ORIGINAL ARTICLE

# Randomized Trial of Trauma-Focused Group Therapy for Posttraumatic Stress Disorder

## *Results From a Department of Veterans Affairs Cooperative Study*

*Paula P. Schnurr, PhD; Matthew J. Friedman, MD, PhD; David W. Foy, PhD; M. Tracie Shea, PhD; Frank Y. Hsieh, PhD; Philip W. Lavori, PhD; Shirley M. Glynn, PhD; Melissa Wattenberg, PhD; Nancy C. Bernardy, PhD*

**Background:** Department of Veterans Affairs Cooperative Study 420 is a randomized clinical trial of 2 methods of group psychotherapy for treating posttraumatic stress disorder (PTSD) in male Vietnam veterans.

**Methods:** Vietnam veterans (360 men) were randomly assigned to receive trauma-focused group psychotherapy or a present-centered comparison treatment that avoided trauma focus. Treatment was provided weekly to groups of 6 members for 30 weeks, followed by 5 monthly booster sessions. Severity of PTSD was the primary outcome. Additional measures were other psychiatric symptoms, functional status, quality of life, physical health, and service utilization. Follow-up assessments were conducted at the end of treatment (7 months) and at the end of the booster sessions (12 months); 325 individuals participated in 1 or both assessments. Additional follow-up for PTSD severity was performed in a subset of participants at 18 and 24 months.

**Results:** Although posttreatment assessments of PTSD severity and other measures were significantly improved from baseline, intention-to-treat analyses found no overall differences between therapy groups on any outcome. Analyses of data from participants who received an adequate dose of treatment suggested that trauma-focused group therapy reduced avoidance and numbing and, possibly, PTSD symptoms. Dropout from treatment was higher in trauma-focused group treatment. Average improvement was modest in both treatments, although approximately 40% of participants showed clinically significant change.

**Conclusions:** This study did not find a treatment effect for trauma-focused group therapy. The difference between the effectiveness and adequate dose findings suggests the possible value of methods to enhance the delivery of cognitive-behavioral treatments in clinical practice settings.

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In 1990, the National Vietnam Veterans Readjustment Study estimated that over 960 000 men (30.6%) who served in the Vietnam War had experienced posttraumatic stress disorder (PTSD) at some point since the war and that 15.2% currently had PTSD.[1] Now, more than 10 years later, PTSD continues to trouble many Vietnam veterans. A number of these veterans receive treatment from the Department of Veterans Affairs (VA) health care system, which spends substantial resources on PTSD care and disability compensation.[2] Users of the VA tend to have chronic PTSD and comorbid psychiatric problems such as depression and substance abuse, as well as significant functional impairment.[1,2]

Finding an effective method to treat PTSD in Vietnam veterans is of relevance to the VA, but any method that is useful for treating chronic PTSD is of much broader relevance. Approximately one third of individuals in the general population who have experienced PTSD develop a chronic form.[3]

Recently published practice guidelines for PTSD treatment indicate the greatest support for cognitive-behavioral approaches.[4] A particularly effective cognitive-behavioral technique is "exposure," in which a patient is guided through a vivid remembering of a traumatic event (or a feared stimulus) repeatedly until the patient's emotional response decreases through habituation. Studies have shown exposure therapy to be effective for treating PTSD in civilians[5,6] and in veterans.[7,8] However, exposure therapy is not appropriate for all patients,[4] and it may be difficult to deliver successfully to veterans with chronic, combat-related PTSD.[7,9]

*Author affiliations are listed at the end of this article. A list of the key personnel of the Department of Veterans Affairs Cooperative Study 420 can be found on page 487.*

The present study tested a method of exposure-based treatment—trauma-focused group therapy (TFGT)[10]—that was developed specifically for patients who might not otherwise tolerate or comply with individual exposure therapy. The treatment embeds exposure in a group context that includes psychoeducation, cognitive restructuring, relapse prevention, and coping skills training. The group is used to create a feeling of safety and to increase the capacity of each patient to tolerate exposure. The approach provides patients with opportunities for exposure to their own traumatic events as well as vicarious exposure to traumatic events experienced by other group members. Furthermore, the group context helps normalize symptoms, increase therapeutic opportunities, increase generalizability of skill acquisition, and improve self-esteem by allowing members to help one another.[11]

Trauma-focused group therapy was evaluated by using a nonspecific comparison design,[12] which controls for benefits that are common to most types of psychotherapy, to permit inferences about the specific benefits of the treatment being investigated. A present-centered group treatment (PCGT) that avoided trauma-focused references, cognitive restructuring, and other TFGT components served as the comparison condition. We expected that TFGT would be superior to PCGT for treating PTSD symptoms, other psychiatric symptoms, and psychosocial problems and for reducing service utilization.

There is little conclusive evidence on the effectiveness of a group format for treating PTSD. Most previous studies of group therapy for PTSD have used either a nonrandomized control group or no control group.[13] We identified 2 randomized clinical trials,[14,15] both of which focused on female sexual assault survivors and used a waitlist control group. Only 1 study,[15] which tested a cognitive-behavioral intervention, found that group treatment reduced PTSD symptoms.

This article reports the results of intention-to-treat analysis, in which the data from each participant are analyzed according to that participant's assigned condition, regardless of compliance. We chose this approach because it is the only analysis that is grounded in the randomization of individuals and because it permits inferences about the question of policy: "Is it better to adopt a policy of Treatment A if possible, with deviations if necessary, or a policy of Treatment B if possible, with deviations as necessary, for patients who seem to have this disease?"[16(p29)] Our aim is to determine whether a broad policy of adopting TFGT would be helpful for male Vietnam veterans who use the VA system. In support of this objective, the study incorporated several elements of "effectiveness" designs[17]: relatively nonselective inclusion criteria, the use of nonexpert therapists, the retention of patients who need nonstudy treatment, and an assessment battery that comprehensively measures multiple outcome domains.

Often, intention-to-treat analysis is performed by using an individual's last measurement before treatment dropout as the last outcome or by carrying it forward. This method has been criticized for the bias it can introduce.[18] Instead, we attempted to measure participants regardless of the number of treatment sessions they attended or their treatment dropout status.[19] To our knowledge, no previous studies of PTSD treatment have taken this approach, which is standard in clinical trials in other fields of medicine. Therefore, we also performed secondary analyses to examine the effect of TFGT among participants who completed most of the scheduled sessions.

## METHODS

A detailed description of the methods has been published elsewhere.[20]

### PARTICIPANTS

Thirty-six male Vietnam veterans with combat-related PTSD were enrolled through outpatient programs at each of 10 VA medical centers (N=360). Individuals who were taking psychoactive medications had to have a stable regimen for at least 2 months before study entry. However, medication changes were allowed during the study if clinically justified. Individuals had to terminate other psychotherapeutic treatment for PTSD, except for 12-step programs. Exclusion criteria were current or lifetime *DSM-IV* psychotic disorder, mania, or bipolar disorder; current major depression with psychotic features; current alcohol or other drug dependence; unwillingness to refrain from substance abuse at treatment or work; significant cognitive impairment; and severe cardiovascular disorder.

### MEASURES

The primary outcome was PTSD severity according to *DSM-IV*[21] criteria as measured by the Clinician-Administered PTSD Scale (CAPS).[22,23] We also examined CAPS severity scores for the PTSD symptom clusters defined in *DSM-IV*: reexperiencing ("B"), avoidance/numbing ("C"), and hyperarousal ("D"). Other measures included the PTSD Checklist[24]; the 12-item version of the General Health Questionnaire[25]; the family, legal, drug, and alcohol composite scores of the Addiction Severity Index[26]; the mental and physical component scores of the 36-Item Short-Form Health Survey[27]; the Quality of Life Inventory[28]; and questions about service utilization in the previous 6 months (not including study visits).[2,29] Comorbid psychiatric diagnoses and Global Assessment of Functioning scores at study entry were established by the *Structured Clinical Interview for* DSM-IV–*Patient Version* (SCID-P).[30]

Assessments were performed by a master's- or doctoral-level clinician who was unaware of treatment assignment. All SCID-P and CAPS assessments were audiotaped. An independent, doctoral-level psychologist checked 8.33% of CAPS tapes (n=120) and 25% of SCID-P tapes (n=90) for reliability. The intraclass correlation for PTSD severity on the CAPS showed excellent agreement ($r=0.85$). Kappas for SCID-P diagnoses showed modest agreement ($\kappa=0.50$-$0.70$), except for current major depression ($\kappa=0.78$), lifetime alcohol abuse or dependence ($\kappa=0.81$), and lifetime drug abuse or dependence ($\kappa=0.90$).

### PROCEDURE

Screening information was obtained in 3 phases (**Figure 1**). In the first phase, the referring clinician was consulted to establish provisional psychiatric diagnoses, and patient records were searched to confirm that the veteran had served in the Vietnam theater. In the second phase of screening, the interviewer met with a veteran to explain the study, administer a brief assessment of cognitive function, and obtain information about

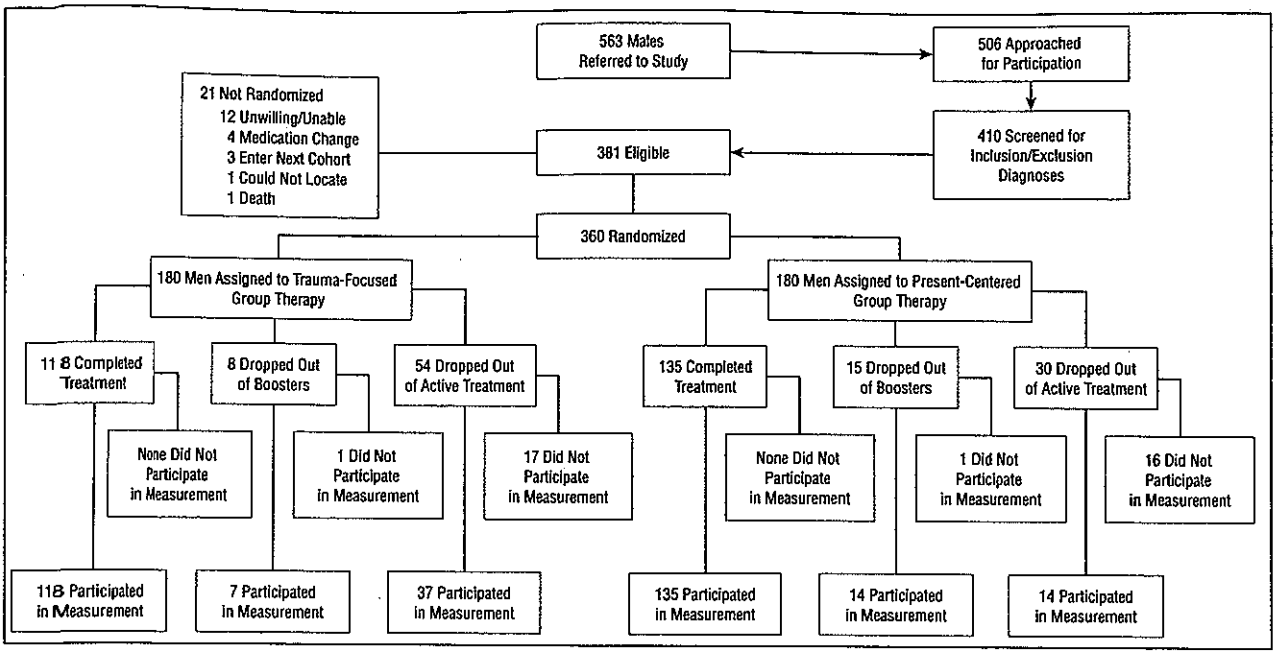


**Figure 1.** Enrollment and participation in treatment and measurement.

the veteran's cardiovascular health. Veterans who reported any cardiovascular problems were referred to a cardiologist to determine whether the problems would prevent participation in TFGT. In the third phase of screening, veterans gave consent and were interviewed to assess inclusion and exclusion diagnoses. Four patients died during the trial, all in the PCGT group: 1 of suicide and 3 of natural causes.

Because TFGT and PCGT are group therapies, it was necessary for a site to assemble a cohort of 12 individuals before treatment could begin. There were 3 cohorts per site. Participants were individually randomized to either TFGT or PCGT in groups of 6 each. The randomizations were performed using permuted blocks of 4 in 3 blocks of CAPS severity scores to ensure balance in treatment groups by CAPS score.

Participants were assessed using the complete outcome battery at study entry, at the end of active treatment (7 months), and at the end of booster sessions (12 months). In addition, a subset of measures was administered to participants in cohort 1 at 18 and 24 months and to those in cohort 2 at 18 months. This article focuses on the 7- and 12-month data; however, the CAPS data from the longer follow-ups are included in the primary analyses.

## TREATMENT

Trauma-focused group therapy and PCGT were delivered weekly for 30 weeks according to a manualized protocol for each treatment. After the 30 weekly sessions, the groups shifted to a monthly schedule for 5 booster sessions. All sessions lasted 1½ hours, except for exposure sessions, which lasted 2 hours; in TFGT, 15-minute telephone calls also were delivered monthly during the booster phase. A manualized case management protocol, delivered by master's- or doctoral-level clinicians, was begun as soon as a participant was enrolled to minimize dropout and provide interim clinical care. Case management was provided monthly or more often if needed for specific problems.

The treatments are described in greater detail elsewhere.[10,20] Briefly, in TFGT, sessions 1 through 5 were introductory sessions that included education about PTSD, coping resource assessment, and self-management of symptoms. Sessions 6 through 8 involved premilitary autobiographies. Sessions 9 through 22 involved war zone scene identification, exposure, and cognitive restructuring. Sessions 23 through 30 involved relapse prevention.

In PCGT, sessions 1 through 4 focused on initiation of rapport, education about PTSD symptoms and associated features, and the connection between PTSD symptoms and difficulties in relationships and problem solving. Sessions 5 through 24 focused on identification and clarification of individual members' specific issues and the development of plans for dealing with these issues, relying heavily on interaction of group members for input and feedback. Sessions 25 through 30 reviewed experience and progress in the group.

In TFGT, each participant was scheduled to have 2 sessions devoted to his trauma. An audiotape of one of these sessions (usually the first) was made, and the participant was expected to listen to it at least 8 times as homework, for a minimum of 10 exposures. In groups with 2 or more dropouts, participants had 3 in-group exposures to maintain the total number of sessions at 30; additional relapse prevention sessions were used as needed to ensure that all TFGT groups met for 30 sessions.

Two master's- or doctoral-level clinicians with previous experience in treating PTSD led each group. They were not required to have formal training in exposure techniques or cognitive-behavioral therapy. They provided only 1 of the 2 treatments and were randomly assigned to the treatment they provided. Before initiating the study described herein, we conducted pilot TFGT groups at all sites and PCGT groups at 2 sites.

All the sessions were videotaped. Telephone supervision based on the videotapes was provided weekly. Three sessions from each of the 60 groups (n=180, 10%) were rated by a senior clinician who was independent of the treatment delivery. Thirty-two specific elements were rated for protocol adherence on a scale from −2 ("not enough") to 2 ("too much"), with 0 indicating "just right." The same elements were rated for therapist competence, which ranged from 0 ("poor") to 4 ("highly competent").

**Table 1. Description of 325 Male Vietnam Veterans Who Participated in at Least 1 Follow-up Assessment at 7 or 12 Months***

| | TFGT (n = 162) | PCGT (n = 163) | Total (N = 325) |
|---|---|---|---|
| Age, mean (SD), y | 50.6 (3.7) | 50.8 (3.8) | 50.7 (3.7) |
| Global Assessment Scale score, mean (SD) | 51.3 (7.9) | 51.6 (8.5) | 51.2 (8.4) |
| Amount of service-connected PTSD disability (in men with disability), mean (SD), % | 56.3 (29.5) | 58.5 (33.0) | 57.4 (31.2) |
| Post–high school education | 104 (64.2) | 114 (70.0) | 218 (67.1) |
| Unemployed | 86 (53.1) | 77 (47.2) | 163 (50.2) |
| Married or cohabitating | 84 (51.5) | 87 (53.4) | 171 (52.6) |
| Nonwhite race | 53 (32.7) | 57 (35.0) | 110 (33.8) |
| Service-connected PTSD disability | 91 (56.2) | 86 (52.8) | 177 (54.5) |
| Any current psychiatric disorder | 112 (69.1) | 106 (65.0) | 218 (67.1) |
| Mood disorder | 95 (58.6) | 87 (53.4) | 182 (56.0) |
| Anxiety disorder | 56 (34.6) | 47 (28.8) | 103 (31.7) |
| Substance abuse | 9 (5.6) | 6 (3.7) | 15 (4.6) |
| Any lifetime psychiatric disorder | 157 (96.9) | 156 (95.7) | 313 (96.3) |
| Mood disorder | 138 (85.2) | 142 (87.1) | 280 (86.2) |
| Anxiety disorder | 63 (38.9) | 53 (32.5) | 116 (35.7) |
| Substance abuse or dependence | 132 (81.5) | 124 (76.1) | 256 (78.8) |

Abbreviations: PCGT, present-centered group therapy; PTSD, posttraumatic stress disorder; TFGT, trauma-focused group therapy.
*Data are given as number (percentage) of participants except where indicated otherwise.

## STATISTICAL ISSUES

### Sample Size Estimation

For sample size estimation, an effect size of $d=0.50$ was judged to be the minimum effect that would be clinically meaningful. A difference of 0.50 SDs represents a decrease of approximately 10 points on the CAPS in treatment-seeking Vietnam veterans with PTSD, for whom the SD is roughly 20.[29] In a 2-group comparison, 64 men per group is required to have 0.80 power to find an effect of $d=0.50$ or larger at $P<.05$, 2-tailed; 85 individuals per group is required to have 0.90 power to find the same effect. As explained in detail elsewhere,[20] the sample size was adjusted to account for the group nature of the intervention. The observed intraclass correlation from the primary mixed-model analysis was $r=0.04$ for the 325 men who participated in follow-up, so power to find an effect of $d=0.50$ approached 1.0.

### Analysis

The SAS PROC MIXED[31] software program with the Satterthwaite option for calculating degrees of freedom was used to account for missing data and the clustering of participants within groups. The main analysis of CAPS severity scores included all points (7, 12, 18, and 24 months) to maximize power. An initial model included as fixed effects baseline CAPS severity, treatment, cohort, and site, all 2-way interactions, and the 3-way interaction. Next, we reran the model deleting nonsignificant interactions (treatment × site and treatment × cohort × site). Two levels of random effects were included in the initial and final models. The first level had a random intercept and a random time slope for individuals nested within group, and the second level had a random intercept for group.

The final model was used for the analysis of data from all other outcomes at 7 and 12 months; analyses for CAPS severity scores were rerun using only 7- and 12-month data to facilitate comparisons with other measures. In these analyses, a treatment × month interaction was included to estimate the adjusted means for each point. Change from pretreatment was evaluated by computing difference scores for the 7- and 12-month data and by using the final model (except for the pretreatment score) to test whether these scores differed from 0. Clinical significance was evaluated by computing the percentage of participants who improved at least 10 points in CAPS severity.

Primary analyses were performed according to the intention-to-treat principle, that is, by using data from all participants regardless of their compliance. We also performed secondary analysis of data from men who received an adequate amount of treatment, defined as 80% of the weekly sessions, that is, 24 or more of the 30 sessions.

Adherence and competence ratings were analyzed by using PROC MIXED[31] to test a model that included group and session as random effects and treatment, site, cohort, and the treatment × cohort interaction as fixed effects.

## RESULTS

**Table 1** gives descriptive information about the 325 men who participated in at least 1 follow-up assessment at 7 or 12 months. On average, the men were middle aged. Most had education beyond high school. Just more than half were unemployed, and more than half were married. Almost all participants had a history of Axis I disorder, typically a mood or substance use disorder. At study entry, two thirds of the men had at least 1 mood, anxiety, or substance use disorder. There were no differences between treatment groups on any of the variables listed in Table 1.

Comparing the 325 men who participated in measurement with the 35 who were lost to follow-up, we found that the groups differed on only 3 of the variables listed in Table 1. Individuals who were lost to follow-up had lower Global Assessment of Functioning scores (47.4 vs 51.2; $t_{358}=2.87$; $P=.004$) and were more likely to be unemployed (71% vs 50%; $\chi^2_1=5.73$; $P=.02$) and to have a lifetime history of substance abuse or dependence (97% vs 79%; $\chi^2_1=6.81$; $P=.009$). The 2 groups did not differ on mean baseline CAPS severity scores: 82.34 for those lost to follow-up vs 81.22 for those who participated in measurement ($t_{358}=0.34$; $P=.73$).

**Table 2. Outcomes as a Function of Treatment and Time of Measurement: Intention-to-Treat Analysis (N = 325)***

| Measure | Trauma-Focused Group Therapy | | | Present-Centered Group Therapy | | |
|---|---|---|---|---|---|---|
| | Pretreatment | 7 mo† | 12 mo† | Pretreatment | 7 mo† | 12 mo† |
| CAPS total severity score | 80.41 (1.45) | 74.00 (1.32)‡ | 72.79 (1.51)‡ | 82.01 (1.44) | 76.03 (1.32)‡ | 74.82 (1.49)‡ |
| CAPS B cluster score | 22.02 (0.55) | 20.84 (0.54)§ | 20.37 (0.59)§ | 22.66 (0.56) | 21.15 (0.54)‖ | 19.97 (0.58)‡ |
| CAPS C cluster score | 32.68 (0.72) | 28.43 (0.75)‡ | 28.64 (0.85)‡ | 33.33 (0.72) | 30.28 (0.75)§ | 30.26 (0.84)§ |
| CAPS D cluster score | 25.71 (0.48) | 24.59 (0.44)§ | 24.10 (0.47)‡ | 26.02 (0.49) | 24.77 (0.44)‖ | 24.79 (0.46)‖ |
| PTSD Checklist severity score | 61.84 (0.91) | 59.70 (0.84)§ | 58.78 (0.89)§ | 62.60 (0.94) | 61.03 (0.84) | 60.00 (0.88)‖ |
| General Health Questionnaire | 32.69 (0.55) | 31.16 (0.49)‡ | 31.88 (0.53)‖ | 33.45 (0.54) | 31.62 (0.49)§ | 31.19 (0.53)‡ |
| SF-36 physical component | 41.78 (0.94) | 40.35 (0.68) | 40.24 (0.73) | 40.06 (0.95) | 39.96 (0.68) | 38.93 (0.71)§ |
| SF-36 mental component | 30.72 (0.86) | 31.84 (0.73) | 30.92 (0.81) | 30.54 (0.85) | 30.75 (0.73) | 31.83 (0.79) |
| Outpatient visits (previous 6 mo) | 39.17 (3.46) | 22.99 (1.80)‡ | 20.84 (2.14)‡ | 40.92 (3.30) | 26.32 (1.80)‡ | 26.30 (2.11)‡ |
| Inpatient days (previous 6 mo) | 7.57 (2.20) | 2.34 (1.01)‡ | 1.23 (0.91)‡ | 5.29 (1.30) | 3.39 (1.02)§ | 3.46 (0.89)§ |

Abbreviations: CAPS, Clinician-Administered PTSD Scale; PTSD, posttraumatic stress disorder; SF-36, 36-Item Short-Form Health Survey.
*Data are given as mean (SE).
†Least squares means adjusted for pretreatment values.
‡$P<.001$ vs pretreatment within a treatment group.
§$P<.01$ vs pretreatment within a treatment group.
‖$P<.05$ vs pretreatment within a treatment group.

Of the 325 men who participated in measurement, 51 dropped out during active treatment and 21 dropped out during booster treatment. Dropout during active treatment was greater among TFGT than PCGT men (22.8% vs 8.6%; $\chi^2_1=12.86$; $P<.001$). The groups did not differ in likelihood of dropout from boosters: 4.3% in the TFGT group vs 8.6% in the PCGT group ($\chi^2_1=2.49$; $P=.12$). There was a trend for PCGT participants to have attended more active treatment sessions (mean n=23.49) than TFGT participants (mean n=21.77) ($t_{358}=1.92$; $P=.056$). Participants in the PCGT group also attended more booster sessions (mean n=3.65 vs 3.24) ($t_{358}=2.04$; $P=.04$). Participants attended an average of 10.14 case management sessions during the 12 months of treatment (range, 0-35 sessions); groups did not differ on this measure. In TFGT, participants completed an average of 1.63 in-group exposures (range, 0-3 exposures) and 7.74 homework exposures (range, 0-32 exposures), for a total of 9.37 exposures (range, 0-35 exposures).

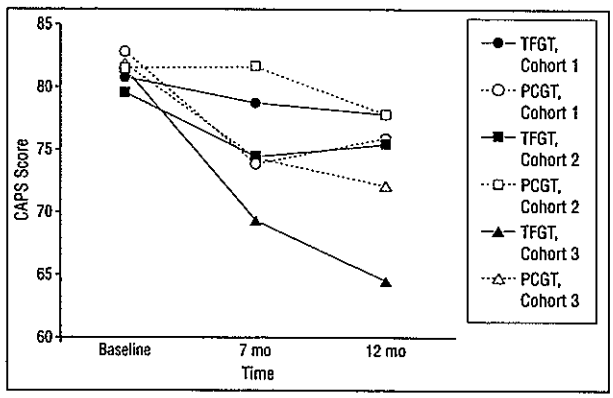


**Figure 2.** Intention-to-treat analyses of Clinician-Administered PTSD Scale (CAPS) scores at 7 and 12 months (N=325). Baseline values are observed means and 7- and 12-month values are least squares means. PTSD indicates posttraumatic stress disorder; TFGT, trauma-focused group therapy; and PCGT, present-centered group therapy.

## INTENTION-TO-TREAT ANALYSES

Intention-to-treat analysis of CAPS severity scores at 7, 12, 18, and 24 months showed significant main effects of site ($F_{9,26.7}=3.16$; $P=.01$) and cohort ($F_{2,25.6}=5.07$; $P=.01$), but not for treatment ($F_{1,25.7}=1.15$; $P=.29$). There also were significant treatment × cohort ($F_{2,25.4}=3.58$; $P=.04$) and site × cohort ($F_{18,25.3}=2.03$; $P=.0498$) interactions. Although neither interaction was predicted, the treatment × cohort interaction was explored to clarify the absence of the expected overall treatment effect. Tests of the effect of treatment within each cohort indicated that PCGT was better than TFGT in cohort 1 ($P=.047$), TFGT was better than PCGT in cohort 2 ($P=.03$), and the treatments did not differ in cohort 3 ($P=.17$).

**Table 2** gives information about intention-to-treat analysis of the 7- and 12-month data for all measures. There was no main effect of treatment on any measure. A treatment × cohort interaction similar to that observed in the main CAPS analyses was observed in the 7- and 12-month data for CAPS severity (**Figure 2**), CAPS C cluster (which measures avoidance and numbing symptoms), and PTSD Checklist severity scores ($P<.05$ for all). There were no significant treatment × month interactions.

Additional analyses examined change from pretreatment for the 7- and 12-month data within each treatment group (Table 2). There were significant reductions on the CAPS, PTSD Checklist, and General Health Questionnaire in both groups, although the average amount of change was not clinically significant. There were no changes on the Quality of Life Inventory or any of the Addiction Severity Index scales (data not shown) and only 1 change on the 36-Item Short-Form Health Survey. Amount of inpatient and outpatient utilization decreased; however, note that the outpatient scores do not reflect study visits for therapy or case management.

The treatments did not differ with respect to clinical effectiveness. At 7 months, 37.5% of the PCGT group and 38.8% of the TFGT group showed a decrease of at least

**Table 3. Outcomes as a Function of Treatment and Time of Measurement: Participants Who Attended 24 or More Sessions (n = 217)***

| | Trauma-Focused Group Therapy | | | Present-Centered Group Therapy | | |
|---|---|---|---|---|---|---|
| Measure | Pretreatment | 7 mo† | 12 mo† | Pretreatment | 7 mo† | 12 mo† |
| CAPS total severity score | 79.97 (1.91) | 73.64 (1.61)‡ | 72.55 (1.85)‡ | 81.40 (1.67) | 77.78 (1.58) | 76.49 (1.80)§ |
| CAPS B cluster score | 22.08 (0.72) | 20.99 (0.64) | 20.62 (0.70)§ | 22.20 (0.70) | 22.22 (0.63) | 20.47 (0.69)§ |
| CAPS C cluster score | 32.58 (0.90) | 27.50 (1.13)‡ | 27.61 (1.24)‡ | 33.09 (0.81) | 31.07 (1.12) | 31.56 (1.23) |
| CAPS D cluster score | 25.31 (0.62) | 24.73 (0.52) | 23.98 (0.56)‖ | 26.11 (0.55) | 24.90 (0.51) | 24.86 (0.55) |
| PTSD Checklist severity score | 61.37 (1.19) | 59.66 (1.08)§ | 58.44 (1.20)‖ | 62.41 (1.14) | 62.09 (1.06) | 60.99 (1.18) |
| General Health Questionnaire | 32.92 (0.69) | 30.29 (0.64)‡ | 31.66 (0.72)§ | 33.90 (0.64) | 32.06 (0.63)§ | 31.36 (0.71)‖ |
| SF-36 physical component | 42.16 (1.21) | 41.30 (0.78) | 41.88 (0.81) | 39.45 (1.12) | 40.04 (0.77) | 38.86 (0.78)§ |
| SF-36 mental component | 30.65 (1.06) | 31.61 (1.03) | 30.81 (1.12) | 29.76 (0.96) | 29.70 (1.02) | 31.01 (1.09) |
| Outpatient visits (previous 6 mo) | 38.59 (3.72) | 20.92 (1.85)‡ | 19.41 (2.34)‡ | 36.50 (3.08) | 24.08 (1.82)‡ | 25.17 (2.28)‡ |
| Inpatient days (previous 6 mo) | 7.24 (2.69) | 1.99 (1.34)‖ | 1.41 (1.01)‡ | 4.88 (1.41) | 2.54 (1.31)‖ | 2.77 (0.99)‖ |

Abbreviations: CAPS, Clinician-Administered PTSD Scale; PTSD, posttraumatic stress disorder; SF-36, 36-Item Short-Form Health Survey.

*Data are given as mean (SE). See the "Adequate Dose Analyses" subsection of the "Results" section for information about differences between treatment groups.

†Least squares means adjusted for pretreatment values.

‡$P<.001$ vs pretreatment within a treatment group.

§$P<.05$ vs pretreatment within a treatment group.

‖$P<.01$ vs pretreatment within a treatment group.

10 points in PTSD severity on the CAPS. At 12 months, these values were 43.2% and 44.7%, respectively.

## ADHERENCE AND THERAPIST COMPETENCE

Adherence was excellent, and therapists were judged to be competent. There were small, but significant, differences between treatment groups on both measures. Adherence, for which the optimal score is 0, was lower in PCGT (mean score, −0.07) than in TFGT (mean score, 0) ($F_{1,165}=14.91$; $P<.001$). Therapist competence was higher in TFGT (mean score, 2.24) than in PCGT (mean score, 1.98) ($F_{1,45}=17.86$; $P<.001$). (Note that denominator degrees of freedom differ across analyses because of the method used to calculate degrees of freedom.[31]) The treatment × cohort interaction was not significant for either measure, and the means did not suggest that the treatment × cohort interaction for CAPS scores could be explained by either adherence or competence. Also, average within-group change in CAPS severity from pretreatment to posttreatment was uncorrelated with the average within-group ratings for either adherence ($r=-0.09$) or competence ($r=-0.10$).

## ADEQUATE DOSE ANALYSES

Secondary analyses focused on the 217 men who attended at least 24 active treatment sessions. Participants in TFGT and PCGT did not differ in the likelihood of attending 24 or more sessions: 58.9% vs 61.7%, respectively ($\chi^2_1=0.29$; $P=.59$). Within this subsample, the TFGT and PCGT groups did not differ on baseline CAPS scores or on any of the baseline measures listed in Table 1 (lowest $P=.12$).

The initial model for CAPS severity scores at 7, 12, 18, and 24 months showed that scores in TFGT participants were lower than those in PCGT participants ($F_{1,157}=5.56$; $P<.001$). In the final model, with nonsignificant interactions (site × cohort and treatment × site × cohort) deleted, the treatment main effect was marginally significant ($F_{1,183}=3.53$; $P=.06$). There also were significant effects of site ($F_{9,184}=3.69$; $P<.001$), cohort ($F_{2,184}=5.77$; $P.004$), site × cohort ($F_{18,183}=1.68$; $P=.046$), and treatment × cohort ($F_{2,183}=3.44$; $P=.03$). As in the intention-to-treat analyses, we explored the treatment × cohort interaction. Tests of the effect of treatment within each cohort indicated that the treatments did not differ in cohort 1 ($P=.26$) but that TFGT was better than PCGT in cohorts 2 and 3 ($P=.04$ for both).

**Table 3** gives information about intention-to-treat analysis of the 7- and 12-month data for the adequate dose subsample. There was a significant main effect of treatment, favoring TFGT, on the CAPS C cluster scores ($P=.02$). A treatment × cohort interaction similar to that observed for CAPS severity score at all 4 points was observed in the 7- and 12-month data for CAPS severity ($P=.03$) and PTSD Checklist ($P=.05$) severity scores. Also, there were significant treatment × month interactions for CAPS B cluster ($P=.02$) and General Health Questionnaire ($P=.04$) scores, showing that TFGT participants had lower scores at 7 months only.

The results of analyses to examine change from baseline were similar to the results of intention-to-treat analyses, except that the PCGT group showed fewer significant changes in symptoms than the TFGT group (Table 3). Again, there were no changes on the Quality of Life Inventory or the Addiction Severity Index (data not shown). As in the intention-to-treat analyses, the treatments did not differ with respect to clinical effectiveness. At 7 months, 34.5% of the PCGT group and 37.1% of the TFGT group showed a decrease of at least 10 points in PTSD severity on the CAPS. At 12 months, these values were 38.0% and 49.0%, respectively.

## COMMENT

Interpreting the results of this study requires a clear understanding of our primary aim, which was to determine whether the widespread use of TFGT would be helpful for male Vietnam veterans who use the VA system. The study

## Department of Veterans Affairs Cooperative Study 420 Key Personnel

### Co-Principal Investigators

Matthew J. Friedman, MD, PhD, Department of Veterans Affairs (VA) National Center for Posttraumatic Stress Disorder (PTSD), White River Junction VA Medical and Regional Office Center, White River Junction, Vt; and the Departments of Psychiatry and Pharmacology, Dartmouth Medical School, Hanover, NH; and Paula P. Schnurr, PhD, National Center for PTSD, White River Junction VA Medical and Regional Office Center; and the Department of Psychiatry, Dartmouth Medical School.

### Executive Committee Members

David W. Foy, PhD, Graduate School of Education and Psychology, Pepperdine University, Culver City, Calif; Fred D. Gusman, MSW, National Center for PTSD, VA Palo Alto Healthcare System, Palo Alto, Calif; Terence M. Keane, PhD, National Center for PTSD, Boston VA Medical Center (VAMC), and the Department of Psychiatry, Boston University School of Medicine, Boston, Mass; Charles Marmar, MD, San Francisco VAMC, and Department of Psychiatry, University of California at San Francisco; Bruce Rounsaville, MD, Department of Psychiatry, Yale University School of Medicine, New Haven, Conn; M. Tracie Shea, PhD, Providence VAMC and the Department of Psychiatry, Brown University School of Medicine, Providence, RI; and Daniel Weiss, PhD, San Francisco VAMC and the Department of Psychiatry, University of California at San Francisco.

### Data-Monitoring Board

David H. Barlow, PhD; Theodore Colton, PhD; Roger K. Pitman, MD; and Patricia A. Resick, PhD (chairperson).

### VA Cooperative Studies Participants

Frank Y. Hsieh, PhD, VA Cooperative Studies Program, VA Palo Alto Healthcare System; Philip W. Lavori, PhD, VA Cooperative Studies Program, VA Palo Alto Healthcare System, and the Department of Health Research and Policy, Stanford University, Palo Alto; and Yajie Wang, MS, VA Cooperative Studies Program (statistical programmer).

### Project Management

Nancy C. Bernardy, PhD, National Center for PTSD, White River Junction VA Medical and Regional Office Center, and the Department of Psychiatry, Dartmouth Medical School (project manager); Shirley M. Glynn, PhD, West Los Angeles VAMC, Los Angeles, Calif (therapy supervisor); Phillip Massad, PhD, White River Junction VA Medical and Regional Office Center (case management supervisor); Veronica Thurston, MPH, National Center for PTSD, White River Junction VA Medical and Regional Office Center (assistant project manager); and Melissa Wattenberg, PhD, National Center for PTSD, Boston VAMC (therapy supervisor).

### VAMC Sites and Participating Site Investigators

*Boston:* Lisa Fisher, PhD; *Miami, Fla:* Pamala Adams, PhD (formerly Elizabeth Jackson, MD); *Minneapolis, Minn:* Michael Dieperink, MD (formerly Arthur S. Blank, MD); *New Orleans, La:* Madeline Uddo, PhD; *Palo Alto:* Fred D. Gusman, MSW; *Providence:* William Unger, PhD; *San Diego, Calif:* Murray Stein, MD; *San Francisco:* Frank Schoenfeld, MD; *Seattle, Wash:* Miles E. McFall, PhD; and *West Haven, Conn:* Steven M. Southwick, MD (formerly Andrew Meisler, PhD).

incorporated elements of effectiveness designs[17] so that we could assess the relative advantage of TFGT in a clinically realistic manner. We also collected and analyzed data from all possible randomized participants, even those who did not attend any treatment (because this sometimes happens in clinical practice). To our knowledge, no other randomized clinical trial has evaluated any type of PTSD treatment under such conditions.

Intention-to-treat analyses found no consistent differences between TFGT and PCGT for treating PTSD or other outcomes, and data on manual adherence and therapy quality did not clarify the pattern of findings. Analyses conducted to investigate whether TFGT might work better than nonspecific PCGT when an adequate amount of treatment has been received suggested that TFGT was better than PCGT for treating avoidance and numbing and, possibly, overall PTSD symptoms.

Thus, the short answer to the question of whether the VA should promote systemwide use of TFGT for Vietnam veterans seems to be no, but it could be yes if we can learn more about who will stay in treatment or how to increase the likelihood that more veterans will stay in treatment. However, the effect of TFGT in the adequate dose analyses could be due to selection bias, despite the comparability of treatment groups in the likelihood of members attending at least 80% of sessions and a lack of pretreatment differences between groups among adherent participants. Further evidence is needed before firm conclusions about amount of treatment can be drawn.

One explanation for our modest findings is that TFGT is not an adequate treatment. We think this is unlikely. Trauma-focused group therapy contains elements of proven efficacy: exposure,[5-8] cognitive restructuring,[5,6,32] and relapse prevention.[33] A particular question is whether TFGT includes a sufficient amount and type of exposure: by design, 2 or 3 in-group exposures and 8 homework exposures. This differs from procedures used by Foa (eg, see Foa et al[5] and Marks et al[6]), in which a trauma narrative might be repeated several times within a session in an attempt to ensure that the distress evoked by the narrative is reduced by the end of the session. Yet, even if TFGT might be more effective if it included more

in-group exposure, the total combination of elements should have made it more powerful than PCGT, which was designed to control for the nonspecific benefits of psychotherapy.

Trauma-focused group therapy embeds exposure in a group context to help patients tolerate exposure. Dropout from treatment was still higher in TFGT than in PCGT, but it was lower than has been observed in other studies[9,10] of Vietnam veterans and comparable to that in previous studies[5,6] of treatments that combined exposure with other cognitive-behavioral elements. One possibility is that dropout could be further minimized by using motivational interviewing, which has shown positive effects on treatment adherence among psychiatric patients.[34]

We did not require our therapists to be experts in cognitive-behavioral therapy, as has been the case in other studies[5,8,32] of cognitive-behavioral treatments for PTSD. The patient population also differs from most previous randomized clinical trials[5,6,15] of psychotherapy for PTSD, which have focused on civilians. Male Vietnam veterans with PTSD who use VA services have significant comorbidity and functional difficulties, even compared with male Vietnam veterans with PTSD who do not use VA services.[35] Users of VA services show limited treatment responsiveness as well.[29,36] In our study, which had intensive supervision by expert therapists and in which the quality of therapy was documented as good to excellent, the amount of change after treatment was comparable to the amount observed in VA program evaluation findings.[29]

Seligman[17] suggested that psychotherapy research should combine the rigor of efficacy trials with the realism of effectiveness studies. We encourage wider recognition of the need for randomized clinical trials that attempt to evaluate PTSD treatments under conditions that translate readily to clinical practice.

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*From the Department of Veterans Affairs (VA) National Center for Posttraumatic Stres Disorder, White River Junction, Vt (Drs Schnurr, Friedman, and Bernardy); Departments of Psychiatry (Drs Schnurr, Friedman, and Bernardy) and Pharmacology (Dr Friedman), Dartmouth Medical School, Hanover, NH; Department of Psychology, Pepperdine University, Culver City, Calif (Dr Foy); Mental Health and Behavioral Sciences Service, Providence VA Medical Center, Providence, RI (Dr Shea); Department of Psychiatry, Brown University, Providence (Dr Shea); VA Cooperative Studies Program, Menlo Park, Calif (Drs Hsieh and Lavori); Department of Health Research and Policy, Stanford University, Palo Alto, Calif (Dr Lavori); Research Service, West Los Angeles VA Medical Center, Los Angeles, Calif (Dr Glynn); Department of Psychiatry and Behavioral Sciences, University of California, Los Angeles (Dr Glynn); VA Outpatient Clinic, Boston, Mass (Dr Wattenberg); and Department of Psychiatry, Tufts University School of Medicine, Boston (Dr Wattenberg).*

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*Corresponding author and reprints: Paula P. Schnurr, PhD, VA National Center for PTSD (Mail Stop 116D), VA Medical and Regional Office Center, White River Junction, VT 05009 (e-mail: paula.schnurr@dartmouth.edu).*

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