Central Texas VA Healthcare System research protocol.
Title: Addressing the Health Concerns of VA Women with Sexual Trauma
Sponsor: Department of Defense
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Version date: 10.26.2018

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Appendices:

1. Study Measures
2. Interview questions (informant, exit)
3. Recruitment Flyer
4. Recruitment letter
5. Phone script

Addressing the Health Concerns of VA Women with Sexual Trauma

Section 1. Overview of the study and procedures

The VA Women's Health Research Agenda[1] underscores the importance of improving the safety and health outcomes of returning Veteran women. With greater numbers of women joining the military, the need for gender-specific VA-based interventions is increasingly important [2,3]. Posttraumatic stress disorder (PTSD), intimate partner violence (IPV), and alcohol use are closely interrelated and significant concerns for women Veterans with a history of sexual trauma (ST). Given that screening for military sexual trauma (MST) is mandated within VAs, a computer delivered intervention has the potential to be easily integrated into the standard of care for women who screen positive for MST and/or other lifetime STs, increasing the identification of high-risk women Veterans. Our proposal would provide a computer-based intervention on a VA computer issued laptop that could improve delivery service and fill a healthcare gap for a vulnerable Veteran population.

The long-term goal of the proposed work is to make a significant impact on advancing health services research by introducing and testing a novel and potentially powerful service tool that may improve service delivery to address the co-occurring health concerns for VA women with lifetime ST. The intervention, Safe and Healthy Experiences (SHE), a brief modular, computer-based intervention, will target interrelated health risks for women Veterans with lifetime ST (i.e. alcohol misuse, IPV, and PTSD). SHE will be designed to provide individualized assessment, feedback, and referrals for women Veterans with lifetime ST. The intervention we propose will be based on motivational interviewing (MI), a well-defined intervention strategy that has yielded particularly promising results in a range of clinical issues, including interpersonal violence[4], and a range of patient populations, including male and female Veterans[5]. MI is a collaborative and non-confrontational approach that emphasizes increasing a participant's awareness of successful steps towards her own well-being. MI is consistent with an empowerment model, which is a highly recommended intervention model for victimized women[6] and both MI and an empowerment model converge on important principles for intervening with victimized women[7].

We anticipate that findings from the proposed study will provide the necessary groundwork to examine the efficacy of SHE in a future, large clinical trial. If the SHE intervention is found to be feasible, acceptable and efficacious in improving outcomes for women Veterans with lifetime ST, the ultimate goal would be for our program to be integrated into clinical care and widely disseminated. We have proposed two phases of research directed toward these aims: 1) develop and refine an integrated screening and behavior intervention for VA women with lifetime ST in a brief modular computer-based format that can be administered in a VA primary care setting, and 2) collect data on the feasibility, acceptability, and initial efficacy of the intervention in improving the health of VA women, and increasing utilization of treatment and resources.

The study aims are to:

1. Develop our proposed preliminary computer-based intervention, incorporating information gained in informant interviews.

2. Perform a small open trial (n = 20) of SHE to assess feasibility of recruitment of target population and acceptability of intervention and study procedures.

3. Conduct an initial randomized control trial in a sample of no more than 155 women Veterans who screen positive for lifetime sexual trauma (ST) and have at least one risk factor (i.e., screen positive for intimate partner violence (IPV), posttraumatic stress

disorder (PTSD), and/or heavy drinking) to demonstrate the feasibility of SHE and the acceptability of SHE via participant report of ease of use, helpfulness, and overall satisfaction.

4. Examine preliminary evidence for the hypotheses that, relative to the control condition, screening and referral only (SR), SHE will result in:
    - Decreases in the number of risks (i.e., heavy drinking (4+ drinks on one occasion), screen positive for PTSD, screen positive for IPV) at the 2- and 4-month follow-up (*primary*).
    - Increases in resource and treatment utilization over the 2- and 4-month follow-up period (*secondary*).

The data will be used to demonstrate whether the effects of the intervention look promising to support a future large-scale randomized control trial and to suggest, in concert with results from clinical trials in related fields, the range of effect sizes that would be reasonable to expect in a future trial.

This is a multi-site study. At the Providence, RI based site (Women and Infants Hospital and Brown University), the specialized computer-based assessment and interactive intervention sessions will be developed and designed and staff members will also assist with data management. The Central Texas VA Healthcare System site will be the data collection site and the main site for participant recruiting, consenting, enrollment, intervention and follow-up. Staff at the two sites will work collaboratively throughout the project to supervise study staff, for reporting to the DOD and IRB's and in designing the assessment and intervention sessions, however, only the study staff at the Central Texas site will have access to participant PHI.

Section 2. Study Background

Sexual trauma is a wide spread and significant public health concern among women Veterans[8-10]: Lifetime Sexual Trauma (ST) (i.e., behaviors that range from unwanted sexual touching to attempted or completed rape) disproportionately affects women and can threaten the health and well-being of women[8-10]. Women Veterans have increased rates of ST compared to civilian women[11,12]. For women Veterans, lifetime ST can occur prior to, during or after military service[13]. A recent study of women Veterans (N=1004) reported that two thirds (62%) of participants reported lifetime sexual assault, including 11% reporting attempted rape and 51% reporting at least one completed rape, and the highest rates of rape occurred during childhood and the military service[13]. Women Veterans report substantially higher rates of MST than male Veterans[14-16]. For women, prevalence rates of MST range from 22% to 45%.[17-23] MST is associated with a range of consequences, including PTSD, depression, health complaints, and complications in sexual functioning[18-21,24]. Research has found that among women Veterans, lifetime ST victims report a more extensive trauma history and demonstrate greater psychological impairment compared to those reporting other types of trauma[19]. Lifetime ST is associated with multiple health problems and risks[25-29], increased health care utilization[30], decreased work capacity[31], and a range of mental health consequences[10,32,33], that include PTSD, problem drinking and IPV.

PTSD is more prevalent among women Veterans than women in the community: PTSD is especially prevalent in women: 3.6% of men vs. 9.7% of women have lifetime PTSD[34,35]. Additionally, epidemiological studies have found ST is associated with the highest likelihood of PTSD[36,37]. Given this, and the fact that women Veterans have higher rates of ST compared to civilian women[11,12], it is not surprising that female Veterans' rates of lifetime PTSD (22%) are more than double the rate of women in the general community.[38,39] PTSD among women Veterans has been associated with poor psychiatric and physical functioning[20]. Compared to male Veterans, women Veterans with PTSD were more likely to have higher

mental health, primary care, and emergency care use[40]. PTSD is a disorder of great morbidity. Even subthreshold PTSD is associated with significant psychosocial impairment, comorbidity, suicidality, and subjective distress [41-44].

Problematic alcohol use is prevalent among women Veterans*:* Rates of problematic alcohol use among female Veterans are estimated at 31%[13,45,46]. A large study of women Veterans who had some contact with the VA health care system reported that these women Veterans were at high risk for the negative consequences of alcohol and drug use, in rates that are greater than in the general population[13]. The individual and community consequences of alcohol misuse are estimated at over $184.6 billion[47], and include motor vehicle accidents[48], violent crime victimization and perpetration[49], mental health problems[50,51] and a range of medical consequences[52]. Despite these alcohol-related consequences, women Veterans report low utilization of substance use treatment services[53].

IPV is more prevalent among women Veterans than women in the community: Veteran women are more likely than non-Veteran women to report lifetime IPV victimization (33.0% vs. 23.8%)[54]. Consistent with the larger literature, IPV among women Veterans is associated with increased health risks, including increased heart health risk factors, smoking, and heavy drinking[54]. IPV has wide-ranging and profound effects on health, adversely affecting eight of ten of the leading health indicators identified by the Department of Health & Human Services (DHHS) [55-57] and leading to an estimated medical cost burden up to USD 7.0 billion annually[10,58]. Fatalities from IPV account for 30-50% of all female homicides in the U.S. each year[56,57].

The need to screen and intervene for PTSD, IPV, and alcohol misuse among women Veterans with lifetime ST: ST is strongly associated with PTSD, IPV, and alcohol misuse. Community based studies have found that ST is associated with the highest likelihood of PTSD[36,37]. Women with ST are also likely to be victims of IPV[59]. In addition, alcohol use often increases following experiences of ST [60-65]. Alcohol, PTSD, and IPV, are also interrelated risks for women. For instance, IPV exposure is associated with heavy drinking among women Veterans[54] and alcohol misuse problems are more prevalent among women Veterans diagnosed with PTSD[46] as well as women Veterans with higher levels of PTSD[66,67]. Despite the high-risk profile of women Veterans with lifetime ST, only 38% of ST survivors seen within a VA primary care setting used mental health services in the past year[19]. Although there is a current mandate of screening for MST, researchers have recommended that this screening include pre- and postmilitary sexual assault history because of the high rates of lifetime ST, the range of ST-related morbidities, as well as the importance of connecting more Veterans to much needed services[19]. Furthermore, the Veterans Health Administration (VHA) has no systematic screen and intervention for other ST-related traumas (e.g., IPV[68], childhood STs, or STs after military service) in place, nor does the VHA screen and address the serious health risks associated with lifetime ST within a comprehensive program.

Primary care clinics are ideal settings to reach our target population: Primary care settings are frequent points of health care contact for VA women[19], making the visit itself the ideal, and possibly only, opportunity to provide behavioral interventions. Research has identified numerous health care providers' barriers to screening and intervention for lifetime ST, IPV, PTSD, and alcohol that include lack of time and support resources, low level of confidence in screening and intervening, lack of education and training, and fear of offending the patient[69-72]. Despite the high prevalence of alcohol use, IPV, and PTSD among VA women with lifetime ST and the significant morbidity associated with having coexisting problems (see Section A1 for details), current systems are not in place to adequately evaluate and intervene with these co-occurring problems.

Use of a computer-based format will optimize the consistency, feasibility, and uptake of an intervention for women Veterans with ST: Computer-delivered interventions for women Veterans with lifetime ST is a novel approach and can overcome existing obstacles by providing brief interventions, at a low cost, without requiring substantial investments of time or energy from health care providers. Other advantages include: **First**, as technology-based screening becomes a routine part of health care, the proportion of women Veterans with any ST

history who are screened would increase dramatically. **Second**, because women may disclose stigmatized behaviors more readily in computer-based interviewing, a higher proportion of women would be identified. Research has found that audio computer-assisted self-interview (ACASI) screening consistently identifies a higher prevalence of interpersonal trauma among women (when compared to written or interview format) and was the most preferred approach by women participants[73]. **Third**, computer-delivered brief interventions can take place in waiting or examination rooms without limitation of provider time, willingness, or ability. Further, touch screen technology makes interacting with the computer easy and intuitive for anyone. Simple headphones and spoken text allow the computer to be accessible to those at any literacy level, and confidential in even the most public of settings. Computer-delivered brief interventions require little direct clinician involvement. They can be adapted to be culturally and linguistically specific, and can provide individualized feedback to participants immediately and in an engaging manner. They can deliver assessments and, based on the results, provide individualized recommendations for change. They are able to store information so that progress over time can be accurately monitored and reviewed with the participant. They minimize the bias that can arise in clinical relationships. An intervention, if proven effective, can also be widely disseminated while maintaining treatment fidelity among clinical sites. Adult women have reported increasing comfort with the use of technology, including the Internet and email, for obtaining health information[74].

Summary: The proposed project will develop and assess an innovative, high-reach, easily implementable, low-cost computer-delivered intervention (Safe and Healthy Experiences; SHE) for women Veterans with any lifetime ST that will address known barriers in early identification and intervention of ST-related risks within a primary care setting. Since screening for MST is mandated within the VA, the SHE intervention also closes the gap between efforts to identify ST and then link Veterans to effective care. If the proposed project is found to be feasible and effective, it represents a cost-effective service that may be scaled up nationwide with ease, fidelity, and speed to address the health needs of VA women with lifetime ST.

Section 3. Study Methods

Overview

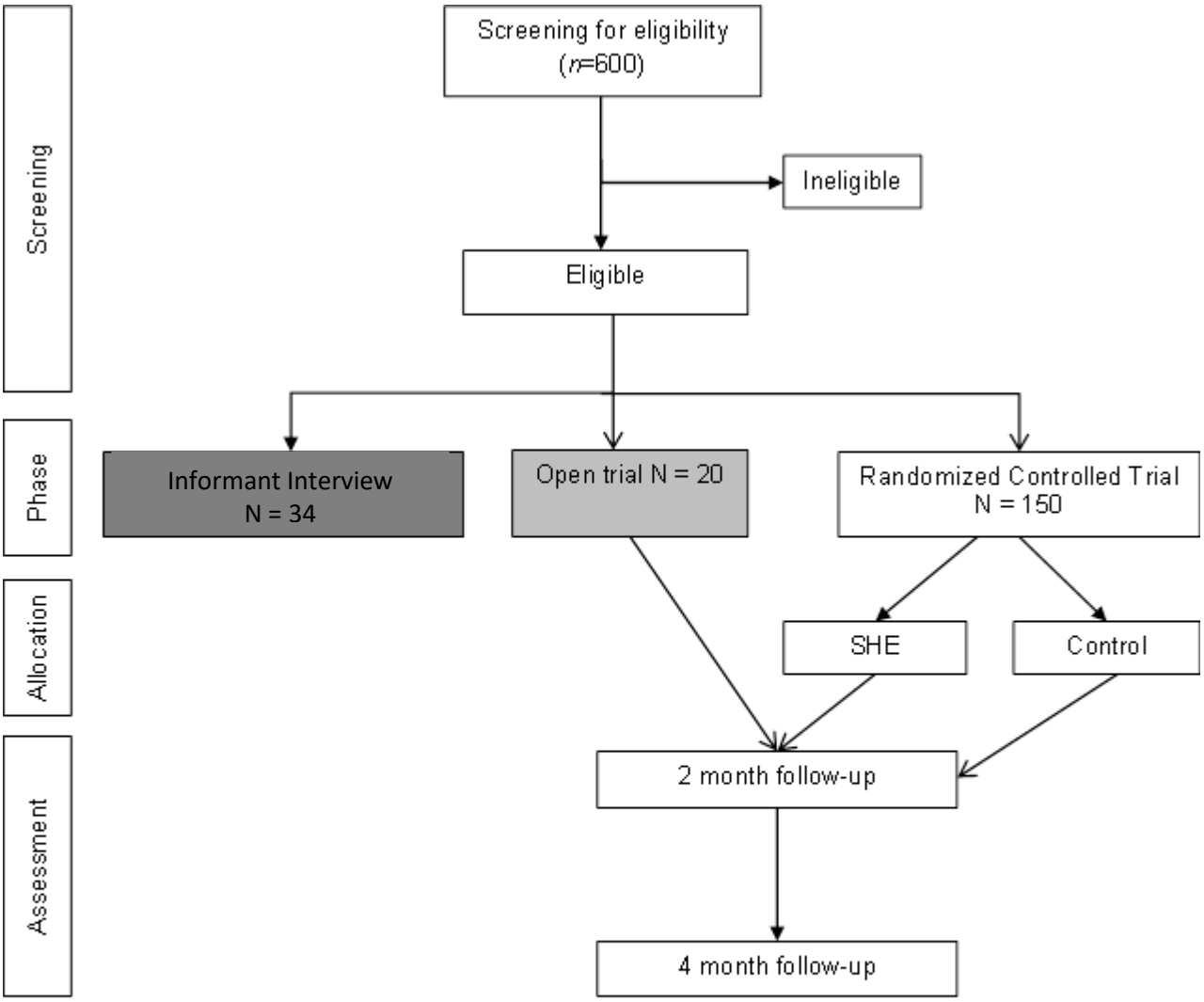
All study assessments and intervention sessions will be delivered on a laptop/tablet device using audio computer-assisted self-interview software. Veterans will input responses to assessment measures directly.

The specific aims of this research proposal are as follows:

1. Development Aims: Stage 1A aims to adapt the structure, and content of our existing interventions to develop a computer-based screening and brief health intervention program that includes modules on: 1) alcohol use; 2) PTSD, and 3) IPV and tailor the modules to women Veterans with lifetime ST using information gathered from informant interviews with 34 women Veterans with lifetime ST. The resulting computer-based intervention will be refined through an open pilot trial in a sample of 20 women with lifetime ST seeking VA primary care and with at least one ST-related risk.

2. Trial Aims: Stage 1B aims to conduct an initial randomized controlled trial in a sample of no more than 155 women with lifetime ST who screen positive for at least one of the risk factors (heavy drinking, PTSD or IPV) to demonstrate the feasibility of the proposed recruitment methods, design, and delivery of the intervention. We will examine evidence for the hypotheses that the intervention, relative to the control group, at the 2- and 4-month follow-up period from baseline, will reduce the number of risks (i.e., heavy drinking (4+ drinks), a positive screen for PTSD, a positive screen for IPV). As a secondary outcome, we will also examine whether the intervention, relative to the control group, increases resource and treatment utilization over the 2- and 4-month follow-up from baseline. The team will review experiences

and outcomes for both the open trial and the initial randomized control study. Results from this proposal will be used as data for a future large-scale randomized control trial. The team of investigators brings a wealth of complementary experience and is extremely well-suited to carry out the proposed research.



- *Once a study phase is full it is closed.*
- *Participants can only participate in one phase.*
- *All patients screened will receive referral information, consults and warm-hand off as needed/requested.*

Intervention Development

At the site in Providence, RI, the team of investigators will design a preliminary outline of each of the modules for the computer-based intervention. The new intervention will be theory-driven, consistent with the MI model of behavior, and informed by our existing empirically-based programs that address alcohol use[75], IPV[76], and PTSD[77]. Each module will

be carefully designed to attend to the unique cultural background and experiences of women who have served in the military. Dr. Zlotnick (PI) has had extensive experience in developing interventions for high risk women[78,79], women with interpersonal violence[76,77] and women with PTSD[77,80-82]. Dr. Shea (Co-I) has research and clinical expertise in the area of PTSD in Veteran populations. Dr. Creech (Co-I; CTVHCS site PI) has extensive research and clinical expertise in Women Veterans mental health, military sexual trauma, and intimate partner violence interventions for Veterans. Dr. Kahler (Co-I) is highly experienced in developing motivational interventions to address alcohol use, including protocols that include personalized feedback reports, and serves as the Director of Biostatistics for the Center for Alcohol and Addiction Studies. Dr. Tzilos (Co-I) has specific expertise in the development of computer-based MI protocols for problem drinking with women, including the use of CIAS software. Finally, Dr. Orchowski (Co-I) has expertise in the development of scripts and videos for use in risk reduction programs for women with ST.

Subjects

We will sample consecutive eligible patients from Women's Primary Care at the Waco and Temple VA medical centers. Participants will be women Veterans seeking treatment in women's primary care.. Participants must report a history of lifetime ST and have at least one of the following risks: 1) Alcohol (i.e., report exceeding the national recommended limits for daily drinking (4 or more for women) on at least one occasion in the past month); 2) PTSD (i.e., screen positive for current PTSD) and screen positive for IPV within the last 12 months. Participants who indicate one or more of these risk factors will be included in the study. Other inclusion criteria will be ability to understand study procedures in English, be between the ages of 18 and 65, and willingness to complete follow-up session. In future studies, the computer software can be modified to present information in Spanish for the Latina population.

Inclusion/ Exclusion Criteria

Inclusion Criteria

-Female Veterans

-Lifetime history of ST with at least one risk factor: heavy drinking, screen positive for current PTSD or for IPV within last 12 months

-Age 18-65

-Seeking treatment through the Women's Primary Care Clinics at the Central Texas VA Healthcare System.

-Ability to understand study procedures in English

-Not actively in suicidal or homicidal crisis warranting imminent hospitalization

For this study, we will test the proposed intervention for English-speaking women Veterans only, because translation of the intervention and related assessments could not take place within the time constraints/demands of the current study. In future studies, the computer software can be modified to present information in Spanish for the Latina population. We specified the upper age limit because it reduces the likelihood of including women Veterans who have age-related brain diseases, which might confound our findings.

Inclusion of Women This proposal is primarily designed to investigate the efficacy of an intervention for women Veterans with ST. By definition, no adult men will participate in this study and adult women will be adequately represented. We will enroll women Veterans meeting inclusion criteria. Males will be excluded from participation because research has indicated a high prevalence of lifetime ST against women Veterans.

Inclusion of Minorities We expect that the representation of minorities in our sample will closely align to the demographics profile of women Veterans receiving care at CTVHCS. Specifically, American Indian/Alaska Native (.9%); Asian (1.4%); Black/African American (35.3%); Hispanic (9.4%); Native American/Other Pacific Islander (1.5%); White (45%).

Inclusion of Children: Children under the age of 18 will not be included. The target population is women Veterans, and the minimum age to serve in the military is 18.

Recruitment Procedures

The primary recruitment sites will be the women's primary care clinics at CTVHCS. Specifically, we plan to recruit from the clinics in Waco and Temple.

Screening and Informed Consent Procedures

Screening: Two recruitment strategies will be utilized:

1. Potential participants who are at the clinic for a medical visit will be approached while in the waiting room. Participants will be given the study flyer and asked if they would be interested in participating in a study on women veterans' health that will take about 45 minutes that day. Depending on the time of her appointment, she may be screened either before or after. If the participant is unable to be screened that day, she will be invited to come back at another time for screening or to be screened at her next appointment. We have obtained approval for waiver of HIPAA authorization for the purposes of recruitment in order to track future appointments for women who are interested in being screened at a later date, to predict clinic flow, and to identify potential participants. As determined by patient flow at the clinics, it is anticipated that the research assistant for the study will split her time between the women's clinic in Temple (2-3) days a week and the women's clinic in Waco (2 days a week).
2. The study analyst will utilize VA administrative databases to request a list of all female Veterans that have had an appointment at the Temple VA Women's clinic and Waco VA Women's clinic within the past month, and any upcoming appointments in the current and upcoming month. At the Temple clinic, data will be pulled only from the days that recruitment did not take place. Following standard VA procedures and data pull approval processes, once every month during the recruitment period the study analyst will pull the contact information (addresses and phone numbers) of female Veterans with appointments 30 days prior to the data pulling date and 30 days following that date. These women will be sent a letter informing them of the study and the follow up phone call they will receive from a research assistant inquiring about their interest in taking the screener. If a Veteran indicates that she is not interested at any point in this process (e.g., after the first letter, or during the follow-up call), their name will be marked off the list and they will not be contacted again.

3. Potential participants will also be recruited through advertisement at enrollment sites (e.g., blood lab; see attached flyer) and additionally at the Mental Health and Substance Abuse clinics located at the Waco and Temple VA campuses. The women's clinic in Temple has a dedicated research office that is connected to the waiting room and the study team has access to another research office in building 205 for appointments as well. The Waco women's clinic is adjacent to the COE building which has private rooms dedicated to research.

For women who are interested, the research assistant (RA) will escort them to a private office or other private space where the RA will introduce the computer screener for the study, which will be described as a survey to help women Veterans be healthy. Women's clinic staff will be informed that the veteran is being screened for the study and of her whereabouts as clinic operations will always take priority. In a private setting, potential participants will be told that the purpose of screening is to find women who may be eligible for a study on risk factors among women Veterans and what is involved with participating in the study. Potential participants will be asked to provide signed informed consent and HIPAA authorization. Following consent, participants will be asked if they had anything alcoholic to drink on the same day of their

appointment at the women's clinic. If so, the participant will be provided with referrals, and screening will be postponed until their period of intoxication is over on the same day or rescheduled for a later date. To guarantee that the participant is not intoxicated prior at the time of screening, any participant who had either initially endorsed drinking alcohol prior to their rescheduled appointment and who did not endorse drinking alcohol on the day of their rescheduled appointment or participants who do not endorse drinking alcohol but exhibit behaviors consistent with intoxication (e.g., slurred speech, belligerence, etc…) will be administered a breath alcohol test, and must register <.02 breath alcohol content. Once it is determined that the participant is not intoxicated, she will complete the 30-minute screener using the CIAS software delivered on a VA issued/ approved laptop computer or desktop computer to determine study eligibility. Participants will wear headphones to hear the audio for the computerized screening and a screen protector will be on the computer so no one could inadvertently observe the screen. The use of audio computer-assisted self-interview software to conduct screening will maximize identification rates of women Veterans with ST, IPV, alcohol misuse, and PTSD. The screener will include a brief series of questions about general health, exercise, diet, smoking, and sunscreen. The screener will also include the following well-validated, reliable and recommended measures: Participants must report a history of lifetime ST (as identified by the Sexual Experiences Survey—Short Form Victimization (SES-SFV)[83], items from the VA MST screener[84-86], and the Childhood Sexual Victimization Questionnaire (CSVQ)[87,88]) and have at least one of the following risks: 1) Alcohol (i.e., report exceeding the national recommended limits[89,90] for daily drinking (4 or more for women) on at least one occasion in the past three months as indicated on the Graduated Frequency Measure (GFM)[91].); 2) PTSD (i.e., screen positive for current PTSD with a cut point of ≥36[92] on the PTSD Checklist for DSM-V [93]; and IPV within the last 12 months (i.e., score 4 or more on the Woman Abuse Screening Tool (WAST)[99]).

All patients screened will receive a standard health information brochure with further information and resources on the health topics mentioned, including local resources for IPV and ST and referrals for mental health and substance use treatment within the VA and in the general community. If the participant desires, study staff will facilitate a consult to the appropriate mental health service within VA for further assessment and treatment. Study staff will also provide a warm hand-off to the Women Veterans Coordinators and Domestic Violence Coordinators as needed/desired.

Informant interviews, open and randomized trials: After eligibility has been determined interviewers will review the appropriate Informed Consent forms for the next phase of the study in greater detail. The participant will be fully informed of the nature and extent of study participation, the objectives of the study, and the intervention to which they may be randomly assigned. Participants also will be informed of the fee payment structure that applies to the follow-up assessments they will complete following the treatment phase. Interviewers will be trained to ensure that all participants comprehend the nature of the study and the wording of the consent form, and will provide a copy of the forms for potential participants to take home.

After reviewing the consent form, the interviewer will ask potential participants to sign the informed consent form that corresponds to the appropriate phase of the study. They will also be asked to sign a HIPAA authorization form.

Measures

(See appendix for measures) All assessments for this study will be completed on a laptop/tablet computer through web administration at in-person sessions held in women's primary care or dedicated research space at the VA in Waco and Temple.

Overview of assessments: Standard instruments will be administered to gather demographic data and to assess key constructs of ST, PTSD, IPV, alcohol use, as well as resource and treatment utilization. If other relevant constructs are identified in informant interviews, we will add measures to assess these constructs during the initial randomized control trial. Participants will complete screening assessments, and individuals randomized to the SHE intervention or SR

(control condition) will complete assessments at a 2- and 4-month follow-up. One of the two research assistants who is not involved in recruitment will be available during the assessments and masked to the intervention condition. If a participant is called for her medical appointment during her screening or assessments, the research assistant will offer to continue after her medical appointment or schedule a return visit.

All assessments are well established, with adequate reliability and validity, well-matched to our program components and aims. The baseline battery is designed to minimize assessment with the control group in order to take into account growing concerns regarding the motivational properties of assessment, leading to substantial Type II error in other MI-based intervention studies[100,101]. The baseline assessment will occur immediately following the consent procedures, and will be self-administered on a laptop computer. Items from the screening and baseline assessments that will be used to generate the personalized feedback report (PFR) used in the intervention modules are marked with an asterisk (*).

Screening measures: As described above, the screener will include the following brief series of questions about general health and the following well-validated, reliable and recommended measures. Lifetime ST will be assessed via the SES-SFV[83], items from the VA MST screener[84-86], as well as the CSVQ[87,88]. Specifically, the SES-SFV will assess experiences of unwanted sexual contact, sexual coercion, attempted rape and rape experienced from the age of 14 to the time of the survey. The SES-SFV is commonly utilized in research of sexual trauma, and utilizes a series of 10 behaviorally-oriented and sexually-explicit questions to assess several types of victimization experiences. Prior research with the SES-SFV suggests that versions of the scale[102] demonstrate good test-retest reliability (r = .93)[103], and adequately captures the legal definitions of attempted rape and rape[104]. The quantity and frequency of alcohol use will be assessed during the screening using the Graduated Frequency Measure (GFM)[91]. An algorithm is utilized to quickly score the measure to determine whether the participant exceeds the national recommended limits[89,90] for daily drinking (4 or more for women) over the specified recall period. Symptoms of PTSD will be assessed with PTSD Checklist for DSM-5 (PCL-5)[93]. Individuals will be classified as screening positive for current PTSD if the sum score is equal to or greater than 33 [92]. The PCL-5 is considered a "best practice" instrument in the assessment of PTSD. At screening, IPV in the past year will be assessed with the Woman Abuse Screening Tool (WAST)[99], which was originally designed for use in primary care settings, is an 8-item instrument that measures physical, sexual, and emotional abuse in the last 12 months[93 and is consistent with the definition of IPV as defined by The American College of Obstetricians and Gynecologists[99,105]. It has correctly classified 100% of nonabused women and 92% of abused women in a known-group analysis[99], has good internal reliability[106], and has adequate concurrent validity[106]. Consistent with similar studies, IPV status is positive if a woman obtains a score of 4 or more on the WAST.

Baseline and follow-up measures of ST: During the baseline assessment, further detail will be gleaned regarding the characteristics of ST experienced by study participants. A series of follow-up questions will be administered following the SES-SFV to ascertain characteristics of the assault, including the age at the time of the assault and whether the assault occurred during military service, (i.e., age 17 and younger, age 18 but before military service, during military service, after military service). The SES-SVF will also be administered at follow-up to assess for sexual victimization over the interim.

Baseline and follow-up measures of alcohol use:

Participants who screen eligible for the study, and enroll will complete additional measures of alcohol use at the baseline assessment. At baseline and at follow-up, alcohol use will be assessed with the 30-day Alcohol Timeline Follow back* (TLFB)[107], a calendar-assisted measure used to garner a retrospective account of drinking behavior. The TLFB will be used to calculate any vs. no heavy drinking (i.e. 4 or more drinks on one occasion during the past 30 days) for primary study analyses. At each follow-up point, the TLFB will assess substance use

since the previous follow-up point. The TLFB has excellent reliability[108] and validity for alcohol[109], and is sensitive to change as used in this study[107,110]. The TLFB is commonly utilized to provide feedback to participants regarding the quantity and frequency of alcohol use, and provide an estimation of blood alcohol content on average and peak drinking day.

Problems associated with alcohol use will be assessed at baseline and over the follow-up using the Alcohol Use Disorder Identification Test (AUDIT)[111,112]. The AUDIT is a 10-item assessment for alcohol use problems, alcohol dependence and problem drinking. Participants respond to each item along 5-point scale ranging from 0 to 4, whereby higher scores reflect more severe alcohol use patterns. Responses are summed to reflect a total score ranging from 0 to 40, with higher scores reflecting higher severity of an individual's use of alcohol. The AUDIT was developed utilizing an international validation trial[111,112]. Shields and Caruso's (2003)[113] examination of the reliability of the AUDIT across 24 studies suggests that the median internal consistency of the AUDIT is high. Test-retest reliability of the AUDIT is reported to be high (r =.86)[114]. Construct validity for the scale is demonstrated through high correlations with the Michigan Alcohol Screening Test (r=.88)[115]. Participants will also complete the Readiness to Change Questionnaire (RCQ)[116], which implements the trans-theoretical model of change to assess readiness to change drinking habits. The RCQ is a 12-item assessment that was developed to measure a drinker's stages of readiness to change that could be used in conjunction with brief interventions within medical settings. Reliability and validity of the RCQ is well documented[116]. This assessment will be administered at baseline for inclusion in the personalized feedback form, as well as over the follow-up to examine facilitation of readiness to change as a function of intervention participation.

Baseline and follow-up assessments of IPV: : The Composite Abuse Scale (CAS[118,119]) will assess the chronicity and occurrence of violence with their current partner (over the past year). At subsequent assessments it will be administered for the time since last assessment. The CAS, a widely used self-report of behaviors, has 30 items presented in a six point format requiring respondents to answer "never", "only once", "several times", "monthly", "weekly" or "daily"-over the specified time period. The CAS has 4 subscales that measure severe, combined abuse, emotional abuse, physical abuse, and harassment. The CAS has recently been published in the Centers for Disease Control and Prevention compendium of intimate partner violence measures. The scale will be coded categorically (no violence vs. any on one or more CAS subscales of combined abuse, emotional abuse, physical abuse, and harassment) for the primary study analyses. The scale will also permit exploratory analyses of decreasing the frequency of violence among participants.

The 15-item checklist the Safety-Promoting Behavior Checklist (SPBC) will be used to assess the participant's use of strategies that could protect her from IPV in the future (e.g., hiding money and extra clothing).. All questions begin with the phrase, "Have you ever . . ." followed by specific safety-promoting behaviors. In subsequent assessments the same series of questions, it will be administered for the time since last assessment. The SPBC has been used successfully in interventions for women with IPV that have like SHE targeted an increase in safety behaviors[120,121].

Assessment of PTSD symptoms: Symptoms of PTSD will be assessed over the follow-up with the PCL-5*[93-98]. To assess for the occurrence of other forms of trauma, at baseline and at follow-up participants will complete the Trauma History Screen (THS)[122]. The THS is 13-item self-report measure that examines 11 events and one general event, including military trauma, sexual assault and natural disasters. For each event, respondents are asked to indicate whether the event occurred ("yes" or "no") and the number of times it occurred. Addition items assess age at the time of the event, whether there was actual or a threat of death or injury, feelings of helplessness and feelings of dissociation, a 4-point scale for duration of distress ("not at all" to "a month or more") and a 5-point scale for distress level ("not at all" to "very much"). The THS is written for a low reading level and is commonly utilized in research. The THS will be administered at baseline and at follow-up (with reference to the interim period) to aide in classifying participants according to DSM criteria for PTSD.

Assessment of treatment utilization: Utilization of treatment will be assessed with questions from an adapted Treatment Services Review (TSR).[123] Utilization of community resources and VA resources will be assessed with questions from an adapted Effectiveness in Obtaining Resources Scale (EOR). The EOR assesses women's effectiveness in obtaining resources from 11 different types of community resources including church or clergy, health care, legal services, police, or social services[124]. The EOR has been successfully used in research evaluating the efficacy of advocacy services for women with interpersonal violence[125]. In addition to assessing actual use of treatment resources, we will also examine whether the intervention is associated with changes in perceptions of treatment resources through the Attitudes towards Seeking Professional Psychological Help Scale—Short Version (ASPH)[126]. Participants respond to items such as, "I would want to go to a therapist if I were worried or upset for a long period of time" along a 4-point scale, ranging from "disagree" to "agree". Higher scores are indicative of more positive attitudes towards seeking psychological care. Adequate reliability and validity of the scale are reported across several studies[127-129].

For participants in the trial, we will also conduct a chart review using the VA Computerized Patient Records System to assess for mental health appointment attendance before and after the trial. This will entail documenting the number of mental health appointments attended at VA 4 months before the trial and 4 months after. The purpose of this information is to objectively document whether SHE increases engagement in VHA mental healthcare.

Assessment of acceptability: Satisfaction with CIAS Software Scale (SCSS)[130] assesses participant satisfaction on items tapping on likeability, ease of use, level of interest, and respectfulness using a 1 – 5 Likert scale (1 = low, and 5 = high). This scale will be administered after every SHE module. The Client Satisfaction Questionnaire (CSQ) is an 8-item questionnaire which assesses the participant's satisfaction with the intervention[131]. The scale has good psychometric properties and correlates highly with other intervention measures [124,132,133]. Only participants in SHE will complete these two measures immediately after the intervention.

Measures of family and relationship functioning: Prior research on Veterans has suggested that family and relationship functioning may influence treatment engagement, therefore we will include such measures as a covariate in analyses and to examine how family functioning may predict treatment completion, appointment attendance. The Quality of Marriage Index (QMI; Norton, 1983) will be used to assess relationship distress (6 items). The Family Assessment Device 12 (FAD; Epstein, .Baldwin, Bishop) is a brief measure of general family functioning.

Table 1: Schedule of Assessment Measures

Schedule of Assessments										
		Screening		Baseline		2-month		4-month		
		SHE	Control	SHE	Control	SHE	Control	SHE	Control	Measure Purpose
ST	SES-SFV+MST screener	X	X			X	X	X	X	Screening
	CSVQ	X	X							Screening
h o	GFM	X	X							Screening

	TLFB			X	X	X	X	X	X	Primary Outcome and Feedback
	RCQ			X	X	X	X	X	X	Attitude Change
	AUDIT			X	X	X	X	X	X	Exploratory Analyses
IPV	WAST	X	X							Screening
	CAS			X	X	X	X	X	X	Primary Outcome
	SPBC			X	X	X	X	X	X	Attitude Change
PTSD	THS			X	X	X	X	X	X	Primary Outcome
	PCL-5	X	X			X	X	X	X	Primary Outcome and Screening
Tx Use	EOR			X	X	X	X	X	X	Primary Outcome
	TSR			X	X	X	X	X	X	Primary Outcome
	ASPH			X	X	X	X	X	X	Attitude Change
Acceptability	SCSS			X						Treatment Acceptability
	CSQ-8			X						Treatment Acceptability
lationship Functioni	QMI/ FAD-12			X	X	X	X	X	X	Secondary outcomes/covariate

Retention

Participants will be considered non-completers if they do not attend all modules of the intervention commensurate with their risk profile. Careful efforts will be made to minimize attrition, and pilot work will identify and address barriers to study participation. To maximize

retention, research staff will attempt to make regular contact with subjects to collect data at each assessment interval, regardless of whether they completed the intervention. Contact information will be recorded at baseline. Women will have the opportunity to complete modules of the intervention at a time of their choosing over a one-week period. As needed and appropriate, women who experience barriers to traveling to the VA to complete follow-up assessments (e.g., no childcare, travel distance, etc…) will have the option of completing follow-up assessments over the phone with a study staff member.

Compensation

Screening: Every participant that take part in the screener will be compensated $10 in the form of a gift card to a local store after completing screener. Every participant will also be eligible to be entered in a drawing. One out of every participant that is screened will be randomly selected for a $100 gift card.

Informant Interviews: Participants that take part in the informative interviews will receive a $30 gift card.

Open trial: Participants in the open trial will be compensated $30 in the form of a gift card to a local store at the end of their first assessment. Then will receive a $40 gift card for the completion of the 2-month assessment and a $50 for the completion of the 4-month assessments. If they complete all computer delivered interventions sessions and follow-up assessments, they will receive an additional $30 gift card at the completion of the 4-month assessment. They will receive for the interview at the end of the SHE intervention, an additional $30 gift card. In total for completing all assessment and exit interview participants will be compensated up to $180 in gift cards.

In addition, they will be given a $5 gift card for each assessment that is not rescheduled. If they return 2 postcards that are sent which ask them to confirm their current address, they receive $5 gift card for each postcard that they send back. In total, they will be compensated up to $205 in gift cards.

Randomized trial: Participants in the randomized trial will be compensated $30 in the form of a gift card to a local store at the end of their first assessment. Then will receive a $40 gift card for the completion of the 2-month assessment and a $50 for the completion of the 4-month assessments. If assigned to the SHE Intervention and complete all SHE sessions and follow-up assessments they will receive an additional $30 gift card at the completion of the 4-month assessment. If not assigned to the SHE intervention, but complete all three assessments, participants will receive an additional $30 gift card after the completion of the 4-month assessment. In total for completing all assessment (and SHE intervention sessions if assigned to SHE), participants will be compensated up to $150 in gift cards.

In addition, they will be given a $5 gift card for each assessment that is not rescheduled. If they return 2 postcards that are sent which ask them to confirm their current address, they receive $5 gift card for each postcard that they send back. In total, they will be compensated up to $175 in gift cards.

Overview of Participant Remuneration by Phase			
Screening	**Informant Interview**	**Open Trial ($205)**	**RCT ($175)**
$10 gift card; Entered into drawing for $100 gift card	$30 gift card	$30 complete first assessment	$30 complete first assessment
		$40 complete two month assessment	$40 complete two month assessment
		$50 complete 4 month assessment	$50 complete 4 month assessment
		Full completion all assessments – bonus	Full completion all assessments – bonus

		of $30	of $30
		Exit interview $30	
		$ 5 bonus each assessment not re-scheduled	$ 5 bonus each assessment not re-scheduled
		$5 return postcard $5 return 2nd postcard	$5 return postcard $5 return 2nd postcard

Section 4. Treatment and Procedures

Informant interview procedures

(see appendix for sample questions) The goal of this component is finalize intervention content and procedures. The informant interviews will explore such issues as the women's perceptions of the relationship between sexual trauma, alcohol use, IPV, and PTSD symptoms, and barriers to accessing care. Comfort in using technology will also be assessed, as well as ways to make intervention components interesting and user-friendly. Information will be used to assist us with the development of SHE.

women will be scheduled to participate at a mutually convenient time and these interviews will be conducted in research space at the Waco or Temple VA medical centers.

Interviews will be recorded and the recordings will be transcribed verbatim by the research assistant, all individual identifiers removed, and transcripts corrected for accuracy. Each interview will be reviewed again in order to edit any incorrectly transcribed text. After the recording is made it will be transferred to the secure research W drive for transcription and then the original recording on the digital recorder will be deleted.

Coding: A coding guide will be developed through a carefully documented and iterative process. First, PI's Creech and Zlotnick will create a proposed coding structure based on the original interview questions. Second, transcripts will be coded independently by at least 2 coders (PI and research assistant) to generate additional and/or refined codes within the coding structure. This process will continue with additional transcripts in an iterative fashion until the coding structure is well defined. All revisions to the coding structure will be documented. Third, once the coding structure is solidified, all transcripts will be double coded independently by 2 coders (PI and research assistant) who will meet to discuss their coding, resolving any discrepancies. Transcript coding takes approximately 2 hours per transcript, followed by an in-person meeting to reach concordance of codes. Formal Analyses for Themes and Content Using NVivo: The coded transcripts will be entered into NVivo qualitative management and analysis software. Once the codes are entered into NVivo, PI Creech\Zlotnick will summarize themes and responses for presentation and publication.

Randomization (RCT only)

The computer program will randomly assign participants to condition and the research assistant will remain blinded.

SHE Intervention (open trial and RCT)

As stated previously, this study will develop and test a brief modular, computer-based intervention that will target interrelated health risks for women Veterans with lifetime ST (i.e. alcohol misuse, IPV, and PTSD). In the proposed study, the SHE intervention will be specifically tailored, innovative and relevant to a diverse, group of Veteran women in a number of ways including the images and content used in the intervention. The computer-assisted self-interview

(CASI) software to be used in this study is unique in many ways. It is highly interactive and individualized, incorporates visual feedback, involves synchronous interactivity, presents questions one item at a time using a visually attractive screen and provides only the most pertinent information for the participant. Pleasing and culturally-sensitive graphics change with each screen to help maintain interest. The use of headphones and spoken text allows the computer to be accessible to those at any literacy level, and provides a confidential setting regardless of study location.

The content of SHE will be theory-driven, consistent with the MI model of behavior change, and consistent with the literature on effective interventions for our target population and targeted risk factors. Motivational Interviewing (MI), a well-defined intervention approach, has wide dissemination, and demonstrated efficacy across a range of behavioral areas and across a range of settings, including primary care clinics[4,134,135]. MI involves the facilitation of internal motivation to change through alignment of behavior change with deeply held beliefs, values, and goals. Consistent with the Transtheoretical Model (TTM)[136], MI utilizes stages and processes of change, evolving readiness and self-efficacy to change. Ambivalence about change is considered normative within the motivational interviewing framework. The client's readiness to make changes is not assumed. Instead, an important exercise in MI is the exploration of level of readiness to change. Therefore, the intervention is appropriate for varying levels of readiness to change.

The MI model is of particular value for women with ST in reducing their risks because MI has a non-confrontational and collaborative approach, emphasizes increasing a participant's awareness to successful steps towards their own well-being, identifies participant's strengths, and builds upon participant's successes, which is in keeping with the empowerment model, a highly recommended intervention for survivors of interpersonal violence[137]. In fact, recently, a workgroup[7] suggested that the empowerment model for women with interpersonal violence and MI models converge around important principles, such as increasing autonomy, self-efficacy, and skill sets.

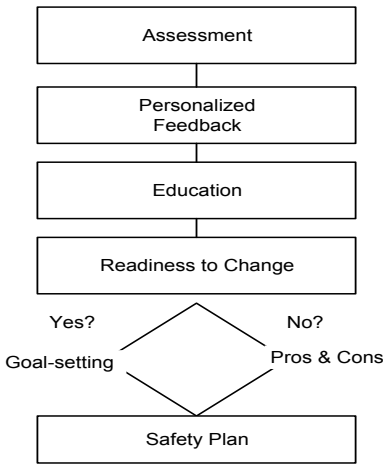
Some aspects of these therapies are difficult to translate *literally* into a computer-based intervention (e.g., empathy). The software relies heavily on realistic interactions with a three-dimensional animated narrator to mimic the empathic, conversational nature of person-delivered brief, motivational interventions. Throughout the development phase of the study, we will receive feedback on participants' sense of autonomy, of being supported and reinforced in their decisions, and of the tone of the module. Further, Dr. Daniel Squires (consultant), who has experience with computer-based interventions and experience in methods of translating traditional therapies to the person-computer interface will provide input on how best to present the MI intervention. The software, including the three-dimensional animated narrator, has been found in previous research to be well-understood and well-liked by women[75,130].

The investigators' experience with empirically tested programs that address alcohol use[75,138,139], IPV[76], and/or PTSD[76] will also inform the development of SHE. More specifically, regarding brief MI-based interventions for alcohol, Dr. Kahler has developed and tested MI based interventions that address heavy drinking[138] and alcoholism[139]. Dr. Tzilos has adapted the proposed study software to screen and intervene with alcohol misuse in a sample of urban, high-risk pregnant population[75]. Dr. Zlotnick has successfully developed and tested empowerment based interventions for women with IPV[76] and women with PTSD[76]. Dr. Creech is an expert in mental health and sexual trauma among women Veterans and women Veterans issues, as well as in intimate partner violence among Veterans and military populations.

All SHE sessions will take place within the primary care clinic setting or designated research space and consist of three computer delivered intervention modules, each designed to be completed in approximately 30 minutes and tailored to the current risk profile of each participant. The first intervention module will take place after the baseline assessment and remaining modules, if needed, will be given at a session within one week after the first session. Each module will be designed so that it can be administered individually, or in tandem with the other modules. Women will complete only the modules aligning with their risk profile. During the development phase, we will explore various orderings of the modules (i.e., alcohol module

prior to IPV module) so that all women receiving more than one module receive the information in the same order.

At the beginning of each SHE module, a narrator will first introduce the session in an empathic, concerned, non-authoritarian, and nonjudgmental conversation. After providing an overview of the session and establishing rapport, each intervention module will begin with a baseline **assessment** of the risk factor. Participants will then receive immediate "profiles" **(personalized feedback)** based on their answers to baseline assessments. For instance, for IPV a relationship profile will summarize participant's relationship safety including information about the types and severity of IPV experienced (The Composite Abuse Scale; ; CAS[118,119]). For alcohol use, part of the personalized feedback will include the Drinker Inventory of Consequences (DrInC)[117] to provide feedback on alcohol use consequences and the Brief Drinker Profile[140] to provide feedback regarding family history and risk for alcohol dependence.



Next there will be an **education** component that will briefly deliver facts about the risk: For instance, educational information on alcohol will be provided regarding alcohol use among women Veterans, prevalence, especially among women with ST, and risks, including IPV. For PTSD, the educational component will include prevalence among women Veterans, symptoms, causes including MST and combat exposure, and negative consequences of PTSD, including alcohol risk, and revictimization.

Next, participants will indicate their **readiness** to change. For alcohol use, women will be asked, "are you willing/ready to quit?" which would lead to a bifurcated treatment response such that those participants reporting a goal of immediate abstinence will move more quickly to a section consistent with primarily goal-setting. Those who do not wish to quit will be queried regarding their interest in cutting down (i.e., reducing the quantity/frequency of drinking), and/or reducing the number of negative consequences associated with drinking. Those participants that are currently not interested in or are ambivalent about changing their alcohol use will receive elements including pros/cons and normed feedback. Computer software can easily deliver such a bifurcated treatment approach – such an intervention design is consistent with evidence that motivational approaches may work best with less motivated individuals[141]. For the IPV and PTSD modules, participants will indicate their readiness to utilize relevant resources (e.g., seek mental health for PTSD, remain in treatment, or re-engage in treatment, use IPV hotlines, talk to health care providers and/or support person about IPV/PTSD and IPV/PTSD resources), and the intervention will be tailored on the readiness of each participant. Consistent with MI, those reporting a goal of readiness to utilize resources will move more quickly to a section consistent with primary goal-setting which will include affirmations about utilizing resources, and encouraging the use of formal and informal social supports for maintenance of gains as well as self-care strategies; those who are not ready will receive elements including **pros/cons** and normed **feedback**.

At the end of each module, there will be video clips inserted of women Veterans with the particular risk factor, discussing ways in which they were able to reduce their risk, such as access care/resources, remain in treatment, and/or implement strategies to reduce the risk of IPV, and/or increase formal and informal support and self-care strategies. Each module will have a selection of videos that will be tailored to the woman Veteran's profile. For instance, for women Veterans with PTSD who are in treatment, there will be a video clip of a women Veteran with PTSD discussing how treatment has helped her, and discussing ways in which she has increased her support system as well as self-care strategies. Participants will then have the option to create a personalized **Safety Plan**. Participants will select from a menu of potential personal change goals relevant to each risk module (e.g., reduce frequency or quantity of alcohol use; stop alcohol use; implement x% of a safety plan for IPV; implement complete safety plan) or optionally, can

enter their own change goals in free text. Participants will be provided with an optional one-page print-out of the Safety Plan as a resource.

Format and Design of the Intervention: SHE will be created for use on a laptop computer using Dr. Steven Ondersma's Computerized Intervention Authoring Software (CIAS)[142,143]. Dr. Tzilos (Co-I) has been trained by Dr. Ondersma to use this software and has conducted a pilot clinical trial (AA016256) whereby she specifically adapted this software to screen for and reduce alcohol use in women[75]. The CIAS software is highly individualized, and involves synchronous interactivity, and relies heavily on realistic interactions with a three-dimensional animated narrator to mimic the empathic, conversational nature of person-delivered brief, motivational interventions. Moreover, this software incorporates visual feedback, presenting questions one item at a time using a visually attractive screen that provides only the most pertinent information for the participant. We will also work with a graphic designer to create intuitive and engaging pages and to guide media production for video vignettes specific to women Veterans and audio-instruction.

Control (RCT only)

The control condition will involve screening and referral only. Patients will be provided with at least referrals to mental health treatment. If the participant desires, study staff will also facilitate a consult to the appropriate mental health service within VA for further assessment and treatment. Study staff will also provide a warm hand-off to the Women Veterans Coordinators and Domestic Violence Coordinators as needed/desired.

Data Analysis

Overview of data analysis: Dr. Kahler will provide expertise with regard to statistical, research, and data management methods for the study.The sample size of the study allows good power to detect effects of approximately medium magnitude. Smaller effects may not reach significant, but can provide valuable data on likely effect size ranges for planning a larger scale trial. A small set of primary outcomes were selected with the goal of reducing Type I error and examining preliminary intervention effects. Data collected during the open pilot trial and initial randomized control trial will be analyzed separately. Preliminary analyses will include studies of patterns of missing data, dropout rates, and correlations among outcome measures. We will identify the appropriate distributional models for dependent variables. Continuous variables showing significant skew or kurtosis will be transformed. Using an-intent-to treat sample, comparisons between **SHE** and **SR** groups will be conducted using general linear models with a logistic regression model for our main outcome (number of risks). Using a general linear model we will also examine differences between the two conditions in terms of utilization of medical, psychological, and IPV-related services/resources at the two and four month follow-up period (secondary outcome).

Data checking: Participants' data will be directly exported from CIAS to a database that is under the VA firewall immediately after each participant session. All data will be screened for missing data, outliers ($Z > 3.29$), and distribution abnormalities, with log transformation as needed. We will compare treatment groups on baseline characteristics (e.g., demographics). Analyses will adjust for baseline levels of dependent variables but will not test or adjust for any other baseline differences between conditions that result from randomization. Missing outcome data can create problems with the analysis and interpretation of intervention outcomes. We will conduct analyses to determine degree of attrition bias, and any variables shown to be associated with attrition will be included in the analytic models. Analyses will be based on all available data.

Feasibility acceptability of intervention and study procedures (Open trial): To assess the clarity, structure, content, and acceptability of the intervention we will assess the total intervention completion rate, retention rate, participant session ratings and total treatment acceptance scores gathered during the Open Trial. We will not have a comparison group for

participants in the open trial; however, we will examine rates of alcohol use, PTSD symptom severity, IPV occurrence and treatment/resource utilization at 2-months and 4-months post baseline. We will also examine women's immediate post-intervention ratings of the SHE intervention to explore the perceived utility of various program components (see appendix for exit interview questions).

Study and treatment feasibility/acceptability (Aim 3): Feasibility of the SHE intervention will be assessed by examining rates of session attendance, rates of treatment/assessment completion, rates of dropout, and reasons for termination. We will assess acceptability of the intervention via self-reported ease of use, helpfulness, and overall satisfaction using the SHE participants' responses from the Satisfaction with CIAS software scale[130] and from the CSQ[131]. We will examine means, modes, and median scores for these measures.

Feasibility of the research procedures will be assessed by examining study recruitment rates, refusal rates, follow-up rates and participants' willingness to be randomized. For follow-up retention rate (dichotomous), a chi-square analysis will be used. An urn randomization procedure will be utilized to avoid group differences at baseline. The success of random assignment in equating groups on baseline characteristics will be assessed. This will involve comparison of groups on demographic characteristics and number of risks. Should groups differ on any variables that show a relation to outcome, outcome analyses will be conducted both with and without adjusting for these covariates.

Primary outcomes (Aim 4a): Following the intention-to-treat principle, all women who completed the baseline assessment and who are randomized will be included in the analyses. Analyses will first test the hypothesis that SHE reduces the number of risks relative to control. Quantification of post-intervention behavioral change will be estimated by comparing the distributions of the number of risks in the two groups at baseline and follow-up. Within-person changes in the number of risks over time will also be examined. Specifically, women will be characterized by the number of risks (one through 3) at baseline. That will serve as a covariate in a model predicting number of risks at 2 and 4 months, which will be analyzed using generalized estimating equations (GEE) with a Poisson distribution specified. GEE is a method of repeated measures analysis commonly utilized for binary outcomes that allows for the inclusions of both categorical and continuous independent variables, as well as appropriate modeling of covariates when observations are correlated across time. The primary between group independent variable will be program group; dummy coded using the intervention as the reference category.

To further illustrate program effects, each of the participants will then be classified over the follow-up as 1) resolving all risks; 2) resolving some but not all risks; and 3) resolving no risks or increasing the number of risks. Intervention effectiveness will be measured by comparing the proportion of women resolving all risks, to the proportion of women resolving no risks or increasing risks between the groups. The proportion of women resolving all risks will also be compared to the proportion of women resolving some risks between groups.

Secondary outcome (Aim 4b): Analyses will also examine comparisons between groups in the extent of change in use of treatment (TSR and CPRS number of mental health visits) [123] and resource utilization (EOR[124]) (secondary outcome) as well as the extent of change on individual risk factors overtime using generalized estimating equations (GEE) (i.e., occurrence of IPV as measured by the CAS[118,119], screen positive for PTSD diagnosis as measured by the cut point of $\geq$33 on PCL-5[93], heavy drinking status as measured by the TLFB[107]).

Analyses will also examine comparisons between groups in the extent of change in use of treatment (CPRS number of mental health visits and TSR)[123] and resource utilization (EOR[124]) as well as explore change in individual risk factors using (i.e., extent of alcohol use (AUDIT)[111,112], severity of PTSD symptoms (PCL-5[93]), frequency of IPV (CAS[118,119]) using GEE. Outcomes of treatment and resource utilization, IPV, PTSD and alcohol use will be classified as continuous dependent variables. Scores from the outcome variables at follow-up will serve as the dependent variables. Intervention group will serve as the independent variable.

We will also calculate effect sizes for treatment efficacy for the aforementioned continuous study outcomes by examining the difference between the estimated adjusted means of the two groups at the end of the study divided by their standard deviation.

Supplemental analyses: In light of the challenges in promoting behavior change within treatment studies, we have included a limited number of assessments in order to promote analyses of the whether the intervention is associated with changes in the attitudes and beliefs that may serve as a mechanism of behavior change. Towards this goal, we will explore whether participants in SHE, relatively to control, vary in their attitudes towards seeking psychological care (ASPH), readiness to change drinking behavior (RCQ), and safety behaviors (SPBQ). These analyses will test whether SHE increases the mediators, whether the mediators are associated with the related behavioral outcomes, and whether there is a significant indirect effect of SHE through each mediator. We will use the products of coefficients method to test for significance[144] of the indirect effects.

Power Analysis: Given the developmental nature of this study, our primary objective will be to determine a reasonable effect size for the SHE intervention for planning a future randomized trial, rather than to determine statistical significance between groups. Sample size requirements were estimated based on having adequate power to find clinically meaningful effects of the intervention on each of the primary outcomes, including reducing the percent of participants who screen positive for the health risk of PTSD, while also acknowledging the need to maintain a modest sample size in the initial test of a novel treatment approach. As documented below, we determined that an initial sample size of no more than 155 would meet these goals.

Research conducted by Himmelfarb and colleagues (2008)[145] indicated that approximately 60% of VA women who screened positive for MST indicated PTSD. Given that we will identify women not only with MST, but a lifetime ST, we conservatively estimate that 60% of women included in the study will screen positive for PTSD. With an initial sample of no more than 155 women, retaining 126 over the 4-month follow-up, power would be .80 to detect an effect size h of .53 (equivalent to a medium effect size), with an alpha of .05, over the 4-month follow-up. This would be achieved, for example, with rates of PTSD at follow-up of 34% in the program vs. 60% in control.

The sample size of no more than 155 women would also be sufficient for detecting changes in the proportion of women indicating an alcohol use problem or occurrence of IPV over the follow-up. Based on findings suggesting that 7-14%[16,146] of VA women with MST report SUD, and 64%[147] of women with any lifetime sexual abuse report alcohol abuse, we conservatively estimate that 40% of women included in the study will screen positive for alcohol problems. Thus, the sample of no more than 155 accounting for attrition would allow a power of .80 to detect an effect size h of .44 of changes in alcohol use problems over the follow-up. This would be achieved with rates of alcohol use problems of 20% vs. 40% in control. Further, based on data indicating that 33%[148] of women with a history of sexual victimization are revictimized, 44% of active duty military women report lifetime IPV[149], and studies indicating that IPV revictimization ranges from 18% to 74% [150,151]over 6- to 9-month follow-ups (see Kuijpers et al., 2011[152]), we conservatively estimate that 40% of women with a history of lifetime ST presenting at the VA would report lifetime IPV, and 25% would report a revictimization experience over the 4-month follow-up. A sample of no more than 155 accounting for attrition would allow a power of .80 to detect an effect size h of .46 in changes in IPV revictimization over the 4-month follow-up. This would be achieved with rates of IPV revictimization of 8.5% in the SHE program vs. 25% in the control group.

The sample size of no more than 155 will also be sufficient for detecting changes in the proportion of women who reduce the number of risks over the follow-up. Among the full sample of no more than 155 women, power would be .85 to detect an effect size h of .44 in any reduction (i.e., 1 to 0 risks, 2 to 1 risk, 3 to 2 risks, etc.) in the number of risks; which would be achieved, for example, with 20% of women in control and 40% of women in SHE reducing the number of risks reported over the follow-up. Power would also be adequate to examine reductions in the number of risks among women experiencing various numbers of risks (i.e., women reporting 1 risk vs. 2. vs. 3). In light of high comorbidity between PTSD, IPV, and

substance use, we projected that 50 women will report 1 risk, 50 women will report 2 risks, and 50 women will report three risks. Thus, among women reporting each number of risks (i.e., we expect 50 women will report 1 risk), power would be .73 to detect an effect size h of .64, which would be achieved with 20% of women in the control group reporting a reduction, and 50% of women in SHE reporting a reduction.

Limitations The limitations of this study include: potential issues related to disclosure of sensitive information, the use of self-report, assessment reactivity and effect on measured outcomes, the inclusion of only English-speaking participants, generalizability of study results to other Veteran or service member populations, and an inability to meaningfully examine ethnic/racial differences in the proposed sample.

Revision: Based upon experience during the Development and Trial Phase, evaluation of the program, and feedback from participants, the Investigator Team will revise the intervention. Information regarding the recruitment methods and retention of participants will be utilized in the design of a later clinical trial. This final revision phase will generate the final "product" of this treatment development study, to be used in the application to evaluate SHE in a large-scale clinical trial.

Section 5. Privacy and Confidentiality

Data Management:

Identifiers: Given the sensitive nature of this research, the computer software will simply generate a code number for each participant. Data will only be identified with the study's ID of the participant. Participants will complete the assessments on a VA issued laptop or tablet.

Confidentiality: All paper forms (informed consent; HIPPA) with participant information will be marked with a code number and not with the participants' name. PI Creech and approved CTVHCS study staff will keep the link between the participant code number and name in a password protected master file separate from coded data on the Central Texas secure research (W) drive. The paper files will be stored in locked file cabinet in a locked room at the VHA VISN 17 Center of Excellence in Waco, TX.

No participant will be identified in any publications or presentations arising from this study. Records will be maintained in accordance with the Department of Veterans Affairs Record Control Schedule 10-1. It may be necessary or required for the study investigators to break confidentiality and release personal identifiers and health information when mandated by law. For example, state law requires health care workers to report any suspected abuse or neglect of a child, or person 65 years or older, or an adult with disabilities to the Texas Department of Family and Protective Services.

A Certificate of Confidentiality will be obtained from the National Institutes of Health prior to the commencement of research. The purpose of this certificate is to protect the identity of research subjects participating in studies that collect sensitive information. No information about participants will be released without their permission or where required by law (such as the examples given above). All employees who are to handle data will be trained in confidentiality policies and procedures. In the event that theft, loss, or other unauthorized access of sensitive data and non-compliance with security controls occur, study staff has been instructed to follow the CTVHCS standard operating procedure on incidence reporting.

Disposition of the data: Paper files containing identifiers will be kept in locked file cabinets in a locked room at the Center Of Excellence in Waco, TX. Coded paper files will be kept in separate locked file cabinets. Only approved study staff will have access to the files. Electronic data will be stored on the secure VA password-protected server with access restricted

to research staff. Records will be maintained and retained in accordance with the Department of Veterans Affairs Record Control Schedule 10-1.

Incident Reporting: Any incidents affecting the security of the data such as theft, loss, or unauthorized access of sensitive data will be reported to the ISO and PO per VA regulations.

Section 6. Technical Specifications

Survey/Intervention Administration: Study assessments and intervention sessions will occur only through web administration at in-person sessions held in women's primary care or dedicated research space at the VA in Waco and Temple. We will use the Computerized Intervention Authoring Software (CIAS), developed by Dr. Steve Ondersma, and licensed through Interva, Inc. The Computerized Authoring Intervention Software (CIAS) is a sophisticated web-based program designed to allow development and modification of computer-delivered assessment and intervention modules for research studies. This software utilizes SSL technology for encrypting of communications between remote computers and the server itself, and is currently used in a number of major NIH-funded research studies. A license to use the CIAS system will be purchased by grant funds, and no software or data will be downloaded to the VA issued laptop/tablet.

To access the system, investigators and study staff will utilize Kiosk Mode on study laptops or tablets, which will limit participant computer access to a unique and non-searchable FIPS 140-2 compliant study website. Each participant will be set up with the day's screening, assessment or intervention session using only software-generated unique and non-identifying user IDs. No protected health information will be entered into the surveys or interventions.

The intervention and assessment sessions will be constructed by project staff affiliated with the parent site in Providence, RI.

Identifiers/linking data:
No IP addresses or other electronic identifiers will be recorded. Participants will not enter their name or any other identifying information or PHI into the web site. All data storage devices, will be VA issued and monitored by information management services. Only study personnel authorized by the Principal Investigator (PI) will have access to the data, and the file server is protected from the internet by a firewall.

A password protected master participant tracking spreadsheet will contain the linking information that matches the unique participant IDs to participant names. This spreadsheet will reside only on the secure research W drive. Other PHI such as participant addresses and phone numbers (for follow-up contact), and date of participation will be contained in the master tracker. This information will only be accessible to PI Creech and her research staff that is approved to work on the study.

Data Retrieval: Data collected through the CIAS system resides on a firewall-protected server in Southfield, Michigan that uses AES-256 encryption in transit. All data will be downloaded from the CIAS server on a weekly basis and stored in a password protected file on the secure central Texas VA research server (W drive) in a restricted folder (e.g. W:\Research

Projects\Creech). The progress of participants will be closely monitored to ensure that each subject record is erased as quickly as possible. Any staff no longer associated with the study will have access to the study files removed.

Data Transfer:
For each participant at the first study visit, the most data to transport would be the informed consent documents for the study. For the interview phase of this study, this will also include recordings of interviews conducted. Study data collected at the Temple campus (informant interviews recordings) will be transported to the approved data storage location at the Waco Campus where it will be uploaded to the secure research W drive. Personally identifying information (e.g. Informed Consent Form with name and date of consent) will be kept in a separate locked carrying case from the data during transport. No other paper data is collected as part of this study. The digital recorder used will be FIPS 140-2 compliant.

De-identified data encrypted via FIPS 140-2 will be transferred to other institutions for data analysis (e.g. Women and Infants Hospital and Brown University) through UPS with a chain of custody. Listed are the following people and addresses that de-identified data will be sent to:

Caron Zlotnick
Butler Hospital
345 Blackstone Blvd
Providence RI 02906

The data will not be returned, and will be handled in compliance with VHA's Records Control Schedule (RCS 10-1). All de-identified data will be managed in accordance with the VHA Handbook 1605.1 APPENDIX B.

Records destruction information: "Any and all paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation."

Records retention information: "The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1)."

Reporting: Any incidents involving theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls will be immediately reported to the IRB chair, Privacy Officer and Information Security Officer.

Data Analysis Software: Data will be analyzed using the software programs SPSS and MPLUS that are already owned by the VA either using local copies of the software or through VA Informatics and Computing Infrastructure (VINCI).

Data use: Only IRB approved personnel will have access to the data collected in this study. Access to the study data will be terminated when personnel are no longer part of the research

team. De-identified copies of the study datasets will be sent to the parent site. The datasets will be checked by the Privacy Officer before they are sent to the parent site to verify removal of all 18 individually-identifiable information.

VINCI: VINCI is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources. VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC), located in Austin, Texas. This secure enclave with 105 high-performance servers and 1.5 petabytes of high-speed data storage has multiple layers of security and disaster recovery to prevent data loss.

To ensure the protection of Veteran data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources are approved in accordance with the requirements of National Data Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. All data transferred from VINCI is subject to audit for compliance.

VA-credentialed research or operations staff are granted access to study-specific data along with tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer within the VA. If not working within a VA or VHA hosted office environment containing VA network access, researchers may apply for and then access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment enables data analysis to be performed directly on VINCI servers, offering a number of advantages: uniform security standards for access; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter and more consistent control of data quality; and the ability to standardize and update terminology and format as technology and methodology improve.

Only study team personnel explicitly authorized by data stewards will have access to project data. The study principal investigator has the responsibility for security of study. VINCI data managers and VA OI&T personnel not under the purview of the study principal investigator control the servers, network, processors, firewall and software in the VINCI environment, including access rights granted to study personnel.

When study personnel are no longer part of the research team, the study principal investigator will amend the data access request to terminate that person's access to all study data and notify the VA Information Security Officer of such action. No sensitive patient data may be shared with anyone who does not have a VA appointment. All study team personnel with access to sensitive patient data must stay current on required VA information security and privacy policy trainings.

Study data stored on VINCI servers is located at the Austin Information Technology Center, 1615 Woodward St., Austin, TX 78772-0001. The specific server where the data are stored within the VINCI environment will be chosen by VINCI personnel. The server name and location within the Austin Information Technology Center may be changed at any time at the discretion of VINCI personnel.

Section 7. Data Safety and Monitoring

Safety monitoring plan

Frequency of DSM: In this study, we will use the FDA definition of serious adverse events (SAEs). RAs will report SAEs to the PI immediately. Data and safety of patients will be monitored by PI Creech . At a weekly meeting attended by PI Creech , study staff, participants' safety, participants' clinical status and adverse experiences will be reviewed. Entrance criteria of all participants will also be reviewed at these meetings. The PI will ensure that information on participants' adverse effects are systematically collected and evaluated.

Dr. Creech will immediately report any serious adverse events that are observed to the DSMB, medical monitor, Central Texas VAHCS IRB, and to the U.S. Army Medical Research and Materiel Command's (USAMRMC) Human Research Protection Office (HRPO). The initial SAE report will be followed by submission of a completed SAE report to the local IRB and HRPO. Outcomes of SAEs will be periodically reported to HRPO. A summary of the SAEs that occurred during the previous year will be included in the Quarterly Technical Progress Report that is submitted to HRPO.

A Data and Safety Monitoring Board (DSMB) will be assembled to evaluate the data and safety to women veterans enrolled in the study. The DSMB will consist of 4 senior doctoral-level/MD board members who have experience in clinical trials and/or alcohol/IPV/PTSD intervention research and/or research with women veterans as well as the ethical issues involved with a randomized controlled study, as indicated by peer-reviewed journal articles in these areas. We do not anticipate any difficulty in recruiting these qualified, independent board members as there is a pool of such researchers at the Providence, RI site and at the Central Texas site who have the relevant experience.

The DSMB will convene twice in Year 1, and then once during Year 2 for a meeting. Initially, the Board will convene with the PI Creech and PI Zlotnick to review the study protocol and review the guidelines for data and safety monitoring. This will include establishing standard procedures for daily (whenever there has been contact with a participant) and weekly monitoring by the local internal reviewers (PI and study personnel). At this meeting and at each subsequent meeting, the DSMB will evaluate recruitment, the progress of the trial, subject retention, data quality and confidentiality. In addition, they will review participants' clinical status, rates of adverse events and whether or not there have been any changes in risk to participating subjects. This review will ensure that subject risk does not outweigh study benefits. In the DSMB's review of adverse events, if non-serious adverse events are occurring at a significantly higher rate in one condition than the other, then the DSMB will make appropriate recommendations for changes in the protocol, if needed. If Serious Adverse Events (SAEs) occur at a significantly higher rate in one condition than the other, then the DSMB might consider terminating the trial, if changes to

the protocol are unlikely to address the high occurrence of the SAEs. We do not anticipate that this will occur, because we have taken several steps to avoid or protect against the occurrence of SAEs as outlined in the Human Subject Recruitment and Safety Procedures section. A report generated from each of these meetings will be retained at the study site and will be forwarded to the local IRBs, USAMRAA, and will be included in the Quarterly Technical Progress Report.

The DSMB will be available to convene outside of the appointed meeting schedule, if necessary, due to concerns regarding a particular subject, or due to any troublesome developments in subjects' experiences during the study. The DSMB will make appropriate recommendations for changes in the study protocol, if needed. The safety of participants will be monitored during each contact with study participants. Both anticipated and unanticipated adverse events and problems will be formally monitored and recorded. Unanticipated serious adverse events or problems will be reported to the DSMB, medical monitor, within 24 hours.

A Medical Monitor will be appointed to this study. This individual will not otherwise be associated with this protocol, and will be able to provide appropriate medical care to research volunteers for conditions that may arise during the conduct of the study. Adverse experiences that are both serious and unexpected will be immediately reported by telephone to the U.S. Army Medical Research and Materiel Command's (USAMRMC) Human Research Protection Office (HRPO). A written report will follow the initial telephone call within 3 working days to the U.S. Army Medical Research and Materiel Command and to the appropriate local Institutional Review Boards (IRBs). The Medical Monitor is required to review all serious and unexpected adverse events (per ICH definitions) associated with the protocol, and provide an unbiased written report of the event within 10 calendar days of the initial report to the addresses above.

All study personnel and investigators will annually complete the required VA training and courses in human participant research protections. PI Creech will maintain documentation of human research training requirement for all study personnel and submit the required information and training certificates to the VA Research Office with every new protocol submission. All investigators at both sites are certified in human subjects education by their respective institutions. Monitoring of safety in the proposed study will be the responsibility of all personnel on the project, with primary responsibility and supervision by Dr. Creech. The Institutional Review Board at the Central Texas VAHCS will approve the protocol and the Statement of Informed Consent for the study and will provide oversight of data and safety issues. Separate reviews of the protocol and consent form are made by the safety officer at the VA Medical Center. The study protocol will receive IRB approval prior to soliciting or requesting consent from any participants. Moreover, the study will be reviewed on an annual basis (continuing review) by the IRB committee with regard to recruitment and retention and annual reports will be made by the PI to the IRB chair of the Central Texas VAHCS regarding the progress of the proposed project, including any issues pertinent to recruitment, retention, confidentiality, and safety of human subjects. Any incidents that involve a breach of this plan or serious accident/injury will be reported to the IRB chair. As discussed, potential risks, albeit minimally likely, include distress or discomfort with questions regarding trauma history.

Adverse Event Reporting

In the case of an adverse Effect (AE) or a Serious Adverse Effect (SAE), a written report of the AE or SAE will be prepared for the Chair of the IRB at the Central TX VAHCS. Any such AEs or SAEs will be presented to the full IRB committees. SAEs will be reported within 24 hours. Examples of serious adverse effects include death, life- threatening adverse events,

suicide attempts, and inpatient hospitalization. The report of such AEs or SAEs will include whether they were expected or unexpected, a rating of severity of the event, a brief narrative summary of the event, a determination of whether a causal relationship existed between the study procedures and the event, whether the informed consent should be changed as a result of the event, and whether all enrolled participants should be notified of the event. The annual progress reports to the IRB require summary information regarding all AEs and SAEs occurring during that year. A medical monitor who is independent of the research will be named. The medical monitor will be called upon to review all AEs and SAEs, and to provide input regarding the possible connection to the study protocol.

Risks / Benefits Assessment

***Risks/Benefits Assessment*:**

Foreseeable risks: There are four major areas of low to moderate risk associated with participation in the proposed study: 1) It is possible that some women may feel coerced into participating in the research. 2) There is risk to confidentiality and loss of privacy. We will be collecting considerable information about the participants that may create some distress and could cause social and psychological risk if released inappropriately. 3) Research participants may decompensate when completing the assessments included in the research proposal. 4) Participation may place women at risk for further victimization if an abusive partner finds out about their participation in the research. The procedures we will use to minimize these risks are described below.

Data and safety monitoring will take place to assure the safety of subjects. All participants will be reminded that their participation is voluntary and that they can withdraw at any time without penalty. Additionally, the risks described above will be minimized by the following procedures:

1. We will minimize the risk of potential coercion by following standard procedures for obtaining informed consent. We will begin this process during the intake for the screening phase and the trial phase, where we will clarify the nature of the study and possible alternatives upfront. Prior to enrolling women in the research, we will fully explain the study procedures, risks, benefits, and alternatives to women. Participants will be reminded that study participation is voluntary and that refusing to participate or withdrawing from the study at any time will not impact in any way their relationship to the Central Texas VA or any other VAMC, or existing services they receive within the community Veterans will have the opportunity to discuss any uncomfortable feelings with the assessment or intervention with the research assistant who will be available during both the assessment and intervention. The Veteran will also be informed that the veteran's well-being and safety takes priority over research considerations. Furthermore the veteran will be informed that should they experience any problems, they should report them to the research assistant or to the principal investigator of this study. All reimbursements for participating will be commensurate with participants' time required for participating in the research.

2. We will minimize potential risks due to loss of confidentiality of research data by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All participants will be informed about the limits of confidentiality concerning suicidal intent, homicidal intent, suspected child abuse, and suspected elder abuse. All information will be treated as confidential material and will be available only to research

staff. All information will be kept in locked file cabinets in locked offices. Computer data files will be available only to authorized personnel and no names or obvious identifying information will be stored in data files. Information, including assessments, collected in this study will not be entered into participants' medical records at the PVAMC. No participant will be identified in any report of the project. Veterans will be informed that federal and non-federal monitoring agencies such as the Department of Veterans Affairs may access the veteran's research records related to this study to monitor the security of the trial. Furthermore, veterans will be informed that complete confidentiality cannot be promised to subjects, particularly to subjects who are military personnel, because information bearing on their health may be required to be reported to appropriate medical or command authorities. Written consent will be obtained to contact other persons for the purpose of locating the participant for follow-up and participants can refuse or revoke such consents. All study personnel who handle data will be trained in confidentiality policies and procedures.

Participants in the open trial or randomized control study phase will update their contact information at each follow-up interview to ensure that this information remains appropriate. To further protect participants, a Confidentiality Certificate will be sought after the grant has been funded. Potential subjects will be informed that a Certificate of Confidentiality has been obtained for this project and that this certificate will protect the investigators from being forced to release any research data in which participants can be identified, even under court order or subpoena, although this protection is not absolute. Potential subjects will be informed of the situations in which they may not be protected under the Certificate of Confidentiality. No information about participants will be released without their permission or where required by law.

Audio recording of informant interviews and exit interviews is also needed to produce structured transcripts and identify themes. This is accomplished through the use of digital audio recorders, which can hold hundreds of hours of voice recordings. These digital recordings will be uploaded to the CTVHCS secure research server (W drive). Participants will be asked to give informed written consent to audio recording at the time of study entry. To assure the confidentiality and protection of participants with respect to audio taping, the following steps will be taken: a) each recording will be labeled with the participant's study identification number, and the recording date; b) all recordings will be stored in a restricted folder on the secure research server CTX W drive c) access to the audio recordings will be limited to the specially trained staff who will code the recordings and create structured transcripts; d) once the recordings are transcribed they will be stripped of all identifiers for the purposes of analyses; at the end of the study, the recorder will be given to OI&T for sanitization.

All data and medical information obtained about the veteran, as an individual, will be considered privileged and held in confidence; the veteran will not be identified in any presentation of the results. Assessments and intervention sessions will occur at the CTVHCS. Veterans will be informed that their VA medical records will note their enrollment in a research study with a copy of their consent form attached. In addition, their attendance at each intervention session will be noted in their medical records. This will include, if applicable, any safety issues (e.g., suicidal or homicidal statements they made) and how these were addressed in treatment. The veteran will be informed that none of the other data from this study will be included in their Medical records. All study data stripped of identifying information, will be locked in a file cabinet. Records will be maintained per Veterans Affairs Record Control Schedule 10-1. All of the study data will be coded without the use of the veteran's name and social security number and will be done in accordance with the law. Research information about

the veteran will remain in locked private research files and will be available only to staff connected with this study or individuals involved in human subjects protection. Any reports or publications of this study will not include information that could be used to identify the veteran.

All forms with participant information will be marked with a code number and not with the participants' name. The PIs will keep the link between the participant code number and name in a separate restricted folder on the CTVHCS secure server (W drive). . Information that might potentially allow an individual participant to be identified will not be allowed in any publications or reports sent to individuals outside the study.

In accordance with VA policy, incidents such as theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls will be reported immediately to the ISO and PO.

3. We will minimize the risk of distress. Participants from our target population face the risk of increased distress during assessment procedures, during the control condition, or during the experimental condition. The potential that veterans might develop uncomfortable feelings during assessments and the intervention will be discussed during the consent process. Possible distress due to sensitive items will be noted clearly in the informed consent information sheet (for screening) and in the written informed consent form (for participants). Participants will be informed that they can refuse to answer any question or stop the assessment or intervention at any time. They will be informed that they can chose to resume the assessment or intervention or refuse to participate further. Veterans will have the opportunity to discuss any uncomfortable feelings with the assessment or intervention with the research assistant who will be available during both the computer-based assessment and intervention. Moreover, clinical backup will be provided during all assessments and during the intervention phase of the study by a licensed clinician to help facilitate any stabilization and referral process for participants who decompensate during study procedures. The need for additional services will also be monitored during all follow-up assessments. The veteran will also be informed that the veteran's well-being and safety takes priority over research considerations. Furthermore the veteran will be informed that should she experience any problems, she should report them to the research assistant or to the principal investigator of this study.

To further address possible distress due to sensitive items, participants will be asked by the computer program if anything the computer has asked or done is making them feel upset right now. The computer program will notify the research team at completion of the screening, intervention session, or assessment, if any participant answers yes to this question, in addition to notifying the research assistant (RA) if the participant endorsed any items indicative of possible need/desire for further assistance. (Note that the computer program will not provide details regarding any answers, only that there is a need to follow-up with the participant verbally to evaluate the need for assistance). At a minimum, all participants indicating some distress will be given a list of referral and resource options.

Any participant verbalizing or showing signs of distress will be asked to remain in the assessment or intervention setting until their distress is at a manageable and comfortable level. No participant judged to be in danger of harm to self or others will be allowed to leave the study setting unaccompanied. All study personnel who interact with study participants (including phone contacts) will have been professionally trained to respond to negative emotions if these should occur and to access emergency services if necessary. All participants will be reminded of appropriate safety procedures including providing them with emergency contact numbers such as 911 and the number for the Veterans Crisis Line. All research personnel will be trained in the

protocol for homicidal or suicidal risk and research procedures for these situations. A licensed clinician will be available at all times by phone Research staff will contact the licensed clinician if there are any safety concerns.

The assessment instruments and program techniques are commonly used in research and clinical practice. We will minimize distress by presenting questions/program techniques in a supportive manner, assuring participants that they may refuse to answer questions that make them uncomfortable, and may terminate the assessment and/or intervention at any time. Any participant verbalizing or showing signs of distress will be asked to remain in the assessment or treatment setting until their distress is at a manageable and comfortable level. No participant judged to be in danger of hurting him/herself or others will be allowed to leave the study setting unaccompanied. All study personnel who interact with study participants will have been professionally trained to respond to negative emotions if these should occur and to access emergency services if necessary.

Moreover, clinical backup will be provided during all assessments and during the intervention phase of the study by a licensed clinician to help facilitate the stabilization and referral process for participants who decompensate during assessment procedures. Dr. Creech is a licensed clinical psychologist and she will be available by phone or in person during study assessments. Since the study will take place in women's primary care during normal operating hours, access to emergency resources will be readily accessible The need for additional services will also be monitored during all follow-up assessments. Participants will be formally assessed at intake and then at the 2- and 4-month follow-up period. If a participant indicates distress during any phase of the study, the clinical back up will be contacted to facilitate the stabilization and referral process. Women veterans who report significant suicide or homicidal risk will be referred for appropriate additional care, but will remain in the research protocol. During any phase of the study, women who report significant homicide or suicide risk will be immediately referred for evaluation for psychiatric admission at the closest emergency department. All participants will be eligible for emergency services through the CTVHCS.

Referral to treatment and counseling during the study. After screening and prior to randomization, all study participants will receive a list of appropriate referrals (e.g., 24-hour hotlines for sexual trauma and intimate partner violence (IPV), as well as mental health and substance abuse treatment). Additionally, no referral, or counseling will be withheld in any way at any time during the study. At follow-up assessments, any participant who screens positive for heavy drinking or PTSD will be referred for appropriate clinical care, for example consults will be placed for further care if the Veterans desires. In addition to referrals within the VA, we have a list of free or low-cost substance use and mental health treatment clinics in Central Texas.. Likewise, at follow-up assessments, any participant who reports current ST and/or IPV will be provided with information on ST/IPV and a list of local IPV/ST resources and an offer for contact with the local VA Domestic Violence coordinator or Women Veterans Program Manager.

4. We will minimize the risk of study-related partner violence. Women who have abusive partners may be at increased risk for abuse if he or she were to find out about the woman's participation in the research project. The measures suggested by Sullivan and Cain (2004)[22] will be taken to maximize participant safety throughout the research.. Outgoing phone calls will go through the VA landline phone system which is identified at the receiving end as a general VA number not specific to any VA Hospital department. All incoming phone calls will go through a study specific cell phone. This line is answered, "The Women's Program," and partner violence is never mentioned. Details of the research are not provided to anyone other than the actual participant. During each contact, participants will first be asked if it

is a safe time to speak. Safe contact for follow-up assessments will be negotiated at each stage of the research. Both written and verbal contacts will be vague. Follow-up interviews will be scheduled at VA primary care or in the research space at the Center of Excellence. Safety plans will be negotiated up front (e.g., code words, cover story for reason for interview) if ever the abuser were to interrupt a phone call or assessment. Any handouts with important information (e.g., hotline numbers) will be available in wallet size copies without any reference to the study or name of organization. Participants' safe contact information will be updated monthly to determine if the contact information they previously provided is still accurate and safe. Participants will be given contact information for the research team and/or interventionist and asked to let us know if the contact information they provided is no longer safe. A licensed clinician will be available for consultation on difficult cases at all times by phone. If a woman discloses that she is in an abusive relationship, she will be provided with the battered women's crisis line for emergencies, referrals to battered women's shelters, and told how to obtain a restraining order and she will be connected with the VA women's health coordinator and domestic violence coordinator for additional assistance. All participants will be reminded that if they are currently in an abusive relationship, their partner could find the infromed consent form from the study and this could place them in danger because it makes mentions of partner violence. They may wish to store it/dispose of the form in a secure location.

If the partner of the participant is also abusing her child[ren], then the interventionist, supervisor, or research staff person involved will let the woman know that she as the mother is responsible for protecting her child[ren] and if her partner hurts them and she fails to call child welfare or the police, she could be charged with neglect and her children could be taken away. The supervisor/research staff will encourage the woman to call child welfare herself as child welfare is more likely to view the woman favorably under these circumstances. The research personnel involved will provide the woman with the relevant phone number/s. The research personnel involved will let the woman know that she/he will be calling child welfare her/himself because it is the law. This same procedure will be followed for any other case of suspected child abuse.

Potential Benefits of the Proposed Research to the Subjects and Others

The main benefit for participants is their contribution to the scientific understanding of an intervention for women veterans with ST that targets IPV, heavy drinking, and PTSD. The information gained through this research will help us to develop and empirically evaluate the efficacy of an intervention for this population.

The potential risks associated with participation in this study appear to be mild to moderate. Although there is a risk for distress, the procedures proposed for monitoring distress should ensure that participants who require a higher level of care receive it. The potential benefits of study participation who receive the SHE intervention are great, and include reduction in IPV, heavy drinking, and posttraumatic stress disorder (PTSD) symptoms. Half of the participants in this study will not receive any form of intervention, and thus are unlikely to receive any direct health benefit; however, women in both conditions as well as all women who participate in the screening phase of the study will receive a list of referrals and consults to VA mental healthcare will be placed as requested/needed. Moreover, participants are helping other women veterans seeking primary care treatment through providing information that could potentially improve heavy drinking, PTSD symptoms, and IPV. There is no cost to participants to participate in this study. Based on the foregoing discussion, it is our view that the potential benefits of participating in this study appear to outweigh the minimal risks of participating.

Potential risks include distress associated with discussing traumatic or other disturbing events or emotions, and breach of confidentiality.

Importance of Knowledge to be Gained

The ultimate objective of this research is to provide a low-cost and effective intervention that may be scaled up with ease, fidelity and speed in VA primary care settings nationwide for women veterans with any lifetime ST. Lifetime ST is highly prevalent among women veterans with two thirds (62%) reporting a sexual assault during their lifetime, and up to 45% reporting military sexual trauma. ST is strongly associated with posttraumatic stress disorder (PTSD), intimate partner violence (IPV), and alcohol misuse. Numerous barriers prevent consistent delivery of interventions appropriate for women veterans with any lifetime ST; a high-risk population. The SHE program will address the needs of women veterans with lifetime ST within a primary care setting. Primary care settings present an ideal opportunity to provide behavioral interventions for our population because they are frequent points of health care contact for VA women. Findings from this proposal will lay the groundwork for a larger clinical trial of the SHE program in multiple VA primary care settings. This treatment development study is especially timely, since number of women veterans enrolled in the VA system is estimated to grow by 33% in the next three years. Furthermore, since screening for MST is mandated within VAs, a computer delivered intervention has the potential to be easily integrated into the standard of care for women veterans who screen positive for any ST history and could potentially increase the identification of high-risk women veterans. In addition, given the VA will institute mandatory screening for domestic violence in all women veterans within the next two years, SHE represents an ideal intervention to be paired with this screening.

The computer-based intervention, SHE, is easily transported and inexpensive, and if successful, SHE could be applied rapidly and widely in different settings and with different populations with ST, including male veterans as well as service members. Finally, there is strong potential for significant impact in terms of quality of life for women veterans and service members, and for their families, and in reducing costs of disability and health care, and more broadly societal costs.

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