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## A Randomized Clinical Trial Comparing Affect Regulation and Social Problem-Solving Psychotherapies for Mothers With Victimization-Related PTSD

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Addressing affect dysregulation may provide a complementary alternative or adjunctive approach to the empirically supported trauma memory processing models of cognitive behavior therapy (CBT) for posttraumatic stress disorder (PTSD). A CBT designed to enhance affect regulation without trauma memory processing—trauma affect regulation: guide for education and therapy (TARGET)—was compared to present centered therapy (PCT) and wait-list (WL) conditions in a randomized clinical trial with 146 primarily low-income and ethnorracial minority mothers with PTSD. TARGET achieved statistically and clinically significant improvement on PTSD and affect regulation measures compared to WL, with more consistent and sustained (over a 6-month follow-up period) evidence of improvement than PCT. Drop-out rates (~25%) were comparable in TARGET and PCT, similar to

those previously reported for trauma memory processing CBTs. Symptom worsening was rare (2–8%) and transient. Affect regulation-based CBT without trauma memory processing warrants further research as a potentially efficacious therapy for victimization-related PTSD.

*Keywords:* PTSD; women; psychotherapy; affect regulation

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Empirically supported models of cognitive behavior therapy (CBT) for adults with posttraumatic stress disorder (PTSD)—that is, prolonged exposure (PE), cognitive processing therapy (CPT), and eye movement desensitization and reprocessing (EMDR)—help clients to process trauma memories in order to reduce avoidance and associated reexperiencing, emotional numbing, and hyperarousal symptoms (Cahill, Rothbaum, Resick, & Follette, 2009). Survivors of childhood interpersonal trauma often experience severe affect dysregulation (Charuvastra & Cloitre, 2008), and adaptations of trauma memory processing techniques have been developed to address these problems (e.g., Cook, Schnurr, & Foa, 2004; Jaycox & Foa, 1996; Resick, Nishith, Weaver, Astin, & Feuer, 2002). Studies have shown that women with severe affect dysregulation can tolerate and benefit from CBT with trauma memory processing (Rauch et al., 2009; Resick, Nishith, & Griffin, 2003). However, high levels of emotions such as anger, guilt, or shame have been found to be associated with poor response in PE (Jaycox & Foa, 1996), and dysregulated affect was found to be predictive of autobiographical memory problems

that may interfere with trauma memory processing in PTSD (Dalglish, Rolfe, Golden, Dunn, & Barnard, 2008). Moreover, high drop-out rates from trauma memory processing CBT have been reported by studies of women with PTSD secondary to histories of child abuse (Cloitre et al., 2010; McDonagh-Coyle et al., 2005). These findings raise the possibility that, for some victimized women with PTSD, trauma memory processing may exceed their capacity for affect regulation (McDonagh-Coyle et al., 2005).

A recent meta-analysis of therapy outcome studies with adult survivors of childhood sexual abuse found that CBT was superior to other modalities for anxiety, depression, and other internalizing problems, but not for problems associated with more severe affect dysregulation (e.g., externalizing or interpersonal problems; Taylor & Harvey, 2010). Thus, some PTSD clients, particularly those with extensive victimization histories, may respond best to therapy if affect regulation problems are directly addressed (Cloitre et al., 2010). Clients who have severe difficulties with affect regulation and their therapists also may prefer not to engage in trauma memory processing, or not to do so until the client has acquired affect regulation skills (Cloitre et al., 2010; Cook et al., 2004). Affect regulation interventions have been shown to improve the functioning of high-risk professionals (i.e., police officers; Berking, Meier, & Wupperman 2010) and to enhance the efficacy of CBT with psychiatric inpatients (Berking et al., 2008). Therefore, adaptations of CBT designed to enhance affect regulation without, or prior to, trauma memory processing merit study in order to increase the options for personalizing PTSD treatment. The resultant options could enable clinicians to use empirically based PTSD treatments that do not require trauma memory processing with clients who initially refuse to disclose trauma memories in detail or repetitively, potentially enabling those clients to acquire affect regulation skills that may either reduce their PTSD symptoms directly or prepare them for trauma memory processing.

Two manualized PTSD CBT models that do not include trauma memory processing have been designed to enhance skills for affect regulation, anxiety management, and interpersonal functioning: skills training for affect and interpersonal regulation (STAIR) and seeking safety have shown promise in clinical and field trial studies with women (Cloitre, Koenen, Cohen, & Han, 2002; Cloitre et al., 2010; Desai, Harpaz-Rotem, Najavits, & Rosenheck, 2008; Hien et al., 2010; Zlotnick, Johnson, & Najavits, 2009) and girls (Najavits, Gallop, & Weiss, 2006). STAIR, an eight-session individual therapy, was found to be most efficacious in reducing PTSD severity and enhancing affect regulation when followed by PE,

but has not been evaluated as a stand-alone therapy except for short-term outcomes (Cloitre et al., 2002, 2010). Seeking Safety is a lengthier (i.e., up to 26 sessions) individual or group therapy designed for comorbid PTSD and substance abuse. Seeking Safety has shown evidence of efficacy in several studies, and was found to reduce PTSD symptoms primarily with the most distressed participants (Hien et al., 2010). Although STAIR and Seeking Safety address affect regulation, each also teaches a variety of additional skills (e.g., assertiveness, problem solving, relaxation) that may account for their effects. Thus, the efficacy of CBT singularly focused on enhancing affect regulation has not yet been tested.

Trauma Affect Regulation: Guide for Education and Therapy (TARGET; Ford & Russo, 2006) was developed for the above purpose. TARGET teaches a single sequential skill set designed based on research showing that affect regulation involves recognizing, modulating, and recovering from negative emotion states (Kessler & Staudinger, 2009) and accessing and sustaining positive emotion states (Eisner, Johnson, & Carver, 2009). The TARGET skill set was also designed to remediate affect dysregulation, that is, to enhance the client's abilities to anticipate and prevent or recover from (by regaining emotional equilibrium) the rapid acceleration of emotional distress associated with traumatic victimization (Cloitre et al., 2010). TARGET thus provided a basis for determining whether a CBT focused on affect regulation skills can reduce PTSD symptom severity and related affective and cognitive impairments without trauma memory processing.

### Study Goals

The comparison therapy in this study was another CBT that has been shown to reduce PTSD without trauma memory processing, but that does not address affect regulation: present centered therapy (PCT; McDonagh-Coyle et al., 2005). Although PCT was not as successful as PE in achieving remission from PTSD in the McDonagh-Coyle et al. (2005) and Schnurr et al. (2007) studies, PCT showed short-term evidence of benefits comparable to PE and had fewer dropouts (9 and 21% vs. 41 and 38%, respectively). PCT was used as an active comparison therapy in order to determine whether TARGET has sufficient efficacy to merit subsequent controlled trials as an alternative to, or an adjunctive augmentation of, trauma memory processing CBTs such as PE, CPT, or EMDR. PCT teaches social problem-solving skills designed to enhance coping with PTSD symptoms, based on research showing that social support resources often are depleted or not utilized by victimized women (Charuvastra & Cloitre, 2008).

A wait-list (WL) condition also was included in order to ensure that TARGET's effects are not attributable to the passage of time and repeated assessments, and specifically that they are comparable to those reported in repeated measures treatment outcome studies with victimization survivors (Taylor & Harvey, 2010).

A secondary objective of the study was to test the efficacy of affect regulation-focused CBT with underserved women who have experienced interpersonal victimization. Women in studies of CBT for PTSD typically have been White and college educated, with notable exceptions (e.g., Foa et al., 2005), rather than from low income (Rayburn et al., 2005; Schumm, Briggs-Phillips, & Hobfoll, 2006) or ethnoracial minority (Pole, Gone, & Kulkarni, 2008) backgrounds (Cahill et al., 2009; Taylor & Harvey, 2010). Histories of victimization (e.g., childhood abuse or neglect, domestic violence) are prevalent among women and associated with persistent PTSD, low social support, and affect dysregulation (Charuvastra & Cloitre, 2008; Gill, Page, Sharps, & Campbell, 2008; Seedat, Stein, & Carey, 2005). Also, a meta-analysis of therapy outcome studies with adult survivors of childhood sexual abuse found an inverse relationship between extent of past victimization and improvement in internalizing symptoms (Taylor & Harvey, 2010).

In addition, given evidence that violence, PTSD, and affect dysregulation may occur in intergenerational cycles (Newcomb & Locke, 2001; Schechter et al., 2007), it is important to address PTSD effectively with mothers (Yehuda, Bell, Bierer, & Schmeidler, 2008), and to do so as early as possible in their children's lives (Lieberman, Ghosh Ippen, & Marans, 2009). PTSD therapy that focuses on affect regulation with low-income ethnoracial minority background mothers of young children thus may be particularly important as an approach to preventing intergenerational transmission of traumatic stress disorders. Evidence of efficacy for dyadic affect regulation-focused child-parent psychotherapy with mothers caring for traumatized young children offers indirect support for this view (Lieberman et al., 2009). The present study takes a related but different approach, that is, enhancing affect regulation when it is the mother who has PTSD, to attempt to intervene before, rather than after, her child experiences any adverse indirect impacts.

### Study Hypotheses

The study was designed to test the primary hypothesis that TARGET would be superior to PCT and to a WL condition in reducing PTSD symptom severity and posttraumatic beliefs. The secondary hypothesis was that TARGET would be

superior to PCT and to WL in improving affect regulation and coping skills, and comparable to PCT on interpersonal functioning outcomes. The tertiary hypothesis was that TARGET would be superior to PCT and WL in reducing anxiety, depression, guilt, and parenting insecurity and stress.

### Method

#### PROCEDURE

Participants were enrolled between February 4, 2005, and December 29, 2006, at health clinics, family service centers, community centers, and residential treatment centers in the Hartford, Connecticut, area, which has high rates of urban problems as assessed by arrest records, drug arrests, violent crime, firearm injuries and fatalities, family violence, and HIV rates. Applicants were screened for eligibility, assessed, and assigned to a treatment condition by one of three female interviewers according to a protocol approved by the Institutional Review Boards of the University of Connecticut Health Center and Saint Francis Medical Center. Three interviewers conducted all baseline, posttherapy, and follow-up assessments, after being trained to reliability with each structured interview, checked periodically with independent ratings, and supervised by the first and second authors. All interviews were conducted in English and were completed within 4 weeks of the study schedule, with the last follow-up on November 6, 2007. Experimental condition was assigned at the end of the baseline interview via an Excel-generated standard sequence-concealed number. All interviewers were blind to the experimental condition in baseline interviews, but due to technical difficulties they were not blind to experimental condition at posttherapy or follow-up interviews.

Exclusion criteria included evidence of substantial cognitive impairment (i.e., score < 16 on the Orientation, Attention, and Recall sections of the Mini Mental State Exam [MMSE; Folstein & Folstein, 1975]), on one-to-one suicide watch (current or past suicidal ideation was not an exclusion), past-month psychiatric hospitalization, refused audiotaping, monolingual Spanish-speaking. Inclusion criteria were age 18–50 years old, mother or primary caregiver for a child 5 years old or younger, current full or partial PTSD, and past exposure to victimization or incarceration. The child's age ( $\leq 5$  years old) was set based on evidence of the importance of the preelementary school-age period in consolidating attachment working models (Lieberman et al., 2009) and social bonds (Charuvastra & Cloitre, 2008), which are protective against childhood psychosocial problems and PTSD when a parent has PTSD.

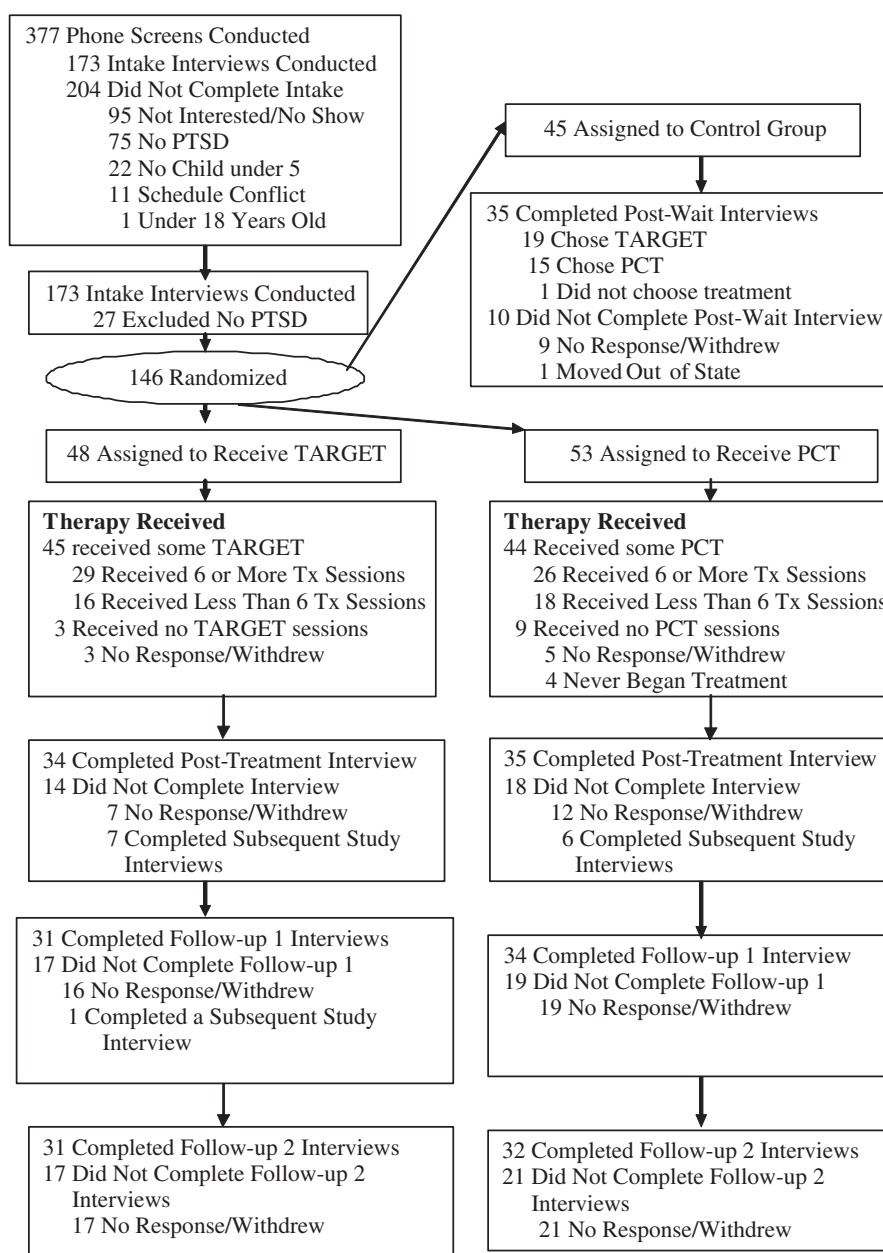


FIGURE 1 Participant flow through enrollment, randomization, treatment, and assessments.

PARTICIPANTS

One hundred forty six women (ages 18–45;  $M=30.7$ ,  $SD=6.9$ ) completed the screening and baseline assessment and then were randomized (by a study assessor using numbers concealed in sealed envelopes previously prepared by a different study staff member using the Excel random number generator) to WL ( $N=45$ ), TARGET ( $N=48$ ), or PCT ( $N=53$ ). (See Fig. 1.) Participants were compensated for attending each assessment interview (ranging from \$35 at baseline to \$50 at the

final follow-up interview). Participants' ethnoracial backgrounds included 40% African American ( $N=59$ ), 18% Latina ( $N=26$ , with 17 self-identified as Puerto Rican, 4 as Hispanic, 2 Cuban, 2 Dominican, and 1 Peruvian), 41% White not Hispanic ( $N=60$ ), and 1% other. Most participants lived alone (42% never married, 22% divorced, separated, or widowed). More than half (57%) had not completed high school or had a terminal high school degree, whereas 21% had attended some college and 22% were college graduates. Almost



half had been homeless ( $N=70$ , 48%), and 35% were either homeless ( $N=21$ ) or had lived with their parents in the past year ( $N=28$ ). Most had family incomes below \$30,000 per year (94%,  $N=118$ , 20 cases with missing data) with a median income of \$5,361 annually. A subgroup (14%) had mild cognitive impairment on the MMSE.

Most (72%) participants met Structured Clinical Interview for DSM-IV (SCID-P; First, Spitzer, Gibbon, & Williams, 1996) criteria for a current Axis I disorder other than PTSD. These included anxiety disorders (61%) and depressive (34%), bipolar (8%), or psychotic (9%) disorders. One in three (35%) was currently in mental health treatment, primarily (28%) for pharmacotherapy. Based on the Global Assessment of Individual Needs (GAIN; see below), almost half of the sample (43%,  $N=60$  of 141, due to five cases with missing data) met criteria for past substance dependence or abuse (39% and 37%, respectively,  $N=56$  and 52, respectively). One in nine met criteria for substance abuse (11%,  $N=16$ ) or dependence (11%,  $N=16$ ) in the past year. Past substance abuse most often involved marijuana (31%,  $N=43$ ), cocaine (28%,  $N=39$ ), or alcohol (26%,  $N=36$ ). Past substances of dependence included cocaine (30%,  $N=41$ ), alcohol (25%,  $N=35$ ), and heroin (12%,  $N=17$ ). Substance abuse and dependence in the past year were reported for alcohol (9% and 12%, respectively) or cocaine (9% for each). One in four participants currently was in addiction treatment (23%). Forty-three percent ( $N=60$ ) had been arrested (range=1–29 times), for drug use (15%,  $N=21$ ), larceny (14%,  $N=20$ ), or assault (14%,  $N=20$ ).

#### ASSESSMENTS

Structured interviews were used to assess trauma history, PTSD, and other psychiatric disorders (the latter only at baseline), followed by administering self-report questionnaires in the order shown below. Assessments were conducted within 2 weeks before (baseline), after (posttest), and at 3- and 6-month follow-ups of treatment. Interrater reliability was assessed with randomly selected 25% samples of baseline ( $N=39$ ) and posttest/follow-up ( $N=64$ ) interviews by audiotape review by an independent interviewer. Self-report questionnaires were administered at each assessment time point to measure primary outcomes (i.e., PTSD-related symptoms and beliefs), secondary outcomes (i.e., affect regulation and interpersonal functioning), and tertiary outcomes (i.e., anxiety, depression, and guilt symptoms and parenting variables).

#### TRAUMA HISTORY AND DIAGNOSTIC MEASURES

##### *Traumatic Events Screening Inventory (TESI)*

History of trauma was assessed at baseline with the TESI (Ford & Smith, 2008) structured interview's behaviorally specific questions about the type, number of episodes, and developmental/chronological index (i.e., before age 6, before age 18, age 18 or later, in the past year) of experiences fulfilling the DSM-IV (American Psychiatric Association, 1994) criteria for Criterion A1 (life threat, severe injury, or violation of personal integrity, witnessed or directly experienced) and Criterion A2 (fear, helplessness, horror). Seventeen questions inquire at a fifth-grade reading level, in English or Spanish, about direct exposure to and witnessing of potentially traumatic accidents, illness, disasters, deaths of significant others by accident, illness, murder, or drivers under the influence of substances, family violence, community violence, and sexual assault or molestation. Categorical scores result for 18 trauma history variables based on 6 trauma types (accident/illness, separation/loss, family violence, community violence, physical assault, sexual assault/molestation) and 3 developmental epochs (0–5.9, 6–17.9, past year). Independent interrater reliability in this study for the presence or absence of a traumatic event within each category was strong, ranging from  $\kappa=.84$  to .91.

##### *Clinician Administered PTSD Scale (CAPS)*

The CAPS (Blake et al., 1995; Weathers, Keane, & Davidson, 2001) is a reliable and validated structured interview for DSM-IV (American Psychiatric Association, 1994) categorical diagnoses for full and partial (i.e., meets Criterion B and Criterion C or D; Schnurr et al., 2000) PTSD. The CAPS also yields ordinal symptom severity scores for PTSD and Criteria B, C, and D. CAPS scores the intensity, 0 (*none*) to 4 (*extreme distress*) and frequency, 0 (*never*) to 4 (*daily or almost every day*) of each PTSD symptom. Independent interrater reliability for the CAPS total score (intraclass correlation=.97 at baseline, .94 at posttest/follow-up) and detecting full or partial PTSD (92% agreement,  $\kappa=.77$ ) was strong, and adequate for distinguishing full versus partial PTSD (82% agreement,  $\kappa=.61$ ). Diagnosis discrepancies (primarily due to Criterion C avoidance/numbing symptoms) were resolved by the first author. Severity scores >50 are clinical range, with >70 reflecting severe PTSD (Weathers et al., 2001). Normative sample data have not been reported (F. Weathers, personal communication, October 13, 2008) but a study of adult violence and accident trauma survivors reported mean and standard

deviation scores for those who did and did not meet criteria for PTSD as  $M(SD)=47(11)$  and  $33.5(11)$ , respectively (Scragg, Grey, Lee, Young, & Turner, 2001). For clinical significance (Jacobson, Roberts, Berns, & McGlinchey, 1999), a threshold for a nonclinical range score therefore was set at  $\leq 30$ . Full remission at posttest or follow-up was defined more conservatively as not meeting criteria for either partial or full PTSD and a CAPS total severity score  $\leq 20$  (Cloitre et al., 2010; Weathers et al., 2001). Partial remission was defined as meeting criteria for partial but not full PTSD.

*Structured Clinical Interview for DSM-IV (SCID-P)*  
The SCID-P (First et al., 1996) is a reliable and validated structured interview for DSM-IV (American Psychiatric Association, 1994) diagnoses. SCID modules for affective, anxiety, and psychotic disorders were administered to assess current major depression, bipolar disorder, panic disorder, agoraphobia, social phobia, and generalized anxiety disorder. Independent interrater reliability was acceptable for each of those diagnoses ( $\kappa = .76-1.00$ ).

#### PTSD-RELATED MEASURES (PRIMARY OUTCOMES)

*Post-Traumatic Cognitions Inventory (PTCI)*  
This 36-item measure (Foa, Ehlers, Clark, Tolin, & Orsillo, 1999) reliably and validly assesses posttraumatic beliefs. Subscales for posttraumatic beliefs about oneself (PTCI-S) and about the world (PTCI-W) were used and had acceptable internal consistency in this sample (Cronbach's  $\alpha = .94$  and  $.88$ , respectively).

*Interpretation of PTSD Symptoms Inventory (IPSI)*  
This 10-item measure (Halligan, Tanja, Clark, & Ehlers, 2003) reliably assesses appraisal of distress concerning unwanted trauma memories (intrusive symptoms [IS]; 7 items, range=0–28) and distress concerning problems in remembering a traumatic event (memory deficits [MD]; 3 items, range=0–12) on a 0–4 scale. The IPSI total score was used due to its concurrent and predictive validity in relation to postassault PTSD (Halligan et al.) and had acceptable internal consistency ( $\alpha = .90$ ).

*Trauma Memory Questionnaire (TMQ)*  
The TMQ (Halligan et al., 2003) includes 13 items that reliably assess perceived disorganization (D; 5 items, range=0–20) and intrusiveness (I; 8 items, range=0–32) of trauma memories. The I subscale was used in this study based on evidence of its predictive validity for identifying individuals at risk for developing postassault PTSD (Halligan, Tanja, Clark, & Ehlers, 2003), and had acceptable internal consistency in this sample ( $\alpha = .90$ ).

#### AFFECT AND INTERPERSONAL REGULATION MEASURES (SECONDARY OUTCOMES)

*Generalized Expectancies for Negative Mood Regulation (NMR)*

The NMR (Catanzaro & Mearns, 1995) is a 30-item scale (range=30–150) that reliably and validly assesses self-perceived ability to identify, manage, and utilize adaptively negative emotion states on a 1–5 scale (from *strongly agree* to *strongly disagree*), and had acceptable internal consistency in this sample ( $\alpha = .92$ ).

*Coping Orientation to Problems Experienced (COPE)*

This 53-item questionnaire (Carver, Scheier, & Weintraub, 1989) provides reliable and valid self-ratings of the frequency, 1 (*never*) to 4 (*regularly*), of the use of three types of coping strategies: active, affective, and negative (Murphy, Johnson, Chung, & Beaton, 2003). One subscale from each domain was used in the present study, respectively, the action, use of humor, and blame subscales. Although internal consistency could not be calculated because each subscale included only two items, the item pairs for each subscale were highly correlated ( $rs = .57-.70$ ,  $p < .001$ ). The three COPE subscales were relatively independent, with only weak or inverse intercorrelations ( $rs = -.11-.26$ ).

*Inventory of Interpersonal Problems–Short Form (IIP-32)*

This 32-item (Barkham, Hardy, & Startup, 1996) rationally and factor analytically derived measure of problems in relationships has shown evidence of reliability and validity with clinical and community samples. The subscale for problems with “(over) involvement” was used in the present study, and had acceptable internal consistency in this sample ( $\alpha = .74$ ).

#### ANXIETY, DEPRESSION, AND GUILT MEASURES (TERTIARY OUTCOMES)

*State-Trait Anxiety Inventory, State Version (STAI-S)*

The STAI-S (Spielberger, Gorsuch, & Lushene, 1970) assesses the strength (on a 0–4 scale) of 20 physiological, cognitive, affective, and behavioral symptoms of anxiety in the present moment, with demonstrated reliability and validity in clinical and nonclinical populations, and acceptable internal consistency in this sample ( $\alpha = .91$ ). Scores  $> 40$  are considered clinical range, with scores  $> 50$  reflecting severe anxiety (Kaneda & Fujii, 2000). Per Foa and Jaycox (1999), the threshold for a score within the nonclinical range was set at  $\leq 35$ .

*Beck Depression Inventory (BDI)*

The BDI (Beck, Steer, & Garbin, 1988) is a 21-item measure of depressive symptoms, each of which has four possible answers with behavioral indices (score range=0–63), which has been shown to be reliable and valid in clinical samples, and had acceptable internal consistency ( $\alpha = .94$ ). Scores  $\geq 8$  reflect subclinical depression,  $\geq 19$  reflect moderate to severe depression, and  $\geq 30$  reflect severe depression. Per Foa and Jaycox (1999), the threshold for a score within the nonclinical range was set at  $\leq 7$ .

*Trauma-Related Guilt Inventory (TRGI)*

This 32-item (Kubany et al., 1996) Likert rating scale validly and reliably assesses several aspects of guilt. The distress related to guilt subscale was used and had acceptable internal consistency in this sample ( $\alpha = .84$ ).

## PARENTING STRESS AND RELATIONAL SECURITY MEASURES (TERTIARY OUTCOMES)

*Parenting Stress Index Short Form (PSI)*

This 36-item measure (Abidin, 1995) with a 4-point Likert scale reliably (i.e., adequate test–retest and internal consistency) and validly (i.e., convergent, criterion) assesses perceived stress as a parent. The parenting distress subscale was used and had acceptable internal consistency in this sample ( $\alpha = .81$ ).

*Relationship Scales Questionnaire (RSQ)*

This 30-item (5-point scale; Griffin & Bartholomew, 1994) reliable and validated self-report questionnaire measures endorsement of four relationship styles (secure, fearful, preoccupied, dismissing) on a scale from (*not at all like me*) to (*very much like me*). A 6-item secure attachment subscale was used in the present study as a measure of trust in close relationships, and had acceptable internal consistency ( $\alpha = .66$ ).

## THERAPY INTERVENTIONS

*Trauma Affect Regulation: Guide for Education and Therapy (TARGET)*

TARGET (Ford & Russo, 2006) provides psychoeducation linking PTSD symptoms and affect dysregulation as the result of biological adaptations to survival threats that lead to susceptibility to rapid intense emotional reactivity and difficulty in regaining emotional equilibrium. Restoring affect regulation is described as requiring seven practical steps or skills summarized by an acronym, “FREEDOM”: Focusing the mind on one thought at a time; Recognizing current triggers for emotional reactions; distinguishing dysregulated (“reactive”) versus adaptive (“main”) Emotions, Evaluations

(thoughts), goal Definitions, and behavioral Options; and self-statements affirming that taking responsibility for recovering from intense emotions is crucial not only to one's own personal well-being but also to Making a positive contribution to primary relationships (e.g., as a parent) and the community.

TARGET was delivered in twelve 50-minute sessions of individual therapy. In the first eight sessions, FREEDOM steps are learned and practiced incrementally with modeling and coaching by the therapist, via imaginal rehearsal in therapy sessions and in vivo in individualized homework assignments, using a template (“Personal Practice Exercise for FREEDOM”) that walks the client through each FREEDOM step as she applies it to preparing for or analyzing experiences in which she had difficulty with posttraumatic affect dysregulation. The final four sessions are devoted to rehearsing and applying the full skill set to anticipate and prevent or manage PTSD symptoms in current life events. TARGET also provides a creative arts activity designed to enhance positive and negative emotion recognition in the context of autobiographical narrative construction (the “lifeline”). The lifeline involves using collage, drawing, poetry, writing, and music to depict life experiences that the client views as emotionally significant (including but not limited to traumatic events). The FREEDOM steps serve as the organizing framework for each lifeline, with the client assisted in identifying trauma-related triggers, feelings, thoughts, goals, and behavior as well as examples of counterbalancing resilient feelings, thoughts, goals, and behavior. The goal of the lifeline is to enhance affect regulation by providing guided practice in applying the FREEDOM skills to reconstructing and organizing affectively salient memories from across the full life span.

*Present Centered Therapy (PCT)*

This manualized 12-session supportive therapy was adapted from the 14-session version codeveloped by the article's first author (McDonagh-Coyle et al., 2005). PTSD education explains that traumatic events lead to problems in relationships as a result of the “traumagenic dynamics” of betrayal, stigma, powerlessness, and sexualization (Finkelhor, 1987). PCT does not include trauma memory narrative work, and uses an acronym to help clients learn a social problem-solving skill set—SIBEDR: State the problem, gather Information, Brainstorm, Explore potential solutions, Decide on a course of action, and Review the results to refine the course of action. The first six sessions are devoted to learning the social problem-solving skill



set, and the final six sessions involve reviewing the application of the skill set to resolving problems in current relationships that are caused by PTSD symptoms such as intrusive memories, avoidance, and hypervigilance. PCT thus differs from TARGET by focusing on enhancing social problem-solving rather than affect regulation. PCT also does not include education about the biology of traumatic stress. PCT also includes homework exercises that differ from TARGET's, providing the client with instructions on keeping a written journal to track relational problems and application of SIEBDR problem-solving steps between sessions.

*Therapists and fidelity monitoring.* Eight experienced female therapists (one African American, two Latina, five White) with doctoral degrees in clinical psychology ( $N=2$ ), psychiatry ( $N=1$ ) or master's degrees in social work, counseling, or marriage and family therapy ( $N=5$ ) conducted either TARGET ( $N=5$ ) or PCT ( $N=3$ ). Therapists received more than 40 hours of training and case supervision by the first author. Each rated the credibility of the therapy as high to very high. To document fidelity to each treatment model and clinical competence, all therapy sessions were audiotaped and a 20% sample was rated by two independent clinically trained raters using fidelity (dichotomous present/absent ratings) and competence (7-point scales ranging from poor to satisfactory to excellent; Resick et al., 2002). The fidelity checklists defined unique essential items for each session of each treatment. Fidelity to each model was 100%, with no evidence of the use of unique TARGET elements in PCT sessions or vice versa. The psychoeducation or skills training prescribed by each model was provided in more than 90% of the TARGET sessions and more than 80% of the PCT sessions. Competence ratings were not specific to the therapy models (i.e., thorough assessment, maintaining session focus, reflective listening, empathic responding) and resulted in high satisfactory to excellent ratings for all therapists in all sessions (TARGET:  $M=5.2-5.5$ ,  $SD=1.0-1.2$ ; PCT:  $M=4.9-5.0$ ,  $SD=0.9-1.2$ ). Competence was comparable for both models, except that TARGET therapists were rated superior to PCT therapists on empathic responding ( $t=2.00$ ,  $df=95$ ,  $p=.048$ ).

*Treatment credibility and therapeutic alliance.* Following Sessions 1, 4, 10, and in the posttest participants completed the Expectancy of Therapeutic Outcome (ETO) scale (Resick et al., 2002). The ETO is a 7-item scale with 9-point ratings ranging from 1 (*not at all*) to 3 (*a little*) to 5 (*somewhat*) to 7 (*a lot*) to 9 (*extremely*) for the credibility of the therapy, confidence in its helpfulness in achieving symptom reduction and positive functioning outcomes, and

willingness to recommend the treatment. At those time points, participants also completed the Working Alliance Inventory (WAI-7), a 7-item scale with answer anchors ranging from 0 (*strongly disagree*) to 2 (*neither agree nor disagree*) to 4 (*strongly agree*) adapted from the original WAI for adults receiving psychiatric case management services (Neale & Rosenheck, 1995). The WAI-7 has items selected to represent the three WAI primary factors (trust in the therapist and the therapist's ability to understand, provide a collaborative working relationship, and help the participant to achieve his or her goals), and showed evidence of internal consistency and predictive validity in relation to measures of change in client-rated symptom reduction and functioning. The WAI-7 had good internal consistency in the present study ( $\alpha=.95$ ).

#### STATISTICAL ANALYSES

Prior to hypothesis testing, data screening was completed and no outliers resulting in non-normal/linear distributions were detected. Missing data due to drop outs, missed interviews, or incomplete measures were analyzed using the SPSS Missing Value Analysis program and found to be random except for four variables: the BDI in the PCT and WL conditions, the PTCI in the PCT and TARGET conditions, the IPSI in the TARGET condition, and the STAI in the WL condition. For those variables, conditions, and time points, participants reporting more severe problems were more likely to have missing data at later time points; however, these exceptions to random missing data were equally distributed across conditions and thus no statistical adjustment was deemed necessary because they were unlikely to affect between-group analyses.

Intent-to-treat analyses consistent with the CONSORT definition were conducted using mixed-model regression in order to include all participants in each analysis regardless of missing data (Bryk & Raudenbush, 1992; Singer, 1998). Within-subject effects were examined to test for change over time in each experimental condition. Interaction effects for experimental condition by time point were examined to test for differences in change over time, followed by pairwise  $t$ -test comparisons of the conditions' weighted scores at each posttest or follow-up time point. All tests were two-tailed. In order to control for the effects of age, marital status (living with a partner vs. living alone), education (high school or less vs. some college or more), ethnicity (Black or Latina vs. White), and comorbid major depression, bipolar disorder, anxiety disorder, obsessive-compulsive disorder, or psychotic disorders, these variables were included as covariates. These variables may moderate the effects of

treatment, but the goal of the present study was to test for effects of each therapy across the full range of participants while controlling for demographic/disorder factors in order to ensure that the effects were uniquely associated with therapy per se. Effect-size estimates (Cohen's  $d$ ; Cohen, 1988) were calculated for differences in baseline posttest change between each pair of conditions (i.e., PCT vs. WL; TARGET vs. WL; TARGET vs. PCT):  $d = M_1 - M_2 / \sigma_{\text{pooled}}$  where  $\sigma_{\text{pooled}}$  = square root of  $(\sigma_1^2 + \sigma_2^2) / 2$ . Medium ( $d = .35-.75$ ) effects were expected comparing the active therapies TARGET (Frisman, Ford, Lin, Mallon, & Chang, 2008) and PCT (McDonagh-Coyle et al., 2005) to WL, and small ( $d < .25$ ) effects were expected comparing the active treatments (Benish, Imel, & Wampold, 2008). The  $N$ s of 45–53 per cell were sufficient at  $p < .05$  (one tail) to detect small effects ( $d = .20$ ) with .25 power, and medium ( $d = .50$ ) effects with .80 power (Cohen, 1988, p. 54). PTSD remission and clinically significant change were assessed posttherapy and both follow-ups, the latter based on a criterion of achieving nonclinical range scores on the CAPS, BDI, and STAI (Jacobson et al., 1999) and >40% improvement from baseline on the CAPS (Foa & Jaycox, 1999).

## Results

### TREATMENT CREDIBILITY AND THERAPEUTIC ALLIANCE

Both TARGET and PCT received uniformly high ratings for therapy credibility on the ETO, with TARGET scores higher at Sessions 1 ( $t = 2.41$ ,  $df = 86$ ,  $p = .018$ ), 4 ( $t = 2.83$ ,  $df = 57$ ,  $p = .006$ ), and posttest ( $t = 2.42$ ,  $df = 60$ ,  $p = .019$ ), but equivalent at Session 10 ( $t = 0.76$ ,  $df = 36$ ,  $p = .451$ ). Actual ETO scores ranged from 3 (*a little*) to 9 (*extremely*) for both therapies. TARGET: Session 1 ( $M = 7.4$ ,  $SD = 1.6$ ); Session 4 ( $M = 7.3$ ,  $SD = 1.1$ ); Session 10 ( $M = 7.9$ ,  $SD = 0.9$ ); and posttherapy ( $M = 7.7$ ,  $SD = 1.0$ ). PCT: Session 1 ( $M = 6.6$ ,  $SD = 1.7$ ); Session 4 ( $M = 6.3$ ,  $SD = 1.5$ ); Session 10 ( $M = 7.7$ ,  $SD = 1.1$ ); and posttherapy ( $M = 6.9$ ,  $SD = 1.6$ ). Treatment credibility/expectancy ratings were stable across therapy and at posttest, with nonsignificant improvement for both TARGET and PCT. Therapeutic alliance was also rated consistently positively for both TARGET and PCT with no differences ( $t = 0.36-1.60$ ,  $df = 38-86$ ,  $p = .12-.73$ ) between conditions and ratings ranging from 1 (*disagree*) to 4 (*strongly agree*). TARGET: Session 1 ( $M = 3.3$ ,  $SD = 0.7$ ); Session 4 ( $M = 3.4$ ,  $SD = 0.5$ ); Session 10 ( $M = 3.6$ ,  $SD = 0.5$ ); and posttherapy ( $M = 3.6$ ,  $SD = 0.5$ ). PCT: Session 1 ( $M = 3.1$ ,  $SD = 0.6$ ); Session 4 ( $M = 3.2$ ,  $SD = 0.4$ ); Session 10 ( $M = 3.5$ ,  $SD = 0.6$ ); and posttherapy ( $M = 3.4$ ,  $SD = 0.5$ ).

### BASELINE COMPARISON OF EXPERIMENTAL CONDITIONS

Comparison of the experimental conditions with chi-square tests for categorical variables and ANOVA for continuous measures identified no demographic differences and few differences on the outcome measures at baseline (see Table 2). PCT and TARGET were lower than WL on the PTCI-S, COPE-Blame, and PSI-D, and TARGET was lower than WL on the MDI-D and BDI,  $F(2, 132-134) = 3.29-5.47$ , with Scheffe post hoc tests for pairwise comparisons  $p < .05$ . At baseline, all participants met criteria for full or partial PTSD, with full PTSD present for 80%, 74%, and 87%, respectively, of the TARGET, PCT, and WL participants ( $p > .35$ ).

### TREATMENT EFFICACY

Mixed-model regression analyses showed evidence of change from baseline to posttherapy for TARGET and PCT, and no change for the WL condition. Specifically, Group  $\times$  Time interaction terms for most variables were statistically significant (see Table 1), except for the IIP-Involvement, STAI, and PSI-Distress measures ( $p > .05$ ). Baseline-adjusted posttest mean scores consistently favored TARGET and PCT over WL on all primary measures and two-thirds of the measures overall (see Table 2).

Table 1  
Group  $\times$  Time Interaction  $F$  Values for Change From Baseline to Posttherapy

Measure	$F$	$df$	$p$
CAPS	8.31	2,132	.001
PTCI-Self	4.87	2,133	.009
PTCI-World	3.46	2,133	.03
TMQ-Intrusion	5.85	2,132	.004
IPSI	5.42	2,133	.005
Negative Mood Regulation	6.03	2,129	.003
COPE-Humor	3.27	2,129	.04
COPE-Active	2.33	2,129	.10
COPE-Blame	5.97	2,129	.003
IIP-Involvement	0.19	2,125	.83
State-Trait Anxiety Inventory	1.67	2,119	.19
Beck Depression Inventory	4.32	2,129	.01
TRGI-Distress Scale	3.69	2,132	.03
PSI-Distress	0.41	2,115	.83
RSQ-Secure	1.66	2,132	.19

Note. CAPS=Clinician Administered PTSD Scale; PTCI=Posttraumatic Cognitions Inventory, self and world subscales; TMQ=Trauma Memory Questionnaire, intrusion subscale; IPSI=Interpretations of PTSD Symptoms; COPE=Coping Orientation to Problems Experienced, humor, active, and blame subscales; IIP=Inventory of Interpersonal Problems, involvement subscale; TRGI=Trauma Related Guilt Inventory, distress subscale; PSI=Parenting Stress Inventory, distress subscale; RSQ=Relationship Style Questionnaire, secure attachment subscale.

Table 2  
Change From Baseline to Posttest by Treatment (TARGET, PCT) or Control (Wait-List) Group (N= 146)

Measure	Baseline M(SD)			Posttreatment M(SD)			Effect Size (d)		
	Wait-list	TARGET	PCT	Wait-list	TARGET	PCT	T vs.	P vs.	T vs.
							WL	WL	P
<b>PTSD Measures</b>									
CAPS	68.7 (17.0)	62.3 (18.1)	61.9 (21.3)	62.5 <sup>a</sup> (23.3)	38.7 <sup>*b</sup> (25.6)	39.7 <sup>*b</sup> (21.4)	-.74	-.69	-.05
PTCI-Self	67.1 <sup>a</sup> (28.3)	51.3 <sup>b</sup> (23.5)	53.7 <sup>b</sup> (25.4)	65.9 <sup>a</sup> (31.0)	36.1 <sup>*b</sup> (19.5)	45.9 <sup>*c</sup> (23.1)	-.64	-.43	-.22
PTCI-World	33.5 (10.0)	31.9 (11.1)	31.4 (11.0)	32.5 <sup>a</sup> (11.7)	26.3 <sup>b</sup> (11.1)	26.8 <sup>b</sup> (11.0)	-.48	-.47	-.01
TMQ-Intrusion	6.9 (6.2)	4.7 (5.6)	4.6 (5.1)	6.2 <sup>a</sup> (5.7)	2.7 <sup>*b</sup> (4.3)	4.2 <sup>c</sup> (5.3)	-.17	-.10	-.07
IPSI	34.7 (16.6)	27.8 (12.9)	30.1 (15.6)	34.8 <sup>a</sup> (16.1)	18.9 <sup>* b</sup> (11.2)	22.6 <sup>*b</sup> (11.6)	-.61	-.60	-.02
<b>Affect and Interpersonal Regulation Measures</b>									
NMR	96.9 (20.0)	106.1 (18.1)	103.1 (20.2)	96.8 <sup>a</sup> (20.3)	120.8 <sup>*b</sup> (15.1)	109.0 <sup>c</sup> (18.3)	.74	.43	.31
COPE-Humor	4.3 (1.9)	4.5 (2.0)	4.0 (1.7)	3.9 <sup>a</sup> (1.8)	5.2 <sup>*b</sup> (1.9)	4.2 <sup>a</sup> (1.6)	.54	.33	.21
COPE-Active	5.8 (1.6)	6.1 (1.4)	5.6 (1.6)	5.7 <sup>a</sup> (1.5)	6.7 <sup>*b</sup> (1.3)	5.9 <sup>a</sup> (1.7)	.45	.29	.17
COPE-Blame	5.4 <sup>a</sup> (1.9)	4.4 <sup>b</sup> (1.7)	4.4 <sup>b</sup> (1.8)	5.7 <sup>a</sup> (2.0)	3.8 <sup>*b</sup> (1.7)	3.8 <sup>*b</sup> (1.6)	-.53	-.70	-.15
IIP-Involvement	6.3 (4.6)	5.2 (3.7)	5.6 (4.0)	5.2 (4.0)	3.4 <sup>*</sup> (3.3)	4.1 <sup>*</sup> (4.2)	-.10	-.12	-.01
<b>Associated Symptoms and Parenting Measures</b>									
STAI	43.0 (10.9)	38.1 (13.0)	41.6 (13.0)	42.6 <sup>a</sup> (12.9)	31.4 <sup>*b</sup> (11.3)	37.4 (13.3)	-.37	-.27	-.11
BDI	21.8 <sup>a</sup> (11.5)	16.0 <sup>b</sup> (10.8)	17.8 (10.2)	21.5 <sup>a</sup> (13.8)	11.6 <sup>*b</sup> ( 10.9)	11.9 <sup>*b</sup> (10.1)	-.36	-.62	.25
TRGI-Distress	2.8 (0.8)	2.5 (0.9)	2.6 (0.8)	2.4 <sup>a</sup> (0.9)	1.9 <sup>*b</sup> (1.0)	1.8 <sup>*b</sup> (0.8)	-.35	-.57	.21
PSI-Distress	37.6 <sup>a</sup> (7.9)	32.2 <sup>b</sup> (7.4)	32.9 <sup>b</sup> (9.7)	35.1 (10.6)	28.7 (8.9)	29.3 (10.1)	-.07	-.25	.18
RSQ-Secure	13.5 (3.3)	13.7 (3.8)	14.0 (3.5)	13.4 <sup>a</sup> (4.0)	15.2 <sup>*b</sup> (3.9)	14.2 <sup>b</sup> (2.9)	.50	.16	.33

Note. CAPS=Clinician Administered PTSD Scale; PTCI=Posttraumatic Cognitions Inventory, self and world subscales; TMQ-Intrusion=Trauma Memory Questionnaire, intrusion subscale; IPSI=Interpretations of PTSD Symptoms; NMR=Generalized Expectancies for Negative Mood Regulation; COPE=Coping Orientation to Problems Experienced, humor, active, blame subscales; IIP Involvement=Inventory of Interpersonal Problems, involvement subscale; STAI=State Trait Anxiety Inventory, State Form; BDI=Beck Depression Inventory; TRGI-Distress=Trauma Related Guilt Inventory, distress subscale; PSI-Distress=Parenting Stress Inventory, distress subscale; RSQ-Secure=Relationship Style Questionnaire, Secure Attachment; T vs. WL=effect size comparing regression-corrected pre–post change for TARGET vs. Wait-list conditions; P vs. WL=effect size for regression-corrected pre–post change comparing PCT vs. Wait-list ; T vs. P=effect size for regression-corrected pre–post change comparing TARGET vs. PCT. Means with different superscripts differ  $p < .05$ ; \* $p < .05$ .

Comparison of TARGET versus PCT on baseline-adjusted posttest mean scores generally favored TARGET but typically with small effect sizes (see Table 2 and below). Additional mixed-model regression analyses comparing TARGET and PCT at posttest versus 3-month follow-up versus 6-month follow-up means showed that improvement associated with TARGET and PCT generally persisted at the 3- and 6-month follow-up periods, and reflected additional improvements on several variables particularly for the TARGET group (see Table 3 and below).

*Primary Outcomes: PTSD and Posttraumatic Symptoms and Cognitions*

TARGET was associated with significantly lower TMQ and PTCI-Self scores at posttest than PCT (although with small effect sizes,  $d = .07$  and  $.22$ ), and with statistically significant change from baseline. On the other primary outcome measures, TARGET and PCT were associated with equivalent change. Effect sizes were medium for TARGET or PCT versus WL, except for the TMQ (effects  $\leq .25$

for both treatments). The results were unchanged with number of therapy sessions as a covariate and when analyses were conducted including only participants who attended at least half of the therapy sessions (results not presented but available from first author).

At posttreatment, 76% of WL participants and 45% in each active treatment condition met criteria for full PTSD (22/48 in TARGET, 24/53 in PCT, respectively; see Fig. 2), and 24%, 34%, and 40% met criteria for partial PTSD, in the TARGET, PCT, and WL conditions, respectively. The group differences overall were statistically significant,  $\chi^2(df=4) = 15.5$ ,  $N = 146$ ,  $p = .004$ . No WL participant met criteria for full remission (i.e., no partial or full PTSD), versus 15% in PCT (8/53) and 21% in TARGET (10/48), respectively. TARGET and PCT did not differ,  $\chi^2(df=1) = 0.6$ ,  $N = 101$ ,  $p = .45$ , and each treatment group was significantly more likely to fully remit than WL,  $\chi^2(df=1) = 10.5$ ,  $7.4$ ,  $N = 93$ ,  $98$ ,  $p < .001$  and  $= .007$ , respectively. TARGET participants were more likely to achieve clinically significant change (17%, 8/48) than WL (0%),  $\chi^2(df=1) = 8.2$ ,  $N = 93$ ,

Table 3  
Stability of Change Following Therapy by Treatment (TARGET, PCT) Group, for Participants With Complete Data (N=67)

Measure	Post-Treatment M(SD)		3-Month Follow-up M(SD)		6-Month Follow-up M(SD)	
	TARGET	PCT	TARGET	PCT	TARGET	PCT
<b>PTSD Measures</b>						
CAPS	38.7 (24.6)	39.7 (21.4)	37.3 (25.8)	37.5 (22.5)	36.0 (26.2)	31.9 (19.9)
PTCI-Self	36.1 (19.5)	45.9 (23.1)	42.8 (27.6)	48.1 (21.9)	32.1 (10.6)	39.7 (20.0)
PTCI-World	26.3 (11.1)	26.8 (11.0)	26.5 (12.2)	27.8 (11.4)	24.3 (10.9)	25.1 (11.4)
TMQ-Intrusion	2.7 <sup>a</sup> (4.3)	4.2 <sup>b</sup> (5.3)	3.8 (4.8)	4.8 (5.2)	3.0 (5.0)	4.0 (5.4)
IPSI	18.9 (11.2)	22.6 (11.6)	20.4 (14.0)	24.2 (13.6)	15.1 (7.1)	19.5 (10.4)
<b>Affect and Interpersonal Regulation Measures</b>						
NMR	120.8 <sup>a</sup> (15.1)	109.0 <sup>b</sup> (18.3)	115.4 (17.3)	112.5 (16.3)	120.8 (16.2)	116.1 (15.8)
COPE-Humor	5.2 (1.9)	4.2 (1.6)	4.5 (1.6)	4.5 (1.8)	4.6 (2.1)	4.2 (1.9)
COPE-Active	6.7 (1.3)	5.9 (1.7)	6.3 (1.6)	5.7 (1.7)	6.8 (1.3)	6.3 (1.8)
COPE-Blame	3.8 (1.7)	3.8 (1.6)	4.0 (1.6)	3.6 (1.4)	3.5 (1.4)	3.7 (1.6)
IIP-Involvement	3.4 (3.3)	4.1 (4.2)	4.3 (4.2)	4.0 (3.7)	2.6 <sup>a</sup> (3.1)	4.9 <sup>b</sup> (4.4)
<b>Associated Symptoms and Parenting Measures</b>						
STAI	31.4 (11.3)	37.4 (13.3)	36.8 (14.5)	35.5 (13.4)	31.1 (9.6)	32.7 (11.2)
BDI	11.6 (10.9)	11.9 (10.1)	12.8 (12.6)	10.9 (9.5)	7.6 (9.0)	9.0 (9.0)
TRGI-Distress	1.9 (1.0)	1.8 (0.8)	1.7 (1.1)	1.9 (0.9)	1.6 (0.9)	1.6 (0.7)
PSI-Distress	28.7 (8.9)	29.3 (10.1)	29.0 (9.8)	31.7 (10.0)	26.9 (6.6)	26.4 (8.7)
RSQ-Secure	15.2 (3.9)	14.2 (2.9)	15.1 (3.5)	14.5 (2.9)	15.7 (3.6)	14.9 (3.0)

Note. Means with different superscripts differ  $p < .05$ . CAPS=Clinician Administered PTSD Scale; PTCI=Posttraumatic Cognitions Inventory, Self and World subscales; TMQ-Intrusion=Trauma Memory Questionnaire, Intrusion subscale; IPSI=Interpretations of PTSD Symptoms; NMR=Generalized Expectancies for Negative Mood Regulation; COPE=Coping Orientation to Problems Experienced, Humor, Active (problem solving), Blame (self-blame) subscales; IIP Involvement=Inventory of Interpersonal Problems, Involvement subscale; STAI=State Trait Anxiety Inventory, State Form; BDI=Beck Depression Inventory; TRGI-Distress=Trauma Related Guilt Inventory, Distress subscale; PSI-Distress=Parenting Stress Inventory, Distress subscale; RSQ-Secure=Relationship Style Questionnaire, Secure Attachment subscale.

$p = .004$ , and marginally more than PCT (3/53, 5.5%),  $\chi^2(df=1) = 3.2$ ,  $N = 101$ ,  $p = .07$ .

At the 3-month follow-up assessment, full remission was achieved by 19% of the PCT group (10/53) and 29% of TARGET participants (14/48), whereas partial remission was achieved by 55% in PCT (29/53) and 66% in TARGET (31/48). Clinically significant change at the 3-month follow-up was found for 11% in PCT (6/53) and 21% in TARGET (10/48). These between-group differences were not

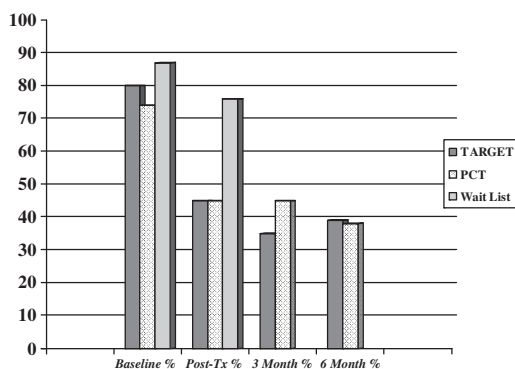


FIGURE 2 Percent of participants meeting criteria for full PTSD at each assessment time point by experimental condition.

statistically significant,  $\chi^2(df=1) < 1.6$ ,  $N = 101$ ,  $p > .20$ .

At the 6-month follow-up assessment, one in three (33%) TARGET participants (16/48) and one in four (24.5%) PCT participants (13/53) were in full remission (i.e., no full or partial PTSD). Approximately 60% of participants in each treatment condition were in partial remission (i.e., no full PTSD), 29/48 in TARGET and 32/53 in PCT. At the 6-month follow-up, clinically significant change was achieved by 22.5% in TARGET (11/48) and 15% in PCT (8/53). These between-group differences were not statistically significant,  $\chi^2(df=1) < 1.0$ ,  $N = 102$ ,  $p > .30$ .

With regard to the maintenance of gains or further improvement across the follow-up period, one difference (favoring TARGET) was found. The Group  $\times$  Time interaction was significant for TMQ-Intrusion,  $F(2, 65) = 4.25$ ,  $p = .018$ ; TARGET showed continued improvement and PCT remained stable. Further improvement was found for both therapies at the follow-up assessments on the PTCI-Self,  $F(2, 65) = 7.02$ ,  $p = .002$ , and the IPSI,  $F(2, 65) = 6.11$ ,  $p = .004$ .

Overall, the results modestly support the first hypothesis. TARGET was associated with larger



changes than PCT on all five PTSD-related measures and statistically significantly on two (TMQ and PTCI-Self). TARGET also was associated with higher rates of full remission from PTSD and clinically significant change than PCT at all assessments. The groups were not statistically significantly different, but there was a trend toward a higher likelihood of clinically significant change for TARGET (vs. PCT) at posttest. Although both therapies maintained or improved upon the reductions in PTSD-related problems achieved at posttest over the follow-up period, on the measure of trauma memory intrusiveness (the TMQ) TARGET showed greater improvement.

#### *Secondary Outcomes: Affect Regulation, Coping, and Interpersonal Functioning*

At posttest, small effects (.17–.31) favored TARGET (vs. PCT) on change on the NMR, COPE-Humor, and COPE-Active measures (see Table 2). A small effect (.15) favored PCT (vs. TARGET) on COPE-Self-blame. Effect sizes were medium for TARGET or PCT versus WL (approaching large for TARGET on the NMR, and for PCT on COPE-Self-blame) except for the IIP (effects  $\leq .15$  for both treatments). Both therapies maintained gains achieved at posttest in affect regulation and coping, and further improvement was found for both across the follow-up assessments on COPE-Active,  $F(2, 64)=3.75$ ,  $p=.029$ . One difference was found (favoring TARGET): the Group  $\times$  Time interaction was significant for the IIP-Involvement score. On this score, TARGET continued to improve and PCT worsened,  $F(2, 65)=3.85$ ,  $p=.026$ .

Thus, Hypothesis 2 was partially supported, with TARGET showing somewhat greater improvement on affect regulation and positive coping than PCT, although these differences were not statistically significant. However, contrary to Hypothesis 2, PCT showed somewhat greater reductions than TARGET in self-blame coping. In addition, contrary to Hypothesis 2, there was a statistically significant difference at the 6-month follow-up assessment favoring TARGET over PCT on the IIP (i.e., problems with interpersonal involvement).

#### *Tertiary Outcomes: Associated Symptoms and Parenting Variables*

At posttest, small effects ( $d = .11$  and  $.33$ ) favored TARGET (vs. PCT) on the STAI and RSQ (see Table 2). Small effects ( $d = .18$ – $.25$ ) favored PCT (vs. TARGET) on the BDI, TRGI, and PSI. Medium effect sizes at posttest favored TARGET or PCT versus WL (see Table 2) except on the PSI ( $d \leq .25$  for both treatments) and the STAI and RSQ for

PCT (effect sizes  $d \leq .27$ ). Further improvement was found for both therapies at the follow-up assessments (see Table 3) on the BDI,  $F(2, 65)=3.16$ ,  $p=.049$ ; TRGI,  $F(2, 65)=7.02$ ,  $p=.002$ ; and PSI,  $F(2, 65)=7.03$ ,  $p=.002$ . Hypothesis 3 was partially supported, with TARGET showing somewhat (but not statistically significant) greater reductions in anxiety and gains in relational security than PCT. However, neither therapy showed evidence of reducing parenting distress, and contrary to Hypothesis 3, PCT showed greater (again, not statistically significant) reductions than TARGET in guilt and depressive symptoms.

#### DOSE OF THERAPY AS A MODERATOR OF TREATMENT OUTCOME

Approximately half of study participants assigned to an active treatment received fewer than half the planned number of therapy sessions: 40% in TARGET (including 7% who received no sessions), and 51% in PCT (including 17% who received no sessions). (See Fig. 1.) Results of partial correlations controlling for baseline CAPS score showed that the number of TARGET or PCT sessions attended was unrelated to change on CAPS total score at posttherapy and at the 3- and 6-month follow-ups, respectively,  $r_p = .11$ ,  $.12$ , and  $.15$  for TARGET, and  $.10$ ,  $-.08$ , and  $-.29$ , respectively, for PCT ( $p > .05$ ). Mixed-model regression analyses of change over time were repeated including only TARGET and PCT participants who completed at least half of the treatment sessions, with no change in the results (analyses not reported but available from the first author).

#### ADVERSE EFFECTS

Drop-out rates for TARGET and PCT, using a stringent criterion of attending fewer than half of the 12 treatment sessions and not completing a posttherapy or follow-up assessment, were consistent with those reported in prior studies of CBT for adult PTSD: 25% of participants randomized to TARGET (12/48) and 26% randomized to PCT (14/53). Other participants (15% in TARGET, 20% in PCT) who attended fewer than half of the treatment sessions but who continued in the study's posttest or follow-up assessment interview(s) were not considered dropouts. A higher percent of participants randomized to TARGET (61%, 29/48) than PCT (49%, 26/53) attended at least half of the therapy sessions. However, the difference was not statistically significant and appeared largely due to more PCT participants ( $N=9$ ) never starting therapy (TARGET,  $N=4$ ). A comparable percentage of participants who

attended at least one session of therapy also completed at least half of the therapy in TARGET (67%) and PCT (64%).

No adverse outcomes related to either treatment or any of the study assessments occurred. One participant receiving PCT (2%) and three who received TARGET (6%) showed evidence of symptom worsening at posttest, using a CAPS total severity score at least 7 points higher than at baseline as the criterion (Cloitre et al., 2010). However, by the 6-month follow-up all of these participants had improved from baseline, suggesting the worsening was transient. From posttreatment to the 3-month follow-up assessment, three PCT participants (6%) and four TARGET participants (8%) reported worsened PTSD symptoms; all but two (in TARGET) were improved by the 6-month follow-up assessment. From posttreatment to the 6-month follow-up assessment, no PCT participants and three TARGET participants (6%) reported worsened PTSD symptoms.

### Discussion

Study results show that TARGET, a relatively brief (12 weekly sessions) one-to-one CBT focused on enhancing affect regulation without trauma memory processing, was efficacious in reducing PTSD and enhancing affect regulation with a sample of predominantly low-income ethnoracial minority mothers of young children. The findings replicate evidence of efficacy for TARGET from prior studies that were done with a different population (i.e., adolescent girls with full or partial PTSD; Ford et al., *in press*; men as well as women in substance abuse treatment; Frisman et al., 2008) and in a different format (i.e., group therapy; Frisman et al., 2008). Effect sizes of change (vs. WL) achieved by TARGET on the PTSD-related, affect regulation and coping, and internalizing symptom outcome measures were similar to those reported by a meta-analysis of psychotherapy studies for adult survivors of childhood sexual abuse (i.e., generally .40–.75; Taylor & Harvey, 2010). The changes and sustained benefits associated with TARGET were also generally comparable in degree and breadth to those reported in studies of CBT exposure or CPT for PTSD with women (Cloitre et al., 2010; Foa & Jaycox, 1999; McDonagh-Coyle et al., 2005; Resick et al., 2002; Schnurr et al., 2007). The TARGET drop-out rate (25%) was comparable to rates reported in those studies, and lower than that reported (39–41%) for prolonged exposure alone by McDonagh-Coyle et al. (2005) and with a modified prolonged exposure protocol by Cloitre et al. (2010). As seen with PE in the latter two studies, TARGET

completers tended to maintain or increase the gains achieved in therapy over the follow-up period. No serious adverse events were reported by TARGET (or PCT) participants, and worsening of symptoms was rare and apparently transient. The findings generally support the efficacy of TARGET for low-income mothers (predominantly of ethnoracial minority background) with PTSD. The discussion considers how the specific findings relate to the study hypotheses, the methodological limitations and precautions needed in interpreting those findings, and implications for future clinical research and practice.

### EFFICACY OF TARGET IN REDUCING PTSD (HYPOTHESIS 1)

Study findings generally support Hypothesis 1, attesting to TARGET's efficacy compared both to a robust alternative therapy (PCT) and WL. Although TARGET had only a small effect size compared to PCT or WL in reducing trauma memory intrusiveness (i.e., TMQ), when covariates were included in the mixed-model regression analyses, at posttest TARGET recipients reported lower levels of trauma memory intrusiveness than PCT or WL participants. TARGET recipients also reported more improvement in trauma-related beliefs about themselves than PCT or WL participants. However, TARGET was not superior to PCT in reducing PTSD symptom severity (on the CAPS and IPSI) or trauma-related beliefs about the world—although both TARGET and PCT achieved substantial improvements compared to WL on those PTSD-related measures. These findings suggest that TARGET may address trauma-related symptoms by increasing the individual's sense of personal control, both specifically in relation to reducing the intrusiveness of trauma memories and in broader appraisals of their self-efficacy (vs. viewing themselves as powerless and ineffective). Some TARGET participants correspondingly reported substantially less severe PTSD symptoms. However, for those who still experienced significant PTSD symptoms on the CAPS or IPSI, trauma memory processing CBT may be needed in order to enable them to not only feel more in control of troubling memories but also to actually be able to overcome PTSD's pattern of anxious avoidance of trauma reminders.

### EFFICACY OF TARGET IN ENHANCING AFFECT AND INTERPERSONAL REGULATION (HYPOTHESIS 2)

Hypothesis 2 also received support from results suggesting TARGET's superiority to PCT and WL in enhancing emotion regulation (the NMR), and

positive coping (the COPE active and humor subscales). The findings suggest that TARGET may achieve its focal goal of enhancing affect regulation, both through improved regulation of or recovery from distressing emotions and via enhancing access to positive emotions (e.g., determination, humor). Unexpectedly, TARGET was associated with greater self-reported gains in interpersonal involvement than PCT over the follow-up period. Neither therapy had strong initial effects on interpersonal problems, consistent with findings from a meta-analysis of therapy outcome studies with adult survivors of childhood sexual abuse in which interpersonal functioning was the therapeutic target that was least well achieved across a variety of therapy modalities (Taylor & Harvey, 2010). In addition, TARGET was associated with greater gains than PCT in improving relational security. Thus, enhancing affect regulation may contribute to CBT's ability to improve interpersonal outcomes, even without specifically teaching interpersonal skills, with adults with victimization histories (Cloitre, Stovall-McClough, Zorbach, & Charuvastra, 2008; Tull, Barrett, McMillan, & Roemer, 2007).

#### EFFICACY OF TARGET FOR ASSOCIATED SYMPTOMS AND PARENTING (HYPOTHESIS 3)

Another finding contrary to Hypothesis 2 was that self-blame was more effectively reduced by PCT than TARGET. This finding is discussed in relation to Hypothesis 3 because study results also showed PCT to be more efficacious than TARGET in reducing guilt and depressive symptoms. TARGET did appear to reduce self-blame, guilt, and depressive symptoms (vs. WL), but not as much as in the social problem-solving intervention. Thus, TARGET may enable participants to increase their awareness of and ability to tolerate and modulate negative emotions rather than directly diminishing emotional distress. Alternately, PCT may enable participants to feel, or be, more effective in solving relational problems, and this may provide an alternative or complementary way to resolve persistent trauma-related distress instead of, or in addition to, enhanced affect regulation. PCT may be particularly helpful with depressive symptoms because problem-solving therapy has a strong evidence base for treating moderate to severe depression (Nezu, 1987). Nevertheless, by the follow-up period, TARGET was associated with equivalent and possibly greater sustained reductions in depressive symptoms than PCT. Use of the affect regulation skills taught in TARGET, when sustained over time, may help women not only reduce PTSD but also the affect dysregulation

associated with depression (e.g., anaclitic/sociotropic, introjective/autonomous, and self-criticism problems; Shahar, Soffer, & Gilboa-Shechtman, 2008).

Hypothesis 3 also was not supported and appears to require revision regarding parenting, because neither TARGET nor PCT achieved statistically or clinically meaningful change in self-reported parenting stress. Enabling low-income mothers with PTSD who are parenting a young child to reduce parenting stress may require interventions designed to help them with parenting and the dyadic relationship (Lieberman et al., 2009) or with social resources (Schumm et al., 2006), in addition to or instead of PTSD treatment. Enhanced parenting skills, dyadic support, and social support are particularly important for low-income mothers with PTSD because, in addition to reducing their PTSD symptoms, both they and society stand to benefit if these women are better able to protect their young children from developing secondary stress reactivity and vulnerability to subsequent PTSD or related problems. Therefore, other key indices of mothers' parenting capacities, such as parenting practices, emotional availability and responsiveness, direct facilitation of the child's cognitive behavioral development, and modeling of emotion regulation (Lieberman et al., 2009), as well as measures of their child's functioning, may need to be assessed in order to elucidate the potential benefits of TARGET for parenting.

#### METHODOLOGICAL LIMITATIONS

A fundamental limitation was that the study was underpowered to detect the expectable (Benish et al., 2008; Cloitre et al., 2010; Schnurr et al., 2007) small differences between two active therapies. However, the small effect sizes favoring TARGET over PCT were similar to those found in prior studies for PE with the same (McDonagh-Coyle et al., 2005) or a similar (Schnurr et al., 2007) version of PCT. The consistent pattern of superiority of TARGET over PCT across several measures and domains is similar to that of PE (vs. PCT) in those studies, suggesting that TARGET warrants the next step in efficacy testing, that is, a direct comparison to PE or another trauma memory processing CBT, in a large well-powered randomized clinical trial.

Other methodological limitations suggest that the current study findings should be considered preliminary. A failure to ensure that interviewers were blinded to participant assignments at posttest and follow-up assessments made it impossible to determine whether the superiority of PCT and TARGET versus WL on the one structured

interview outcome measure, the CAPS, was free from the effects of interviewer expectancies. This artifact may partially account for the apparent superiority of TARGET over PCT on PTSD remission and clinically significant change, although interviewers were not given detailed information about the therapies and were consistently told in training and supervision that the two therapies were of equal potential efficacy. Moreover, results from self-administered questionnaires (e.g., PTCI-Self, TMQ) showed evidence of greater change in PTSD-related domains for TARGET than PCT. Replication with interviewers fully blinded to participant assignments is needed to confirm the study's findings regarding change in PTSD.

Other methodological limitations included an absence of measures of change in substance use symptoms or of collateral treatment received by participants, as well as a relatively short follow-up period, a good deal of attrition at posttest and follow-up, and the high rate of nonattendance of therapy sessions. Given the prevalence of past substance abuse in this population of victimized low-income women, and TARGET's past development and testing in substance abuse treatment (Ford & Russo, 2006; Frisman et al., 2008), the effects of TARGET on substance use problems should be examined in future studies. Although women from this population often are underserved due to socioeconomic and cultural factors, some participants may have received services for themselves or their child and family that may have contributed to their study outcomes, and this should be systematically assessed in future studies. Although the 6-month follow-up period is a short time in the lives of mothers facing multiple adversities, it is as long a follow-up interval as reported by all but a few PTSD treatment studies, and longer than in more than 75% of studies of therapy for adult survivors of child abuse (Taylor & Harvey, 2010). The results demonstrating sustained gains over a 6-month period provide at least initial evidence of durable benefits.

Regarding missing data due to attrition, there was no systematic pattern of missing data that could be detected. The dose of treatment received by participants on average (approximately 60% of the planned 12 sessions) was lower than that typically reported in clinical trial studies for PTSD (e.g., 75% attendance on average in the study by Cloitre et al., 2010). This may have led to a diminished ability to demonstrate the efficacy of either treatment, but the two therapies did not differ on attendance levels, and number of sessions attended was not correlated with change on the primary PTSD measure for either

TARGET or PCT at any posttest or follow-up assessment. Nor did participants who received a more optimal dose of therapy ( $\geq 50\%$  sessions) show any differences in outcomes compared to when the full sample's outcomes were analyzed. Thus, practical approaches to enhancing therapy attendance clearly are needed with this population, and the relatively poor level of attendance may have led to a low estimate of treatment efficacy, but the high levels of nonattendance do not appear to have fundamentally altered study outcomes.

Lastly, as noted above, inclusion of women with partial as well as full PTSD may have reduced the study's statistical power to detect change and between-group effects, due to lesser levels of symptom severity associated with partial versus full PTSD. However, partial PTSD has been shown to be associated with substantial psychosocial impairment (Stein, Walker, Hazen, & Forde, 1997), and therefore warrants consideration as a target for therapeutic intervention. It is also possible that TARGET's apparent efficacy was due in part to the inclusion of women with less severe (i.e., partial) PTSD. However, this seems unlikely because the mean baseline group CAPS severity scores in the present study (i.e., 62–68) were comparable to those generally reported in studies of CBT for adults with PTSD (e.g., 63–66 in Cloitre et al., 2010).

#### IMPLICATIONS FOR CLINICAL RESEARCH AND PRACTICE

Affect regulation appears to provide a promising focus for continued development of CBT for PTSD. In concert with the results of the recent study by Cloitre et al. (2010), the present study's findings suggest that therapy addressing affect regulation may prepare women with victimization-related PTSD to both complete (i.e., low drop-out rates, 15–25%) and benefit from (i.e., 50% and 67% reductions in PTSD severity at posttest and 6-month follow-up, respectively) CBT. The present study adds the possibility for researchers and clinicians that an affect regulation-based CBT could serve as an alternative option for PTSD treatment as well as a strategy to augment trauma memory processing CBT. Cloitre and colleagues found that a briefer (eight-session) CBT that combined affect and interpersonal regulation skills greatly enhanced retention and efficacy for exposure therapy with women with childhood abuse-related PTSD. The STAIR intervention was also associated with lesser but still clinically significant improvements without exposure therapy. TARGET's remission and clinically significant improvement rates, which were calculated on an



intent-to-treat basis (i.e., conservatively coding missing data as not remitted or changed), were lower at posttest (17–21%) but comparable or higher at the 3-month (21–29%) and 6-month (22.5–33%) follow-up assessments than those reported by Cloitre and colleagues for full remission in the STAIR/PE group or STAIR/Support groups (i.e., 24–27% at posttest; 13–24% at the 6-month follow-up)—and substantially higher than in Cloitre et al.'s Support/PE group at posttest and 6-month follow-up (i.e., 6% and 0%, respectively). Thus, TARGET recipients were somewhat more likely to achieve sustained full remission from PTSD and clinically significant change over the follow-up period than was found for the STAIR recipients who did not receive PE—and TARGET was equally or slightly more successful in those respects than STAIR combined with PE. These rates compare favorably to those reported in other studies of PE, CPT, and EMDR for women with PTSD (Cahill et al., 2009).

While preliminary, study findings suggest that a therapy such as TARGET, which is designed exclusively to enhance affect regulation skills, may be efficacious in remediation of victimization-related PTSD. Interestingly, the FREEDOM skill set taught in TARGET incorporates many of the strategies used in trauma memory processing in PE (Cook et al., 2004; Foa et al., 2005), CPT (Resick et al., 2002), and EMDR (Seidler & Wagner, 2006)—but TARGET differs from those modalities in applying the skills to processing of *traumatic stress reactions in clients' current day-to-day lives* rather than trauma memories. Of note, TARGET recipients were particularly likely to report trauma memories to be less intrusive over the follow-up period despite not having formally processed those memories. Thus, learning a structured method for processing emotionally distressing experiences that are trauma related may generalize to a greater willingness and ability to process, rather than avoid, trauma memories—and perhaps to view trauma memories as less intrusive, inescapable, and overwhelming. This hypothesis warrants systematic empirical testing that is beyond the scope of the present study.

It is also possible that a single consistent therapy modality may be more readily learned, adopted, and deployed with fidelity and competence by practitioners in the field than therapies such as STAIR or Seeking Safety that offer complex combinations of affect and interpersonal regulation skills. PE has eliminated stress inoculation and cognitive restructuring components that were part of earlier protocols in order to achieve a maximal dose of exposure therapy (Foa, Hembree, & Rothbaum, 2007). Although CPT and EMDR use multiple therapeutic

tactics, they tend to have a singular focus. CPT emphasizes constructing and refining trauma narratives with detailed attention to associated perceptions and cognitions. EMDR emphasizes desensitization of trauma memories via reexposure with a distress-reducing attentional focus. TARGET also has a singular focus, albeit on processing recent reexperiencing episodes rather than trauma memories.

TARGET thus offers clinicians who are concerned about clients' adverse reactions to trauma memory work a potentially viable initial alternative to trauma memory processing therapy. As clients show gains in their affect regulation capacities, clinicians may be more likely to consider providing trauma memory processing therapy even if they were initially reluctant to do so. Thus, the availability of an affect regulation therapy for PTSD such as TARGET can broaden the repertoire of real-world clinicians and enable them to better deploy a full range of evidence-based treatments (including those that involve trauma memory narrative work) with their patients (Courtois, Ford, & Cloitre, 2009).

In sum, study results suggest that an approach to CBT designed to enhance affect regulation without trauma memory processing may be efficacious with victimized mothers who often face severe socioeconomic challenges (Gill, Szanton, & Page, 2005; Schumm et al., 2006) including homelessness (approximately 33% of the study sample) and behavioral health (Harris & FalLOT, 2001) problems including substance abuse (approximately 40% of the study sample). The promising findings for TARGET are particularly relevant because women with these severe resource deficits often are underrepresented in studies testing CBT for PTSD, and underserved by public mental health services. Their children may also be at risk for PTSD, hence the importance of intervening early while the children are still in the formative period of early childhood, as was done in the present study. Intervening before girls with PTSD become mothers, as in a recent study (Ford et al., in press) of TARGET with victimized high-risk (delinquent) girls, offers yet another avenue to enhance the helping professions' ability to prevent the intergenerational transmission of PTSD.

Although the strong evidence base for PE, CPT, and EMDR justifies their use as the first-line treatments for PTSD (Cahill et al., 2009; Seidler & Wagner, 2006), TARGET may provide a viable alternative for low-income women with victimization-related PTSD. Direct comparison of TARGET to these trauma memory processing CBTs in randomized clinical trials with this and other populations suffering from victimization-

related PTSD will be necessary, however, before clinicians can consider TARGET to be a potential first-line treatment option. Further research is also needed to replicate these findings with this and other high-risk or highly impaired traumatized populations (Ford, Courtois, Van der Hart, Nijenhuis, & Steele, 2005), as well as to determine whether TARGET can serve as an augmentation to trauma memory processing CBTs similar to the incremental utility demonstrated by the STAIR intervention (Cloitre et al., 2010).

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