Seeking Safety treatment for male veterans with a substance use disorder and post-traumatic stress disorder symptomatology

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ABSTRACT

Aims To determine whether substituting Seeking Safety (SS), a manualized therapy for comorbid substance use disorders (SUD) and post-traumatic stress disorder (PTSD) for part of treatment-as-usual (TAU) improves substance use outcomes. Design Randomized controlled effectiveness trial. Settings Out-patient Veterans Administration Health Care System SUD clinic. Participants Ninety-eight male military Veterans with a SUD and co-occurring PTSD symptomatology. Measurements Drug and alcohol use and PTSD severity, measured on the first day of treatment, and 3 (i.e. the planned end of SS sessions) and 6 months following the baseline assessment. Treatment attendance and patient satisfaction were measured following treatment (3-month follow-up). Active coping was measured at treatment intake and following treatment. Findings SS compared to TAU was associated with better drug use outcomes ($P < 0.05$), but alcohol use and PTSD severity decreased equally under both treatments ($P's < 0.1$). SS versus TAU was associated with decreased treatment attendance, client satisfaction and active coping (all $P's < 0.01$). However, neither these factors nor decreases in PTSD severity mediated the effect of treatment on drug use. Conclusions The manualized treatment approach for substance use disorder, Seeking Safety, is well received and associated with better drug use outcomes than 'treatment as usual' in male veterans with post-traumatic stress disorder. However, the mechanism of its effect is unclear.

Keywords Dual diagnosis, post-traumatic stress disorder, PTSD, seeking safety, substance abuse, substance use disorder, therapy.

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INTRODUCTION

Post-traumatic stress disorder (PTSD) interacts directly with substance use disorders (SUD) to worsen SUD symptoms and make recovery less likely [1]. Estimates suggest that 35–50% of people with a current diagnosis of SUD have comorbid PTSD: a much higher percentage than the general population [2,3]. Patients with SUD and PTSD present with greater drug use severity [4] and show poorer SUD treatment outcomes [1] than patients with SUD without PTSD. Research suggests that an exacerbation of PTSD symptoms is the most important factor in predicting relapse following substance abuse treatment among patients with comorbid PTSD [4]. Interventions that successfully address the negative impact of comorbid PTSD could improve SUD outcomes significantly for a substantial proportion of SUD patients.

This randomized controlled effectiveness trial investigated whether Veterans with a SUD and co-occurring PTSD symptomatology in a US Veterans Health Administration (VA) out-patient specialty SUD program would benefit from a specialized treatment track for these comorbid disorders. The VA runs the largest substance use disorder treatment program in the world, and the high prevalence of PTSD and SUD in returning Veterans from Operation Enduring Freedom/Operation Iraqi
Freedom (OEF/OIF) has increased US priority on developing effective treatment options for these comorbidities [5]. We assigned patients randomly to receive treatment-as-usual (TAU) or a Seeking Safety (SS), a present-focused, manualized, cognitive–behavioral integrated treatment for PTSD and SUD, designed for both genders [6]. Its primary goal is to reduce both PTSD and SUD by focusing on safe coping skills addressed through cognitive, behavioral, interpersonal and case management domains. The special treatment track substituted SS groups and case management for the clinic’s core substance use-focused group therapy and case management sessions.

SS outcomes have been reported in 16 previously published studies, most of which included severely disordered clients from vulnerable populations (see [7] for a review). Four of the studies included Veterans [8–12]. Typically, study participants had comorbid PTSD/SUD symptoms for years, a history of multiple traumas starting in childhood, substance dependence and additional co-occurring psychiatric disorders. Results were consistently positive across studies, with significant reductions in SUD and improvement over comparison conditions. However, these studies were limited by factors such as small sample sizes, poor follow-up rates and/or uncontrolled pilot and non-equivalent control designs. Furthermore, two studies utilizing elements of an efficacy trial found that SS and an active comparison treatment led to similar reductions in substance use and PTSD symptoms in women drawn from the community [13,14]. We addressed the limitations of previous studies and mixed findings regarding the clinical superiority of SS over comparison treatments by conducting a rigorous randomized trial (RCT) with strong methodology.

METHODS

Trial design

This RCT was designed to test the effectiveness of enhancing VA SUD treatment programs by using SS in a special track for patients with co-occurring PTSD symptomatology. It is not an RCT of the efficacy of the SS program per se, but rather an RCT of how SS fares when incorporated into a front-line practice setting. Treatment dosage was identical with SS groups offered at the same time and amount as core TAU groups. However, groups differed in two respects: (i) all patients in SS groups had co-occurring PTSD symptomatology, while TAU groups included patients with and without PTSD symptomatology; and (ii) SS groups were smaller because they did not include patients without PTSD. The trial used a parallel design with a 1:1 allocation ratio. The only change to methods after trial commencement was the inclusion of individuals who screened positive for PTSD but did not meet full criteria (n = 9), in addition to individuals meeting full criteria for PTSD. Including all patients who screened positive for PTSD was deemed to be more feasible for clinical implementation in a busy out-patient SUD treatment program.

Randomization

The study project manager assigned participants to groups. Participants were stratified on partnered status, OEF/OIF participation and use of illicit drugs based on previous findings suggesting that: (i) partnered patients have better SUD outcomes [15]; (ii) those with recent rather than chronic PTSD are more likely to experience symptom improvement [16]; and (iii) illicit drug use can increase severity of psychosocial problems [17]. Patients were block-randomized within each stratification group. The random allocation sequences were generated by the study statistician and implemented by use of sequentially numbered containers.

Blinding

Patients and care providers were aware of their treatment assignment. Research staff who enrolled participants and conducted outcomes assessment were blind to treatment assignment. To maintain blinding, staff conducting outcomes assessment were password-restricted from accessing data with information regarding treatment assignment, and participants were warned not to divulge information that might compromise blinding during interviews.

Participants

Eligibility criteria were: (i) male Veteran status and VA health-care eligibility; (ii) a diagnosis of any current alcohol or drug use disorder; (iii) having completed an intake for out-patient SUD treatment at the VA Oakland out-patient mental health clinic; and (iv) meeting criteria for current PTSD on a preliminary screen with the primary care PTSD screener [18] and partial (i.e. defined as meeting criteria for two out of three PTSD symptom clusters, or at least one symptom in each symptom cluster [19,20]) or full PTSD in clinical evaluation using the Clinician Administered PTSD Scale (CAPS) [21]. Exclusion criteria were: (i) current participation in other day- or in-patient mental health treatment; (ii) any contraindications communicated by that patient’s primary clinician; and (iii) acute psychosis, mania, dementia or suicidal intent.

Only male Veterans were included in this study because: (i) prior RCTs and controlled trials on SS focused on females (e.g. see [6]); (ii) men have generally been

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excluded in trials of SS; and (iii) in 2010, 96.3\% of patients treated at VA SUD clinics were male.

**Procedures**

The study team recruited participants from a VA outpatient SUD treatment clinic. Patients in the initial phases of treatment were informed of the study and, if interested, were screened for PTSD and exclusion criteria. Participants who screened positive for PTSD and did not meet exclusion criteria were randomized into one of two treatment conditions. All but two participants met diagnostic criteria for full or partial PTSD based on the CAPS; these two were excluded from analyses. Additionally, if patients met exclusion criteria at any point in the study, they were excluded from the study and data analyses.

**Interventions**

**Clinic TAU**

All new clinic patients started by attending at least three group therapy sessions, which focus on motivational enhancement and encouraging treatment engagement. Participants were recruited from these groups, and received full intake assessments and treatment program planning during this time. Participants then entered twice-weekly ‘recovery’ groups, focusing on building abstinence and, after approximately 90 days of therapy, focusing on maintaining abstinence. As needed, patients attended additional groups on smoking cessation, sobriety support, cocaine recovery, alcohol recovery, dual diagnosis recovery, family therapy, anger management, cognitive behavioral therapy, fitness, relaxation, health education, hepatitis education and developing outside activities. All patients were assigned a case manager, and case management and individual therapy were available as deemed appropriate. Patients made use of clinic services as indicated by their treating clinician or as desired. Participants assigned to TAU attended an average of 9.1 (standard deviation (SD) = 8.5) groups and 2.7 (SD = 3.5) individual TAU treatment sessions during the 3-month trial treatment period.

**SS treatment track**

Participants randomized to the SS condition received TAU with one exception: twice-weekly ‘recovery’ groups were replaced with SS groups led by a psychologist on the research team, and case management was conducted by the psychologist based on the SS manual. Patients in the SS condition made use of other clinic services as needed or desired, consistent with the SS model and standard clinic practice. SS groups were held at the same time as ‘recovery’ groups to ensure that patients substituted SS for these core treatment groups rather than add them on. Patients were encouraged to attend 24 group sessions (3 months of twice-weekly groups) of SS, plus weekly individual case management sessions. SS was conducted as one topic per session, with all topics covered; in keeping with the manual’s flexibility, there was no prescribed sequence to the sessions. Therefore, we utilized rolling admissions to the SS groups, as was conducted in ‘recovery’ groups in the TAU condition. Participants assigned to SS attended an average of 13.3 (SD = 7.9) group and 5.9 (SD = 5.3) individual SS treatment sessions during the 3-month trial treatment period.

The therapists and social workers (Bachelor’s- or Master’s-level of education) who administered TAU had been trained didactically and co-facilitate groups with other providers until they exhibit mastery, as is standard practice in the clinic. The psychologist (PhD-level of education) who administered SS received intensive SS training by a study team member experienced in the use of SS with VA populations. Group therapy sessions were recorded and 20\% were selected randomly for review. A clinical psychologist experienced in SS listened to the selected recordings, scored them using the SS adherence scale [22] and provided feedback and ongoing supervision to the study psychologist to maintain adherence. Close adherence to the SS treatment was maintained, as the mean and standard deviation for adherence across format and content for 67 sessions (mean = 2.3, SD = 0.3) were comparable to those found in other studies [23].

**Measures**

Primary outcomes were drug and alcohol use severity and a secondary outcome was PTSD symptom severity. All outcomes were measured at three time-points: (i) the first day of treatment (i.e. baseline); (ii) 3 months following baseline assessment, corresponding to the planned end of SS or ‘recovery 1’ sessions; and (iii) 6 months following baseline assessment, corresponding to a 3-month post-trial treatment follow-up period.

The Addiction Severity Index (ASI) drug and alcohol composite scores were used to measure past 30 days substance use [24]. The ASI assesses life-time and current use of all major classes of drugs of abuse, history of substance-related problems and history of SUD treatment. To facilitate interpretation, total days of drug use was calculated by summing the number of days that the patient used individual drugs in the last 30 days across all illicit substances. PTSD symptom severity was measured with the Impact of Events Scale—Revised [25].

As potential mediators of the effect of treatment condition on our primary outcome variables, four theoretically relevant factors were measured: (i) attendance of SS- or TAU-specific group and individual sessions by chart
review; (ii) patient satisfaction at 3-month assessment using the Client Satisfaction Questionnaire [26]; (iii) changes in active coping from pre- to post-treatment using four approach-oriented subscales (logical analysis, positive reappraisal, guidance/support and problem solving) from the Coping Responses Inventory [27]; and (iv) changes in PTSD symptom severity from pre-to-post treatment.

Sample size

Statistical power calculations were based upon effect sizes detected in a representative study of SS [28]. The study was ended after 74% of the originally planned sample was obtained. Notably, construction severely limited access to the clinic. However, as this issue affected participants in both treatment conditions, it is unlikely that transportation issues confounded our results.

Statistical methods

To test our primary hypothesis, we investigated treatment condition differences in change of drug and alcohol use and PTSD symptom severity over three time-points. For each outcome, a trajectory for each participant was modeled yielding estimates of each individual’s score at the beginning of treatment (intercept), the individual’s slope and error (the fit of the linear model to participant’s data). Three between-person parameters were also estimated: (i) the average baseline score for all participants; (ii) the average slope over time in the TAU condition; and (iii) the effect of being in SS on the average slope. This last parameter is a measure of change per unit time associated with being in SS after accounting for baseline averages and the non-independence of observations within treatments. Because this was an RCT we did not allow the intercept to vary between treatment groups. The full maximum likelihood estimation method and an unstructured covariance specification were used. All participants who met inclusion and not exclusion criteria and attended an information meeting to be informed of their treatment condition were included in the analysis regardless of their subsequent level of attendance at treatment groups, thus comprising an intent-to-treat analysis.

Through exploratory analyses we investigated potential mediators (treatment attendance, treatment satisfaction, approach coping, PTSD severity) of treatment effects. We tested for mediation by examining established mediation criteria [29]. First, we investigated whether potential mediators were associated with treatment condition by exploring treatment condition differences in variables representing these factors. Secondly, we investigated whether potential mediators were independent predictors of change in drug or alcohol use over three time-points using parallel analyses to those described above. Each potential mediator was used to predict each outcome, with PTSD symptom severity as a covariate and treatment condition excluded from these analyses. Thirdly, if the potential mediator met the first two required criteria, we included it as a covariate in an identical analysis to that used to establish treatment condition differences in drug/alcohol use over time. Reductions in the effects of treatment condition on drug/alcohol use when including a given potential mediator as a covariate would signify partial or full mediation of the treatment effect.

RESULTS

Participant flow

See Fig. 1 for depiction of participant recruitment, allocation to treatment and completion of follow-up. Approximately 125 patients expressed interest in study participation, with 117 participants enrolled formally into the study and randomized to treatment condition. Fifty-nine participants were randomized to SS, five were lost to follow-up between initial assessment and disclosure of treatment assignment and five were withdrawn by study staff because they met exclusion criteria, leaving 49 participants who met inclusion criteria and were treated. Fifty-eight participants were randomized to TAU, six were lost to follow-up between initial assessment and disclosure of treatment assignment and three were withdrawn by study staff because they met exclusion criteria, leaving 49 participants who met inclusion criteria and were treated.

Participants included (n = 98) and not included in the analyses below did not differ in age (t(101) = -0.6, P = 0.53), ethnicity ($\chi^2 = 10.9$, d.f. = 5.0, P = 0.05), housing status ($\chi^2 = 0.1$, d.f. = 1.0, P = 0.94), employment status ($\chi^2 = 0.2$, d.f. = 1.0, P = 0.68), education level ($t_{44} = 0.3$, $P = 0.75$), OIF/OEP status ($\chi^2 = 1.1$, d.f. = 1.0, P = 0.29) or whether they were using alcohol only ($\chi^2 = 0.2$, d.f. = 1.0, P = 0.64). However, significantly more participants included (21.4%) versus not included (0.0%) in analyses were currently married or in a long-term relationship ($\chi^2 = 7.0$, d.f. = 1, P < 0.01). Participants did not differ on demographics, or primary and secondary outcomes at baseline as a function of treatment condition (Tables 1 and 2).

Among participants completing SS, 42 participants (85.7%) completed post-treatment follow-up 1 and 39 participants (79.6%) completed follow-up 2. Among participants completing TAU, 41 participants (83.7%) completed post-treatment follow-up 1 and 35 participants (71.4%) completed follow-up 2. Neither harm nor unintended effects of SS or TAU were observed during the trial.
Outcomes and estimation

Based on examination of plotted data representing drug and alcohol use for each participant, we found that a linear model best accounted for the data (Fig. 2). Means and SD of drug and alcohol composite scores for SS and TAU at each time point are presented in Table 2.

Models examining drug use composite scores estimated average baseline score for all participants at 0.095 [standard error (SE) = 0.008, P < 0.01]. Drug use composite scores did not change significantly over time in the sample as a whole [β = -0.002, SE(β) = 0.002, P = 0.32]. However, SS (compared to TAU) was associated with significantly greater improvement over time [β = -0.005, SE(β) = 0.003, P < 0.05]—suggesting roughly 0.03 points or 3% more improvement over the 6-month study compared to TAU. In terms of total days of drug use in the past 30 days, SS participants experienced a 2.0 (SD = 10.6)-day reduction from a baseline of 5.1 (SD = 10.1), whereas TAU participants experienced a 0.5 (SD = 11.3)-day increase from a baseline of 6.2 (SD = 13.3).

Models examining alcohol use composite scores estimated average baseline score for all participants at 0.234 [SE(β) = 0.023, P < 0.01]. Alcohol use composite scores changed significantly over time in the sample as a whole [β = -0.015, SE(β) = 0.004, P < 0.01]. In contrast, rate of decrease in alcohol use over time did not differ between treatment groups [β = -0.002, SE(β) = 0.005, P = 0.61].

Models examining PTSD scores estimated average baseline score for all participants at 47.1 (SE(β) = 1.84, P < 0.01). PTSD scores changed significantly over time in the sample as a whole [β = -1.89, SE(β) = 0.472, P < 0.01]. In contrast, rate of decrease in PTSD over time did not differ between treatments groups [β = 0.348, SE(β) = 0.602, P = 0.56].

Investigation of potential mechanisms of treatment

We next explored whether treatment attendance, client satisfaction and/or change in active coping and PTSD symptoms over the course of therapy accounted for treatment condition differences on drug composite scores. SS patients, compared to TAU patients, attended significantly more treatment sessions (t = 3.2, P < 0.01, Cohen’s d = 0.69), had significantly greater client satisfaction (meanSS = 3.5, SDSS = 0.4; meanTAU = 3.2, SDTAU = 0.7; t = 2.8, P < 0.01, Cohen’s d = 0.53) and significantly greater increases in active coping through treatment (meanSS = 4.5, SDSA = 7.7; meanTAU = -0.4, SDTAU = 7.2, t = 2.8, P < 0.01, Cohen’s d = 0.53).
Table 1  Demographic characteristics and baseline levels of alcohol use and drug use for all participants randomized to Seeking Safety (SS) and treatment as usual (TAU).

<table>
<thead>
<tr>
<th></th>
<th>SS (n = 49)</th>
<th>TAU (n = 49)</th>
<th>( t_{ss} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [mean (SD)]</td>
<td>55.1 (9.2)</td>
<td>52.9 (10.0)</td>
<td>-1.1</td>
</tr>
<tr>
<td>Ethnicity [n (%)]</td>
<td></td>
<td></td>
<td>( \chi^2 = 4.0 )</td>
</tr>
<tr>
<td>African American</td>
<td>32 (65.3)</td>
<td>27 (55.1)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>7 (14.3)</td>
<td>12 (24.5)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>4 (8.2)</td>
<td>3 (6.1)</td>
<td></td>
</tr>
<tr>
<td>Native American</td>
<td>2 (4.1)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (4.1)</td>
<td>3 (6.1)</td>
<td></td>
</tr>
<tr>
<td>Homeless or in transitional housing [n (%)]</td>
<td>19 (38.8)</td>
<td>20 (40.8)</td>
<td>( \chi^2 = 0.1 )</td>
</tr>
<tr>
<td>Currently unemployed [n (%)]</td>
<td>34 (69.4)</td>
<td>29 (59.2)</td>
<td>( \chi^2 = 1.0 )</td>
</tr>
<tr>
<td>Highest level of education [mean (SD)]</td>
<td>11.7 (2.3)</td>
<td>13.2 (2.9)</td>
<td>-0.9</td>
</tr>
<tr>
<td>OIF/OEF [n (%)]</td>
<td>2 (4.1)</td>
<td>2 (4.1)</td>
<td>( \chi^2 = 0.0 )</td>
</tr>
<tr>
<td>Currently married or in long-term relationship [n (%)]</td>
<td>11 (22.4)</td>
<td>10 (20.4)</td>
<td>( \chi^2 = 0.1 )</td>
</tr>
<tr>
<td>Using alcohol only [n (%)]</td>
<td>12 (24.5)</td>
<td>7 (14.3)</td>
<td>( \chi^2 = 1.6 )</td>
</tr>
<tr>
<td>Days of alcohol use to intoxication in previous 30 days</td>
<td>4.9 (9.1)</td>
<td>4.2 (7.9)</td>
<td>-0.4</td>
</tr>
<tr>
<td>Used illicit drug during life-time [n (%)]</td>
<td>40 (81.6)</td>
<td>43 (87.8)</td>
<td>( \chi^2 = 1.4 )</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>9 (18.4)</td>
<td>21 (42.9)</td>
<td>( \chi^2 = 7.3^{**} )</td>
</tr>
<tr>
<td>Cannabis</td>
<td>30 (61.2)</td>
<td>32 (65.3)</td>
<td>( \chi^2 = 0.3 )</td>
</tr>
<tr>
<td>Cocaine</td>
<td>29 (59.1)</td>
<td>34 (69.4)</td>
<td>( \chi^2 = 1.2 )</td>
</tr>
<tr>
<td>Heroin</td>
<td>6 (12.2)</td>
<td>7 (14.3)</td>
<td>( \chi^2 = 0.1 )</td>
</tr>
<tr>
<td>Hallucinogens</td>
<td>6 (12.2)</td>
<td>7 (14.3)</td>
<td>( \chi^2 = 0.1 )</td>
</tr>
<tr>
<td>Opiates (not prescribed)</td>
<td>3 (6.1)</td>
<td>3 (6.1)</td>
<td>( \chi^2 = 0.0 )</td>
</tr>
<tr>
<td>Days of illicit drug use in previous 30 days</td>
<td>5.1 (10.1)</td>
<td>6.2 (10.4)</td>
<td>-0.5</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>0.1 (0.3)</td>
<td>0.8 (4.3)</td>
<td>( t_{ss} = 1.2 )</td>
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<tr>
<td>Cannabis</td>
<td>3.0 (8.1)</td>
<td>3.5 (8.2)</td>
<td>( t_{ss} = 0.3 )</td>
</tr>
<tr>
<td>Cocaine</td>
<td>1.9 (5.8)</td>
<td>1.3 (3.1)</td>
<td>( t_{ss} = -0.7 )</td>
</tr>
<tr>
<td>Heroin</td>
<td>0.0 (0.0)</td>
<td>2.9 (0.4)</td>
<td>( t_{ss} = 1.0 )</td>
</tr>
<tr>
<td>Hallucinogens</td>
<td>0.0 (0.0)</td>
<td>0.0 (0.0)</td>
<td>( t_{ss} = 0.0 )</td>
</tr>
<tr>
<td>Opiates (not prescribed)</td>
<td>0.1 (0.6)</td>
<td>0.3 (1.5)</td>
<td>( t_{ss} = 0.7 )</td>
</tr>
</tbody>
</table>

**P < 0.01. OIF/OEF: Operation Enduring Freedom/Operation Iraqi Freedom; SD: standard deviation.

Table 2  Means and standard deviations (SD) of drug and alcohol use composite scores and post-traumatic stress disorder (PTSD) severity scores at three time-points for patients randomized to Seeking Safety (SS) and treatment as usual (TAU).

| Drug use | Alcohol use | PTSD severity |
|----------|-------------|---------------|---------------|
| Mean (SD) | Mean (SD) | Mean (SD) | SS TAU | SS TAU | SS TAU |
| Time 1 (baseline) | 0.09 (0.08) | 0.11 (0.08) | 0.26 (0.26) | 0.23 (0.24) | 46.8 (19.5) | 47.7 (16.3) |
| n_{SS} = 49 | n_{TAU} = 49 |
| Time 2 (3-month follow-up) | 0.06 (0.06)† | 0.10 (0.09)* | 0.17 (0.19)† | 0.15 (0.13)† | 40.8 (20.9) | 42.4 (21.3) |
| n_{SS} = 42 | n_{TAU} = 41 |
| Time 3 (6-month follow-up) | 0.05 (0.06)† | 0.09 (0.09)* | 0.14 (0.17)† | 0.14 (0.15)† | 38.9 (16.7)† | 36.5 (16.9)†‡ |
| n_{SS} = 39 | n_{TAU} = 35 |

*Treatment groups differ at P < 0.05 using independent-samples t-test. †Within-group means at baseline differ significantly from follow-up at P < 0.05 using paired-samples t-tests. ‡Within-group means at 3- and 6-month follow-ups differ significantly at P < 0.05 using paired-samples t-tests.
$SD_{SS} = 8.9; t_{SS} = 2.7, P < 0.01, \text{Cohen's } d = 0.59)$. None of these factors were associated independently with change of drug use over time [all $\beta = 0.000$, range $SE(\beta) = 0.000-0.002$, all $P > 0.73$], and thus did not represent mediators of effects of treatment condition on drug use over time. Changes in PTSD symptoms during the course of treatment did not vary significantly between treatment condition ($mean_{SS} = -5.8$, $SD_{SS} = 19.4$; $mean_{TAU} = -5.5$, $SD_{TAU} = 19.4$; $t_{SS} = 0.1$, $P = 0.95$, Cohen's $d = -0.02$), and thus did not represent a mediator of effects of treatment condition on drug use over time.

Figure 2: Plots of drug use (upper panel) and alcohol use (middle panel) composite score and post-traumatic stress disorder (PTSD) severity score means at three time-points (baseline, 3-month follow-up, 6-month follow-up) for patients in Seeking Safety (SS) and treatment as usual (TAU).
DISCUSSION

In this, the first well-controlled RCT of SS with adequate sample size and good follow-up rates, we found support for the use of a SS track as a useful modification of TAU to reduce drug use in male Veterans with a severe SUD and co-occurring PTSD symptomatology. Additionally, SS performed as well as TAU in terms of reducing alcohol use and PTSD symptoms, and participants in the SS condition had significantly greater treatment attendance, treatment satisfaction and improvement in active coping. Although these factors may be beneficial for promoting recovery more broadly they, or reductions in PTSD severity occurring during treatment, did not account for reductions in drug use.

The central strengths of this study were our adherence to a randomized, controlled design, adequate sample size and excellent follow-up rates, which are typically lower in longitudinal studies including participants with PTSD and a SUD. We are therefore confident that our findings provide support for the feasibility and benefit of addressing PTSD and SUD simultaneously and early during SUD treatment, rather than requiring separate or sequential treatments or a period of abstinence prior to PTSD-focused care. Notably, improvements were found with a treatment-resistant and predominantly minority population. Also, SS was learned quickly by clinicians, and integrated and implemented successfully into SUD care in a pre-existing out-patient clinic.

Our promising findings should be interpreted in light of several limitations. First, although multiple clinicians delivered care within each treatment arm, the two treatments were delivered by different sets of clinicians with different training and levels of education. Thus, we cannot be certain that effects were due to the treatment rather than to the teams of clinicians. Secondly, this study included several participants who met only partial criteria for PTSD [7,20]. However, this limitation is tempered by the fact that inclusion of these participants increased the ecological validity of the study. Thirdly, this study did not test the efficacy of SS, and we cannot dismantle the effect of providing smaller, more clinically homogeneous therapy groups from the effects of providing SS per se. Finally, our study only included male Veterans, thereby limiting generalization of results to females and non-veterans. However, past studies with these populations have evidenced positive outcomes.

These findings are timely and important. SS simultaneously addresses PTSD early within SUD treatment, is appealing to Veterans and staff [7,30] and uses techniques familiar to the majority of addiction treatment professionals, which may facilitate clinical implementation. Furthermore, compared to other evidence-based treatments for PTSD (e.g. cognitive processing therapy; [31]), SS is less costly in terms of requirements for training, supervision and consultation, which may also increase feasibility of use.

Declarations of interest

The views expressed here are those of the authors and do not necessarily represent those of the Department of Veterans Affairs. All authors declare that they have no conflicts of interest. World Health Organization clinical trial registration number: NCT00265564.

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