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Synergy between Seeking Safety and Twelve-Step Affiliation on Substance Use Outcomes for Women

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Abstract

Objective—The Recovery Management paradigm provides a conceptual framework for the examination of joint impact of a focal treatment and post-treatment service utilization on substance abuse treatment outcomes. We test this framework by examining the interactive effects of a treatment for comorbid PTSD and substance use, Seeking Safety, and post-treatment Twelve-Step Affiliation (TSA) on alcohol and cocaine use.

Method—Data from 353 women in a six-site, randomized controlled effectiveness trial within the NIDA Clinical Trials Network were analyzed under latent class pattern mixture modeling. LCPMM was used to model variation in Seeking Safety by TSA interaction effects on alcohol and cocaine use.

Results—Significant reductions in alcohol use among women in Seeking Safety (compared to Health Education) were observed; women in the Seeking Safety condition who followed up with TSA had the greatest reductions over time in alcohol use. Reductions in cocaine use over time were also observed but did not differ between treatment conditions nor were there interactions with post-treatment TSA.

Conclusions—Findings advance understanding of the complexities for treatment and continuing recovery processes for women with PTSD and SUDs, and further support the chronic disease model of addiction.

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Keywords

trauma; group therapy; AA; NA

Introduction

Nearly 90% of women who present for substance abuse treatment report lifetime exposure to trauma (Dansky, Saladin, Brady, Kilpatrick, & Resnick, 1995; Lincoln, Liebschutz, Chernoff, Nguyen, & Amaro, 2006; Mills, Lynskey, Teesson, Ross, & Darke, 2005; Najavits, Weiss & Shaw, 1997; Reynolds, Hinchliffe, Asamoah & Kouimtsidis, 2011). Between 30–60% of these women present with co-occurring PTSD and substance use disorders (Brady, 2001; Chilcoat & Menard, 2003; Donovan, Padin-Rivera, & Kowaliw, 2001; Najavits, Weiss, & Shaw, 1997; Triffleman, 2003). Treatment for co-occurring substance use disorders (SUD) and PTSD has been particularly challenging, as these patients have greater rates of relapse and higher rates of repeated service use compared to patients with either of the two disorders alone (Back, 2010; Cottler, Compton, Mager, Spitznagel, & Janca, 1992). Current treatment recommendations for comorbid PTSD and SUDs underscore the importance of an integrated therapeutic approach rather than a “split” approach in which an individual is treated for the trauma first and then the addiction or vice versa (Foa, Keane, & Friedman, 2000; Jacobsen, Southwick, & Kosten, 2001).

Seeking Safety as an Integrative Treatment

Seeking Safety is an intervention that was developed as a cognitive–behavioral therapy specifically designed to address the co-occurrence of PTSD and SUDs among women with trauma experiences (Najavits, 2002). Seeking Safety has been examined in a number of contexts and populations (e.g., female veterans, low income urban women, adolescent girls) (Desai, Harpaz-Rotem, Najavits, & Rosenheck, 2008; Hien, Cohen, Miele, Litt, & Capstick, 2004; Najavits, Gallop, & Weiss, 2006) and in multiple types of designs (e.g., controlled trials and non-randomized pilot studies; Cook, Walser, Kane, Ruzek, & Woody, 2006; Gatz et al., 2007; Najavits, Weiss, Shaw, & Muenz, 1998; Zlotnick, Najavits, & Rohsenow, 2003). Seeking Safety has been linked to significant decreases over time in substance use disorders, with these decreases being greater than treatment-as-usual and comparable to relapse prevention (Hien et al., 2004). However, in a separate multisite hybrid (i.e., combined efficacy/effectiveness; Rounsaville, Carroll & Onken, 2001) clinical trial within the National Institute on Drug Abuse’s Clinical Trials Network (Hien, Wells et al., 2009), Seeking Safety had no impact on substance use outcomes among the overall, intent-to-treat sample. Thus, studies which can elucidate the factors that may influence *when* and *for whom* this treatment is most effective (or ineffective) with respect to substance use outcomes are crucially needed.

Evaluating Post-Treatment Outcomes: Recovery Management

The justification for examining the joint impact of integrative PTSD and SUD treatments, such as *Seeking Safety*, and services outside of the formalized behavioral treatment context emerges from the Recovery Management paradigm. Proponents of this perspective have

suggested that several factors, including adjunct recovery services that are unrelated to the focal treatment (particularly in outpatient settings), can influence or modify treatment outcomes in relation to the services that individuals received *in* treatment. The impact of factors that are unrelated to a focal treatment protocol can grow exponentially, even as patients are far-removed from the formalized treatment context (McLellan, Chalk & Bartlett, 2007; McLellan, McKay, Forman, Cacciola, & Kemp, 2005; Scott & Dennis, 2009). McLellan et al., (2007) alluded to this quandary, stating "how far treatment programs can go in supporting recovery before extra-treatment related recovery services become primary in the recovery process will probably be dependent on many factors" (p.333).

As the fields of substance abuse treatment and health services move toward a continuing care model, the designs of SUD treatment trials, and treatment of comorbid PTSD and SUDs in particular, will need to incorporate evaluations of the primary treatment, as well as extra-treatment related recovery services. Incorporating a continuing care model in the context of behavioral therapies development and in the evaluation of larger systems of care falls within a larger impetus for advancing treatment and health services research to increase the connection between research and practice (Laudet, 2008).

Twelve-Step Affiliation Programs as Adjuncts to Addictions Treatment

For patients who have substance use disorders in the absence of PTSD, several studies have shown Twelve-Step Affiliation (TSA) (e.g, Alcoholics Anonymous or Narcotics Anonymous) is a strong prognostic indicator associated with better substance use outcomes (Chi, Kaskutas, Sterling, Campbell & Weisner, 2009; Kaskutas, 2009; Morgenstern, Labouvie, McCrady, Kahler, & Frey, 1997; Project MATCH, 1998; Scott & Dennis, 2009; Ye & Kaskutas, 2009); this also suggests promise for TSA as a potential form of continuing care that supplements and/or enhances the effects of outpatient treatment. TSA may serve to sustain beliefs and commitment to specific abstinence-related goals, enhance active coping efforts, and provide emotional support in a context that encourages abstinence (Ouimette et al., 2001; Ouimette, Moos, & Finney, 1999, 2000; Winzelberg & Humphreys, 1999).

Although there is evidence suggesting the positive effects of TSA extend to populations with PTSD and SUDs 2-to-5 years post-intervention, particularly among male combat veterans (Ouimette et al., 2003), relatively few studies have examined the impact of TSA in concert with outpatient treatment on PTSD and SUD treatment outcomes. Further, studies of PTSD and SUD treatment efficacy targeting women have not examined the impact of extra-treatment recovery supports in the context of receiving active treatments and their corresponding outcomes.

Treatment by Attendance Moderation Effects—Evidence is also emerging that treatment attendance can moderate treatment efficacy and effectiveness. In fact, recent work that has examined both observed (Barkham, Connell, Stiles, Miles et al., 2006) and latent attendance patterns (Hien, Morgan-Lopez, Campbell, Saavedra et al., in press; Morgan-Lopez & Fals-Stewart, 2007) has suggested that attending around half of available sessions may be optimal, at least among patients who self-select their treatment dosage (Feaster, Newman & Rice, 2003). It has been suggested that patients in treatment may mutually

regulate their level of improvement and the duration of treatment to reach their own personal level of optimal functioning (Barkham et al., 2006); conversely, attendance at all sessions, particularly for women with comorbid PTSD & SUDs, may be related to greater post-treatment impairment (Najavits, Weiss, Shaw & Muenz, 1998) and may require some form of post-treatment aftercare such as TSA.

The purpose of the current study is to examine the additive and interactive effects between Seeking Safety and post-treatment TSA and how these effects vary across treatment attendance patterns. Many women who experience interpersonal trauma, if treated for resulting PTSD and/or substance abuse problems, have to return to the very context (e.g., family, significant other, etc.) in which the trauma occurred (Mohr, Averne, Kenny, & Del Boca, 2001; Norman, Tate, Anderson, & Brown, 2007; Tate, Brown, Unrod, & Ramo, 2004; Saladin et al., 2003). Seeking Safety emphasizes, among other topics, the concept of carving out a safe place for one's self during and after treatment. TSA programs have the potential to provide women with an environment that will be supportive of their recovery from substance use beyond the outpatient context. Furthermore, an analysis of whether Seeking Safety and post-treatment TSA have joint additive effects (i.e., independent main effects) on alcohol and cocaine use or whether Seeking Safety may interact with TSA a) fits well within the tenets of the Recovery Management paradigm (e.g., McLellan et al, 2005; 2007) and b) is consistent with data on positive treatment outcomes for TSA for patients with PTSD and SUDs (Laudet, 2008; Ouimette et al., 2001; 2003). Thus, the present study aims to re-analyze the NIDA Clinical Trials Network (CTN) "Women and Trauma" data to specifically examine differential substance treatment outcomes for those receiving Seeking Safety compared to those receiving a health education control intervention. Unlike previous evaluations of Seeking Safety, we simultaneously account for a) participation in post-treatment TSA as a potential moderator of post treatment outcome trajectories (Scott & Dennis, 2009) and b) variation in treatment outcome by patterns of attendance and group membership turnover (Morgan-Lopez, Saavedra, Hien & Fals-Stewart, 2011; Morgan-Lopez & Fals-Stewart, 2007).

Method

Participants

Participants were 353 women receiving community-based, intensive, outpatient substance abuse treatment from six geographically diverse programs across the United States. Participants were eligible for the study if they reported at least one lifetime traumatic event and met DSM-IV criteria for either full or subthreshold PTSD in the past 30 days. Sub-threshold PTSD differed from full PTSD only in the number of symptom clusters that needed to be present; that is they had to meet criteria B (re-experiencing the trauma) and either criteria C (avoidance of trauma reminders) or D (hyperarousal) instead of both. Other inclusion criteria were: 1) being a female; 2) 18–65 years of age; 3) using alcohol or illicit substances within the past six months; and 4) meeting a current (within the prior year) diagnosis of drug or alcohol abuse or dependence. Women were excluded if they had: 1) impaired mental cognition; 2) significant risk of suicidal/homicidal behavior; 3) history of schizophrenia-spectrum diagnosis; or 4) a history of active (past two months) psychosis.

Recruitment occurred over 21-months in 2004 and 2005. Interested treatment program clients were assessed for eligibility during a screening assessment and then completed a baseline interview. After the baseline assessment, participants were randomized into one of two treatment groups: Seeking Safety or an active control condition, Women's Health Education. Women completed brief, weekly assessments for substance use, PTSD symptoms, and service utilization during treatment and were reassessed using the full assessment battery 1-week, 3-, 6-, and 12-months post treatment.

The average age of participants was 39.2 (s.d. = 9.3) with 45% Caucasian, 34% African-American, 6% Latina and 13% Multi-racial. Thirty-six percent of participants were single and 46% of participants were separated or divorced. Eighty percent of participants met criteria for Full PTSD and the majority of women reported lifetime physical and/or sexual abuse (see Table 1). Descriptives for treatment attendance, TSA attendance and ASI-Lite substance use outcomes across both treatment conditions are shown in Table 2.

Study Treatment

Treatment consisted of two 90-minute sessions per week for 6 weeks. Groups ranged in size from two to eight women and operated with an open, rolling admission so that participants entered the group at any point in the 12-session cycle (i.e., a participant might enter the group at session 7 and complete treatment with session 6). The general protocol was for participants to remain in the study treatment regardless of attendance unless they missed four consecutive sessions with no study contact but these participants were still encouraged to participate in the 1-week, 3-month, 6-month and 12-month post-treatment follow-up assessments.

Seeking Safety Treatment (Najavits, 2002)—Seeking Safety, a short-term manualized therapy, applies cognitive-behavioral strategies to the goals of reducing substance use and the negative impact of trauma exposure and was developed for use with both individuals and groups. Sessions are structured and include basic education on substance use disorders and PTSD, action skills to prevent drug use and control PTSD symptoms, cognitive restructuring with particular attention to maladaptive thoughts associated with substance use and trauma symptoms, and a focus on relationship issues and developing effective communication skills to build a healthy support network. Session topics are appropriately adapted to address participant's immediate reports of unsafe behavior and coping skills. The group format allows for women to discuss the application of coping skills in their lives and participants provide support and reinforcement to each other.

Women's Health Education (Miller, Pagan, & Tross, 1998)—Women's Health Education is a psychoeducational intervention that focuses on topics such as female anatomy, human sexual behavior, pregnancy and childbirth, nutrition, and diabetes. Women's Health Education provides facilitator attention, expectancy of benefit, and an issue oriented focus equivalent in attention to Seeking Safety, but does not provide theory driven techniques such as cognitive behavioral therapy and psychoeducation specific to substance abuse and PTSD. Topic presentations use mini-lecture, video, story-telling and/or text readings, as well as exercises to facilitate group discussion and application of materials.

Measures

Substance Use—Alcohol and cocaine use were collected for the prior 30-days using the *Addiction Severity Index-Lite* (*ASI-Lite*, revised from the fifth edition of the ASI; McLellan et al., 1992). Assessments were taken at baseline, 1 week post-treatment, and at 3-, 6- and 12-month follow-ups; the key outcomes were binary indicators of any use of each substance in the past 30 days.

Twelve-Step Affiliation—The post-treatment TSA measure from the *Non-Study Medical Services (NSMS)* instrument, a brief interview eliciting the variety and intensity of services received after study treatment. The one week follow-up measure asks participants how many times since their last assessment they attended Twelve-Step or Self-Help meetings; however, the 3-, 6- and 12-month follow-up measures asked how many times in the past 30 days they attended Twelve-Step or Self-Help meetings. In order to put the measures on a common metric, the total number of days they attended was divided by either the number of days that had passed since their previous assessment (1-week FU) or divided by 30 (3, 6 and 12 month FU) which captures the proportion of the possible days attended during the period in question.

Model Description

As noted elsewhere (Morgan-Lopez & Fals-Stewart, 2006; 2007; 2008a; 2008b), standard analytic approaches used for modeling treatment outcomes (e.g., repeated measures ANOVA, group-clustered latent growth models) have limited utility in accounting for the changes over time in treatment group membership (i.e., loss and addition of group members) that occur within open enrollment groups. Group-clustered latent class pattern mixture modeling (LCPMM; Lin, McCulloch, & Rosenheck, 2004; Roy, 2003; see also Muthén, Jo, & Brown, 2003) has been shown in both real (Morgan-Lopez & Fals-Stewart, 2007) and simulated treatment outcome data (Morgan-Lopez & Fals-Stewart, 2008b) to be a promising approach for modeling specific nuances of the open enrollment group process (i.e., group membership turnover, latent attendance classes within treatment groups).

LCPMMs account for (a) variability in the treatment effect across a finite number of latent attendance classes among individuals in the same treatment group and (b) can be structured to model relations between attendance class membership and variation in patients' points of entry into treatment. The logic underlying the utility of LCPMMs to the analysis of data from substance abuse treatment trials with rolling/open enrollment groups is that, within any point of the trial, the proportions of different types of attendance patterns (and, therefore, different subtypes of patients) are allowed to vary at any given slice in time at which the trial is running (Morgan-Lopez & Fals-Stewart, 2007, 2008a). Moreover, as group composition and norms change over time, in concert with changes in the membership of the group (e.g., the proportion of dropouts decreases over time as the group becomes more cohesive), it may affect the efficacy of the treatment during particular periods of the history of the group; we do note that, it would not be expected that the same level of group cohesion would occur as would be the case with closed groups (see e.g., Morgan-Lopez & Fals-Stewart, 2006 for an extended discussion).

The focal point of the LCPMM model is a categorical latent variable (called "Attend" in Figure 1) which represents membership in one of a finite number of latent classes (e.g., Attend = 1, 2…..C). This variable represents multiple hidden subpopulations within treatment outcome data which will vary between-classes along three sets of variables (see Figure 1). First, classes can vary in their probabilities of treatment attendance, which are a series of binary indicators of whether each patient showed up (0 = no-show, 1 = show) beyond the initial session for each person. Second, differences may emerge on the distributions of the timing of treatment entry (i.e., "Start Week") which may show (a) fluctuations over time in the proportions of patients from each sub-population and (b) be indicative of variation in the makeup of treatment groups that is dependent on calendar time (Morgan-Lopez & Fals-Stewart, 2007, 2008b). Finally, the treatment effects on growth over time in the outcome for the in-treatment (β_{ITI}) and post-treatment (β_{PTI}) slopes that underlie the substance use outcome measures ($y_{baseline}$-$y_{12\ month}$) may depend on (i.e., interact with) latent attendance class membership.

The model also includes a continuous latent variable called "TSA" (Twelve-Step Affiliation), with indicators that are repeated measures of participation in Twelve-Step meetings from 1-week through 1-year post treatment[1]. Initially, a parallel growth process was explored with these TSA indicators but there was insufficient variability in slopes over time on TSA to warrant such a model. Instead, a random intercept structure was used for the TSA indicators which essentially models a weighted average (with the factor loadings serving as weights) of the number of times in the past month patients attended Twelve-Step meetings across all four post-treatment time points. The continuous latent TSA variable served as a) a within-class predictor of changes over time in substance use and b) a within-class moderator of the post-treatment Seeking Safety/Women's Health Education treatment effect. Any potential covariance between treatment condition (SS/WHE) and post-treatment TSA was also modeled to address potential confounding (though this covariance would turn out to be non-significant).

While class-specific effects are of interest, overall effects (combined across classes) are also examined. If there is more than one class, the growth parameters (i.e., conditional growth parameter means, treatment effects) from each class are averaged and weighted by the class proportions and standard errors are calculated using the delta method (see Hedeker & Gibbons, 1997, p.74–76, Morgan-Lopez & Fals-Stewart, 2007, p.593) in order to estimate the overall treatment effect; note that this weighted averaging can now be conducted in a single step within an LCPMM analysis (e.g., via the Model Constraint command in Mplus v5.2). Both overall and class-specific treatment effects will be presented here.

[1]Measures of in-treatment TSA were not included in the models because the conceptual model implied by the Recovery Management/Continuing Care paradigms speaks more specifically to the impact of post-treatment services rather than in-treatment services. However, we examined the impact of in-treatment TSA (and in-treatment interactions with Seeking Safety) on in-treatment changes in alcohol and cocaine outcomes using both conventional (group-clustered) latent growth models and (group-clustered) LCPMMs. Under both analytic frameworks (and controlling for Seeking Safety and the SS x TSA interaction), in-treatment levels of TSA were related to *baseline* levels of cocaine ($p<.001$) and alcohol use ($p=.027$). However, in-treatment TSA levels were unrelated to *in-treatment changes over time* in alcohol and cocaine use ($ps>.88$). As a result, in-treatment measures of TSA were not included in the main analysis models.

Results

Preliminary Identification of Functional Form

The group stratified finite mixture modeling facilities within Mplus 5 (Muthén & Muthén, 1998–2009) were used for all analyses under robust maximum likelihood estimation (i.e., Mplus MLR estimation under stratification; Asparhouov, 2005). Prior to fitting the models of interest, the observed proportions for alcohol and cocaine use across pre-intervention and the four follow-up assessments were plotted in order to get a sense of the optimal functional form. Bauer and Curran (2004) notes that, in addition to modeling the correct functional form of the relation between time and repeated measures, ensuring that theoretically relevant non-linear relations between predictors and growth parameters (e.g., Seeking Safety x TSA interactions) are modeled can minimize the likelihood of overextraction of latent classes. It was concluded, based on the graphical analyses that the optimal functional form for the two substances was piecewise linear with two distinct periods of growth: a) pre-intervention to 1 week follow-up and b) 1-week follow-up through 12 month follow-up. The timesteps for each of these three growth parameters (intercept, 1^{st} slope, 2^{nd} slope) were structured such that the intercept was set at pre-intervention levels (i.e., estimated level probability of use in the week prior to the participant's 1^{st} treatment session).

Graphical analyses were supplemented by a series of unconditional growth models (with logit link functions for categorical outcomes for this and all subsequent analyses) examined under alternate functional forms. Using χ^2 difference testing, the fit of the above-described unconditional two-piece piecewise linear model did not differ significantly from unconditional models which included a quadratic growth factor for growth during the post-treatment phase ($\Delta\ \chi^2$ for all three substances at or exceeding $p = .10$). Thus, the two-piece piecewise linear functional form was used for all subsequent analyses.

Identification of Optimal Number of Attendance Classes

Next, a series of two-piece linear (group-stratified) LCPMMs with logit link functions, with varying numbers of latent attendance classes, was fit to determine the optimal number of classes. Bayesian Information Criterion (BIC) and entropy were used to determine the optimal number of classes. While the Bootstrap Likelihood Ratio Test (BLRT) had been recommended for determining the optimal number of classes for mixture models (Nylund, Asparouhov & Muthén, 2007), very recent work suggests that the BLRT is sub-optimal, and the BIC optimal, for mixture models in the presence of covariates (Nylund-Gibson & Masyn, 2009). As shown in Table 3 the BIC suggests 3 classes are optimal across both the alcohol and cocaine models.

Probabilities of treatment attendance across classes—Across the two sets of 3-class LCPMM analyses, a similar pattern emerged for treatment attendance (only patterns from the alcohol model are shown to avoid redundancy). The first class, called "Completers", never decreased below a 90% probability of treatment attendance; the class membership (based on posterior probabilities of class membership as opposed to the most likely class assignment) was between 30–31% of the total sample across both substances. The second class under the 3-class models is called "Dropouts". This class never exceeded a

41% probability of attending treatment and by the 4th session they would have attended, they had virtually 0 probability of attendance for the remainder of the protocol; this class made up around 27% of the sample across both substances. The third class is referred to as the "Titrators" class. Through the 7th session, Titrators ranged between a 50–80% probability of attending treatment, with further decreases in the probability of showing up for treatment across sessions, but with probabilities that never approached 0 as in the Dropout class; this class ranged between 42–43% of the sample across both substances.

In addition to preliminary analyses for minimizing the extraction of spurious classes, additional confidence in the number and structure of the classes from the LCPMM models come from a) auxiliary information such as previous work and b) substantive theory regarding the number of classes and class structure (Muthén, B.O., 2003). First, it is noted that the number and structure of these classes is consistent with other studies using LCPMM for modeling attendance patterns and treatment outcome trajectories jointly in independent datasets (e.g., Morgan-Lopez & Fals-Stewart, 2007). Further, the notion of classes of individuals who attend most sessions (Completers) and drop out of studies early (Dropouts) is a staple of all treatment outcome research while classes of individuals who self-titrate their treatment dosage is also common in AOD treatment (Barkham et al., 2006; Feaster, Newman & Rice, 2003).

Distributions of the Month of Trial Entry—The histogram (alcohol model only) in Figure 2 shows fluctuation in the number of patients within each class in the three-class model(s) throughout the 22 month span of calendar time for recruitment into the trial. As noted earlier, the overall split in class membership in this analysis was around 30% Completers/26% Dropouts/44% Titrators; this is in contrast with a class membership structure of 48% Completers/24% Dropouts/28% Titrators for recent analyses of these data that did not incorporate indicators of TSA into treatment outcome analyses (Hien et al., 2012). Prior to Month 10, Dropouts made up 34% of the sample but only 19% of the sample beyond Month 10 suggesting lower dropout probabilities during the second half of the trial; conversely, "Titrators" made up 36% of the sample from Months 1–10 and increased to 50% beyond Month 10. Further, in comparing the most likely class memberships from the current analysis with the recent re-analysis, there appeared to be four types of patients in general: 1) patients whose most likely class membership was Completers in both analyses (30%), 2) patients whose most likely class membership was Titrators in both analyses (22%), 3) patients whose most likely class membership was Dropout in both analyses (22%) and 4) patients whose class membership was Completers in the main outcomes analysis but were Titrators in the current analysis (20%).

Model Results

Overall (weighted-averaged) effects are emphasized in the text and described in detail while within-class treatment effects are shown in Table 5. Across all classes, latent post-treatment TSA was not significantly related to post-treatment alcohol use ($p = .27$) and cocaine use over time ($p = .29$). Also, treatment condition was unrelated to post-treatment TSA ($p = .97$).

Alcohol Model—Overall, there were significant in-treatment decreases in the rates of alcohol use within the WHE condition (b = -.581 (.296), t = −1.96, p=.050); however, the differences between Seeking Safety and WHE in-treatment slopes were non-significant (p=. 30). The treatment intervention by post-treatment TSA interaction was significant, b = −2.888 (SE = . 933), t = −3.094, p = .002. This result suggests that the largest decreases in alcohol use rates over time were for women in the Seeking Safety condition who also had greater usage of post-treatment TSA.

A variant of simple slopes analysis (Aiken & West, 1991) was used to assess Seeking Safety/Women's Health Education differences on the post-treatment slope for alcohol use at specific levels of TSA (15% and 65%[2] of available TSA sessions; mean at 1-week post-treatment = 41% of possible sessions); TSA indicators were re-centered to reflect 0 points of 15% and 65% respectively and then models were re-analyzed to assess changes in the SS/WHE treatment effect across levels of TSA. For "low" post-treatment TSA utilization, the post-treatment slope within WHE showed non-significant increases in the rates of alcohol use, b = .120 (.089), t = 1.343, p=.18, with no differences between Seeking Safety and WHE changes in rates, b = .215 (.562), t = .382, p=.70. For "high" post-treatment TSA utilization, the post-treatment slope within WHE showed significant post-treatment decreases in the rates of alcohol use, b = −1.578 (.159), t = −9.921, p<.001, with significantly steeper decreases in alcohol use rates for women in Seeking Safety, b = -.842 (. 313), t = −2.688, p=.007; based on class-specific estimates, it appears that the overall Seeking Safety x post-treatment TSA interaction effects are driven by significant class-specific interaction effects in both the Completers class (p<.05) and the Dropouts class (p<. 001).

Cocaine Model—For cocaine, there were in-treatment reductions in the rates of cocaine use (b = -.756 (.384), t = −1.970, p=.049), followed by further non-significant decreases in the rates of cocaine use (p=.11). However, neither in-treatment nor post-treatment treatment differences in slopes were observed between Seeking Safety and WHE (ps>.20) on cocaine use nor were any interactions with post-treatment TSA observed (p=.93).

Discussion

The present study re-analyzed the CTN "Women and Trauma" study data and examined differential substance abuse treatment outcomes for those receiving Seeking Safety compared to Women's Health Education accounting for moderating effects of participation in post-treatment TSA and modeling attendance patterns and membership turnover. Evaluation of integrative treatments among patients with comorbid PTSD and SUDs may benefit from a chronic care perspective that moves beyond a singular focal treatment to better capture the recovery process (Dennis, Foss, & Scott, 2007; McLellan et al., 2005; Scott, Foss, & Dennis, 2005; Scott, Dennis, & Foss, 2005). To date, studies on PTSD and

[2]Though a formal "regions of significance" test was not conducted, a series of simple slopes analyses were conducted to assess post-treatment treatment effects of Seeking Safety on alcohol use at 10% increments for TSA. From these analyses, it was revealed that statistically significant differences between Seeking Safety and Women's Health Education emerged at the point where patients were attending at least 60% of the available TSA sessions.

SUD treatment efficacy and effectiveness targeting women, such as Seeking Safety, have not examined the potential complimentary impact of extra-treatment recovery supports.

At the average rate of post-treatment TSA, significant reductions in substance use were observed that were specific to the attendance pattern (Completer, Titrator or Dropout) and the substance (alcohol or cocaine) for women in Seeking Safety compared to Women's Health Education. On average, significant reductions in rates were observed for alcohol use among women in Seeking Safety (compared to Women's Health Education) who were in the Completers and Titrators class, with treatment effects on cocaine approaching significance. However, several important interaction effects between Seeking Safety and post-treatment TSA were observed, whereby women in Seeking Safety who also sought post-treatment TSA generally were observed to have the greatest benefits; in some cases, and across some classes, women who were in Seeking Safety and *who did not* follow up with TSA post-treatment actually saw worse substance use outcomes compared to those in Women's Health Education. These findings, where some women benefit from the synergy between Seeking Safety and TSA, and those who did not receive TSA did more poorly *without* it, may provide an explanation of why evaluations of treatments for PTSD and SUDs have shown mixed findings (e.g., McGovern, Lambert-Harris, Acquilano, Xie, & Weiss, 2009). Consideration of the full complexities of open enrollment trials are essential to be able to detect more subtle patterns of treatment response that may be diluted in head to head comparisons that do not incorporate patterns of services and impact of extra-treatment recovery supports (Dennis, Perl, Huebner, & McLellan, 2000).

Capturing the joint impact of formalized outpatient treatment and extra-treatment recovery supports that occur post-treatment also reflects the chronic care perspective on SUDs, where the joint impact of a focal treatment and post-treatment recovery services may be more efficacious than outpatient treatment without follow-up services (Laudet, 2008; Morgenstern et al., 1997; Scott & Dennis, 2009). Although it might be the case that women who reported attending post treatment TSA may also be more motivated and invested in continuing recovery, several aspects of TSA are likely to facilitate maintenance of treatment gains. First, TSA programs are highly accessible and are the most common form of aftercare in this population relative to the limited availability of other long-term addiction services. Second, TSA programs offer social support, ongoing connection to treatment with less commitment required, and are delivered in groups of women (and men) with similar problems and similar goals. Third, TSA complements what women learned in Seeking Safety; in particular, Seeking Safety emphasizes the concept of carving out a safe place for one's self during and after treatment. Ruptures in intimate partnerships, family and other social supports are a frequent consequence of addiction, traumatic stress, and other comorbidities; re-engaging these important supports is often critical to successful recovery.

TSA programs may provide a place for women to seek and receive support for their recovery from substance use and, presumably, their trauma experiences. TSA also is likely to be comprised of individuals with similar histories of comorbid psychiatric disorders (Bogenschutz, Geppert & George, 2006). In many cases, given the preponderance of women in this population who have to return to the very environment in which the traumatic events occurred, TSA groups may be one of the few safe places these women have, assuming they

can feel safe within a TSA group. This is noteworthy, because it may speak to the importance of considering the gender mix of the TSA group in which women enter after outpatient treatment, because women with interpersonal trauma histories who avoid AA/NA may be more likely to do so if the groups are male-dominated. Women tend to make up 20–35% of AA/NA groups (Alcoholics Anonymous, 2005; Kelly, Stout, Tonigan, Magill & Pagano, 2010), but the extent to which the male-to-female ratio within TSA groups impacts a) variation in women's entry into, and outcomes from, TSA groups remains to our knowledge an open question.

Women in the Seeking Safety condition who did not attend TSA post treatment were at higher risk for increased substance use. Seeking Safety focuses on trauma-related issues and PTSD symptoms. If women lack social supports or other connections post-treatment to help continue the management of trauma-related and/or recovery-related issues, there may be increased risk of relapse. The significant deterioration experienced by women who received Seeking Safety but did not report post-treatment TSA may be related to post-treatment relapse as women cope without support offered by group members striving for similar goals and return to primary contexts where, in many cases, the trauma is still very salient (Mohr et al., 2001).

Clinical Implications and Future Directions

The present study extends current knowledge on treating conditions with high risk for relapse, such as PTSD and comorbid SUDs, and the adjunctive benefits of TSA for extending treatment effects. Findings underscore the importance of maintaining an ongoing connection to some form of recovery services and the need for continued social support, particularly among a population of women who are most vulnerable. More generally, the results of the present study highlight the need for behavioral clinical trials to examine contextual factors such as managing post-study treatment addiction recovery a priori in order not to obscure critically important findings. TSA reinforces commitment to specific abstinence-related goals, and provides emotional support in a context that encourages abstinence. Paired with insight and skills learned in Seeking Safety, following treatment up with TSA may help women with trauma manage their substance symptoms more effectively. Our findings suggest that providers may consider the use of TSA in combination with Seeking Safety to promote potential synergistic effects, or the trauma specific aspects of Seeking Safety could possibly be adapted to incorporate more directly the principles of TSA.

Limitations—Evaluation of the findings from the present study should take certain limitations into consideration. First, TSA was not systematically randomized, as participants self-selected into TSA post-treatment. It should be noted however, there was no relation between treatment condition and TSA and thus this "self-selection", and factors potentially related to self-selection (e.g., motivation), did not differ across the Seeking Safety and WHE conditions. This would be particularly true if in-treatment attendance and post-treatment TSA were in- and post-treatment proxies for motivation (i.e., more motivated patients went to more treatment sessions and more TSA sessions). Second, the present study only focused on self-reported post-treatment TSA attendance. Although attendance is indeed an important

indicator of participation in TSA, and several interaction effects were observed on post-treatment outcomes, collection of richer process-related TSA measures that consider level of engagement and involvement were not assessed in the present study and should be examined in future studies.

Despite these limitations, the present study advances our understanding of the complexities involved in the treatment and continuing recovery process for women with PTSD and SUDs. These data support integrative outpatient treatment that is specific to treating PTSD and SUDs simultaneously (Najavits, 2002) and to encourage contact with post-treatment services that may provide a continuously safe and supportive recovery community.

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Appendix 1

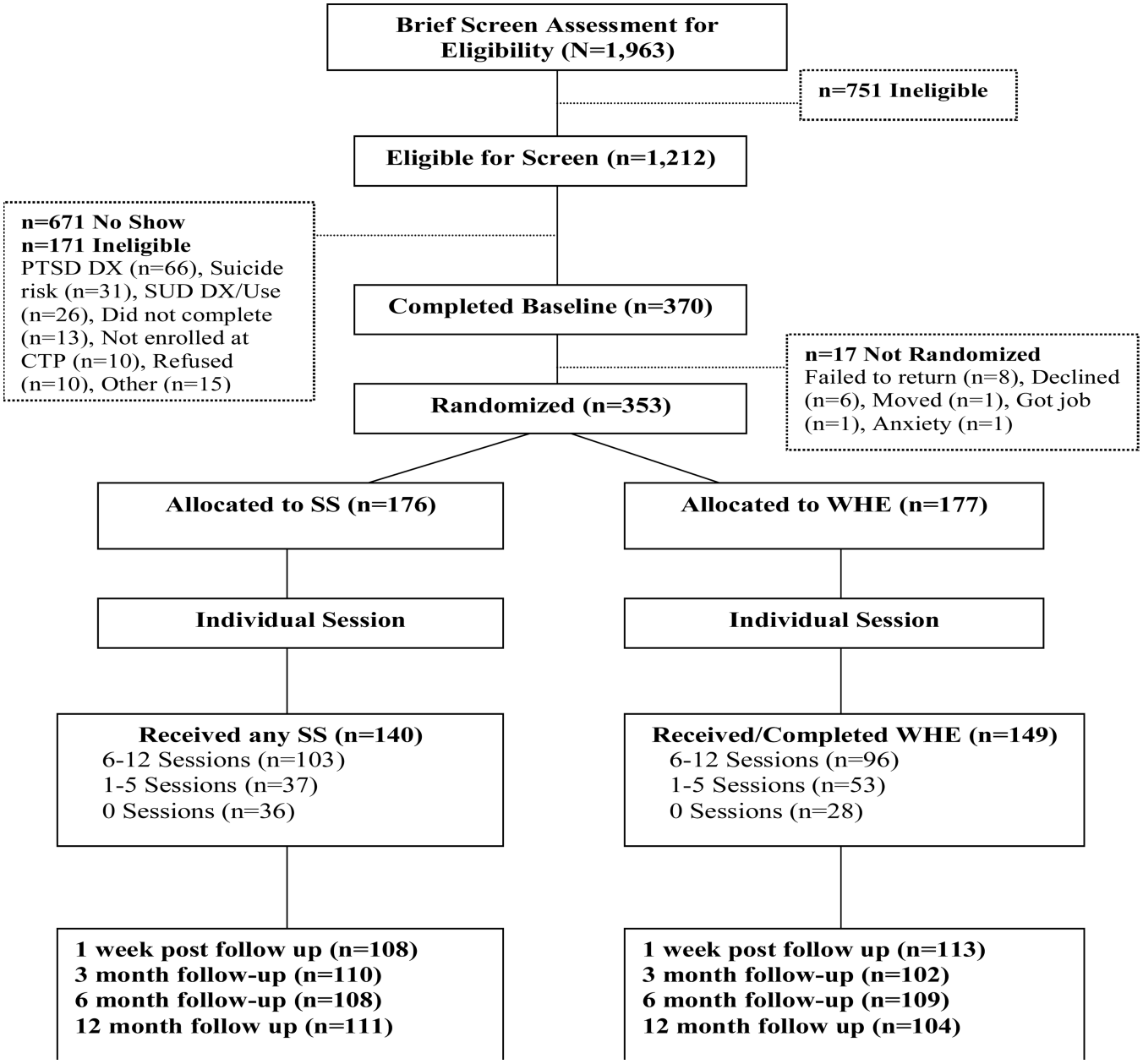
CONSORT Statement Checklist for Reporting a Randomized Trial

PAPER SECTION **And topic**	**Item**	**Descriptor**	**Reported on Page #**
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	1–2
INTRODUCTION Background	2	Scientific background and explanation of rationale.	3–6
METHODS Participants Interventions	3	Eligibility criteria for participants and the settings and locations where the data were collected.	6–8
	4	Precise details of the interventions intended for each group and how and when they were actually administered.	8–9
Objectives	5	Specific objectives and hypotheses.	7
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	9–10

PAPER SECTION **And topic**	**Item**	**Descriptor**	**Reported on Page #**
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	N/A
Randomization Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	Hien 09
Randomization --Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	Hien 09
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	Hien 09
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	8
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	10–11
RESULTS Participant flow	13	Flow of participants through each stage. Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	Appendix 2
Recruitment	14	Dates defining the periods of recruitment and follow-up.	7
Baseline data	15	Baseline demographic and clinical characteristics of each group.	Table 1
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible.	N/A
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision.	15–20
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	13–14
Adverse events	19	All important adverse events or side effects in each intervention.	Hien 09
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	20–24
Generalizability	21	Generalizability (external validity) of the trial findings.	22–23
Overall evidence	22	General interpretation of the results in the context of current evidence.	20–22

Appendix 2

Study Progress Diagram



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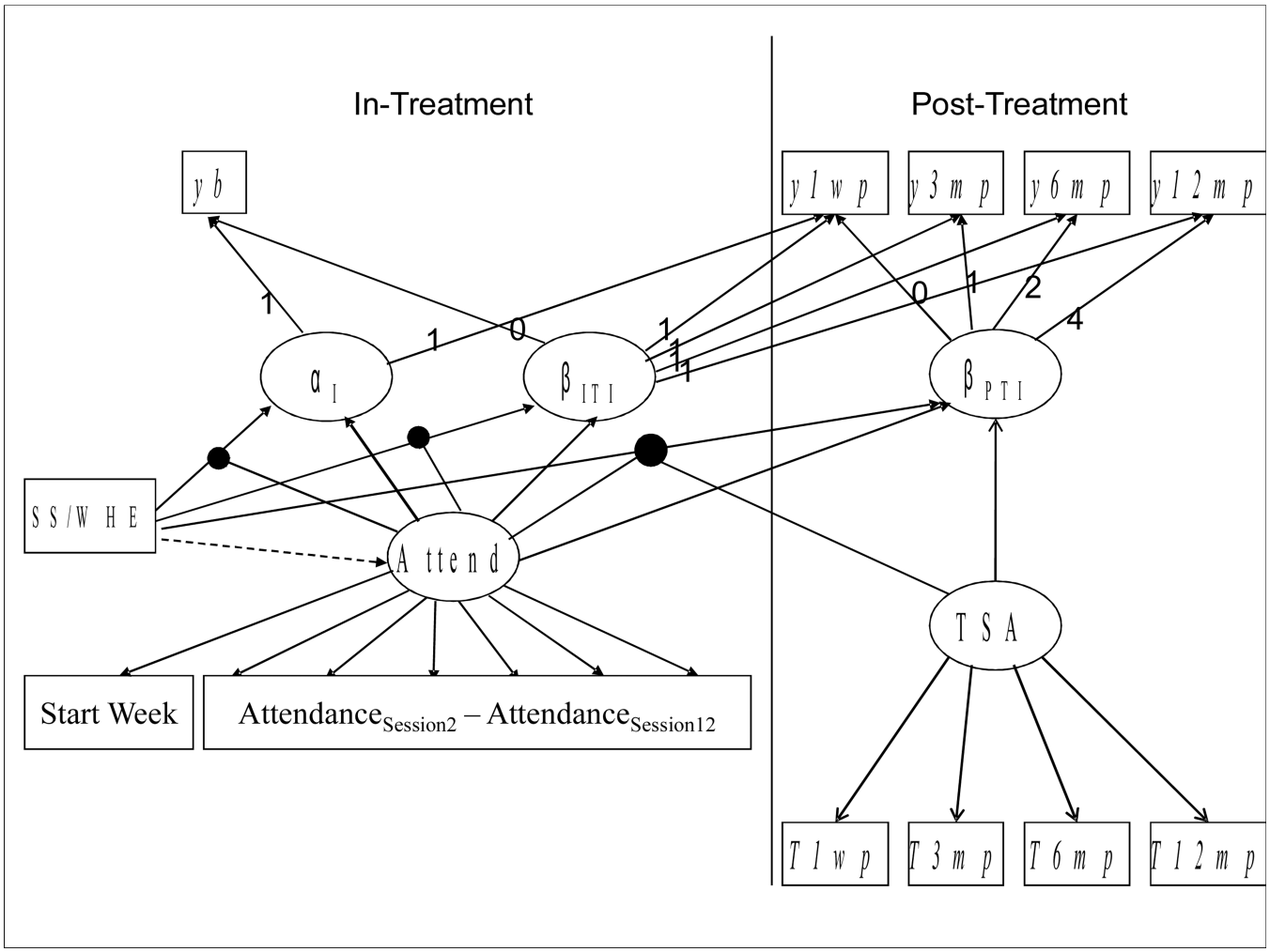

Figure 1.

Seeking Safety by Post-Treatment TSA Interaction Model

Attend = Latent Class Variable. Start Week = Calendar time variable indicating the week of the trial. $Attendance_{Session2\text{-}Session12}$ = Binary indicators of treatment attendance from Session 2 through Session 12. α_I = In-treatment intercept. β_{ITI} = In-treatment slope. β_{PTI} = Post-treatment slope. $y_{baseline}$-$y_{12month}$ = Repeated substance use outcome measures. TSA = Continuous latent variable capturing the average TSA attendance across 1 year post-treatment.

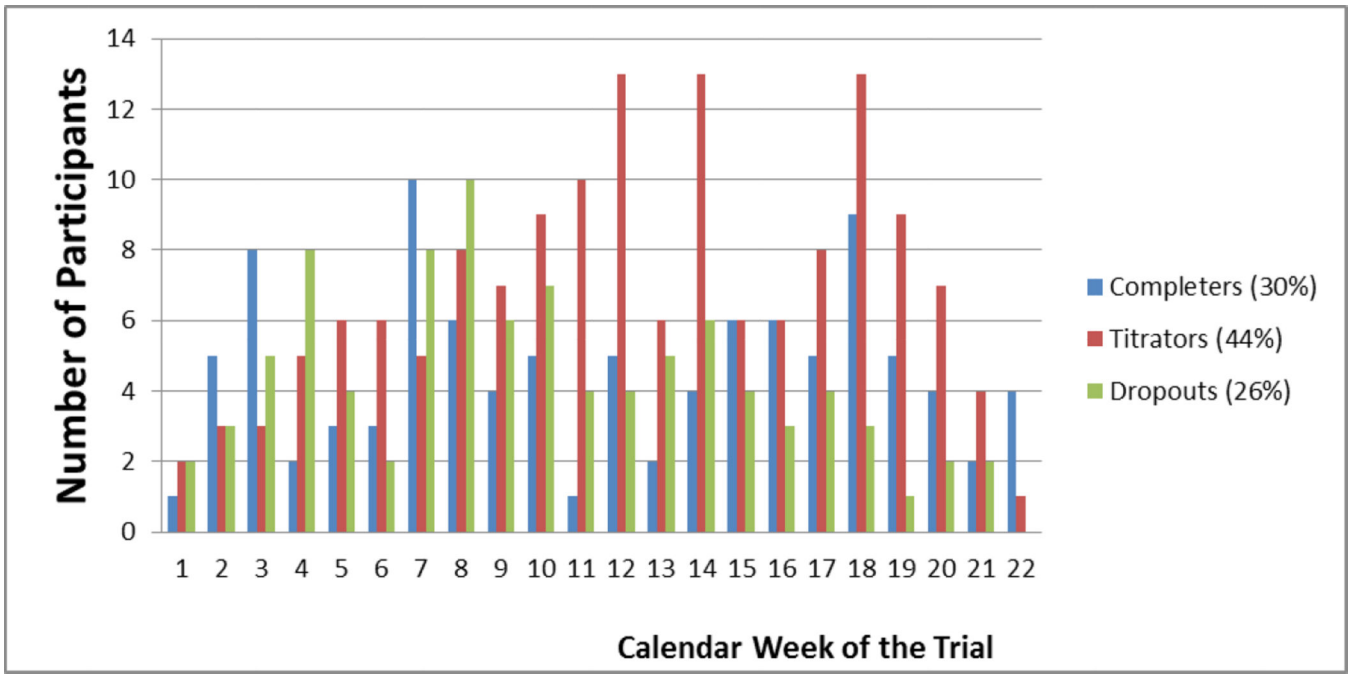

Figure 2.
Histogram of the Week of Trial Entry for each Attendance Class by Calendar Time

Table 1

Baseline Participant and Diagnostic Characteristics by Treatment Group (N=353)

	Total	Seeking Safety[a] N=176	Women's Health Education[a] N=177
Variables	**Mean(SD) or %**		
Age (years)	39.2(9.3)	39.3(9.5)	39.0(9.1)
Race/Ethnicity			
African American/Black	34.0	33.0	35.0
Caucasian	45.6	47.2	44.1
Latina	6.5	4.0	9.0
Multi-racial/Other	13.9	15.9	11.9
Education (years)	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
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
PTSD Diagnosis (% meeting full criteria)	80.4	76.7	84.2
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

[a]There were no statistical differences between treatment groups on any variable.

Table 2

Treatment Attendance, TSA Attendance and Substance Use Outcome Descriptives

	Seeking Safety (n=177)	WHE (n=176)
Treatment Attendance (Proportions)		
Week 2	.782	.707
Week 3	.760	.660
Week 4	.657	.623
Week 5	.613	.571
Week 6	.615	.454
Week 7	.617	.540
Week 8	.555	.472
Week 9	.514	.509
Week 10	.492	.441
Week 11	.454	.427
Week 12	.481	.387
TSA Attendance		
1-Week Post-Treatment	.415	.440
3 Months Post-Treatment	.328	.335
6 Months Post-Treatment	.285	.275
12 Months Post-Treatment	.203	.225
ASI-Lite Alcohol		
Baseline	.477	.418
1-Week Post-Treatment	.285	.304
3 Month Post-Treatment	.341	.276
6 Month Post-Treatment	.334	.374
12 Month Post-Treatment	.405	.348
ASI-Lite Cocaine		
Baseline	.409	.356
1-Week Post-Treatment	.243	.269
3 Month Post-Treatment	.250	.227
6 Month Post-Treatment	.210	.244
12 Month Post-Treatment	.256	.268

Table 3

Global Fit

	Bayesian Information Criterion (BIC)	
Number of Classes	**Alcohol**	**Cocaine**
2	8421	8337
3	8329	8224
4	8343	10507

Table 4

Average Classification Probabilities

Outcome Model	Average Posterior Probabilities		
	Completers	Titrators	Dropouts
Classes – Alcohol			
Completers	.921	.071	.008
Titrators	.075	.870	.054
Dropouts	.027	.049	.925
Classes – Cocaine			
Completers	.844	.101	.056
Titrators	.042	.925	.032
Dropouts	.004	.036	.960

Table 5

Class-Specific Treatment Effect Estimates

	Classes		
	Completers (31.4% Alc 30.2% Coc)	**Titrators (41.2% Alc 41.9% Coc)**	**Dropouts (27.4% Alc 27.9% Coc)**
Three-Class Alcohol Model			
Intercept	−.97(.33)***	−.09(.40)	−.13(.45)
WHE I-T Slope	−1.98(.54)***	−.25(.31)	.53(.84)
WHE P-T Slope	.08(.11)	−.02(.24)	−1.21(1.30)
SS v. WHE: Intercept	1.01 (.66)	−.26(.40)	.24(.27)
SS v. WHE: I-T Slope	.90(.33)***	−.79(.30)**	−.78(1.24)
SS v. WHE: P-T Slope	.21(.19)	−.06(.31)	−.61(1.67)
TSA: P-T Slope	−.03(.78)	−2.22(2.04)	−13.52(14.47)
(SS v. WHE) × TSA: PTS	−3.36(1.69)*	−1.55(1.07)	−4.34(.31)***
Three-Class Cocaine Model			
Intercept	−2.36(.59)***	.50(.64)	−1.12(.36)***
WHE I-T Slope	−1.53(.30)***	−.59(.42)	−.15(.73)
WHE P-T Slope	.99(.59)	−.11(.43)	−4.62(2.62)
SS v. WHE: Intercept	.87(.55)	−.35(.37)	1.04(.40)
SS v. WHE: I-T Slope	−2.74(1.70)	−.11(.58)	−.37(.46)
SS v. WHE: P-T Slope	.78(.47)	−.42(.42)	2.90(2.85)
TSA: P-T Slope	.69(.66)	−2.36(5.60)	−23.74(12.56)
(SS v. WHE) × TSA: PTS 5.48(.42)***	.02(.57)	−3.50(1.11)***	

p<.05*,

p<.01**,

p<.001***

SS = Seeking Safety. WHE = Women's Health Education. I-T = In-Treatment. P-T = Post-Treatment. TSA = Twelve-Step Affiliation.