May 12th, 2020

Research Protocol and embedded Statistical Analysis Plan for RISE RANDOMIZED CLINICAL TRIAL

PI: Dr. Katherine Iverson

VA Boston Healthcare System

Recovering From Intimate Partner Violence Through Strengths and Empowerment (RISE)

NCT03261700

Funded by the VA Office of Research and Development, Health Services Research and Development (HSR&D) Services, IIR 16-062.

Research Protocol and Analysis Plan are from the approved research protocol from the VA Boston Healthcare System Institutional Review Board and focus on the background, significance, procedures, measures, etc. for the randomized clinical trial of RISE, as reported in ClinicalTrial.gov. Note that this RCT was completed as part of a larger study to develop, refine, and evaluate RISE (VA HSR&D IIR 16-062: Iverson).

The Statistical Analysis Plan is found on pages 17-18 of this protocol, under "Quantitative Analysis".

Introduction: This HSR&D-funded study consists of three phases toward the overall goal of refining and evaluating a patient-centered brief counseling intervention for female VA patients who experience intimate partner violence (IPV). The draft intervention of **R**ecovering from **I**PV through **S**trengths and **E**mpowerment (RISE) was developed by Drs. Iverson, Gregor and Gerber during Dr. Iverson's HSR&D Career Development Award. Phase 1 of the research consists of gathering stakeholder feedback from VA patients and providers to initially tailor and refine the RISE intervention manual and delivery characteristics. Phase 2 consists of a small, formative open trial to pilot-test the RISE intervention and make additional modifications to the RISE intervention manual and implementation characteristics prior to preparing the intervention for effectiveness testing. Phase 3 consists of a randomized clinical trial (RCT) at the VA Boston Healthcare System to examine the effects of RISE on psychosocial outcomes relative to an information/referral comparison condition. We have received IRB approval for all phases of this study. The study takes place at the VA Boston Healthcare System. **This Phase 3 RCT is the focus of this protocol and analytic plan.**

(1) Rationale

a. Statement of the problem: Intimate partner violence (IPV) is a major health concern for women Veterans. IPV is associated with numerous physical and mental health conditions. VHA is implementing IPV screening programs to identify female patients who experience past-year IPV. Despite strong evidence that screening increases detection of IPV, less is established about how to intervene following IPV disclosure in health care settings, in order to improve health outcomes. Existing healthcare-based interventions result in minimal effects on health and well-being, likely because they are too brief and generic. In response, the PI has developed **R**ecovering from **I**PV through **S**trengths and **E**mpowerment (RISE), based on the IPV-related health care needs and preferences of women Veterans. RISE is designed to be delivered in primary care and is an individualized, variable-length, modular-based intervention that addresses 1) safety planning; 2) education on the health effects of IPV; 3) increasing coping skills and self-care; 4) enhancing social support; 5) making difficult decisions; and 6) connecting with resources. **This study is aimed at refining and evaluating RISE for use with female VA patients who have experienced past-year IPV.**

Phase 3 consists of a Hybrid 1 randomized clinical trial (RCT; n=68) to examine the effects of RISE on women Veterans' psychosocial outcomes (e.g., empowerment, self-efficacy, health, and service use) relative to an information/referral comparison condition. A secondary aim is to examine the feasibility and acceptability of RISE in the context of the RCT.

Specific Aims

Phase 3:

Aim 3. Examine the effects of RISE on WVs' individual psychosocial outcomes with an effective-implementation Hybrid 1 RCT [50] that compares RISE to an information/referral condition with up to 68 female patients at VA Boston. We will collect pre-treatment, post-treatment, and 1-month follow-up patient data to examine the effects of RISE on key psychosocial outcomes.

(2) Background and Significance

(a) Background:

Societal Impact of Intimate Partner Violence:

Intimate partner violence (IPV) against women is a significant public health issue. IPV victimization includes psychological, physical, or sexual aggression perpetrated by a past or current intimate partner. Women are much more likely than men to experience severe violence and health-related impacts.[1] Nearly 7 million women are physically assaulted, raped, or stalked by an intimate partner in the United States (U.S.) annually.[1] These assaults are a leading cause of injury to women. At least 3 women are murdered by intimate partners every day in the U.S.[2] IPV is also associated with poor physical and mental health.[3-5] Physical health problems range from injuries or conditions directly caused by assaults, to other chronic musculoskeletal, cardiovascular, gastrointestinal, and reproductive health conditions.[4,6,7] Mental health problems often include posttraumatic stress disorder (PTSD), depression, anxiety, substance abuse, and suicidality.[4-7] IPV also increases risk for financial difficulties, unemployment, and homelessness.[8]

Veterans Health Administration Response to IPV:

IPV is a critical issue for the Veterans Health Administration (VHA). Women are the fastest growing group of VHA patients, with their population recently increasing by 80%.[9] Women Veterans (WV's) are at higher risk for IPV than their non-Veteran peers, with Co-I Dr. Dichter finding that 1 in 3 WVs report lifetime IPV, compared to 1 in 4 women in the general U.S. population.[10] Research by our team finds that up to 30% of WVs experience past-year IPV.[6,11,12] As a result, WVs are considered an important population for IPV screening and counseling interventions.[13-16] In response, VHA Women's Health Services (**WHS**) and the IPV Assistance Program of Care Management and Social Work Services (**CMSWS**) are implementing IPV screening programs for women and are seeking an effective intervention to implement into care (Veterans Health Administration Domestic Violence Task Force; U.S. Department of Veterans Affairs).

Limitations in Current Healthcare-Based IPV Interventions:

Tests in healthcare settings of brief counseling interventions for IPV have resulted in minimal effects on patients' health and safety.[17-19] Existing interventions typically consist of one 10- to 35-minute session and are focused on referral to community-based resources.[20,21] A systematic review conducted by Co-I Dr. Bair-Merritt found that these types of interventions result in very modest effects on patient outcomes, with increased service usage being the most common benefit.[21] A recent review of IPV screening trials highlighted insufficient intensity of post-disclosure counseling interventions, concluding that existing interventions are too brief, unstructured, and generic.[18] Such minimal intervention effects of the current standard of care have led leaders in the field to call for the development and testing of new and more comprehensive IPV interventions,[18,22,23] especially for delivery in primary care.[21,24] The Recovering from IPV through Strengths and Empowerment (RISE) intervention fills this need.

Opportunity for IPV intervention during primary care visits:

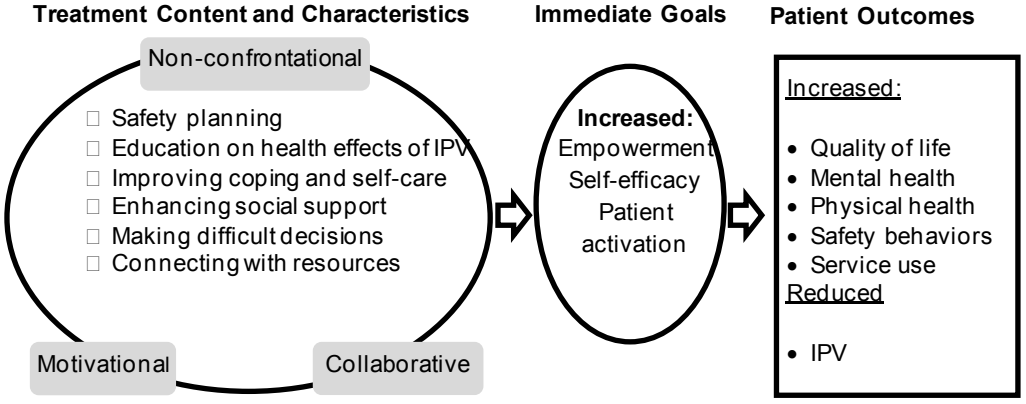
Women who experience IPV present frequently for health services, with some evidence showing a 4-fold increase in utilization attributable to IPV, especially in primary care.[25,26] IPV screening in primary care is safe and effective for identifying abused women,[17] yet screening without offering structured intervention to those who disclose IPV offers limited benefit.[27,28] VHA identifies primary care settings as key contexts for

implementing IPV screening programs.[29] Our research suggests VA primary care settings are ideal for implementing and evaluating IPV interventions, as the Patient Aligned Care Teams (PACT) structure facilitates uptake of IPV screening and counseling.[30] VHA does not, however, have protocols for what post-disclosure counseling should entail. This proposal capitalizes on the roll-out of IPV screening programs, aiming to enhance their effectiveness.

RISE Background and Theoretical Basis:

RISE is a promising and innovative intervention for IPV. The PI, who has 14 years of clinical specialization in IPV, developed RISE based on her HSR&D CDA findings in conjunction with two national experts in women's primary care and behavioral health, Drs. Gerber and Gregor (Co-Is). RISE was developed using rigorous methods, including extensive literature review, as well as focus groups and surveys with WVs who experienced IPV[11,31] and qualitative interviews with VA providers.[30,32] It was subsequently piloted successfully in clinical practice. RISE is a primary care-based trauma-informed psychosocial intervention for female patients who experience IPV. RISE is designed to overcome the limitations of existing brief interventions for IPV. It is variable-length and consists of an initial session of up to 60 minutes, with up to 5 additional 60-minute sessions (i.e., up to 6 sessions total). This format is consistent with brief counseling standards established for Primary Care Mental Health Integration (PC-MHI) (VHA Handbook 1160.01). Many VA primary care clinics have implemented PC-MHI, which may be ideal for implementing RISE (personal communication, Dr. Sally Haskell, WHS Deputy Chief Consultant, June 10, 2015). VHA also recommends that all VAMCs designate domestic violence coordinators (DVCs) who provide education to clinicians, connect patients with IPV-related resources, and provide some clinical care. A strength of RISE is that it can be delivered by various providers within primary care (e.g., PC-MHI providers, nurses, social workers) or by providers closely aligned with primary care. This flexibility accommodates the realities of real world practice, including the limited clinical role of many DVCs.

Figure 1. Conceptual Model of Impact of RISE on Psychosocial Outcomes



RISE has a strong theoretical basis[33,34] that is trauma-informed and highly aligned with VHA's emphasis on flexible, empowerment-driven, patient-centered care individually tailored to women's needs and preferences. See Figure 1 for conceptual model underlying RISE. Studies have found increased empowerment, self-efficacy, and patient activation to alleviate mental health symptoms and lead to improved service utilization and quality of life among women who have experienced IPV.[35-38] RISE is expected to improve patients' physical and mental health, safety, service use, and quality of life through enhancing empowerment, self-efficacy and patient activation

RISE is a modular-based intervention that incorporates several aspect of Motivational Interviewing (MI). Compared to highly structured protocols, modular interventions have been found to be more flexible and

better able to address individual patients' needs, preferences, and circumstances,[39] as well as more effective and acceptable to providers.[40] Through use of non-confrontational and collaborative MI techniques,[41] such as eliciting patient perspectives and reflective listening, the provider empowers women to choose from 6 modules (see Table 1) to focus on during the session based on her individual needs. MI is used to set goals and plan for behavior change, as desired and driven by the patient. MI is an efficacious approach for many psychosocial problems and for numerous behavioral changes[42] and highly theoretically relevant for women who experience IPV. **The draft RISE manual, which will be modified and refined based on findings from Aim 1a, is found in the Appendix**.

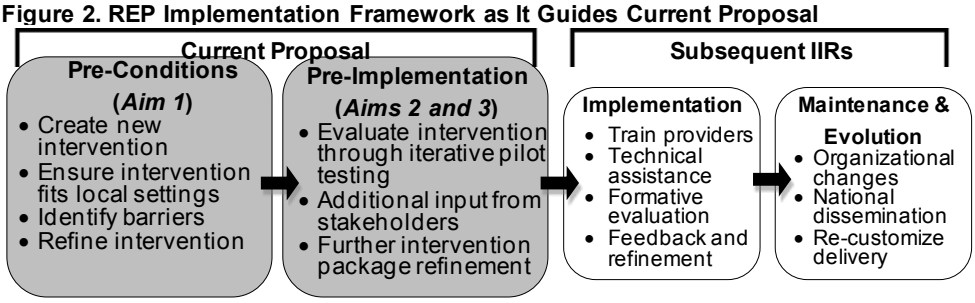
Table 1. RISE Modules (based on IPV intervention literature, theory, and stakeholder recommendations)	
Safety Planning	Safety of self, children and pets in different situations (e.g., in an argument, leaving, stalking)
Education on Health Effects of IPV	Effects of IPV on physical, psychological, and social health, including effects on children
Improving Coping and Self-Care	Learning basic coping and self-care strategies (e.g., diaphragmatic breathing, pleasant events)
Enhancing Social Support	Skills for approaching friends or family to enhance emotional and practical support
Making Difficult Decisions	Thinking through options and choices when making difficult decisions (e.g., ending relationship)
Connecting with Resources	Resources available in VA and the community (e.g., mental health, housing, legal aid, shelter)

Delivery of RISE:

RISE includes the essential components of prior brief counseling interventions for IPV[21] but provides a more comprehensive and individualized approach to improving women's health and safety. In the initial session, women are offered safety planning tips and a resource list. Women are then given a menu of options to select from based on their current needs and preferences. For example, a woman may choose to focus on safety planning in detail or she may select coping skills/self-care to better manage stress. The principles of empowerment and flexibility undergird the format. The patient can choose to focus on the same module in her next session or select a new module. This pattern is repeated for up to 6 sessions or when the woman no longer needs or desires further intervention, consistent with brief counseling standards (VHA Handbook 1160.01). In the latter case, it is a collaborative decision made between the patient and provider. An important feature of RISE is laying the groundwork for necessary referrals (e.g., to mental health) that women are offered during and upon completion of RISE. Given the current state of the pandemic, COVID-19, we are requesting to deliver RISE via teletherapy (phone) and videoconferencing using VA-approved platforms (e.g., VVC). More specifically, we are requesting that the PI (Dr. Iverson) the two RISE providers on the study, Drs. Danitz and Brennan, who are both licensed clinical psychologists, be able to conduct RISE sessions from their homes via telephone, with adherence to VVC requirements. In order to ensure participant safety when conducting teletherapy or videoconferencing, providers will confirm the participant's address and phone number at the beginning of the call and follow usual clinical guidance for managing any emergent SI or other risk issues, as we would in routine care. We will ensure the participant is in a safe place where she can speak freely. With participant permission in advance of the session, we will send RISE resources and handouts as well as our in-session measures, which we will collect at the beginning of the session via teletherapy. While teleworking RISE providers have full access to CPRS, suicide coordinators, and have access to clinical resources, such that providers are able to address any emergent concerns that arise for participants. As such this delivery modality does not pose any increased risk to participants or study providers, and is in accordance with recommended precautions and procedures of social distancing during this unprecedented time.

Replicating Effective Programs (REP) Framework Guides This Project:

Figure 2. REP Implementation Framework as It Guides Current Proposal



As shown in Figure 2, the proposed study is guided by an established implementation framework. Use of an implementation framework that is (a) theory-based, (b) highly specified, and (c) widely used in VHA can facilitate incorporation of RISE into routine VHA care. The REP framework,[43,44] based on principles of Social Learning Theory and Diffusion of Innovation, is an ideal guide for the current work. REP emphasizes tailoring and refining interventions for healthcare practice through extensive stakeholder input and iterative cycles of pilot testing. Using the REP framework to guide this proposal enables us to address up front potential challenges to future implementation. We will ground our tailoring and evaluation of RISE in REP's first and second phases: pre-conditions and pre-implementation. These two phases require a fine-grained understanding of patient and provider perspectives that impact implementation efforts, as well as VHA operations partners' needs. We will therefore incorporate multilevel stakeholder engagement throughout the proposed study to inform RISE modifications.

(b) Significance:

Advancing Innovations in VHA Health Care:

The VHA Blueprint for Excellence[45] identifies promoting patient-centeredness and "advancing innovations in WV's health care" as key transformational strategies. Newly released VHA breakthrough priorities include improving the Veteran experience and increasing access to care.[46] This project advances these goals for IPV care. Up to 30% of WVs experience past-year IPV, which contributes to numerous physical and mental health conditions among WVs.[6,10,11,15] Despite national VHA recommendations to screen female patients for IPV,[47] there is a lack of empirically supported brief counseling intervention for those who disclose IPV. This project will fill this gap by evaluating an innovative, patient-centered brief counseling intervention for IPV that is tailored to WVs' unique healthcare needs and preferences.[45] RISE holds great promise for improving patient outcomes because it is evidence-informed, conceptually-driven, and embodies essential components of patient-centered care. RISE is empowerment-based[33,34] and flexible (i.e., modular and variable-length).[48] Given the high prevalence of IPV among WVs and its significant health effects, RISE is expected to reduce morbidity among VHA patients. As such, our proposal is highly responsive to the HSR&D priority area of improving health care and health outcomes for WVs.

Importance to VHA Operation Partners:

Addressing the misalignment between VHA guidelines and actual practice is of high importance to our VHA operational partners in WHS, CMSWS, Women's Mental Health Services (MHS) and PC-MHI/Primary Care. This project will yield a high return on investment by producing a flexible patient-centered intervention that can be rigorously applied and tested in VHA, thereby addressing a critical gap in current IPV care. This research may also assist our operational partners in broadening their focus beyond IPV screening and

interventions for women. VHA currently recommends a case-finding approach for men (i.e., asking about IPV upon clinical suspicion).[47] Although the need for IPV interventions is most urgent for WVs because of the clear disparities in IPV and linked health outcomes,[1,15] RISE could eventually serve as a viable intervention for men who experience IPV.

Innovative Design:

The well-documented gap between the identification of clinical innovations and their implementation into routine care[40,49] exists partly due to a research methodology in which efficacy is first established, followed by effectiveness research, with little early systematic effort to understand the potential for implementation. An innovative and efficient solution is to collect implementation data in the context of effectiveness research (i.e., our Hybrid 1 RCT design) to inform refinements that will facilitate the intervention's ultimate integration into routine care.[49,50] If RISE proves effective, this program of research will increase the speed in which VHA is able to implement RISE nationally and can provide a methodological template for other studies.

(c) Relevance to Veterans:

This research will lead to enhancement in care for female Veterans and likely improve their experience with IPV-related care in VA. IPV alienates female Veterans from family members and friends, placing them at risk for psychosocial and physical health problems and poor social and occupational functioning. As more women return from Iraq, Afghanistan, and neighboring countries, it is critical that researchers focus their attention on identifying effective brief counseling interventions for this population to enhance the quality of VA care for women Veterans and improve women's psychosocial health.

In particular, this study will directly inform efforts to improve care for women Veterans by focusing refinement and testing of an evidence-informed intervention. This is important for two primary reasons. First, as noted above, women Veterans are at high risk for IPV, and thus it is especially important that healthcare systems that treat women Veterans screen for IPV and offer evidence-based counseling for women who screen positive or otherwise disclose IPV. Second, the VA is the largest single provider of health care to women Veterans, so the current study's findings will have particular relevance to the provision of care in VA for women who have experienced IPV. It is imperative that acceptable evidence-based counseling interventions become available in VA because the rates of women seeking VA care will continue to increase in coming years.

(3) Work Accomplished

The PI, Dr. Iverson, has extensive experience in conducting IPV and treatment-related research. Several of her prior studies were supported by a VA Health Services Research and Development (HSR&D) Services Career Development Award (HSR&D CDA2 10-029) entitled "Intimate Partner Violence, Health, and Health Care Among Women Veterans." This CDA focused on delineating best practices for the IPV screening and immediate follow-up procedures. Much of this work was conducted in collaboration with co-investigators on this study team. Some of this work (and that of co-investigators) is summarized in the next section, and provided the groundwork for the current proposal.

Understanding IPV experiences and expertise in implementing research findings in clinical practice:

In several studies, using community- and Veteran-specific surveys, medical records reviews, and in-depth interviews, our team has documented the high prevalence of IPV among WVs[6,8,10] as well as strong associations between IPV and WV's physical and mental health.[6,51-53] Dr. Iverson, a clinical psychologist with expertise in trauma-informed counseling, has conducted research to understand the broad scope of WVs' cumulative experiences with trauma, including IPV, and the ways in which clinical response can effectively assist patients in recovering from trauma. This work has included understanding the role of coping skills among women who have experienced IPV[54,55] and the ways in which prior trauma is associated with IPV risk.[8,55,56] Dr. Iverson and colleagues (including Co-I's Dichter, Gerber, Vogt, and Wiltsey-Stirman) have conducted research to inform an IPV screening program in VHA and collaborated with clinical/operations partners to facilitate the program's implementation. Using mail-based surveys of WVs in VISN 1, Dr. Iverson validated a screening tool, the E-HITS, which VHA adopted for use in clinical programs.[12,30] Drs. Iverson and Gerber conducted a quality improvement project that included input from VA patients and providers and three of this proposal's VHA operational partners (WHS, CMSWS, and MHS) to develop and refine an IPV educational brochure for patients that has been disseminated nationally to all VAMCs.

Development of RISE.

Dr. Iverson used focus groups with WVs to understand patient perspectives on IPV screening and counseling in the healthcare setting. WVs expressed preferences for screening procedures and emphasized the importance of counseling interventions in response to IPV disclosures.[31] WVs indicated that detecting IPV without offering follow-up intervention can increase patients' self-blame. As one WV explained, "You can't make the woman answer…but if she tells you and you don't follow-up, then in the back of her mind, she's saying, 'Well, I told them and they don't seem to care…I guess it's just like he says. I deserve it.'" Focus groups with WVs identified factors that would facilitate the receipt of IPV counseling, including tailored approaches to counseling that recognize, in the words of one WV, that "everybody is at different stages of recovery, we're all different, and may need different things." Dr. Iverson's qualitative work was followed by a web-based survey of a national sample of 411 WVs, 55% of whom experienced lifetime IPV.[11,31,32] Approximately 80% of WVs who experienced IPV indicated interest in receiving counseling for IPV in primary care and preferred it to be delivered in an individual format.[11] Content priorities were physical safety, learning about the health effects of IPV, and enhancing coping skills and social support. To understand provider perspectives, Drs. Iverson and Dichter conducted in-depth interviews with VHA providers.[30,32] Providers stressed the absence of follow-up interventions within VHA as a primary barrier to adoption of IPV screening. These study findings informed the individually-tailored, flexible, trauma-informed, modular approach used in RISE.

Drs. Iverson, Gregor and Gerber developed the RISE manual based on an extensive review of the IPV intervention literature and the qualitative and quantitative findings detailed above, in accordance with intervention development standards.[57] They have piloted RISE in their clinical work in primary care and mental health with a handful of patients, who have given positive qualitative feedback regarding acceptability and safety. For example, upon completing the Safety Planning module, one WV noted, "Using this handout to talk about safety is really useful...I can plan out what to do to protect myself and my dog when (partner) goes into a rage...It helps me feel like I have options." Upon completing RISE, another WV shared, "I learned skills to help me deal with my situation differently." Drs. Iverson also informally surveyed relevant VA providers. Feedback

from a DVC demonstrates the face validity and potential usefulness of RISE: "This type of protocol is really needed in VA. We don't have anything like it, which is why screening is so inconsistent…I especially like that RISE is tailorable to the needs of the individual patient in front of you since you know how different each situation is." Another provider suggests its acceptability to clinicians: "I love that patients get to choose what to focus on. I would be more likely to address IPV with patients if I used RISE rather than refer out." Our VHA operations partners in WHS, CMSWS, and MHS also express support for the feasibility and acceptability of RISE.

(4) Work Proposed

We will conduct a multi-method project with observational and interventional components and use a mixed methods analytic approach. This project is guided by REP's pre-conditions and pre-implementation phases (see Figure 2 above). While phase 3 was initially intended to be multisite, due to feasibility and low enrollment problems at the VA Connecticut site (as evidenced by low participant recruitment and enrollment in Phase 2) we received a VA HSR&D Project modification to HSR&D to have Boston be the sole site for the RCT phase 3. <u>The timeline for all activities is provided in bullet points below.</u>

(a-b) Timeline/Key Questions/Study Sites

<u>Timeline for Proposed Research.</u>

- Phase 3 - Conduct RCT of RISE with WVs (n = up to 68) (Approximately September 2018- September 2020; Dissemination and implementation activities in FY2021).

Study Setting

While Phase 3 was initially intended to be multisite, due to feasibility problem identified in phases 1 and 2, the RCT was conducted at VA Boston. In consultation with the DSMB, we have decided to discontinue involvement of VA Connecticut and continue the RCT solely at VA Boston to meet the primary objective of the study.

Phase 3

Specific Aims for Phase 3 Research:

3. Examine the effects of RISE on WVs' (*n*=60-68) individual psychosocial outcomes (e.g., empowerment, self-efficacy, health symptoms, service use, and quality of life) in an RCT that compares RISE to an information/referral condition.

Sub-aim **3a.** Evaluate the feasibility and acceptability of RISE in the context of the RCT.

(c) Method and Data Analysis

<u>Aim 3</u>

Randomized clinical trial (RCT): The goal of Aim 3 is to test the RISE intervention in comparison to an information/referral condition for women VA patients who have experienced past-year IPV. We selected a Hybrid Type 1 RCT design to evaluate the initial effectiveness RISE while gathering information on barriers and facilitators of implementation. We selected an information/referral comparison condition because a) this intervention is consistent with the current standard of care at the two study sites (and in the community); b) many other VA facilities are supposed to provide information and referrals for women who disclose IPV (according to VHA recommendations); and 3) an information/referral condition conforms to the US Preventive Services guidelines and to the suggestions of the Department of Health and Human Services. [29]Participants will receive the information/referral condition for up to 60 minutes in order to standardize the comparison condition while also ensuring that women receive at least the minimum standard of care. At VA Boston, up to 68 female patients will be recruited and randomly assigned. Assuming 15% loss to follow-up based on current study estimates, we will aim to enroll 68 women to ensure sample size of n=60 for participants with post-treatment and/or follow-up assessments (i.e., at least 2 data points). To address our sub-aim, providers will be invited to participate in brief (30-minute), semi-structured qualitative interviews toward the end of the RCT to provide perspective on RISE implementation.

Female VHA patients: Eligibility, recruitment, and procedures

Inclusion criteria are the same as the criteria that we have successfully adopted for Phase 2 of the study. Specifically, female VHA patients (n= 60-68) who meet the following inclusion criteria will be eligible to participate: (1) have experienced past-year IPV; (2) willingness to participate in pre-treatment, post-treatment and follow-up assessments (including questionnaires and post-treatment interviews), as well as to be randomly assigned to an intervention condition; (3) not at acute risk of suicide or homicide requiring hospitalization; (4) not demonstrating symptoms of mania, psychosis, or intoxication at the time of screening or sessions; (5) capacity to consent to study; (6) willingness to have the intervention session(s) audio recorded. Prior participation in the RISE open trial as part of Aim *2* will be an additional exclusion criteria, and during the COVID-19 pandemic while enrollment is solely virtual due to restrictions on face-to-face appointments, inability/unwillingness to do the enrollment session virtually so researchers can obtain a screenshot of the ICF, receive materials by mail, and/or provide personal email (i.e., to receive VVC appointment information, intervention materials) are additional exclusion criteria.

Patient recruitment. We will include all of the same recruitment procedures we have used for Phase 2. Recruitment will include self-referrals (in response to advertisements posted in the VA or on social media or being informed of the study by a clinical provider), and the PI (KI) or project manager (Dr. Danitz) being added as an additional signer on notes in CPRS by providers who have patients who express interest in the study. This type of recruitment is common among active VA Boston treatment studies, including our Phase 2 work. This is an ideal feature as it minimizes burden for interested patients and providers, while also mirroring how the interventions would ultimately be delivered in routine care. For clinic referrals, women who disclose IPV will be provided with care as usual at the two sites (e.g., provided with information/resources) and will be informed by their provider of the study opportunity. As we have done in Phase 2, in our efforts to inform providers and clinics about this study and referral pathways, we will remind clinicians to discuss the study opportunity with relevant patients (i.e., those who have experienced past-year IPV) in a non-coercive manner that maximizes safety of patients. We will provide clinicians with preferred language to document within the CPRS referrals. Specifically, when adding research staff as co-signers, we ask that clinicians note in CPRS that they discussed the "Women's Treatment Preferences Study" as well as women's preferred contact number and best/safest times to reach the patient. Clinicians may also state that the women veteran is interested in the Women's Treatment Preferences Study but prefers to contact study staff directly, in which case women will be provided with study fliers. We will also post advertisements on Craigslist, as well as the Boston VA Twitter and

Facebook pages (see attached recruitment postings). We propose continuing to recruit in this way (i.e., via clinician referrals and social media postings) during the COVID-19 pandemic.

Recruitment Letter Considerations:

Our Co-I, Dr. Melissa Dichter, has conducted recent HSR&D-funded research at the Philadelphia VAMC and Portland VAMC to enlist women VA patients who have experienced past-year IPV. She has developed safe and effective recruitment methods for recruiting that she has used in this work that we would like to apply for our study. She has presented these recruitment methods on two national VA Cyber Seminars on recruiting women to participate in research (see her Power Point presentation attached). For their IPV study, they sent letters to women who had visits at the respective study sites within the past-year. These letters included vague language about a study to understand women's interpersonal relationships and healthcare needs, direct mention of financial compensation, and invited women to "opt out" of being contacted. This strategy, although time consuming for the research team, was effective in securing their desired sample size of 160+ women who experienced past-year IPV. Of note, only 3.2% of the women who received letters opted out of being contacted. Of those who were reached by phone, there were only two women across the two study sites who indicated that they did not like being contacted for research by VA (but it was not specific to it being about IPV). It is notable that not one single woman expressed concerns to the interview team about being contacted via letters or phone using the opt-out method. We understand that VA Boston has been moving away from opt out strategies. However, we believe this method is highly appropriate for our study

To balance concerns of IRB and what is effectively done in other related research, we propose to recruit via patient letters by contacting potential participants included on a patient list generated from the electronic medical records/CPRS (i.e., Corporate Data Warehouse), which will be saved in a password protected file in a secure drive behind the VA firewall. Potential participants on this list include women ages 18-55 who have had a primary care or mental health appointment at VA Boston within the past year. This letter is purposefully generic to protect the privacy and safety of women who receive the letter. The letter includes information about the voluntary nature of the study and the option to "opt out" from further contact by notifying us by phone or pre-stamped letter and self-addressed envelope. Women who do not opt out within 10 days of the letter being sent will be contacted. Women may contact us directly to learn more about the study and determine if they are eligible to participate. Our phone screen script includes necessary elements of consent and confirmation that women are in a private, safe space where they can speak before moving forward with the phone screening (please see phone screen script attached to this amendment). We will temporarily discontinue recruiting via letters during the COVID-19 pandemic and will plan to resume this previously approved recruitment strategy after stay at home orders are lifted and the study team returns to the VA Boston medical center.

To augment these recruitment efforts, we will also recruit via flyers and brochures advertising the study opportunity in strategic locations within VA, including the Women's Health Center and other key locations (e.g., mental health clinics, HUD-VASH, etc.). A previously approved submission included flyers and handouts, which contain information about the purpose of the study and phone number for learning more about the study. Interested women will have the option of meeting with study staff to learn more about the study and participate in eligibility screening. Women may also schedule a phone screening at a time that is convenient and safe for them.

Upon contact with research staff, interested women will participate in a brief screening interview to determine eligibility (by phone for those who call and in-person for others), after which a member of the research team (PI, PM or RA) will examine patient's electronic medical record to ensure that she does not meet exclusionary criteria (see attached list of exclusionary criteria to be examined in CPRS; any questionable criteria will be reviewed by PI and/or PM to determine eligibility). As per approved Phone Screening Script for Phase 3, study staff obtain verbal consent during the phone screening to mail a letter if the participant is unable to be reached by phone (please see patient letter in appendix). Ineligible women and those who decline

participation will be offered information on relevant resources within VA and the community (e.g., Passageway Program at Brigham and Women's Hospital, National DV Hotline, etc.). Patients who meet inclusion criteria will be scheduled based on participant and provider availability as soon as possible, ideally within two weeks. At this visit they will fully review and sign informed consent documents and HIPAA Authorization (see Informed Consent document and HIPAA forms attached). Because women will be asked to complete questionnaires that include demographics information about themselves and IPV exposure, participants will complete the HIPAA authorization form. Patients will complete the pre-treatment assessment questionnaires (described below), after which patients will receive their randomly assigned 60-minute intervention session (RISE or information/referral, which is referred to as the "Make the Connection" intervention in the informed consent form). In some cases (particularly during the COVID-19 pandemic, given the requirement to not hold face to face meetings), informed consent will be conducted remotely rather than face to face appointment. In those situations, study staff will speak with potential study participants during the phone screening prior to their informed consent/enrollment appointment to ensure that is safe for participants to receive study materials in the mail, after which two copies of the informed consent (one for the study team, one for the participant to keep) will be mailed to the participant along with an addressed stamped envelope. During the phone screening, study staff will also confirm that it is safe for participants to receive emails, which will be used for telehealth appointments and the distribution of study materials. A videoconference session using VA-approved platforms (e.g., VVC) will be scheduled with the participant, during which the study team member reviews the ICF with the participant. If the participant agrees to sign the ICF, they will hold up the signed ICF page to the computer camera so the study team member can take a screen shot of the signed ICF. The screen shot will be saved directly to our secure project folder (in a file separate from any other data collection) as documentation of the signed ICF. The participant will be asked to mail the signed ICF back to the study team using the provided pre-stamped addressed envelope. If the original signed ICF is received, it will be saved along with the printed screen shot picture of the signed ICF.

Randomization and intervention delivery.

Patients (women veterans) will be randomized within site to condition. Randomizing providers to only one condition risks that RISE delivery skill may be imbalanced across conditions. We recognize that when providers are involved in both conditions, provider learning may blend into both conditions (e.g., use of motivational interviewing (MI) skills for selecting RISE modules influencing information/referral delivery). We anticipate the risk of the latter is limited because the RISE materials explicitly prompt MI strategies whereas the comparison condition does not. Thus, providers will deliver both interventions. This will also allow providers to contrast RISE with a more minimal intervention when providing perspectives on feasibility and acceptability. We will record all sessions in both conditions and we will assess and monitor condition fidelity and treatment differentiation using adherence checklists that contain the critical RISE and the information/referral elements. We will use software to conduct a simple randomization process to assign women to an intervention condition. The individuals conducting the informed consent will not be aware of the participants assigned condition until the participant has completed the signed informed consent and HIPAA Waiver (assignment of condition will be in a sealed envelope). Although we had considered using stratified randomization to balance conditions on patient characteristics (e.g., age, IPV frequency), there is no a priori reason to expect such factors to significantly influence our primary outcomes, although we will include demographic/relationship factors as covariates in our analyses if demographic/relationship characteristics differ across groups (see Quantitative Data Analysis Plan below). During COVID-19, following the participant's consent, the study team will email intervention materials to the participant for use during their same day intervention session.

Information/referral intervention. The information/referral condition is referred to as the "Make the Connection" intervention in the informed consent form. The title of this intervention reflects some of the underlying purpose of the information/referral condition, which is to make the connection between IPV and

health, and finding out how to connect with resources that may be of use. Provision of education about IPV and resource information is considered the "standard of care" within VHA (and the community). Participation in this information/referral intervention consists of a one-time 60 minute brochure-based educational session. In this session, providers will walk through an IPV educational brochure with the participant (see attachment). This brochure was developed by Drs. Iverson and Gerber to guide clinician responses to IPV disclosures within VHA. Using the brochure as a guide, the providers will provide tailored psychoeducation and discussions about: (1) the different forms of IPV (i.e. physical, sexual, psychological, etc.); (2) the effects of IPV on physical, mental, and social health; (3) discussion of safety planning; and (4) local and national IPV-related resources. Supportive statements and validation will be provided throughout (i.e., IPV is not your fault; I'm sorry this is happening to you). The provider will inquire about potential VHA referrals that may be of interest to the woman, and place consults/make referrals as requested. Similarly, the provider will offer to make phone calls with the participant to any of the community resources that she may be interested in learning more about. The intervention will conclude ensuring the woman has the National Domestic Violence Hotline, and offer a discreet 'wallet card' for women who desire to take that information with them. They will be informed they will be contacted by phone to schedule their post-treatment assessments. Intervention sessions will occur in private office space within primary care and/or mental health (e.g., Women's Division of the National Center for PTSD) or within a private location within the providers' home during the COVID-19 crisis.

RISE. The RISE will be delivered as per the refined manual, with its variable-length format (1 to up to 6 sessions within an approximate 10 week period). Following completion of the initial 60-minute RISE session, the provider and participant will determine whether they will have an additional session, and if so, it will be scheduled. Because RISE is specifically designed to be variable-length and patient-centered, it is possible that a participant may only desire to have 1 RISE session. Based on patient and provider feedback during Phase 2, all 6 of the RISE sessions can be up to 60 minutes. Originally, the subsequent sessions were intended to be 30-40 minutes, but that has proved infeasible. Both patients and providers have suggested that more time is allotted for subsequent sessions. Participants may have up to 6 RISE sessions in total. Intervention sessions will occur in private office space within primary care and/or mental health (e.g., Women's Division of the National Center for PTSD). During times of unforeseen circumstances, such as the COVID-19 public health crisis of 2020, the clinical research sessions will be offered in telehealth format from the homes of licensed clinical psychologists Dr. Sara Danitz and Dr. Laura Brennan, ensuring safe and private conditions for both the interventionists and the participants by following VA Boston's and national VVC guidance for such clinical care. Individuals in the RISE condition will also complete the four brief validated self-report measures of empowerment, self-efficacy, patient activation, and valued action at the beginning of each RISE session to gauge treatment progress in real time and guide module selection, as we have done in Phase 2. Note these measures will be collected by the interventionist over the phone for any telehealth visits. This process takes approximately 10 minutes (leaving approximately 50 minutes for the RISE session). Participants will initially be emailed RISE intervention materials following their consenting/enrollment session, after which they will have the option to receive RISE intervention materials via USPS mail.

Female VHA Patient Assessments. Data collection takes place throughout the study and is modeled after a prototypical Hybrid 1 trial [50]. We will administer a full battery of psychosocial assessment at pre-treatment, post-treatment assessment (i.e., 10-weeks post enrollment), and 1 month follow-up (i.e., 14 weeks post-enrollment) described below under "Measures." Participants in the RISE condition will also complete four brief measures of empowerment, self-efficacy, patient activation and valued action at the beginning of each RISE session. At the posttreatment and follow-up assessment, patients will complete a brief audio-recorded semi-structured interview about their experiences with their respective intervention. The post-treatment and follow-up assessments will either be conducted by phone or in person, depending on the participant's preference (thus allowing for them to determine what is most safe and preferable for them). Women will be compensated with

$25 for completing the pre-treatment assessment. Upon completion of the post-treatment assessment, women will receive $50 in cash or by check for their time and participation. Upon completion of the follow-up assessment, women will receive a $75 in cash or by check for their time and participation. A timeline of all measures is available below in Table 4.

Table 4. Timeline of Assessments	**Pre**	**10-week**	**14-week**
Demographics (age, race, sexual orientation, # deployments)	X		
Demographics (relationship status, housing status)	X	X	X
Personal Progress Scale	X	X	X
Patient Activation Measure- Short Form (PAM-13)	**X**	**X**	**X**
Valued Living Questionnaire (VLQ)	X	X	X
Center for Epidemiological Studies- Depression Scale (CES-D)	X	X	X
Health Service Use	X	X	X
The Conflict Tactics Scale-Revised (CTS-2)	X	X	X
PTSD Checklist for DSM-5 (PCL-5)	X	X	X
Patient Health Questionnaire- 15 (PHQ-15)	X	X	X
12-item Short Form Survey (SF-12)	X	X	X
Safety Behaviors Checklist (SBC)	X	X	X
Connor-Davidson Resilience Scale (CD-RISC 25)	X	X	X
Client Satisfaction Questionnaire 8 (CSQ-8)	X	X	X
Depression Anxiety Stress Scale- (DASS)	X	X	X
Coping Strategy Inventory-Short Form (CSI-SF)	X	X	X
Acceptability		X	X
IPV-Related Head Injury	X		

VHA providers: Eligibility, recruitment, and procedures.

There will be at least 2-4 VA providers at each of the two sites (n=4-8 total), and following the discontinuation of the VA Connecticut-West Haven Site, there will be at least 2-4 VA providers at VA Boston. Various types of providers will be included (e.g. psychologists, social workers). Providers will participate in training on RISE and the information/referral condition, providers will audiotape their sessions and participate in weekly consultation. Providers will also have the option to enroll and participate in a 30-minute phone interview near the end of the RCT in order to help us learn about the acceptability and feasibility of implementing RISE in VA, including barriers and facilitators to RISE implementation and completion of two brief quantitative measures regarding the perceptions of the intervention and its implementation ("described under Measures"). These interviews will be brief (approximately 30 minutes), audio recorded, and administered by a trained/qualified Project Manager, PI (Iverson) or Research Assistant via telephone. The interviews will be recorded and transcribed. We recognize that VA employees are a vulnerable population and will take special care to ensure that participants understand that their participation is completely voluntary and will not affect their VA employment in any way (see additional details under Potential Risks and Adequacy of Protection Against Risk). VA providers can be of any gender, age, and racial/ethnic background.

Measures

For Women VA Patient Participants:

Demographics: A brief measure of background information (e.g., age, race, sexual orientation, relationship status, number of deployments, housing status). Background information surrounding age, race, sexual orientation, and number of deployments will be collected at Pre, while demographic information on relationship status and housing status will be collected at all three timepoints (table 4).

Personal Progress Scale – Revised[35]: A measure of empowerment in women, demonstrating excellent reliability and validity in diverse sample of women.

General Self-efficacy Scale (GSS)[65a]: A reliable and valid 10-item scale that is designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life.

Patient Activation Measure-Short Form (PAM-13)[65b]: A brief validated measure of patient activation including: patient knowledge, skill, and confidence for self-management. The 13-item abbreviated measure has psychometric properties similar to the original 22-item version.

Valued Living Questionnaire (VLQ)[66]: The VLQ is a two-part questionnaire that measures (a) the importance of 10 valued areas of living, and (b) the extent to which one's actions are consistent with one's values. For each domain (e.g., family, physical self-care, friends/social life), respondents use a 1–10 scale to rate how important each value is to them and how consistently they have lived in accordance with this value over the past week. Responses from both importance and consistency are multiplied to derive a value composite score.

Center for Epidemiologic Studies – Depression Scale (CES-D)[67]: The CES-D is a psychometrically sound and widely-used 20-item questionnaire designed to measure the frequency of past-week depressive symptoms. It is sensitive to change over relatively short periods of time.

Health Service Use (HSU)[68]: Assesses VA and non-VA health service use using a modified version of Dr. Dawne Vogt's health service use (HSU) measure. This measure has been used in prior studies by Dr. Vogt (HSR&D IIR 12-345) and has been modified slightly for the purposes of this study. This will allow us to examine whether RISE leads to increased access and engagement with relevant health services.

The Conflict Tactics Scale-Revised (CTS-2)[69]: is a 39-item, behaviorally specific measure of intimate partner conflict, including physical, sexual, and psychological IPV. This measure has strong psychometric properties[70] and is the most commonly-used measure of IPV. This measure will be used to assess the scope of past-year IPV experiences in this sample.

PTSD Checklist for DSM-5 (PCL-5)[70]: The PCL-5 assesses the 20 DSM-5 symptoms of posttraumatic stress disorder.

15-item Patient Health Questionnaire (PHQ-15)[71]: The PHQ-15 assesses somatic symptoms by asking patients whether symptoms are present and the extent of their severity on a scale from 1 (not bothered at all) to 3 (bothered a lot).

12-item Short Form Survey (SF-12)[72]: The SF-12 assesses health-related quality of life with questions regarding patients' abilities to perform their usual activities. The measure includes two subscales for physical and mental health.

Safety Behaviors Checklist (SBC)[73]: The SBC assesses patients' behaviors to safeguard themselves against intimate partner violence and plan escape from an intimate partner, including such items as "Have you ever hidden money?" and "Do you have a hidden bag with extra clothing available?"

Connor-Davidson Resilience Scale (CD-RISC 25)[74-75]: The CD-RISC 25 is a validated self-report measure of resilience (Campbell-Sills & Stein, 2007). Items include statements about one's response to stress in the domains of control, commitment, hardiness, goal-orientation, self-esteem, adaptability, social skills, humor, strengthening through stress, and endurance of pain. Participants were asked to rate their level of agreement on a 5-point Likert scale from "*not true at all*" to "*true nearly all the time*" to items such as "I am able to adapt when changes occur." The summed resilience scores range from 0-40, with higher scores indicating greater resilience. The CD-RISC 25 is considered a high-quality resilience scale with acceptable psychometric support (Windle, Bennett, & Noyes, 2011). This measure has been used both in studies that conceptualize resilience as a stable, within-person trait, and as a modifiable construct.

Client Satisfaction Questionnaire-8 (CSQ-8)[76]: The CSQ-8 evaluates patients' satisfaction with the service they received (i.e., RISE or the information/referral), with items including "How satisfied are you with the amount of help you have received?" and "If you were to seek help again, would you come back to our program?" (post-treatment and 1 month follow-up only).

Depression Anxiety Stress Scale (DASS) (DASS-Anxiety Subscale)[77]: The anxiety subscale contains 14 items which assess autonomic, skeletal muscle effects, situational anxiety, and subjective experiences of anxious affect. 4-point severity/frequency scales are used and summed. The DASS has been shown to have high internal consistency and yield meaningful discriminations in a variety of settings (Loviband & Loviband, 1995).

Coping Strategy Inventory- Short Form (CSI-SF) [78-79]: The CSI-SF was structured to reflect the original CSI scale, with four 4- item subscales: (a) Problem–Focused Engagement, (b) Problem-Focused Disengagement, (c) Emotion-Focused Engagement, and (d) Emotion-Focused Disengagement. Respondents were asked to rate the general frequency with which they utilize each listed coping strategy on the survey and to indicate their choices in the following manner: 1 = "Never", 2 = "Seldom", 3 = "Sometimes", 4 = "Often" and 5 = "Almost Always". Individuals receive scores for each first-tier subscale (Engagement vs. Disengagement: range = 8 – 40), as well as for each of the four second tier subscales (Problem-Focused Engagement, Problem-Focused Disengagement, Emotion-Focused Engagement, and Emotion-Focused Disengagement: range = 4 – 20). Each of the four 2nd tier subscales created contained four items each. The CSI-SF demonstrates reliability and validity.

Acceptability: Brief qualitative and semi-structured interview questions assess patients' perceptions of the feasibility and acceptability of their respective intervention (post-treatment and 1-month follow-up only).

Military sexual trauma (MST)[85]: MST will be measured with the two following dichotomous (yes/no) VA clinical reminder items: "When you were in the military… a) did you ever receive unwanted, threatening, or repeated sexual attention (for example, touching, cornering, pressure for sexual favors, or inappropriate verbal remarks, etc.?; b) did you have sexual contact against your will or when you were unable to say no (for example, after being forced or threatened or to avoid other consequences)?" Evaluation of these items against

clinical interview yielded a sensitivity of .92 and specificity of .89 for the first question and a sensitivity of .89 and specificity of .90 for the second question (McIntyre et al., 1999).

Combat exposure: We developed a single dichotomous (yes/no) item to assess exposure to combat: "During any of your deployments, did you have any exposure to combat (for example, you fired a weapon, were under fire, or saw people who were injured or killed in battle)?" Only those participants who indicate that they have been deployed will be prompted to complete this question.

IPV-Related Head Injury[86]: We adapted the VA-DoD TBI screener to assess a history of IPV-related head injuries, probable TBI history, and TBI-related sequelae (Donnelly et al., 2011). Because concussion is a relatively common consequence of IPV to the face or head. We would like to assess whether IPV-related TBI history, with or without current symptoms, attenuates the effectiveness of treatment. It may be an important area to address as part of counseling for women who have experienced IPV. This 4-item screener allows us to determine probable IPV-related TBI history, with and without current symptoms. Studies using this measure suggests its utility in determining IPV-related TBI history among a sample of women Veterans (e.g., Iverson & Pogoda, 2015).

Quantitative Data Analyses (Aim 3)

We will conduct multilevel longitudinal data analyses to examine change in psychosocial outcomes. Time will be coded as 0, 1, and 2 respectively for pretreatment, posttreatment, and 1-month follow-up; therefore, the Level-1 intercept will represent initial status and the Level-2 time coefficient will represent change over time. We will also evaluate a model using linear and quadratic polynomial contrasts and orthogonal contrasts to evaluate non-linear (i.e., non-constant) change. We will add a dummy-coded intervention variable (RISE vs. information/referral condition) as a predictor of the Level-1 change parameters (initial status and change over time) to evaluate the treatment x time interaction (i.e., does group membership moderate change in the outcomes?). This analytic strategy will produce effective and efficient tests of change in outcomes, even in the presence of attrition, and provides us with flexibility to assess and adjust for control variables, if needed (e.g., age, IPV frequency). We will calculate effect size estimates and 95% confidence intervals, which produce an estimate of d from multilevel analyses that is comparable to d's produced using traditional methods (e.g., repeated measures ANOVA). To examine the range of effect sizes that might be reasonable to expect in a future trial, we will calculate effect sizes and 95% confidence intervals for all of our primary and secondary outcomes.

The study will incorporate a 2 x 3 (Condition: RISE vs. information/referral x Time: pretreatment, post, and 1-month follow-up) mixed-factorial multi-measurement design producing N=60 x 3 time points=180 measurement observations (or up to N=68 x 3 timepoints = 204). The intervention in this study is a difference over and above standard care (not in isolation), so it is expected that the effect will be modest (d=.5, f^2=.15, PV=.1). Traditional approaches to repeated measures can thus be used to assess power. However, the design affords two alternate methods. The interaction term from the multilevel model will have 118 degrees of freedom, given the study design, which is more than sufficient to render a power = .95 for the primary outcomes. A simulation was also conducted leveraging the inputs from the prior studies, assuming a modest effect size, to determine power. In all simulated conditions, power is estimated >.80 for primary outcomes. Consistent with the American Statistical Association recommendations, we will examine effect sizes and 95% confidence intervals, along with p-values in our tests.

We will assess the feasibility and acceptability of RISE and the comparison condition by looking for consistent patterns in rates of intervention attendance (i.e., number of RISE sessions attended) and reasons for RISE termination. We will examine the acceptability of both interventions using data from the CSQ-8 and qualitative data from patient interviews. Provider quantitative measures of feasibility and acceptability will be primarily

descriptive in nature, including mean summary scores and proportion of participants rating the intervention as feasible and acceptable. Lower scores will indicate a need to examine a given dimension more closely. We will integrate qualitative analyses within the quantitative analyses for the purposes of expansion, development, and convergence.

Qualitative Data Analyses (Aim 3)

Interview data will be analyzed using rapid methods. These data will be used to contextualize and interpret quantitative findings, including identification of barriers to and facilitators of RISE implementation to inform future research. Rapid content analysis allows for a quick and accurate reduction of qualitative data and produces results useful for efficient intervention refinement. Exit interviews with women veterans will be digitally recorded and transcribed verbatim for analysis. We will use Co-I Dr. Hamilton's established rapid content analysis approach to efficiently derive key findings from transcripts to tailor and refine the RISE manual and implementation protocol.[66] In this approach, data analysis occurs concurrently with data collection. As transcripts become available, they will be reviewed and summarized by members of the research team using structured templates organized by key topics from the interview guides. Consistent with our team's successful approach across multiple prior projects, we will transfer the summaries into matrices and use matrix analysis methods to identify themes related to the intervention and implementation.[78] Matrices streamline the process of noting simultaneously and systematically similarities, differences, and trends in responses across groups of informants. Matrix analysis facilitates the discovery of relationships and patterns, expediting synthesis and summary.[78] The process begins with review of available transcripts by study team members, making notes of key themes and impressions. Team members meet to discuss comparison and generate an initial coding manual and matrices for summary of emergent findings based on inductive and deductive approaches. Using constant comparison, each item will be checked or compared with the rest of the data to establish analytic categories thus allowing for reflection of the nuances of the data. Dr. Iverson will update the coding model as the analyses lead to further refinement. Once interrater reliability is achieved, 20% of transcripts will be coded by at least two individuals to ensure interrater reliability is still being achieved and to avoid coder "drift". Dr. Iverson has significant experience with qualitative and mixed method data analysis and interpretation, with experience in rapid content analysis to modify interventions. She will oversee all qualitative and mixed method analyses, with help from a trained and qualified project manager (PM; Dr. Danitz), with consultation from Dr. Hamilton. Dr. Iverson, Dr. Danitz, and RA will have primary responsibility for analyzing the qualitative data.

4.d Potential Limitations and Solutions to Limitations.

Recruitment

Recruitment of Female VA Patients (Aim 3). As noted above, we will use a variety of recruitment methods, including clinic referrals and self-referrals based on flyers and social media postings, and mailed letters. These referrals may result from spontaneous disclosure or routine IPV screening. Screening does not, however, always lead to disclosure. In the event that we have difficulty meeting our enrollment goals, we will broaden our recruitment efforts. Dr. Iverson will troubleshoot problems with recruitment procedures with Co-Investigators and, with IRB approval, implement recommended strategies as needed (e.g., actively recruit and conduct intervention at the Brockton campus).

Based on our experience with recruitment in Phase 2, we recognize the need to broaden our letter recruitment strategy. In order to do mail recruitment from a list of potential participants generated from VA

administrative data, we will collect the following data on potential study participants prior to receiving informed consent: name, mailing address, telephone number, and medical record/social security number. This information will be necessary to recruit participants, and the HIPAA Waiver of Authorization (attached) reflects this additional recruitment method. Research staff will mail a recruitment letter to potentially eligible patients, asking patients to contact research staff with questions and/or to indicate their interest in participating in the study, or to opt out of further contact if they do not wish to participate in the study (Aim 3 only). We will provide phone numbers and a self-addressed letter and stamped self-addressed envelope for opting out to make this process as easy as possible for women. All recruitment materials are intentionally vague (i.e., no mention of IPV or study focus) for safety purposes. Patients who contact research staff will be asked if they are in a space where they can speak privately. Once confirmed, research staff will describe the purpose of the study and what study participation entails, explain eligibility criteria, determine eligibility, and ask the participant (if eligible) if she is interested in participating. If yes, research staff will record the patient's name and preferred contact number. If patients do not respond to the recruitment letter, they will be contacted by study staff.

Data Analyses for Aim 3

Qualitative. The rapid qualitative analyses are time and resource intensive. As such, Dr. Iverson has budgeted for a full-time project manager and research assistant to ensure timely transcription and analyses of interview data. The coding team will hold weekly meetings focus on analysis and thematic summaries in order to stay on track with the timeline of this study. If additional resources are needed for transcribing focus groups and interview data, and/or for coding, Dr. Iverson may be able to request additional resources through the Women's Health Sciences Division of the National Center for PTSD and the Center for Healthcare Organization and Implementation Research (e.g., additional PM or RA time for participation in qualitative analysis team). Any such changes would undergo IRB approval prior to initiation of protocol modifications or additions to the team.

Quantitative. RISE is designed to be variable-length, with a special focus on empowering women to choose which modules, and relatedly, how many sessions (with an upper limit of 6) are right for her situation and needs. Thus, it is possible that some women may only desire or be able to attend one session, and therefore may only have quantitative data two assessment periods (i.e., pretreatment and posttreatment). We view this pre-post data as acceptable, as this is a pilot test and we will still be able to examine general levels of improvement on outcomes. In addition to examining changes in quantitative variables over time at the group-level, we will be able to graphically examine individual women's trajectories, which will further enable us to meet our Aim 2 goals. That being said, we do expect that the majority of participants will opt for multiple sessions based on the feedback we've received in Phase 1 focus groups with women VA patients. Part of the purpose of this open trial will be to begin to understand how many sessions (and which types of modules) women choose to inform the implementation protocol for the RCT in Phase 3.

Subjects and generalizability. While the findings from this study will be highly informative, they will not be definitive. Our RCT design for Phase 3 provides a strong test of RISE, controlling for any spontaneous changes in outcomes (e.g., Hawthorne effect) and enabling comparison of changes observed in patient outcomes during RISE to what we observe in the information/referral condition. This increases confidence that changes observed in the RISE condition are a result of the intervention, as opposed to assessment or contact with project personnel. Generalizability will, however, be limited due to the use of only one site. The effectiveness of RISE will need to be more rigorously evaluated in a larger study with a diverse array of WVs (e.g., rural women, racial/ethnic minorities). In the likely event that RISE demonstrates effectiveness, we will submit a subsequent IIR employing a multi-site RCT that is fully powered to evaluate a range of psychosocial outcomes using an effectiveness-implementation Hybrid 2 design. This will allow us to more comprehensively evaluate RISE with a diverse array of women Veterans (e.g., rural women, racial/ethnic minorities) and providers while also

evaluating implementation strategies. Additionally, this study focuses on refining and evaluating RISE for WVs. Although we will not be able to confidently generalize results to male patients or non-VHA settings, the findings will likely hold implications for men and could be applied to other health care settings in future studies.

References

1. Black MC, Basile KC, Breiding MJ, et al. *The National Intimate Partner and Sexual Violence Survey (NISVS): 2010 Summary Report.* Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention;2011.
2. Grisso JA, Wishner AR, Schwarz DF, Weene BA, Holmes JH, Sutton RL. A population-based study of injuries in inner-city women. *Am J Epidemiol.* 1991;134(1):59-68.
3. Coker AL, Davis KE, Arias I, et al. Physical and mental health effects of intimate partner violence for men and women. *American Journal of Preventive Medicine.* 2002;23(4):260-268.
4. Campbell JC. Health consequences of intimate partner violence. *The Lancet.* 2002;359(9314):1331-1336.
5. Dutton MA. Pathways Linking Intimate Partner Violence and Posttraumatic Disorder *Trauma Violence Abuse.* 2009;10:211-224.
6. Iverson KM, King M, Resick PA, Gerber MR, Kimerling R, Vogt D. Clinical utility of an intimate partner violence screening tool for female VHA patients. *Journal of General Internal Medicine.* 2013;28:1288-1293.
7. Campbell JC, Lewandowski LA. Mental and physical health effects of intimate partner violence on women and children. *Psychiatric Clinics of North America.* 1997;20(2):353-374.
8. Kimerling R, Iverson KM, Dichter ME, Rodriguez A, Wong A, Pavao J. Prevalence of Intimate Partner Violence among Women Veterans who Utilize Veterans Health Administration Primary Care. *Journal of General Internal Medicine.* 2016;31(8):888-894.
9. Frayne SM, Phibbs CS, Friedman SA, et al. *Sourcebook: Women Veterans in the Veterans Health Administration. Volume 1. Sociodemographic characteristics and use of VHA care.* Washington, DC: Women's Health Evaluation Initiative, Women Veterans Health Strategic Health Care Group, Veterans Health Administration, Department of Veterans Affairs; 2010.
10. Dichter ME, Cerulli C, Bossarte RM. Intimate partner violence victimization among women veterans and associated heart health risks. *Women's Health Issues.* 2011;21(4 Suppl):S190-194.
11. Iverson KM, Stirman SW, Street AE, et al. Female veterans' preferences for counseling related to intimate partner violence: Informing patient-centered interventions. *General Hospital Psychiatry.* 2016;40:33-38.
12. Iverson KM, King MW, Gerber MR, et al. Accuracy of an intimate partner violence screening tool for female VHA patients: A replication and extension. *Journal of Traumatic Stress.* 2015;28(1):79-82.
13. Sweeney AC, Weitlauf JC, Manning EA, Sze JA, Waldrop AE, Hasser C. Intimate partner violence: Perspectives on universal screening for women in VHA primary care. *Women's Health Issues.* 2013;23:e73-e76.
14. Association of Women's Health OaNN. AWHONN Position Statement: Intimate Partner Violence. *Journal of Obstetric, Gynecologic, & Neonatal Nursing.* 2015;44(3):405-408.
15. Gerber MR, Iverson KM, Dichter ME, Klap R, Latta RE. Women veterans and intimate partner violence: Current state of knowledge and future directions. *Journal of Women's Health.* 2014;23:302-309.
16. Ghandour RM, Campbell JC, Lloyd J. Screening and counseling for intimate partner violence: A vision for the future. *Journal of Women's Health.* 2014.
17. Nelson HD, Nygren P, McInerney Y, Klein J. Screening women and elderly adults for family and intimate partner violence: A review of the evidence for the U. S. Preventive Services Task Force. *Annals of Internal Medicine.* 2004;140(5):387-396.
18. O'Doherty LJ, Taft A, Hegarty K, Ramsay J, Davidson LL, Feder G. Screening women for intimate partner violence in healthcare settings: abridged Cochrane systematic review and meta-analysis. *Bmj.* 2014;348:g2913.
19. Hegarty K, O'Doherty L, Taft A, et al. Screening and counselling in the primary care setting for women who have experienced intimate partner violence (WEAVE): a cluster randomised controlled trial. *The Lancet.* 2013;382(9888):249-258.
20. Patient Protection and Affordable Care Act. In:2010.
21. Bair-Merritt MH, Lewis-O'Connor A, Goel S, et al. Primary care-based interventions for intimate partner violence: a systematic review. *Am J Prev Med.* 2014;46(2):188-194.
22. Jewkes R. Intimate partner violence: the end of routine screening. *The Lancet.* 2013;382(9888):190-191.

23. Rhodes KV, Rodgers M, Sommers M, et al. Brief motivational intervention for intimate partner violence and heavy drinking in the emergency department: a randomized clinical trial. *JAMA.* 2015;314(5):466-477.
24. Hegarty K, Taft A, James-Hanman D, Johnson M, Feder G. Interventions for intimate partner violence. *The Lancet.* 2015;385(9963):111-112.
25. Rivara FP, Anderson ML, Fishman P, et al. Healthcare utilization and costs for women with a history of intimate partner violence. *American Journal of Preventative Medicine.* 2007;32(2):89-96.
26. Coker AL, Reeder CE, Fadden MK, Smith PH. Physical partner violence and medicaid utilization and expenditures. *Public Health Reports.* 2004;119(6):557-567.
27. Klevens J, Kee R, Trick W, et al. Effect of screening for partner violence on women's quality of life: a randomized controlled trial. *Jama.* 2012;308(7):681-689.
28. Feder G, Ramsay J, Dunne D, et al. How far does screening women for domestic (partner) violence in different health-care settings meet criteria for a screening programme? Systematic reviews of nine UK National Screening Committee criteria. *Health technology assessment (Winchester, England).* 2009;13(16):1-+.
29. U.S. Preventive Services Task Force. Screening for intimate partner violence and abuse of elderly and vulnerable adults: U.S. Preventive Services Task Force recommendation statement. In:2013.
30. Iverson KM, Wells ST, Wiltsey-Stirman S, Vaughn R, Gerber MR. VHA primary care providers' perspectives on screening female veterans for intimate partner violence: A preliminary assessment. *Journal of Family Violence.* 2013;28:823-831.
31. Iverson KM, Huang K, Wells SY, Wright JD, Gerber MR, Wiltsey-Stirman S. Women veterans' preferences for intimate partner violence screening and response procedures within the Veterans Health Administration. *Research in Nursing and Health.* 2014;37:302-311.
32. Dichter ME, Wagner C, Goldberg E, Iverson KM. Intimate Partner Violence Detection and Care in the Veterans Health Administration: Patient and Provider Perspectives. *Women's Health Issues.* 2015;25(5):555-560.
33. Dutton MA. *Empowering and Healing the Battered Woman: A Model for Assessment and Intervention.* New York, NY: Springer Publishing Company; 1992.
34. Cattaneo LB, Goodman L. What is empowerment anyway? A model for domestic violence practice, research, and evaluation. *Psychology of Violence.* 2015;5(1):84-94.
35. Johnson DM, Worell J, Chandler RK. Assessing psychological health and empowerment in women: The personal progress scale revised. *Women & health.* 2005;41(1):109-129.
36. Goodman LA, Bennett Cattaneo L, Thomas K, Woulfe J, Chong SK, Fels Smyth K. Advancing Domestic Violence Program Evaluation: Development and Validation of the Measure of Victim Empowerment Related to Safety (MOVERS). 2014.
37. Song L-y. The Association between the Utilisation of Empowerment Strategies and Clients' Changes of Self in the Field of Intimate Partner Abuse: From the Perspective of Social Workers. *British Journal of Social Work.* 2013:bct134.
38. Johnson DM, Zlotnick C, Perez S. Cognitive behavioral treatment of PTSD in residents of battered women's shelters: Results of a randomized clinical trial. . *Journal of Consulting and Clinical Psychology.* 2011;79:542-551.
39. Weisz JR, Chorpita BF, Palinkas LA, et al. Testing standard and modular designs for psychotherapy treating depression, anxiety, and conduct problems in youth: a randomized effectiveness trial. *Archives of General Psychiatry.* 2012;69(3):274-282.
40. Chorpita BF, Weisz JR, Daleiden EL, et al. Long-term outcomes for the Child STEPs randomized effectiveness trial: A comparison of modular and standard treatment designs with usual care. *Journal of consulting and clinical psychology.* 2013;81(6):999.
41. Miller WR, Rollnick S. *Motivational interviewing: Preparing people to change.* 2 ed. NY: Guilford Press; 2002.
42. Burke BL, Arkowitz H, Menchola M. The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials. *Journal of consulting and clinical psychology.* 2003;71(5):843.

43. Kraft JM, Mezoff JS, Sogolow ED, Neumann MS, Thomas PA. A technology transfer model for effective HIV/AIDS interventions: Science and practice. *AIDS Education Prevention.* 2000;12(5 Suppl):7-20.
44. Kilbourne AM, Neumann MS, Pincus HA, Bauer MS, Stall R. Implementing evidence-based interventions in health care: application of the replicating effective programs framework. *Implement Sci.* 2007;2:42.
45. Blueprint for Excellence. In: Administration VH, ed. *Department of Veteran Affairs*2014.
46. Jordan FG. VA SEC Lays Out VA's 2016 Breakthrough Priorities. *U.S. Department of Veterans Affairs* 2016; http://www.dublin.va.gov/features/0001_12_Priorities.asp. Accessed May 4, 2016, 2016.
47. Force VHADVT. *Plan for Implementation of the Domestic Violence/Intimate Partner Violence Assistance Program.* Department of Veterans Affairs, Veterans Health Administration;2013.
48. Scholl I, Zill JM, Harter M, Dirmaier J. How do health services researchers understand the concept of patient-centeredness? Results from an expert survey. *Patient preference and adherence.* 2014;8:1153-1160.
49. Weisz JR, Chu BC, Polo AJ. Treatment Dissemination and Evidence-Based Practice: Strengthening Intervention Through Clinician-Researcher Collaboration. *Clinical Psychology: Science and Practice.* 2004;11(3):300-307.
50. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care.* 2012;50(3):217–226.
51. Gobin RL, Iverson KM, Mitchell K, Vaughn R, Resick PA. The impact of childhood maltreatment on PTSD symptoms among female survivors of intimate partner violence. *Violence and victims.* 2013;28(6):984-999.
52. Iverson KM, Pogoda TK. Traumatic brain injury among women veterans: an invisible wound of intimate partner violence. *Medical Care.* 2015;53(4 Suppl 1):S112-119.
53. Mercado R, Foynes MM, Carpenter SL, Iverson KM. Sexual Intimate Partner Violence as a Form of MST: An Initial Investigation. *Psychological services.* 2015;12:348-356.
54. Iverson KM, McLaughlin KA, Adair KC, Monson CM. Anger-related dysregulation as a factor linking childhood physical abuse and interparental violence to intimate partner violence experiences. *Violence and victims.* 2014;29(4):564.
55. Iverson KM, Litwack SD, Pineles SL, Suvak MK, Vaughn RA, Resick PA. Predictors of Intimate Partner Violence revictimization: The relative impact of distinct PTSD symptoms, dissociation, and coping strategies. *Journal of Traumatic Stress.* 2013;26:102-110.
56. Iverson KM, Mercado R, Carpenter SL, Street AE. Intimate partner violence among women veterans: Previous interpersonal violence as a risk factor. *Journal of Traumatic Stress.* 2013;26:767-771.
57. Czajkowski SM, Powell LH, Adler N, et al. From Ideas to Efficacy: The ORBIT Model for Developing Behavioral Treatments for Chronic Diseases. *Health Psychology.* 2015;34(10):971-982.
58. Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Am J Public Health.* 2003;93:1261 - 1267.
59. Gitlin LN. Introducing a new intervention: An overview of research phases and common challenges. *American Journal of Occupational Therapy.* 2013;67(2):177-184.
60. Curran GM, Thrush CR, Smith JL, Owen RR, Ritchie M, Chadwick D. Implementing research findings into practice using clinical opinion leaders: barriers and lessons learned. *Joint Commission Journal on Quality and Patient Safety.* 2005;31(12):700-707.
61. Vogt DS, King DW, King LA. Focus groups in psychological assessment: enhancing content validity by consulting members of the target population. *Psychol Assess.* 2004;16(3):231-243.
62. Onwuegbuzie A, & Leech, N. . The role of sampling in qualitative research. *Academic Exchange Quarterly.* 2005;9:280-284.
63. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field methods.* 2006;18(1):59-82.
64. Stetler CB, Legro MW, Wallace CM, et al. The role of formative evaluation in implementation research and the QUERI experience. *J Gen Intern Med.* 2006;21:S1 - S8.

65. Hamilton A. *Qualitative methods in rapid turn-around health services research.* VA HSR&D December 11, 2013 2013.
65a. Schwarzer, R., & Jerusalem, M. (1995). Generalized Self-Efficacy scale. In J. Weinman, S. Wright, & M. Johnston, Measures in health psychology: A user's portfolio. Causal and control beliefs (pp. 35-37).
65b. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health services research.* 2005;40(6p1):1918-1930.
66. Wilson KG, Sandoz EK, Kitchens J, Roberts M. The Valued Living Questionnaire: Defining and measuring valued action within a behavioral framework. *Psychological Record.* 2010;60:249-272.
67. Radloff LS. The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement.* 1977;1:385-401.
68. Vogt D. Work and Family Functioning in Women Veterans: Implications for VA Service Use. *HSR&D IIR 12-345.*
69. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised conflict tactics scale (CTS2): Development and preliminary psychometric data. *Journal of Family Issues.* 1996;17:283-316.
70. Weathers F, Litz B, Keane T, Palmieri P, Marx B, Schnurr P. The PTSD Checklist for DSM-5 (PCL-5). *Scale available from the National Center for PTSD at www ptsd va gov.* 2013.
71. Kroenke K, Spitzer RL, Williams JB. The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. *Psychosomatic medicine.* 2002;64(2):258-266.
72. Ware JE, Kosinski M, Keller SD. *SF-12: How to score the SF-12 physical and mental health summary scales.* 1995.
73. McFarlane JM, Groff JY, O'Brien JA, Watson K. Secondary prevention of intimate partner violence: A randomized controlled trial. *Nursing Research.* 2006;55(1):52-61.
74. Campbell-Sills, L., & Stein, M. B. (2007). Psychometric analysis and refinement of the Connor–Davidson Resilience Scale (CD-RISC): Validation of a 10-item measure of resilience. Journal of Traumatic Stress, 20(6), 1019-1028.
75. Windle, G., Bennett, K. M., & Noyes, J. (2011). A methodological review of resilience measurement scales. Health and Quality of Life Outcomes, 9(1), 8. doi: 10.1186/1477-7525-9-8
76. Nguyen TD, Attkisson CC, Stegner BL. Assessment of patient satisfaction: development and refinement of a service evaluation questionnaire. *Evaluation and program planning.* 1983;6(3):299-313.
77. Lovibond, P. F., & Lovibond, S. H. (1995). The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behaviour Research and Therapy, 33(3), 335-343.
78. Tobin DL, Holroyd KA, Reynolds RV, Wigal JK. The Hierarchical Factor Structure of the Coping Strategies Inventory. Cognitive Therapy and Research, Vol. 13, No. 4, 1989, pp. 343-361.
79. C.C. Addison, B.W. Campbell-Jenkins, D.F. Sarpong, J. Kibler, M. Singh, P. Dubbert, G. Wilson, T. Payne, H. Taylor, Psychometric evaluation of a Coping Strategies Inventory Short-Form (CSI-SF) in the Jackson Heart Study Cohort, *Int. J. Environ. Res. Public Health* 4 (4) (2007) 289–295.
80. Aarons GA. Mental health provider attitudes toward adoption of evidence-based practice: The Evidence-Based Practice Attitude Scale (EBPAS). *Mental health services research.* 2004;6(2):61-74.
81. Cook JM, Thompson R, Schnurr PP. Perceived Characteristics of Intervention Scale Development and Psychometric Properties. *Assessment.* 2014:1073191114561254.
82. Averill JB. Matrix analysis as a complementary analytic strategy in qualitative inquiry. *Qualitative Health Research.* 2002;12(6):855-866.
83. Sullivan CM, Cain D. Ethical and safety considerations when obtaining information from or about battered women for research purposes. *Journal of Interpersonal Violence.* 2004;19(5):603-618.
84. Iverson KM. Intimate Partner Violence Screening Programs in VHA: Informing Scale-Up and Spread of Best Practices. VA Boston Healthcare System: Health Services Research & Delivery; 2017.

85. McIntyre LM, Butterfield MI, Nanda K, Parsey K, Stechuchak KM, McChesney AW, Koons C, Bastian LA. Validation of a trauma questionnaire in veteran women. *J. Soc. Gen. Internal Med.,* 14 (3) (1999), pp. 186-189.
86. Donnelly KT, Donnelly JP, Dunnam M, Warner GC, Kittleson CJ, Constance JE, Bradshaw CB, Alt M. Reliability, sensitivity, and specificity of the VA traumatic brain injury screening tool. *Journal of Head Trauma Rehabilitation.* 2011;26(6):439-453.