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RESEARCH ARTICLE

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Randomized clinical trial pilot study of prolonged exposure versus present centred affect regulation therapy for PTSD and anger problems with male military combat veterans

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A randomized controlled trial pilot study (www.ClinicalTrials.org; NCT01228539) with *N* = 31 U.S. male military recent combat veterans with PTSD and severe anger problems was conducted comparing 10-session individual therapy versions of Trauma Affect Regulation: Guide for Education and Therapy (TARGET) versus prolonged exposure (PE). TARGET had fewer drop-outs than PE (i.e., 29% vs. 64%). At post-test, improvements were found for both interventions in increased emotion regulation and hope, and reduced PTSD symptoms, hostility, experiential avoidance, and mental health problems. At a four-month follow-up, comparable proportions (approximately 40%) of recipients in each therapy maintained clinically significant gains. Self-rated expectancy of therapeutic outcome and working alliance was comparable for both PE and TARGET early in therapy, at mid-treatment, and at the end of treatment. While preliminary, these results suggest that TARGET may be a viable therapeutic option for male military veterans with PTSD and anger problems.

KEYWORDS

anger, clinical trial, male, military veterans, psychotherapy, PTSD

1 | INTRODUCTION

Military personnel deployed to war zones are at risk for posttraumatic stress disorder (PTSD), with prevalence estimates for recent conflicts in Afghanistan and Iraq ranging from 13.5–15.7% (Dursa, Reinhard, Barth, & Schneiderman, 2014; Kok, Herrell, Thomas, & Hoge, 2012). Military combat-related PTSD often is complicated by problems with anger, aggression, violence, and suicidality (Gonzalez, Novaco, Reger, & Gahm, 2016; Hellmuth, Stappenbeck, Hoerster, & Jakupcak, 2012; Novaco & Chemtob, 2015): one in three veterans with PTSD report having threatened someone with violence, and 14–20% report destroying property or getting into fights, versus 5–10% of those with mild or no PTSD symptoms (Jakupcak et al., 2007). Military veterans in mental health services also identify anger management more often than any other problem as one of their top goals (Rosen, Adler, & Tiet, 2013), and PTSD is strongly associated with anger problems among military veterans (Orth & Wieland, 2006; Worthen et al., 2014).

Prolonged exposure (PE) is a manualized psychotherapy for PTSD (Steenkamp, Litz, Hoge, & Marmar, 2015) that has been disseminated nationally in the United States by the Department of Veterans Affairs healthcare system (Karlin et al., 2010). PE may reduce military veterans' anger symptoms in the hyperarousal PTSD symptoms cluster (Rauch et al., 2009). PE was found to reduce anger in female assault survivors with PTSD, although initially high-anger participants still had higher levels of state anger than low-anger participants at follow-up (Cahill, Rauch, Hembree, & Foa, 2004). However, in a study of a civilians receiving PE, over half of the patients who completed treatment and showed a good response still reported anger/irritability

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problems at clinically significant symptom levels (Zayfert & DeViva, 2004). Thus, research is needed to see if anger can be reduced to a greater extent than has been shown in previous research with PE.

Additionally, despite evidence of efficacy for PE with military PTSD, there is a substantial subgroup of nonresponders in randomized clinical trial studies (Steenkamp et al., 2015) and routine outpatient care (Kehle-Forbes, Meis, Spoont, & Polusny, 2016). Moreover, the median dropout rate reported for PE with military PTSD across several studies was 30% (Steenkamp et al., 2015), and a higher dropout rate (38.5%) for PE has been reported in routine outpatient care for military PTSD with veterans (Kehle-Forbes et al., 2016). Alternatives to PE therefore may be needed as an option for military veterans with PTSD and anger problems.

Therapies for PTSD that are designed to enhance current psychosocial functioning without requiring trauma memory processing represent a potential alternative to PE. Lower dropout rates have been reported in therapies for PTSD that do not require trauma memory processing than in PE, with civilian (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013) and military (Steenkamp et al., 2015) PTSD. A meta-analysis of PTSD treatment studies (Imel, Laska, Jakupcak, & Simpson, 2013) concluded that, while "trauma focus" was not associated with dropout across or within studies, "trauma-focused treatments resulted in higher dropout compared with present-centered therapy (PCT)" (Imel et al., p. 394). Dropout rates of 9–21% have been reported for therapies with military veterans that do not require the processing of trauma memories (Steenkamp et al., 2015). However, therapies such as PCT that do not require the processing of trauma memories have less robust outcomes in direct comparison studies than PE for civilian (Bisson et al., 2013) and military (Steenkamp et al., 2015) PTSD—with one recent notable exception, a randomized clinical trial with civilians that demonstrated that interpersonal psychotherapy had comparable PTSD outcomes to PE, and fewer dropouts among participants with comorbid major depression (Markowitz et al., 2015).

Emotion dysregulation plays a key role in PTSD and anger problems in men (Tull, Jakupcak, Paulson, & Gratz, 2007), and present-centred therapies for PTSD that focus on affect regulation also have shown evidence of lower attrition than trauma memory processing therapies (Bisson et al., 2013). A study with civilian women showed that a present centred emotion regulation-focused therapy (Trauma Affect Regulation: Guide for Education and Therapy; TARGET; Ford, 2015) was more efficacious in reducing PTSD and related symptoms (Ford, Steinberg, & Zhang, 2011) than a well-validated therapy that was adapted from interpersonal psychotherapy and designed to strengthen interpersonal and social problem solving skills; TARGET was designed to provide affect regulation skills similar to those taught in another evidence-supported PTSD therapy, Skills Training for Affect and Interpersonal Regulation, but differs from Skills Training for Affect and Interpersonal Regulation in teaching a sequential skill set for processing current PTSD intrusive re-experiencing or dissociative reactions.

The present study therefore was designed as an initial pilot randomized clinical trial comparing the outcomes of PE versus TARGET with male military veterans with PTSD and anger problems. Because PE has been shown to enhance emotion regulation (Jerud, Zoellner, Pruitt, & Feeny, 2014), the study also was designed to assess change in emotion regulation. Study hypotheses were that (a) PE and TARGET would be associated with equivalent and clinically significant reductions in PTSD and anger problems and improvements in emotion regulation and (b) the present-centred therapy (TARGET) would have a lower dropout rate than the trauma memory processing therapy (PE). This study is the first to directly compare PE and TARGET and had limited statistical power due to a small sample size. The study was funded and designed therefore as a pilot, to determine whether a fully powered clinical trial comparing the present-centred therapy to PE would be warranted.

Key Practitioner Message:

- Anger is an important clinical outcome in therapy for many military veterans with PTSD
- A present-centred trauma-focused affect regulation therapy for PTSD reduced both PTSD symptoms and hostility in male military veterans
- Prolonged exposure therapy and the affect regulation therapy had comparable outcomes for military veterans with PTSD and anger problems at posttherapy and follow-up
- The dropout rate among military veterans with PTSD and anger problems was lower for the present-centred affect regulation therapy than prolonged exposure therapy

2 | METHOD

2.1 | Participants

Participants were 31 men (ages 22–62; *M* = 36.5, *SD* = 9.8) who provided written informed consent between November 2010 and May 2012 to flyers and public service announcements offering therapy for PTSD and anger problems at no cost, based on a research protocol approved by the University of Connecticut Health Center Institutional Review Board. Inclusion criteria included male gender, deployment in the U.S. military at least once in Afghanistan or Iraq, diagnosis of PTSD related to combat exposure confirmed by research interview, and severe problems with anger or aggressive behavior. Exclusion criteria included cognitive impairment sufficient to prevent provision of valid consent (Minimental State Exam [Folstein, Folstein, & McHugh, 1975] memory, orientation score < 16, see below), imminent danger of suicide, abuse of alcohol or other substances in the past month, and inpatient psychiatric or addiction treatment in the past month. Eligible applicants were randomized to PE (*n* = 14) or TARGET (*n* = 17).

Participants' ethnoracial backgrounds were *n* = 3 (10%) African American, *n* = 2 (7%) *Hispanic*, and *n* = 26 (84%) *White* not *Hispanic*. Most participants were single, divorced, separated, or widowed (*n* = 18, 58%), while 42% (*n* = 13) were married or living with a primary partner. All participants had completed a high school degree or GED;

one-quarter (*n* = 8, 26%) had a bachelor's or higher degree. Annual personal income ranged from $8,000 to $160,000 per year, with a median annual income of $43,200. At intake, all participants were met criteria for current military-related PTSD and met criteria on the Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 1996) for one (*n* = 11, 36%) or more than one (*n* = 20, 64%) comorbid Axis I disorders (range = 1–6, *Mdn* = 2 comorbid diagnoses). All also disclosed problems with intense anger, and more than three-quarters (*n* = 24, 77%) acknowledged at least one of four possible types (*M*[*SD*] = 1.71[0.69]) of physical aggression (i.e., threatening or causing physical violence with or without a weapon, or destroying property) in the past 4 months, on a 4-item screen for anger problems in military veterans (Jakupcak et al., 2007).

2.2 | Procedure and measures

The study was registered with www.ClinicalTrials.org (NCT01228539). Participants were randomized on a 1:1 basis to the study treatments using a random number generator. An experienced masters-level research diagnostic assessor blind to participant experimental assignment conducted all assessments. To determine interrater reliability, independent review of audiotaped study interviews was done by a doctoral-level experienced research assessor who was blind to experimental assignments and evaluation time point and had no other role in the study. Multiple measures were used for each outcome domain (i.e., PTSD, anger problems, and emotion regulation) in order to assess a range of features within each domain.(e.g., PTSD-related cognitions as well as PTSD symptoms; recent hostility as well as trait anger).

2.2.1 | PTSD

The Deployment Risk and Resilience Inventory (DRRI; Vogt, Proctor, King, King, & Vasterling, 2008) was used at baseline to confirm exposure to military traumatic stressors during deployment and to assess *predeployment* trauma history, family stress and cohesion, and military preparation, *deployment* environment, family and life concerns, unit support and relationships, fear of harm, combat or postbattle experience, and exposure to toxic substances, and *postdeployment* support and life events. The DRRI was conducted as an interview and scores reported as descriptive data.

PTSD diagnosis and symptoms at baseline, posttherapy, and follow-up were assessed with the Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995; Weathers, Keane, & Davidson, 2001), a reliable and validated interview for DSM-IV PTSD diagnosis and symptom severity. CAPS scores rate the intensity (0 "none" to 4 "extreme distress") and frequency (0 "none" to 4 "daily or almost daily") of each symptom. Interrater reliability was confirmed by independent ratings of 33–50% of CAPS interview tapes at baseline (*N* = 10), post-test (*N* = 8), and follow-up (*N* = 8) for PTSD diagnosis (100% agreement, κ = 1.00) and total PTSD symptom severity scores (Spearman's rho = .98). PTSD symptom severity scores >40 were considered in the clinical range, with >70 reflecting severe PTSD (Weathers et al., 2001).

Cognitive alterations associated with PTSD were assessed with the (a) Post-Traumatic Cognitions Inventory (PTCI; Foa, Ehlers, Clark, Tolin, & Orsillo, 1999), a 36-item measure of posttraumatic beliefs about the world, self, and self-blame, that is, reliable, valid, and sensitive to treatment change (Cronbach's α=.97 in the current sample) and (b) Trauma Memory Questionnaire (Halligan, Michael, Clark, & Ehlers, 2003), a 13-item questionnaire that reliably and validly uses a 5-point Likert-like scale to assess trauma memory-related disorganization (D; five items) and intrusiveness (I; eight items; α=.83).

2.2.2 | Anger problems

The State–Trait Anger Expression Inventory Trait Anger subscale (Spielberger, Reheiser, & Sydeman, 1995) is a 10-item scale (rated from 1 "almost never" to 4 "almost always") that is internally consistent (α=.87 in the current sample) and has been validated with military returnees (Jakupcak et al., 2007). The Brief Symptom Inventory Hostility subscale (Derogatis & Melisaratos, 1983) has five items rated on a 5-point scale from 0 (not at all) to 4 (extremely) and is internally consistent (α=.86 in the current sample) and has been validated with military veterans (Jakupcak et al., 2007).

2.2.3 | Emotion regulation

The Generalized Expectancies for Negative Mood Regulation (NMR) is a 30-item scale (rated from 1 "strongly agree" to 5 "strongly disagree") that reliably (α=.86 in the current sample) and validly assesses the ability to identify, manage, and utilize adaptively a variety of negative emotion states (Catanzaro, Wasch, Kirsch, & Mearns, 2000). The Acceptance and Action Questionnaire is an internally consistent (α=.64) 16-item scale that has convergent validity in relation to measures of emotion avoidance (Bond et al., 2011) and deficits in emotional acceptance, awareness, and clarity (Tull et al., 2007). The Hope Scale (Snyder et al., 1996) is a six-item scale that reliably (α=.79) and validly assesses optimism and self-efficacy. The SF-12 Mental Component scale (Gandek et al., 1998) is a six-item measure that reliably and validly assesses overall ability to manage emotional health-related problems with a 1–100 standardized population-normed scale.

2.2.4 | Therapy expectancies and working alliance

Prior to Sessions 4, 7, and 10, the four-item Expectancy of Therapeutic Outcome scale (Resick, Nishith, Weaver, Astin, & Feuer, 2002) was administered, with 9-point ratings (score range = 0–36) for treatment credibility, confidence in outcome, and willingness to recommend the treatment (α=.97). The Brief Working Alliance Inventory (Neale & Rosenheck, 1995) was administered concurrently. The Brief Working Alliance Inventory is a reliable (α=.96) seven-item questionnaire with ratings from 0 = strongly disagree to 4 = strongly agree (score range = 0–28), designed to assess client beliefs concerning the importance of therapy and the therapist's ability to understand, collaborate, and be helpful.

2.3 | Therapy interventions and procedures

PE was delivered according to manualized guidelines (Foa, Hembree, & Rothbaum, 2007). PE begins with two sessions devoted to PTSD psychoeducation, initiating in vivo exposure, teaching a breathing technique for stress reduction, and identifying a past trauma event

for imaginal exposure. In vivo exposure involves homework activities in which the participant gradually confronts present-day reminders of past traumatic experiences. Imaginal exposure involves multiple repetitions of imagining oneself actually back in the selected traumatic event. The therapist helps the participant to imagine being in the traumatic event as if it was happening in the present moment, with affective intensity titrated to engage emotional processing without raising the participant's level of distress so high as to result in dissociation, overwhelming distress, or avoidance. Imaginal exposure is conducted for up to an hour in each of the next seven sessions. A final closure session is provided in order to review the participant's achievements and plan for the future.

TARGET was delivered following manualized guidelines (Ford, 2015). TARGET begins with psychoeducation in the first session, explaining based on neuroscience research how PTSD symptoms are the result of the brain's "alarm" (amygdala) becoming stuck in survival mode, as if traumatic threats were still occurring. In the second and third sessions, current day triggers for these PTSD "alarm reactions" are identified, and a skill designed enable the participant to begin to reset the brain's alarm by inhibiting impulsive emotional and behavioural reactions is taught. The skill is a novel approach to mental focusing that involves three steps summarized by the acronym SOS: Slow down, Orient, Self-check (stress and personal control levels). In the next six sessions, TARGET teaches a sequence of six incremental skills designed to replace alarm reactions (i.e., PTSD intrusive re-experiencing, avoidance, emotional numbing, and hypervigilance symptoms) with emotional self-regulation. The self-regulations skills are practiced in homework exercises scheduled on a regular basis between sessions. Once they have begun to master the self-regulation skills in session and in practice exercises, participants are encouraged to apply the skills to handle daily stressors, including when they experience PTSD symptoms or other stress reactions that interfere with their functioning. As in PE, a final closure session is devoted to reviewing the participant's achievements and plans for the future.

Both therapies were provided in 10 weekly 75–90 minute outpatient sessions to equate for therapist contact. Five therapists (one male Ph.D., one female Ph.D., one male M.A.-level Ph.D. student, and two female M.A.-level Ph.D. students) were randomly assigned to participants and were trained to conduct both therapies in order to prevent artefact due to nesting therapists within therapy conditions. Intensive training (4 days prior to conducting any treatment; 1-day refresher at study midpoint), supervision (including session-by-session review of every taped session for the first two cases, and weekly review of samples of taped sessions and progress review with each case for all subsequent cases), and fidelity monitoring (100% for the 1st two cases; 15% of all subsequent cases' sessions evenly distributed across sessions and cases for each therapist) were conducted in order to ensure highly competent delivery of each treatment model with fidelity to the model. Therapists rated the credibility of each treatment for this population as very high prior to and after conducting pilot cases. Training and supervision were conducted by PE trainers from the University of Pennsylvania and a local certified PE provider and by the model developer for TARGET. Supervisors rated fidelity and competence using standard checklists for PE (Foa et al., 2007) and TARGET (Ford et al., 2011) based on reviewing videotapes of therapy sessions. Fidelity was achieved on >95% of all items across all sessions in each therapy, with no instances of use of terminology or procedures from the other therapy.

Treatment completion (vs. dropout) was defined as attending at least 80% of the 10 sessions in each model. All but one completer attended all 10 sessions. The exception was a participant who attended all scheduled sessions and study assessments but was able to complete only 8 treatment sessions within the study window of 14 weeks due to schedule conflicts.

2.4 | Statistical analyses

The PE and TARGET cohorts were compared on demographics and study measures with chi-square for categorical variables and *t* tests for ordinal measures. Raw change scores were calculated for all outcome measures and effect sizes (Cohen's [1988] *d*) compared with baseline levels were calculated. Dichotomous clinically significant change scores were calculated for PTSD symptoms (>12 points lower CAPS scores; Steenkamp et al., 2015) and emotion regulation (>17 points lower NMR scores, a one standard deviation and > 20% change; Borkovec & Costello, 1993). Chi-squared analyses compared the proportion of TARGET versus PE participants: (a) no longer diagnosed with PTSD and (b) reporting clinically significant change.

3 | RESULTS

3.1 | Baseline characteristics of PE and TARGET participants

On an intent to treat basis, PE and TARGET participants did not differ in age (*M*[*SD*] = 36.4[10.6] and 36.5[9.4], $t = 0.01$, $df = 29$, $p = .99$), marital status (43% and 41% married or living with a primary partner; 36% in both cohorts previously divorced; $x^2[1] = 0.26$, $p = .25$), years of education (*M*[*SD*] = 13.6[1.9] and 13.6[2.1], $t = 0.17$, $df = 29$, $p = .87$), or military rank (14% and 6% officers, $x^2[1] = 0.62$, $p = .43$). All PE participants' ethnicities were non-*Hispanic White*, but 30% of TARGET participants were *Black* or *Hispanic* ($X^2(1) = 4.91$, $p = .03$). Almost half (41%) of the TARGET cohort had lost a job prior to deployment, compared with 14% of the PE cohort, although this difference was not statistically significant ($x^2[1] = 1.55–2.67$, $p > .09$).

The PE and TARGET cohorts did not differ on predeployment trauma history (any vs. none; $x^2[1] = 0.26–1.31$, $p = .25$), including exposure to natural disasters (43% and 24%), toxic substances (21% and 18%), combat (21% vs. 29%), a parent or family member with mental illness (57% vs. 41%), a parent with substance abuse problems (43% vs. 35%), death of a family member or close friend (71% vs. 57%), witnessing violent physical assault or death (24% vs. 21%), victim of physical assault (21% vs. 35%) or sexual (7% vs. 6%) assault as an adult, childhood emotional abuse (36% vs. 24%), domestic violence (43% vs. 41%), corporal punishment (57% vs. 47%), and physical abuse (36% vs. 35%) or sexual abuse (7% vs. 17%).

Study cohorts also did not differ on DRRI predeployment family stress and cohesion, predeployment preparation, deployment

TABLE 1 Baseline scores and completer posttherapy scores with effect size estimates of baseline-to-post-test change by completers

		Baseline intent-to-treat scores				Baseline completer scores				Posttherapy completer scores			
Measure	Therapy	*n*	*Mean*	*SD*	*SE*	*n*	*Mean*	*SD*	*SE*	*Mean*	*SD*	*SE*	ES *d*
CAPS	TARGET	17	85.3529	20.57590	4.99039	11	91.5000	15.72780	4.54022	51.8182	33.24701	10.02435	**2.54**
	PE	14	72.4286	17.99023	4.80809	5	64.2000	11.56287	5.17107	52.6000	30.42696	13.60735	0.50
NMR	TARGET	17	93.8824	20.39572	4.94669	11	89.3333	21.32149	6.15498	106.8182	16.73809	5.04672	**0.91**
	PE	14	99.5000	12.68403	3.38995	5	105.2000	22.58844	1.15758	110.8000	22.23061	9.994183	0.25
PTCI	TARGET	17	131.0588	48.07217	11.65921	11	139.1667	48.86686	14.10665	104.0909	47.07750	14.19440	0.73
	PE	14	110.7143	32.22142	8.61154	5	94.0000	11.02270	4.92950	97.8000	37.25185	16.65953	−0.14
TMQ	TARGET	17	30.2941	9.30568	2.25696	11	32.8333	8.90182	2.56973	22.8182	8.02270	2.41893	**1.18**
	PE	14	26.5714	9.33739	2.49552	5	20.0000	8.91628	3.98748	14.6000	12.54193	5.60892	0.50
STAX-trait	TARGET	17	21.7059	7.53960	1.82862	11	22.0000	7.27386	2.09978	20.0909	7.23125	2.18030	0.26
	PE	14	20.7143	4.63147	1.23781	5	20.6000	1.51658	0.67823	19.4000	4.15933	1.86011	0.38
BSI hostility subscale	TARGET	17	1.5529	0.70189	0.17023	11	1.6167	0.65759	0.18983	0.9091	0.87345	0.9091	**0.92**
	PE	14	1.6429	1.03233	0.27590	5	1.1600	0.71274	0.31875	0.8000	0.56569	0.8000	0.56
AAQ total score	TARGET	17	70.2941	11.55295	2.80200	11	72.2500	11.97820	3.45781	61.9091	12.56546	3.78863	**0.85**
	PE	14	69.7857	7.66790	2.04933	5	64.0000	7.84219	3.50714	62.2000	5.80517	2.59615	0.26
Hope Scale	TARGET	17	31.5882	6.11411	1.48289	11	30.5833	4.85159	1.40053	35.8182	7.90972	2.38487	**0.80**
	PE	14	32.4286	5.98349	1.59916	5	33.0000	4.52769	2.02485	35.0000	7.58288	3.39116	0.32
SF-12 Mental Component	TARGET	16	4.0625	0.77190	0.19298	11	3.9167	0.51493	0.14865	4.4545	0.52223	0.15746	**1.02**
	PE	14	4.7857	0.89258	0.23855	5	5.2000	0.83666	0.37417	5.0000	0.70711	0.31623	−0.26

Note. large (≥0.80) effect size estimates in **bold font**. AAQ = Acceptance and Action Questionnaire; BSI=Brief Symptom Inventory; CAPS = Clinician Administered PTSD Scale; ES = effect size (Cohen's *d*); GSI = Global Severity Index; NMR = Generalized Expectancies for Negative Mood Regulation Scale; PE = prolonged exposure; PCTI = Posttraumatic Cognitions Inventory; SF-12 = Short Form-12 Health-related Functioning Scale; STAX-trait = State Trait Anger Expression Trait Scale; TARGET = Trauma Affect Regulation: Guide for Education and Therapy; TMQ = Trauma Memory Questionnaire.

environment, family and life concerns, unit support and relationships, fear of harm, combat or postbattle experience, and exposure to toxic substances, or postdeployment support and life events (t = 0.07–1.34, df = 29, p > .19).

PE and TARGET participants also did not differ at baseline on current mental health treatment (65% and 77%, x^2[1] = 0.55, p = .46) and psychotropic medication (64% vs. 53%, x^2[1] = 0.41, p = .52), nor whether they met criteria for a major depressive episode (50% vs. 53%), bipolar disorder (7% vs. 0%), obsessive–compulsive disorder (OCD; 14% vs. 18%), panic disorder (43% vs. 41%), and social/specific phobia (21% vs. 18%; x^2[1] = 0.01–1.26. p > .25). The medications primarily were antidepressants and anxiolytics; four TARGET participants and one PE participant received an antipsychotic, and one TARGET participant took a mood stabilizer. Most participants in mental health treatment were in the care of a psychiatrist; four participants in each treatment condition were in ongoing mental health counselling. No change in medication or mental health treatment were reported by any participant during their study participation.

At baseline, there were some differences between participants in the two treatment conditions that suggested that TARGET recipients may have had more extensive initial mental health and behavioural problems than PE recipients. TARGET recipients had marginally higher baseline CAPS PTSD symptoms than PE recipients (85.4[20.6] vs. 72.4[18], t = 1.74, df = 29, p = .076). TARGET participants also were more likely than PE participants at baseline to meet criteria for generalized anxiety disorder (GAD; 36% vs. 0%, x^2[1] = 6.13, p = .01) and to have been in a physical fight in the past 4 months, (36% vs. 0%, x^2[1] = 6.13, p = .01). Additionally, TARGET participant reported more severe mental health-related functional impairment at baseline than PE participants (SF-12 MC: 4.1[.08] vs. 4.8[.09], t = 2.19, df = 29, p = .024).

3.2 | Treatment dropouts and completers

The overall dropout rate was high (14 of 31 participants, 45%). All dropouts occurred prior to the treatment midpoint (i.e., at or before Session 4). Four PE participants (29%) and three (17%) from TARGET dropped out after session one. Five additional PE participants (35%) and two TARGET participants (12%) dropped out before or immediately after session four. TARGET's dropout rate (29%) was comparable to those reported in randomized clinical trials of PE with military veterans (i.e., 23–39%; Steenkamp et al., 2015; Table 1) and less than half of the dropout rate in PE (65%), X^2(1) = 3.77, p = .050. On an intent to treat basis, PE participants completed one third fewer sessions than TARGET participants (i.e., M = 4.71 vs. 7.65 sessions completed), t = 2.08, df = 29, p = .046.

TARGET completers were more symptomatic and impaired at baseline than PE completers (see Table 1). TARGET (vs. PE) completers had significantly higher CAPS PTSD total (t = 3.48, df = 15, p = .003), intrusive re-experiencing (t = 3.22, df = 15, p = .006), and hyperarousal (t = 3.18, df = 15, p = .006) symptoms. TARGET completers also had more severe posttraumatic cognitions (t = 3.02, df = 15, p = .01) and intrusive memories (t = 3.03, df = 15, p = .008), poorer emotion regulation (t = 2.23, df = 15, p = .027), more severe psychiatric symptoms on the Brief Symptom Inventory (t = 3.22, df = 15, p = .042), and more impairment due to mental problems (t = 3.91, df = 15, p = .001). More TARGET completers (n = 8, 67%) versus PE completers (n = 1, 20%) met criteria for major depression at baseline. Most (n = 5) TARGET completers with major depression also met criteria for GAD, and 37.5% had triple comorbidity with OCD. The one PE completer with major depression did not meet criteria for GAD or OCD.

TARGET was equally likely to be completed by men of ethnoracial minority backgrounds (80% completion rate) as *White* participants (67% completion rate). No test of PE's completion rate by ethnicity was possible because all PE participants were *White*.

3.3 | Expectancy of therapeutic outcome and therapeutic working alliance

At Session 4, Session 7, and post-test, Expectancy of Therapeutic Outcome ratings were slightly lower for PE (n = 5–6; M = 20.3–27.4, SD = 3.7–10.2) than TARGET (n = 11; M = 27.2–28.6, SD = 5.1–7.3), but the differences were not significant (t = 0.45–1.94, df = 14–15, p = .06–.66). The two conditions were virtually identical at midtherapy Session 7, but the limited statistical power may have obscured differences in clients' expectancies between the two therapies early in therapy and at the close of therapy (i.e., an absolute mean difference favouring TARGET of 6.8 points at Session 4, Cohen's d = 0.95, and 5.8 points at posttherapy, d = .71, medium to large effects).

Similarly, Working Alliance Inventory (WAI) ratings at Session 4, Session 7, and post-test also were slightly lower for PE (n = 5–6; M = 18.2–23.6, SD = 3.8–7.7) than TARGET (n = 11; M = 23.0–24.2, SD = 3.5–4.4) but not significantly different (t = 0.29–1.76, df = −14–15, p = .10–.78). Although the two conditions were virtually identical on men WAI ratings at midtherapy and the end of therapy, early in therapy TARGET recipients rated the WAI on average 8 points higher than PE recipients (d = 0.78, a medium to large effect).

3.4 | Outcomes at post-test and follow-up

At post-test and follow-up, 60% (N = 3 of 5) PE completers (21% on an intent-to-treat basis) no longer met criteria for a PTSD diagnosis, as did a similar proportion of TARGET participants (n = 6; 56% of completers, 36% on an intent-to-treat basis). By comparison, the proportion of military veterans in prior randomized clinical trials of PE who no longer met PTSD diagnostic criteria was similar to that of the TARGET cohort but higher than that for the PE condition in the present study (i.e., 39–44%; Steenkamp et al., 2015, Table 1).

CAPS total scores at post-test on average for both PE and TARGET completers were approximately 52 (see Table 1), comparable to those reported on an intent-to-treat basis in randomized clinical trials with military veterans of PE and other trauma memory processing therapies (i.e., 48–74) but higher than reported in one completer study (i.e., 30; Steenkamp et al., 2015; Table 1). CAPS change scores for completers were variable for both treatments (PE range = +20 to −57; TARGET range = +2 to −93). As a result, more than threefold difference in average CAPS post-test change scores for TARGET (M[SD] = −38.70[29.91]) versus PE (M[SD] = −11.60[34.23]) was not statistically significant (t = 1.58, df = −13, p = .13). The post-test decrease on average in CAPS

scores for TARGET was greater than that reported on an intent-to-treat basis in randomized clinical trials with military veterans of PE and other trauma memory processing therapies (i.e., 18–27.5) but lower than reported in one completer study (i.e., 49; Steenkamp et al., 2015; Table 1). Similarly, at follow-up, there was a twofold difference in average change scores between PE (*M*[*SD*] = −16.80[29.12]) and TARGET (*M*[*SD*] = −33.13[36.24]) completers, but this was not statistically significant (t = 0.85, df = −11, p = .41).

On the NMR, PE completers on average increased 5.5 points from baseline (n = 5; M = 105.2, SD = 2.6) to post-test (N = 5; M = 110.8, SD = 22.2), and 11 points at follow-up (n = 5; M = 116.2, SD = 15.5). TARGET completers on average increased 17.5 points on the NMR from pretest (n = 11; M = 89.3, SD = 23.3) to post-test (n = 11; M = 106.8, SD = 16.7) and 12 points at follow-up (N = 11; M = 101.2, SD = 22.8). PE and TARGET completers' change scores on the NMR were not significantly different (t = 0.21–0.77, df = 13 and 11, p > .40). Post-test and follow-up NMR scores on average in both treatment conditions were comparable to those reported in a randomized clinical trial with women with chronic PTSD following a combined PE plus affect regulation therapy (i.e., 108.5–113.7) and an affect regulation therapy combined with supportive psychotherapy (i.e., 99.6–105.7; Cloitre et al., 2010, Table 2). NMR improvement on average at post-test and follow-up in TARGET and at follow-up in PE (i.e., an approximately 11–17 points increase) was comparable to that reported in the study with women with chronic PTSD by Cloitre et al. (2010).

At post-test, 73% of TARGET completers (n = 8 of 11) and 40% of PE (n = 2 of 5) completers achieved clinically significant improvement on the CAPS, a statistically significant difference (x^2[1] = 2.41, p = .02). At follow-up, however, the proportion of completers achieving clinically significant improvement was comparable for TARGET (37.5% n = 3 of 8) and PE (n = 2 of 5), x^2(1) = 0.08, p = .93. Clinically significant improvement on the NMR by completers at both post-test and follow-up was comparable for TARGET (n = 4 of 11, 36% and n = 3 of 8, 37.5%, respectively) and PE (n = 2 of 5, 40%, at both assessments), x^2(1) = 0.08–0.19, p > .85.

At post-test and follow-up, change scores for the CAPS and NMR were highly correlated (r = .736 and .734, p = .003–.007). Clinically significant improvement on the CAPS and the NMR were marginally related at posttherapy (x^2[1] = 3.75, p = .05) and significantly related at follow-up (x^2[1] = 5.08, p = .02). All participants achieving clinically significant improvement on the NMR achieved clinically significant improvement on the CAPS. However, a substantial subgroup of completers who made clinically significant gains on the CAPS did not achieve clinically significant improvement on the NMR (i.e., 50% at post-test; 37.5% at follow-up).

Estimated effect sizes of change scores from baseline to post-test revealed large effects (d > 0.80, range = 0.80–2.54; see Table 1) for TARGET completers on the CAPS, NMR, and five of the seven other outcome measures. A medium-to-large effect size was found for change on the PTCI and a small effect size for change in anger-proneness (State–Trait Anger Expression Inventory Trait Anger). Effect size estimates for change from baseline to post-test by PE completers were medium to small (range = −.26–.56), with two measures (PTCI, SF-12 MC) showing slight worsening on average (Table 1).

4 | DISCUSSION

Study results preliminarily suggest that a present-centred affect regulation therapy, TARGET, may have comparable efficacy to PE, a well-validated trauma memory processing therapy, in treating military veterans for PTSD and comorbid anger problems. TARGET completers reported large effect size improvements on seven of the nine outcome measures, and the only small effect size change for TARGET completers was on a trait measure of anger. TARGET and PE also had comparable proportions of recipients who maintained clinically significant improvement at a 4-month follow-up, and expectancy of therapeutic outcome and working alliance was rated by recipients as high in both treatments.

Early termination of trauma-focused psychotherapy is common among veterans with PTSD, particularly when complicated by comorbid problems such as severe anger (Kehle-Forbes et al., 2016). Less than 60% of this sample completed the full course of treatment, and all dropouts occurred before the fourth session of treatment. However, the affect regulation therapy (TARGET) had more than twice the treatment completion rate of PE (71% vs. 35%), despite TARGET completers beginning therapy with more severe psychiatric symptoms and impairment and a higher likelihood of past arrests than PE completers. The 29% dropout rate in TARGET was lower than the 38.5% rate reported for PE (and another evidence-based trauma memory processing therapy, Cognitive Processing Therapy [CPT]) with military veterans in outpatient PTSD treatment (Kehle-Forbes et al., 2016). This adds to the evidence with civilian populations (Ford, 2017) that affect regulation therapies may be particularly effective in retaining recipients.

Study results raise questions about both the mechanism of change and the ability of time-limited psychotherapy to achieve sustained benefits with military veterans with PTSD and anger problems. Although TARGET completers reported more than a threefold greater level of gains in emotion regulation than PE completers at the end of therapy, the difference was not statistically significant and both therapies achieved clinically significant improvement in emotion regulation only for a minority of recipients. TARGET was associated with a large effect size improvement in hostility but only small improvements in trait anger (which were comparable to those for PE). PE also has been shown to enhance emotion regulation among civilian adults with PTSD (Jerud et al., 2014) Thus, targeting emotion regulation skills explicitly may not be necessary to achieve enhanced emotion regulation capacities in therapy for comorbid PTSD and anger problems, and improvements in emotion regulation may be a byproduct rather than cause of improved PTSD symptoms. However, the breadth of large effect size gains by affect regulation therapy recipients suggests that present-centred emotion regulation-focused therapy may yield a range of benefits sufficient to be an alternative to trauma memory processing therapies for military veterans with PTSD. This is consistent with evidence with civilian samples that present-centred therapies for PTSD that address PTSD-related psychosocial deficits lead to better retention (Bisson et al., 2013) and are noninferior in reducing symptoms and enhancing functioning (Cloitre et al., 2010; Markowitz et al., 2015), compared with the trauma memory processing PE therapy. Other potential therapeutic mechanisms that may be related to

enhanced emotion regulation but may also independently account for retention and clinical improvement in psychotherapies for PTSD also warrant further study (e.g., reduced comorbid symptoms, enhanced interpersonal effectiveness, and remoralization).

The pattern identified in this study of dropout occurring relatively early in treatment is consistent with recent findings showing that dropout in PE, CPT, and an alternative therapeutic writing approach to PTSD treatment, tended to occur on or before the fifth treatment session (Gutner, Gallagher, Baker, Sloan, & Resick, 2016). Similarly, a study of PE and CPT in routine outpatient care for military veterans with PTSD found that most dropouts occurred on or before the sixth treatment session (Kehle-Forbes et al., 2016). Kehle-Forbes et al. (2016) also found that younger military veterans were most likely to dropout—veterans who were predominantly from the cohort involved in the current study. Thus, evidence is accumulating to suggest that retention early in PTSD treatment is an important challenge requiring continued clinical innovation and research with younger military veterans.

Several methodological limitations make these findings at most preliminary and in need of replication. The small sample size, high level of attrition, and high levels of variability in treatment outcomes resulted in bivariate analyses that were statistically under-powered and prevented the application of multivariate statistical analyses of treatment outcomes on an intent-to-treat basis. In addition, study randomization procedures did not produce TARGET and PE cohorts that were comparable in initial symptom and impairment levels and ethnoracial backgrounds. The PE cohort thus may have shown less PTSD symptom change due to beginning with lower symptom levels (i.e., due to range restriction) or lower expectancies of benefit and perceptions of a therapeutic working alliance. The exact length of sessions for each therapy model was not monitored, although therapists verified that all sessions for both treatments were conducted within the 75–90 min window and session tapes rated for interrater reliability all were actually 80–90 min in length for both models. Although the CAPS was revised for the most recent edition of the DSM, the DSM-IV version was used because the study was conducted before the DSM-5 was finalized. Effect size estimates for this small-*N* pilot sample also may have been subject to undetected bias (Leon, Davis, & Kraemer, 2011).

5 | CONCLUSION

Both TARGET and PE were associated with improvements in PTSD and severe anger problems with military veterans who completed a 10-session course of treatment, although the dropout rate in PE was double that in TARGET. Study results were preliminary due to the limitations of low statistical power and the high level of attrition in the PE condition but suggest that additional research is needed to more definitively test the possibility that TARGET may be a viable option for therapeutically engaging and successfully treating military veterans with PTSD and severe anger problems.

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