Treatment of PTSD in Residents of Battered Women's Shelters

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Research Strategy

A. Significance

A1. Violence against women is a significant public health problem. Recent research suggests that approximately 1 in 4 women report a history of IPV [1] with IPV being one of the leading causes of injuries to women [2]. Further, a well established literature finds a significant relationship between maternal IPV and maternal child abuse and child maltreatment [3, 4]. In response to the need to provide physical safety, emotional support, and case management to IPV victims, nationally there are about 2,000 community-based battered women shelters throughout the US, servicing approximately 300,000 women and children each year [5]. Considering the number of women who seek help from these facilities and that victims in shelter have already instituted a change in their life, a prime time to intervene may be while these women are already seeking help from shelters. Moreover, sheltered IPV (S-IPV) victims typically have limited resources, are vulnerable to re-victimization, and are likely to be highly distressed and therefore, benefit from treatment. However, research demonstrates that IPV victims face multiple barriers to accessing typical community-based treatment[6], including safety issues, transportation, childcare needs, and access to medical insurance, and many fail to initiate treatment[7]. Also, few shelters offer treatment for IPV victims, even though PTSD is extremely prevalent in this population and offering treatment in shelter helps address many of the barriers faced by victims in accessing appropriate psychological treatment[8].

A2. PTSD is highly prevalent and associated with significant morbidity in IPV victims. A meta-analysis of the mental health consequences associated with IPV found PTSD to be one of the most prevalent disorders in IPV victims, with a weighted mean prevalence of 63.8% [9]. Further, S-IPV victims tend to present with more severe abuse and related injury and exhibit higher rates of PTSD than do women who do not seek shelter [10]. IPV-related PTSD is associated with significant morbidity, impairment, and loss of personal and social resources [11] and can be associated with serious consequences for women in shelter. Conservation of resource theory [12] posits that there is a downward, bidirectional spiral between loss of personal and social resources and PTSD, in which resource loss contributes to the development of PTSD. PTSD can then lead to a further loss of resources, which may contribute to difficulty in establishing long-term safety. Additionally, PTSD can interfere with victims' ability to effectively use important shelter and community resources necessary for establishing safety for themselves and their children[13]. Further, research suggests that PTSD is associated with attentional biases to threat-relevant information. Specifically, two recent studies using a visual search task found more severe PTSD to be associated with attentional interference of threat-related information (i.e., difficulty in disengaging attention from threatening stimuli), which can lead to an over-valuation of trauma related information [14-16]. This difficulty in disengaging from trauma-related stimuli may cause increased distress and contribute to the use of avoidant behaviors in effort to decrease this distress[14-16]. These avoidant behaviors can make it more difficult for victims to effectively evaluate safety in new situations[17]. Moreover, PTSD is associated with higher cortisol reactivity to trauma cues [18, 19]. Research suggests that these heightened cortisol levels may inhibit traumatic memory retrieval [20], potentially limiting one's ability to use information from prior traumatic events in determining the degree of threat in future potentially dangerous situations (i.e., future contact with abuser). Consistently, research finds PTSD in IPV victims to be associated with increased risk of being re-abused by their abuser [17, 21, 22]. Given that cessation of violence is necessary for recovery from its traumatic effects, it seems imperative to address IPV-related PTSD symptoms as soon as they are identified (i.e., before women leave the safety of the shelter). HOPE educates victims on how the traumatic effects of the abuse can influence their ability to effectively access community and shelter resources and to accurately attend to and evaluate new threatening situations. Further, through the amelioration of PTSD symptoms, HOPE may resolve the cognitive and physiological response to threatening stimuli, thereby increasing victims' ability to attend, evaluate, and respond to future dangerous situations. Hence, beginning treatment while IPV victims are in shelter may increase their ability to effectively use resources and improve their safety planning ability, helping break the cycle of violence for women and their children.

B. Innovation

B1. No existing treatments address the unique needs of sheltered IPV victims with PTSD. The only other empirically supported treatment for IPV-related PTSD [23, 24] was designed for women who have permanently left their abuser and have established physical safety. Hence this treatment fails to address the unique needs of recent S-IPV victims who face ongoing threats of further abuse, reunion with their abuser, and have substantial resource needs (e.g., housing, accessing legal remedies, employment). Furthermore, this treatment for non-shelter IPV victims incorporates exposure techniques and might be contraindicated for S-IPV victims. Exposure-based PTSD treatments typically excludes recent IPV victims[23-26], as this treatment aims to habituate victims to abuse-related stimuli, which could interfere with victims' ability to appropriately judge and

maintain safety, as much of their fear is indeed real. Although exposure-based treatments have been adapted for other recent trauma victims (e.g., survivors of natural disasters), S-IPV victims are unique as they are at high-risk for being re-abused, and are often ambivalent about leaving the relationship, further increasing their potential for exposure to further abuse and requiring a unique treatment focus. Further, presence of recent IPV has been found to be associated with non-engagement in one specific PTSD treatment that incorporates exposure, cognitive processing therapy[7].

B2. An Innovative Treatment: HOPE. Although CBT treatments with an exposure component are typically considered the first line treatment for PTSD, other CBT treatments (e.g., cognitive-restructuring) have been validated, found to be as effective as exposure treatments, and have been used with a variety of PTSD populations[25, 27-32]. *H*OPE adopts a cognitive-behavioral (CBT) approach; however, in an effort to more effectively address IPV victims' needs and improve engagement in treatment, HOPE expands upon traditional treatments, through its incorporation of the empowerment and stabilization treatment models for IPV victims; models of care that experts in the field of IPV have strongly recommended [33, 34]. Empowerment can be conceptualized as "helping women to become more independent and assertive about attaining her goals and achieving change and psychological growth [35]" Consistently, HOPE focuses on increasing the woman's independence and control by emphasizing protection, (i.e., focusing on increased safety, enhanced choice-making and problem-solving in decisions about relationship, relocation, and other transitional issues). According to the stabilization model, the most urgent clinical need in IPV victims is the establishment of physical and emotional safety. Thus, HOPE emphasizes empowerment and targets goals of safety, self-care, and protection, and the exchange of information on IPV and PTSD symptoms, which [34] meshes well with the treatment needs of S-IPV victims. HOPE, (see appendix) [13, 36, 37] is an individual CBT 16-session treatment, addresses the cognitive, behavioral, and interpersonal dysfunction associated with PTSD in IPV victims. Additionally, HOPE addresses McCann et al.'s [38] five schematic areas of dysfunction (i.e., safety, trust, power/control, esteem, intimacy). HOPE is unique in that it adopts a multicultural approach, is designed to be initially delivered in-shelter, encourages collaboration with shelter staff, incorporates individual goals and engagement strategies, and prioritizes immediate safety needs and empowerment and choice throughout treatment. Additionally, HOPE provides education on child abuse and assists women in accessing community resources for both them and their children. Within HOPE, treatment is individualized, in that participants' goals drive therapy and are used to prioritize specific modules within the HOPE program.

B3. HOPE is the only treatment, to date, that addresses the unique needs of residents of sheltered IPV victims with PTSD. Incorporating the literature on IPV, PTSD, and CBT, HOPE [13, 36, 37] was specifically designed for IPV victims with ongoing safety concerns, with treatment beginning in shelter and continuing after exiting shelter when women are extremely vulnerable to returning to their abuser and being re-abused. HOPE also addresses many of the clinical challenges of working with IPV victims with ongoing safety and case management concerns. Unlike other PTSD treatments for victims of IPV [23, 24] that incorporate exposure techniques which are contraindicated when the threat for victimization is ongoing, HOPE meets IPV victims "where they are," addressing the unique needs of recent S-IPV victims who face ongoing re-victimization (i.e., safety planning, managing necessary contacts with abuser, co-parenting with an abuser, whether to reunite with an abuser). Further, given that PTSD can interfere with IPV victims' ability to effectively use the shelter and community resources needed to extricate themselves from the abuse and establish long-term safety [13, 39], HOPE targets PTSD symptoms through CBT techniques while emphasizing the need to access the material and personal resources necessary to safely re-enter the community after leaving shelter. Additionally, since PTSD symptoms can interfere with victims' ability to attend to and adequately judge new threat-related information [14-16], HOPE assists women in better understanding how their PTSD symptoms in general, and their emotional numbing symptoms in particular, can interfere with their ability to safety plan, providing women the tools they need to effectively judge their risks for future violence. Moreover, HOPE incorporates an empowerment approach to treatment (see B2). Finally, HOPE addresses many of the treatment barriers faced by S-IPV victims by offering sessions in shelter and/or other safe, flexible and easily accessible settings after leaving shelter, having childcare available during therapy sessions, and offering flexibility in scheduling. *Therefore, HOPE is innovative in its target population, and its content and approach to treatment.* Further, our pilot data with HOPE support the initial acceptability and feasibility of HOPE (see C1). *If HOPE is found to be efficacious in the treatment of IPV-related PTSD relative to a credible, attention-matched control condition this would make HOPE the only treatment with empirical support for this vulnerable and underserved population of women. Furthermore, HOPE may hold promise for a more heterogeneous population of IPV victims who have contact with their abuser.*

B4. HOPE was specifically designed to serve as an evidence-based model program that could be implemented in a wide-range of shelter programs across the United States. Incorporating mental health treatment in the shelter may improve the standard shelter services that victims receive during this critical period in their lives. Moreover, since HOPE is manualized, and includes an established comprehensive training program and measures to ensure that treatment is being delivered according to the dictates of the manual, the treatment is portable to other settings and can potentially provide a national model of treatment for residents of battered women shelters with PTSD, significantly improving the standard of care in residents of battered women's shelters. Although the primary aim of the proposed study is to test the efficacy of HOPE relative to an attention-matched control, the proposed study is also designed to facilitate the dissemination of HOPE in future research. *C*ommunity therapists will deliver the interventions, and feedback will be obtained from shelter staff, therapists, and other stakeholders in developing a dissemination plan for a future dissemination study.

B5.The proposed study will investigate innovative outcomes of HOPE treatment. The theoretical underpinnings of HOPE assume that IPV-related PTSD and its associated impairment interferes with IPV victims' ability to access and effectively use important community and shelter related resources needed to establish long-term safety for themselves and their children. Further, empowerment is considered a key mechanism of change in HOPE. Our pilot work with HOPE is the first study that we know of to specifically look at re-abuse and empowerment as an outcome of therapy with recent (i.e., < 1 mo) IPV victims [37]. Moreover, we propose to investigate objective measures of stress responding which may impact IPV victims' safety planning ability, in addition to traditional measures of self-reported symptoms, as they have important theoretical and practical implications to our target population. As stated in A2, research has repeatedly found PTSD to be associated with increased attentional interference of threat relevant information, specifically a difficulty in disengaging attention [14-16]. Therefore, in the proposed study, we also intend to measure biases in attention to threat-related cues using a visual search task with a lexical component [15, 40] in order to determine if treatment of IPV-related PTSD with HOPE is associated with victims' decreased biases in attention to threat-related stimuli, that is, in less interference in disengaging attention. Also as described in A2, several studies have documented an elevated cortisol response to traumatic cues in PTSD victims compared to healthy or trauma-exposed controls [18, 19]. Further, research has demonstrated a decrease in this cortisol reactivity in response to PTSD treatment with paroxetine [41]; however, no published research to date has investigated cortisol reactivity in response to psychosocial treatment. Thus, we also propose to measure salivary cortisol reactivity in response to treatment to determine if treatment with HOPE is associated with a normalization of cortisol reactivity. In addition to victim safety and objective measures of the stress response, we also intend to investigate whether HOPE is associated with decreased child abuse potential (i.e., known correlates of child abuse) in recent IPV victims. Research demonstrates that maternal IPV is associated with maternal child abuse and maltreatment [3, 4]. Further, psychiatric symptoms have been shown to be associated with higher child abuse potential [42, 43]. Consistently, research has found IPV to be associated with increased child abuse potential [44], with current mental health symptoms being the strongest predictor of child abuse potential [43]. Research also suggests that victims of IPV living in shelters have greater abuse risk than victims of IPV in other housing environments [43]. This increased risk for child-abuse potential in sheltered victims of IPV with PTSD can have substantial implications for both mothers and children. Given HOPE's dual focus on IPV-related PTSD and the access to shelter and community resources, we anticipate that by (1) treating the PTSD and (2) improving participants' ability to effectively access much needed resources, we will be directly impacting many of the risk factors for maternal child abuse and therefore participants' child abuse potential. *To our knowledge, the proposed study is the first to investigate the impact of the psychosocial treatment of PTSD on empowerment, child abuse potential, attentional biases to threatening stimuli using a visual search task with a lexical component, and cortisol reactivity, all extremely relevant outcomes for this vulnerable population. Further, the proposed study also includes a cost-effectiveness analysis of HOPE*.

C. Approach: Research Design and Methods

C1. Preliminary Studies

Recruitment and Retention. The current research proposal builds from the success of research from both a career development award (K23 MH067648) and treatment development study (R34MH080786). We have established relationships with local shelters and have completed recruiting for two treatment studies and one naturalistic prospective study with over 200 shelter residents over the last 7 years in the development of HOPE. Refusal rates for both our treatment studies were low (0 - 1.6%). Further, we have had excellent retention rates. In our first study of the shelter version of HOPE [37], retention rates for each follow-up time points were as follows: 97.1% at 1-wk post-shelter, 94.3% at 3-months post-shelter, and 94.6% at 6-mo post-shelter. Further, in our work with the expanded version of HOPE (the treatment for our proposed study), we retained

80% of participants at the 6-month post-treatment follow-up, which occurs 9 months after participants leave shelter. *Therefore, our research procedures and retention strategies have been overwhelmingly successful in recruiting and retaining a rather transient population that is historically difficult to follow in longitudinal research.*

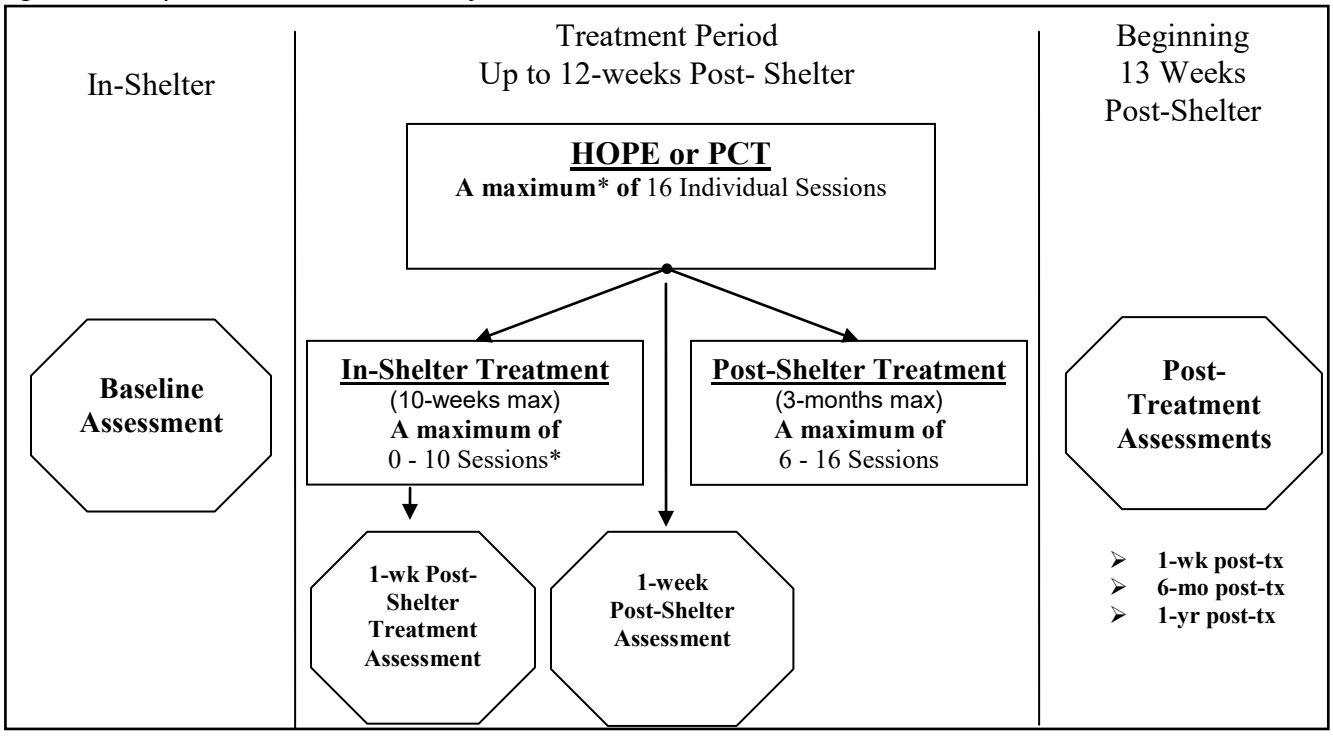
Acceptability and Feasibility. Pilot work with HOPE clearly demonstrates the feasibility of engaging residents of battered women's shelters in HOPE. Our data show that our population has chronic PTSD symptoms that have persisted an average of nearly 38 months. Our initial randomized trial of the shelter version of HOPE [37] had low treatment drop-out rates (5.7%), high credibility ratings (average of 6.78 on 8 point scale), and satisfaction with treatment was also high (e.g., averages of 3.4 – 3.5 on 4 point satisfaction ratings). Further, consistent with research that finds that 38% of IPV victims fail to initiate treatment[7] and with the literature that describes the barriers to accessing mental health treatment in IPV victims [6], our data support that simply offering referrals to community based treatment is not successful, with 60% of control participants failing to follow-up with referrals for community-based treatment while in shelter. Given that 83% of our sample either reported further IPV, contact with their abuser, and/ or another significant trauma after leaving shelter, we expanded HOPE to also include sessions after women leave shelter (i.e., 16 sessions starting in shelter and extending until 3-months post-shelter). Results of a recently completed randomized clinical trial of this expanded version of HOPE support the acceptability and feasibility of continuing treatment after shelter. Of the 30 participants who were randomized to the expanded HOPE, 25 (83%) completed 10 or more sessions of HOPE, with women completing an average of 80% of available post-shelter sessions (*M*=12.7 sessions). *Thus, results clearly support our ability to maintain our engagement with women in HOPE after leaving shelter.* This study also had low treatment drop-out rates (6.7%), high credibility ratings (*M* = 6.94 on 8-point scale) and high treatment satisfaction (*M* = 3.8 on 4-point scale). *Thus, our work to date suggests that the strategies included in the expanded version of HOPE have been successful in addressing many of the clinical and research challenges faced by victims of IPV who seek shelter.*

Initial Efficacy of HOPE. Our pilot work with both the shelter and expanded version of HOPE also provides initial support of the efficacy of HOPE. In a randomized trial of the shelter version of HOPE [37], we found HOPE to be associated with significant treatment gains, most importantly, reduced PTSD arousal (*d* = 1.05) and avoidance symptoms (*d* = .52) and lower likelihood of experiencing further abuse by a current or former partner. Further, women who completed a minimal number of sessions of HOPE were over 2 times less likely to meet criteria for PTSD or subthreshold PTSD after leaving shelter (OR's range from 2.33 to 4.44 from 1-week to 6-months post-shelter). Additionally, women who completed at least 5 sessions of HOPE were over 12 times less likely to report being abused over the course of a 6-month follow-up (OR = 12.6) relative to participants who did not receive HOPE. Participants who received HOPE also reported less severe depression and greater degree of social support and empowerment across the 6-month follow-up than did women who only completed standard shelter care. Finally, data suggest that HOPE may have an impact on children, where participants in the control group experienced an increase in parenting stress from 1-week post-shelter to 3-months post-shelter, while participants' in the treatment group level of parenting stress remained stable. This finding suggests that HOPE may provide skills that generalize to parenting in IPV victims. Results of a recently completed randomized trial of the expanded version of HOPE that will be used in the proposed study found significant treatment effects for PTSD (*Cohen's d* = .67), social adjustment (*Cohen's d* = .44) and social support satisfaction (*Cohen's d* = .89) and trends for depression severity (Cohen's d = .45), revictimization severity (*Cohen's d* = .51), and empowerment (Cohen's d =.5). Minimal attendance analyses find significant treatment effects for depression severity (*Cohen's d* = .65), social adjustment (*Cohen's d* = .63), empowerment (*Cohen's d* = .72), and trends for PTSD (*Cohen's d* = .72), revictimization severity (*Cohen's d* = .55), social support satisfaction (*Cohen's d* = .95). Overall, women who participated in HOPE exhibited less severe PTSD symptoms, less revictimization, fewer depression symptoms, and less impaired functioning, as well as a greater degree of empowerment, and greater satisfaction with social support relative to those who did not complete HOPE. Chi-square analyses also revealed that significantly fewer HOPE participants met criteria for IPV-related PTSD at post-treatment and were unemployed 6-months after leaving shelter relative to controls. *Therefore, results of our randomized pilot study of this expanded version of HOPE provide evidence of the feasibility and initial efficacy of on participants' PTSD symptoms and abuse severity.*

Drs. Johnson and Delahanty have previously collaborated in a study investigating salivary cortisol levels in IPV victims [45]. Using similar methodology as proposed here in which 4 salivary samples were collected over a 1-hour period (see C2), the cortisol awakening response was investigated in a sample of 52 shelter residents. Results suggested that IPV-related PTSD severity was associated with significantly greater cortisol output the first hour after wakening. Thus, pilot data support the use of cortisol response within S-IPV victims as well as the ability of the research team to successfully collect multiple saliva samples from shelter residents.

C2. Study Design: To test our hypotheses that HOPE will significantly reduce severity of IPV-related PTSD and re-abuse in S-IPV victims compared to PCT, we plan to enroll 186 residents of battered women shelters with IPV-related PTSD into a prospective randomized controlled trial comparing HOPE to a attention-matched control condition (i.e., PCT). Residents of battered women shelters meeting study eligibility (see below) will be randomized into one of the two study arms. Participants will be offered 16 sessions of therapy (see Figure 1), either HOPE or PCT, beginning while women are in shelter (0-10 sessions) and continuing until 3-months post-shelter (6-16 sessions). The number of sessions attended within the shelter environment is dependent on participants' length of shelter stay, with a maximum of 10 sessions in shelter. Participants will then complete the remaining 6-16 sessions of HOPE outside of shelter. Therapy sessions will occur in shelter or another convenient, safe, and confidential location. Participants will be blinded to whether or not they received the investigative treatment or control condition. Blinded outcome assessments will be administered 1-week post-shelter treatment, 1-week post-shelter, and 1-week, 6-months, and 1-year-post-treatment.

Figure 1. Proposed model for delivery of treatment and assessment of outcome.



*Participants who are still in shelter after their 10th session will participate in monthly booster sessions.

Rationale for the study design: Pilot work with HOPE has determined that HOPE is associated with improved outcomes relative to standard shelter services alone. Given that there is no other existing PTSD treatment appropriate for this population that could serve as a comparison condition the next logical stage in evaluating the efficacy of HOPE is to determine if HOPE offers improvement over a credible control condition that controls for the nonspecific components of therapy. PCT (see appendix) is a problem-focused, supportive therapy that is frequently used as an attention-matched control condition in clinical trials of PTSD [46, 47]. PCT does not incorporate any of the hypothesized active ingredients of HOPE (e.g., cognitive-restructuring, acquisition of new behavioral skills, safety planning, access to resources, and empowerment strategies), but does provide psychoeducation on PTSD. Further, PCT is also clinically realistic, as many practitioners incorporate this approach into their standard practice [48]. Therefore, we chose to compare HOPE to PCT, in order to determine if components specific to HOPE are responsible for observed effects, rather than nonspecific factors consistent with supportive therapy. Dr. Shea who has established expertise in PCT[46] will assist in adapting PCT to meet the needs of the proposed study, as well as in the training and supervision procedures for the PCT arm of this study.

Sample and recruitment: Participants will be 186 women recruited over 27 months from six battered women's shelters in five different counties within a 55 mile radius of the University of Akron (see letters of support) and randomized either to receive HOPE (*n* = 93) or PCT (*n* = 93). Both treatments will start while women are residents of shelter and extend after they leave shelter. Given that the length of shelter stay is variable and outside of experimenter control, session frequency will be individualized based on length of shelter stay. We are currently employing this model in our work with HOPE with success (see C1). Participants in both treatment conditions will receive up to ten individual sessions while in shelter, and 16 sessions in for up

to three months after they leave shelter (see Figure 1). Women in both conditions who continue to stay in shelter after they complete the shelter-based treatment will be offered monthly booster sessions until they leave shelter. As women are admitted to the shelter, they will be informed of the research study and volunteers will be recruited. Shelter staff will provide all new residents with a brochure describing the research and ask if a research assistant can meet with them to tell them more about the study. Flyers advertising the study will also be posted within the shelter. Finally, research staff will regularly attend house meetings, providing more detailed information regarding the study and how to participate. Participants will be instructed to call a confidential research line, where they will complete a brief phone screen to determine if they meet any exclusionary criteria for the study. We have successfully used these recruitment strategies with pilot work with HOPE. **Inclusion criteria** will be (1) resident of a battered women's shelter with documented IPV in the month prior to shelter admission as defined by the Revised Conflict Tactic Scales (CTS-2 [49]) and (2) IPV-related PTSD as measured by the Clinician Administered PTSD Scale for DSM-IV (CAPS [50]). **Exclusion criteria** will be (1) presence of significant suicidal ideation or risk as defined by the Modified Scale for Suicide Ideation (MSSI [51]), (2) current psychotic symptoms on the SCID-I/P psychotic screen, (3) lifetime bipolar disorder as determined by the SCID-I/P, (4) presence of recent (i.e., last 3 months) substance dependence as defined by the substance abuse module on the SCID-I/P [52], (5) concurrent psychosocial treatment for PTSD, and (6) any change in type or dose of psychotropic medication in the last month (Only 28% of participants met similar exclusionary criteria in our pilot work, suggesting that our sample is generalizable to a large portion of our target population). These criteria were chosen to increase the generalizability of findings (i.e., not excluding other Axis I or II diagnoses), while excluding women who would likely require different or supplemental treatment (e.g., suicide risk, bipolar disorder, psychosis, substance dependence).

Feasibility of sample and procedures: We have successfully implemented HOPE in 4 of the 6 shelters included in this proposal, with two therapists coordinating with these four sites. Additionally, one of the project coordinator's primary responsibilities will include assisting in coordinating the 6 research sites, including recruitment, scheduling of assessments and therapy sessions, as well working with shelter staff to streamline research procedures within individual shelter systems. Given our prior experience and the support we have from shelters (see letters of support), we feel confident that we can coordinate this project within the six proposed research sites. In our pilot work with 4 of the shelters from the current study we enrolled an average of 6-7 participants each month. As recruitment for the proposed study will include two additional shelters with a combined average of 16 additional admissions each month, we do not anticipate difficulties in meeting our recruitment goal of 7 participants per month over the course of 27 months. Moreover, we have clearly been able to establish the appropriate relationships with the shelters, and have demonstrated that we can engage women in both our research procedures and HOPE. Additionally, we have optimized our research procedures for conducting longitudinal research with a very transient and high-risk group of women (see C1). Finally, we have established relationship with local hospitals and community agencies (i.e., homeless shelters) allowing us to offer diverse locations for follow-up and therapy appointments. *Thus it is clearly feasible to engage IPV victims in shelters in the proposed research and to follow their progress long-after they leave the shelter, despite the fact that many of these women lead chaotic lives.*

Adequacy of Sample Size: Optimal Design 2.0 Software [53] was used to conduct power analyses for hierarchical linear modeling (see C3) of treatment effects. An alpha level of .05 was chosen for each of the primary hypotheses. Given that our pilot research has found medium effect size (ES) on the higher end of the continuum for PTSD severity and medium ES for re-abuse severity (see C1), a more conservative medium ES (delta = .60; which is on the lower end of the continuum of medium effect sizes) was assumed in an effort to account for the potential for reduced effects in the current study. We also assumed an ES variability of .07 across the 6 shelters where recruitment will occur. An ES variance of .07 corresponds to a standard deviation of approximately.2, which for ES = .60 reflects substantial variation in treatment ES across shelters. Thus, we are powering the study to be able to detect a medium ES, even if there is substantial ES variability across shelters. Additional assumptions for the power analysis included a proportion of explained variance by the blocking variable (i.e., shelter) of .1 and a proportion of explained variance by the level 1 covariate (i.e., baseline PTSD or violence severity), of .3. There is little literature on which to base estimates of these two parameters for the proposed study, but these parameters have relatively little effect on sample size requirements given the specified ES, ES variability, and number of shelters. For example, the most extreme value of 0 (instead of .1) for the proportion of explained variance by the blocking variable would only increase the necessary sample size by 2 per shelter. Also, even an extreme value of .1 (instead of .3) for proportion of explained variance by the baseline level of the outcome variable would only increase the necessary sample size by 5 per shelter. Using the parameter estimates specified above and a desired power of .80, results of the

power analysis indicated that 25 participants were required per shelter for a total *N* of 150. In our pilot research we had retention rates of 81-95% (see C1). Thus, assuming the more conservative attrition rate of approximately 20%, we would need 31 participants per shelter, for a total of 186 participants to achieve a power of .80 to detect medium-sized treatment effects for our primary outcomes.

Randomization: In order to ensure that the treatment conditions are balanced on variables that might influence outcome (i.e., use of psychotropic medications and substance use), participants in each subgroup will be assigned to their treatment condition using an urn randomization procedure [54]. Urn randomization is a stratified randomization technique that randomly assigns participants in a given subgroup to treatment conditions, but systematically biases the randomization in favor of balance among treatment conditions. We will stratify participants according to comorbid substance use disorder (SUD) and use of psychotropic medications to obtain an equal distribution of participants using medications or with SUD in each condition.

Potential for Cross-Contamination: The shelter is a close community and participants in HOPE may share HOPE specific components with participants in PCT. We considered randomizing treatment assignment to shelter rather than participants in an effort to eliminate the potential for cross-contamination. However, this strategy significantly reduced our power and required a sample size that was not feasible or cost effective. Further, in our pilot work with HOPE only 2 participants in the control group reported that participants in HOPE shared HOPE-specific information with them, with exploratory analyses revealing no differences in PTSD outcomes between those who reported exposure and those who did not. Further, HOPE focuses on empowerment and provides individualized feedback and customized handouts, thus the content of HOPE cannot be easily learned through exposure to a handout or a brief conversation. However, to minimize the likelihood of cross-contamination between treatment and control groups, we will (1) instruct participants to not share their materials (i.e., workbook) with other shelter residents, (2) assess whether participants randomized to HOPE shared HOPE specific information with other shelter residents, and whether participants randomized to PCT were exposed to specific HOPE components during our follow-up procedures, and (3) assess use of HOPE specific skills in the PCT group in order to determine if women in PCT were actually implementing skills taught only in HOPE. Thus, we will try to minimize the potential for sharing HOPE-specific information and skills between participants, but also assess whether cross-contamination is a significant problem (see C3).

Noncompleters: In general, women who do not attend at least 8 sessions (i.e., ½ of sessions, as prior work with HOPE finds treatment effects when participants attend approximately 50% of sessions) will be considered noncompleters. Women will not be discontinued from the treatment protocol for noncompliance. All women will be invited to continue treatment and follow-up assessments. Given the unpredictable and demanding lives of our target group, most of whom are low-income, flexibility is important to make the treatment accessible to them (see assessment and retention sections for how we will address barriers in scheduling appointments).

Clinical Deterioration/Suicidal Risk. To increase safety, participants will be removed from the treatment phase of the trial as a result of clinical deterioration or suicidal risk (see E1 for procedures, assessment & definitions). Participants will remain in the research sample, be followed, and included in all analyses.

Therapists: Therapists for the intervention will consist of 4 community therapists who have been rated as qualified practitioners of HOPE or PCT (see below). Licensed, Master level (psychology, social work, counseling, or other related field) therapists will be recruited from the two local community mental health agencies who have served as our primary referral sources for this population throughout our pilot work (and thus are representative of the types of agencies most likely to treat victims of IPV who seek shelter). Each therapist will be required to have a minimum of two years of experience working with trauma populations, as well as training and experience in CBT interventions. Potential therapists will be interviewed by the PI. The interview will include questions about their training in trauma and CBT. Role-plays will also be used to assess the adequacy of their training and their ability to learn the proposed treatment protocols.

Therapist training procedures: Procedures for training and monitoring therapists will mirror those used in prior research utilizing community therapists [55]. Dr. Shea, will assist in refining the training and monitoring protocols of community level therapists. To optimize the rapid acquisition and maintenance of therapist skills, supervision will initially be intensive, with supervision being titrated to skill level so that it becomes less intensive as therapists acquire more experience. Dr. Johnson will oversee weekly group supervision sessions with all community therapists. Dr. Johnson will provide individual supervision titrated to skill level to each of the community therapists. Dr. Johnson and the project coordinator will review therapists' audiotapes on a weekly basis and provide feedback during individual and group supervision sessions. The therapists will be closely monitored for competence and adherence throughout the study and if at any time a therapist does not achieve good adherence, the therapist will be replaced with another therapist who will have received the training and completed the certification process. If a therapist has problems delivering the treatment, then data associated

with this therapist will not be included in any analyses. We are confident that we will be able to successfully train community therapists in HOPE, as we have successfully trained master-level graduate students in HOPE in our prior research. Further, we are using rigorous training procedures that have been successful in prior clinical trials with PTSD treatments [55]. Finally, HOPE is a very structured treatment with a detailed and well scripted manual, leaving very little room for therapists to veer from standardized treatment procedures.

The four community therapists will be trained in either the conduct of HOPE or PCT. We chose to train therapists in only one treatment modality in order to eliminate the risk of contamination in the control group and assure that HOPE is compared to a true attention-matched control condition. Therapists will be randomly assigned to deliver either HOPE or PCT. Existing systematic training programs (certification processes) in the conduct of HOPE and PCT that have been implemented in prior research will be used for the proposed study. As in prior research utilizing community therapists [55] each therapist will have two closely supervised training cases prior to taking on participants enrolled in the randomized trial. For both HOPE and PCT, the overall training objectives are for therapists to understand and learn to perform the intervention, to avoid using techniques or materials not part of the intervention, to ensure the use of relatively consistent procedures across different participants, and to deliver the intervention in a culturally sensitive manner. HOPE training (see training manual in appendix) includes a two-day workshop on HOPE conducted by Dr. Johnson, that includes lectures on IPV and PTSD, the theoretical conceptualization of HOPE, and the structure of, techniques used in, and conduct of HOPE sessions. The training program will also teach strategies for maintaining the therapist and participant safety when conducting HOPE sessions post-shelter, as well as procedures for managing emergency situations. Role-plays of appropriate and effective as well as faulty strategies to conduct the sessions, and strategies to manage participants whom may have difficulty in comprehending or utilizing the techniques will be included in the workshop. PCT training will also include a two-day workshop on PCT conducted by Dr. Johnson. Drs. Johnson and Zlotnick will work closely with Dr. Shea in adapting the existing didactic training program for this study. Therapists will be trained in general issues in working with IPV victims, including strategies for managing emergencies. The workshop will include a description of the theoretical rationale behind PCT, as well as specific PCT strategies. Training will also be provided outlining specific strategies that are not to be used as a part of PCT (e.g., cognitive-restructuring, skills training, and other overlapping components with HOPE). Role-plays of appropriate and effective as well as faulty strategies to conduct the sessions, and strategies to manage more difficult clients will be included in the workshop.

Assessment: Participants will be assessed at six primary time points: (1) baseline, (2) 1-week post-shelter (PS) treatment (tx), (3) 1-week PS, (4) 1-week post-tx (i.e., 13 weeks PS), (5) 6-months post-tx, and (6) 1-year post-tx using a combination of well-known structured interviews and self-report questionnaires with demonstrated reliability and validity. For data and safety monitoring purposes (see E2), participants will also complete an abbreviated assessment designed to assess for clinical deterioration and re-abuse at mid-shelter tx (i.e., 5 weeks after begin tx), mid-PS tx (i.e., 6-weeks PS) assessment, and 3- and 9-months post-tx (see Table 1). Assessment procedures will mirror those that have been successful in our pilot work with HOPE. While women are residents of the shelter, assessments will take place at the shelter. Follow-up assessments will occur at the safest and most convenient location for the women (e.g., hospital, public library, in-home visit). In the event that a participant cannot attend a follow-up assessment in person (e.g., moves out of state) interviews will be conducted via phone. Three blind research assistants will conduct all follow-up assessments, under the supervision of the project coordinator. The RAs will be trained in the administration of all interviews and research procedures. This training will include strategies for the accurate assessment of PTSD and IPV using training procedures already in place in Dr. Johnson's research lab. A minimum of 80% agreement on all ratings will be required to establish inter-rater reliability. The RAs will be blind to treatment condition, as well as to the study design and hypotheses. Table 1 contains a summary of measures given at each assessment period. All measures will be administered electronically with software available from Questionnaire Development System (QDS). Self-report measures will be administered with the Audio Computer Administered Self Interview (ACASI) module, and all interviews will be administered with the Computer Assisted Personal Interview (CAPI) module. We chose to use ACASI to increase women's likelihood of disclosing stigmatized experiences, to streamline data entry, and to improve data reliability.

Primary outcomes include IPV-related PTSD severity and degree of re-abuse. PTSD symptom severity, as well as PTSD diagnostic status will be assessed with the **Clinician Administered PTSD Scale (CAPS [50])** at all major time points. PTSD will be assessed for both the index IPV and the other most traumatic event, allowing us to explore treatment effects both specific to IPV and more broadly. Self-report symptoms of PTSD severity will also be assessed with the **Davidson Trauma Scale (DTS[56])** at all time points. IPV severity will be assessed with the **Revised Conflict Tactic Scales (CTS2)** at all time-points. Abuse severity rather than

presence of abuse was chosen as a primary outcome as it is consistent with a large body of research demonstrating severity of a traumatic event, rather than the occurrence of the event itself to be an important predictor of PTSD severity[57]. Further, given that the occurrence of abuse is not entirely in the victims' control, safety planning strategies seem more likely to assist women in reducing the overall severity of the abuse, rather than each individual act of abuse. We operationalized abuse severity as the sum of the number of abusive acts, a scoring method found to provide a valid measure of abuse severity[58].

Secondary outcomes will be assessed at all major time points. Since HOPE is associated with significant decreases in depression (see C1) and PTSD and depression frequently co-occur [59], depression will be assessed with the **Center for Epidemiological Studies Depression Scale (CESD [60])**. Additionally, given the established relationships between IPV and child abuse and maltreatment [22] and mental health symptoms and child abuse potential in victims of IPV living in shelters [42], we will also assess participants' child abuse potential with the brief form of the **Child Abuse Potential Inventory (CAPI [61])**. The brief CAPI is a well validated and frequently employed measure that assesses 7 known correlates of child abuse (i.e., distress, family conflict, rigidity, happiness, feelings of persecution, loneliness, financial insecurity) without directly assessing violence towards children, making the measure acceptable to parents. The impact on quality of life (as both a secondary outcome and for cost analyses described in C3) will be assessed using the **Veterans SF-12 (VR-12)** (the U.S. government's public use variant of the SF-12)[62] . Our prior work found the VR12 discriminates well between the quality of life losses associated with different levels of PTSD[63] . This research also found that Sengupta's HUI3 scoring[64] was the best of 50 existing scorings of the VR-12. That scoring measures functional status in quality-adjusted life years (QALYs), the quality of life measure routinely used in clinical trials of pharmaceuticals. Additionally, given that HOPE adopts an empowerment approach and a primary treatment goal is to increase participants' effective use of personal and social resources, the **Personal Progress Scale Revised (PPS-R)[65]** will be used to assess empowerment, **the Social Support Questionnaire (SSQ [66])** will be used to assess degree and quality of social support, and the **Effectiveness in Obtaining Resources (EOR) Scale** [67] will be used to assess perceived effectiveness in accessing community and shelter resources. Finally, as HOPE is a CBT that targets dysfunctional cognitions, the **Posttraumatic Cognitions Inventory (PTCI)[68]** will be used to assess trauma-relevant cognitions.

Objective Measures of Stress Responding will be assessed at baseline, post-treatment, and 1-yr follow-up:

Attentional Biases in PTSD will be measured using a visual search task (VST) with a lexical decision component recently used in research assessing attentional biases in PTSD. Four different word types (i.e., trauma, general threat, semantically-related neutral, uncategorized neutral words) and "non-words" matched for word length and perceived frequency of usage will serve as stimuli for the VST. Stimuli will be presented on computer monitor using E-Prime software and response latencies will be recorded by the computer. Participants will first be presented with a fixation cross. They will then be presented with the stimulus screen which includes four letter strings in a rectangular array, with one (the "oddball") being the target stimulus. Participants are instructed to indicate as quickly and as accurately as possible whether the target is a word or non-word by pressing one of two keyboard keys.

To standardize diurnal influences on cortisol levels, assessment of cortisol reactivity will occur between the hours of 4PM and 7PM. After participants arrive at the assessment, they will sit quietly and complete the least invasive interview materials during the first half-hour of the interview. This is done to reduce the influence of travel and novelty of the assessment on cortisol levels. Following this rest period, participants will watch a 5-min clip of a video depicting IPV. This video will serve as the trauma cue. Using Salivettes sampling device (Sarstedt, Newton, NC), four saliva samples will be collected at 0 (baseline: prior to trauma cue), 15, 30, and 45 minutes after the 5-min video clip. Saliva samples will be stored at -80° C until assay. Saliva samples will be processed at the Center for Psychosomatic Research (Trier, Germany) using a time resolved immunoassay with fluorescence detection (DELPHI) [69].

Assessment of Comorbidity, Exclusion Criteria, and Use of Relevant Services: The mood, anxiety, substance and psychotic screening modules from the **SCID-I/P** [52] and the **Traumatic Stress Schedule (TSS[70])** which assesses lifetime occurrence of criterion A1 traumatic events will be administered at baseline to assess comorbid diagnostic information and trauma history in order to describe the sample and assess it's generalizability to other populations. Additionally, diagnostic information from the SCID-I/P will be used to determine if women qualify for the research protocol or if they require an appropriate referral (see exclusionary criteria). The Substance Module of the SCID-I/P will also be administered at each primary follow-up to assess for relapse or new onset of a substance dependence disorder, which will result in removal from the clinical trial during the treatment period (see E1). The **Modified Scale for Suicidal Ideation (MSSI [51])** will be used to assess the exclusionary criteria of suicide risk throughout the study (see E1). Since treatment over the f/u

period may impact long-term outcome, receipt of mental health treatment over the follow-up and/or medication changes or initiation of new medications over the treatment or follow-up periods will be measured with a modified version of the treatment section of the **Longitudinal Interval Follow-up Evaluation (LIFE)** [71]. The LIFE will also be modified to assess use of other pertinent resources for our target population for use in the economic analysis (see C3).

Satisfaction with Treatment. The **Client Satisfaction Questionnaire (CSQ** [51]**)** and an **End of Treatment Questionnaire** that addresses participants' perceptions of the helpfulness of the overall program and specific content, as well as the degree to which they used specific skills from HOPE or PCT, will be used to evaluate treatment satisfaction, as well as assess for contamination in the control group (see above).

Table 1. Summary of Planned Assessments and Assessment Periods

Assessment Periods										
Assessments	**Baseline**	**Mid-shelter tx**	**1-wk PS tx**	**1-wk PS**	**Mid-PS tx**	**1-wk post-tx**	**3-mo post-tx**	**6-mo post-tx**	**9-mo post-tx**	**1-yr post-tx**
CAPS	X		X	X		X		X		X
DTS	X	X	X	X	X	X	X	X	X	X
CTS-2	X	X	X	X	X	X	X	X	X	X
CESD	X		X	X		X		X		X
CAPI	X		X	X		X		X		X
VR-12	X		X	X		X		X		X
SSQ	X		X	X		X		X		X
EOR	X		X	X		X		X		X
PPS-R	X		X	X		X		X		X
PTCI	X		X	X		X		X		X
VST	X					X				X
CORTISOL	X					X				X
TSS	X									
SCID-I/P*	X		X	X		X		X		X
LIFE	X		X	X		X		X		X
CSQ						X		X		X

Note. MSSI administered at any time point if participant endorses SI. CAPS administered at mid-tx assessments if DTS increases 50%. *Only the substance module of SCID-I/P administered at follow-up.

Adherence and Competence: All therapy sessions will be recorded. Dr. Sara Perez, a consultant on this project who is well-trained in treatment of IPV-related PTSD, as well as in HOPE, serving as a therapist in our pilot work with HOPE will rate adherence and competence of the delivery of 5% of randomly selected HOPE and PCT sessions (i.e., 74 HOPE and 74 PCT sessions). She will also participate in the PCT training with the study therapists and consult with Dr. Shea in order to develop competence in rating PCT sessions. HOPE and PCT have established adherence and competence scales used in prior research (see appendix) [37, 46].

Retention: Our lab has developed procedures that exceptionally maximize retention and these were adapted for the proposed research protocol. In our original study of HOPE we retained over 94% of participants for 6 month follow-up and we retained 80% of participants in our study of the expanded HOPE at 9-months post-shelter. In our experience, the key element in maintaining contact with participants is continuity of well-trained staff. All staff will be extensively trained in the retention protocol and to the extent possible, the same RAs will track participants throughout the study. Moreover, the same RA will complete follow-up assessments throughout the study. The project coordinator will conduct weekly staff meetings to monitor retention efforts and to ensure the integrity of the tracking protocol. The procedures to safely maximize retention are based on those that have been successful with residents of battered women's shelters in prior research [72, 73]. Permission to contact the participant and significant others will be obtained at baseline and the safety of further contact will be evaluated throughout the research protocol. While participants are still shelter residents, the shelter will be contacted twice per week to inquire about the status of residents and to determine if a resident is planning to depart shelter. During the initial assessment, we will obtain releases that allow shelter staff to provide the research staff with follow-up contact information. Additionally, during the initial assessment, the names, contact information, and permission to contact will be obtained of all persons who know how to contact the participant. Prior to their departure from the shelter, detailed contact information will be obtained and information obtained

at intake will be updated and new releases will be obtained as necessary. We will also collect information regarding community resources (i.e., social services, primary care physicians) with whom the women may be involved and permission to contact these agencies in order to locate participants. When we are unable to contact women by phone, letters and outreach will be used to schedule follow-ups. Additionally, women will receive appointment cards with all details regarding their next appointment. The women will also be provided pens and keychains at each time point that include our research number. Also, child-care and bus passes will be provided whenever necessary. Finally, financial incentives will be built into the study in the form of participant fees to be paid upon completion of all post-shelter and follow-up assessments. Financial incentives designed to reimburse women for childcare and transportation costs for sessions that occur outside of shelter will also be provided. Additionally, as women may eventually return to an unsafe environment (i.e., back to their abuser), safe methods of contact will be negotiated at each stage described above and participants will be encouraged to contact the research team if they feel that contact at any location is no longer safe (see E1).

Dissemination: *One of the primary reasons we propose to evaluate HOPE in a wide-range of shelters is to inform future dissemination of HOPE*. Upon completion of the treatment phase, a series of focus groups (*N* = 5) will be run with shelter staff (e.g., shelter directors, case managers), the community therapists who delivered HOPE, as well as relevant administrators and clinical supervisors from our community collaborators. Focus groups will solicit feedback on barriers and potential successful strategies that can improve our ability to implement HOPE across a range of community, shelter, and IPV settings. Feedback will also be solicited regarding logistical issues in how HOPE can be translated into the current IPV and treatment systems (e.g., staffing patterns), fit or match with implementation of HOPE within the different agencies (e.g., fit with existing services and supervision procedures in place), infrastructure support (e.g., agency support, fiscal benefits or burden, administrative burden), and organizational mission or support (e.g., support by clinical and administrative support). *This data will be used to create a dissemination plan to inform a future dissemination study of HOPE.*

C3. Data Analytic Plan

Prior to conducting analyses for the main project aims, a series of routine procedures will be conducted to ensure the data accuracy/adequacy. We will also examine the distribution of our key variables for skewness, variability, missing data, and outliers. Data will be transformed to achieve normality if needed. At this time, we will also assess the effectiveness of the randomization procedures. If between-group differences exist, relevant variables will be included as covariates in outcome analyses. We will also explore whether contamination is a significant issue by comparing members of the control groups reporting they were exposed to specific HOPE content to those who were not exposed to determine if such exposure impacts outcome, and control for exposure in analyses below if necessary. Although only a small percentage of participants in our pilot work reported initiation of a new medication (3.3%), change in dose or type of ongoing medications (3.3%), or cessation of a medication (5%), we will also explore whether medication changes during treatment impacted outcome, and control for medication changes in analyses if necessary (see below). Additionally, we will preliminarily investigate therapist effects on attendance, attrition, and primary outcomes and use this data to inform future research with HOPE that will more directly assess therapist effects. Finally, pattern mixture methods[74, 75] will be used to assess the ignorability of missingness in all outcome analyses described below. All analyses will include an intent-to-treat analysis (using data from all randomized participants) and a minimal attendance analysis (i.e., attending at least ½ of sessions). For intent-to-treat analyses, missing data will be handled using multiple imputation with an expectation maximization algorithm.

Primary and Secondary Outcomes: Hierarchical linear modeling (HLM) will be used to analyze the different trajectories that may occur between the two treatment groups. Separate HLMs will be conducted for all primary outcomes (i.e., PTSD and re-abuse severity), as well as for each secondary outcome. Additional time-varying (e.g., medication changes measured at multiple time points) and time-invariant covariates (e.g., length of shelter stay) that might explain additional variability in symptom level and change can also be modeled. Additionally, using the procedures described by Jacobson and Traux [76], the reliable change index will be computed for primary outcomes at 1-week post-treatment in order to assess whether the change in PTSD symptoms experienced by HOPE participants was clinically meaningful. Exploratory analyses will also be conducted to determine what constitutes an adequate dose of HOPE.

Other Secondary Outcomes: Mixed design ANOVAs will be used to analyze treatment effects for attentional biases and cortisol reactivity. Cortisol reactivity will be assessed by analyzing the area under the curve (AUC) of the reactivity curve. This will be computed in two ways: area under the curve with respect to increase (AUC_i) and area under the curve with respect to ground (AUC_G) [77]. Mixed design ANOVAs that include a between-subjects factor (treatment group) and within-subjects factor (assessment time point) will be used to compare

both AUC_I and AUC_G values at each of the three time points as a function of treatment group. To evaluate treatment effects on attentional biases, we will conduct mixed design ANOVAs that include a between-subjects factor (treatment group) and within-subjects factors (e.g., word type; assessment time point). A group X word type X assessment time point interaction will be tested and deconstructed to determine, for example whether HOPE participants show reduced (relative to controls) attentional interference (i.e., less difficulty disengaging attention) to trauma-related stimuli (but not other types of stimuli) following treatment.

The cost effectiveness analysis (CEA) measure will be cost/QALY gained, computed as [intervention cost minus direct cost savings]/QALYs saved. We will follow widely accepted CEA guidelines[78, 79], including computing estimates from societal and government perspectives, adjusting future costs to present value with a 3% discount rate, and analyzing how sensitive the results are to higher and lower discount rates. Most intervention costs will be tracked in the project accounting system. The exception is the cost of social services with PCT versus HOPE. To estimate these costs, we will track the number of visits by type of service, then price those visits using average service prices. We are not powered to and will not try to track medical costs, especially since some domestic violence injuries can have lasting medical consequences. Instead, we will use our existing violent injury cost model [80-83] and sexual violence costs[84] to cost each injury type tracked in our CTS data, then sum and compare the estimated costs of the injuries in the control versus the treatment groups. We will rely on published costs of depression by severity[85, 86] to compute the savings from reduced depression. These sources include direct medical and mental health care costs, as well as long-term QALY losses and life table effects. The evaluation data will record short-term employment impacts. The QALY measures partially incorporate those impacts so we will take care not to double count. Following guidelines,[78, 87] we will count employer savings due to reduced presenteeism of employed people who reduced their depression through HOPE as direct costs, using presenteeism impacts from Stewart[88]. Using Oracle's Crystal Ball Excel add-in, we will enter uncertainty ranges for all parameters in the cost/QALY calculation. From that information, we will develop a Cost-Acceptability Curve that determines the probability that HOPE is preferred to standard care as a function of the value of a QALY. One third of all cost/QALY analyses now take this approach to uncertainty analysis[89] and we have guidelines exist on how to interpret the results.

Mediators and Moderators of Treatment Response: Exploratory regression analyses will be conducted to evaluate whether treatment effects are mediated by degree of empowerment, effective use of resources, and trauma-related cognitions, as well s to determine if participants' PTSD symptoms post-treatment mediate severity of re-abuse over follow-up. The statistical significance of the mediated, or indirect effects, will be tested using bootstrapping methods which under most conditions, provide the most powerful way to obtain confidence intervals for mediated effects [90]. Regression analyses will also be used to evaluate potential moderators of treatment response, that is, to determine for whom a relationship between intervention and treatment outcome exists. Interaction terms (i.e., treatment group X potential moderator) will be tested for minority status and for baseline measures of IPV severity, PTSD severity, attentional biases to trauma cues and physiological reactivity to trauma cues.

Treatment Integrity. Descriptive analyses will be run for the adherence and competence scales for both HOPE and PCT. Bivariate correlational analyses will be run to determine if degree of adherence and competence relates to outcome. Any cases where a session was found to have inadequate adherence and/or competence will not be used in analyses.

Figure 2.

D. Timeline and Milestones

Study time line for four-year project:

Start up period (Y1, Months 1-6): Includes program refinement, institutional review board approval, therapist, RA, project coordinator, rater, and assessment training, and database development. Recruitment period (Y 1 Mo 6- Y3 Mo 9). Intervention (Y1 Month 6 – Y3 Mo 12). Follow up (Y1 Month 9 Y 4 mo 11). Evaluation (Y5 mo 6-12): The data safety monitoring committee will meet bi-annually to evaluate the safety of the intervention program and to review blinded analysis and any adverse events. The analysis will begin after outcome assessments are complete and the data are cleaned. Dissemination (Y5 mo 6-12): Manuscript preparation, community and national presentations, focus groups with shelter and community staff and other stakeholders to assist in developing a dissemination plan to inform a future dissemination study of HOPE. *Our ultimate goal is to package HOPE as an evidence-based, cost-effective and feasible model program that improves residents of battered women's shelters engagement in therapy and can be implemented on a large scale in a wide range of settings relevant to recent victims of IPV*.