

# A Peer Support Specialist-Delivered Sexual and Intimate Partner Violence Prevention Program for Women in Substance Use Treatment (THRIVE): Protocol for a Single Arm Trial

Heidi Zinzow, Irene Pericot-Valverde, Lauren Smalls, Madelyn Brancato, Greyson Chapman, Allison Smith, Ava Thompson, Caroline Greco, Meghan Shank, Kacey Eichelberger, Kimbley Smith, Alain Litwin

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## A Peer Support Specialist-Delivered Sexual and Intimate Partner Violence Prevention Program for Women in Substance Use Treatment (THRIVE): Protocol for a Single Arm Trial

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#### Abstract

**Background:** The majority of persons in substance use treatment have an interpersonal violence history, with sexual and intimate partner violence disproportionately affecting women. Both violence history and substance use place women at risk for cumulative trauma exposure and adverse outcomes, including substance use disorders (SUDs), posttraumatic stress disorder (PTSD), depression, and physical health problems. There is an urgent need for interventions to reduce these health disparities by preventing victimization and revictimization among women with SUDs. The Healthy Relationships and Interpersonal Violence Education program (THRIVE) adapts evidence-based strategies for this population and is informed by the information, motivation, behavioral skills (IMB) theoretical model. Topics include the intersection of substance use and violence, consent, risk detection, protective behavioral strategies, and help-seeking. THRIVE employs a novel approach by engaging peer support specialists (PSS) to deliver the program. PSS are trained advocates with lived experience who can help overcome barriers to care, including stigma and accessibility.

**Objective:** The first objective is to determine the preliminary efficacy of THRIVE, including its effect on violence-related knowledge and attitudes, protective behavior, victimization, substance use, and mental health. The second objective is to determine program acceptability and feasibility.

Methods: The protocol entails a single arm trial of THRIVE with 60 women in behavioral and/or medication-assisted substance use treatment, recruited from three outpatient and residential treatment sites. Interview data will also be collected from ten participants and two PSS. Participants complete assessments at four time points over three months (baseline, post-intervention, one- and three-month follow-up). Self-report questionnaires assess violence prevention knowledge and attitudes, sexual self-efficacy, protective sexual/dating strategies, trauma-focused service use, sexual and intimate partner violence victimization, substance use, posttraumatic stress disorder symptoms, and depression symptoms. To determine feasibility, quantitative and qualitative data assess recruitment, retention, engagement, perceived usefulness, barriers and facilitators of participation and adoption, and working alliance with PSS.

Results: A total of 60 participants were recruited and completed the intervention between June and October 2024.

Conclusions: THRIVE will address critical gaps in the field by: 1) expanding violence prevention strategies to SUD treatment settings; 2) integrating sexual and intimate partner violence prevention, 3) incorporating a focus on illicit substance use, and 4) engaging PSS to overcome barriers to care. The long-term objective of this project is to develop an accessible, scalable, and efficacious prevention program that reduces incidence of sexual and intimate partner victimization, substance use, and violence-related mental health disorders for women in substance use treatment. Clinical Trial: NCT06608979

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# **Original Manuscript**

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## Abstract (450 words)

Background: The majority of persons in substance use treatment have an interpersonal violence history, with sexual and intimate partner violence disproportionately affecting women. Both violence history and substance use place women at risk for cumulative trauma exposure and adverse outcomes, including substance use disorders (SUDs), posttraumatic stress disorder (PTSD), depression, and physical health problems. There is an urgent need for interventions to reduce these health disparities by preventing victimization and revictimization among women with SUDs. The Healthy Relationships and Interpersonal Violence Education program (THRIVE) adapts evidence-based strategies for this population and is informed by the information, motivation, behavioral skills (IMB) theoretical model. Topics include the intersection of substance use and violence, consent, risk detection, protective behavioral strategies, and help-seeking. THRIVE employs a novel approach by engaging peer support specialists (PSS) to deliver the program. PSS are trained advocates with lived experience who can help overcome barriers to care, including stigma and accessibility.

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strategies to SUD treatment settings; 2) integrating sexual and intimate partner violence prevention,

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The long-term objective of this project is to develop an accessible, scalable, and efficacious

prevention program that reduces incidence of sexual and intimate partner victimization, substance

use, and violence-related mental health disorders for women in substance use treatment.

**Keywords:** women; sexual violence; sexual assault; intimate partner violence; dating violence;

substance use; prevention; peer support specialists; peer recovery coaches

**Trial Registration** 

ClinicalTrials.gov Identifier: NCT06608979

Introduction

**Interpersonal Violence History in Substance Use Treatment** 

Women with substance use disorders (SUDs) are a high-risk group, with significant prevalence of

trauma history. A vast majority (60-90%) of persons in substance use treatment report a trauma

history, with women being at greatest risk for prior and repeated exposure to interpersonal

violence.1-4 Interpersonal violence is an overarching term that encompasses both sexual and

intimate partner violence. Sexual violence (SV) can be defined as nonconsensual sexual contact

through physical force or inability to consent (e.g., incapacitation due to drugs or alcohol). It can include harassment, unwanted contact, coerced sex, or attempted or completed rape, and more recently has been expanded to include cyber sexual violence. <sup>4,5</sup> Intimate partner violence (IPV) often co-occurs with sexual violence and includes physical violence, sexual violence, stalking, and psychological aggression that occurs in the context of a current or former romantic relationship.<sup>6</sup> Given the high prevalence of interpersonal violence among women with SUDs, there is an urgent need for interventions to prevent victimization and revictimization in this population.

#### Interpersonal Violence, Substance Use, and Health

Interpersonal violence is a significant public health problem associated with a host of physical and mental health outcomes, including posttraumatic stress disorder (PTSD), depression, substance use disorders, chronic pain, gastrointestinal disorders, and a variety of chronic health conditions. <sup>7-9</sup> Both trauma history and substance use place women at risk for exposure to cumulative interpersonal violence, and two-thirds of sexually victimized women experience revictimization <sup>10,11</sup> Substance use is frequently cited as a coping mechanism for managing posttraumatic stress and the aftereffects of violence exposure, and also places women at risk for interpersonal violence victimization. <sup>11,10</sup> For example, research has indicated that individuals in treatment for co-occurring disorders such as PTSD and substance use disorder are at greater risk for violent victimization compared to persons with SUD alone. <sup>12</sup>

Despite the intersection of trauma and substance use problems, there is a disconnect between trauma-informed services and substance use treatment. <sup>13</sup> The Substance Abuse and Mental Health Services Administration (SAMHSA) has proposed a model of trauma-informed care to adopt in behavioral and substance use treatment facilities, further emphasizing the importance of an integrated approach to substance use treatment. <sup>14</sup> Without efficacious violence prevention programs integrated in these settings, women with SUDs will continue to suffer from trauma-related health disparities.

#### **Barriers to Care**

In addition to a lack of access to integrated service delivery models, women with SUDs and trauma history face multiple barriers to care. These barriers inhibit engagement with prevention and recovery, as well as curtail help-seeking behavior. Barriers include stigma, lack of acknowledgment of violent incidents, mistrust in formal systems, being a member of an oppressed or minoritized group, problematic gender role norms, lack of available resources, and fears of negative consequences. Furthermore, the strain on healthcare systems to address the current mental health crisis has limited the availability of mental health professionals to deliver preventative care and clinical interventions. 17,18

## Potential of Peer Support Models to Advance Trauma-Informed Care

The SAMHSA model for trauma-informed care highlights the important role of peer support services in overcoming these barriers and in ensuring a continuum of care. Peer support specialists (PSS) are individuals who have achieved recovery from mental health conditions. PSS use both their lived experience and relevant training to guide and mentor other individuals in treatment or recovery. <sup>19</sup> Peer support programs are based on the principles of mutual respect and support, empowerment, shared responsibility, and an empathy and connection that can be achieved outside of the constraints of a hierarchical (expert/patient) relationship. <sup>20</sup> These programs aim to reduce marginalization and stigma, while offering an extension of mental health care beyond the bounds of formal services. Peer support specialists (PSS) not only offer a means of overcoming resource demands, but they can also address other significant barriers to care—stigma, mistrust in formal systems, and limited availability of providers representing minoritized identities. <sup>21</sup> Peer norms are a significant predictor of substance use and violent perpetration and victimization, and the involvement of peers as prevention educators could be especially fruitful in shifting these norms. <sup>22,23</sup> Violence prevention programs are sorely needed in substance use treatment settings, and PSS can

serve as an important resource for offering the tools to prevent victimization, revictimization and their associated mental health sequelae among women with SUDs.

Peer support programs were integrated into formal mental health systems in the 1980s and currently represent one of the fastest growing sectors of the mental health workforce. <sup>19</sup> Research has established the value of PSS models for suicide prevention and managing mental health conditions, <sup>24</sup> <sup>25</sup> but has yet to evaluate peer support models for offering violence prevention in various mental healthcare settings. Our program extends this promising model to implement needed prevention programming via trusted and trained peer facilitators in substance use treatment settings.

## **Violence Prevention Programs**

Numerous evidence-based programs for SV and IPV prevention have been developed and supported by prior research. However, they have almost exclusively been delivered in college and other school-based settings. A recent meta-analysis showed that campus SV prevention programs have significant impact on rape myth acceptance, knowledge and attitudes towards sexual assault, knowledge of consent, and victimization.<sup>26</sup> Most of these programs are geared towards a broad audience of potential victims, perpetrators, and bystanders. The Enhanced Assessed Acknowledge Act (EAAA) model is one of the few models to show efficacy for specifically addressing risk for sexual victimization among women by employing risk recognition, reducing barriers to active resistance, and engaging in protective strategies. Participants demonstrated decreased rape myth acceptance, increased resistance strategies, and decreased incidence of completed rape at 6 months. To our knowledge, very few programs address alcohol use problems in the context of SV prevention. One web-based program, which used normative feedback on drinking behavior significantly reduced SV risk among women with severe SV history and also reduced alcohol use among college women with SV and heavy episodic drinking histories.<sup>27</sup> Our own team has developed and tested college prevention programs, including a digital app (Make a Change) and a

web-based program for college athletes (All In) that employed education on consent, protective strategies, and alcohol risk reduction. These programs demonstrated reductions in SV risk factors, including violence-supportive peer norms and drinking behavior. <sup>28,29</sup> Prior programs offer guidance in terms of evidence-based prevention content, although none have been tested among treatment-seeking populations or individuals with SUDs outside of alcohol use disorders. Furthermore, despite the shared risk factors and concurrence of sexual and intimate partner violence, none of these programs integrate strategies for addressing these co-occurring forms of violence.

#### **Theoretical Framework**

The Healthy Education and Interpersonal Violence Education (THRIVE) program is informed by the Information-Motivation-Behavioral Skills (IMB) model, which posits that three constructs influence behavior change and its consequent effects on health outcomes: 1) information and knowledge about the behavior; 2) motivation to perform the behavior, and 3) the behavioral skills necessary to perform the behavior.<sup>30</sup> Regarding information and knowledge, literature on interpersonal violence has indicated that knowledge of consent, recognizing and acknowledging sexual assault, and endorsement of rape and partner violence myths are associated with victimization risk. Motivational factors associated with protective behaviors and victimization include peer norms, intentions, and risk recognition related to SV and IPV. Behavioral skills and behaviors that reduce likelihood of victimization include risk recognition, coping and resistance skills for risky situations, self-efficacy to perform these skills, protective behavioral strategies (e.g., sexual assertiveness, safety planning), substance use harm reduction strategies, and help-seeking.<sup>31-34</sup> THRIVE program components align with each of these theoretical and empirical risk and protective factors as depicted in Figure 1.

## **Study Aims**

The study will examine the preliminary efficacy and feasibility of THRIVE, a PSS-delivered interpersonal violence prevention program for women in substance use treatment. The first objective is to determine the preliminary efficacy of THRIVE. Proximal outcomes include violence-related knowledge and attitudes, protective sexual/dating behavior, and help-seeking. Distal

outcomes include victimization, substance use, and mental health. The second objective is to determine program acceptability and feasibility. These objectives will be achieved via single arm trial with 60 women in outpatient and residential substance use treatment.

#### Method

## **THRIVE Program Development**

We conducted preliminary program content development following an iterative process. We first developed content based on evidence-based and theoretically-informed strategies from the literature, as well as our prior prevention programs with college women. <sup>29</sup> <sup>28</sup> Second, we adapted and refined the content based on two rounds of interviews with two expert consultants, five providers at substance use treatment clinics, five peer support specialists, and five women in SUD treatment. Interviews assessed feasibility and acceptability, strengths and weaknesses of the program, preferred delivery modalities, and suggestions for improvement. Participants unanimously agreed that the content would be useful and appropriate for women in SUD treatment. Participants indicated that a flexible format would be preferred in terms of offering individual versus group sessions. Women in SUD noted that they would respond well and prefer to have a PSS deliver sensitive content related to sexual assault psychoeducation and substance use.

We added components specific to this population based on feedback from participants. These include risk reduction information for drugs (rather than primary focus on alcohol from most prevention programs), addition of discussions about exchanging sex for drugs, a scenario-based skills building component, increased interactivity (question and answer, myths vs. facts exercises), and handouts with key takeaways.

#### Intervention

The intervention consists of two 60-minute sessions delivered in-person by PSS in either group or individual format. The sessions include a combination of information, interactive exercises to fuel discussion on knowledge, attitudes, and behaviors, and skills building activities. Handouts

accompany each session with key takeaways and resources. Topics include: 1) definitions of sexual and intimate partner violence, 2) consent, 3) healthy vs. unhealthy relationships, 4) help-seeking and resources for trauma-related care, 5) protective behavioral strategies, 6) safe dating, 7) alcohol and drug safety 8) sexual assertiveness, 9) overcoming barriers to protective strategies, 10) creating a behavior change plan. See Table 1 for intervention content. In addition to the prevention education program, PSS will screen each participant for PTSD using the PC-PTSD-5. The participants who score three or greater (indicating a potential PTSD diagnosis) will be referred to local mental health providers who provide trauma-informed care.

#### **Study Design**

We will develop elements for a larger clinical trial by pilot testing a two-session program in a single arm trial with 60 participants. To examine preliminary efficacy, we will collect self-report questionnaires at baseline, post-intervention, one-month, and three-month follow-up. To analyze feasibility and acceptability we will examine retention, adherence and survey data from the trial. We will also conduct exit interviews with 10 participants and two PSS. These data will be used to inform future refinement of the protocol in preparation for a larger clinical trial.

## Knowledge, attitude, behavior

Proximal outcomes include knowledge, attitudes, behaviors. Regarding knowledge and attitudes, we will assess knowledge of sexual and intimate partner violence, knowledge of consent, attitudes towards sexual and dating violence (acceptance of rape supportive beliefs and partner violence/dating myths), sexual self-efficacy (perceived barriers to engaging in protective strategies), and knowledge of resources. Regarding behavioral intentions and behaviors, we will assess intentions to engage in protective strategies and trauma-related service use (behavioral health care, accessing local and national resources).

#### Victimization, substance use, mental health

Primary distal outcomes include: 1) sexual victimization (ranging from unwanted sexual contact to rape) and 2) intimate partner victimization (psychological and/or physical), including any exposure over the course of three months. Secondary outcomes include substance use and mental health outcomes, including depression and PTSD.

#### Feasibility and acceptability

Outcomes include recruitment, retention, barriers and facilitators of implementation and engagement, satisfaction, alliance with PSS, and PSS adherence to the protocol.

#### **Ethical Considerations**

The study was approved by the Prisma Health IRB (#2042281). The study is registered with clinicaltrials.gov, NCT06608979. Prior to screening for eligibility, the research coordinator will obtain verbal consent for screening, which briefly describes the study, and reinforces the confidentiality of all survey information. Interested patients who are eligible for the study after the initial screen will provide verbal consent to proceed after reviewing a written informed consent document. The participants will review the consent document again prior to proceeding with each self-report survey. Surveys do not record identifying information, and participants will be assigned a participant number to link survey data.

## **Setting**

The study will be conducted at three sites that provide substance use treatment in Greenville, SC.

1) Prisma Health Addiction Medicine Clinic provides care to over 3000 opioid use disorder patients per year, including medication-assisted treatment, peer recovery support, and counseling. 2) The Phoenix Center is a comprehensive substance use treatment program with an intensive outpatient program, inpatient detoxification and rehabilitation programs, outpatient buprenorphine program,

and a residential program for pregnant women and mothers (Serenity Place). They serve over 2000 individuals per year. PSS are contracted to work with the patients at Phoenix Center. 3) The Magdalene Clinic at Prisma Health offers prenatal care, peer support services and counseling to pregnant persons with substance use disorders. They serve over 100 individuals per year and work closely with Addiction Medicine and Phoenix Centers.

#### **Participants and Procedure**

#### THRIVE pilot trial

#### **Participants**

We will recruit and enroll 60 women in substance use treatment for a single arm trial of THRIVE. Inclusion criteria include 1) adults (≥18), 2) identify as female, 3) currently enrolled in substance use treatment (behavioral and/or pharmacological), 4) willing to accept random assignment to waitlist (usual care) or THRIVE. Exclusion criteria include 1) having a severe medical or psychiatric disability that could impair ability to perform study-related activities (determined by the clinician), 2) unable to independently read and/or comprehend the consent form or other study materials, 3) unable to read/speak English.

#### Recruitment

Participants will be recruited via referral from clinicians and research coordinators at the three recruitment sites, using flyers, email, and verbal communications.

## Screening and Consent

The research coordinator will enroll potential participants from the Addiction Medicine Center, Phoenix Center, and Magdalene Clinic by contacting patients who are referred by clinicians and staff at each of these clinics. Potentially eligible participants will be given a flyer about the study and asked if they are interested in considering participation. Potential participants who express interest in learning about our study will have a discussion with the research coordinator. Prior to the

administration of any study measures, the research coordinator will obtain verbal consent for screening, which briefly describes the study, and reinforces the confidentiality of all survey information. Interested patients who are eligible for the study after the initial screen will provide verbal consent to proceed after reviewing a written informed consent document.

#### Assessment Plan

Research assessments will consist of 20-30-minute online self-report questionnaires at a total of four assessment points: baseline, post-intervention, one month follow-up and three month follow-up. Ten participants from the intervention group will be selected for exit interviews that will be conducted post-intervention. We will also conduct interviews with the two PSS who are facilitating the program. Participants will attend baseline, intervention, and post-test visits in person at one of the three study sites. The research coordinator or research assistant will attend all baseline and post-test visits (immediately preceding/following THRIVE sessions) in person to collect online survey data using a tablet PC. Qualtrics software is employed to administer the online surveys and extract the data. Follow-up surveys will be collected via online surveys delivered to participants' phone numbers or email addresses. Participants will receive \$30 for each of four assessments (maximum of \$120). Participants completing exit interviews will receive an additional \$30.

#### Measures

See Table 2 for a list of study measures and constructs.

#### Knowledge, attitudes, and behavior

Proximal outcomes will be assessed via the following self-report surveys: 1) Illinois Rape Myth Acceptance Scale<sup>36</sup> a 20-item scale assessing acceptance of rape supportive beliefs and norms (e.g., "if a woman was raped while she was drunk, she is responsible for what happened") Attitudes Towards Dating Violence Scale, <sup>37</sup> a 15-item scale assessing acceptance of dating and partner violence myths (e.g., stereotypic gender roles, acceptance of partner violence), 3) ARC3 Consent Scale<sup>38</sup> a 7-item scale assessing understanding of consent in sexual situations (e.g., "if you and your partner are both drunk, you don't have to worry about consent"), 4) Barriers to Resistance

Scale, <sup>34</sup> a 13-item scale which assesses sexual self-efficacy, sexual assertiveness, and perceived barriers to resisting in sexually coercive situations (including substance use), 5) <u>Dating Behavior Survey</u>, <sup>39</sup> a 15-item scale assessing intentions to engage in risky and protective behaviors, such as using substances on a date, arranging for transportation, and making safety plans and 6) <u>Resistance Responses to Sexual Aggression</u>, <sup>40</sup> a 16-item scale assessing perceived likelihood of engaging in resistance responses in sexually aggressive situations, including verbal and physical strategies, 7) <u>Knowledge of Resources Scale</u>, <sup>38</sup> which will be adapted to local context to assess familiarity with local and national resources for trauma-focused care (resulting in 13 items), and 8) <u>Trauma-related service use</u>, assessing past month frequency of accessing a list of local and national resources (13 items). The outcome measures are self-report scales that will be summed to create mean and total scores.

#### Sexual and intimate partner victimization

Victimization outcomes will be assessed with: 1) the <u>Sexual Experiences Survey-Short Form</u>,<sup>41</sup> a 7-item scale which assesses self-reported experiences of various forms of victimization (unwanted sexual contact, sexual coercion, attempted rape, rape) via several tactics (verbal, physical, drug-oralcohol facilitation) and 2) <u>Revised Conflict Tactics Scale</u>,<sup>42</sup> a 20-item scale assessing IPV, including psychological, physical, and sexual victimization by an intimate partner (marital, dating, or cohabitating relationship). Victimization will be scored as a dichotomous outcome, and will be measured as lifetime and past three months.

#### Substance use and mental health

A secondary set of distal outcomes will be assessed with the 1) <u>CAGE-AID</u>,<sup>43</sup> a conjoint screening questionnaire for alcohol and other drug use 2) <u>Primary Care PTSD Screen for DSM-5</u> (<u>PC-PTSD-5</u>) <sup>35</sup> a 5-item scale which screens for DSM-5 PTSD criteria; and 3) <u>Patient Health Questionnaire</u> (<u>PHQ-2</u>)<sup>44</sup> which screens for DSM-5 depression criteria. The distal outcome measures are self-report scales in Likert format that will be summed to create mean and total scores.

#### **Quality Assurance and Implementation**

Two female PSS will be hired for the study, and will have been trained as both Certified Peer Support Specialists (CPSS) and Certified Assertive Community Engagement Specialists under the National Association of Alcohol and Drug Abuse Counselors (NAADAC). They are required to be at least one year in recovery. PSS will receive at least 10 hours of training by the PI using the PSS training manual and THRIVE intervention protocol developed in our prior research. As part of the training, PSS will conduct at least two mock sessions under observation by the PI. PSS will also meet weekly with the PI, a licensed clinical psychologist, for supervision once they begin delivering the program. Although not a criterion for the study, PSS may have trauma history, which will be assessed and addressed by the PI to ensure PSS' own mental health concerns are adequately managed and monitored. PSS will be trained in recognizing adverse events and signs of distress, as well as how to refer to mental health and medical professionals to address these concerns as they arise. Intervention fidelity will be monitored with a checklist developed by the research team to assess completion of each THRIVE component. Two members of the research team will rate 50% of a random selection of sessions using a fidelity scale. Raters will code at least 10 practice sessions, which will be reviewed with the research team until acceptable reliability is achieved, and they will attend regular recalibration meetings to prevent drift.

## **Analysis**

#### **Analytic Sample**

The primary analytic sample will include all participants who completed the baseline survey, called the intention-to-treat (ITT) sample. We will also conduct modified ITT analyses including only participants who attended one THRIVE session.

#### Missing data

Every effort will be made to limit the amount of missing primary outcome data in this study. However, the primary analytic strategy relies on mixed-effects models, which is unbiased under

missing at random (MAR) assumptions and is most often acceptable in longitudinal data analysis. Furthermore, as a sensitivity analysis, we will also apply fully specific conditional specification multiple imputation methods, which are applicable to non-ignorable missing data. Characteristics of patients who are lost to follow-up will be compared to those that complete the study to assess the degree of any selection bias due to attrition.

#### Statistical Analyses

To test the effects of THRIVE on primary and secondary outcomes, linear mixed effects models (LMMs) for continuous outcomes and generalized linear mixed effects models (GLMMs) for binary outcomes will be used, with subject-specific random intercepts to account for correlations of longitudinal outcomes measured at post-intervention (week 2), one month follow-up, and three-month follow-up. Covariates, including recruitment sites and any demographic variables correlated with primary outcomes, will be included as fixed effects in all analysis models. The primary knowledge, attitude and behavior outcomes will be continuous outcomes, and secondary outcomes such as experience of SV or IPV will be binary outcomes. In addition, with that model, we will also identify post-baseline time points where changes in outcomes from baseline are significant.

## THRIVE acceptability and feasibility

For our second objective of assessing acceptability and feasibility, we will collect 5 sources of data during the course of the study, following the procedures described above. We will also collect interview data per procedures described below.

#### Measures

The pilot trial data sources include: 1) Recruitment and retention: study logs will record enrollment, attendance, retention rates, and percent of assessments completed, 2) Adherence scales completed by research team members for 50% of sessions will assess PSS fidelity to the protocol 3) Satisfaction and engagement scale: four Likert scale survey items from our prior study, e.g. "how engaging did you find the program?," 5) Qualitative feedback: two items from the self-report surveys

will elicit areas for improvement and strengths of the protocol.

#### **Interviews**

We will conduct semi-structured interviews with a randomly selected subsample of 10 completers, as well as with the two PSS. The interviews will assess program feasibility, acceptability, strengths, and weaknesses. This includes feasibility of attending appointments, acceptability study location, satisfaction with the research team, and intervention format and modality. Interviews will also assess alliance with PSS and suggestions for improvement.

#### **Participants**

Inclusion criteria for the interviews will be: 1) women who have completed the program and completed the final session of THRIVE in the past week; 2) for the PSS criteria will be that they delivered the THRIVE intervention.

#### Recruitment

Ten women who completed THRIVE will be randomly selected and recruited via phone or email contact from the research coordinator.

## Screening and Consent

Potential participants who express interest in participating in our study will have a discussion with the research coordinator. Prior to the administration of any study measures, the research coordinator will obtain verbal consent for screening, which briefly describes the study, reinforces the confidentiality of all survey information, and assesses eligibility. Interested patients who are eligible for the study after the initial screen will provide verbal consent to proceed after reviewing a written informed consent document.

## Assessment plan

Participants will be provided a copy of the THRIVE prevention program content to review, either via email or hard copy. Participants will then complete a 30 minute semi-structured interview assessing

program acceptability, feasibility, strengths, weaknesses, areas for revision or improvement, and barriers/ facilitators to implementation. A member of the research team will conduct the interviews virtually for the PSS, and in-person for the women in treatment. Participants will receive \$30 for completion of the interview.

#### **Analysis**

Descriptive statistics will be used to describe recruitment and retention rates and to calculate means on survey items assessing feasibility and acceptability. A benchmark of ≥75% of agree/strongly agree (equivalent to an average score of ≥4) responses will be employed. 68,69 For the satisfaction and engagement scale, qualitative survey items will be coded by two research team members. Interviews will be recorded, transcribed, and uploaded to NVIVO for analysis. The research team will conduct a line-by-line reading of transcripts to identify inductive codes that emerge from the data. The team will then collaborate to develop a codebook that includes operationalized definitions of each of these inductive codes as they apply to the topics addressed in the interviews (i.e., feasibility, acceptability, strengths, weaknesses, areas for improvement, barriers/facilitators to implementation). A study investigator and the research coordinator will code a subset of the data, then convene to resolve discrepancies and revise codes until consensus is achieved on the codebook. Two research team members will then code the entire dataset and meet to achieve consensus on final codes. The results from these analyses will be used to inform further refinement of the THRIVE protocol before proceeding to a larger randomized controlled trial.

#### Results

Recruitment and enrollment from the three sites was completed between June and October 2024. Of 78 women recruited and enrolled, 60 (77%) completed the intervention and post-test. Across the three sites, 55% were from Prisma Addiction Medicine Clinic, 41% from Phoenix Center, and 4% from Magdalene Clinic. Participants were 88% White, 5% Black, 1% Hispanic, 1% Native American, 3% Other, and 1% Multiracial. Mean age was 35.3 (SD = 9.6). Most commonly reported substances used included tobacco (91%), alcohol (71%), cannabis (77%), opioids (74%), and amphetamines

(74%; See Table 3). Follow-up data collection is ongoingl.

#### **Discussion**

This study will evaluate an interpersonal violence prevention program for women with SUDs to fill a vacuum in programs with demonstrated efficacy for this population. This will be the first study to test an evidence-based sexual and intimate partner violence prevention program for women in substance use treatment. It will address the nexus of two significant public health problems—interpersonal violence and substance use disorders. Although a majority of women in substance use treatment have a history of sexual or intimate partner violence, trauma history and risk for revictimization are rarely addressed in substance use treatment settings.

Both violence history and substance use place women at risk for cumulative trauma exposure and adverse outcomes, including SUDs, PTSD, depression, and physical health problems. For women in substance use treatment, victimization can lead to escalation of substance use and inability to achieve recovery. However, women face barriers to care in seeking trauma-focused services, and there is a lack of available evidence-based violence prevention programs within substance use treatment settings. Therefore, there is a significant need for research to develop and test violence prevention services that could mitigate the sequelae of victimization and revictimization among women in substance use treatment.

An additional gap in the literature that will be addressed by the THRIVE program is the lack of integration of prevention programming for sexual and intimate partner violence, despite their shared risk factors. These forms of violence share risk factors such as exposure to child adversity, stereotypical gender role conformity, and substance use.<sup>46</sup> An intervention that is both pragmatic and attempting to achieve maximum impact will address multiple forms of interpersonal violence simultaneously. The THRIVE program is one of only a few programs to adopt an integrated

approach to these two co-occurring forms of violence. 46,47

THRIVE will also be the only known program to address use of illicit substances as a risk reduction strategy for violence prevention. Prior prevention programs have singularly focused on alcohol use.<sup>27</sup> However, our data from the program development phase suggested the need to address unique concerns around illicit substance use, such as vulnerability during withdrawal, coercion by dealers, and exchange of sex for drugs.

Furthermore, THRIVE will be the first program to engage PSS as violence prevention educators. Consistent with recommended models of trauma-informed care in substance use treatment settings, 48 we will incorporate trained peer support specialists as educators who can lift stigma, offer empathy and trust, reduce barriers to engagement, and fill gaps in mental health service provision. While PSS have delivered prevention programming in the mental health sector, this will be the first known study to develop and test a PSS-delivered violence prevention program. In addition, training PSS in health promotion skills related to violence and substance use will provide them with professional skills and confidence to work with their clientele. A PSS violence prevention model also offers scalable and cost-effective solutions for workforce development and expansion of mental health services.

Finally, THRIVE places unique emphasis on help-seeking and overcoming barriers to care as violence prevention strategies. Encouraging help-seeking will promote access to resources that could mitigate mental health conditions and victimization-related adversity as a means of both health promotion and risk reduction. Our preliminary research indicates that participants find this content both necessary and missing from existing prevention programs.<sup>29</sup> One benefit of employing PSS as facilitators is that they are trained and capable of both modeling appropriate resource utilization as well as offering warm handoffs to other services.

Upon successful completion of this research study, we expect to demonstrate the feasibility, acceptability, and preliminary efficacy of THRIVE. This program will address gaps in the evidence base by emphasizing the critical intersection of violence and substance use, expanding effective strategies to a high-risk population, and implementing a novel peer-delivered format to overcome barriers to care. Our long-term goal is to develop an accessible, scalable, and efficacious prevention program that reduces incidence of sexual and intimate partner victimization, substance use, and violence-related mental health disorders for women in substance use treatment. Ultimately, reducing victimization is expected to reduce substance use escalation, as well as to sustain recovery from substance use disorders over the long term.

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## **Authors' Contributions**

HZ and IP-V conceptualized the study, and HZ is the principal investigator. AL and KE consulted on study design and serve as recruitment leads for study sites. KS serves as recruitment lead for one study site. AS, MS, CG, MB, AT assist with data collection and analysis. LS serves as project coordinator and assists with data collection and analysis. All authors reviewed the protocol and manuscript.

#### **Conflicts of Interest**

None declared

#### References

1. Hines DA. Predictors of sexual coercion against women and men: A multilevel, multinational study of university students. *Arch Sex Behav.* 2007;36:403–422

- 2. Green JG, McLaughlin KA, Berglund PA, et al. Childhood adversities and adult psychiatric disorders in the national comorbidity survey replication I: associations with first onset of DSM-IV disorders. *Arch Gen Psychiatry.* 2010;67(2):113–123
- 3. Ruback RB, Clark VA, Warner C. Why are crime victims at risk of being victimized again? Substance use, depression, and offending as mediators of the victimization–revictimization link. *J Interpers Violence*. 2014;29(1):157–185
- 4. Breiding MJ, Smith SG, Basile KC, Walters ML, Chen J, Merrick MT. Prevalence and characteristics of sexual violence. *Stalking, and.* 2014
- 5. Tjaden PG, Thoennes N. Extent, nature, and consequences of rape victimization: Findings from the National Violence Against Women Survey. 2006
- 6. Breiding M, Basile KC, Smith SG, Black MC, Mahendra RR. Intimate partner violence surveillance: Uniform definitions and recommended data elements. Version 2.0. 2015
- 7. Sells DJ, Rowe M, Fisk D, Davidson L. Violent victimization of persons with co-occurring psychiatric and substance use disorders. *Psychiatric Services*. 2003;54(9):1253–1257
- 8. Ducharme LJ, Knudsen HK, Roman PM. Availability of integrated care for co-occurring substance abuse and psychiatric conditions. *Community Ment Health J.* 2006;42:363–375
- 9. Zinzow HM, Littleton H, Muscari E, Sall K. Barriers to formal help-seeking following sexual violence: review from within an ecological systems framework. *Victims & Offenders*. 2022;17(6):893–918

10. Coombs NC, Meriwether WE, Caringi J, Newcomer SR. Barriers to healthcare access among US adults with mental health challenges: A population-based study. *SSM-population health*. 2021;15:100847

- 11. Singh V, Kumar A, Gupta S. Mental health prevention and promotion—A narrative review. *Frontiers in Psychiatry.* 2022;13:898009
- 12. Stratford AC, Halpin M, Phillips K, et al. The growth of peer support: an international charter. *Journal of mental health.* 2017
- 13. Mead S, Hilton D, Curtis L. Peer support: a theoretical perspective. *Psychiatr Rehabil J.* 2001;25(2):134
- 14. Earnshaw VA. Stigma and substance use disorders: A clinical, research, and advocacy agenda. *Am Psychol.* 2020;75(9):1300
- 15. Waterman EA, Banyard VL, Edwards KM, Mauer VA. Youth perceptions of prevention norms and peer violence perpetration and victimization: A prospective analysis. *Aggressive Behav.* 2022;48(4):402–417
- 16. Hackman CL, Witte T, Greenband M. Social norms for sexual violence perpetration in college. *Journal of aggression, conflict and peace research.* 2017;9(4):305–313
- 17. Schlichthorst M, Ozols I, Reifels L, Morgan A. Lived experience peer support programs for suicide prevention: A systematic scoping review. *Int J Ment Health Syst.* 2020;14. doi:10.1186/s13033-020-00396-1
- 18. Fuhr DC, Salisbury TT, De Silva MJ, et al. Effectiveness of peer-delivered interventions for severe mental illness and depression on clinical and psychosocial outcomes: a systematic review and meta-analysis. *Soc Psychiatry Psychiatr Epidemiol.* 2014;49:1691–1702

19. Kettrey HH, Thompson MP, Marx RA, Davis AJ. Effects of campus sexual assault prevention programs on attitudes and behaviors among American college students: A systematic review and meta-analysis. *Journal of Adolescent Health*. 2023;72(6):831–844

- 20. Gilmore AK, Lewis MA, George WH. A randomized controlled trial targeting alcohol use and sexual assault risk among college women at high risk for victimization. *Behav Res Ther.* 2015;74:38–49
- 21. Orchowski, L.M. Zinzow, H.M., Thompson, M.P. & Wood, S. Open pilot trial of an interactive digital application for campus sexual violence prevention. J. *Journal of Community Psychology.* 2023
- 22. Thompson MP, Zinzow HM, Kingree JB, et al. Pilot trial of an online sexual violence prevention program for college athletes. *Psychology of violence*. 2021;11(1):92
- 23. Fisher WA, Fisher JD, Harman J. The information-motivation-behavioral skills model: a general social psychological approach to understanding and promoting health behavior. *Social psychological foundations of health and illness*. 2003:82–106
- 24. Kelley EL, Orchowski LM, Gidycz CA. Sexual Victimization Among College Women: Role of Sexual Assertiveness and Resistance Variables. *Psychology of violence*. 2016;6(2):243–252. doi:10.1037/a0039407
- 25. Zinzow HM, Thompson M. Beliefs about consent and sexual assault perpetration in a longitudinal study of college men. *Violence Vict.* 2019;34(3):548–565
- 26. Rozee PD, Koss MP. Rape: A Century of Resistance. *Psychol Women Q.* 2001;25(4):295–311. doi:10.1111/1471-6402.00030
- 27. Norris J, Nurius PS, Dimeff LA. Through Her Eyes: Factors Affecting Women's Perception of and Resistance to Acquaintance Sexual Aggression Threat. *Psychol Women Q.* 1996;20(1):123–145.

doi:10.1111/j.1471-6402.1996.tb00668.x

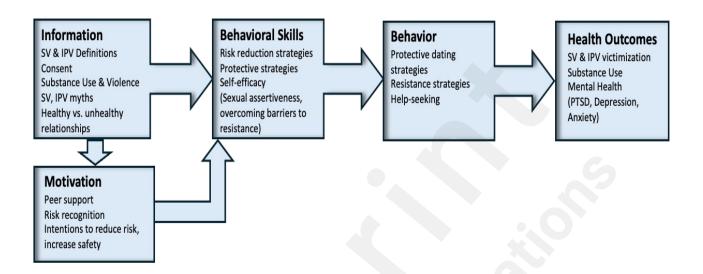
- 28. Prins A, Bovin MJ, Smolenski DJ, et al. The primary care PTSD screen for DSM-5 (PC-PTSD-5): development and evaluation within a veteran primary care sample. *Journal of general internal medicine*. 2016;31(10):1206–1211
- 29. Payne DL, Lonsway KA, Fitzgerald LF. Rape myth acceptance: Exploration of its structure and its measurement using the Illinois rape myth acceptance scale. *Journal of research in Personality*. 1999;33(1):27–68
- 30. Price EL, Byers ES, Belliveau N, et al. The attitudes towards dating violence scales: Development and initial validation. *J Fam Violence*. 1999;14:351–375
- 31. Swartout KM, Flack Jr WF, Cook SL, Olson LN, Smith PH, White JW. Measuring campus sexual misconduct and its context: The Administrator-Researcher Campus Climate Consortium (ARC3) survey. *Psychological trauma: theory, research, practice, and policy.* 2019;11(5):495
- 32. Breitenbecher KH. The convergent validities of two measures of dating behaviors related to risk for sexual victimization. *J Interpers Violence*. 2008;23(8):1095–1107
- 33. Macy RJ. A coping theory framework toward preventing sexual revictimization. *Aggression and Violent Behavior.* 2007;12(2):177–192
- 34. Koss, M.P., Anderson, R.A., Peterson, Z., Littleton, H., Abbey, A., Kowalski R., Thompson, M., Canan, S. White, J.W. McCauley, H., Orchowski, L., Fedina, L., Lopez, E., Allen, C., & Swartout, K. The Revised Victimization Version of the Sexual Experiences Survey (SES-V): Process, Foundations, Evidence, and Items. *Journal of Sex Research*. under review
- 35. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised conflict tactics scales (CTS2) development and preliminary psychometric data. *J Fam Issues*. 1996;17(3):283–316

36. Brown RL, Rounds LA. Conjoint screening questionnaires for alcohol and other drug abuse: criterion validity in a primary care practice. *Wis Med J.* 1995;94(3):135–140

- 37. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 2003;41(11):1284–1292
- 38. Koss MP, Abbey A, Campbell R, et al. Revising the SES: A collaborative process to improve assessment of sexual aggression and victimization. *Psychol Women Q.* 2007;31(4):357–370
- 39. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*. 2001;16(9):606–613
- 40. Bishop LS, Benz MB, Palm Reed KM. The impact of trauma experiences on posttraumatic stress disorder and substance use disorder symptom severity in a treatment-seeking sample. *Professional Psychology: Research and Practice*. 2017;48(6):490
- 41. Abramsky T, Watts CH, Garcia-Moreno C, et al. What factors are associated with recent intimate partner violence? Findings from the WHO multi-country study on women's health and domestic violence. *BMC Public Health*. 2011;11(1):1–17
- 42. Smith SG, Basile KC, Gilbert LK, et al. National intimate partner and sexual violence survey (NISVS): 2010-2012 state report. 2017
- 43. Substance Use and Mental Health Services Administration (SAMHSA).(2014). SAMHSA's concept of trauma and guidance for a trauma-informed approach. *HHS Publication No.(SMA)*. 2019:14–4884

## **Figures and Tables**

Figure 1. Alignment of THRIVE Program Components with the IMB Model



**Table 1**THRIVE Program Content

Topic	Content	Outcome Measure	IMB Mode I
Session One: Be in	n the Know		
What is sexual assault?	Definitions and types of sexual violence Types of perpetrators	Rape Myth Acceptance Scale	I
What is drug-or- alcohol- facilitated assault?	Definitions and types of drug-or-alcohol- facilitated sexual assault; How it occurs		I
What is consent?	What is and is not consent Enthusiastic consent	Consent Scale	I
Red flags	Intimate partner violence: Warning Signs of Unhealthy Relationships	Attitudes Towards Dating Violence	M, B
What is healthy?	Healthy relationships		M, B
Myths vs. Facts	Exercise: myths and facts about interpersonal violence	Rape Myth Acceptance Scale Attitudes Towards Dating Violence	>I
Resources	Local/national resources for interpersonal violence	Knowledge of Resources Scale	I
<b>Session Two: Safe</b>	ty Skills	. 0, (3)	
How to respond	How to respond if someone is pressuring or hurting you	Dating Behavior Survey	В
Alcohol and drug safety			I, M
Safe dates	Safe dating and protective behaviors	Resistance	I, B
Be assertive	Sexual assertiveness	Responses to Sexual	В
Overcoming barriers	Barriers to protective behaviors and how to overcome them	Aggression (SA)	M, B
Skill building	Recognizing and responding to risk (example scenario)		В
Make a plan	Personalized behavior plan		В
Help-seeking	Resources for interpersonal violence	Service Use Scale	В

I = Information, M = Motivation, B = Behavioral Skills

**Table 2**Pilot Trial Outcomes and Measures

Construct	Measure	Baseline	Post- inter- vention	1 mo. FU	3 mo. FU	IMB Model
Proximal Outcomes: Knowl	edge, Attitude, Behavior					
Sexual Violence Attitudes	Illinois Rape Myth Acceptance Scale-short form <sup>36</sup>	X	X	X	X	I
Partner Violence Attitudes	Attitudes Towards Dating Violence Scale <sup>37</sup>	Х	X	X	Х	I
Knowledge of Consent	ARC3 Consent Scale <sup>38</sup>	Х	X	х	X	
Sexual Self-Efficacy	Barriers to Resistance Scale <sup>34</sup>	X	X	х	X	В
Behavioral Intentions	Dating Behavior Survey <sup>39</sup> Resistance Responses to Sexual Aggression <sup>40</sup>	X	X	x	X	М
Knowledge of Resources	Knowledge of resources scale, (locally adapted) <sup>38</sup>	Х	X	×	Х	I
Help-seeking (Trauma- related Service Use)	Frequency of use of behavioral health services, local/national resources	X		х	X	В
Primary Distal Outcomes: V	/ictimization					
Sexual Victimization	Sexual Experiences Survey-Short Form <sup>49</sup>	Х		x	Х	Н
Intimate Partner Violence Victimization	Revised Conflict Tactics Scale Short Form (CTS- 2S) 42	X		х	Х	Н
Secondary Distal Outcomes	s: Substance Use and Men	tal Health				
Substance Use	CAGE-AID	Х	Х	Х	Х	В
PTSD	PC-PTSD-5 <sup>35</sup>	Х	Х	Х	Х	Н
Depression	Patient Health Questionnaire-2 (PHQ- 2) 50	X	X	×	Х	Н
Acceptability and Feasibility						
Feasibility	Recruitment and Retention: Enrollment		Х		Х	

	and attendance tracking, % of assessments completed					
Adherence	THRIVE adherence scale (rating of PSS fidelity to protocol)	During				
Acceptability/Engagement	Peer Support Specialist Interviews Exit interviews			х		
Acceptability/Engagement	Satisfaction scale Qualitative survey items- feedback on protocol		Х	x	,	

I = Information, M = Motivation, B = behavioral skills, behavior, H = health outcomes

**Table 3**Types of Substances Used by Enrolled Participants (n =78)

Substance Type	n	%
Tobacco	71	91.0%
Alcohol	55	70.5%
Cannabis	60	76.9%
Opioids (Heroin, Fentanyl, etc.)	58	74.4%
Amphetamine Type Stimulants	58	74.4%
Inhalants	19	24.4%
Sedatives	48	61.5%
Hallucinogens	33	42.3%
Cocaine	46	59.0%

# **Supplementary Files**

# **Figures**

Alignment of THRIVE program components with the IMB model.

