

Posttraumatic Stress Disorder: Psychological Factors and Psychosocial Interventions

Elizabeth A. Hembree, Ph.D., and Edna B. Foa, Ph.D.

© In this article, we propose that successful processing of traumatic events involves emotional engagement with the trauma memory, organization of the trauma narrative, and correction of dysfunctional cognitions that often follow trauma. We further propose that the success of psychosocial treatments of posttraumatic stress disorder hinges on the ability of the treatments to address impairments in these processes. We focus our presentation of psychosocial interventions on cognitive-behavioral treatments (CBT), since this approach had gained the most empirical support to date, and describe the results of controlled trials that compare the relative efficacy of several CBT interventions.

(*J Clin Psychiatry* 2000;61[suppl 7]:33–39)

In this article, we describe several psychosocial treatments for posttraumatic stress disorder (PTSD) that have gained empirical support and are recommended as first-line interventions by expert consensus. Our focus is on cognitive-behavioral therapy, as this is the treatment approach that has gained the most empirical support to date. We begin with a discussion of factors that may hinder mechanisms of natural recovery and thus maintain post-trauma sequelae, and we argue that psychosocial treatments of PTSD will be effective to the extent that they address these factors. We then describe the results of controlled studies that illustrate the relative efficacy of the various cognitive-behavioral treatment programs.

A CONCEPTUALIZATION OF PTSD

Many victims recover from traumatic experiences without developing significant long-term sequelae. This raises the question of what factors determine whether individuals will process a trauma successfully and recover or whether they will fail to do so and exhibit chronic PTSD. This question has clear implications for treatment because treatment may be successful to the extent that it targets the factors that hinder natural recovery. Three factors that we consider critical to the successful processing of traumatic events are emotional engagement with the trauma

memory, organization of the trauma narrative, and the correction of dysfunctional cognitions that are common immediately after a traumatic event.

Traditional as well as contemporary conceptualizations of the psychological effects of trauma and its treatment have postulated that special processing of the traumatic experience needs to take place for recovery to occur. Indeed, the idea that the treatment of traumatized individuals should include some form of exposure to the traumatic event has a long history in psychiatry. For example, Fenichel² advocated that in order to reduce anxiety and reactivity and promote mastery, the details of the trauma, including emotional reactions, should be reconstructed.

Although trauma theorists generally agree that emotional engagement is a necessary condition for adequate processing of a traumatic event, few studies have directly examined the emotional engagement hypothesis. Two retrospective studies^{3,4} and one prospective study⁵ provided some support for this hypothesis. Each of these studies found a high correlation between reported dissociation during or immediately after the trauma (i.e., absence of emotional engagement) and subsequent PTSD. In a prospective study of female assault victims, Gilboa and Foa reasoned that a high level of PTSD symptoms shortly after a severe trauma is a normal reaction and therefore can be viewed as reflecting appropriate emotional engagement (E.B.F., E. Gilboa, Ph.D., unpublished data, 1996). Conversely, a low level of PTSD symptoms shortly after the trauma could signal low engagement. Accordingly, Gilboa and Foa predicted that victims whose peak PTSD symptoms occurred shortly after the trauma will show better recovery later on than victims with delayed peak reaction. To test this hypothesis, they divided recent rape victims into 2 groups: those whose peak PTSD severity occurred within 2 weeks after the trauma and those with peak PTSD

From the Center for the Treatment and Study of Anxiety, University of Pennsylvania, Philadelphia.

Presented at the roundtable "Update on Posttraumatic Stress Disorder," which was held June 29–30, 1999, in Tysons Corner, Va., and supported by an unrestricted educational grant from Pfizer Inc.

Reprint requests to: Elizabeth A. Hembree, Ph.D., Department of Psychiatry, University of Pennsylvania School of Medicine, Philadelphia, PA 19104.

between 3 and 6 weeks posttrauma. Consistent with the prediction, at 14 weeks postassault, victims in the first group exhibited less severe depression and PTSD than did victims in the second group.

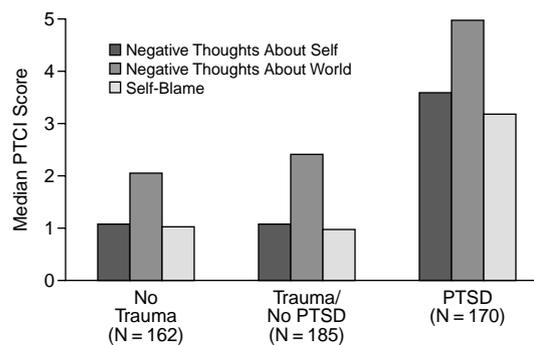
Jaycox et al.⁶ examined the influence of emotional engagement on treatment outcome in a group of 37 women with chronic PTSD. Using self-reported distress level during imaginal exposure to the memory of a traumatic event (i.e., imaginal reliving) as an index of emotional engagement, Jaycox et al. investigated changes in the women's distress levels during successive sessions of exposure therapy. They reported that patients who showed high initial distress and gradual habituation across sessions improved more in treatment than those who showed either moderate or high initial distress and no habituation. Thus, the results emerging from several areas of research are supportive of the emotional engagement hypothesis.

The second factor thought to influence recovery is the degree to which the victim is able to organize the trauma narrative. Our clinical observations of patients with chronic PTSD suggest that their trauma narratives are characterized by an abundance of speech fillers, repetitions, and incomplete sentences and that these narratives often reflect confusion and a discontinuity of time and space. On the basis of studies of trauma narratives during treatment, we have hypothesized that the natural process of recovery involves organizing and articulating the traumatic memory. Support for this hypothesis comes from the finding that the degree of trauma narrative articulation (as measured by reading level) shortly after the trauma predicted PTSD symptom severity 3 months later.⁷

The third factor that hinders the processing of a traumatic event is the presence of dysfunctional cognitions. Cognitive theories (e.g., Beck et al.,⁸ Clark⁹) hold that specific disorders are characterized by distinct cognitive distortions. For example, socially phobic individuals tend to interpret others' behavior in a way that is consistent with their negative self-evaluation (e.g., "He's not talking to me because he thinks I'm stupid"). Panic patients interpret physical sensations of autonomic arousal as signaling an impending heart attack or loss of control. Individuals with PTSD also evidence particular dysfunctional cognitions. Foa and Riggs¹⁰ suggested that 2 classes of erroneous cognitions characterize the chronic PTSD sufferer: (1) the perception of the world as extremely dangerous; and (2) the conception of oneself as extremely incompetent.

Why these 2 particular classes of erroneous cognitions? Foa et al.¹¹ suggested that a pathologic trauma memory, thought to underlie PTSD, is distinguished from a non-PTSD or "normal" trauma memory by a particularly large number of stimulus elements that are associated with the meaning "danger," which lead to the perception of the world as extremely dangerous. Foa et al.¹¹ further theorized that the pathologic trauma memory is highly accessible and is distinguished by particularly strong responses

Figure 1. Median PTCI Scale Scores by Participant Group^a



^aData from Foa and colleagues.¹³ Abbreviations: PTCI = Posttraumatic Cognitions Inventory, PTSD = posttraumatic stress disorder.

(e.g., PTSD symptoms of intrusive thoughts, flashbacks, arousal, hypervigilance, avoidance behavior). Foa and Jaycox¹² further proposed that PTSD is characterized by numerous erroneous associations between response elements and evaluation of oneself as incompetent (e.g., "How can I have flashbacks and nightmares for such a long time. . . . It means that I am weak and may lose my mind"). Thus, the following are common erroneous cognitions underlying PTSD: "The world is extremely dangerous," "People are untrustworthy," "No place is safe," "I am incompetent," "PTSD symptoms are a sign of weakness," and "PTSD symptoms are dangerous" (e.g., signal loss of control).

To examine PTSD-related cognitions, Foa and colleagues¹³ administered a self-report inventory to trauma victims with and without PTSD and compared their responses to those of nontraumatized individuals. The data are presented in Figure 1. As can be seen, there was no difference in the self-reported cognitions of those without history of trauma and those that had experienced trauma but did not have PTSD. In contrast, the group with current PTSD endorsed significantly more negative thoughts about themselves and the dangerousness of the world and about self-blame.

Thus, Foa and colleagues¹³ (cf. Foa and Rothbaum¹⁴) have posited that we will best understand the success of any psychosocial treatment if we construe it as promoting changes in 2 main erroneous cognitions underlying PTSD: that "the world is extremely dangerous" and "I am extremely incompetent." They argued that successful psychotherapy must access the trauma-related memories, feelings, and thoughts (i.e., promote emotional engagement with the trauma memory), help organize the traumatic memories, and facilitate the modification of dysfunctional cognitions. Similar conceptualizations have been offered by other experts (e.g., Resick and Schnicke,¹⁵ Ehlers and Clark¹⁶) and have fostered the development of cognitive therapy programs for PTSD.

COGNITIVE-BEHAVIORAL TREATMENT OF PTSD

PTSD was introduced into the DSM-III (*Diagnostic and Statistical Manual of Mental Disorders, Third Edition*¹⁷) as an anxiety disorder nearly 2 decades ago. Having thus captured the interest of cognitive behavior therapists, it was initially conceptualized as a complex phobia with extensive generalization that produces generalized anxiety disorder-like symptoms. Therefore, treatments that were effective with other anxiety disorders were applied to patients with PTSD. Two sets of cognitive-behavioral procedures have been commonly employed with this disorder: exposure procedures and anxiety management procedures. Exposure procedures encompass techniques designed to help patients confront feared situations, objects, memories, or images and include systematic desensitization and flooding. In contemporary exposure treatments, patients are typically encouraged to confront the feared and avoided memories and situations in 2 main ways: imaginal exposure, in which the patient is instructed to vividly imagine the traumatic event and describe it aloud, along with the thoughts and feelings that occurred during the event; and in vivo exposure, which consists of confrontation with external situations, places, or activities that will trigger trauma-related fear and anxiety.

The second set of treatments comprises anxiety management procedures. This form of cognitive-behavioral treatment includes a set of skills or tools for managing anxiety such as breathing and relaxation training, positive self-dialogue, cognitive restructuring, social skills training, thought stopping, and role playing. A commonly used and relatively well studied anxiety management treatment for PTSD is Meichenbaum's¹⁸ stress inoculation training (SIT), adapted by Veronen and Kilpatrick¹⁹ for use with rape victims.

In the early 1980s, various forms of exposure therapy were typically utilized with Vietnam veterans, and SIT was the treatment employed for female assault victims. More recent outcome studies for PTSD have examined the efficacy of cognitive therapy, combinations of exposure and cognitive therapy, and eye movement desensitization and reprocessing (EMDR).^{20,21} Recent studies have included patients with traumatic experiences such as motor vehicle accidents, natural disasters, and childhood sexual abuse, in addition to combat and assault survivors. The brief description of selected outcome studies that follows is not a comprehensive literature review; for a more thorough review of psychosocial treatments, see Foa and Meadows.²²

Keane and colleagues²³ conducted a study of the efficacy of exposure therapy with relaxation for Vietnam veterans with PTSD. They found that veterans treated with imaginal exposure (termed "implosive therapy") improved significantly more on measures of PTSD symptoms, depression, and anxiety compared with wait list control,

although effects were modest. The treatment did not produce improvement in numbing and social avoidance. Similarly, Cooper and Clum²⁴ reported that veterans with PTSD treated with imaginal exposure showed greater improvement in reducing reexperiencing symptoms, sleep disturbance, and anxiety than did comparable patients treated with "standard" treatment.

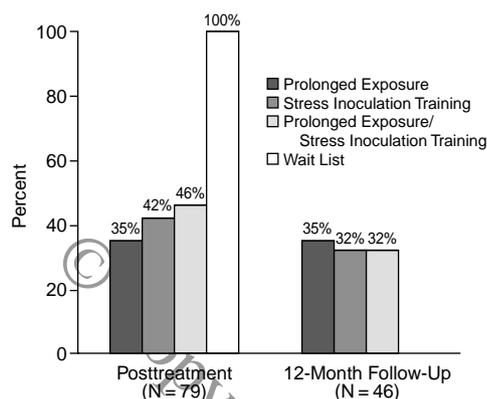
In the early 1980s, there was reluctance to use exposure therapy with rape victims, and the preferred therapy was SIT. Veronen and Kilpatrick¹⁹ and their colleagues studied the efficacy of the SIT program that they developed for rape survivors. The success of this program was later compared with assertion training, supportive counseling, and wait list control in a group of female rape victims with PTSD.²⁵ Results showed that all active treatments were more effective than wait list, but the effects were modest and were equivalent across active treatments.

In the last decade, many studies have compared exposure therapy to other cognitive-behavioral therapies. In our PTSD program at the Center for the Treatment and Study of Anxiety (Philadelphia, Pa.), we have developed manual-based exposure treatment and have compared its efficacy with that of SIT in 2 studies. In the first of these, Foa et al.²⁶ randomly assigned women with rape-related PTSD to exposure (imaginal and in vivo), SIT, supportive counseling, or wait list control. Participants in each of the active conditions received 9 sessions of treatment over 5 to 6 weeks. Results indicated that all treatments were superior to wait list; exposure and SIT were both quite effective and tended to be more effective than supportive counseling, although the differences were not always significant.

In the second study comparing exposure with SIT, Foa and colleagues²⁷ replicated and extended these findings. They randomly assigned 96 female assault victims to prolonged exposure alone (PE), SIT alone, the combination of exposure and SIT (PE/SIT), or wait list control. Exposure therapy consisted of education about common reactions to trauma, breathing training, prolonged and repeated exposure to the trauma memory (imaginal reliving), and repeated in vivo exposure to realistically safe situations the client avoided because of assault-related fear. SIT consisted of education about common reactions to trauma, breathing and relaxation training, thought stopping, guided self-dialogue, cognitive restructuring, covert modeling, and role playing. The combined treatment condition included the components of both programs. Participants again received 9 sessions of treatment over 5 to 6 weeks.

Results indicated that female rape and nonsexual assault victims treated with PE alone, SIT alone, or the PE/SIT combination showed much reduction in PTSD severity and depression, whereas the wait list control group did not show any improvement. Figure 2 shows the percentage of treatment completers in each group who retained a diagnosis of

Figure 2. Percent of Treatment Completers With PTSD Diagnosis^a



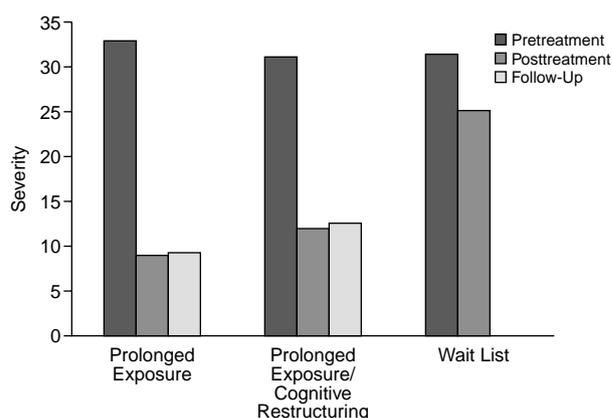
^aData from Foa and colleagues.²⁷

PTSD at posttreatment and at the 12-month follow-up. Immediately after treatment, only 35% of patients who had received prolonged exposure, 42% of those who had received SIT, and 46% of the combined group retained their PTSD diagnosis. In contrast, all subjects in the wait list condition still had PTSD at the end of the waiting period. At follow-up of 12 months, 35% of patients who had received exposure, 32% of patients who had received SIT, and 32% of the combined group had PTSD.

We also examined the percentage of patients completing each treatment that achieved good end state at posttreatment, which was defined for these purposes as 50% or greater improvement in PTSD severity and scores in the normal range on self-reported depression and anxiety measures. Immediately after treatment, 46% of patients receiving exposure therapy, 21% of patients receiving SIT, and 32% of patients receiving the combined therapy met this stringent criterion for responder status and generally retained their gains through the 12-month follow-up. Contrary to expectations, patients in the combined PE/SIT group did not show superior outcome compared with the single treatment approaches. Instead, exposure alone was superior to SIT and PE/SIT on several indices of treatment outcome.

At present, we are conducting a third study of treatment for female assault victims with chronic PTSD (E.B.F.; E.A.H.; N.C. Feeny, Ph.D., unpublished data, 2000). To date, 96 participants have been randomly assigned to exposure alone, exposure plus cognitive restructuring, or wait list control. The length of treatment has increased because sessions were conducted once a week for 9 weeks. In addition, treatment is extended to 12 sessions for patients who have not achieved at least 70% improvement in self-reported PTSD severity by session 8. Thus far, we have found that the efficacy of 9 or 12 sessions of exposure alone is again equivalent to the combination of exposure

Figure 3. PTSD Symptom Severity as Determined by Mean Scores on the PTSD Symptom Scale-Interview Version^a



^aE.B.F.; E.A.H.; N.C. Feeny, Ph.D., unpublished data, 2000. At posttreatment, prolonged exposure and prolonged exposure/cognitive restructuring < wait list ($p < .05$).

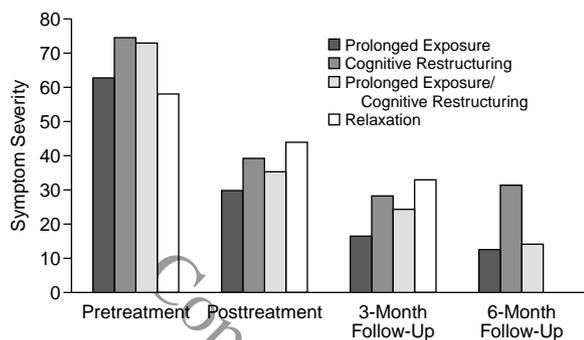
plus cognitive restructuring on measures of PTSD and depression (Figure 3). Interestingly, on the basis of results from the 96 women who have completed the program thus far, exposure alone has emerged as a more efficient program compared to exposure and cognitive restructuring: 57% of women in the exposure alone condition have been able to end therapy at 9 sessions by meeting the success criterion of at least 70% improvement in PTSD symptoms; in contrast, only 23% in the combined group met this criterion after 9 sessions.

Our findings that exposure therapy is particularly efficient are consistent with studies that have been conducted in other PTSD treatment centers. In St. Louis, Patricia Resick and colleagues have developed Cognitive Processing Therapy (CPT), a treatment specifically tailored to the concerns of rape victims. CPT is a 12-session program that employs cognitive therapy to correct maladaptive cognitions of rape victims with particular emphasis on the themes of safety, trust, power, esteem, and intimacy. This therapy also includes several sessions of exposure in the form of writing down the trauma narrative and rereading it to oneself and to the therapist. In one uncontrolled study, Resick and Schnicke¹⁵ reported that CPT conducted in a group setting showed good outcome compared with a naturally occurring wait list. Importantly, this study also demonstrated that cognitive-behavioral therapy can be conducted in group format with successful outcome.

In an ongoing study, Resick and colleagues²⁸ are comparing individually administered 12-session CPT with 9 sessions of imaginal and in vivo exposure. Preliminary data indicated that both treatments are highly and equally effective in ameliorating PTSD and that gains are maintained through a 9-month follow-up period.

In recent years, several researchers have extended PTSD treatment studies into populations other than female

Figure 4. PTSD Symptom Severity as Determined by Mean Total Frequency Scores on the Clinician Administered PTSD Scale (CAPS; total N = 87)^a



^aData from Marks et al.²⁹

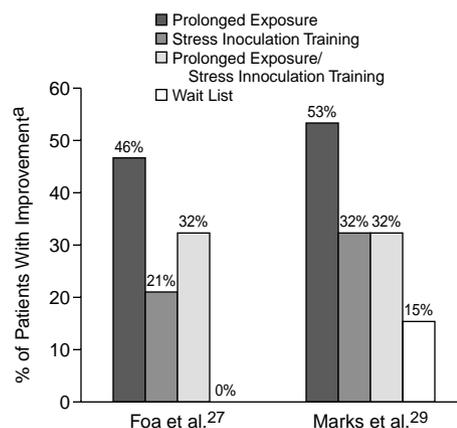
assault victims and male combat veterans, and these studies have produced similar findings. Marks and colleagues²⁹ randomly assigned 87 patients with chronic PTSD resulting from mixed trauma (e.g., motor vehicle accidents, criminal victimization) to 1 of 4 treatments: exposure, cognitive restructuring (CR), exposure and CR combined, and relaxation. The relaxation was perceived as an attention control condition. Treatment included 10 sessions conducted over 16 weeks. Results showed that exposure, CR, and exposure plus CR were equally effective, and that all 3 treatments were superior to relaxation. All 3 treatments produced highly significant improvement that was maintained throughout the follow-up period. Figure 4 depicts PTSD severity for each group as measured by the Clinician Administered PTSD Scale (CAPS).³⁰ As is suggested by the means, at the 6-month follow-up the groups that received exposure, either alone or in combination with CR, showed continued improvement, while the group that received cognitive restructuring alone had not improved as much.

Using the same end state indicators of 50% or greater reduction in PTSD severity and normal scores on depression and anxiety, we compared the percentage of responders in each treatment condition for the Foa et al.²⁷ and Marks et al.²⁹ studies. As shown in Figure 5, a similar pattern emerged from both studies: a greater percentage of patients in the exposure-only groups were responders compared with the other groups.

Tarrier et al.³¹ compared imaginal exposure (without in vivo exposure) to cognitive therapy in a sample of patients whose PTSD resulted from a variety of traumatic events. Exposure and cognitive therapies were found to be significantly and equally effective at ameliorating PTSD severity as measured by the CAPS. However, the effects of both treatments were more modest than those reported in previous studies, raising a question about the manner in which treatments and/or assessments were administered.

EMDR has become quite popular in some circles of trauma therapists. In EMDR, the therapist asks the patient

Figure 5. Percentage of Patients With Good End State Functioning at Posttreatment



^aImprovement defined as $\geq 50\%$ improvement in PTSD severity, Beck Depression Inventory score < 7 , and/or State-Trait Anxiety Inventory state scale score < 35 .

to generate images and thoughts about the trauma, evaluate their aversive qualities, and make alternative (i.e., healthier) appraisals or cognitions. The patient is then asked to hold on to the image of the trauma or the alternative cognition, depending on the stage of the session, while visually tracking the therapist's fingers as he or she moves them rapidly back and forth in front of the client's face. This procedure is repeated multiple times within a single session until the patient reports reduction in anxiety.

The efficacy of EMDR has been assessed in a number of studies, although most suffer from methodologic problems. Overall, these studies suggest that EMDR is more effective than no treatment (i.e., wait list control). In one of the most well-controlled studies of EMDR, Rothbaum³² randomly assigned 18 female rape victims with PTSD to either 4 sessions of EMDR or a wait list. At posttreatment, 90% of EMDR patients (compared with 12% of no-treatment patients) no longer met criteria for PTSD. Treatment gains as measured by both independent assessor and self-report were maintained at the 3-month follow-up. Wilson and colleagues³³ also found that 3 sessions of EMDR significantly reduced PTSD severity, anxiety, and general distress compared to wait list control. However, only about half of their 80 participants actually met criteria for PTSD diagnosis at pretreatment, and outcome was based only on self-report measures.

Deville and Spence³⁴ conducted the only study to date that compared EMDR with an empirically validated cognitive-behavioral treatment for PTSD: exposure combined with stress inoculation training (PE/SIT). Patients with PTSD resulting from a variety of traumas received 9 sessions of either EMDR or PE/SIT. Results showed that both treatments reduced self-reported PTSD symptoms at

Table 1. Meta-Analysis: Summary^a

Treatment/Condition	No. of Trials	% Dropout	Effect Size	
			Self-Report	Observer ^b
Psychotherapies	27	14.0	1.17	1.51
Medication	19	31.9	0.69	1.05
Controls	14	16.6	0.43	0.81

^aData from Van Etten and Taylor.³⁸

^bIndependent evaluator rating.

posttreatment, with the PE/SIT patients showing greater improvement than EMDR patients. The PE/SIT group maintained their gains from posttreatment to 3-month follow-up, whereas the EMDR group relapsed during the follow-up interval. In addition, EMDR and PE/SIT were rated as equally (“moderately”) distressing. The latter treatment was rated as more credible and was associated with higher expectancies for change.

Several studies of EMDR have been designed to evaluate the role of saccadic eye movements in the efficacy of this treatment since these movements occupy a central role in the EMDR theory. None of these studies found EMDR with and without eye movements to differ in treatment outcome. For example, Pitman and colleagues³⁵ treated 17 veterans with chronic PTSD with standard EMDR and with EMDR with eyes fixed (i.e., no eye movements during the otherwise standard procedure) in a crossover design. The mean number of sessions across both conditions was 10. On independent evaluation, EMDR with and without eye movements did not reduce PTSD severity. On self-report measures (in particular, the Impact of Events Scale³⁶), both treatments reduced trauma-related symptoms, with the eye-fixed group showing more reduction than the standard procedure group. A 5-year follow-up study³⁷ found that the small improvement in both groups disappeared. Consistent with the findings of other dismantling studies, Pitman et al.³⁵ concluded that the eye movements are not an active component of the treatment.

Taken together, the empirical studies on EMDR to date suggest that this treatment is probably effective for chronic PTSD, but the saccadic eye movements do not influence outcome. More well-controlled studies are needed. Shapiro²¹ and other proponents of EMDR have claimed that EMDR is a more effective, efficient, and well-tolerated treatment for PTSD than other treatments such as exposure therapy. The one comparative study conducted thus far³⁴ does not support these claims.

We conclude this brief review of selected outcome studies with results from a meta-analysis of PTSD treatment that included 61 studies on pharmacologic and psychosocial interventions.³⁸ Outcome measures included assessor-rated and self-reported measures of PTSD, anxiety, and depression. The analysis for medication trials showed large effect sizes for observer-rated (i.e., assessor-rated) and moderate effect sizes for self-rated PTSD symptom severity. Taking into account both sets of ratings, the

SSRIs show the greatest efficacy. Dropout rate for these medication trials averaged about 32%. The analysis of psychotherapy studies showed large effect sizes for both assessor and self ratings for cognitive-behavioral treatments and EMDR. Dropout rate for these psychotherapy trials averaged 14%. The analysis of control conditions revealed a strong placebo effect in all types of control conditions, especially for observer-rated symptoms. In a summary of the overall results of this meta-analysis (Table 1), psychosocial treatments showed the largest effect sizes, followed by medication trials, and then the control conditions.

A problem with Van Etten and Taylor's³⁸ study is that they did not consider the quality of the studies used in the meta-analysis. In response to this criticism, Tolin³⁹ conducted another meta-analysis of the psychotherapy outcome studies, but this time weighting the studies for methodological quality, based on the “gold standards” proposed by Foa and Meadows.²² Tolin³⁹ reported that when methodological quality was considered, exposure therapy studies (but not behavior therapy that did not include exposure) yielded larger mean weighted effect sizes than did EMDR studies at follow-up.

In summarizing the research on psychosocial treatments for chronic PTSD, studies have clearly demonstrated the efficacy of several cognitive-behavioral treatments in ameliorating PTSD symptoms, depression, and anxiety. The comparative studies have generally found equivalence in outcome among exposure, cognitive therapy, stress inoculation, and combinations of these interventions. Studies are mixed with regard to the efficacy of EMDR, but it appears that EMDR may be an effective treatment for PTSD. Results of dismantling studies suggest that the eye movements are superfluous.

Follow-up evaluations ranging from 3 to 12 months in the cognitive-behavioral studies indicate that treatment gains are maintained and, in some cases, even increased relative to their level at posttreatment. This is especially true for treatments that include exposure therapy, either alone or in combination. Treatment dropout rates for cognitive-behavioral therapy are relatively low, averaging 14% in the 27 studies analyzed by Van Etten and Taylor,³⁸ suggesting that the treatments are generally well tolerated.

While we have made much progress in developing effective psychosocial treatments for PTSD, many patients do not benefit sufficiently,⁴⁰ and others either refuse to enter treatment or drop out prematurely. The symptoms experienced by individuals with chronic PTSD sometimes interfere with their readiness to engage in treatment (especially the symptom of avoidance). Successful treatment requires a strong and collaborative relationship between patient and therapist.

Factors associated with treatment completion include younger age, being in a relationship, higher income, lower initial severity of PTSD, lower initial anxiety, depression, guilt, working full-time, and less severe trauma.⁴¹ It

seems, then, that the more functional patients complete treatment, and those who may need it most drop out. Factors associated with good outcome of exposure and cognitive therapy include perception of treatment as credible, high motivation, high and regular attendance, and absence of ongoing environmental stress.

Patients with severe PTSD often have problems trusting other people, including the therapist. Therefore the therapist should make special efforts to offer support and convey empathy and caring, including calling the patient between sessions. Flexibility in scheduling (and rescheduling) appointments is often required.

Disclosure of off-label usage: The authors have determined that, to the best of their knowledge, no investigational information about pharmaceutical agents has been presented in this article that is outside U.S. Food and Drug Administration-approved labeling.

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