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Multisite Randomized Trial of Behavioral Interventions for Women With Co-Occurring PTSD and Substance Use Disorders

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The authors compared the effectiveness of the Seeking Safety group, cognitive–behavioral treatment for substance use disorder and posttraumatic stress disorder (PTSD), to an active comparison health education group (Women's Health Education [WHE]) within the National Institute on Drug Abuse's Clinical Trials Network. The authors randomized 353 women to receive 12 sessions of Seeking Safety (M = 6.2 sessions) or WHE (M = 6.0 sessions) with follow-up assessment 1 week and 3, 6, and 12 months posttreatment. Primary outcomes were the Clinician Administered PTSD Scale (CAPS), the PTSD Symptom Scale–Self Report (PSS-SR), and a substance use inventory (self-reported abstinence and percentage of days of use over 7 days). Intention-to-treat analysis showed large, clinically significant reductions in CAPS and PSS-SR symptoms (d = 1.94 and 1.12, respectively) but no reliable difference between conditions. Substance use outcomes were not significantly different over time between the two treatments and at follow-up showed no significant change from baseline. Study results do not favor Seeking Safety over WHE as an adjunct to substance use disorder treatment for women with PTSD and reflect considerable opportunity to improve clinical outcomes in community-based treatments for these co-occurring conditions.

Keywords: PTSD, substance abuse, comorbidity, cognitive–behavioral treatment, randomized control trial

Twenty years of epidemiology confirm the high level of co-occurring trauma-stress related disorders, such as posttraumatic stress disorder (PTSD) and addictive disorders among women in community-based drug treatment, revealing a significant need for therapeutic approaches that can address adverse psychiatric consequences (e.g., Breslau, Davis, Andreski, & Peterson, 1991; Resnick, Kilpatrick, Dansky, Saunders, & Best, 1993; Shore, Vollmer, & Tatum, 1989). Yet, treatment research in this area remains limited.

Quasi-experimental and small controlled studies (i.e., Finkelstein et al., 2004) suggest that a services model integrating cognitive–behavioral treatment for trauma with substance abuse services can result in modest improvements in outcome (e.g., Amaro et al., 2007; Morrissey et al., 2005). For PTSD without co-occurring substance abuse, cognitive–behavioral approaches have shown evidence of efficacy (e.g., Cloitre, Koenen, Cohen, & Han, 2002; Foa, Rothbaum, & Riggs, 1991). There has been concern, however, that discomfort aroused by focusing on the trauma could be harmful in substance dependent patients, who might escalate substance use or flee treatment. At the same time, the demand for specific interventions for patients with trauma and substance abuse has been mounting in community-based treatment systems (Cohen, Dickow, Horner, Zweben, & Balabis, 2003; Morrissey et al., 2005).

To address this need, Najavits (2002) developed Seeking Safety, an integrated cognitive–behavioral treatment of PTSD and substance use disorder. Thus far, Seeking Safety has been researched in various studies, including a multisite controlled trial with homeless women veterans (Desai, Harpaz-Rotem, Najavits, & Rosenheck, 2008), two randomized control trials with low-income urban women and adolescent girls (Hien, Cohen, Miele, Litt, & Capstick, 2004; Najavits, Gallop, & Weiss, 2006), a controlled trial (Gatz et al., 2007), and eight uncontrolled pilot studies (e.g., Cook, Walser, Kane, Ruzek, & Woody, 2006; Najavits, Weiss, Shaw, & Muenz, 1998; Zlotnick, Najavits, & Rohsenow, 2003). Overall, Seeking Safety has shown consistent positive outcomes on a variety of measures, superiority to treatment as usual, comparability to a gold standard treatment (relapse prevention), positive results in populations typically considered challenging (e.g., the homeless, prisoners, adolescents, public sector clients, and veterans), and high acceptability among diverse clients and clinicians.

One of the goals of the National Institute on Drug Abuse's Clinical Trials Network is to conduct multisite studies to promote dissemination of promising evidence-based treatments into the community, using a blended research-to-practice model. Thus, Seeking Safety appeared to be a logical choice for such evaluation, given that it had already achieved positive results on various controlled and uncontrolled trials and that it had been widely implemented in clinical practice, but had a limited number of randomized controlled trials and no rigorous multisite trials. Further, despite this existing literature on Seeking Safety, it was still unclear how the model would fare when conducted with a the smaller number of sessions more typical to community-based programming and when delivered by community practitioners.

With these questions in mind, the National Institute on Drug Abuse Clinical Trials Network undertook a multisite clinical trial to test the effectiveness of Seeking Safety when delivered by community-based clinicians across a range of substance abuse treatment programs to a broadly representative patient sample. Seeking Safety was adapted from 25 to 12 sessions. The active comparison group, Women's Health Education (WHE), was intended to control for therapeutic time and attention but may have also included other active therapeutic elements. To inform future treatment-development efforts, it was important for our trial to address whether the specific elements of Seeking Safety were responsible for observed treatment effects. Although there were

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We acknowledge the work and support of the six regional research training centers involved in the implementation of this study and the invaluable commitment of the patients and staff at the seven participating community-based treatment programs. Staff from the National Institute on Drug Abuse's Clinical Trials Network collaborated in the design and conduct of the study, assisted with data management and quality assurance during the trial, and provided comments for consideration on this article.

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numerous prior studies of Seeking Safety, the current project represents the first large-scale randomized controlled study with a high level of rigor (a combination of formal training of clinicians, adherence monitoring, interview-based diagnostic evaluation, and rigorous inclusion/exclusion criteria). It was hypothesized that Seeking Safety delivered by community-based substance abuse counselors and their supervisors would produce superior outcomes to WHE when added to outpatient treatment. The main outcome variables were severity of PTSD symptoms and self-reported abstinence over 7 days confirmed with urine and saliva tests, both during treatment and over a 12-month follow-up period. In addition, a priori subgroup analyses were planned to examine outcomes separately for minimal attendance (i.e., those who received 6 sessions or more of either active treatment).

Method

Studies conducted in the National Institute on Drug Abuse Clinical Trials Network attempt to replicate real-world conditions to evaluate feasibility of intervention implementation in community clinics. To this end, this study used a hybrid model research design (Carroll & Rounsaville, 2003), which retained key elements of an efficacy trial: diagnostic assessment with clinician raters unaware of the goals of the experiment, randomization to an active treatment and a credible comparison group, multiple longitudinal standardized assessments, and standards for therapist competence and adherence. Yet, the design also allowed for certain elements to replicate real-world conditions (effectiveness): rolling group admissions and group format, broader inclusion criteria admitting participants with subthreshold and full PTSD and in different stages of substance abuse treatment, treatments delivered by community-based counselors and supervisors, and multiple sites with varying treatment as usual.

All procedures were reviewed and approved by institutional review boards associated with the lead research team and each treatment site, and all patient participants gave written informed consent. Because participating counselors and supervisors at each site were selected and randomly assigned to conduct one of the two treatments, they were also considered research participants and gave written informed consent. A certificate of confidentiality, issued by the National Institute on Drug Abuse, was obtained for each clinic participating in the study. The study was approved and periodically reviewed by a Data and Safety Monitoring Board convened for review of Clinical Trials Network studies. Rigorous quality assurance procedures, including local quality assurance monitoring and regularly scheduled conference calls, were in place throughout the course of the study to ensure data collection integrity.

Participants

Participants were women enrolled in seven community-based substance abuse treatment programs (CTPs) across the United States. To be eligible, participants needed to have had at least one traumatic event in their lifetime and to have met *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., text rev.; *DSM–IV–TR*; American Psychiatric Association, 2000) criteria for either full or subthreshold PTSD. For subthreshold PTSD, participants had to fulfill *DSM–IV–TR* Criteria A (exposure to a traumatic stressor), B (re-experiencing symptoms), E (symptom duration of at least 1 month), and F (significant distress or impairment of functioning) as well as either C (avoidance and numbing symptoms) or D (symptoms of increased arousal) but not both as in full PTSD. This is a commonly used definition of subthreshold PTSD (Blanchard, Hickling, Taylor, Loos, & Gerardi, 1994; Grubaugh et al., 2005). Other inclusion criteria were that participants (a) were between 18 and 65 years of age, (b) had used alcohol or an illicit substance within the past 6 months and had a current diagnosis of drug or alcohol abuse or dependence, and (c) were capable of giving informed consent.

Women were excluded if they had an advanced stage medical disease as indicated by global physical deterioration, impaired cognition as indicated by a Mini-Mental Status Exam (Folstein, Folstein, & McHugh, 1975) score of less than 21, significant risk of suicidal/homicidal intent or behavior, a history of schizophrenia-spectrum diagnosis, a history of active (past 2 months) psychosis, and involvement in litigation related to PTSD. Participants were also excluded if they did not speak English or if they refused to be video- or audiotaped.

CTPs

Seven CTPs participated in the study, with the number of participants randomized at each site ranging from 7 to 106. The site randomizing 7 participants was dropped from the study because of slow recruitment but did complete assessments, randomization, and treatment as prescribed in the protocol. The sites were a mixture of urban ($n = 5$) and suburban ($n = 2$) settings located in the Western ($n = 1$), Midwestern ($n = 1$), Northeastern ($n = 2$), and Southeastern ($n = 3$) United States. All participating programs offered a combination of outpatient individual and group treatment components, reflecting varying orientations and philosophies of addiction treatment. All but one of the sites had mixed gender programs, and three sites offered some gender-specific, trauma-informed services, although participants in the study did not receive these services for the duration of the time in the study.

Procedures

Design. This study used a randomized, controlled, repeated measures design to assess the effectiveness of Seeking Safety (Najavits, 2002) plus standard substance abuse treatment in comparison to an active comparison treatment, WHE, plus standard substance abuse treatment. Counselors and supervisors at each site were nested within treatment conditions; each site delivered each of the treatment conditions. After baseline assessment, participants were randomly assigned to one of the two conditions consisting of two sessions per week over approximately 6 weeks. Participants were assessed weekly during treatment and at 1 week and 3, 6, and 12 months posttreatment.

Recruitment and baseline assessment. The study was advertised through brochures, fliers, newspaper, and other print media as well as through referrals from CTP treatment staff. Potential participants who were not already in treatment at a CTP and who responded to an advertisement needed to enroll in outpatient treatment at the CTP to participate. Recruitment occurred over a 21-month period in 2004 and 2005. Interested participants completed a brief in-person or telephone screen to ascertain likely

eligibility, followed by an in-person screening assessment to confirm eligibility. All participants who completed a screening assessment first signed an informed consent, which included appropriate language from the Health Insurance Portability and Accountability Act. Finally, a third (baseline) interview was completed, with additional study consent, to further assess substance use, PTSD, and social characteristics. Baseline interviews lasted approximately 2.5 to 3 hr. Independent assessors who remained unaware of randomization assignment performed all baseline and posttreatment assessments. After completion of the baseline assessment, eligible participants were randomized to Seeking Safety or WHE.

Randomization. Randomization was stratified by prescription psychotropic medication use and by whether the participant met criteria for an alcohol use disorder only (as opposed to a drug use disorder only or both drug and alcohol use disorders concurrently). A statistician generated one blocked randomization list (block size known only to the statistician) for the entire study. Each CTP received sets of 60 sealed, tamper evident, security envelopes, containing one randomization number and the corresponding treatment assignment.

Treatments. In consultation with the developer, Lisa Najavits, the Seeking Safety treatment was abbreviated from 25 to 12 core sessions to better fit within a feasible time frame for community-based outpatient treatment programs. Seeking Safety is a structured cognitive–behavioral treatment with both safety/trauma and substance use components integrated into each session (Najavits, 2002). All sessions have the same structure: (a) check in, including reports of any unsafe behaviors and use of coping skills, (b) session quotation, a brief point of inspiration to affectively engage participants and link to the session topic, (c) relating the material to the participants' lives, in which hand-outs are used to facilitate discussion and structured skill practice, and (d) check out, including a commitment to specific between-session skills practice. Each session covered a different topic as follows: safety, taking back power from PTSD, when substances are in control, honesty, setting boundaries in relationships, compassion, healing from anger, creating meaning, integrating the split self, taking good care of oneself, red and green flags, and detaching from emotional pain (grounding).

The WHE active comparison condition was adapted from a protocol developed to be an attention control group for a treatment grant for female partners of injection drug users (Miller, Pagan, & Tross, 1998). It is a psychoeducational, manualized health curriculum focused on topics such as understanding the female body, human sexual behavior, pregnancy and childbirth, sexually transmitted diseases, HIV, and AIDS. WHE was designed to provide equivalent therapeutic attention, expectancy of benefit, and an issue-oriented focus, but without theory-driven techniques (i.e., those of Seeking Safety) or any explicit focus or psychoeducation specific to substance abuse or trauma. All WHE sessions followed a common format: (a) introduction of topic, (b) review of group rules and between-session assignment, (c) topic presentation, (d) a video, storytelling, and/or text readings, and(e) topic exercises in a variety of formats to facilitate group discussion and application of session materials, and (f) setting between-session goals.

Each intervention consisted of an initial individual session with the therapist to discuss the result of the participant's random assignment, intervention format, and group rules. Research staff contacted participants to schedule this session within 1 day of randomization, which was done immediately after the baseline assessment. Participants had to attend the individual session before starting treatment. Both groups had an open, rolling enrollment format, lasted approximately 75–90 min, and ran as long as at least 3 women were enrolled ($n = 20$ for those who had to wait 6 weeks or longer to begin their group treatment). Because of the criterion of needing 2 women present to conduct the group, many women took longer than 6 weeks to complete the interventions. Even if women could not immediately enter a group, the individual session took place right after randomization.

Training and fidelity. Therapists and therapist supervisors from each site (heretofore referred to as *local supervisors*) were selected on the basis of willingness to be randomized and after submitting an audiotaped therapy session exemplifying their ability to deliver a cognitive–behavioral style of therapy. All counselors were women. About 6% had less than a bachelor's degree, 39% held a bachelor's degree, and 56% had a master's degree or greater. Half of the counselors were White, 28% were Black, and 22% were Latina. Supervisors were more likely to be White (67%) and to have a master's degree or doctorate (83%). After signing informed consent, two counselors and two local supervisors per site were randomized to deliver one of the two study interventions. All counselors and local supervisors attended a comparable centralized 3-day workshop, and local supervisors received another half day of training focused on how to carry out supervision. Following training, counselors and local supervisors became certified once they successfully completed a training group of at least four sessions in the treatment to which they were assigned. An expert from the lead training team (Lisa R. Cohen, Gloria M. Miele, and two Seeking Safety trainers) rated the videotaped certification sessions for adherence to the manual and competency in the delivery of the interventions. The local supervisors used the certification sessions to obtain interrater reliability with the lead expert trainers on the adherence measures.

Once the trial was underway, all intervention sessions were videotaped, and a proportion of the tapes rated by local supervisors ($\geq$50%). Throughout the study, therapists met weekly with local supervisors for supervision, and if adherence fell below competency criterion, additional supervision was provided. To ensure competency on an ongoing basis, local supervisors had weekly conference calls with lead node experts (Lisa R. Cohen, Gloria M. Miele, and two Seeking Safety trainers). The lead node experts rated a randomly selected quarter (29%) of the therapists' session tapes reviewed by the local supervisor, comparing their ratings with the local supervisors' ratings to ensure supervisor fidelity and interrater reliability. For both interventions during the study, supervisor fidelity was determined by whether the ratings of lead node experts and site supervisors were in agreement on fidelity at a 70% level, with specific adherence measures for each treatment.

Treatment as usual. All study participants were enrolled in one of the participating CTPs and were asked to attend treatment as usual at the program during the 6-week treatment phase of the study. As mentioned earlier, treatment as usual was not kept constant across sites but was allowed to vary. Outpatient treatment differed across sites in frequency and length of sessions per week, although most offered intensive outpatient services of 3 days per week or more. The treatment orientation of the programs also varied, but none of the programs provided trauma-focused treatment to participants during the study. During the study treatment

and follow-up phases, treatment-as-usual data were collected and categorized as mental health, outpatient medical, inpatient substance abuse treatment, emergency room or hospitalization, and 12-step meeting attendance. Participants who dropped from the CTP prior to completing treatment were removed from the treatment portion of the study but continued with follow-up assessments.

Measures

After screening and baseline assessments, randomized participants met weekly with the research assistant throughout the treatment phase of the study. During these weekly visits, urine drug screen, saliva alcohol tests, adverse events, self-reported PTSD symptoms, and substance use data were collected. The research assistant met with the women as a group to read and ensure completion of the self-report assessments. Following the intervention phase of the study, assessments were conducted by the independent assessor, who was unaware of randomization assignment, at 1-week, 3-month, 6-month, and 12-month follow-ups.

Sociodemographics. Basic demographic data, including age and race/ethnicity, were collected at the screening assessment, and marital status, monthly income, employment pattern (prior 3 years), domestic living situation (prior 3 years), and prior treatment episodes were collected at baseline.

PTSD. PTSD was assessed with the Clinician Administered PTSD Scale (CAPS; Blake et al., 1995), a structured interview that measures traumatic life events and frequency and intensity of signs and symptoms of PTSD in the past 30 days and is used as a measure of *DSM–IV* PTSD diagnosis and treatment outcome. The scale has three symptom cluster subscales: Re-Experiencing, Avoidance/Numbing, and Hyperarousal. Cluster severity scores are calculated by summing the frequency and intensity of scores for each of the three subscales; an overall total scale score is obtained by summing subscale scores. Independent assessors had weekly conference calls with the lead team to maintain competency and interrater reliability on the measure. A 30-point or greater improvement on the CAPS can be used to determine clinically significant improvement of PTSD symptoms (Weathers, Keane, & Davidson, 2001). Questions ascertaining childhood versus adult physical and sexual abuse were asked separately. Childhood sexual abuse was defined as any sexual activity against one's will when under the age of 18.

Substance use diagnosis. Substance use diagnostic data were collected with the Composite International Diagnostic Interview for *DSM–IV* (Robins et al., 1989), a fully structured, interviewer-administered measure used to determine lifetime and current substance disorder diagnoses for alcohol, marijuana, stimulants, opioids, cocaine, and sedatives.

Several assessment instruments were administered at baseline, weekly throughout the treatment phase, and at each follow-up assessment. The Substance Use Inventory consists of a series of self-report questions about quantity and frequency of substance use. This inventory was adapted from the Time Line Follow-Back measure (Weiss, Hufford, Najavits, & Shaw, 1995) and includes questions about alcohol, cocaine, heroin, marijuana, sedatives, and stimulants. The Post Traumatic Stress Disorder Symptom Scale–Self Report (PSS-SR) is a self-report inventory that assesses the frequency and intensity of PTSD symptoms (Foa, Riggs, Dancu, Constance, & Rothbaum, 1993). The PSS-SR was used to assess PTSD symptom severity throughout the treatment phase of the study. Biologically confirmed abstinence from drugs of abuse was obtained by use of the SureStep urine drug screen card, a rapid visual immunoassay for the qualitative detection of 10 drug and drug metabolites in human urine. Recent alcohol use was tested with the ALCO-Screen Saliva Alcohol Test, distributed by Jant Pharmacal Corporation, which uses a reactive pad to test for the presence or absence of alcohol blood content greater than 0.02%. The Substance Use Inventory and PSS-SR captured data from the past week at baseline and all follow-up times and since the last assessment during the treatment phase to assess substance use during the entire treatment phase.

Participants were compensated with cash or vouchers valued at $20 for the completion of the screening and $20 for the completion of the baseline assessments. For the follow-up compensation, participants received $20 in cash or vouchers for completion of the 1-week posttreatment follow-up, $30 for the 3-month follow-up, $40 for the 6-month follow-up, and $50 for the 12-month follow-up assessments. In addition, they received $10 for completion of weekly treatment assessments. These amounts varied by site, depending on local research study comparability.

Statistical Methods

The demographic information and severity of symptoms at baseline between the two treatment groups were compared with the *t* test for continuous variables and the chi-square test for categorical variables.

The overall data analytic strategy used was applied similarly for each of four models examining each of the four main outcome variables. The main outcome variables were PSS-SR severity, total CAPS severity, a continuous measure of the number of days participants used drugs or alcohol during the past 7 days, and self-reported abstinence in the prior 7 days confirmed with urine and saliva tests. First, generalized linear models (with identity link function for normal data) were used to examine the effect of treatment group (Seeking Safety vs. WHE) on the primary outcome measures over time for the intention-to-treat sample of all randomized participants. All outcome measures were obtained at baseline, weekly during the treatment, 1 week posttreatment, and over the follow-up period, with the exception of the CAPS, which was not conducted during treatment. We modeled each of four outcomes as a function of treatment, time of assessment, and baseline value of that outcome (before randomization). All models included preselected baseline covariates: race/ethnicity, age, and education level. Preliminary analyses examined potential additional covariates (frequency of services utilization during treatment as a measure of treatment as usual, medication use, and duration of time in the active treatment phase), but none were found to be significantly different across Seeking Safety and WHE groups, and none were included in the primary outcome analyses. The possible interactions among treatment, the baseline level of the outcome measure, and time were tested and were included in the final model only if statistically significant ($p < .05$) with backward elimination procedures. Time was defined as the assigned week of the treatment not the actual week of treatment. Baseline was Time 0. The first assigned treatment was Week 1. The generalized estimating equations (Diggle, Liang, & Zeger,

1994) were used to estimate and test the models. The generalized estimating equations methodology is able to handle correlated data arising from repeated measurements, requires no parametric distribution assumption, and provides robust inference with respect to misspecification of the within-subject correlation. This analysis also allows for examination of continuous and categorical data, which may be missing for some participants either because of a missed session or dropout; thus, complete information for all participants is not needed. All inferences from incomplete or missing data are presumed valid provided that the data are missing at random (Little & Rubin, 2002). Because the two treatments did not differ in treatment attendance, study retention, or follow-up completion, the inference for the treatment effect was valid.

The outcome measures were heterogeneous across the small number of sites, and testing differences in treatment effects among the clinical sites was desired; thus, the site was always tested as an additional fixed effect in each of the four models. The models also included an indicator of the study phase (during intervention vs. follow-up) and possible interactions with treatment and time of assessment, except for the model predicting total CAPS score because the CAPS was not assessed during treatment. Comparisons between the two groups during the intervention phase (Week 1 to 1 week posttreatment) and during follow-up (3, 6, and 12 months posttreatment) were made with contrast statements. The study was powered to detect small-to-medium primary outcome effects ($d = .3$; see Brown & Prescott, 1999; Raudenbush & Liu, 2000), and power analyses were performed with S-Plus 6 (Insightful Corporation, 2001) with $\beta = 0.8$ and $\alpha = .05$. No corrections were made for multiple dependent variables.

As an a priori subgroup analysis, models were also fit to examine the effect of treatment assignment on the participants who completed at least six of the intervention sessions, defined at the point of study design as having received at least minimal exposure to the intervention (minimal attendance analysis). The participants' weekly PSS-SR severity score was added as a time-dependent covariate to the generalized linear model for the participants' abstinence status of drug use described earlier. PROC GENMOD in SAS 9.1.3 (SAS Institute, 2003) was used to conduct all analyses.

Results

Study Sample

Figure 1 shows the patient flow from screening through 12-month follow-up. A total of 353 women met all eligibility criteria and were randomized into the study. Table 1 presents demographic, psychiatric, and trauma-related characteristics of the sample. The average age of the sample was 39.2 years. Of the participants, 45% were Caucasian, and 34.0% were African American. Almost 18% were married, and 41.1% lived with a partner. More than half (55.0%) were unemployed. They had received an average of five previous courses of treatment for alcohol or drug abuse before enrolling in this study. About one quarter of participants (25.6%) were in a controlled environment in the 30 days prior to study enrollment. All participants met *DSM–IV* criteria for either full (80.4%) or subthreshhold PTSD (19.6%). The most frequently diagnosed substance use disorder was cocaine dependence (70.5%), followed by alcohol (56.1%), marijuana (27.2%), and opioid dependence (25.6%).

The average CAPS total score among all participants was 62.9 ($SD = 19.4$), consistent with a severe level of PTSD symptoms at baseline (Weathers et al., 2001). A summary of lifetime exposure to traumatic events revealed that the majority of participants had experienced physical abuse (84.8%) or sexual abuse (67.6%) during adulthood. Very high rates of childhood abuse histories (70.1% sexual and 58.7% physical abuse) were also reported. Many of the participants reported other traumatic experiences, including transportation accidents (72.7%) and a life-threatening illness (39.8%). There was no significant difference between the two treatment groups on any demographic or baseline diagnostic characteristics.

Treatment Attendance and Study Retention

The median time from randomization to first treatment was 7 days. Overall, 81.9% ($n = 289$) of participants attended at least 1 group treatment session. Over half ($n = 199$, 56.4%) completed at least 6 treatment sessions ($n = 43$, 12.2% completed all 12 sessions). The average number of sessions completed was 6.2 ($SD = 4.5$) in the Seeking Safety group and 6.0 ($SD = 4.3$) in the WHE group. Participants also received treatment as usual during the treatment phase of the study. During treatment, participants attended, on average, about 1.5 mental health visits per week ($M = 1.3$, $SD = 1.6$, for Seeking Safety; $M = 1.5$, $SD = 2.7$, for WHE) and attended three 12-step meetings ($M = 3.4$, $SD = 4.1$, for Seeking Safety; $M = 2.8$, $SD = 3.7$, for WHE) in addition to study treatment. A total of 248 (70.3%) participants had at least 1 visit during the follow-up phase, and 64 participants (18.1%) had no visits following randomization. Again, the two treatment groups did not differ on treatment attendance, other service utilization, study retention, or follow-up completion over the course of the study.

Counselor and Supervisor Fidelity

Seeking Safety supervisors rated a total of 257 counselor sessions. The mean standardized score (based on a 5-point Likert scale) on the Seeking Safety Adherence Scale (Najavits & Liese, 2004) was 3.8, representing an acceptable level of counselor adherence. The internal consistency reliability of the total scale was .82, which is excellent, and the average measure reliability (intraclass correlation) was good (.73). WHE supervisors rated a total of 193 counselor sessions. The mean adherence score was 4.0 out of a possible 5-point scale, corresponding to a rating of *good* on the adherence scale. The internal consistency reliability was .98, considered excellent, and average measure reliability (intraclass correlation) was good (.77).

PTSD Outcomes

PSS-SR severity. The PSS-SR severity score across the trial period is shown in Figure 2 and summarized in Table 2. In the final model, there was a significant Study Phase × Treatment × Time interaction effect, $\chi^2(1) = 4.18$, $p < .05$, on PSS-SR outcomes over the course of the study, which indicated that the Treatment × Time effect on participants' PSS-SR score was different between the 6-week intervention period and the follow-up period. The final model for PSS-SR severity included age, education, race/ethnicity, site, baseline PSS-SR severity, treatment, study phase (treatment week vs.

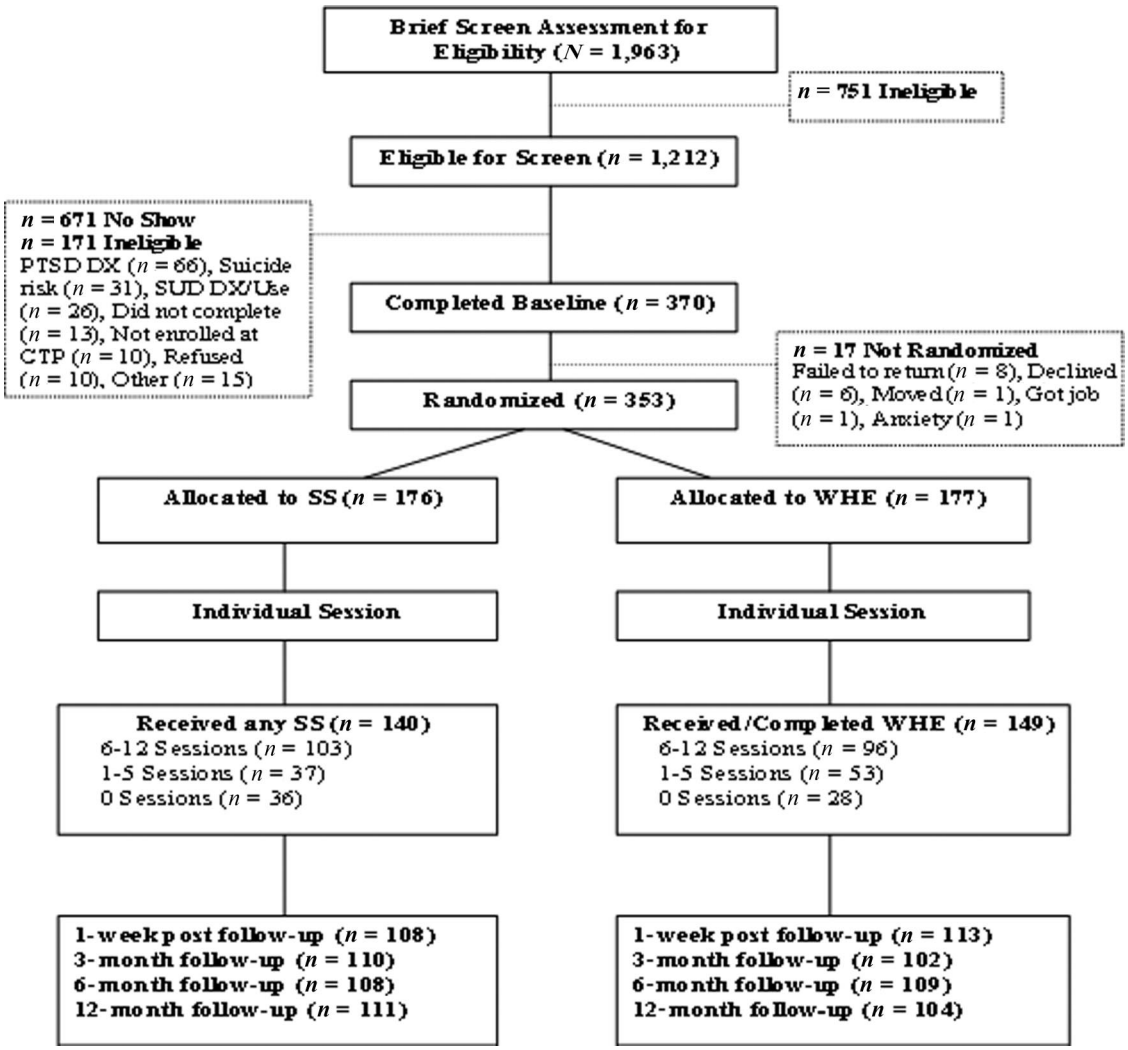

Figure 1. CONSORT diagram of participant flow through the protocol. SS = Seeking Safety; WHE = Women's Health Education; PTSD = posttraumatic stress disorder; DX = diagnosis; SUD = substance use disorder; CTP = community-based substance abuse treatment program.

follow-up), a two-way PSS-SR Severity × Treatment Week interaction, a two-way Treatment Week × Follow-Up interaction, and a three-way Treatment Week × Follow-Up × Treatment interaction as a result of a backward elimination. Significant effects included education, $\chi^2(1) = 4.62$, $p < .05$, and site, $\chi^2(6) = 27.29$, $p < .001$ (in one site, baseline PSS-SR severity was significantly higher than in the rest of the sites, which did not statistically differ from one another). During the 6-week treatment phase, the mean value of PSS-SR severity in both groups decreased. Participants in the WHE group showed more reduction in PSS-SR severity than those in Seeking Safety group during the first week. After the first week, the mean value of PSS-SR severity in the Seeking Safety group decreased significantly more quickly than in the WHE group, $\chi^2(1) = 3.85$, $p = .05$. By the end of treatment (1 week posttreatment), there was no significant difference in mean PSS-SR severity between the Seeking Safety and WHE groups ($M = 32.7$, $SD = 13.9$, for Seeking Safety vs. $M = 33.8$, $SD = 15.1$, for WHE; $p = .59$). The PSS-SR severity score continued to decrease in both groups during the follow-up phase, but this was at a significantly slower rate compared to the treatment phase, $\chi^2(1) = 7.99$, $p < .01$. By the end of the 12-month follow-up period, the two groups showed no differences in mean PSS-SR severity ($M = 29.2$, $SD = 14.3$, for Seeking Safety vs. $M = 29.1$, $SD = 15.5$, for WHE; $p = .97$). The Baseline PSS-SR Severity × Time interaction was also significant, $\chi^2(1) = 9.96$, $p < .01$, such that participants with higher baseline PSS-SR severity improved more quickly than those with lower baseline PSS-SR severity during the treatment.

CAPS total. In the final model, the analysis revealed no treatment effect on CAPS total score, $\chi^2(1) = 0.07$, $p = .78$. The final model for CAPS total included age, education, race/ethnicity, site, baseline CAPS total, treatment, and time as a result of the backward elimination method. Significant effects included site, $\chi^2(6) = 43.08$, $p < .001$, baseline CAPS total, $\chi^2(1) = 42.27$, $p < .001$, and time, $\chi^2(1) = 57.87$, $p < .001$. At baseline, the average CAPS

Table 1
Baseline Participant and Diagnostic Characteristics by Treatment Group for the Intention-to-Treat Sample (N = 353)

Variable	Total	Seeking Safety ($N = 176$)[a]	Women's Health Education ($N = 177$)[a]
Age[b]	39.2 (9.3)	39.3 (9.5)	39.0 (9.1)
Race/ethnicity[b]			
African American/Black	34.0	33.0	35.0
Caucasian	45.6	47.16	44.1
Latina	6.5	3.98	9.0
Multiracial	13.3	15.34	11.3
Other	0.6	0.6	0.6
Marital status			
Married	17.6	14.8	20.3
Single	36.8	37.5	36.2
Divorced/separated	45.6	47.7	43.5
Years of education[b]	12.5 (2.4)	12.7 (2.3)	12.4 (2.6)
Employment			
Employed	40.2	40.3	40.1
Unemployed	55.0	54.6	55.4
Student/retired/disabled	4.8	5.1	4.5
Prior alcohol/drug treatment episodes	5.0 (7.9)	5.1 (7.4)	5.0 (8.2)
Controlled environment (past 30 days)	25.6	28.2	23.0
Currently prescribed psychotropic medication[c,d]	44.8	45.5	44.1
Current substance abuse or dependence diagnosis			
Cocaine	70.5	72.7	68.2
Stimulants	7.7	8.5	6.8
Opiates	25.6	25.6	25.6
Marijuana	27.2	27.8	26.6
Alcohol	56.1	59.7	52.5
Current alcohol abuse or dependence diagnosis only[d]	8.8	8.5	9.0
Baseline 7-day abstinent rate	46.2	44.1	46.9
PTSD diagnosis (% full)	80.4	76.7	84.2
CAPS severity, total	62.9 (19.4)	61.6 (19.36)	64.2 (19.4)
Lifetime traumatic experiences			
Child physical abuse	58.7	61.1	56.3
Adult physical abuse	84.8	83.4	86.2
Child sexual abuse	70.1	73.6	66.7
Adult sexual abuse	67.6	65.1	70.1
Transportation accident	72.7	72.2	73.3
Life-threatening illness	39.8	41.5	38.1
Exposed to violent death	19.3	16.5	22.2

Note. Values are either means (with standard deviations) or percentages. PTSD = posttraumatic stress disorder; CAPS = Clinician Administered PTSD Scale.
[a] There were no statistical differences between treatment groups on any variable. [b] The variables were used as covariates in the models. [c] Psychotropic medication was defined as medication prescribed for an emotional, psychological, or psychiatric purpose to include depression, anxiety, psychosis, mood stabilization, or sleep disturbance. [d] Variables included in randomization stratification.

total score was 61.6 ($SD = 19.4$) for the Seeking Safety group and 64.2 ($SD = 19.4$) for the WHE group. Posttreatment, the mean CAPS total score in both the Seeking Safety and the WHE group decreased from baseline ($M = 31.7$, $SD = 23.4$, vs. $M = 32.7$, $SD = 23.4$); $t(215) = 20.1$, $p < .001$. Thus, clinically significant reductions (i.e., 30 or more scale points) were attained for 47.7% of those in the Seeking Safety group and for 45.9% of those in WHE group. The baseline CAPS total score was a strong predictor of outcome whereby higher baseline CAPS total scores predicted higher CAPS total scores throughout the study. Site was also a significant predictor of outcome, such that two of the sites differed statistically from the rest in CAPS scores at each time point, $\chi^2(6) = 43.08$, $p < .001$, with one having higher and one having lower scores.

Substance Use Outcomes

Seven-day abstinence from any illicit drug or alcohol use. In the final model, there were no treatment-specific effects evident on abstinence rates. The final model for abstinence rates included age, education, race/ethnicity, site, baseline abstinence status, treatment, time, study phase (treatment week vs. follow-up), and a Study Phase × Time interaction. Significant effects included baseline abstinence status, $\chi^2(1) = 48.59$, $p < .001$, and site, $\chi^2(6) = 45.28$, $p < .001$ (one was significantly lower and two were significantly higher than the remaining four sites). Throughout the trial, the 7-day abstinence rate of any illicit drug or alcohol use was not significantly different between the two treatment groups. The baseline abstinence rates were 45% and 47%, respectively, for Seeking Safety and WHE.

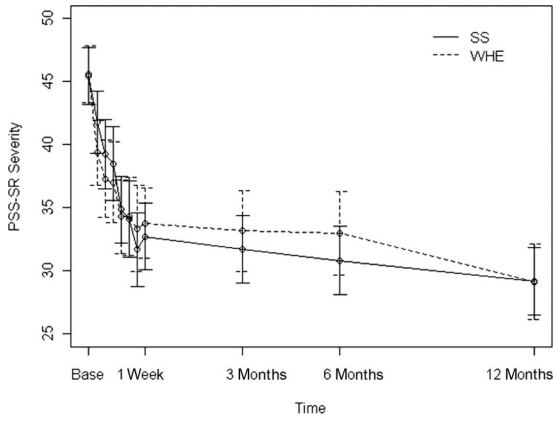

Figure 2. Mean (with 95% confidence interval) Post-Traumatic Stress Scale–Self-Report (PSS-SR; Foa et al., 1993) severity at baseline, at 1-week posttreatment, and at 3-, 6-, and 12-month follow-up for the intention-to-treat sample ($N = 353$). *Study phase* refers to time in treatment (baseline to 1-week posttreatment) versus the follow-up period (3, 6, and 12 months posttreatment). There is a significant Study Phase × Treatment × Time interaction effect, $\chi^2(1) = 4.18$, $p = .04$. SS = Seeking Safety; WHE = Women's Health Education.

By 1 week posttreatment, these rates slightly increased to 54% and 55%, but this change was not statistically significant. At the 12-month follow-up, lower abstinence rates (43% for Seeking Safety and 41% for WHE) were noted in comparison to baseline levels.

Percentage of days using drugs or alcohol. In the final model, no treatment effects were observed on number of days participants used drugs or alcohol. The final model for days of use included age, education, race/ethnicity, baseline days of use, site, treatment, time, and a Baseline Days of Use × Time interaction. Significant effects included a two-way Baseline Days of Use × Time interaction, $\chi^2(9) = 27.40$, $p < .001$, whereby the effect of baseline drug use at Week 1 was stronger than effects in other weeks, and site, $\chi^2(6) = 15.53$, $p = .02$, whereby in one site the baseline number of days of use was higher, and in two sites it was lower. Because the number of days using drugs or alcohol was recorded as the number of days since last assessment and because the time intervals between two assessment times varied during treatment, the percentage of days of use was used in the model. Because there was no clear linear time trend for the number of days with drug or alcohol use, time was treated as a categorical variable. At baseline, the average number of days with drug or alcohol use over the prior 7 was 1.66 days ($SD = 2.56$) for the Seeking Safety group and 1.60 days ($SD = 2.52$) for the WHE group. After receiving 6 weeks of treatment, fewer days with drug or alcohol use during the prior 7 were reported in both groups, with 0.80 days per week for the Seeking Safety group and 0.78 days per week for WHE, but this effect was not statistically significant. During the follow-up period, the number of days with drug or alcohol use increased, but again this effect was not statistically significant. At the 12-month follow-up, the average number of days with drug or alcohol use in the prior 7 returned to baseline levels: 1.65 days per week (Seeking

Table 2
Relevant Means, Standard Deviations, Odds Ratios, Confidence Intervals, and Effect Sizes for the Primary PTSD and Substance Use Outcomes for the Intention-to-Treat ($N = 353$) and Minimal Attendance Samples ($N = 199$) at Baseline (Based on Raw Data), 1 Week Posttreatment, and Over the Follow-Up Study Period (Model Based)

	ITT analysis			Minimal attendance analysis		
Outcome	Baseline	1 week posttreatment	Average over follow-up	Baseline	1 week posttreatment	Average over follow-up
PSS-SR						
SS	45.4 (15.3)	32.7 (13.9)	30.0 (13.0)	45.8 (15.7)	32.6 (14.1)	29.8 (12.9)
WHE	45.6 (15.3)	33.8 (15.1)	32.0 (15.0)	47.0 (15.8)	34.9 (15.8)	31.7 (14.7)
ES	0.01	0.07	0.15	0.08	0.15	0.14
CI	−0.17, 0.18	−0.10, 0.26	−0.05, 0.30	−0.11, 0.24	−0.04, 0.32	−0.05, 0.30
CAPS						
SS	61.6 (19.4)	31.7 (23.4)	24.3 (22.1)	63.3 (19.8)	32.0 (23.8)	24.1 (21.9)
WHE	64.2 (19.4)	32.7 (23.4)	27.1 (23.4)	63.7 (20.2)	34.9 (22.8)	27.0 (22.8)
ES	0.14	0.04	0.12	0.02	0.12	0.13
CI	−0.05, 0.31	−0.14, 0.23	−0.05, 0.31	−0.15, 0.20	−0.06, 0.30	−0.04, 0.30
Abstinence rate						
SS	45%	54%	46%	48%	51%	45%
WHE	47%	55%	43%	51%	57%	43%
OR	0.96	1.05	1.04	1.15	1.28	1.04
CI	0.71, 1.65	0.62, 1.78	0.94, 1.16	0.66, 2.00	0.69, 2.34	0.93, 1.16
Days of drug use						
SS	1.7 (2.6)	0.8 (1.8)	1.4 (2.1)	1.5 (2.5)	0.8 (1.7)	1.4 (2.2)
WHE	1.6 (2.5)	0.78 (1.8)	1.5 (2.1)	1.4 (2.5)	0.5 (1.6)	1.5 (2.1)
ES	0.02	0.01	0.07	0.02	0.15	0.03
CI	−0.16, 0.20	−0.17, 0.19	−0.11, 0.24	−0.15, 0.19	−0.04, 0.32	−0.14, 0.20

Note. PTSD = posttraumatic stress disorder; PSS-SR = Post-Traumatic Stress Scale–Self-Report (Foa et al., 1993); SS = Seeking Safety groups; WHE = Women's Health Education groups; ES = effect size; CI = confidence interval; CAPS = Clinician Administered PTSD Scale (Blake et al., 1995); abstinence rate = biologically confirmed yes/no for 1 week postassessment; OR = odds ratio; days of drug use = number of days of biologically confirmed self-reported use over the previous 7 days prior to assessment.

Safety) and 1.68 days per week (WHE), respectively. The most significant predictor of percentage of days of drug or alcohol use at follow-up was the baseline number of days of use.

Minimal attendance analysis. During the 6-week treatment, over half ($n = 199$, 56.4%) completed at least six treatment sessions (59% for Seeking Safety and 54% for WHE). After fitting the same models as intention-to-treat analyses, the results were similar for all main outcomes except CAPS. For participants who attended at least six group sessions, a statistically nonsignificant but notable main treatment effect on CAPS total score was observed, $\chi^2(1) = 3.13$, $p = .08$, effect size = .22, after controlling for the baseline CAPS total scores; the corresponding result for intention-to-treat analysis was, $\chi^2(1) = 0.07$, $p = .78$. The Seeking Safety group showed an overall lower CAPS total score compared with the WHE group throughout the follow-up period, but this difference was not at a level of statistical significance.

Discussion

Implications of Main Effectiveness Findings

Despite the widespread recognition of the prevalence and adverse prognostic implications of trauma and trauma-related disorders among women in treatment for substance use disorders, treatment research on this problem has been limited. This study, the largest randomized clinical trial of a trauma-focused behavioral therapy for women with co-occurring substance use disorder, compared the effects of a trauma-focused group therapy, Seeking Safety, to an attention control group, WHE, among women enrolled in community-based substance abuse intensive outpatient treatment programs across the United States. Both treatments were associated with large and clinically significant reductions in PTSD symptoms, which occurred rapidly during the acute treatment phase and were sustained over 12 months of follow-up. There were no overall differences in PTSD outcomes between the treatments, but among those who had a minimally adequate exposure (minimal attendance) to treatment, there was a trend toward lower symptom severity posttreatment on one clinician-rated measure (CAPS). It is important not to overstate the apparently different findings for clinician-rated versus self-reported PTSD symptoms. The CAPS result, even for participants who received minimal treatment or greater, was at a notable, but statistically nonsignificant level. In addition, the PSS-SR means were in the same direction, although they were not significant, and the effect sizes for Seeking Safety versus WHE differences postbaseline were similar. Previous treatment studies have varied regarding agreement between clinician- and patient-rated symptoms (Forbes, Creamer, & Biddle, 2001; Monson et al., 2008). In the current study, there were no overall effects of time or treatment on substance use outcomes.

This study was designed to contain the essential features of a rigorous efficacy trial. Both Seeking Safety and WHE were manual guided. The active comparison condition was intended to be clinically credible and to provide equivalent professional time and attention, isolating the specific elements of the focus on trauma, substance abuse, and their interaction from nonspecific elements of treatment engagement and therapeutic alliance. Clinicians delivering the interventions were carefully trained, supervised, and monitored for fidelity to the treatment manuals. Although there had been various prior studies of Seeking Safety (including four with control conditions), the current study extends the prior literature in its larger sample size and more rigorous methodology. Prior studies had consistently evidenced significant superiority of Seeking Safety compared to treatment-as-usual controls (Desai et al., 2008; Gatz et al., 2007; Hien et al., 2004; Najavits et al., 2006), high acceptability of the treatment, and significant improvements in trauma-related symptoms, substance use, and associated problem areas. In the only other randomized controlled trial (Hien et al., 2004) comparing Seeking Safety to an active treatment control (cognitive–behavioral relapse prevention), both arms achieved equivalent positive outcomes and were superior to a treatment-as-usual community control.

Results of the present study are similar to the prior randomized controlled trial (Hien et al., 2004) in that Seeking Safety and the attention control were associated with substantial but similar reductions in PTSD symptoms. The present trial does show a very modest indication for superiority of the trauma-focused approach in Seeking Safety—PTSD symptom scores declined more rapidly in Seeking Safety during treatment and tended to be lower at a clinically significant level at the end of treatment among those with at least minimal treatment attendance. This should encourage further treatment-development research in an effort to enhance the efficacy of the trauma-focused approach for women with PTSD and substance abuse. Steps to consider include the following: (a) incorporating additional behavioral interventions for PTSD, such as exposure therapy (e.g., Foa et al., 1991); (b) combining behavioral treatment with medications shown to be effective for PTSD, such as selective serotonin reuptake inhibitor antidepressants (e.g., Brady et al., 2005); (c) incorporating strategies to improve adherence to treatment, such as voucher incentives for attendance (Petry & Martin, 2002); and (d) testing longer term treatment models to determine whether the impressive trajectory of improvement observed during the 6-week treatment (Figure 2) could be extended, resulting in even greater reductions in symptoms over follow-up. The latter would be consistent with McLellan, Lewis, O'Brien, and Kleber's (2000) argument that substance abuse is a chronic illness for which long-term treatment models are needed.

Considerations for Implementation and Study Effectiveness

Seeking Safety was originally developed as a 25-session treatment. For this study, the number of sessions was reduced to 12, to create a treatment model considered to be feasible given the limitations of counselor time and reimbursement under which community-based treatment programs in the United States currently operate. However, this change could have attenuated the effectiveness of Seeking Safety. Given that Seeking Safety was designed for group or individual modality, our findings underscore that group modality is feasible and can produce comparable results to an active comparison condition.

The improvement in PTSD symptoms observed among participants in the WHE comparison group is intriguing and should not be overlooked. WHE may have been more than a nonspecific control, rather acting as an active comparison group. The impact of trauma on the body is now well known (e.g., van der Kolk et al., 1996), and a number of treatments have proliferated that address body issues as a central feature of recovery from traumatic stresses (Fitch & Dryden, 2000; Price, 2005). It is plausible that the

material presented in WHE was relevant to trauma survivors' understanding of their body and how to think about proper self-care. WHE was also conducted in a group format, and qualitative feedback suggested it enjoyed strong support from staff and participants. Future treatment-development efforts should consider incorporating some of these potential strengths of the body-centered health model of WHE.

When treating patients with combined PTSD and substance abuse, a prevailing clinical concern has been that discussion of past trauma or PTSD symptoms could increase arousal and stress and could either exacerbate substance use or cause patients to flee treatment. There was no evidence for such phenomena in the present data. PTSD symptoms improved during trauma-focused treatment (Seeking Safety), and there was no increase in either treatment-as-usual dropout or adverse events in Seeking Safety compared with the WHE active comparison (see Killeen et al., 2008, for a separate review of these findings). This should further encourage treatment-development efforts for trauma-focused treatments, although providing effective coping skills for the dysphoria and arousal associated with traumatic memories should remain a priority. Seeking Safety, as currently designed, does not contain explicit elements of exposure therapy. If exposure techniques are tested among patients with comorbid PTSD and substance use disorder, there should be careful attention to the management of arousal and its impact on substance use and treatment retention.

Study Limitations

The absence of a treatment-as-usual or minimal-treatment control group is a design limitation that restricts causal interpretations of the impact of the specific elements of Seeking Safety and WHE treatments on PTSD outcomes. However, our prior randomized controlled trial showed no improvement in PTSD symptoms over time in a community control (Hien et al., 2004). Other controlled and/or randomized trials of Seeking Safety compared to treatment as usual have favored Seeking Safety (Desai et al., 2008; Gatz et al., 2007; Najavits et al., 2006). One large, quasiexperimental study compared outcome for clinical programs that were implementing integrated treatment for trauma and substance abuse with outcomes for other programs selected as matched controls and providing treatment as usual (Morrissey et al., 2005). This study showed only a 15% to 20% reduction in PTSD symptoms for the control programs over a 12-month follow-up (Morrissey et al., 2005) compared with the 35% to 40% reductions observed here. (In that study, Seeking Safety was used by four of the nine sites.) Notably, in the present study, although participants were enrolled in intensive outpatient programs, most had a relatively low dose of treatment as usual (on average one mental health or substance abuse session per week). Taken together, these findings suggest that the improvements in PTSD symptoms observed in Seeking Safety and WHE are less likely to have been attributable to contact with the research team, the passage of time, or treatment as usual. In a context where treatment as usual is more intensive, the effects of these groups may be attenuated.

A second possible explanation for the present findings is that observed improvements in PTSD symptoms were due to nonspecific elements of manual-guided treatments, such as attention from therapists, treatment alliance, or membership in a supportive group of women who shared a history of trauma and PTSD, rather than to the specific elements of Seeking Safety and WHE. However, as discussed earlier, it may be that Seeking Safety and WHE each have unique active elements. Again, future research should examine whether a more powerful treatment would result from combining elements of both or whether patient-level predictors can be found that would help match patients to these contrasting behavioral approaches.

Another important finding is the lack of improvement in substance use outcomes in either Seeking Safety or WHE. Abstinence and lower levels of substance use at baseline predicted abstinence and level of substance use over treatment and follow-up. Substance use at baseline for participants in this study was not as high as typically seen at treatment entry, with nearly 50% of participants abstinent and a mean of 2 days of drug use in the week prior to baseline. However, in contrast to this study, all other studies of Seeking Safety showed significant reductions in substance use. Participants in the current study were at various points in their treatment: Some had just entered outpatient treatment from inpatient care, some came from detoxification, some were beginning outpatient treatment at approximately the same time they entered the study, and some were already enrolled and receiving outpatient services. This variation and an inclusion criterion of substance abuse or dependence at some point in the prior 6 months may have contributed to the high level of recent (1 week) abstinence. This criterion was adopted to allow for the variety of circumstances under which women may enter outpatient treatment (i.e., from detoxification, inpatient treatment, or jail or as a result of legal or employment consequences that were recently brought to bear even though the woman may have discontinued use at an earlier time). Although potentially limiting power to observe treatment effects on substance use outcomes, including women with recent abstinence does reflect real variation in the population seen in community-based treatment and thus does not diminish ability to generalize from these results to community treatment populations. A conceptual model for this study was that substance use and PTSD are causally linked and that therefore effective treatment of PTSD would result in less substance use. However, the absence of robust differences in PTSD outcome between Seeking Safety and WHE limits our ability to assert this mediated model.

With seven study sites, the sites were treated as a fixed effect in the statistical analyses rather than as a random effect. As such, generalizations of the findings beyond the present sample of treatment programs to a larger population of community-based treatment programs must be made with caution. This study may also have limited generalizability to ethnic populations with less representation in this sample, such as Latina women. Also, because the predominant substances used by participants were cocaine and alcohol, findings may not generalize to those with different or less chronic substance use disorders. One additional limitation related to generalizability is the large number of participants who were eligible after the initial brief screen (assessing gross eligibility) but who did not attend the screening interview ($n = 671$). Specific data were not available about why these participants did not attend the screening interview but could perhaps shed light on the acceptability of the study for a subpopulation of clients.

Four other limitations are worth noting. First, the study achieved lower follow-up rates relative to previous work with similar populations (Hien et al., 2004; Morrissey et al., 2005). There is no evident bias in attrition from follow-up (Seeking Safety vs. WHE

differences), but it is possible that there is an unmeasured source of bias relating to attrition. Second, it is unknown how the high level of monitoring (for an effectiveness trial) of intervention delivery in this trial affected outcome. A generally untested assumption is that fidelity monitoring improves outcome. If this is the case, interventions such as these would be expected to perform less well under the typical constraints found in community treatment programs (e.g., availability of supervisory time, videotaping treatment sessions). Third, a lack of information on duration of treatment involvement prior to study enrollment limited the ability to control for the effect of current treatment episode length on the association between study intervention and trauma and substance use symptoms. Finally, the analytic approach to potential group cohort effects did not account for clustering within groups, as has been addressed recently by Morgan-Lopez and Fals-Stewart (2006); such analyses may reveal findings that are not in line with the ones reported herein.

Future Directions

This study adds to an emerging body of literature showing the promise of community-based treatments for psychiatric outcomes (e.g., the Substance Abuse and Mental Health Services Administration's study Women, Co-Occurring Disorders and Violence; Morrissey et al., 2005). It also adds to the existing outcome literature on Seeking Safety in representing the largest and most rigorous trial of that model. Future treatment-development research with Seeking Safety should consider conducting groups in varying contexts of treatment as usual (i.e., less intensity vs. high intensity), testing the full 25-session dose of Seeking Safety, examining Seeking Safety in combination with other behavioral treatments for PTSD, and adding a pharmacological intervention to improve impact on PTSD and substance use. This study suggests that the addition of gender-specific treatment for women with co-occurring substance use disorder and PTSD can have a significant effect on trauma symptom reduction for a subset of patients. The pattern of our findings (e.g., nearly half of all patients did not have clinically significant change on PTSD scores, and there were no differences on abstinence rates overall) underscores that therapy groups such as these continue to require future treatment development to provide a better understanding of the complex needs of this patient population.

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