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The "Women and Trauma" study and its national impact on advancing trauma specific approaches in community substance use treatment and research

Denise Hien[a,*], Frankie Kropp[b], Elizabeth A. Wells[c], Aimee Campbell[d], Mary Hatch-Maillette[e], Candace Hodgkins[f], Therese Killeen[g], Teresa Lopez-Castro[h], Antonio Morgan-Lopez[i], Lesia M. Ruglass[a], Lissette Saavedra[i], Edward V. Nunes[d]

[a] Center of Alcohol & Substance Use Studies, Graduate School of Applied and Professional Psychology, Rutgers University-New Brunswick, Piscataway, NJ, United States of America
[b] Addiction Sciences Division, Department of Psychiatry and Behavioral Neuroscience, College of Medicine, University of Cincinnati, Cincinnati, OH, United States of America
[c] School of Social Work, University of Washington, Seattle, WA, United States of America
[d] Department of Psychiatry, Columbia University Irving Medical Center and Division on Substance Use Disorders, New York State Psychiatric Institute, New York, NY, United States of America
[e] University of Washington Alcohol & Drug Abuse Institute, Department of Psychiatry & Behavioral Sciences, Seattle, WA, United States of America
[f] Gateway Community Services, Inc., FL, United States of America
[g] Medical University of South Carolina, Charleston, SC, United States of America
[h] Psychology Department, The City College of New York, New York, NY, United States of America
[i] Behavioral Health Research Division, RTI International, Research Triangle Park, NC, United States of America

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ABSTRACT

Introduction: The "Women and Trauma" Study (WTS) conducted in the National Drug Abuse Treatment Clinical Trials Network (CTN-0015) resulted in research publications, presentations, and a train-the-trainer workshop to support dissemination efforts for skills-based trauma treatment in substance use community treatment. Twelve years after its completion, this paper aims to examine whether and how the WTS contributed to knowledge in the field of trauma and addictions and inspired community treatment programs (CTPs) to train staff to identify and provide trauma-related services. Method: We present findings from two different analyses that explored longer term study impacts on treatment and dissemination: (1) a post-study site survey covering 4 domains from 4/7 programs that participated in delivering the WTS to evaluate their perceptions of study impact on their treatment community; and (2) an analysis of citations of its publications to determine impact on the scientific community. Results: Surveys from responding sites indicated that participation in the study significantly increased their agencies" awareness of the need to take a focused approach to treating trauma issues in this population. Specifically, these sites increased their commitment to using skills-based trauma treatment with the study's target population of female patients with SUD and trauma histories, as well as expanding it to other groups affected by trauma. Citation analysis revealed that according to the Web of Science, as of August 2019, the number of citations of 24 CTN-0015 articles, ranged from 1 to 135 (Mean = 20, SD = 33; Median = 6). Four of the most influential are discussed. Conclusions: This manuscript provides original information about the contributions of the WTS study, demonstrating how the study contributed to serving women with trauma in community substance use treatment.

1. Introduction

An integral part of the National Drug Abuse Treatment Clinical Trials Network (CTN) vision is to address the need for treatment providers to adopt new and effective treatments for diverse client populations, using research to promote the adoption of such treatments. The Women and Trauma Study (WTS, CTN-0015) is the largest multisite randomized clinical trial testing the feasibility and safety of

* Corresponding author.
E-mail address: denise.hien@smithers.rutgers.edu (D. Hien).

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delivering trauma-specific treatment in substance use disorder (SUD) treatment programs. This paper examines how WTS moved the field of trauma and addiction treatment forward and encouraged treatment providers to create trauma-informed spaces and train staff to provide trauma-informed care.

1.1. Background and WTS overview

Post-traumatic stress disorder (PTSD) and alcohol and other SUDs are among the most costly public health problems in the U.S. (Bouchery, Harwood, Sacks, Simon, & Brewer, 2011; Kessler, 2000; National Drug Intelligence Center, 2011). The wide scope of problems associated with comorbid PTSD and SUDs (PTSD + SUD) includes poorer treatment prognosis, longer hospital stays for treatment, lower treatment adherence, and higher suicide rates than patients with SUDs without PTSD (Bradizza, Stasiewicz, & Paas, 2006; McCarthy & Petrakis, 2010; McCauley, Killeen, Gros, Brady, & Back, 2012; Najt, Fusar-Poli, & Brambilla, 2011, Simpson, Lehavot & Petrakis, 2014). The consequences of PTSD + SUD are particularly relevant to women; in comparison to men, women are disproportionately exposed to high-impact traumas, more vulnerable to developing PTSD, and move more rapidly from first-time use to problematic substance use (e.g., Lopez Castro, Saraiya, & Hien, 2017). Many questions related to optimal treatment practices for PTSD + SUD, however, remain unanswered.

The WTS was developed in 2002 to address a need for trauma treatment for female clients suffering from PTSD + SUD. The WTS study used a repeated measures, randomized controlled design to assess the effectiveness of adding a trauma-specific group intervention to a platform of standard SUD treatment. Three-hundred and fifty-three treatment-seeking women with SUDs who also met criteria for DSM-IV full or subthreshold PTSD participated. Trained counselors from 7 outpatient community SUD treatment programs affiliated with the CTN spanning 6 states provided two group interventions: *Seeking Safety* (SS) Najavits, 2002, an integrated treatment for trauma and addiction, and Women's Health Education (WHE), an active control group where neither trauma nor addiction were addressed. Further details related to study design can be found in Hien et al., 2009.

1.2. Summary of key findings

Table 1 is a list of twenty-four publications describing or utilizing data from the WTS since the primary outcome paper was published. The primary outcome analysis demonstrated clinically significant reductions in PTSD symptoms in both SS and WHE groups (Hien et al., 2009). Key secondary analyses showed significant reduction in HIV sexual risk behavior among women who engaged in more risky behavior in the SS group (Hien et al., 2010) and that SS groups were no different than WHE groups in terms of safety, with few reporting any study-related adverse events (Killeen et al., 2008). Additional papers focused on understanding moderators of treatment process and outcome, including patient and treatment characteristics such as racial/ethnic composition and patient-therapist racial/ethnic match, types of substances used (alcohol misuse, cocaine, and cannabis use), and impact of the therapeutic alliance as a predictor of outcome (Hien et al., 2015). Taken as a whole, findings provided support for safely implementing trauma treatments with women in community SUD treatment settings.

1.3. Summary of new methodological research generated by WTS

Federally funded initiatives, focused on the development of quantitative methods geared toward addressing the complexities that arise in treatment research in real-world contexts, were supported in parallel to the development of the CTN (e.g., NIH PA-07-113). With this purpose in mind, NIDA funded a secondary analysis of WTS (R01DA025198; Morgan-Lopez, A.A., PI) for the application of methodologies for modeling treatment outcomes in the presence of continual turnover in group membership (Morgan-Lopez & Fals-Stewart, 2006, 2008a).

The secondary analysis award led to four papers modeling treatment outcomes. Hien et al. (2012) compared analyses based on latent pattern mixture modeling to the standard random effect models reported in Hien et al. (2009). The most clinically relevant findings emerged from the latent attendance subclasses, which identified patterns of attendance, where steeper decreases in post-treatment alcohol use were observed among SS patients depending upon how they attended treatment (Hien et al., 2012). Further analyses showed that class-specific mediation and moderation effects were largely observed among treatment completers, with effects on post-treatment alcohol use a) mediated by in-treatment reductions in PTSD (Morgan-Lopez et al., 2014) and b) moderated by post-treatment Twelve Step affiliation (Morgan-Lopez et al., 2013). Additional empirical work illustrated how to conduct power analyses for open enrollment designs (Morgan-Lopez, Saavedra, Hien, & Fals-Stewart, 2011). Findings from WTS and its secondary analysis methods grant (R01DA025198) served as supporting studies for a National Institute on Alcohol Abuse and Alcoholism funded R01 trial (R01AA025853; Morgan-Lopez and Hien, MPIs) that will use an innovative methodology to integrate and analyze data from more than forty PTSD and alcohol/other drug use disorder (AOD) treatment trials.

1.4. Summary of the highest impact secondary analysis

Our most compelling finding related to the WTS study was published in the *American Journal of Psychiatry* (AJP) in 2010 (Hien et al., 2010). One ongoing concern was that the integration of trauma treatment would adversely affect SUD recovery. Traditional treatment approaches for PTSD + SUD at the time was a sequential model of treatment. Individuals were to achieve “recovery” from their SUD before any trauma treatment could be implemented. In this WTS secondary analysis, the temporal relationship between PTSD and SUD response outcomes throughout the six-week intervention up to the 12-month follow-up was explored. Specifically, do improvements in PTSD symptom severity lead to improvements in SUD, and do improvements in SUD lead to improvements in PTSD severity? The WTS analysis was the first to demonstrate that PTSD severity reductions were associated with SUD improvement; there was minimal evidence of substance use reduction improving PTSD symptoms. Women with more severe baseline SUD severity had greater reductions in PTSD severity scores and in substance use when treated with SS than WHE. These findings opened the door for community SUD treatment programs to expand services to include other PTSD treatment models, demonstrating the feasibility and acceptability of addressing trauma directly.

2. WTS practice and training-related outcomes

We conducted a qualitative survey via phone, email, or in-person (based on interviewee preference) of our WTS sites to assess whether sites had adopted the treatment model and how they felt their experience in the study affected capacity to treat traumatic stress among their clients. In summer 2019, approximately 12 years following study closeout, the participating sites were polled to determine what, if any, impact the WTS study had on their clinical practice. Five of the 7 research coordinators from the participating sites and their associated academic institutions responded to the survey, which consisted of 6 open-ended and 4 closed-ended questions, including several subquestions to gather further information. The questions covered four different topics: Adoption (Immediate or Delayed), Additional Training, Still in Use, and Dissemination Efforts. Supplement Table 2 provides the questions used in the survey.

The five responding sites were geographically located in Florida (2 sites), Ohio, South Carolina, and Washington. There was a wide spectrum of interviewees from each site, representing staff who were working directly on the study team or were in site leadership at the time

Table 1
Women & trauma study publications, main finding, and citation count.

Lead author and publication year	Main finding	Citation count
1. Killeen et al., 2008	Safety (N = 353): No difference between SS, WHE on # study-related adverse events.	22
2. Hien, 2009	Study methods description.	4
3. Hien, 2009	Primary Outcome (N = 353): SS & WHE decreased PTSD symptom severity during tx & (at a slower rate) during follow-up.	110
4. Hien, 2010	PTSD/SU (N = 353): PTSD responders (vs. PTSD/SU nonresponders, SU responders, global responders) more likely to transition to global response during tx; SS (vs. WHE) more effective reducing SU but only among ppts with heavy BL use who had significant PTSD reduction.	135
5. Hien, 2010	Sexual Risk (n = 346): SS ppts with greater sexual risk had greater reductions in # of unprotected sex occasions over follow-up than WHE.	35
6. Hien, 2010	Alcohol (N = 353): Among ppts with alcohol misuse, PTSD sxs lower in SS (vs. WHE) during tx and follow-up.	32
7. Cohen et al., 2010	Eating Disorders (n = 122): Binge eating ppts had greater PTSD severity over follow-up; ppts with no binge eating more likely to be abstinent during tx & follow-up.	23
8. Morgan-Lopez, 2011	Describes approach to power analyses for open-enrollment designs using Monte Carlo simulation of latent class pattern mixture models (parameters derived from WTS).	4
9. Pinto, Campbell, Hien, Yu, & Gorroochurn, 2011	Retention (n = 346): Mean # sessions attended did not differ between SS, WHE; attendance associated with being older, more educated, stronger therapeutic alliance.	12
10. Resko & Mendoza, 2012	Early Attrition (n = 340): Early tx attrition associated with perceived need for psychological tx, history of youth partner violence, stimulant, alcohol & opioid use.	6
11. Ruglass et al., 2012	Alliance (n = 223): SS had greater alliance than WHE at wk. 2; greater alliance at wk. 2 associated with # sessions attended & decreased PTSD severity, but not SU at post-tx for SS and WHE.	17
12. Hien, 2012	Attendance (N = 353): 3 tx attendance patterns: completers, droppers, & titrators; completers showed decrease in alcohol use BL to post-tx; titrators in SS had decreased rates of alcohol use in follow-up compared to WHE.	10
13. Winhusen, Winstanley, Somoza, & Brigham, 2012	Recruitment Method (n = 106, single site): Ppts recruited via advertising had greater drug use & PTSD severity, more likely to meet cocaine use disorder & full PTSD criteria; tx effect sizes (SS vs. WHE) for PTSD symptom reduction greater for advertising (vs. clinic recruitment).	3
14. Cohen, Field, Campbell, & Hien, 2013	Partner Violence (n = 288): Significant risk factors for partner violence in follow-up: living with someone who has an alcohol problem, higher # lifetime traumatic events, recent assault. SS ppts abstinent at baseline less likely to experience partner violence (vs. WHE, nonabstinent SS).	19
15. Morgan-Lopez, 2013	Self-Help (N = 353): Post-tx 12-step not associated with post-tx alcohol or cocaine use; SS ppts in 12-step had greatest reduction in alcohol use rates over time.	4
16. Morgan-Lopez, 2014	Group Membership as Mediator (N = 353): SS had steeper reduction in PTSD frequency & severity, predicting reductions in cocaine & alcohol use; pattern primarily significant among Completers (vs. Titraters & Droppers) & only during tx.	6
17. McHugh et al., 2014	Sleep (N = 353): Most ppts had ≥1 clinical-level sleep sx; decreased at end of tx; improvement in sleep sxs during tx associated with improved PTSD sxs over time.	5
18. Ruglass, 2014	Stimulant Use (n = 141): Heavy vs. light stimulant use associated with greater PTSD severity; SS & WHE decreased PTSD severity & stimulant use over time.	5
19. Ruglass, 2014	Racial/Ethnic Match (n = 224): No association between individual/group (to therapist) racial/ethnic match & session attendance.	1
20. Anderson & Najavits, 2014	Physical Disability (N = 353): Ppts receiving pension for disability had greater somatization & depression scores; ppts with disability had greater reductions in PTSD sxs in SS vs. WHE over follow-up.	5
21. Hien, 2015	Description of benefits & limitations of effectiveness trials conducted in NIDA's CTN using Women & Trauma as a case example.	4
22. López-Castro, Hu, Papini, Ruglass, & Hien, 2015	Pathways (N = 353): 3 trajectories of SU during follow-up: low risk/infrequent use, high risk/infrequent use group; high risk/frequent use; improvement in PTSD severity associated with membership in low risk/infrequent use group.	8
23. Killeen, Brewerton, Campbell, Cohen, & Hien, 2015	Eating Disorders/SU (n = 122): Eating disorder subscale scores (Global, Eating Concern, Weight Concern, Shape Concern) significantly associated with Caucasian race, past 30-day opioid use, greater psychiatric severity, lower employment need.	4
24. Ruglass, Shevorykin, Brezing, Hu, & Hien, 2017	Cannabis & Cocaine (n = 286): Ppts with concurrent cannabis & cocaine use disorder had higher odds of sexual assault (vs. cannabis alone) & alcohol use disorder (vs. cocaine alone).	1

Table Notes: PTSD = Post-traumatic Stress Disorder; SU = Substance Use; SS = Seeking Safety; sx = symptom; tx = treatment; ppts = patients; WHE = Women's Health Education. Citation counts from Web of Science, August 2019. Citations by WTS authors removed from count.

of the study: site Principal Investigators, current and former site administrators, study interventionists, study coordinators, and trainers from the site-associated academic institutions; additionally, 1 current site administrator who was not involved at the time of the study provided information on how the study implementation currently impacts trauma practice at their agency. Interviews last approximately 20–30 min max. Supplement Table 3 summarizes the status of their adoption of the SS model post-WTS participation.

2.1. Survey results

2.1.1. Adoption (immediate or delayed

Four of the responding sites adopted SS into their clinical services immediately. All of the responding sites indicated that study participation significantly increased their agencies' awareness of the need to take a focused approach to treating trauma issues in this population, and this increased awareness was the determining factor in the fifth site's decision to adopt SS several years following the study. As another site stated, “Participating in the trial changed everything in the organization. No one in the organization had ever even assessed for trauma before and now the agency is known regionally as a provider of *Seeking Safety*.” Prior to the study, even though some of the sites reported having made attempts to address PTSD + SUD, such attempts typically were limited to isolated sessions with an individual or single psychoeducational group sessions. Following the study, the responding sites broadened their use of SS to include multiple levels of care, including use of other pertinent SS modules not used in the clinical trial, and to include other populations experiencing trauma as well. Sites reported that the positive client experiences during the study garnered support from other agency staff to establish SS as a standard component of the sites' treatment programming.

2.1.2. Additional training

Sites were initially mixed in their enthusiasm about receiving additional training for their staff in SS following the WTS. While staff in some sites had really enjoyed the experience of implementing the research study, other sites were unsure about implementing it. One site explained, “At the time, trauma-informed care training wasn't common in the organization, and several clinical staff were uncomfortable with the level of PTSD symptoms being exhibited by the women in the study. The clinical team was open to receiving training, but there was not a practice champion for that”. Having a practice trauma treatment champion may have facilitated SS adoption post study.

Four of the five responding sites sent staff to the Train-the-Trainer event provided by the study team following the close of the study, and these site trainers have continued to train additional staff in the intervening years. The number of staff trained has ranged from “about 12” to “over 100”. The fifth site, which delayed adoption of the intervention, eventually obtained training for approximately 4–6 counselors. Most sites indicated that they provide supervision but are not engaged in implementing strict fidelity measures. One site, however, continued to utilize the study's fidelity measure on a regular basis, providing ongoing supervision and coaching through observed and rated sessions.

2.1.3. Continued use since study end

Overall, the responding study sites have evolved in the provision of trauma services with SS to their patient population since the end of the trial. Despite problems with funding and staff shortages, sites have persisted in their commitment to using SS with the study's target population of female patients with SUD and trauma histories, as well as expanding it to other groups affected by trauma. The intervention has been well-received by their clients. As one site put it, “Intensive outpatient clients often choose to continue after being transitioned to a lower level of outpatient care. Anecdotally, sites agreed that it is one of the more successful aspects of the program with women saying they are better able to manage PTSD symptoms and cravings and have increased self-efficacy.” Sites generally indicated that their program or agency became more trauma-informed as a result of participating in the study. As one site stated, “Seeing patients through the lens of trauma made the program staff more sensitive to the issue.” Another site addressed trauma in its policy on risk assessment and management. A third site successfully applied for a number of grants that have allowed the program to enhance the provision of trauma services, including funding for a dedicated trauma team in their residential and outpatient programs.

2.1.4. Dissemination efforts

Beyond site specific dissemination, three of the responding sites have provided SS training to other local agencies and programs within their extended healthcare systems. One site reported that their trauma clinicians are part of a state peer-review system developed to assist clinicians who are implementing evidence-based practices and, thus, are able to enhance the use of SS. Additionally, trainers from two of the larger CTN node institutions have provided multiple regional training sessions to local providers and other SUD agencies, including to all staff at a Native health organization in Alaska. Although it is unclear how many of the training attendees actually implemented SS in their organization, in some cases the trainers have been asked to provide follow-up assistance to the agencies.

3. Citation analysis of WTS publications and dissemination of the *Seeking Safety* model

Between 2008 and 2017, the WTS protocol produced 24 peer-reviewed publications authored by 61 different individuals. We entered each of the 24 publications into a cited reference search in the Web of Science (Clarivate Analytics, 2019). We reviewed titles and authors of each citing article and subtracted any with an author on WTS publications. We also noted and reviewed those citing articles that constituted additional trials of *Seeking Safety*. In addition to the citation search, we used the search term “*Seeking Safety*” in the Medline and PsycInfo databases (EBSCO Industries, Inc., 2019), and consulted the *Seeking Safety* – Library section of Dr. Najavits' website (https://www.treatment-innovations.org) to identify *Seeking Safety* trials before and after WTS.

3.1. Citation analysis results

A Web of Science citation analysis (excluding self-citations), completed in August 2019, counted 1 to 135 citations per paper (Mean = 20, SD = 33, Median = 6). The four most cited papers a) examined the relationships between improvement in PTSD severity and substance use outcomes (Hien, Jiang, Campbell, et al., 2010, 135 cites), b) reported the primary WTS outcomes (Hien et al., 2009, 110 cites), c) tested the impact of SS on HIV risk sexual behaviors (Hien, Campbell, Killeen, et al., 2010, 35 cites) and d) analyzed relationships between alcohol misuse and PTSD outcomes (Hien, Campbell, Ruglass, Hu, & Killeen, 2010, 32 cites). These papers were all relevant to clinical decision-making.

The primary outcome paper of the WTS was published in 2009 (Hien et al., 2009). Prior to its publication, results of 4 controlled (Desai, Harpaz-Rotem, Najavits, & Rosenheck, 2008; Gatz et al., 2007; Hien, Cohen, Miele, Litt, & Capstick, 2004; Najavits, Gallop, & Weiss, 2006) and 7 uncontrolled pilot studies (Cook, Walser, Kane, Ruzek, & Woody, 2006; Holdcraft & Comtois, 2002; Najavits, Schmitz, Gotthardt, & Weiss, 2005; Najavits, Weiss, Shaw, & Muenz, 1998; Weaver, Trafton, Walser, & Kimerling, 2007; Weller, 2005; Zlotnick, Najavits, Rohsenow, & Johnson, 2003) of SS had been published. These demonstrated consistently positive outcomes on a variety of measures. The intervention was being marketed through the developers' website, https://www.treatment-innovations.org, and the SS manual was available on Amazon.com. After publication of the WTS main outcome paper (Hien et al., 2009), additional randomized or controlled and open SS trials with diverse target populations were published (e.g., closed trials: Boden et al., 2012; Crisanti, Murray-Krezan, Reno, & Killough, 2019; Hien et al., 2015; Myers, Browne, & Norman, 2015; Schäfer et al., 2019, e.g., open trials: Barret et al., 2015; Empson et al., 2017; Lange-Altman, Bergandi, Borders, & Frazier, 2017; Norman, Wilkins, Tapert, Lang, & Najavits, 2010; Patitz, Anderson, & Najavits, 2015). Overall, these trials showed one or more desired changes in PTSD symptoms or substance use among participants receiving SS compared to comparators.

4. Discussion

The past two decades have seen an increasing emphasis, nationally, on implementing “trauma-informed care,” prompting guidelines and articles about implementation of such care (Killeen, Back, & Brady, 2015; SAMHSA, 2014). At the same time, with passage of the Affordable Care Act, the movement toward integrated behavioral health care has produced demand for interventions that address co-occurring mental health and SUD. *Seeking Safety* has responded to this demand, as it is highly acceptable to both clinicians and clients, structured, easy to follow, and flexible. Training materials and implementation guidelines are readily available. Many state (e.g., The California Evidence-Based Clearinghouse for Child Welfare, 2006-2019), local (e.g., Think Health LA, 2019), and national (e.g., U.S. Department of Justice National Institute of Corrections, 2020) practice websites list SS as either an "evidence-based or "promising" practice. Most reference its original listing on SAMHSA's National Registry of Evidence-Based Programs and Practices (NREPP), which was frozen in 2018 and replaced by the Evidence-Based Resource Center (SAMHSA, 2019), which does not include a listing of SS. Determining the most influential factors that contributed to programs adopting SS is difficult, but a set of possible determinants includes publication of outcome studies including the

WTS, a developing consensus on the need for trauma-informed care, increased understanding that trauma can be addressed safely even in the context of other comorbid disorders, increased integration of mental health and SUD treatment, and direct marketing of the intervention. Given the plethora of evaluations, both before and after the WTS trial, it is impossible to disentangle the effect of this trial versus others on developments in training, adoption, and implementation of SS. However, as a national multisite study that was cited by 10 of the 19 above-mentioned SS trials, it is likely that WTS played a role in the identification of SS as an evidence-based practice and in its broader implementation in the U.S.

There are several limitations worth highlighting with respect to our method. The absence of response from 2/7 sites suggests that the survey findings may not be sufficiently representative of the whole sample, and may be biased in favor of specific site's positive experiences. Therefore, we caution against extrapolating beyond the survey findings of this one study. Because our comparison group in the WTS did not include a substance use component, we are unable to disentangle whether the trauma versus the substance use components were driving the study outcomes. And, as we emphasized in our discussion, because WTS was only one of a number of efforts to disseminate the SS model, we can only speculate as to the impact of the study more globally. However, it was the largest multisite study to date exploring SS in front line community SUD treatment programs. Study findings suggest new directions for research and treatment and provide a strong rationale for testing more intensive PTSD approaches (e.g., cognitive processing, prolonged exposure). Because SS did not differ from the WHE on reduction of SUD severity, adding approaches that directly target SUD relapse triggers may improve outcomes. In tandem with SAMSHA efforts to promote and enhance trauma-informed care in mental health and substance using populations, clinical and scientific impacts from the WTS underscore the need for a national platform for addressing comorbid disorders that disproportionately impact women.

CRediT authorship contribution statement

Denise Hien: Conceptualization, Methodology, Writing - original draft, Writing - review & editing, Funding acquisition, Project administration. **Frankie Kropp:** Conceptualization, Methodology, Data curation, Writing - review & editing.**Elizabeth A. Wells:** Conceptualization, Methodology, Data curation, Writing - original draft, Writing - review & editing. **Aimee Campbell:** Conceptualization, Methodology, Writing - original draft, Writing - review & editing, Funding acquisition, Project administration.**Mary Hatch-Maillette:** Writing - original draft. **Candace Hodgkins:** Writing - original draft. **Therese Killeen:** Conceptualization, Methodology, Writing - review & editing. **Teresa Lopez-Castro:**Writing - review & editing.**Antonio Morgan-Lopez:** Conceptualization, Methodology, Writing - original draft. **Lesia M. Ruglass:** Conceptualization, Methodology, Writing - review & editing. **Lissette Saavedra:** Conceptualization, Methodology, Writing - original draft. **Edward V. Nunes:** Writing - review & editing, Funding acquisition, Project administration.

Declaration of competing interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jsat.2020.02.003.

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