state lines in the patient's home. It is very likely that legislative action is needed wherein telehealth services originating from federal facilities are protected across state (and across national) lines if they are

being delivered to US citizens, legal residents, or active duty personnel.

4.4. Data protection and HIPAA compliance

There are two general approaches to maintaining patient confidentiality over video-conferencing: third party server recording of all transmitted data versus real time transfer, without recording, of patient data. Vendors of telehealth devices typically bundle the device and the server storage, and assure HIPAA compliance and data integrity. By contrast, providers may not want to engage the services of a third party provider, and may not want session audio and video data to be recorded. In this case, confidentiality, data security, and HIPAA compliance are maintained by high level encryption software, such as that specifically engineered for HBT by “AK Summit” software and others. Using these products, patients are given an encryption program and key that allows them to communicate with their provider who runs a similar program and key. Any intercepted data are encrypted and hence not interpretable.

For the current study, patients randomized to PE-HBT will receive 12, 90-minute sessions of PE delivered via standard desk or laptop computer running AKT4002 software. This software allows users to teleconference with their providers in real time, using federal government tested and approved encryption. Importantly, this software meets federal government standards for encryption, is already Federal Information Processing Standard (FIPS) 140-2 certified (18 months federal government testing) and can be installed on Federal government and VA computers immediately.

5. Conclusions

Overall, the issues and problems confronting telehealth in general and HBT in particular are relatively easily resolved, as demonstrated by recent research in the area [13,14,33]. Several issues do remain, not the least of which is interstate and international licensing standards. These may require new legislation to resolve, which is not unprecedented in health care emerging technologies. Ultimately, this technology will most certainly become widespread because patients appear to like it, want it, and more importantly, need it. We recommend that researchers considering HBT should engage in the following steps: 1) identify an IT representative; 2) identify the technology requirements of the facility; 3) ensure that the system requirements of the selected device are compatible with technology at your facility; 4) ensure that your device and HBT procedures are HIPAA compliant; 5) ensure that all providers are credentialed to provide telehealth services, including completion of the telehealth curriculum offered via the VA Employee Education System (Telehealth Foundations, Telehealth Clinical Applications, and Concepts of Health Informatics); 6) develop a safety plan for providers should a patient become suicidal over HBT.

The lack of research testing HBT delivery of evidence-based psychotherapy against in-person delivery using RCT methodology limits dissemination of HBT and therefore precludes wider acceptance among community providers. The current study is an RCT that will directly compare HBT and in-person PE for PTSD to examine effectiveness, acceptability,

and financial costs. As the practice of HBT becomes more common and widely accepted, patients will experience improved access to evidence-based services.

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Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

PT073980/Award Number W81XWH-08-2-0047



PI: Ronald Acierno

Org: Charleston Research Institute

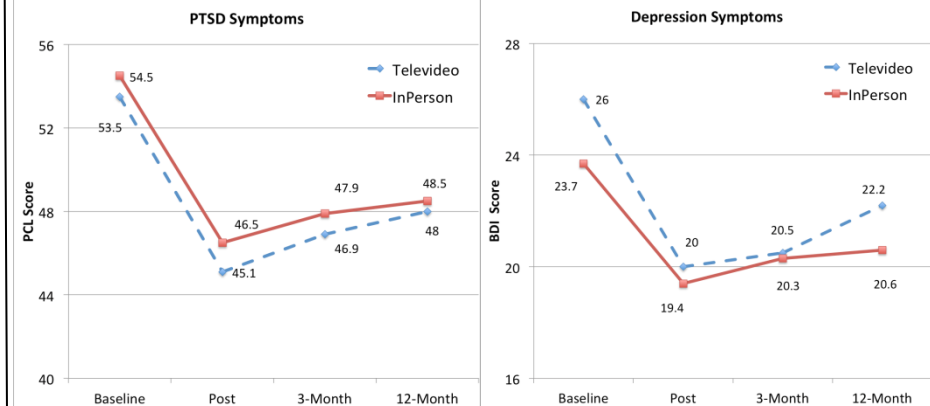
Award Amount: \$1,737,153.87

Study/Product Aim(s)

- **Objective 1:** To evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD symptoms in OIF/OEF, Persian Gulf, and Vietnam Veterans and service members.
- **Objective 2:** To determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Behavioral Activation and Therapeutic Exposure (BA-TE) is an eight-session, manualized treatment program.

Approach

A randomized between groups repeated measures non-inferiority design is being utilized. 250 active duty or Veteran participants with PTSD or Sub-Threshold PTSD are being recruited and randomly assigned to either in person or televideo-based treatment for PTSD. Data collection includes measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and twelve month follow-up.



Accomplishments

Study completed. Major Findings:

- Non-inferiority of Evidence based Treatment for PTSD delivered via Telemedicine compared to Traditional In Person settings was demonstrated: No difference in depression or PTSD outcomes

Timeline and Cost

Activities	Year 1 4/08-4/09	Year 2 4/09-4/10	Year 3 4/10-4/11	Year 4 4/11-4/12	Year 5 4/12-4/13	Year 6+ 4/13-2/15
Initial approvals: IRB/VA/DoD	✓					
Recruitment / Treatment / Follow-up						✓
Data Analysis /Reports						✓
Dissemination						✓
843-489-1270	\$322,201	\$ 293,776	\$297,983	\$305,732		\$241,756

Goals/Milestones ***COMPLETED***

Year 1 Goal – Institutional Human Subject Approvals Submitted. IRB, VA Research, DoD HRPO Approvals Obtained. Recruitment protocols and procedures established.

Year 2 Goals – Recruited and consented participants

Year 3 Goals – Recruited and consented participants

Year 4 Goals – Recruited and consented participants

Year 5 Goals – Recruited and consented participants

Year 6+ Goals – Completed recruitment, analyze data, submit publications. Submit final report and presentations to DoD

Comments

- 4-month no-cost extension (4/13-8/13)
- 6-month no-cost extension (8/13-2/14)
- 12-months funded extension (\$291,940; 8/13-8/14) allowed time and resources to meet recruitment goals, conduct follow-up, and complete data analyses and reports.
- 6-month no-cost extension (8/14-2/15)

Budget Expenditure FINAL

- Actual Expenditure: \$1,737,153.87

Updated: (February 2015)