Online and Shared Decision-Making Interventions to Engage Service Men and Women in Post-Deployment Mental Health Care

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GRANT NARRATIVE

2.0 BACKGROUND

Mental health conditions are prevalent in OEF/OIF/OND war Veterans but many do not seek care. OEF/OIF/OND Veterans experience complex mental health (MH) consequences of deployment(s). Almost a third (32%) of OEF/OIF Veterans in the VA have received a MH diagnosis; PTSD is the most prevalent condition, followed by substance abuse and then depression.[1] OEF/OIF servicewomen have high levels of combat exposures, only slightly lower than men, yet gender differences of the impact of these stressors appear to be minimal.[2-3] A RAND study of a community sample of OEF/OIF war Veterans found rates of MH disorders similar to VA populations, however, only half of OEF/OIF war Veterans meeting criteria for current PTSD or major depression had sought help from a provider for a MH problem in the past year.[4] In a study of almost 50,000 Iraq/Afghanistan Veterans with newly diagnosed PTSD, only a minority (9.5%) received the recommended number and intensity of VA MH treatment sessions within the first year.[5]

Barriers to seeking MH care are well-documented. Stigma and not being able to admit to having a problem or ask for help impede Veterans' willingness to seek needed care.[6] Veterans who have not used VA services report not knowing what benefits are available to them or how to access them.[7] Veterans who have used VA health care identify long waiting periods as one of the greatest barriers to accessing MH services.[8] Care disparities may be further compounded for those who reside in rural locations.[9] Recent era Veterans who wait longer to get outpatient MH treatment have been found to live geographically further from a VA and to be less likely to have improvement in their symptoms of PTSD compared to peers who live closer and seek care sooner.[10] This is of particular concern given approximately 41% of the Veteran population are rural residents and research indicates rural Veterans have lower MH-related quality of life.[9] Our research on Veterans eligible for Choice (Veterans Access, Choice, and Accountability Act of 2014) because of distance barriers to VA care have found that few Veterans had closer access to Community MH Centers. The percent of Veterans living more than 40 miles from their nearest VA health facility who had access to a Community MH Center ranged from 3% to 34% across MyVA Regions.[11]

Online health screening, education, and interventions are effective. There is a recent and growing precedent of using web-based interventions in high risk populations, including interventions that identify MH conditions (e.g., substance abuse, PTSD) and focus on behavior change to promote patient engagement in care.[12] Research investigating online treatment of PTSD[13] suggests that there may be greater follow through with internet-based approaches, which further supports the need for finding creative ways of safely extending education and services beyond traditional methods. The Department of Defense (DoD) provides online feedback to service members on topics ranging from assessments (e.g., post-deployment health) to educational resources (e.g., health promotion).

Online health education and interventions are preferred. VA-enrolled OEF/OIF combat Veterans report a preference to seek readjustment services or information over the internet (53%) and virtually all (97%) have internet use.[14] The majority of OEF/OIF Veterans are computer-literate, and many use the internet as a daily part of their lives.[15] A recent study

found that most Veterans with a MH diagnosis who are engaged in VA care had access to an internet capable device (cell phones and computer) and are interested in using technology for healthcare-related communications.[16]

Informed patients have improved engagement, satisfaction, and outcomes. Information plays a critical role in helping patients become aware of their treatment needs, options, and effective self-care strategies.[17] A lack of knowledge about PTSD, its causes, and available treatments have been identified as important barriers to help-seeking among Veterans.[18] Conversely, considerable evidence suggests that patients who are better informed about their medical/MH conditions and treatment tend to have more favorable outcomes. For example, having adequate information about one's medical condition is associated with better adherence to treatment recommendations.[19] Patients who are better informed tend to be more satisfied with their care[19] and experience reduced uncertainty and anxiety regarding treatment.[19-20] Patient-provider communication patterns involving more information-sharing on the part of the provider have also been associated with greater patient satisfaction, knowledge, and adherence[21] as well as better health outcomes.[22]

Engaging patients in shared decision-making (SDM) improves MH care satisfaction and outcomes. SDM, considered the "pinnacle of patient-centered care,"[23] involves clinicians and patients participating together in the decision-making process, discussing treatment preferences, and reaching agreement about treatment choice.[24] Such a participatory care model of decision-making is a central theme of many evidence-based psychosocial MH treatments and a core component of the chronic care model.[25] Improved health outcomes and patient satisfaction of MH consumers have been associated with SDM.[26] Both men and women report improved patient satisfaction with SDM and MH care receipt.[27] Furthermore, improved self-management of MH conditions has been found, e.g., greater follow-through with treatment plans, and improved therapeutic alliances with clinicians.[28]

Implementation of SDM into routine clinical practice is needed. Currently personal health records (PHR) have little data about patients' health preferences, with the exception of end of life decisions. Integration of SDM, as a part of Meaningful Use regulations, is gaining recognition as feasible and necessary.[29] However, more work needs to be done to overcome difficulties implementing SDM into routine practice because of the time required, lack of explanation on using decision aids, and need for electronic medical record (EMR) inclusion.[29]

Technology efficiently supports access to MH care and population health. There is growing evidence that eHealth tools have the capability to promote health and overcome stigma. MH care stigma frequently results in delays and suboptimal use of care.[30] The Institute of Medicine (IOM) 2001 report, "Crossing the Quality Chasm,"[31] notes that technology can reshape healthcare delivery and recommends that "access to care should be provided over the internet, by telephone, and by other means in addition to in person visits." A web-interface for Veterans to screen for common post-deployment readjustment and MH conditions, at any time and any place, offers a substantial advantage to Veterans who are returning from war and who are unsure if their symptoms are treatable conditions

or lack knowledge about VA services available to them. Enabling this priority population's ability to confidentially screen, then enroll in VA and My HealtheVet (MHV), in order to communicate screening results to VA OEF/OIF/OND Transition Patient Advocates (TPA) or providers has great potential to address unmet need and recognized barriers to VA MH care.

Existing VA technology can be leveraged to promote Veteran access to VA MH care. Within VHA, MHV (My HealtheVet Program Office) is an online PHR available to all Veterans. This PHR can 1) facilitate Veterans' ability to maintain a comprehensive medical history in one place; 2) monitor and promote positive health behaviors; and 3) for those who enroll in VA and become MHV premium members, confidentially message VA providers or care managers to engage more actively in their own care. This PHR has the capability of improving engagement, safety, satisfaction, and health outcomes.[32] PHRs also can provide patients with ownership of their health information so they can share it with multiple providers.[33] Within VHA, only about 20% of Veterans receiving services are registered on MHV. While a majority of Veterans use the internet, only about a quarter of VA MH service users and a fifth of VA general service users access the MHV website for their personal health care.[34] This slow adoption is similar to that in non-VA health care systems.[32] It is encouraging that a qualitative study found that Veterans seeing their records positively affects communication with providers and the health system, enhances knowledge of their health and improved self-care, and allows for greater participation in their care and decision-making regarding when to seek care.[35] Non-VA patients given access to a website allowing a shared medical record report high adoption and satisfaction.[36]

VA is promoting VA provider adoption of MHV secure messaging. The 2014 MHV advance allowing secure messaging with providers offered a great opportunity to improve Veteran-provider communication. In April 2016, VA began allowing staff to obtain workload credit, or increments of time, for MHV secure messages they complete and save into CPRS as progress notes. One study with VA providers found that those who attain workload benefits from secure messaging are more likely to adopt use.[37] Secure messaging has been found to increase patient-provider communication and patient activation while at the same time reducing in-person visits and telephone contacts.[16,38-39]

Technology can address the needs of vulnerable Veteran sub-populations. A recent literature review found that women who have experienced military sexual trauma (MST) experience high levels of organizational distrust, social isolation, and self-perceived stigma which create a significant barrier for participation in treatment and community reintegration. Authors concluded that the use of internet technologies show promise among MST survivors not only as therapeutic tools but also as effective outreach to identify and connect with those difficult to reach.[40] The VHA Handbook (1330.01) indicates that VA women's health care should be delivered in environments that attend to their dignity, safety, and privacy. For some, this environment might be their home as they begin their VA care journey. This work also has implications for males experiencing MST and other forms of trauma.

The PI and her team have studied post-deployment readjustment and MH care access for the past seven years. Findings across five studies show participant age, VA enrollment, military characteristics, and MH screening results are similar for men and women, demonstrating generalizability and eligibility (Appendix 1).

Study I: **Most participants did not know their post-deployment symptoms were treatable psychiatric conditions.** Phase 1 involving 18 focus groups with OEF/OIF service members (65 women/33 men) found most participants: 1) had received no information about VA eligibility or how to access VA services, and 2) frequently noted concerns with post-deployment adjustment, e.g., family re-adjustment. In the Phase 2 cross-sectional study, we found that among Reserve and National Guard (RNG) servicewomen (n=665), **most chose not to seek care.** Almost 80% did not use MH care in the past year despite psychiatric problems at rates consistent with other studies of post-deployment Veterans. This gap in receipt of care occurred despite women's belief that MH counseling can help (82%) and that VA MH providers could better understand their problems (91%).

Study II: **Online interventions can be successfully implemented within VA and can decrease RNG servicewomen's discomfort with seeking MH care.**[41] Dr. Sadler demonstrated feasibility of conducting online interventions behind the VA firewall. One-third (31%) of participants reported that the web-based screening and education (WEB-ED) reduced their reluctance to seek MH care.

Study III: **Servicewomen (82%) would like their WEB-ED screening results linked to a VA secure network (such as MHV) to facilitate VA provider access to the results, and would be more likely to ask questions or secure message a VA provider about their screens if available in MHV (77%).** We found that of 214 RNG women returning from deployment to Iraq or Afghanistan, 83% screened positive on at least one screen, averaging three positive screens for MH conditions. Thus, WEB-ED is effectively reaching a high-risk population with substantial MH consequences from service. Only 16% of the total sample had received VA MH care following their most recent deployment, of which 16% was from a community facility.

Study IV: **Servicemen's screening results were not significantly different from servicewomen's with regard to MH complexity, post-deployment concerns, and care seeking**. Co-Investigator Dr. Mengeling implemented WEB-ED with a Midwestern cohort of RNG OEF/OIF/OND servicemen (N= 200), finding that over half (57%) expressed concern about their post-deployment adjustment but < 20% sought MH care.

Study V: **Half of servicewomen participants indicated that as a direct result of WEB-ED, they will follow up with a provider. Women reported higher satisfaction and intent to seek needed PTSD treatment when they talked by telephone about WEB-ED results and engaged in SDM about treatment options with a MH nurse.** Dr. Sadler's current HSR&D CREATE study with active component and RNG post-deployed servicewomen (n=1,104) found WEB-ED outcomes remain consistent with prior findings of high-risk populations, but in a sample of increased diversity (38% non-white). **Veterans continue to want a direct interface (e.g., MHV) to communicate their WEB-ED/SDM results to a VA provider to facilitate discussion**. Using the Patient Activation Measure, we found that compared to PCL-5 PTSD+ women, PTSD- women were more likely to have high activation

("taking action"/"pushing further" (71% vs 40%). **PTSD+ women were more likely to feel "disengaged & overwhelmed"/"aware but struggling" (60% vs 28%).** This emphasizes the need for Veteran empowerment through information about their MH conditions, treatment options, and SDM.

In summary, available literature combined with our extensive prior studies have set the stage for our proposed study, focused on using technology to increase Veterans' access to and engagement in VA MH care and to promote a SDM interface between Veterans and VA practitioners.

The Consolidated Framework for Implementation Research (CFIR) will be used to guide our study implementation, educational materials, training strategies, and outcomes analyses (Figure 1).[42] CFIR serves as an excellent framework for our purposes as: (a) we propose to develop and test augmentations to enhance the perceived utility, adoption, and impact of our Enhanced WEB-ED (WEB-ED+) intervention; and (b) our approach is consistent with the recommended use of mixed methods focusing on both clinical effectiveness and implementation outcomes to speed the pace from intervention development/refinement to adoption and routine use in clinical or community settings.[43] For implementation of WEB-ED+, all five CFIR domains are included to guide our proposal, but we have tailored the constructs applicable to our work by domain to include: 1) Intervention focuses on refining and augmenting our current version of WEB-ED to build upon existing VA infrastructure (e.g., MHV) and including an electronic SDM component to support VA's priorities of delivering patient-centered care. Key informant input will be solicited to guide refinement and enhancements for adaptability in VA care systems, and to elicit stakeholder perspectives of the relative advantage of WEB-ED+ over the current version; 2) Outer Setting allows us to determine patients' perceptions of their need for VA care and preferences for engagement through VA eHealth and SDM interface to facilitate VA and MH engagement; 3) Inner Setting considers VA processes of care for engaging Veterans (whether enrolled or not enrolled in VA) in needed MH care as well as by supporting existing eHealth access and communication routes (i.e., enrollment, MyHealtheVet); 4) Individual Characteristics comprises determining characteristics of the key informants, i.e., provider knowledge and beliefs about MH needs and care (including SDM), and their sense of self-efficacy with using eHealth/SDM and patient activation to partner with their patients; and 5) the Implementation Process includes executing a randomized controlled trial (RCT) to engage key informants in planning, executing, and evaluating the impact of WEB-ED+ relative to existing WEB-ED measured by increased Veteran care engagement and satisfaction of key stakeholders.

3.0 SIGNIFICANCE

The Institute for Health Care Improvement notes that patients with complex needs encounter a "one size fits all" healthcare system that fails to take into account individuals' goals for care. They propose new care rules that customize services to meet the needs and preferences of the patients and change the balance of power between providers and patients through the interface of SDM. Our prior research has confirmed that recent war Veterans want a health system that respects and values them, is convenient, provides

information to help them understand and manage their post-deployment MH conditions, and connects them to caregivers and others in a way that is patient-centered, effective, and efficient, all of which has led to this proposal. This work supports VA efforts to move beyond traditional avenues to these new care rules in order to fulfill the organizational aims of Veteran engagement in their health care and other needed services (Appendix 2). Our proposed patient-centered intervention builds on our preceding studies by addressing Veterans' preference for their unique MH screening results to be imported into MHV, thereby decreasing stigma, facilitating Veteran communication with VA providers, and seeking key informants' input to promote system adoption. Prior research on transfer of important medical information from PHR using MHV found that Veterans required additional education and awareness to increase their ability to transfer medical information.[33] MHV has the potential to enhance the capability of providers/TPAs to use screening and SDM results to comprehensively and efficiently engage and triage Veterans in needed MH care. MHV linkage broadens the implementation of WEB-ED to reduce barriers to both VA and non-VA enrolled war Veterans' enrollment in MHV and VA. Furthermore, MHV has the potential to activate Veterans currently seen in VA primary care who screen positive for MH conditions and are symptomatic but not accessing VA MH care to help them and their families. Our proposed qualitative component will provide valuable insights about war Veterans' perceptions of eHealth and SDM interfaces, as well as VHA MH services and barriers to engagement in needed care. It will improve our understanding of the most effective recruitment and educational approaches to engage and to empower Veterans to obtain the care they are entitled to and be active partners in their care. It is also critical to promote VA provider adoption of WEB-ED+ with an eHealth interface and SDM to facilitate patient engagement and have more efficient workflow processes. Our proposed WEB-ED+ interface is an innovative way to promote provider engagement in the patient-centered care they wish to provide and in empowering Veterans to be care partners. This is vitally important for Veterans who have experienced a lack of power or control in traumatic exposures associated with their military service. Our proposed work is **responsive to the Under Secretary's Health Priorities for Strategic Action in striving to ensure Veterans have safe, high-quality, personalized, and timely care wherever they receive care.** it is also **consistent with and cross-cuts multiple current HSR&D priorities, including:** A) healthcare access/rural health; B) healthcare equity/ health disparities; C) healthcare informatics (e.g., secure messaging) impact on patient care and on patient and clinician experiences); D) mental & behavioral health; E) women's health; F) implementation science; G) patient-centered care; and H) health promotion. It also addresses HSR&D methods-oriented domains to engage Veterans, providers, and other stakeholders in research methods, outcomes, implementation, and scalability. Our proposed work is also responsive to Veteran and VA system needs in developing innovative tools and strategies for enhancing engagement of Veterans (Strategy 6 of the VA Blueprint for Excellence) and improving their access to care, which addresses MH conditions that afflict our Nation's newest Veterans. It is also consistent with the goals of the VA's **MH recovery orientation** to engage both male and female Veterans in more actively using VA MH care.

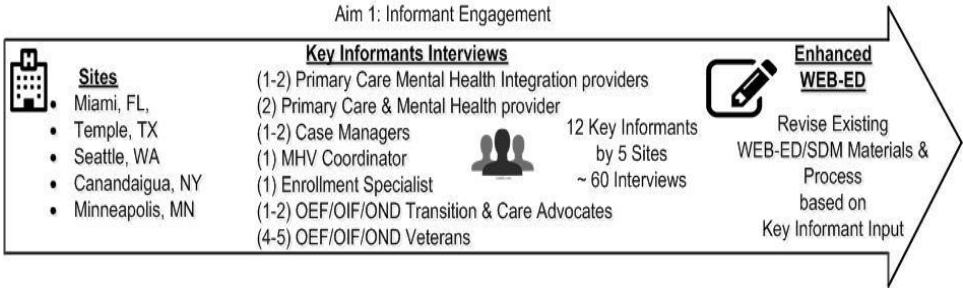
4.0 RESEARCH DESIGN AND METHODS

The goal of this proposed mixed-methods research is to facilitate male and female OEF/OIF/OND war Veterans' engagement in needed VA MH care. To achieve this, we will increase the reach, adoption, and clinical impact of our online-intervention WEB-ED by enhancing it with electronic MHV and VA enrollment as well as SDM interfaces, supported by our prior findings from studies with Veterans.

Methods: To achieve our study aims, we will partner with the HSR&D Women's Health Practice-Based Research Network (PBRN), leveraging their research infrastructure and research/clinical relationships already in place (see Frayne letter). This study will include three phases that correspond with each study aim (see figure above). In *Phase 1* we will obtain CFIR-guided key informant feedback in order to a) refine our current WEB-ED online screening and SDM protocols, and b) conduct process mapping that documents current site-specific processes of engaging OEF/OIF/OND Veterans in VA and VA MH care as they currently exist. In *Phase 2* we will conduct a randomized controlled trial (RCT) to test the effectiveness of "Enhanced" vs. "Current" WEB-ED in increasing Veteran engagement in VA MH care and a SDM interface with their providers. In *Phase 3* we will use qualitative methods in a process evaluation to determine the acceptability of our WEB-ED+ intervention to RCT participants, their providers, and other key informants, identify facilitators and barriers to incorporating WEB-ED+ into the electronic medical record (EMR), and determine perceived differences in Veteran VA and MH care engagement based on feedback from WEB-ED+ participants and their providers.

Specific Aim #1: To obtain key stakeholder perspectives regarding refinement of WEB-ED, including enhancement with shared decision making (SDM) interventions, linkage with MyHealtheVet (MHV), and VA enrollment materials.

Phase 1 (Aim 1): Key Informant Engagement: To address Aim 1, semi-structured interviews guided by CFIR will be conducted by Dr. Sadler to obtain key informant feedback on the WEB-ED+ content which will include: 1) MHV authentication and secure messaging directions; 2) online VA enrollment directions; and two educational SDM educational videos, one for Veterans and one for providers, regarding the benefits and process involved in SDM, respectively; and 3) patient activation scores and their relationship to SDM and care engagement. To complement the qualitative data, Dr. Sadler will engage with local stakeholders and champions at each facility in order to map *clinical workflow* processes (process mapping) at each of the five study sites and determine how to best integrate WEB-ED+ into existing workflows. Process mapping is a method used to create a diagram of clinical workflow to show sequential



steps of a process.[44-45] It also identifies the personnel who are directly involved in the process, as well as critical steps and potential bottlenecks, allowing the team to eliminate unnecessary steps in the process, and suggest potential solutions to barriers that are identified. Specifically, process mapping will document current site-specific processes of engaging OEF/OIF/OND Veterans in VA and VA MH care. Dr. Sadler and team will also identify key decision points along the way that determine how efficiently and effectively these Veterans access patient-centered MH care. **Existing clinical workflow and time delays may result in an unintended consequence of attrition prior to MH care engagement for Veterans both entering and already within the VA.** Thus, mapping a clinical workflow process allows all participants to visualize and come to agreement on the process, shows unexpected complexity where simplification may be possible, and serves as an aid to understand the complete process.[44] Engagement in process mapping will also assist Dr. Sadler to obtain buy-in from key informants and to determine how to best integrate WEB-ED+ into existing workflows and real-world clinical demands. This information will further inform ways that WEB-ED+ could be optimally implemented to help facilitate patient-centered care both for those new to VA and those already enrolled. Quality implementation requires collaboration among multiple stakeholders[46] (Appendix 3). On-site visit interviews allow our research team important insights about the localized nature of health care delivery and how this might impact refinement of WEB-ED+ and its potential adoption and reach.[47] Individual interviews ensure greater likelihood of the participation of key informants at times that accommodate their schedules and equalizes the importance of information from each of them.[48] Informants can view and evolve potential SDM and EMR templates and training materials in printed versions and via laptop computer to view You Tube video clip comparisons (described in Aim 2).

Settings: Interviews with key informants (see figure) will take place at five sites (one site per each MyVA region): Region 1: Canandaigua VA Medical Center (NY); Region 2: Miami VA Healthcare System (FL); Region 3: Minneapolis VA Health Care System (HCS; MN); Region 4: Central Texas Veterans HCS (Temple) (TX); and Region 5: VA Puget Sound (Seattle) (WA). Interviews will take place in private settings. Should key informants at each site identify other individuals whom they believe can provide valuable feedback related to accomplishing our objectives at their site, e.g., women's MH champions, we will attempt to interview them as well (snowball sampling). The PBRN network as well as the number of providers at each site make their engagement feasible for this and subsequent study phases (Appendix 4).

Participants: A total of 60 interviews (12 individuals at each of 5 sites) will be conducted. Key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers (n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2), and OEF/OIF/OND Veterans (n=4-5). An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. We will use site Veteran Panels to engage OEF/OIF/OND male and female war Veterans, when possible, as well as using our Veteran registry obtained VADIR to identify Veterans who are and are not currently VA engaged, respectively. VADIR is the

VA group that interfaces with Defense Manpower Data Center to obtain sample characteristics of service members/Veterans, including postal and military e-mail addresses, and work/home telephone numbers.

Data Collection*:* Prior to implementation of each study phase, Dr. Sadler and Dr. Cook (Medical Director, VISN 23 Mental Health Service Line) will brief VISN/MyVA as well as local VA leadership at each study site about this research and its potential local impact in order to engage their support and to facilitate success. They have done this previously for their current CREATE grant, resulting in highly positive VISN and local support. Notably, the recent MyVA Access- Mental Health Breakthrough Initiative (May 2016) has required that each VA has a memorandum of understanding with MH Operations to identify a standard point of entry to Veterans new to VA, with PCMHI being the preferred entry route if possible. Consequently, Dr. Cook will facilitate obtaining this information prior to engagement at each site in order to assist our selection of key informants. It is anticipated that most sites will have PCMHI as the initial point of access to triage, assess, and treat depending on the MH needs and wishes of the Veteran. Dr. Sadler will work closely with PBRN site leads to engage providers through established processes at each site, e.g., via champions, e-mail, meetings. Following IRB and local union approval, key informants will be recruited at each of the sites with the goal of obtaining their expert opinions. A semi-structured interview guide based on CFIR domains/constructs will be used to allow staff to talk freely about their knowledge and perceptions (Appendix 5). A separate, but consistent, interview script, also guided by CFIR, will be developed for Veterans. Veteran participants will be reimbursed $40 for their time. The interviews will be completed by experienced interviewers in Dr. Sadler's CATI lab and digitally recorded when verbal consent is provided; manual notes will be taken for interviews where consent to record is not provided (which is rare in our experience). The CADRE Qualitative Team will complete verbatim transcription.

Qualitative Analysis (Aims 1 and 3): CFIR will guide the key domains/constructs queried in Phases 1 and 3 with key informants and in Phase 3 with RCT participants and providers (see below). The initial analytic approach to the interview data will use the constant comparison method, whereby we use open coding to identify salient issues and concerns raised by the participants across all of the groups. These open codes will be examined by the investigators in order to develop themes that pertain to the majority of participants, with a focus on addressing the specific aims of the study (rather than all emergent themes). These themes will also be analyzed for their potential "fit" with the CFIR model, i.e., their relevance to the concepts of intervention, outer and inner setting, individual characteristics, and implementation process. Assuming that there will be some degree of fit between emergent themes and conceptual domains, each conceptual domain will be summarized with reference to its applicability to refinements to the intervention as well as overall implementation processes. MAXQDA v12, a qualitative data analysis software program, will be used to assist this process. The codebook will be developed initially by Dr. Sadler and Dr. Hamilton with subsequent co-investigator and qualitative team independent coding of transcripts. In Phase 3 this will be specific to RCT participation (WEB-ED+ versus WEB-ED).

Specific Aim #2: To conduct a randomized controlled trial (RCT) to test differences in VA mental health (MH) care engagement in screen-positive male and female Veterans, comparing: 1) WEB-ED+ integrating secure messaging of screening results, SDM educational video clip, educational materials, and electronic medical record (EMR) SDM template vs. 2) Current WEB-ED.

Phase 2 (Aim 2): Improving Access: RCT Comparing WEB-ED+ vs. Current WEB-ED

Setting: WEB-ED+ will be implemented virtually from Iowa City to the catchment areas of 10 sites (two per MyVA regions); the 5 sites included in Phase 1 and 5 additional sites (1 per MyVA Region): Region 1: Coatesville VA Medical Center (PA); Region 2: Ralph H. Johnson VA Medical Center (SC); Region 3: Edward Hines, Jr. VA Hospital (IL); Region 4: VA Salt Lake City Health Care System (UT); Region 5: VA Sierra Nevada Health Care System (NV). All listed sites are members of the WH PBRN. Note, these sites were selected because a national sample will allow for greater understanding of process differences across VA sites and promote generalizability of findings. In addition, these sites represent: 1) rural/highly rural and urban mix; 2) high density of Veterans deployed to Iraq and Afghanistan (VA-DoD Data Identification Repository VADIR communication); and 3) racial/ethnic diversity. This community sample includes both VA enrolled/users and non-VA Veterans who are eligible for and entitled to post-deployment VA care.

Population: Our target population is OEF/OIF/OND male and female Veterans eligible for VA care, which we will randomly sample from two overlapping populations. The first group includes those who returned from deployment to Iraq or Afghanistan within the preceding four years and who reside within the catchment areas of one of our 10 study sites (identified by zip code). We want to ensure that those who participate and screen positive on one or more of the screens have access to VA care. Consequently, we have selected the time frame of four years post-deployment because these Veterans have priority access to VA care for five years after their most recent deployment. The second group is OEF/OIF/OND Veterans who are already enrolled in VA care and will not be excluded if they have been home from deployment more than four years. The VA Informatics and Computing Infrastructure (VINCI) provided exact numbers of OEF/OIF/OND Veterans seen at each of our 10 sites: ~238K (202K male/37K female). Overlap will potentially occur among those enrolled in VA care and home from deployment less than four years, therefore we will not stratify sample on this variable, but will take care that the same Veterans [name, sex, age, address] are not sampled twice. Our prior studies have found that approximately half of WEB-ED participants are already VA enrolled, although few have sought MH care. Among those who screened positive on WEB-ED, only 14% had received VA MH care prior to study participation. We do not anticipate any problems recruiting sufficient numbers for our sample as less than 1% of VA users would need to participate to reach our recruitment goals. However, if we need to enhance our recruitment efforts, we will do so by adding additional PBRN-affiliated sites

Sample Identification and Recruitment: We will work with VADIR to obtain contact information and military characteristics for OEF/OIF/OND service members. VADIR is able to provide mailing, phone, and military addresses as well as sociodemographic (e.g.,

age) and service information (e.g., rank, number of deployments). We have used VADIR military and sociodemographic data to augment our primary data collections, reduce participant burden, and analyze differences between responders and non-responders. VADIR and Dr. Sadler have a successful working relationship for her current CREATE and three prior grants. We will also work with VA enrollment data and the VA OEF/OIF/OND roster to obtain similar data identifying post-deployed Veterans who have VA care access. We have learned from our prior grants that study participation is maximized when potential participants are postal mailed a study packet (study materials, informed consent document, the web-based study link, and notification that we will also be sending an email in the next few days) and then contacted by email. Non-responders will be re-contacted in 10 days following initial mailing. Our previous work has found that response rates, screening outcomes, and care activation are similar between male and female participants in studies focused specifically to either gender. We will institute adaptive randomized sampling to insure that neither male or female participants are less than 25% of the total sample.

Current WEB-ED screening (Appendices 6-12): All study participants will be asked to complete the online survey and screenings and be provided with their results, tailored educational information, and key points of contact at the VA geographically closest to them (i.e., Current WEB-ED). Pharos Innovations has provided this online interface for all of Dr. Sadler's prior online studies and will for this proposed research if funded. Documentation of informed consent for Phase 2 participation (WEB-ED) is integrated into the web-based interface ("click approval"). Participants receive a hardcopy version of the consent form in the study packet and can read a copy online. This process has been approved in five prior projects using WEB-ED. The consent document will also inform participants that they may be invited to participate in the subsequent study phase that addresses VA and post-deployment care access. WEB-ED includes a **brief pre-intervention survey** that will query stigma associated with MH care, prior and current utilization (VA and non-VA; primary care, MH, emergency) and their reasons for accessing VA or not, knowledge about post-deployment VA eligibility, services and satisfaction with VA care, potential barriers to MH service use, and their use of or barriers to MHV and secure messaging. Those who meet screening criteria for MH conditions and readjustment concerns receive online notification and a recommendation for a face-to-face evaluation, education about each MH domain for which there is a positive screen, and information about access to care. Patients who may have immediate needs will also be provided with specific VA resources, contact names and numbers, as well as information for providers or resources unique to their needs and geographic locations. The 24 hour Veterans Crisis Line (1-800-273-TALK (8255)) will be provided. Patients with negative screens will be informed to seek care if they believe that it is needed. We note that neither our research team's studies using focus groups and telephone interviews with more intensive questions about sexual assault or combat experiences in deployed populations, nor our prior web-based intervention studies, have resulted in any subsequent clinical emergencies. Veterans who have no positive screens will be able to access the same educational information, web links, and video-clips if they choose. **Data security:** Study data and linkage study ID number will be maintained in a locked and limited access research network electronic file

behind the VA firewall. Screens will include the following (those that are **mandatory VA screens currently used in face-to face contact with patients are bolded**):

MH and Trauma Exposure Screens:

1. ***PTSD -*** VA Post-Traumatic Stress Disorder (PTSD) Screen.
2. *Domestic Violence* (DV) - American College of Obstetrician and Gynecologist screen for DV. This was modified to include parallel questions that query participant DV perpetration.
3. *Family Readjustment*- developed from PI's focus groups from another HSR&D funded study.
4. ***Substance Abuse*** - AUDIT-C Substance Abuse Screen.
5. *Prescription Drug Abuse*- DoD Survey of Health Related Behaviors modified for the web.
6. ***TBI*** - VA Traumatic Brain Injury (TBI) Screen, modified to include more descriptive questions.
7. ***Depression*** - Physician's Health Questionnaire (PHQ-8) depression questions (suicide question omitted).
8. ***Anger-*** Dimensions of Anger Reactions (DAR5) Scale.[49]

Trauma Exposure Screens

9. ***Combat Exposure*** - Exposures to Combat Screen.[50]
10. ***Sexual Trauma*** - VA Military Sexual Trauma Screen.

Other:

11. *Patient Activation Measure-13* - 13-item measure of patients' self-report of their health management skills, knowledge, confidence, and motivation.[51] The PAM score will not be considered as a MH indicator but instead a measure associated with access and SDM interface associated with Aim 2 and 3 outcomes.
12. *CollaboRATE* - 3-item measure of the SDM process[52] tailored to the provider or TPA.
13. *Social Determinants of Health Questions* - 6 items[53] that address social needs including: food, housing, finances, and ability to get to medical appointments.

A web-based **satisfaction survey** immediately follows screening and tailored education. In addition to questions about barriers and facilitators to access to care, satisfaction with an online process, and ways that we can make Veterans more satisfied with this screening and educational interface, we will also ask questions from the **SHEP ambulatory care** 2015 survey pertinent to study domains (provider and VA interface satisfaction for outpatients), e.g., did your provider: 1) tell you there was more than one choice for your treatment or care; 2) talk with you about the pros and cons of each choice for your treatment, 3) ask which choice was best for you, 4) listen carefully to you. Our prior studies found most participants completed the screening and education on the same day (92%; mean 26 minutes/median 17 minutes). Participants will be reimbursed $30.00 for WEB-ED completion and an additional $20 for returning their HIPAA and consent forms allowing for subsequent VA chart review and interface with the Veteran's VA provider (Phase 3), inclusive of VA-purchased care from non-VA providers (e.g., Choice, fee-basis). These forms will be made available electronically if Veterans choose to print them and return them to the provided address, and we will automatically send a pre-stamped envelope with the consent document using our established recruitment protocols. A toll-free number will be provided to participants to facilitate contact for any questions or to decline

participation. Note, subjects who engage in WEB-ED+ interfaces will not receive additional reimbursement.

RCT Recruitment and Assignment: Veterans who screen positive on one or more MH screens will be eligible for the RCT and asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT. Those who indicate yes will be sent IRB-approved study information. Those who decline will be thanked again for their participation and contact will be discontinued. We will use adaptive randomization to assign those who consent to WEB-ED+ or Current WEB-ED. Those who are assigned to Current WEB-ED will not be contacted again until Phase 3.

WEB-ED+ augments Current WEB-ED in a next step online interface via Pharos. If successful, this enhancement could be integrated into the next iteration of WEB-ED. Enhanced WEB-ED information and process will be guided and refined by Phase 1 findings as will the preferred means of providing SDM educational YouTube videos and training materials. Enhancements include: **1.** An **eHealth interface** tailored to Veterans' VA and MHV enrollment needs, links for an electronic interface with VA enrollment, MHV and MHV premium status enrollment, and secure messaging guidance (Appendix 13). **2.** A **shared decision-making (SDM) interface** **Veteran SDM-**related educational (e.g., existing YouTube videos) and structured questions about treatment concerns, preferences, and questions and can be accessed through postal and email distribution or Pharos portal. **Provider/TPA SDM** is accessible in the same avenues identified for Veterans. If a TMS training format is preferred, this can be created and accessed the Pharos interface. As presented to key informants in Phase 1, the SDM training models to consider are: 1) The Dartmouth Center for Health Care Delivery Science model that consists of Choice talk, Option talk, and Decision talk about each treatment option and guided by treatment decision aids,[55] and the AHRQ SHARE approach that encourages SDM processes that include: exploring and comparing the benefits, harms and risks of each treatment option through dialog about what matters most to the patient (Appendices 14-18). These models represent an informed choice model of care as opposed to a paternalistic model focused on the patient in a "sick role."[56] The University of Iowa (UI) consultants (see Syrop and Hansen letters), experienced in SDM engagement and training of providers and patients and EMR documentation, will assist us. **The WEB-ED+ Veteran and Provider/TPA SDM interface** (Appendix 19): To return with the informed consent, Veterans will be asked to identify their primary provider. Or, if they are not VA enrolled or have no current provider, the study team will link participants with a TPA at the geographically closest VA. As a minority of Veterans participating in our prior WEB-ED studies have engaged VA MH care, we anticipate this will be a PC provider. If a MH care provider is identified, we will follow the same study process. The Veteran along with their partner provider or TPA will receive information by postal and e-mail outreach by the study team followed by a telephone contact from the Health coach within 10 days of initial outreach. The e-mail will also include a link to a training video that they can access with a unique identification # that will allow them to access a YouTube video about SDM (or TMS type interface). This link is contained in our research network behind the VA firewall which will allow us to determine if the Veteran and Provider/TPA team opened the link and for how long. All **Veterans** will

complete SDM questions online via the Pharos interface where they will also be clearly instructed through the eHealth interface tailored to their unique needs, with resulting secure messaging of screening and SDM results to their provider/TPA. In the **provider/TPA** email we will inform them about the study, what to expect, and encourage engagement but remind them that participation is voluntary. We will also include our toll-free number so the health coach can address any questions or provide additional information. **Study communications will encourage the provider to watch the SDM video (vs TMS-like interface), to review SDM materials (e-mailed or accessible online with a link), to perform SDM with their patients, and to document this SDM interface in CPRS, preferably guided by the SDM template provided in the secure messaged materials from the Veteran and/or provided by the research team**. *We will be clear to both Veteran participants and their providers that it is up to each provider's discretion to decide if and how they wish to participate.* Providers will receive no financial compensation for their participation. However, we will identify in Phase 1 if there is any form of recognition locally or nationally that they would consider of value, e.g. certificate of completion, Hospital Director's letter of appreciation. **3) Access to a health coach** (our research coordinators) will be available through a toll-free number to assist both Veterans and providers/TPAs. They will initiate contact to consenting Veterans and their partnered provider/TPA who are placed in the WEB-ED+ treatment arm both at the initiation of the RCT and prior to Phase 3. Study protocols and checklists will be employed in order to characterize participant and process needs. For study convenience and to minimize burden on staff at study sites, the health coaches (research coordinators) will essentially be carrying out functions that already fall under the purview of existing VA staff (e.g., VA care managers, providers, MHV champions, TPAs). In the event of a possible national dissemination, these functions will be resumed by existing staff in their respective roles but with the benefit of our study findings to assist them. Our results will be especially useful given changes in care access with My VA MH Access transitions. Consequently, the health coach is an FTEE neutral role should a national dissemination result from this work. As Dr. Turvey has done with her prior studies, ***our health coach will also have the authority to authenticate Veterans to expedite the MHV process*.** This will also allow us to overcome site-to-site variability in MHV enrollment and authentication timelines (that can take up to 20 days). Online VA enrollment takes approximately two days for verification. Unlikely difficulty with secure messaging can be addressed by the health coaches who are able to upload results directly into the CPRS.

4) Chart review: VA health services utilization will be obtained from VA chart review for all consenting participants. Utilization measures will include: enrollment in VA, MHV enrollment, secure messaging of results, initiation of telephone or face-to-face contact with a provider or TPA interface about screens or secure messaged results, and MH consult sent or services receipt and location (in PC, PCMHI, or MH). We developed an efficient electronic and chart reviewer interface in our CREATE study, which will be leveraged for this study. The VA EMR will be electronically checked monthly for up to 6 months following WEB-ED completion. Chart reviews will encompass VA purchased care records (inclusive of non-VA provider care received via Choice).

Aim 2 Sample Size and Power: We will aim for 2000 Veterans completing WEB-ED, with approximately 1100 completing the RCT. Not all 2000 will be eligible for the RCT. Based on our five prior studies, ~77-85% of WEB-ED participants screened positive on at least one of the MH screens (~70% screened positive on depression, PTSD, or substance use). We will assume that 70% will eligible for the RCT (~1400) and use adaptive randomization to assign positive-screeners to each RCT arm; two-thirds to WEB-ED+ (~950) and one-third to Current WEB-ED (~450). There are no additional RCT participation activities for those in the Current WEB-ED arm, therefore attrition would be minimal. However, we anticipate there may be attrition among those assigned to WEB-ED+. Our CREATE multi-phase study resulted in attrition of ~30%. Therefore, we expect 650 completers for WEB-ED+. We have increased this sample size to have sufficient power to detect differences per RCT arm. This study is powered to detect whether WEB-ED+ increases VA MH care engagement compared to Current WEB-ED. In our prior work, half indicate that as a direct result of WEB-ED, they will follow up with a provider and 38% with a VA provider, although actual follow-up may be lower (our CREATE study is currently validating participant self-report with chart review data). This proposed study will document VA utilization (including VA purchased care) by VA chart review. We estimated the minimum sample size needed to ensure adequate power (80%) for a variety of assumptions (percentage of Current WEB-ED participants engaging in VA MH care, effect (odds ratios), and variance inflation factors (VIF)[57], using nQuery 4.0. We anticipate random assignment will result in no statistical differences between RCT arms based on WEB-ED data (e.g., prior enrollment in VA, positive screens). However, covariates will be included (e.g., gender, rurality, patient-activation scores, VA site) in multivariate analyses to control for variation due to these other variables. Any significant covariates may point to sources of variability to explore in future research efforts, but we do not anticipate having sufficient power to conduct subsample analyses by gender or VA site.

Estimates of Total Sample Size for 80% Power based on Varying Assumptions

	% assigned to Current WEB-ED who engage in VA MH Care*								
	25%			30%			35%		
OR	No VIF	VIF=0.2	VIF=0.3	No VIF	No VIF	VIF=0.3	No VIF	VIF=0.2	VIF=0.3
1.5	834	1043	1191	759	949	1084	714	893	1020
1.8	387	484	553	354	443	506	336	420	480
2.0	237	296	339	252	315	360	240	300	343

Aim 2 Analyses: We will begin with bivariate analyses (i.e., chi-square test for proportions) to test significance of differences in care engagement between RCT arms. Care engagement is the primary outcome and will be operationalized by VA MH services receipt (yes/no). Our primary analyses will use logistic regression models to estimate the adjusted ORs for treatment engagement controlling for participant characteristics. The logistics regression models will provide an estimate of the association between health care engagement by RCT arm, controlling for covariates such as Veteran gender, prior VA enrollment, severity [screening scores] and complexity [multiple positive screens], patient-

activation scores, and rurality. Potential confounding variables that will be assessed in all hypotheses include socio-economic variables (e.g., age, income, marital status), and military characteristics (e.g., months home from deployment, rank). In addition, depending on the resulting proportions of Veterans who get care in various VA clinics (i.e., PC, PCMHI, MH), we plan to conduct a multinomial logistic regression, treating RCT-arm as a covariate. We have used multinomial logistic regression previously to examine associations with three levels of VA health care use (all, some, none).[58]

Specific Aim # 3: To elicit feedback from key stakeholders in both arms of the RCT (Enhanced vs. Current WEB-ED) regarding 1) the usefulness of an eHealth process of interface, and 2) perceptions of how WEB-ED+, including SDM, influenced patient access to and efficiency of VA patient-centered care delivery, and 3) Veteran and provider satisfaction; and to document the VA processes Veterans used to enroll and engage in VA care.

Phase 3 (Aim 3). Process Evaluation: This phase will consist of a process evaluation to include RCT participants and providers. This is necessary to determine effectiveness of the combined process of an eHealth interface supporting secure messaging of MH information and consequent communication with providers by determining the enhanced: acceptability, "buy in" among Veterans and VA providers, utility in facilitating SDM to support patient-centered care, improvement of efficiency of MH care access and engagement that is patient-centered, and potential barriers and facilitators to sustainability of Enhanced WEB-ED.

Participants: Post-intervention process evaluation will rely on data collected via Computer-Assisted Telephone Interview (CATI), with which our team has extensive experience. We will recruit 76 Veteran participants, and all Veteran-identified VA providers who agree to participate. We will use 3:1 sampling as shown above. It is anticipated that in each of the four groups ("Engaged in VA Care" column) we will have appropriate representation of gender and racial/ethnic groups, but we will monitor this and use purposeful sampling if needed. Fewer numbers of those who did not engage in VA care reflects our expectation of less variation in subgroup data. As we do monthly EMR checks of participants, we will be able to identify provider/TPA interface initiated following WEB-ED and attempt to initiate contact within the month following RCT interface or at 6 months post-RCT vs post-WEB-ED if they have not. We will use a convenience sample of those in each identified comparison group (see above figure) who are first able to be contacted by the study research coordinator or trained research interviewers by telephone.

Recruitment: To contact **Veterans**, the study coordinator will use an IRB-approved call contact protocol, varying times of day and days of week (used successfully by this team) and conduct an approximately 25-minute semi-structured qualitative interview with consenting participants using CATI data collection. In addition, up to two postal mail recruitments will be sent with information, a return postal card indicating preferred contact times or preference to discontinue participation. All participants recruited will be asked for confirmation of their VA care engagement or not, and their current level of distress with current post-deployment readjustment. Veterans will be reimbursed an additional $50.00 for their time and effort to participate with this study phase. **Providers**

will be recruited for participation by e-mail invitation and a response template that allows them to identify a time they would like to be interviewed, a toll-free number so that they can initiate contact themselves, and an option that identifies they would not like to be contacted. VA employees will receive no financial remuneration for their time and effort. However, in Phase 1 we will determine if there are any other non-financial rewards that would be meaningful to them.

Data collection: Semi-structured interviews with qualitative and survey questions will be implemented from Dr. Sadler's CATI laboratory, with established data security and interviewer training/monitoring protocols in place for a decade. Guided by CFIR, we hope to understand participants' perceptions of the intervention to which they were assigned with regard to ease and usefulness, need for improvements, and perceptions of barriers/facilitators to VA and MH services receipt or provision. We will interview both those who did/did not subsequently engage in the eHealth process/secure messaging and among these groups those who did/did not engage in VA MH care consequently. **WEB-ED+ Veteran Participants** will be asked about their use of secure messaging, VA provider engagement, satisfaction with use of WEB-ED results, if their VA provider participated in SDM with them, and satisfaction with the type of care they received. Those not activated to participate in VA care or who did not secure message results will be asked about barriers/facilitators to this process and how we might improve this interface or MH engagement. **Current WEB-ED Veterans** will be asked the same questions except for those specific to WEB-ED+ (Appendix 20). Participants from both RCT arms will be asked about satisfaction with process and care (if sought). **Process Mapping:** A brief *Veteran process map* will be developed from the Veteran's perspective to show whether each step of the WEB-ED RCT process helped create a clear value for them as a care customer or not. Provider/TPAs will be asked parallel questions to the Veterans, respective to each treatment arm. A *Provider process map* will be developed to help us understand the specific roles of individuals in the overall system of care, i.e. the # of teams involved, if there are bottlenecks and delays, rework that occurs in facilitating war Veterans' access to patient-centered MH care, and the potential system impact of WEB-ED+ and perceived value to the provider/TPA. **Satisfaction**: Questions included in the CATI interviews for *Veterans* will include questions from the **SHEP Ambulatory Care 2015 Survey** (as detailed previously). The SDM interface will be further evaluated by **CollaboRATE**, 3-item measure of the SDM process.[52] These include: "How much effort was made to: 1) help you understand your MH issues, 2) listen to the things that matter most to you in your MH issues. and 3) include what matters most to you in choosing what to do next".

OMB Considerations*:* Our prior QUERI and VA HSR&D CREATE studies that serve as the foundation for this proposal were exempt from OMB review since the survey and collection of information being conducted was research to prevent a clinical disorder (identified as a basis for exemption under 5 CFR 1320.3). We anticipate that this will be the case with this study as it addresses prevention of chronic post-deployment MH and social issues entrenchment (e.g., SUD, social determinants). We readily obtained OMB exemption for our HSR&D and DoD funded studies with similar domains in OEF/OIF/OND service members.

Study Feasibility: 1) We are confident of this study's feasibility given the relatively small

sample size needed from the national sampling frame and density of Iraq and Afghanistan war Veterans in these areas, following our current correspondence with VADIR. Given national security concerns, VADIR data is not available until study funding. Therefore, once proposed funding is approved, we will work with VADIR to have a sample consistent with current OEF/OIF/OND post-deployment populations. **2)** VADIR oversees the registry of actively serving and Veteran military members and Dr. Sadler has had a fruitful working relationship with them for four studies, successfully obtaining and updating contact information for deployed study populations. **3)** Our CREATE study findings demonstrates the feasibility of engaging Veterans who participated in WEB-ED into multi-phase SDM, telephone interface, and chart reviews. **4)** This study is also feasible because of our successful relationship with Pharos, the corporation that assists with the web-based implementation and has a dedicated research server behind the VA Firewall. Pharos follows standards for Section 508 compliancy, therefore allowing future accommodation of Veterans with disabilities should there ultimately be a MHV interface. **5)** The VA EMR allows for accessible chart review confirmation and this team is well experienced in interfacing with the national chart review system through CAPRI and VISTA WEB with special research user permission obtained via DART. **6)** The WEB-ED+ technology linkage is feasible. Through MyVA transformation efforts, improved online enrollment was initiated June 30, 2016 resulting in a rapid and user-friendly enrollment process. Furthermore, our health coach will have the authority to expedite Veteran authentication. **7)** The Women's PBRN infrastructure assures successful interface with key informants, in particularly providers, as does the sufficient number of providers at study sites.**8)** Lastly, this research team is uniquely poised to conduct this research, building on a strong track record of success with deployment-related health, application of mixed quantitative and qualitative methods, SDM, and implementation research, along with our expertise in developing cutting edge web-based interfaces to facilitate access to VA care.

5.0 DISSEMINATION PLAN

Dr. Sadler will work closely with Drs. Cook and Kudler (MH), Ms. Capra, MPH (Rural Health), Ms. Kennedy (National VA Care Management), Dr. Turvey (MHV), Dr. Frayne (PBRN), Dr. Fortney (Virtual QUERI); and HSR&D research leadership to facilitate dissemination of findings to respective groups and integration of products into relevant VA initiatives to improve Veterans access to care and address unmet need for MH care (see following table). Dr. Nazi will be highly instrumental in determining next steps with MHV. Dr. Sadler will also communicate findings in her roles as a committee member of the VA/DoD Health Executive Committee Women's Health Work Group that deals with VA-DoD transitions in care, and the VA Office of Care Management and Social Work Integrated Case Management Mode of Care Task Force. Dr. Sadler and her team will present preliminary data at national level research meetings, such as Academy Health and VA HSR&D. They will submit articles to germane peer reviewed journals, such as *Journal of Traumatic Stress, American Journal of Preventive Medicine,* and *Health Services Research*.

eSDM

PI: Anne Sadler
IRB ID #: 201708746

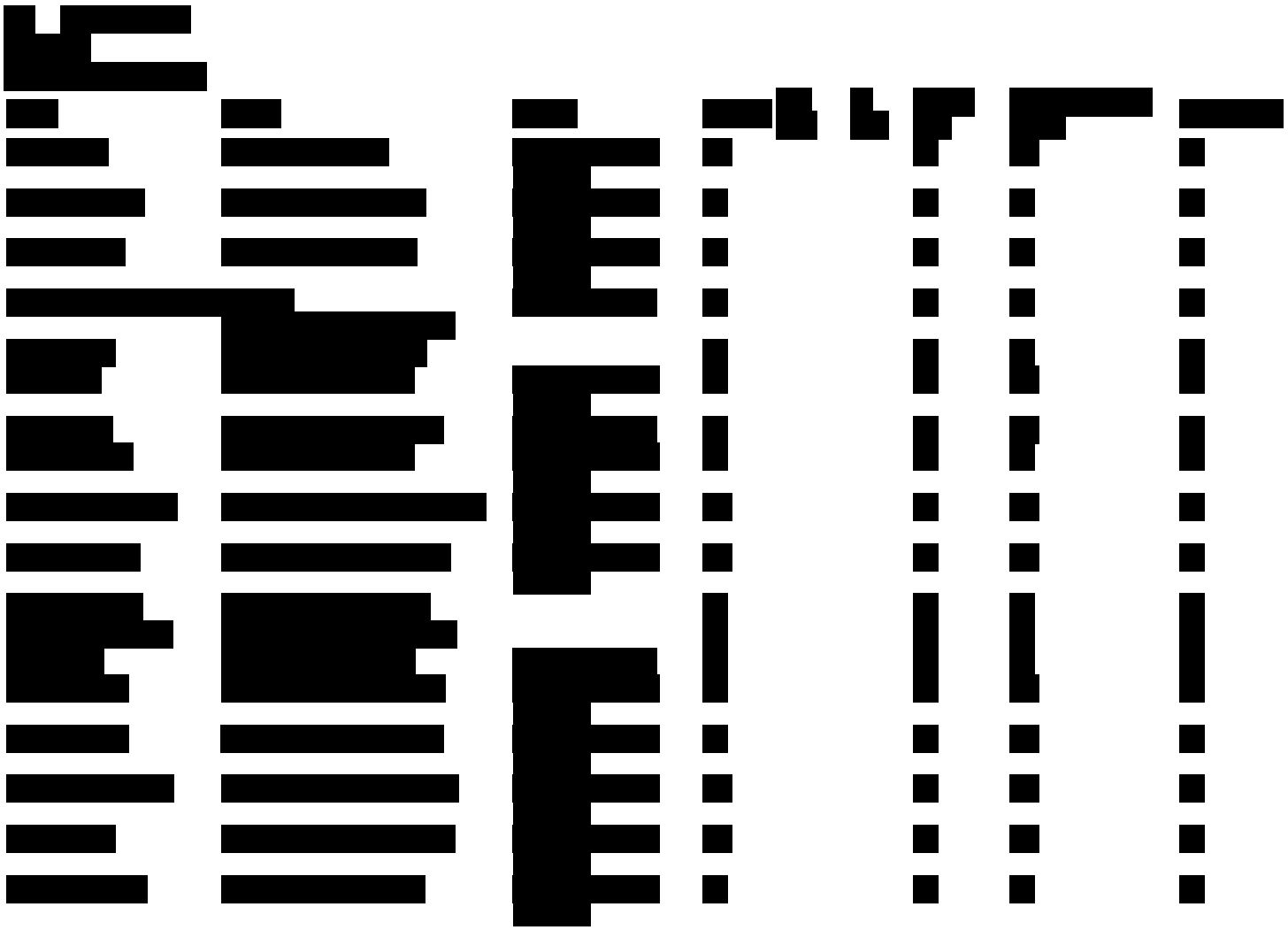
Other Mod and/or Comments

Per VA Research project modification approval received November 2022 (attachment: ORD-ProjectModification_Sadler_IIR_16-096_September2022_rwob for LC sig-lmc.pdf), we are now able to provide subjects with an additional $30 for already returned signed HIPAA form and consent to participate with this study phase. We will notify previous subjects using attachments (Phase 2 New Reimbursement postal mail and Phase 2 New Reimbursement email), and submit this request, anticipating that they should receive this direct deposit within 4 to 8 weeks. For new RCT recruitments we have edited the Phase 2 RCT recruitment to indicate that if they return their signed HIPAA form and consent to participate in this study phase they will received $50.00 (the same amount as those who have already returned these forms will receive). In the attachments 'RCT Intervention Assignment Letter.rtf' and 'Recruitment Scripts.docx,' we have added text describing the additional compensation we are now able to provide, as well as to let subjects know when activities for the study need to be completed. We updated the text for the Follow up Script Phase 2 RCT – No appointment follow-up call at 6 and 10 weeks, as well as the VA Provider Invitation Script for Teams (information summarized from above telephone script and approved email the provider will have already received) to include responses to frequently asked questions from providers. The reimbursement follow up script has been edited to reflect the increased compensation amount we are now able to provide to subjects.

Because of new VA research policy changes, we are now also able to provide subjects with an additional $75.00 upon completion of the RCT “intervention group” steps of this research phase that involves seeing their VA provider (as described in the consent and the encrypted study group assignment email).

The chart review (as described in section VII.E.6) template has been attached. We have made changes to existing RCT attachments to reflect these changes, and added the chart review template, added Dan Corry to the research team, as well as removed Michala Cox from the research team since she no longer works with VA. We also removed Samantha Solimeo from the research team as she no longer works on the project.

Modifications



[redacted]

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

Old Value

Phase 1: A total of 60 interviews (12 individuals at each of 5 sites) will be conducted. Key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers(n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2) and OEF/OIF/OND Veterans (n=4-5). An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. We will use site Veteran Panels to engage OEF/OIF/OND male and female war Veterans when possible, as well as using our Veteran registry obtained VINCI/VADIR to identify Veterans who are and are not currently VA engaged, respectively. Due to delays related to COVID-19, the research team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase. VINCI is a partner with the Corporate Data Warehouse (CDW) and hosts all data available through CDW as well as some unique data. VADIR is the VA group that interfaces with Defense Manpower Data Center to obtain sample characteristics of service members/Veterans, including postal and military e-mail addresses, and work/home telephone numbers. In phase 1, we will also develop a template for use in the VA electronic medical record to document the shared decision-making interface that is a component of our intervention for those in the RCT treatment arm (WEB-ED+). This will be an important material reviewed by our key informants in Phase one interviews. Prior to these interviews, this template will be developed with the assistance of study consultants who have developed templates for shared decision making documentation in a university health care setting and with assistance and with the guidance and initial consultation and prior approval from key VA offices, e.g. National VA Privacy office.

Following IRB approval, Consolidated Framework for Implementation Research (CFIR) guided qualitative interviews will be conducted by Dr. Sadler and other research team members (Cook, Steffensmeier) to determine key informant critiques of the WEB-ED+ content that will include: 1) MHV authentication and secure messaging directions; 2) online VA enrollment directions; and educational shared decision-making (SDM) educational videos, one for Veterans and one for providers, regarding the benefits and process involved in SDM respectively (video links (unlisted, only accessible via links: Shared Decision-Making SDM-Non-SDM https://youtu.be/9Exh5qm2D4s; Shared Decision-Making ‘Veterans’ https://youtu.be/FaevM-mTJtU; Shared Decision-Making ‘Providers’ https://youtu.be/xETkUedZ2N4); 3) decision aids for PTSD, depression and substance use disorder for use by patient and provider, and 4) patient activation scores and their relationship to SDM and care engagement. Dr. Cook and Dr. Sadler will engage top leadership at each study site as well as work with the Women’s Practice Based Research Network leadership site leads at each facility to promote communication and engagement at each VA. To complement the qualitative data, Dr. Sadler will engage with local stakeholders and champions at each facility in order to map clinical workflow processes (process mapping) at each of the five study sites and determine how to best integrate WEB-ED+ into existing workflows. On-site visit interviews allow our research team important insights about the localized nature of health care delivery and how this might impact refinement of WEB-ED+ and its potential adoption and reach. Individual interviews ensure greater likelihood of the participation of key informants at times that accommodate their schedules and equalizes the importance of information from each of them. These interviews will be recorded, and this will be explained during the consent process prior to the start of the interviews. The following attachments will be sent in the following order: Phase 1 Confirmation Email; 2. Interview Direction Email; and 3. Link Email. Phase 1 Confirmation Email is sent immediately after interview is scheduled to confirm date and time of interview. Interview Direction Email is sent after to explain the interview protocol and to allow adequate time for questions. The Link Email is sent 24-hours before the scheduled interview, this email has the link to follow to watch the study video and the access number to the VANTS line. This is to

increase the fidelity to the interviewee's first time watching the Shared Decision-Making video while on the VANTS conference call with the interviewer.

Phase 2: Participants will include two overlapping populations of OEF/OIF/OND male and female Veterans eligible for VA care, which we will randomly sample from two overlapping populations. The first group includes those who returned from deployment to Iraq or Afghanistan within the preceding four years and who reside within the catchment areas of the current PBRN study sites (identified by zip code). We want to ensure that those who participate and screen positive on one or more of the screens have access to VA care. Consequently, we have selected the time frame of 4 years post-deployment because these Veterans have priority access to VA care for five years after their most recent deployment. The second group is OEF/OIF/OND Veterans who are already enrolled in VA care and will not be excluded if they have been home from deployment more than four years. We are doing purposeful sampling to achieve sufficient numbers of men vs women and we will work with VINCI/VADIR to have a sample representative by gender and race consistent with the current OEF/OIF/OND post-deployment populations.

All study participants will be asked to complete the online survey and screenings and be provided with their results and tailored educational information. Documentation of informed consent for Phase 2 participation (WEB-ED) is integrated into the web-based interface ("click approval"). Participants receive a hardcopy version of this form containing the elements of consent in the study packet and can read a copy online. This process has been approved in five prior projects using WEB-ED. The consent document will also inform participants that they may be invited to participate in the subsequent study phase that addresses VA and post-deployment care access. WEB-ED includes a brief pre-intervention survey that will query stigma associated with MH care, prior and current utilization (VA and non-VA; primary care, MH, emergency) and their reasons for accessing VA or not, knowledge about post-deployment VA eligibility, services and satisfaction with VA care, potential barriers to MH service use, and their use of or barriers to MHV and secure messaging. Those who meet screening criteria for MH conditions and readjustment concerns receive online notification and a recommendation for a face-to-face evaluation, education about each MH domain for which there is a positive screen, and information about access to care. Patients who may have immediate needs will also be provided with specific VA resources, contact names and numbers, as well as information for providers or resources unique to their needs and geographic locations. The 24-hour Veterans Crisis Line (1-800-273-TALK (8255)) will be provided. Patients with negative screens will be informed to seek care if they believe that it is needed. We note that neither our research team's studies using focus groups and telephone interviews with more intensive questions about sexual assault or combat experiences in deployed populations, nor our prior web-based intervention studies, have resulted in any subsequent clinical emergencies. Veterans who have no positive screens will be able to access the same educational information, web links, and video-clips if they choose.

A web-based satisfaction survey immediately follows screening and tailored education. In addition to questions about barriers and facilitators to access to care, satisfaction with an online process, and ways that we can make Veterans more satisfied with this screening and educational interface, we will also ask questions from the SHEP ambulatory care 2015 survey pertinent to study domains (provider and VA interface satisfaction for outpatients), e.g.: 1) did their provider tell you there was more than one choice for your treatment or care; 2) talk with you about the pros and cons of each choice for your treatment, 3) ask which choice was best for you, 4) listen carefully to you.

Phase 2 RCT Intervention (WEB-ED+) Veteran Procedures: Veterans who screen positive on one or more MH screens will be eligible for the RCT and asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT. Those who indicate yes will be sent IRB approved study information, including the RCT consent letter (2B), consent and HIPAA forms attached to this application. A summary of the screening results will be sent by encrypted email (attachment Phase 2 encrypted email - treatment arm RCT.rtf) to Veterans in the RCT treatment arm (WEB-ED+). An email will be sent in advance of this to alert Veterans that they will be receiving secure information by encrypted email. Additionally, Veterans will be asked to indicate which screening results bother them the most that they would like to talk with their provider about (To share with Provider). Veterans are asked to return that form along with their signed consent forms. Phase 2 Thank you letter-returned forms will be used to thank participants for returning their signed consent and HIPAA authorization forms.

To receive care in the VA health care system, Veterans must enroll in the VA system. Online VA enrollment links and information (available to every Veteran) will be provided to help RCT participating Veterans with this process. If they are unable to enroll electronically, key points of contact at the VA geographically closest to them will be provided so they can receive assistance with this process. Additionally, enrollment in My HealtheVet (MHV), a secure online ehealth portal, allows Veterans to access their medical records and send secure messages to their VA providers. As part of the RCT, participants will be asked to secure message their screening results summary to the VA provider of their preference. If they are new to the VA, enrolling as a result of the RCT participation, their newly assigned provider will be the individual that they will be asked to secure message their screening results summary. Note, that the study team will be monitoring enrollment and provider assignment of Veterans new to the VA and will invite the provider as soon as the assignment is made. If needed, the study team will be available to secure message the screening results, rather than the Veteran.

Phase 2 RCT Intervention (WEB-ED+) Provider Procedures: once the provider has agreed to participate, they will be sent an email that contains links to 2 short videos about shared decision-making and three brief decision aids (PTSD, depression, substance use disorder).

Using the knowledge both the provider and patient learned from the WEB-ED+ materials, they will discuss treatment options at the patient's appointment.

If subjects do not complete steps in the process, the appropriate attachment (Phase 2 RCT missing VA enrollment, Phase 2 RCT missing MHV premium enrollment, or Phase 2 RCT missing secure messaging) will be sent via email or postal mail if email is not available to support completion of these steps, with a toll free number provided. Further, up to 3 contact calls will be made until the subject is reached, to determine if the participant has discontinued study participation, if the study team can be of further assistance, or to determine the completion barrier(s), and if the Veteran is enrolled- to assist them with MHV barriers by sending the study screening results summary by encrypted email to the participant's preferred or new provider in their stead (eSDM Chart Review-Secure Message) so they are able to progress to their appointment in order to use shared decision-making with their provider about their positive MH screens. Requested Resources Email Scripts will be sent per request of subject as needed. The missing email notice attachment will be used for those in the treatment arm of RCT to encourage them to contact us and update their email address so we can continue their participation with the study. The provider consent notification document will be sent via mail or email letting the participant know that their provider has consented to participate in the RCT.

Those who decline will be thanked again for their participation and contact will be discontinued. We will use adaptive randomization to achieve balance in the assignment of those who consent to WEB-ED+ or Current WEB-ED. Those who are assigned to Current WEB-ED will not be contacted again until Phase 3.

If subjects do not complete the screening, attachments Phase 2G Incomplete Survey Email and Phase 2H Incomplete Survey Letter will be sent to encourage completion.

A medical chart review will be conducted for the subjects who return the signed HIPAA and consent forms for the RCT and prior to the interview for phase 3. Chart reviews will focus on VA outpatient care the subject received (or not) including medication, therapy, & substance use treatment. We will review the time from post-deployment through 6 months after the subject's initial study participation. We will assess/confirm enrollment status and upcoming appointments of participating Veterans using a combination of national visual chart review using CAPRI/JLV, along with accessing enrollment and appointment data from the CDW.

Phase 3: Post-intervention process evaluation will rely on data collected via Computer-Assisted Telephone Interview (CATI), with which our team has extensive experience. We will recruit 76 Veteran participants, and all Veteran-identified VA providers who agree to participate. We will use 3:1 sampling. It is anticipated that in each of the four groups, we will have appropriate representation of gender and racial/ethnic groups, but we will monitor this and use purposeful sampling if needed. Fewer numbers of those who did not engage in VA care reflects our expectation of less variation in subgroup data. As we do monthly EMR checks of participants, we will be able to identify provider/TPA interface initiated following WEB-ED and attempt to initiate contact within the month following RCT interface or at 6 months post-RCT vs post-WEB-ED if they have not. We will use a convenience sample of those in each identified comparison group, who are first able to be contacted by the study research coordinator or trained research interviewers by telephone.

Semi-structured interviews with qualitative and survey questions will be implemented from Dr. Sadler's CATI laboratory, with established data security and interviewer training/monitoring protocols in place for a decade. These interviews will not be recorded. Guided by CFIR, we hope to understand participants' perceptions of the intervention to which they were assigned with regard to ease and usefulness, need for improvements, and perceptions of barriers/facilitators to VA and MH services receipt or provision. We will interview both those who did/did not subsequently engage in the eHealth process/secure messaging and among these groups those who did/did not engage in VA MH care consequently. WEB-ED+ Veteran Participants will be asked about their use of secure messaging, VA provider engagement, satisfaction with use of WEB-ED results, if their VA provider participated in SDM with them, and satisfaction with the type of care they received. Those not activated to participate in VA care or who did not secure message results will be asked about barriers/facilitators to this process and how we might improve this interface or MH engagement. Current WEB-ED Veterans will be asked the same questions except for those specific to WEB-ED+. Participants from both RCT arms will be asked about satisfaction with process and care (if sought).

A Veteran process map will be developed from the Veteran's perspective to show whether each step of the WEB-ED RCT process helped create a clear value for them as a care customer or not. Provider/TPAs will be asked parallel questions to the Veterans- respective to each treatment arm. A Provider process map will be developed to help us understand the specific roles of individuals in the overall system of care, i.e. the # of teams involved, if there are bottlenecks and delays, rework that occurs in facilitating war Veterans' access to patient-centered MH care, and the potential system impact of WEB-ED+ and perceived value to the provider/TPA.

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

New Value

Phase 1: A total of 60 interviews (12 individuals at each of 5 sites) will be conducted. Key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers(n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2) and OEF/OIF/OND Veterans (n=4-5). An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. We will use site Veteran Panels to engage OEF/OIF/OND male and female war Veterans when possible, as well as using our Veteran registry obtained VINCI/VADIR to identify Veterans who are and are not currently VA engaged, respectively. Due to delays related to COVID-19, the research team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase. VINCI is a partner with the Corporate Data Warehouse (CDW) and hosts all data available through CDW as well as some unique data. VADIR is the VA group that interfaces with Defense Manpower Data Center to obtain sample characteristics of service members/Veterans, including postal and military e-mail addresses, and work/home telephone numbers. In phase 1, we will also develop a template for use in the VA electronic medical record to document the shared decision-making interface that is a component of our intervention for those in the RCT treatment arm (WEB-ED+). This will be an important material reviewed by our key informants in Phase one interviews. Prior to these interviews, this template will be developed with the assistance of study consultants who have developed templates for shared decision making documentation in a university health care setting and with assistance and with the guidance and initial consultation and prior approval from key VA offices, e.g. National VA Privacy office.

Following IRB approval, Consolidated Framework for Implementation Research (CFIR) guided qualitative interviews will be conducted by Dr. Sadler and other research team members (Cook, Steffensmeier) to determine key informant critiques of the WEB-ED+ content that will include: 1) MHV authentication and secure messaging directions; 2) online VA enrollment directions; and educational shared decision-making (SDM) educational videos, one for Veterans and one for providers, regarding the benefits and process involved in SDM respectively (video links (unlisted, only accessible via links: Shared Decision-Making SDM-Non-SDM https://youtu.be/9Exh5qm2D4s; Shared Decision-Making 'Veterans' https://youtu.be/FaevM-mTJtU; Shared Decision-Making 'Providers' https://youtu.be/xETkUedZ2N4); 3) decision aids for PTSD, depression and substance use disorder for use by patient and provider, and 4) patient activation scores and their relationship to SDM and care engagement. Dr. Cook and Dr. Sadler will engage top leadership at each study site as well as work with the Women's Practice Based Research Network leadership site leads at each facility to promote communication and engagement at each VA. To complement the qualitative data, Dr. Sadler will engage with local stakeholders and champions at each facility in order to map clinical workflow processes (process mapping) at each of the five study sites and determine how to best integrate WEB-ED+ into existing workflows. On-site visit interviews allow our research team important insights about the localized nature of health care delivery and how this might impact refinement of WEB-ED+ and its potential adoption and reach. Individual interviews ensure greater likelihood of the participation of key informants at times that accommodate their schedules and equalizes the importance of information from each of them. These interviews will be recorded, and this will be explained during the consent process prior to the start of the interviews. The following attachments will be sent in the following order: Phase 1 Confirmation Email; 2. Interview Direction Email; and 3. Link Email. Phase 1 Confirmation Email is sent immediately after interview is scheduled to confirm date and time of interview. Interview Direction Email is sent after to explain the interview protocol and to allow adequate time for questions. The Link Email is sent 24-hours before the scheduled interview, this email has the link to follow to watch the study video and the access number to the VANTS line. This is to

increase the fidelity to the interviewee's first time watching the Shared Decision-Making video while on the VANTS conference call with the interviewer.

Phase 2: Participants will include two overlapping populations of OEF/OIF/OND male and female Veterans eligible for VA care, which we will randomly sample from two overlapping populations. The first group includes those who returned from deployment to Iraq or Afghanistan within the preceding four years and who reside within the catchment areas of the current PBRN study sites (identified by zip code). We want to ensure that those who participate and screen positive on one or more of the screens have access to VA care. Consequently, we have selected the time frame of 4 years post-deployment because these Veterans have priority access to VA care for five years after their most recent deployment. The second group is OEF/OIF/OND Veterans who are already enrolled in VA care and will not be excluded if they have been home from deployment more than four years. We are doing purposeful sampling to achieve sufficient numbers of men vs women and we will work with VINCI/VADIR to have a sample representative by gender and race consistent with the current OEF/OIF/OND post-deployment populations.

All study participants will be asked to complete the online survey and screenings and be provided with their results and tailored educational information. Documentation of informed consent for Phase 2 participation (WEB-ED) is integrated into the web-based interface ("click approval"). Participants receive a hardcopy version of this form containing the elements of consent in the study packet and can read a copy online. This process has been approved in five prior projects using WEB-ED. The consent document will also inform participants that they may be invited to participate in the subsequent study phase that addresses VA and post-deployment care access. WEB-ED includes a brief pre-intervention survey that will query stigma associated with MH care, prior and current utilization (VA and non-VA; primary care, MH, emergency) and their reasons for accessing VA or not, knowledge about post-deployment VA eligibility, services and satisfaction with VA care, potential barriers to MH service use, and their use of or barriers to MHV and secure messaging. Those who meet screening criteria for MH conditions and readjustment concerns receive online notification and a recommendation for a face-to-face evaluation, education about each MH domain for which there is a positive screen, and information about access to care. Patients who may have immediate needs will also be provided with specific VA resources, contact names and numbers, as well as information for providers or resources unique to their needs and geographic locations. The 24-hour Veterans Crisis Line (1-800-273-TALK (8255)) will be provided. Patients with negative screens will be informed to seek care if they believe that it is needed. We note that neither our research team's studies using focus groups and telephone interviews with more intensive questions about sexual assault or combat experiences in deployed populations, nor our prior web-based intervention studies, have resulted in any subsequent clinical emergencies. Veterans who have no positive screens will be able to access the same educational information, web links, and video-clips if they choose.

A web-based satisfaction survey immediately follows screening and tailored education. In addition to questions about barriers and facilitators to access to care, satisfaction with an online process, and ways that we can make Veterans more satisfied with this screening and educational interface, we will also ask questions from the SHEP ambulatory care 2015 survey pertinent to study domains (provider and VA interface satisfaction for outpatients), e.g.: 1) did their provider tell you there was more than one choice for your treatment or care; 2) talk with you about the pros and cons of each choice for your treatment, 3) ask which choice was best for you, 4) listen carefully to you.

Phase 2 RCT Intervention (WEB-ED+) Veteran Procedures: Veterans who screen positive on one or more MH screens will be eligible for the RCT and asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT. Those who indicate yes will be sent IRB approved study information, including the RCT consent letter (2B), consent and HIPAA forms attached to this application. A summary of the screening results will be sent by encrypted email (attachment Phase 2 encrypted email - treatment arm RCT.rtf) to Veterans in the RCT treatment arm (WEB-ED+). An email will be sent in advance of this to alert Veterans that they will be receiving secure information by encrypted email. Additionally, Veterans will be asked to indicate which screening results bother them the most that they would like to talk with their provider about (To share with Provider). Veterans are asked to return that form along with their signed consent forms. Phase 2 Thank you letter-returned forms will be used to thank participants for returning their signed consent and HIPAA authorization forms.

To receive care in the VA health care system, Veterans must enroll in the VA system. Online VA enrollment links and information (available to every Veteran) will be provided to help RCT participating Veterans with this process. If they are unable to enroll electronically, key points of contact at the VA geographically closest to them will be provided so they can receive assistance with this process. Additionally, enrollment in My HealtheVet (MHV), a secure online ehealth portal, allows Veterans to access their medical records and send secure messages to their VA providers. As part of the RCT, participants will be asked to secure message their screening results summary to the VA provider of their preference. If they are new to the VA, enrolling as a result of the RCT participation, their newly assigned provider will be the individual that they will be asked to secure message their screening results summary. Note, that the study team will be monitoring enrollment and provider assignment of Veterans new to the VA and will invite the provider as soon as the assignment is made. If needed, the study team will be available to secure message the screening results, rather than the Veteran.

Phase 2 RCT Intervention (WEB-ED+) Provider Procedures: once the provider has agreed to participate, they will be sent an email that contains links to 2 short videos about shared decision-making and three brief decision aids (PTSD, depression, substance use disorder).

Using the knowledge both the provider and patient learned from the WEB-ED+ materials, they will discuss treatment options at the patient's appointment.

If subjects do not complete steps in the process, the appropriate attachment (Phase 2 RCT missing VA enrollment, Phase 2 RCT missing MHV premium enrollment, or Phase 2 RCT missing secure messaging) will be sent via email or postal mail if email is not available to support completion of these steps, with a toll free number provided. Further, up to 3 contact calls will be made until the subject is reached, to determine if the participant has discontinued study participation, if the study team can be of further assistance, or to determine the completion barrier(s), and if the Veteran is enrolled- to assist them with MHV barriers by sending the study screening results summary by encrypted email to the participant's preferred or new provider in their stead (eSDM Chart Review-Secure Message) so they are able to progress to their appointment in order to use shared decision-making with their provider about their positive MH screens. Requested Resources Email Scripts will be sent per request of subject as needed. The missing email notice attachment will be used for those in the treatment arm of RCT to encourage them to contact us and update their email address so we can continue their participation with the study. The provider consent notification document will be sent via mail or email letting the participant know that their provider has consented to participate in the RCT.

Those who decline will be thanked again for their participation and contact will be discontinued. We will use adaptive randomization to achieve balance in the assignment of those who consent to WEB-ED+ or Current WEB-ED. Those who are assigned to Current WEB-ED will not be contacted again until Phase 3.

Per VA Research project modification approval received November 2022, we are now able to provide subjects **with an additional $30 for already returned signed HIPAA form and consent to participate with this study phase. We will notify previous subjects using attachments (Phase 2 New Reimbursement postal mail and Phase 2 New Reimbursement email), and submit this request, anticipating that they should receive this direct**

deposit within 4 to 8 weeks. For new RCT recruitments we have edited the Phase 2 RCT recruitment to indicate that if they return their signed HIPAA form and consent to participate in this study phase they will received $50.00 (the same amount as those who have already returned these forms will receive).

Because of new VA research policy changes, we are now also able to provide subjects with an additional $75.00 upon completion of the RCT "intervention group" steps of this research phase that involves seeing their VA provider (as described in the consent and the encrypted study group assignment email).

We will send the new funding notice to all RCT consenters first by email, followed by postal mail with follow up a week later via telephone using a 3-call protocol.

If subjects do not complete the screening, attachments Phase 2G Incomplete Survey Email and Phase 2H Incomplete Survey Letter will be sent to encourage completion.

A medical chart review will be conducted for the subjects who return the signed HIPAA and consent forms for the RCT and prior to the interview for phase 3. Chart reviews will focus on VA outpatient care the subject received (or not) including medication, therapy, & substance use treatment. We will review the time from post-deployment through 6 months after the subject's initial study participation. We will assess/confirm enrollment status and upcoming appointments of participating Veterans using a combination of national visual chart review using CAPRI/JLV, along with accessing enrollment and appointment data from the CDW.

Phase 3: Post-intervention process evaluation will rely on data collected via Computer-Assisted Telephone Interview (CATI), with which our team has extensive experience. We will recruit 76 Veteran participants, and all Veteran-identified VA providers who agree to participate. We will use 3:1 sampling. It is anticipated that in each of the four groups, we will have appropriate representation of gender and racial/ethnic groups, but we will monitor this and use purposeful sampling if needed. Fewer numbers of those who did not engage in VA care reflects our expectation of less variation in subgroup data. As we do monthly EMR checks of participants, we will be able to identify provider/TPA interface initiated following WEB-ED and attempt to initiate contact within the month following RCT interface or at 6 months post-RCT vs post-WEB-ED if they have not. We will use a convenience sample of those in each identified comparison group, who are first able to be contacted by the study research coordinator or trained research interviewers by telephone.

Semi-structured interviews with qualitative and survey questions will be implemented from Dr. Sadler's CATI laboratory, with established data security and interviewer training/monitoring protocols in place for a decade. These interviews will not be recorded. Guided by CFIR, we hope to understand participants' perceptions of the intervention to which they were assigned with regard to ease and usefulness, need for improvements, and perceptions of barriers/facilitators to VA and MH services receipt or provision. We will interview both those who did/did not subsequently engage in the eHealth process/secure messaging and among these groups those who did/did not engage in VA MH care consequently. WEB-ED+ Veteran Participants will be asked about their use of secure messaging, VA provider engagement, satisfaction with use of WEB-ED results, if their VA provider participated in SDM with them, and satisfaction with the type of care they received. Those not activated to participate in VA care or who did not secure message results will be asked about barriers/facilitators to this process and how we might improve this interface or MH engagement. Current WEB-ED Veterans will be asked the same questions except for those specific to WEB-ED+. Participants from both RCT arms will be asked about satisfaction with process and care (if sought).

A Veteran process map will be developed from the Veteran's perspective to show whether each step of the WEB-ED RCT process helped create a clear value for them as a care customer or not. Provider/TPAs will be asked parallel questions to the Veterans- respective to each treatment arm. A Provider process map will be developed to help us understand the specific roles of individuals in the overall system of care, i.e. the # of teams involved, if there are bottlenecks and delays, rework that occurs in facilitating war Veterans' access to patient-centered MH care, and the potential system impact of WEB-ED+ and perceived value to the provider/TPA.

VII.E .19 ***Describe the compensation plan including***

- ***Compensation amount and type per visit***
- ***Total compensation***
- ***Pro-rating for early withdrawal from study***

Old Value

Phase 1: Providers will receive no financial compensation for their participation.

Phase 2: $30.00 will be compensated for WEB-ED completion, and an additional $20 will be compensated for return of participant HIPAA and consent forms allowing for consequent VA chart review and with the Veteran's VA provider for all assigned to the RCT portion of Phase 2. Participants need to sign and return a bank form to initiate the electronic **deposit.** The Bad Address Contact Call script will allow the research team to confirm the correct mailing address to send forms to the participant. If the research team is unable to reach the Veteran by phone, the Bad Address Contact Email will be sent. The reimbursement follow up script and email will be used to see if the participant would like reimbursement materials resent so they can be compensated.

Phase 3: $40 will be compensated for each participant (76) who completes the Phase 3 semi-structured Veteran interviews.

VII.E .19 ***Describe the compensation plan including***

- ***Compensation amount and type per visit***
- ***Total compensation***
- ***Pro-rating for early withdrawal from study***

New Value

Phase 1: Providers will receive no financial compensation for their participation.

Phase 2: $30.00 will be compensated for WEB-ED completion, and an additional $20 will be compensated for return of participant HIPAA and consent forms allowing for consequent VA chart review and with the Veteran's VA provider for all assigned to the RCT portion of Phase 2. **Given a recent VA research modification that allows us to reimburse an additional $30 to those who have already returned signed HIPAA and consent forms**

necessary to be reimbursed will be contacted about this increase in reimbursement as well as the new policy change that allows us to reimburse $75.00 for completion of the "intervention group" requirements. Those in the RCT will be notified about this change and those newly recruited will have this change included in their initial recruitment and consent documents. Participants need to sign and return a bank form to initiate the electronic **deposit(s). Those who have already done and are eligible for the additional reimbursement will not need to do so again.** The Bad Address Contact Call script will allow the research team to confirm the correct mailing address to send forms to the participant. If the research team is unable to reach the Veteran by phone, the Bad Address Contact Email will be sent. The reimbursement follow up script and email will be used to see if the participant would like reimbursement materials resent so they can be compensated.

In summary: Per project modification approval received November 2022 (attached), we are now able to provide subjects with an additional $30 for already returned signed HIPAA form and consent to participate with this study phase. We will notify previous subjects using attachment (Phase 2 New Reimbursement postal mail and Phase 2 New Reimbursement email), and submit this request, anticipating that they should receive this direct deposit within 4 to 8 weeks.

Because of new policy changes, we are now also able to provide subjects with an additional $75.00 upon completion of the RCT "intervention group" steps of this research phase that involves seeing their VA provider by March 1, 2023 (as described in the consent and the encrypted study group assignment email). Those who have returned consents and HIPAA forms for the RCT will be notified of this change and encouraged to complete their RCT intervention steps if they have not already. Those newly recruited to the RCT will have this included in their updated Phase 2 RCT consent document.

Phase 3: $40 will be compensated for each participant (76) who completes the Phase 3 semi-structured Veteran interviews.

Attachments

Old Value

Attachment Name	Category	Ver	Size	Type	Attached
Phase 2 RCT Informed Consent.rtf	Informed Consent	13	304 k	E	09/13/21
Phase 2A Consent letter - Current Web-Ed.rtf	Consent Letter	9	729 k	E	07/12/21
Phase 2B Consent letter - RCT.rtf	Consent Letter	11	183 k	E	11/08/21
Sadler 2016 IIR Fall Resubmission2.pdf	Funding Source Grant	1	11 M	E	06/22/17
Phase 3 Invitation Letter - Veterans.rtf	Recruitment Script: Mail	8	179 k	E	09/13/21
Phase 1B Email to Leadership.rtf	Recruitment Script: Email	7	271 k	E	03/08/19
Phase 1C Email to Key Experts.rtf	Recruitment Script: Email	13	203 k	E	09/19/19
Phase 2 RCT Provider Recruitment Email.rtf	Recruitment Script: Email	8	217 k	E	08/10/22
no changes made to content. Just a title change.					
Phase 2 encrypted email - treatment arm RCT.rtf	Recruitment Script: Email	1	117 k	E	09/28/21
Phase 2C Email - Current Web-Ed.rtf	Recruitment Script: Email	13	92 k	E	11/08/21
Phase 2D RCT Recruitment Email.rtf	Recruitment Script: Email	11	159 k	E	11/08/21
Phase 1 VA Key Informant Interview.docx	Subject Data Collection Instruments	4	30 k	E	03/08/19
Phase 1 Veteran Consumer Interview Revised 03-06-20.docx	Subject Data Collection Instruments	6	19 k	E	03/16/20
Phase1_Questions_CFIR_Constructs.pdf	Subject Data Collection Instruments	1	171 k	E	08/10/17
Phase3_Process_Eval_Samp_Ques.pdf	Subject Data Collection Instruments	1	34 k	E	08/10/17
Sadler_eSDM 2021_01_08 Programmed.docx	Subject Data Collection Instruments	2	78 k	E	01/14/21
Sadler_eSDM 2021_01_08 Questions.pdf	Subject Data Collection Instruments	1	7 M	E	01/14/21
Non-participant sociodemographic and military characteristics.docx	Screening: Screening Log	1	13 k	E	08/24/17

Anger Educational Module.pdf	Miscellaneous	3	207 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Bad Contact Info Call Script and Email.docx	Miscellaneous	2	19 k	E	02/07/22
CONTACT INFORMATION FORM - Veterans.docx	Miscellaneous	2	14 k	E	01/14/21
CONTACT INFORMATION FORM.docx	Miscellaneous	4	16 k	E	07/16/19
Crisis Call Procedures-Steps for Managing Crisis Calls + Warm Transfers to VCL 2015.03.docx	Miscellaneous	1	36 k	E	08/10/17
Depression Educational Module updated links 4.20.21.pdf	Miscellaneous	4	155 k	E	05/27/21
This change is to remove broken web links and add current web links.					
Encrypted email notice to Veteran.rtf	Miscellaneous	2	1 M	E	07/12/21
FAQ_eSDM Qualtrics.docx	Miscellaneous	4	17 k	E	07/12/21
FINAL Decision Aid-AUD.pdf	Miscellaneous	1	362 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.					
FINAL Decision Aid-Depression.pdf	Miscellaneous	1	358 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.					
FINAL Decision Aid-PTSD.pdf	Miscellaneous	1	319 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.					
Insomnia Educational Module.pdf	Miscellaneous	1	121 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Interview Sign In Sheet (1).doc	Miscellaneous	5	27 k	E	04/03/19
Intimate Partner Violence Educational Module.pdf	Miscellaneous	3	132 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
LMR SIGNED CONCURRENCE -- BY ROY FERGUSON 00240542 19-C-85212 LMR Concurrence signed Online and Shared Decision Making Interventions for Post-Dep.pdf	Miscellaneous	1	213 k	E	06/26/19
Link Email AGS Final 03_16_2020.docx	Miscellaneous	3	37 k	E	03/16/20
Loneliness & Social Isolation Educational Module.pdf	Miscellaneous	1	243 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
MHV_Linkage_Enrollment_Flowchart.pdf	Miscellaneous	1	729 k	E	08/10/17
Military Sexual Trauma Educational Module.pdf	Miscellaneous	3	185 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Missing email notice to treatment arm RCT participants.docx	Miscellaneous	1	24 k	E	04/05/22
NON SDM 121919.docx	Miscellaneous	1	19 k	E	01/21/20
Phase 1 Confirmation Email.docx	Miscellaneous	1	35 k	E	03/06/19
Phase 1 Leadership Thank You Letter.docx	Miscellaneous	1	72 k	E	03/06/19
Phase 1 Web Link_Mailed Scheduling Template.docx	Miscellaneous	1	12 k	E	03/06/19
Phase 1G Key Expert Thank You Letter.docx	Miscellaneous	1	72 k	E	03/06/19
Phase 2 RCT missing VA enrollment reminder.rtf	Miscellaneous	4	1 M	E	09/13/21
Phase 2 RCT missing MHV premium enrollment reminder.rtf	Miscellaneous	3	1 M	E	09/09/21
Information was added to assist Veterans with enrolling in My HealtheVet secure electronic health record system.					
Phase 2 RCT Provider Instructions Email.rtf	Miscellaneous	4	112 k	E	08/11/22
Phase 2 RCT missing secure messaging reminder.rtf	Miscellaneous	4	1 M	E	09/13/21
Phase 2 Thank you letter-returned forms.rtf	Miscellaneous	2	246 k	E	02/07/22
Phase 2G Incomplete Survey Email.docx	Miscellaneous	2	54 k	E	07/12/21
Phase 2H Incomplete Survey Letter.docx	Miscellaneous	2	53 k	E	07/12/21
Phase 2I Thank you letter.rtf	Miscellaneous	5	1 M	E	07/12/21
Phase 3C Thank you letter.rtf	Miscellaneous	2	1 M	E	05/28/21
Editing changes were made to provide consistent information as given in other documents used in this study and improve readability for the study participants.					
Phase2_RCT_Trmt_Arm_WEBED+_&_SDM.pdf	Miscellaneous	1	494 k	E	08/10/17
Post Traumatic Stress Disorder.pdf	Miscellaneous	3	113 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Postdeployment Family Adjustment Educational Module updated links 5.11.21.pdf	Miscellaneous	4	175 k	E	05/27/21
This change was to remove broken web links. Current web links were added.					
Prescription Drug Misuse Educational Module.pdf	Miscellaneous	3	89 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Protocol_to_address_potential_risks.rtf	Miscellaneous	1	39 k	E	08/10/17
Provider Consent Notification.docx	Miscellaneous	1	16 k	E	04/05/22
Provider Info Sheet to be completed by Veteran.docx	Miscellaneous	3	15 k	E	10/05/21
RCT Control Arm letter.rtf	Miscellaneous	1	109 k	E	09/09/21
This letter informs the Veteran which arm of the study group they have been randomly assigned to and what to expect					
RCT Intervention Assignment Letter.rtf	Miscellaneous	1	161 k	E	09/09/21
This letter informs the Veteran what arm of the study they have been randomly assigned to and what to expect.					
REF 10-22 eSDM Summary Report Error Email Notification.docx	Miscellaneous	1	18 k	E	11/01/22

This is the email to be sent notifying subjects of the incorrect blank template that they received in error. This document was also included as an attachment in the reportable event form.					
Recruitment Scripts.docx	Miscellaneous	21	52 k	E	08/10/22
separated out the Teams script from the telephone call script.					
Reimbursement Follow-up Email_Revised - Final.docx	Miscellaneous	3	36 k	E	05/13/22
Requested Resources Email Scripts.docx	Miscellaneous	1	20 k	E	02/07/22
SDM Provider Animation 121919.docx	Miscellaneous	1	14 k	E	01/21/20
SDM Veteran animation 121919.docx	Miscellaneous	1	13 k	E	01/21/20
Sadler HSRD HX002185-01A2- Union Information with interview questions.pdf	Miscellaneous	1	120 k	E	06/26/19
Sample_WEB_ED_Neg_Screen.pdf	Miscellaneous	1	90 k	E	08/10/17
Sample_WEB_ED_Pos_Screen.pdf	Miscellaneous	1	169 k	E	08/10/17
Screening Summary - Secure Message.rtf	Miscellaneous	4	103 k	E	10/25/21
Skype Script.docx	Miscellaneous	1	14 k	E	06/26/19
Social Determinants of Health Educational Module.pdf	Miscellaneous	1	250 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Study_Q&A - Current Web-Ed.rtf	Miscellaneous	5	86 k	E	09/13/21
Substance & Alcohol Misuse Educational Module.pdf	Miscellaneous	3	151 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Suicide Prevention Educational Module.pdf	Miscellaneous	1	158 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
To share with Provider.rtf	Miscellaneous	1	65 k	E	07/22/21
This form will enable the Veteran to indicate which screening results they are most concerned about and would like to discuss with their health care provider.					
Traumatic Brain Injury Educational Module updated links 4.20.21.pdf	Miscellaneous	5	160 k	E	05/27/21
This change was to remove broken web links and add active links to online information.					
VA10091 05.22.17.pdf	Miscellaneous	1	811 k	E	08/10/17
assurance-document.pdf	Assurance Document	1	39 k	E	08/09/17

New Value

New	Attachment Version	Attachment Name	Category	Ver	Size	Type	Attached
*		Phase 2 RCT Informed Consent 12-14-22.rtf	Informed Consent	16	307 k	E	12/19/22
		Phase 2A Consent letter - Current Web-Ed.rtf	Consent Letter	9	729 k	E	07/12/21
*		Phase 2B Consent letter - RCT.rtf	Consent Letter	13	184 k	E	12/19/22
*		ORD-ProjectModification_Sadler_IIR_16-096_September2022_rwob for LC sig-lmc.pdf	Funding Source Grant	1	1 M	E	12/14/22
		Sadler 2016 IIR Fall Resubmission2.pdf	Funding Source Grant	1	11 M	E	06/22/17
		Phase 3 Invitation Letter - Veterans.rtf	Recruitment Script: Mail	8	179 k	E	09/13/21
		Phase 1B Email to Leadership.rtf	Recruitment Script: Email	7	271 k	E	03/08/19
		Phase 1C Email to Key Experts.rtf	Recruitment Script: Email	13	203 k	E	09/19/19
		Phase 2 RCT Provider Recruitment Email.rtf	Recruitment Script: Email	8	217 k	E	08/10/22
no changes made to content. Just a title change.							
		Phase 2 encrypted email - treatment arm RCT.rtf	Recruitment Script: Email	1	117 k	E	09/28/21
		Phase 2C Email - Current Web-Ed.rtf	Recruitment Script: Email	13	92 k	E	11/08/21
*		Phase 2D RCT Recruitment Email.rtf	Recruitment Script: Email	13	186 k	E	12/19/22
		Phase 1 VA Key Informant Interview.docx	Subject Data Collection Instruments	4	30 k	E	03/08/19
		Phase 1 Veteran Consumer Interview Revised 03-06-20.docx	Subject Data Collection Instruments	6	19 k	E	03/16/20
		Phase1_Questions_CFIR_Constructs.pdf	Subject Data Collection Instruments	1	171 k	E	08/10/17
		Phase3_Process_Eval_Samp_Ques.pdf	Subject Data Collection	1	34 k	E	08/10/17

		Instruments				
	Sadler_eSDM 2021_01_08 Programmed.docx	Subject Data Collection Instruments	2	78 k	E	01/14/21
	Sadler_eSDM 2021_01_08 Questions.pdf	Subject Data Collection Instruments	1	7 M	E	01/14/21
	Non-participant sociodemographic and military characteristics.docx	Screening: Screening Log	1	13 k	E	08/24/17
	Anger Educational Module.pdf	Miscellaneous	3	207 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.						
	Bad Contact Info Call Script and Email.docx	Miscellaneous	2	19 k	E	02/07/22
*	CHART REVIEW 12-14-22.docx	Miscellaneous	1	25 k	E	12/16/22
	CONTACT INFORMATION FORM - Veterans.docx	Miscellaneous	2	14 k	E	01/14/21
	CONTACT INFORMATION FORM.docx	Miscellaneous	4	16 k	E	07/16/19
	Crisis Call Procedures-Steps for Managing Crisis Calls + Warm Transfers to VCL 2015.03.docx	Miscellaneous	1	36 k	E	08/10/17
	Depression Educational Module updated links 4.20.21.pdf	Miscellaneous	4	155 k	E	05/27/21
This change is to remove broken web links and add current web links.						
	Encrypted email notice to Veteran.rtf	Miscellaneous	2	1 M	E	07/12/21
	FAQ_eSDM Qualtrics.docx	Miscellaneous	4	17 k	E	07/12/21
	FINAL Decision Aid-AUD.pdf	Miscellaneous	1	362 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.						
	FINAL Decision Aid-Depression.pdf	Miscellaneous	1	358 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.						
	FINAL Decision Aid-PTSD.pdf	Miscellaneous	1	319 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.						
*	Follow up script with RCT new reimbursement.docx	Miscellaneous	1	17 k	E	12/14/22
	Insomnia Educational Module.pdf	Miscellaneous	1	121 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.						
	Interview Sign In Sheet (1).doc	Miscellaneous	5	27 k	E	04/03/19
	Intimate Partner Violence Educational Module.pdf	Miscellaneous	3	132 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.						
	LMR SIGNED CONCURRENCE -- BY ROY FERGUSON 00240542 19-C-85212 LMR Concurrence signed Online and Shared Decision Making Interventions for Post-Dep.pdf	Miscellaneous	1	213 k	E	06/26/19
	Link Email AGS Final 03_16_2020.docx	Miscellaneous	3	37 k	E	03/16/20
	Loneliness & Social Isolation Educational Module.pdf	Miscellaneous	1	243 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.						
	MHV_Linkage_Enrollment_Flowchart.pdf	Miscellaneous	1	729 k	E	08/10/17
	Military Sexual Trauma Educational Module.pdf	Miscellaneous	3	185 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.						
	Missing email notice to treatment arm RCT participants.docx	Miscellaneous	1	24 k	E	04/05/22
	NON SDM 121919.docx	Miscellaneous	1	19 k	E	01/21/20
	Phase 1 Confirmation Email.docx	Miscellaneous	1	35 k	E	03/06/19
	Phase 1 Leadership Thank You Letter.docx	Miscellaneous	1	72 k	E	03/06/19
	Phase 1 Web Link_Mailed Scheduling Template.docx	Miscellaneous	1	12 k	E	03/06/19
	Phase 1G Key Expert Thank You Letter.docx	Miscellaneous	1	72 k	E	03/06/19
	Phase 2 RCT missing VA enrollment reminder.rtf	Miscellaneous	4	1 M	E	09/13/21
*	Phase 2 New RCT Reimbursement email notification.docx	Miscellaneous	2	24 k	E	12/19/22
*	Phase 2 New Reimbursment postal mail.docx	Miscellaneous	1	21 k	E	12/14/22
	Phase 2 RCT missing MHV premium enrollment reminder.rtf	Miscellaneous	3	1 M	E	09/09/21
Information was added to assist Veterans with enrolling in My HealtheVet secure electronic health record system.						
	Phase 2 RCT Provider Instructions Email.rtf	Miscellaneous	4	112 k	E	08/11/22
	Phase 2 RCT missing secure messaging reminder.rtf	Miscellaneous	4	1 M	E	09/13/21
*	Phase 2 Thank you letter-returned forms.rtf	Miscellaneous	4	247 k	E	12/19/22
	Phase 2G Incomplete Survey Email.docx	Miscellaneous	2	54 k	E	07/12/21
	Phase 2H Incomplete Survey Letter.docx	Miscellaneous	2	53 k	E	07/12/21
	Phase 2I Thank you letter.rtf	Miscellaneous	5	1 M	E	07/12/21
	Phase 3C Thank you letter.rtf	Miscellaneous	2	1 M	E	05/28/21
Editing changes were made to provide consistent information as given in other documents used in this study and improve readability for the study participants.						
	Phase2_RCT_Trmt_Arm_WEBED+_&_SDM.pdf	Miscellaneous	1	494 k	E	08/10/17
	Post Traumatic Stress Disorder.pdf	Miscellaneous	3	113 k	E	07/02/20

We are modifying to add the final educational documents that will be used in the study.							
	Postdeployment Family Adjustment Educational Module updated links 5.11.21.pdf	Miscellaneous	4	175 k	E	05/27/21
This change was to remove broken web links. Current web links were added.							
	Prescription Drug Misuse Educational Module.pdf	Miscellaneous	3	89 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.							
	Protocol_to_address_potential_risks.rtf	Miscellaneous	1	39 k	E	08/10/17
	Provider Consent Notification.docx	Miscellaneous	1	16 k	E	04/05/22
	Provider Info Sheet to be completed by Veteran.docx	Miscellaneous	3	15 k	E	10/05/21
	RCT Control Arm letter.rtf	Miscellaneous	1	109 k	E	09/09/21
This letter informs the Veteran which arm of the study group they have been randomly assigned to and what to expect							
*	RCT Intervention Assignment Letter.rtf	Miscellaneous	3	187 k	E	12/19/22
	REF 10-22 eSDM Summary Report Error Email Notification.docx	Miscellaneous	1	18 k	E	11/01/22
This is the email to be sent notifying subjects of the incorrect blank template that they received in error. This document was also included as an attachment in the reportable event form.							
*	Recruitment Scripts.docx	Miscellaneous	23	66 k	E	12/19/22
	Reimbursement Follow-up Email_Revised - Final.docx	Miscellaneous	3	36 k	E	05/13/22
	Requested Resources Email Scripts.docx	Miscellaneous	1	20 k	E	02/07/22
	SDM Provider Animation 121919.docx	Miscellaneous	1	14 k	E	01/21/20
	SDM Veteran animation 121919.docx	Miscellaneous	1	13 k	E	01/21/20
	Sadler HSRD HX002185-01A2- Union Information with interview questions.pdf	Miscellaneous	1	120 k	E	06/26/19
	Sample_WEB_ED_Neg_Screen.pdf	Miscellaneous	1	90 k	E	08/10/17
	Sample_WEB_ED_Pos_Screen.pdf	Miscellaneous	1	169 k	E	08/10/17
	Screening Summary - Secure Message.rtf	Miscellaneous	4	103 k	E	10/25/21
	Skype Script.docx	Miscellaneous	1	14 k	E	06/26/19
	Social Determinants of Health Educational Module.pdf	Miscellaneous	1	250 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.							
*	Study_Q&A - Current Web-Ed.rtf	Miscellaneous	7	87 k	E	12/19/22
	Substance & Alcohol Misuse Educational Module.pdf	Miscellaneous	3	151 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.							
	Suicide Prevention Educational Module.pdf	Miscellaneous	1	158 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.							
	To share with Provider.rtf	Miscellaneous	1	65 k	E	07/22/21
This form will enable the Veteran to indicate which screening results they are most concerned about and would like to discuss with their health care provider.							
	Traumatic Brain Injury Educational Module updated links 4.20.21.pdf	Miscellaneous	5	160 k	E	05/27/21
This change was to remove broken web links and add active links to online information.							
	VA10091 05.22.17.pdf	Miscellaneous	1	811 k	E	08/10/17
	assurance-document.pdf	Assurance Document	1	39 k	E	08/09/17

Asterisk indicates modified attachment.

Enrollment as Reported on Previous Forms

Type	Approval Date	Total Subjects Approved by IRB	Total Subjects Reported	Enrollment Stopped
Mod	06/07/24	2060		
Mod/CR	02/29/24	2060	1601	Yes
Mod	12/07/23	2060		
Mod	11/15/23	2060		
Mod	11/02/23	2060		
Mod	08/02/23	2060		
Mod	06/28/23	2060		
Mod	05/12/23	2060		
Mod	03/24/23	2060		
Mod/CR	03/21/23	2060	1575	No
Mod	01/12/23	2060		
Mod	12/22/22	2060		
Mod	12/16/22	2060		
Mod	11/21/22	2060		
Mod	11/02/22	2060		
Mod	10/06/22	2060		

Type	Approval Date	Total Subjects Approved by IRB	Total Subjects Reported	Enrollment Stopped
Mod	09/08/22	2060		
Mod	08/11/22	2060		
Mod	07/20/22	2060		
Mod	07/13/22	2060		
Mod	07/13/22	2060		
Mod	06/14/22	2060		
Mod	05/13/22	2060		
Mod/CR	04/05/22	2060	631	No
Mod	03/29/22	2060		
Mod	03/15/22	2060		
Mod	03/14/22	2060		
Mod	02/24/22	2060		
Mod	02/07/22	2060		
Mod	11/30/21	2060		
Mod	11/19/21	2060		
Mod	11/08/21	2060		
Mod	10/25/21	2060		
Mod	10/08/21	2060		
Mod	10/04/21	2060		
Mod	09/20/21	2060		
Mod	09/13/21	2060		
Mod	08/06/21	2060		
Mod	07/29/21	2060		
Mod	07/12/21	2060		
CR	05/02/21		36	No
Mod	04/08/21	2060		
Mod	01/29/21	2060		
Mod	09/11/20	2060		
Mod	08/31/20	2060		
Mod	07/07/20	2060		
Mod	06/18/20	2060		
Mod	06/16/20	2060		
Mod	06/03/20	2060		
CR	06/01/20		36	No
Mod	05/21/20	2060		
Mod	05/05/20	2060		
Mod	03/16/20	2060		
Mod	02/21/20	2060		
Mod	02/16/20	2060		
Mod	02/03/20	2060		
Mod	01/23/20	2060		
Mod	01/02/20	2060		
Mod	09/19/19	2060		
Mod	09/05/19	2060		
Mod	08/19/19	2060		
Mod	07/24/19	2060		
Mod	07/16/19	2060		
CR	07/02/19		0	No
Mod	07/01/19	2060		
Mod	04/03/19	2060		
Mod	03/08/19	2060		
Mod	09/17/18	2060		
Mod/CR	08/13/18	2060	0	No
Mod	06/08/18	2060		
Mod	05/10/18	2060		
New	09/06/17	2060		

Form Content

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-03 VA Only

I.2 ***Project Title:***
Online and Shared Decision-Making Interventions to Engage Service Men and Women in Post-Deployment Mental Health Care

I.3 ***Short Title (optional):***
eSDM

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

This study is a randomized controlled trial using mixed quantitative and qualitative methods. In Aim 1 we will obtain key informant feedback in order to a) refine our current WEB-ED online screening and Shared Decision-Making protocols, and b) conduct process mapping that documents site-specific processes of engaging OEF/OIF/OND Veterans in VA and VA MH care as they currently exist. In Aim 2 we will conduct a randomized controlled trial (RCT) to test the effectiveness of "Enhanced" vs. "Current" WEB-ED in increasing Veteran engagement in VA MH care and a SDM interface with their providers. For Aim 3 we will use qualitative methods in a process evaluation to determine the acceptability of our WEB-ED+ intervention to RCT participants, their providers, and other key informants, identify facilitators and barriers to incorporating WEB-ED+ into the EMR, and determine perceived differences in Veteran VA and MH care engagement based on feedback from WEB-ED+ participants and their providers. To optimize the successful completion of this study, we will build upon our work with the HSR&D Women's Health Practice Based Research Network (PBRN) to leverage the research infrastructure and clinical relationships already in place at study sites. This established PBRN and the network from our current HSR&D CREATE study will also facilitate access to key local informants. It will also facilitate our knowledge of site-specific VA services to enhance our understanding of processes of VA access to mental health (MH) care for war Veterans across sites. This grant is administered completely virtually from the Iowa City VA Health Care System. The sites outside of the Iowa City VA are not engaged in this research. There are three consecutive phases to this study that correspond with each aim.

In summary, phase 1 involves qualitative interviews with key stakeholders/informants; phase 2 involves online intervention (Web-Ed) and RCT; phase 3 involves process evaluation post-intervention, which will involve data collected via Computer-Assisted Telephone Interview (CATI) to determine intervention effectiveness via semi-structured telephone interviews. Chart review will be performed 6 months post phase 2 web intervention. For the WEB-ED in phase 2, if the subject is eligible per the pre-consent screening questions, the informed consent for this online process is integrated into the web-based subject education and participants acknowledge ("click approval") that they have reviewed this prior to participation (attachment 2A Consent Letter - Current Web-Ed). This online document containing the elements of consent will contain the same information as the mailed document and will also inform participants that they may be invited to participate in a subsequent study phase that will address VA and post-deployment care access.

Veteran participants will provide consent for RCT portion of phase 2 (as assigned), the phase 3 telephone interview, and chart review by signing and returning via mail the consent and HIPAA forms prior to participating in the RCT portion of phase 2. For those who participate in the first part of phase 2 and are eligible for the RCT portion of the study, they will be asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT (Web-Ed+). Those who indicate yes will be sent IRB approved study information, including the RCT consent letter (2B), consent and HIPAA forms attached to this application. Those who decline will be thanked again for their participation and contact will be discontinued.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
Specific Aim #1: To obtain key stakeholder perspectives regarding refinement of WEB-ED, including enhancement with shared-decision making (SDM) interventions, linkage with MyHealtheVet (MHV), and VA enrollment materials.

Specific Aim #2: To conduct a randomized controlled trial (RCT) to test differences in VA MH care engagement among screen-positive male and female Veterans randomly assigned to 1) Enhanced WEB-ED (WEB-ED+) integrating online VA and MHV enrollment, secure messaging of screening results, SDM educational video clips for Veteran and providers and decision aids for depression, PTSD and substance use disorder or 2) Current WEB-ED.

Hypothesis 2a: Veterans assigned to WEB-ED+ will be more likely to engage in VA MH care and indicate greater satisfaction with their care engagement.

Exploratory Hypothesis 2b: Veterans who have multiple positive MH screens and who score low on the Patient Activation Measure will be more likely to engage in VA care if they are assigned to WEB-ED+.

Exploratory Hypothesis 2c: Measures of improved access and MH care engagement will be similar for male and female Veterans within RCT arms.

Exploratory Hypothesis 2d: Rural Veterans will be more likely to demonstrate improved access and MH care engagement relative to urban Veterans regardless of RCT arm assignment.

Specific Aim # 3: To elicit feedback from key stakeholders in both arms of the RCT (WEB-ED+ vs. Current WEB-ED) regarding 1) the usefulness of an eHealth interface, 2) perceptions of how the interventions influenced patient access to and efficiency of VA patient-centered care delivery, and 3) Veteran and provider satisfaction; and to document the VA processes Veterans used to enroll and engage in VA care.

Online screening, tailored education, and links to geographically accessible VA resources has been shown to be preferred by Veterans, providing recognition of treatable post-deployment MH concerns, and education that reduces stigma. This study builds upon and augments this prior work with research to understand and evaluate the processes needed to integrate WEB-ED+ into current VHA systems to support efficient care delivery, facilitate patient-centered care, and address unmet need for MH care while also resolving disparities in VA MH care access and engagement for war Veterans. We postulate that WEB-ED+'s enhancement with shared decision-making will be a key component for promoting and sustaining these benefits. WEB-ED+ represents a readily implementable and cost-effective intervention that, with partner collaboration, can be integrated into VA systems through MyHealtheVet (MHV). VA Central Office offices awaiting results of this RCT to inform potential broader adoption of WEB-ED+ to help address high priority system needs include the Offices of: MH Services, MyHealtheVet, Rural Health, Primary Care Services, Transition and Care Management, Military Sexual Trauma, Web Services, Women Veteran's Strategic Healthcare Group, Women's Health Innovation, Family Services.

I.6 ***Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")***

Mental health conditions are prevalent in OEF/OIF/OND war Veterans, but many do not seek care. OEF/OIF/OND Veterans experience complex mental health (MH) consequences of deployment(s). Almost a third (32%) of OEF/OIF Veterans in the VA have received a MH diagnosis; PTSD is the most prevalent condition, followed by substance abuse and then depression. OEF/OIF servicewomen have high levels of combat exposures, only slightly lower than men, yet gender differences of the impact of these stressors appear to be minimal. A RAND study of a community sample of OEF/OIF war Veterans found rates of MH disorders similar to VA populations, however, only half of OEF/OIF war Veterans meeting criteria for current PTSD or major depression had sought help from a provider for a MH problem in the past year. In a study of almost 50,000 Iraq/Afghanistan Veterans with newly diagnosed PTSD, only a minority (9.5%) received the recommended number and intensity of VA MH treatment sessions within the first year.

Barriers to seeking MH care are well-documented. Stigma and not being able to admit to having a problem or ask for help impede Veterans' willingness to seek needed care. Veterans who have not used VA services report not knowing what benefits are available to them or how to access them. Veterans who have used VA health care identify long waiting periods as one of the greatest barriers to accessing MH services. Care disparities may be further compounded for those who reside in rural locations. Recent era Veterans who wait longer to get outpatient MH treatment have been found to live geographically further from a VA and to be less likely to have improvement in their symptoms of PTSD compared to peers who live closer and seek care sooner. This is of particular concern given approximately 41% of the Veteran population are rural residents and research indicates rural Veterans have lower MH-related quality of life. Our research on Veterans eligible for Choice (Veterans Access, Choice, and Accountability Act of 2014) because of distance barriers to VA care have found that few Veterans had closer access to Community MH Centers. The percent of Veterans living more than 40 miles from their nearest VA health facility who had access to a Community MH Center ranged from 3% to 34% across MyVA Regions.

Online health screening, education, and interventions are effective. There is a recent and growing precedent of using web-based interventions in high risk populations, including interventions that identify MH conditions (e.g., substance abuse, PTSD) and focus on behavior change to promote patient engagement in care. Research investigating online treatment of PTSD suggests that there may be greater follow through with internet-based approaches, which further supports the need for finding creative ways of safely extending education and services beyond traditional methods. The Department of Defense (DoD) provides online feedback to service members on topics ranging from assessments (e.g., post-deployment health) to educational resources (e.g., health promotion).

Online health education and interventions are preferred. VA-enrolled OEF/OIF combat Veterans report a preference to seek readjustment services or information over the internet (53%) and virtually all (97%) have internet use. The majority of OEF/OIF Veterans are computer-literate, and many use the internet as a daily part of their lives. A recent study found that most Veterans with a MH diagnosis who are engaged in VA care had access to an internet capable device (cell phones and computer) and are interested in using technology for healthcare-related communications.

Informed patients have improved engagement, satisfaction, and outcomes. Information plays a critical role in helping patients become aware of their treatment needs, options, and effective self-care strategies. A lack of knowledge about PTSD, its causes, and available treatments have been identified as important barriers to help-seeking among Veterans. Conversely, considerable evidence suggests that patients who are better informed about their medical/MH conditions and treatment tend to have more favorable outcomes. For example, having adequate information about one's medical condition is associated with better adherence to treatment recommendations. Patients who are better informed tend to be more satisfied with their care and experience reduced uncertainty and anxiety regarding treatment. Patient-provider communication patterns involving more information-sharing on the part of the provider have also been associated with greater patient satisfaction, knowledge, and adherence as well as better health outcomes.

Engaging patients in shared decision-making (SDM) improves MH care satisfaction and outcomes. SDM, considered the "pinnacle of patient-centered care," involves clinicians and patients participating together in the decision-making process, discussing treatment preferences, and reaching agreement about treatment choice. Such a participatory care model of decision-making is a central theme of many evidence-based psychosocial MH treatments and a core component of the chronic care model. Improved health outcomes and patient satisfaction of MH consumers have been associated with SDM. Both men and women report improved patient satisfaction with SDM and MH care receipt. Furthermore, improved self-management of MH conditions has been found, e.g., greater follow-through with treatment plans, and improved therapeutic alliances with clinicians.

Implementation of SDM into routine clinical practice is needed. Currently personal health records (PHR) have little data about patients' health preferences, with the exception of end of life decisions. Integration of SDM, as a part of Meaningful Use regulations, is gaining recognition as feasible and necessary. However, more work needs to be done to overcome difficulties implementing SDM into routine practice because of the time required, lack of explanation on using decision aids, and need for electronic medical record (EMR) inclusion.

Technology efficiently supports access to MH care and population health. There is growing evidence that eHealth tools have the capability to promote health and overcome stigma. MH care stigma frequently results in delays and suboptimal use of care. The Institute of Medicine (IOM) 2001 report, "Crossing the Quality Chasm," notes that technology can reshape healthcare delivery and recommends that "access to care should be provided over the internet, by telephone, and by other means in addition to in person visits." A web-interface for Veterans to screen for common post-deployment readjustment and MH conditions, at any time and any place, offers a substantial advantage to Veterans who are returning from war and who are unsure if their symptoms are treatable conditions or lack knowledge about VA services available to them. Enabling this priority population's ability to confidentially screen, then enroll in VA and My HealtheVet (MHV), in order to communicate screening results to VA OEF/OIF/OND Transition Patient Advocates (TPA) or providers has great potential to address unmet need and recognized barriers to VA MH care.

Existing VA technology can be leveraged to promote Veteran access to VA MH care. Within VHA, MHV (My HealtheVet Program Office) is an online PHR available to all Veterans. This PHR can 1) facilitate Veterans' ability to maintain a comprehensive medical history in one place; 2) monitor and promote positive health behaviors; and 3) for those who enroll in VA and become MHV premium members, confidentially message VA providers or care managers to engage more actively in their own care. This PHR has the capability of improving engagement, safety, satisfaction, and health outcomes. PHRs also can provide patients with ownership of their health information so they can share it with multiple providers. Within VHA, only about 20% of Veterans receiving services are registered on MHV. While a majority of Veterans use the internet, only about a quarter of VA MH service users and a fifth of VA general service users access the MHV website for their personal health care. This slow adoption is similar to that in non-VA health care systems. It is encouraging that a qualitative study found that Veterans seeing their records positively affects communication with providers and the health system, enhances knowledge of their health and improved self-care, and allows for greater participation in their care and decision-making regarding when to seek care. Non-VA patients given access to a website allowing a shared medical record report high adoption and satisfaction.

VA is promoting VA provider adoption of MHV secure messaging. The 2014 MHV advance allowing secure messaging with providers offered a great opportunity to improve Veteran-provider communication. In April 2016, VA began allowing staff to obtain workload credit, or increments of time, for MHV secure messages they complete and save into CPRS as progress notes. One study with VA providers found that those who attain workload benefits from secure messaging are more likely to adopt use. Secure messaging has been found to increase patient-provider communication and patient activation while at the same time reducing in-person visits and telephone contacts.

Technology can address the needs of vulnerable Veteran sub-populations. A recent literature review found that women who have experienced military sexual trauma (MST) experience high levels of organizational distrust, social isolation, and self-perceived stigma which create a significant barrier for participation in treatment and community reintegration. Authors concluded that the use of internet technologies show promise among MST survivors not only as therapeutic tools but also as effective outreach to identify and connect with those difficult to reach. The VHA Handbook (1330.01) indicates that VA women's health care should be delivered in environments that attend to their dignity, safety, and privacy. For some, this environment might be their home as they begin their VA care journey. This work also has implications for males experiencing MST and other forms of trauma.

The PI and her team have studied post-deployment readjustment and MH care access for the past seven years. Findings across five studies show participant age, VA enrollment, military characteristics, and MH screening results are similar for men and women, demonstrating generalizability and eligibility.

Study I: Most participants did not know their post-deployment symptoms were treatable psychiatric conditions. Phase 1 involving 18 focus groups with OEF/OIF service members (65 women/33 men) found most participants: 1) had received no information about VA eligibility or how to access VA services, and 2) frequently noted concerns with post-deployment adjustment, e.g., family re-adjustment. In the Phase 2 cross-sectional study, we found that among Reserve and National Guard (RNG) servicewomen (n=665), most chose not to seek care. Almost 80% did not use MH care in the past year despite psychiatric problems at rates consistent with other studies of post-deployment Veterans. This gap in receipt of care occurred despite women's belief that MH counseling can help (82%) and that VA MH providers could better understand their problems (91%).

Study II: Online interventions can be successfully implemented within VA and can decrease RNG servicewomen's discomfort with seeking MH care. Dr. Sadler demonstrated feasibility of conducting online interventions behind the VA firewall. One-third (31%) of participants reported that the web-based screening and education (WEB-ED) reduced their reluctance to seek MH care.

Study III: Servicewomen (82%) would like their WEB-ED screening results linked to a VA secure network (such as MHV) to facilitate VA provider access to the results, and would be more likely to ask questions or secure message a VA provider about their screens if available in MHV (77%). We found that of 214 RNG women returning from deployment to Iraq or Afghanistan, 83% screened positive on at least one screen, averaging three positive screens for MH conditions. Thus, WEB-ED is effectively reaching a high-risk population with substantial MH consequences from service. Only 16% of the total sample had received VA MH care following their most recent deployment, of which 16% was from a community facility.

Study IV: Servicemen's screening results were not significantly different from servicewomen's with regard to MH complexity, post-deployment concerns, and care seeking. Co-Investigator Dr. Mengeling implemented WEB-ED with a Midwestern cohort of RNG OEF/OIF/OND servicemen (N= 200), finding that over half (57%) expressed concern about their post-deployment adjustment but < 20% sought MH care.

Study V: Half of servicewomen participants indicated that as a direct result of WEB-ED, they will follow up with a provider. Women reported higher satisfaction and intent to seek needed PTSD treatment when they talked by telephone about WEB-ED results and engaged in SDM about treatment options with a MH nurse. Dr. Sadler's current HSR&D CREATE study with active component and RNG post-deployed servicewomen (n=1,104) found WEB-ED outcomes remain consistent with prior findings of high-risk populations, but in a sample of increased diversity (38% non-white). Veterans continue to want a direct interface (e.g., MHV) to communicate their WEB-ED/SDM results to a VA provider to facilitate discussion. Using the Patient Activation Measure, we found that compared to PCL-5 PTSD+ women, PTSD- women were more likely to have high activation ("taking action"/"pushing further" (71% vs 40%). PTSD+ women were more likely to feel "disengaged & overwhelmed"/"aware but struggling" (60% vs 28%). This emphasizes the need for Veteran empowerment through information about their MH conditions, treatment options, and SDM.

In summary, available literature combined with our extensive prior studies have set the stage for our proposed study, focused on using technology to increase Veterans' access to and engagement in VA MH care and to promote a SDM interface between Veterans and VA practitioners.

[redacted]

II.3 ***The Principal Investigator of this study is:***
Staff

II.5 ***Select research team member who is the primary contact for study participants.***
Anne Sadler

III. Funding/Other Support

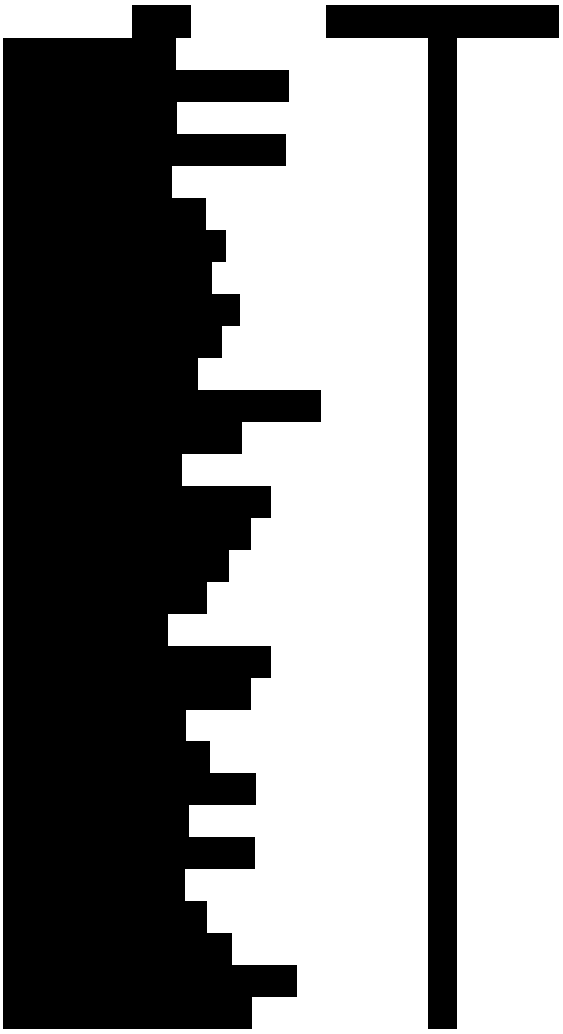
III.1 ***Funding Sources***

Source Entered as Text	DSP Link	Type	Source	Project Title	Name of PI on Grant	Status
Source is entered as text no		Federal Agency	US Department of Veterans Affairs	Online and Shared Decision-Making Interventions to Engage Service Men and Women in Post-Deployment Mental Health Care	Anne G. Sadler, Ph.D., R.N.	

* new source name

III.2 ***What type of funding agreement would be completed?***
Iowa City VAMC

[redacted]



III.5 ***What is the current status of this funding source?***

Source	Status	Other Status Description
US Department of Veterans Affairs	Awarded	

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")***
October 2017

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
No

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
2060

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
60.0

VI.4 ***What is the percentage of adult male subjects?***
60

VI.5 ***What is the percentage of adult female subjects?***
40

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
0

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***

Phase 1: Key Informant Interviews: A total of 60 interviews (12 individuals selected at each of 5 PBRN sites) will be conducted. Key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers(n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2) and OEF/OIF/OND Veterans (n=4-5). An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. We will use site Veteran Panels to engage OEF/OIF/OND male and female war Veterans when possible, as well as using our Veteran registry obtained VADIR to identify Veterans who are and are not currently VA engaged, respectively. Due to delays related to COVID-19, the team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase. VINCI is a partner with the Corporate Data Warehouse (CDW) and hosts all data available through CDW as well as some unique data. VADIR is the VA group that interfaces with Defense Manpower Data Center to obtain sample characteristics of service members/Veterans, including postal and military e-mail addresses, and work/home telephone numbers.

Phase 2: Randomized Controlled Trial: Participants will include two overlapping populations of OEF/OIF/OND male and female Veterans eligible for VA care, which we will randomly sample from two overlapping populations. The first group includes those who returned from deployment to Iraq or Afghanistan within the preceding four years and who reside within the catchment areas of one of our 10 study sites (identified by zip code). We want to ensure that those who participate and screen positive on one or more of the screens have access to VA care. Consequently, we have selected the time frame of 4 years post-deployment because these Veterans have priority access to VA care for five years after their most recent deployment. The second group is OEF/OIF/OND Veterans who are already enrolled in VA care and will not be excluded if they have been home from deployment more than four years. We are doing purposeful sampling to achieve sufficient numbers of men vs women and we will work with VINCI/VADIR to have a sample representative by gender and race consistent with the current OEF/OIF/OND post-deployment populations. Veteran contact information will be provided by the VA Informatics and Computing Infrastructure (VINCI)/VA-DoD Data Identification Repository (VADIR). VINCI/VADIR and Dr. Sadler have a successful working relationship for prior grants. Given lessons learned from our preceding grants we have revised our VINCI/VADIR registry requirements to sample potential participants with both e-mail and postal mail. VINCI/VADIR is able to provide sociodemographic and military information (e.g. age, marital status, race, rank, number of deployments) that will subsequently allow us to compare study participants with refusers and non-responders. This will facilitate follow up and better analysis of the generalizability of findings.

Phase 3: Process evaluation: Post-intervention process evaluation will rely on data collected via Computer-Assisted Telephone Interview (CATI), with which our team has extensive experience. We will recruit 76 Veteran participants, and all Veteran-identified VA providers who agree to participate. We will use 3:1 sampling. It is anticipated that in each of the four groups, we will have appropriate representation of gender and racial/ethnic groups, but we will monitor this and use purposeful sampling if needed. Fewer numbers of those who did not engage in VA care reflects our expectation of less variation in subgroup data. As we do monthly EMR checks of participants, we will be able to identify provider/TPA interface initiated following WEB-ED and attempt to initiate contact within the month following RCT interface or at 6 months post-RCT vs post-WEB-ED if they have not. We will use a convenience sample of those in each identified comparison group, who are first able to be contacted by the study research coordinator or trained research interviewers by telephone.

VI.13.a ***Does this study propose to enroll any subjects who are not Veterans?***
Yes

VI.13.b ***Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment (38 CFR 17.45, 17.92), but only when there are insufficient Veteran patients suitable for the study. Provide an explanation for why there are insufficient Veteran patients suitable for the study.***
To address Aim 1, semi-structured interviews guided by the Consolidated Framework for Implementation Research (CFIR) will be conducted by Dr. Sadler to obtain key informant feedback on the WEB-ED+ content which will include: 1) MHV authentication and secure messaging directions; 2) online VA enrollment directions; and two educational SDM educational videos, one for Veterans and one for providers, regarding the benefits and process involved in SDM, respectively; and 3) patient activation scores and their relationship to SDM and care engagement. To complement the qualitative data, Dr. Sadler will engage with local stakeholders and champions at each facility in order to map clinical workflow processes (process mapping) at each of the five study sites and determine how to best integrate WEB-ED+ into existing workflows. A total of 60 interviews (12 individuals at each of 5 sites) will be conducted. Key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers (n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2), and OEF/OIF/OND Veterans (n=4-5). An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. Due to delays related to COVID-19, the team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase.

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
Over 2.5 million service members have been deployed to Iraq, Afghanistan in the past decade. Given national security and safety concerns, DMDC does not provide comprehensive registry numbers of military/Veteran populations for sample request such as ours. VADIR has reviewed our study specifications and sample requirements in order to provide us with a cost estimate and expressed no concerns regarding feasibility. We are aware that given the overall population numbers noted above we have more than sufficient population numbers to draw from for potential study participants.

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
Phase 1 key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers(n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2) and OEF/OIF/OND Veterans (n=4-5). Key informants will be selected at each PBRN site. An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. We will use site Veteran Panels to engage OEF/OIF/OND male and female war Veterans when possible, as well as using our Veteran registry obtained VADIR to identify Veterans who are and are not currently VA engaged, respectively. VADIR is the VA group that interfaces with Defense Manpower Data Center to obtain sample characteristics of service members/Veterans, including postal and military e-mail addresses, and work/home telephone numbers. Due to delays related to COVID-19, the team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase.

Phase 2 participants will include two overlapping populations of OEF/OIF/OND male and female Veterans eligible for VA care, which we will randomly sample from two overlapping populations. The first group includes those who returned from deployment to Iraq or Afghanistan within the preceding four years and who reside within the catchment areas of one of our 10 study sites (identified by zip code). We want to ensure that those who participate and screen positive on one or more of the screens have access to VA care. Consequently, we have selected the time frame of 4 years post-deployment because these Veterans have priority access to VA care for five years after their most recent deployment. The second group is OEF/OIF/OND Veterans who are already enrolled in VA care and will not be excluded if they have been home from deployment more than four years. We are doing purposeful sampling to achieve sufficient numbers of men vs women and we will work with VADIR to have a sample representative by gender and race consistent with the current OEF/OIF/OND post-deployment populations. Veteran contact information will be provided by the VA-DoD Data Identification Repository (VADIR).

For phase 3 we will recruit 76 Veteran participants, and all Veteran-identified VA providers who agree to participate. We will use 3:1 sampling. It is anticipated that in each of the four groups, we will have appropriate representation of gender and racial/ethnic groups, but we will monitor this and use purposeful sampling if needed. Fewer numbers of those who did not engage in VA care reflects our expectation of less variation in subgroup data. As we do monthly EMR checks of participants, we will be able to identify provider/TPA interface initiated following WEB-ED and attempt to initiate contact within the month following RCT interface or at 6 months post-RCT vs. post-WEB-ED if they have not. We will use a convenience sample of those in each identified comparison group, who are first able to be contacted by the study research coordinator or trained research interviewers by telephone.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

No

VI.20 ***Will subjects provide any information about their relatives?***
No

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
No

VI.26 ***Is this project about pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VI.46 ***Do you propose to enroll any subjects diagnosed with Posttraumatic stress disorder (PTSD)?***
Yes

VI.47 ***Describe how this protocol will take into consideration the perspectives of individuals with PTSD.***
One of the MH (mental health) and Trauma screens within the RCT is the VA Post-Traumatic Stress Disorder (PTSD) Screen.

VI.48 ***Does this study involve a study drug(s)?***
No

VII.A. Project Description (A)

VII.A.1 ***Where will project procedures take place (check all that apply)?***

- U.S. off-campus - Web-based survey Web-based survey For phase 1, members of the Iowa City research team will travel to conduct interviews with key informants will take place at five sites (one site per each MyVA region): Region 1: Albany VA Medical Center (NY); Region 2: Miami VA Healthcare System (FL); Region 3: Minneapolis VA Health Care System (HCS; MN); Region 4: Central Texas Veterans HCS (Temple) (TX); and Region 5: VA Puget Sound (Seattle) (WA). If participants are unable to participate face-to-face on these dates, we can arrange to talk with them by telephone using approved methods of communication, such as Doximity or Cisco SoftPhone. Due to delays related to COVID-19, the team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase.
- VAMC - CADRE research unit & CATI lab

VII.A.2 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***
No

VII.B. Project Description (B)

VII.B.1. ***Does this project involve any of the following (Check all that apply):***

- ☑ **Interventional** – Includes **Clinical (or Treatment) trial**, **Physiology intervention/study**, **Behavioral intervention/study**, **Diagnostic Trial**.
  - ☑ **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and ClinicalTrials.gov & FDA)
  - ☐ **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as “translational” or “basic science” aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.
  - ☑ **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
  - ☐ **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition (ClinicalTrials.gov & FDA)

- ☐ **Observational**
- ☐ **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- ☐ **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.(UI Guide)
- ☐ **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)
- ☑ **Other – Describe:**
  interview study

VII.B.1.a ***Does this project involve any of the following (Check all that apply):***

- ☐ **Phase I trials** – include initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients (ClinicalTrials.gov & FDA)
- ☐ **Phase II trials** – include controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks(ClinicalTrials.gov & FDA)
- ☐ **Phase III trials** – include expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling(ClinicalTrials.gov & FDA)
- ☐ **Phase IV trials** – studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use(ClinicalTrials.gov & FDA)

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***
No

VII.B.6 ***Will any subjects receive a placebo in this study when, if they were not participating, they could be receiving an FDA-approved treatment for their condition?***
No

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***
No

VII.B.18 ***Does this project involve testing the safety and/or efficacy of a medical device?***
No

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- Other - Provider key informants will be recruited via email and phone. Veterans will be recruited via postal mail, phone, as well as email, when possible.
- Use of any information available to the researchers or their colleagues because this person is a patient OR use of any information considered to be Protected Health Information (PHI) OR review of patient/clinic records - VINCI/VADIR will be reviewed to select eligible veterans for recruitment.
- Existing Registry/database - DMDC, VINCI and VADIR databases as previously described.
- Letter -
- E-mail -

[redacted] [redacted]

VII.D.2 ***List the individual data elements you will need to access/use from the patient or clinic records to identify potential subjects for recruitment***
Individual elements: Name and contact information (address, phone, email), DOD military service and health records, VA health records, individual medical record identifiers, and SSN.

Data will be linked across the various CDW domains using unique patient-level identifiers internally assigned by CDW and VINCI, including SIDs (surrogate ids) and ICNs (integration control numbers), and Real Social Security Number (for CAPRI/JLV nationwide chart reviews).

VII.D.3 ***Describe why you could not practicably recruit subjects without access to and use of the information described above***
Without this access we would not be able to recruit veterans to participate in the study. Due to the large number of possible participants, it is not practical to obtain authorization from potential subjects to review records for recruitment purposes. As this study is not conducted in-person, we are unable to approach patients in clinic to obtain this information.

VII.D.4 ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.***
By reviewing records prior to recruitment, we can minimize contacting Veterans who may be ineligible for the study. Due to the large number of possible participants, it is not practical to obtain authorization from potential subjects to review records for recruitment purposes. As this study is not conducted in-person, it is impractical to approach every patient in the clinic to get authorization to review their medical record.

VII.D.5 ***Describe plans to protect the identifiers from improper use or disclosure***
Potential study subjects will be assigned a random coded number to which all data will be associated. Information linking study numbers with personal information and answers will be kept in locked files and databases accessible only to study researchers within the VA. All paper documents containing confidential information will be kept in the secured office space in locked filing cabinets. All study personnel will complete CITI Human Subjects Training and VA confidentiality certifications.

Data are stored on the HSR&D and/or the VINCI server, behind the VA firewall. Data are secured with directory permissions as directed by the PI. Files with identifiable human subject data are password protected. All analysis will occur on VA owned servers and computers. No data will be stored on removable media. Individuals will not be identified in results; aggregate data will be presented. Anyone accessing data must take annual VA Human Subjects, Privacy, and Research Data Security Training.

VII.D.6 ***Describe your plan to retain research records until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1)***
Records will be retained as instructed by NARA and published in the VHA Records Control Schedule. Data will remain on the CADRE server in accordance with NARA requirements, at which time the data will be destroyed per Information Resources Management (IRM) and the latest VA Data Security Protocols for secure file deletion.

VII.D.7 ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule***
Yes

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?***
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
Phase 1 subjects/key informants will consent in person prior to the guided qualitative interviews, or via telephone if participants are unable to participate face-to-face on-site visit dates. When possible, the interviews will be 1:1, so the location will give the participant privacy in which to consent. Some interviews may be completed in a group setting. For participants completing interviews via telephone, they may set up a time that is convenient for them at a location of their choosing.
Phase 2 subjects will indicate consent as part of the online screening. For subjects who are invited to participate in the RCT, a consent form and HIPAA authorization form will be mailed to them after completion of the initial online screening.
Phase 3 subjects will consent via telephone prior to the semi-structured CATI interview.

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
Yes

VII.D.11 ***Describe:***
A toll-free number is provided with in the information summary letter should potential subjects have further questions. Phone calls to return calls for subjects who have left a message on the study toll-free secure voicemail, returned a contact form or email. Phone calls to recruit potential subjects using a call protocol. None of the phases will have the initial contact with a potential subject be a phone call. For phase 1 subjects, if there is no response from prior mail or email recruitment, we will initiate telephone contact consisting of 3 calls during different times of the day in attempts to schedule for the in-person or telephone interview. Providers will complete the interview by phone only if they are unable to complete the interview in person.

[redacted]

[redacted] [redacted]

Name	Consent Process Involvement
[redacted]	[redacted]

VII.D.14 ***The PI has formally delegated the responsibility of conducting the consent process and obtaining consent to the individuals listed above. The individuals delegated this responsibility have received appropriate training to perform these activities.***
Yes

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***
- Consent Document
- Letter or Information sheet containing elements of consent

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
Yes

VII.D.17 ***Choose one of the following to indicate why you are requesting that the IRB waive the requirement to obtain a subject signature as documentation of consent:***
A. The research presents no more than minimal risk (minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

AND

The study involves no procedures for which consent is normally required ouside of a research context. *(This type of waiver is often permitted for a minimal risk mail-out survey that includes a cover letter with all elements of consent, and returning the survey indicates consent. You cannot request this waiver if the study also involves the use of any protected health information (PHI).)*

VII.D.18 ***Explain why this meets the chosen criteria in A. or B. above:***
This research presents no more than minimal risk and that the study involves no procedures for which consent is normally required outside of a research context. Web-based participation will involve use of a randomly assigned study identification number so no personally identifying information will be used on-line. This study replicated protocols we have used in our other research projects with no untoward/adverse outcomes, further confirming our belief this is no more than minimal risk. All phases present no more than minimal risk. The waiver of documentation is for phase 1 and the initial portion of phase 2. Prior to participation in the RCT portion of phase 2, veteran subjects will sign and return via mail the consent and HIPAA authorization forms for this phase attached to this application.

VII.D.18.a ***Does the information you are collecting from subjects involve health information (either oral or written)? NOTE: The VHA considers all identifiable information collected from researcher's individually identifiable information based upon the 18 HIPAA identifiers. (See VHA Handbook 1605.1, Appendix B for explanation of Individually-identifiable Health Information and De-identification).***
Yes

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?***
Yes

VII.D.20 ***List any screening questions you will directly ask the potential subject to determine eligibility.***
Phase 2 Web-Ed Eligibility Questions

1. Have you served in the US Military after October 2001?
o Yes (1)
o No (0)
If participant answers 'No' then they are not eligible. Must have served as a US Military service member since beginning of OEF/OIF/OND to be eligible for participation.
1a. (If yes) What year(s) did you serve in the US Military since 2001?
□ 2001 □ 2009
□ 2002 □ 2010
□ 2003 □ 2011
□ 2004 □ 2012
□ 2005 □ 2013
□ 2006 □ 2014
□ 2007 □ 2015
□ 2008 □ 2016
□2017-2021
2. Were you ever deployed to Iraq or Afghanistan as a US Military service member or in support of Operation Iraqi Freedom, Operation Enduring Freedom, or Operation New Dawn (OEF/OIF/OND)? (select all that apply)
o Yes (1)
o No (0)
Must have answered 'Yes' to above question to be eligible for participation.

3. When did you return from your most recent deployment to either 1.) Iraq and/or Afghanistan or 2.) a deployment in support of Iraq/Afghanistan? (Month, Year)

VII.D.21 ***Will you keep a screening log or other record that would include information on people who do not enroll in the study?***
Yes

VII.D.22 ***Describe the information being collected and the purpose for keeping this information.***
It is necessary to determine differences between participants vs. non-participants to understand if there are differences that might reflect response bias and consequently influence generalizability of our findings. Consequently, we will collect and keep information on military branch, age, era of service, deployment status, rank, race, and geographic location (including zip codes). Note that this identifiable information is already in VADIR provided data. These data are stored on the HSRD server, which is maintained, backed-up, and secured in a locked server room by the Iowa City VA's Information Resources Management (IRM) department. The server can only be accessed by individuals with an IRM-created network account. Data are further secured using network directory permissions assigned by IRM at the direction of the Principal Investigator (PI). This ensures that only study personnel with the approval of the PI (in accordance with IRB requirements) have access to identifiable human subject/patient data. Additionally, files on the network that contain identifiable human subject data are password protected, and individuals accessing the server on a client machine are instructed to password protect their screen saver in order to maintain data security.
Study subjects including those who decline to participate, will be assigned a coded number to which all data will be associated. Linking information will be kept in locked files and databases accessible only to study researchers. All paper documents containing confidential information will be kept in the secured office space in locked filing cabinets. All records will be retained as instructed by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).

VII.D.23 ***Will this information be shared with anyone outside the VA research team members?***
No

VII.D.25 ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***
No

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
The potential participant will receive mailed recruitment letters, emails, as well as have advance notice of upcoming in-person or telephone interviews so they will have time to discuss the study with family and friends before deciding on participation. For phase 2, the potential subject can participate with the study at any time that the study is open and therefore has the capability of discussion of the study with family or friends at the time of their choosing.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***

We anticipate that the recruitment will occur within 6 weeks prior to the first phase of the study.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

Phase 1: The providers selected for phase 1 will be recruited via email and phone contact. Telephone contact will only be initiated after the email is sent. Providers will receive an initial email. 5 days after the initial email is sent, a follow up email will be sent. If still no contact has been made within 3 days, a call protocol consisting of 3 calls will be implemented. Provider emails will also include a web link via Qualtrics, where providers can indicate best times to schedule interviews with them during site visit dates. Once a date and time has been selected, participants will be emailed a confirmation email with time and date, as well as a second email or phone call with this same information if email is not provided. Some subjects may be recruited on-site. If the subject has not received a letter, copies of the letter will be available to them on-site to review prior to participation. VA Skype (internal, secure messaging) recruitment will be used with key informants who do not respond to email invitation. This messaging system will be used as an additional means to contact key informants who do not respond to the email invitation by using the script to answer any questions the potential participant may have, schedule a time to call them to discuss the study or their concerns in more detail, as well as to schedule an interview, if applicable. Potential subjects can indicate if they do not wish to participate via Skype as well.

Phase 2 WEB-ED Recruitment: participants selected from the VA Informatics and Computing Infrastructure (VINCI)/VA/DoD Identity Repository (VADIR) and per Defense Manpower Data Center (DMDC) will be recruited with a mailed recruitment letter (attachment 2A) containing the elements of consent, e-mail, and telephone follow up using call protocols. If we have not heard from the subject within 10 days of the initial mailing, a follow-up email (2C for Web-Ed and 2D for RCT) will be sent with "Do Not Reply" added to the subject line. If we have not had participant contact by 10 days after sending the email, we will resend an additional email. If there is still no response, we will initiate telephone contact consisting of 3 total calls during different times of the day (morning, afternoon, evening) in attempts to address any questions and to encourage online screening completion. A toll-free number will be provided to participants to facilitate contact for any questions. Bad Contact Info Call Script and Email will be used to contact subjects in effort to update their contact information For the WEB-ED, if the subject is eligible per the pre-consent screening questions, the informed consent for this online process is integrated into the web-based subject education and participants acknowledge ("click approval") that they have reviewed this prior to participation (attachment 2A Consent Letter - Current Web-Ed). This online document containing the elements of consent will contain the same information as the mailed document and will also inform participants that they may be invited to participate in a subsequent study phase that will address VA and post-deployment care access.

Veteran RCT Recruitment (WEB-ED+) and Assignment: Veterans who screen positive on one or more MH (mental health) screens will be eligible for the RCT and asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT. Those who indicate yes to study re-contact will be sent IRB approved study information, including the RCT consent letter (2B), consent and HIPAA forms attached to this application. Those who decline will be thanked again for their participation and contact will be discontinued. We will use adaptive randomization to achieve balance in the assignment to the treatment intervention arm of WEB-ED+ relative to the control arm of Current WEB-ED. Participants will be sent a letter to inform them about which arm of the RCT they have been assigned to and the expected participation steps for each arm (RCT Intervention Assignment letter or RCT Control Arm Letter). Those who are assigned to the Current WEB-ED arm of the RCT (those who had positive screens for the current WEB-ED, but randomly assigned to no intervention) will not complete Web-Ed+ and will not be contacted until Phase 3. The phase 2D email - RCT will be used to follow up with subjects who have been selected for participation but have not yet completed the additional online screening per randomization.

A medical chart review will be conducted for all subjects who return the signed HIPAA and consent forms for the RCT. Chart reviews will focus on VA care the subject received (or not) including medication, therapy, & any mental health and substance use treatment. We will review the time from post-deployment through 6 months after the subject's initial study participation.

We will assess/confirm enrollment status and upcoming appointments of participating Veterans using a combination of national visual chart review using CAPRI/JLV, along with accessing enrollment and appointment data from the CDW.

Provider RCT Recruitment (Web-Ed+): Phase 2 Provider Recruitment Email is sent after we receive the information back from the Veteran participant identifying their provider. If a VA provider does not respond to the email invitation, we will contact them via telephone or Teams and follow the Recruitment Script - VA Provider Invitation Script for telephone and Teams. If the Veteran is new to the VA, we will identify the VA provider they are assigned to and then immediately approach that provider. If they do not respond within 1-2 weeks, they may be sent the Teams message again. Once they agree to participate, we send them the Phase 2 Provider Instructions Email.

Phase 3 Veteran Recruitment: To contact participants who have participated in the RCT and agreed to be contacted for phase 3 by returning the signed consent and HIPAA forms, the study research team will use an IRB approved 3 call contact protocol varying times of day and days of week, using the study Q&A document to answer questions, in attempts to schedule an approximately 25 minute semi-structured qualitative interview to willing participants using computer-assisted telephone interview data collection. In addition, up to two postal mail recruitments will be sent with information, a return contact form indicating preferred contact times or preference to discontinue participation. All Veteran participants recruited for phase 3 will be asked for verbal confirmation of their VA care engagement or not, and their current level of distress with current post-deployment readjustment. Providers will also be asked to participate in the interviews for phase 3 and will be contacted via email (phase 3 participation email to providers) and a 3 call contact protocol.

In summary, for the initial portion of phase 2, if the subject is eligible per the pre-consent screening questions, the informed consent for this online process is integrated into the web-based subject education and participants acknowledge ("click approval") that they have reviewed this prior to participation (attachment 2A Consent Letter - Current Web-Ed). This online document containing the elements of consent will contain the same information as the mailed document and will also inform participants that they may be invited to participate in a subsequent study phase that will address VA and post-deployment care access.

Veteran participants will provide consent for RCT portion of phase 2 (as assigned), the phase 3 telephone interview, and chart review by signing and returning via mail the consent and HIPAA forms prior to participating in the RCT portion of phase 2. For those who participate in the first part of phase 2 and are eligible for the RCT portion of the study, they will be asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT (Web-Ed+). Those who indicate yes will be sent IRB approved study information, including the RCT consent letter (2B), consent and HIPAA forms attached to this application. Those who decline will be thanked again for their participation and contact will be discontinued.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
Yes

VII.E.1.a ***Will any subjects be blinded to which study arm they have been assigned?***
No

VII.E.2 ***Describe randomization scheme/assignment including ratio such as 1:1, 2:1 etc.***
For phase 2, we will use adaptive randomization to assign positive-screeners to each RCT arm; two-thirds to WEB-ED+ (~950) and one-third to Current WEB-ED (~450).

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
Yes

VII.E.4 ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)***
Phase 1 interview guide will include content from attachment: Phase 1 CFIR Constructs, and information included in the attachments Phase 1 VA Key Informant interview and Phase 1 Veteran Consumer Interview

Questions for the phase 2 Web-Ed Current are provided in the attachment Sadler_eSDM 2021_01_08 Programmed, which includes programming instructions/skip patterns as well.

Screens in phase 2 Web-Ed + will include the following:
MH and Trauma Exposure Screens:
1. PTSD - VA Post-Traumatic Stress Disorder (PTSD) Screen.
2. Domestic Violence (DV) - American College of Obstetrician and Gynecologist screen for DV. This was modified to include parallel questions that query participant DV perpetration.
3. Family Readjustment- developed from PI's focus groups from another HSR&D funded study.
4. Substance Abuse - AUDIT-C Substance Abuse Screen.
5. Prescription Drug Abuse- DoD Survey of Health Related Behaviors modified for the web.
6. TBI - VA Traumatic Brain Injury (TBI) Screen, modified to include more descriptive questions.
7. Depression - Physician's Health Questionnaire (PHQ-8) depression questions (suicide question omitted).
8. Anger- Dimensions of Anger Reactions (DAR5) Scale.
Trauma Exposure Screens
9. Combat Exposure - Exposures to Combat Screen.
10.Sexual Trauma - VA Military Sexual Trauma Screen.
Other:
11. Patient Activation Measure-13 - 13-item measure of patients' self-report of their health management skills, knowledge, confidence, and motivation. The PAM score will not be considered as a MH indicator but instead a measure associated with access and SDM interface associated with Aim 2 and 3 outcomes.
12. CollaboRATE - 3-item measure of the SDM process tailored to the provider or TPA.
13. Social Determinants of Health Questions - 6 items that address social needs including: food, housing, finances, and ability

to get to medical appointments.

Phase 3 interview (not yet developed) will include content from attachment: Phase 3 Process Evaluation Sample Questions. All materials not yet developed will be submitted in a modification prior to subject recruitment for that phase.

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
Yes

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

Phase 1: A total of 60 interviews (12 individuals at each of 5 sites) will be conducted. Key informant roles include: Primary Care-Mental Health Integration (PCMHI) providers (n=1-2), PC and/or MH providers(n=2), PCMHI or PC and MH case managers (n=1-2), MHV champion (n=1), Enrollment Specialists (n=1), OEF/OIF/OND Transition Patient Advocates (TPA) (n=1-2) and OEF/OIF/OND Veterans (n=4-5). An effort will be made to have a gender mix of key informants. VA personnel can be identified through VA national websites and our PBRN site leads. We will use site Veteran Panels to engage OEF/OIF/OND male and female war Veterans when possible, as well as using our Veteran registry obtained VINCI/VADIR to identify Veterans who are and are not currently VA engaged, respectively. Due to delays related to COVID-19, the research team has decided to move forward with the data collected for phase one, and not to collect any one-to-one Veteran interviews for that phase. VINCI is a partner with the Corporate Data Warehouse (CDW) and hosts all data available through CDW as well as some unique data. VADIR is the VA group that interfaces with Defense Manpower Data Center to obtain sample characteristics of service members/Veterans, including postal and military e-mail addresses, and work/home telephone numbers. In phase 1, we will also develop a template for use in the VA electronic medical record to document the shared decision-making interface that is a component of our intervention for those in the RCT treatment arm (WEB-ED+). This will be an important material reviewed by our key informants in Phase one interviews. Prior to these interviews, this template will be developed with the assistance of study consultants who have developed templates for shared decision making documentation in a university health care setting and with assistance and with the guidance and initial consultation and prior approval from key VA offices, e.g. National VA Privacy office.

Following IRB approval, Consolidated Framework for Implementation Research (CFIR) guided qualitative interviews will be conducted by Dr. Sadler and other research team members (Cook, Steffensmeier) to determine key informant critiques of the WEB-ED+ content that will include: 1) MHV authentication and secure messaging directions; 2) online VA enrollment directions; and educational shared decision-making (SDM) educational videos, one for Veterans and one for providers, regarding the benefits and process involved in SDM respectively (video links (unlisted, only accessible via links: Shared Decision-Making SDM-Non-SDM https://youtu.be/9Exh5qm2D4s; Shared Decision-Making ‘Veterans’ https://youtu.be/FaevM-mTJtU; Shared Decision-Making ‘Providers’ https://youtu.be/xETkUedZ2N4); 3) decision aids for PTSD, depression and substance use disorder for use by patient and provider, and 4) patient activation scores and their relationship to SDM and care engagement. Dr. Cook and Dr. Sadler will engage top leadership at each study site as well as work with the Women’s Practice Based Research Network leadership site leads at each facility to promote communication and engagement at each VA. To complement the qualitative data, Dr. Sadler will engage with local stakeholders and champions at each facility in order to map clinical workflow processes (process mapping) at each of the five study sites and determine how to best integrate WEB-ED+ into existing workflows. On-site visit interviews allow our research team important insights about the localized nature of health care delivery and how this might impact refinement of WEB-ED+ and its potential adoption and reach. Individual interviews ensure greater likelihood of the participation of key informants at times that accommodate their schedules and equalizes the importance of information from each of them. These interviews will be recorded, and this will be explained during the consent process prior to the start of the interviews. The following attachments will be sent in the following order: Phase 1 Confirmation Email; 2. Interview Direction Email; and 3. Link Email. Phase 1 Confirmation Email is sent immediately after interview is scheduled to confirm date and time of interview. Interview Direction Email is sent after to explain the interview protocol and to allow adequate time for questions. The Link Email is sent 24-hours before the scheduled interview, this email has the link to follow to watch the study video and the access number to the VANTS line. This is to increase the fidelity to the interviewee’s first time watching the Shared Decision-Making video while on the VANTS conference call with the interviewer.

Phase 2: Participants will include two overlapping populations of OEF/OIF/OND male and female Veterans eligible for VA care, which we will randomly sample from two overlapping populations. The first group includes those who returned from deployment to Iraq or Afghanistan within the preceding four years and who reside within the catchment areas of the current PBRN study sites (identified by zip code). We want to ensure that those who participate and screen positive on one or more of the screens have access to VA care. Consequently, we have selected the time frame of 4 years post-deployment because these Veterans have priority access to VA care for five years after their most recent deployment. The second group is OEF/OIF/OND Veterans who are already enrolled in VA care and will not be excluded if they have been home from deployment more than four years. We are doing purposeful sampling to achieve sufficient numbers of men vs women and we will work with VINCI/VADIR to have a sample representative by gender and race consistent with the current OEF/OIF/OND post-deployment populations.

All study participants will be asked to complete the online survey and screenings and be provided with their results and tailored educational information. Documentation of informed consent for Phase 2 participation (WEB-ED) is integrated into the web-based interface (“click approval”). Participants receive a hardcopy version of this form containing the elements of consent in the study packet and can read a copy online. This process has been approved in five prior projects using WEB-ED. The consent document will

also inform participants that they may be invited to participate in the subsequent study phase that addresses VA and post-deployment care access. WEB-ED includes a brief pre-intervention survey that will query stigma associated with MH care, prior and current utilization (VA and non-VA; primary care, MH, emergency) and their reasons for accessing VA or not, knowledge about post-deployment VA eligibility, services and satisfaction with VA care, potential barriers to MH service use, and their use of or barriers to MHV and secure messaging. Those who meet screening criteria for MH conditions and readjustment concerns receive online notification and a recommendation for a face-to-face evaluation, education about each MH domain for which there is a positive screen, and information about access to care. Patients who may have immediate needs will also be provided with specific VA resources, contact names and numbers, as well as information for providers or resources unique to their needs and geographic locations. The 24-hour Veterans Crisis Line (1-800-273-TALK (8255)) will be provided. Patients with negative screens will be informed to seek care if they believe that it is needed. We note that neither our research team's studies using focus groups and telephone interviews with more intensive questions about sexual assault or combat experiences in deployed populations, nor our prior web-based intervention studies, have resulted in any subsequent clinical emergencies. Veterans who have no positive screens will be able to access the same educational information, web links, and video-clips if they choose.

A web-based satisfaction survey immediately follows screening and tailored education. In addition to questions about barriers and facilitators to access to care, satisfaction with an online process, and ways that we can make Veterans more satisfied with this screening and educational interface, we will also ask questions from the SHEP ambulatory care 2015 survey pertinent to study domains (provider and VA interface satisfaction for outpatients), e.g.: 1) did their provider tell you there was more than one choice for your treatment or care; 2) talk with you about the pros and cons of each choice for your treatment, 3) ask which choice was best for you, 4) listen carefully to you.

Phase 2 RCT Intervention (WEB-ED+) Veteran Procedures: Veterans who screen positive on one or more MH screens will be eligible for the RCT and asked online at WEB-ED completion for permission to re-contact them about continuing their participation in the RCT. Those who indicate yes will be sent IRB approved study information, including the RCT consent letter (2B), consent and HIPAA forms attached to this application. A summary of the screening results will be sent by encrypted email (attachment Phase 2 encrypted email - treatment arm RCT.rtf) to Veterans in the RCT treatment arm (WEB-ED+). An email will be sent in advance of this to alert Veterans that they will be receiving secure information by encrypted email. Additionally, Veterans will be asked to indicate which screening results bother them the most that they would like to talk with their provider about (To share with Provider). Veterans are asked to return that form along with their signed consent forms. Phase 2 Thank you letter-returned forms will be used to thank participants for returning their signed consent and HIPAA authorization forms.

To receive care in the VA health care system, Veterans must enroll in the VA system. Online VA enrollment links and information (available to every Veteran) will be provided to help RCT participating Veterans with this process. If they are unable to enroll electronically, key points of contact at the VA geographically closest to them will be provided so they can receive assistance with this process. Additionally, enrollment in My HealtheVet (MHV), a secure online ehealth portal, allows Veterans to access their medical records and send secure messages to their VA providers. As part of the RCT, participants will be asked to secure message their screening results summary to the VA provider of their preference. If they are new to the VA, enrolling as a result of the RCT participation, their newly assigned provider will be the individual that they will be asked to secure message their screening results summary. Note, that the study team will be monitoring enrollment and provider assignment of Veterans new to the VA and will invite the provider as soon as the assignment is made. If needed, the study team will be available to secure message the screening results, rather than the Veteran.

Phase 2 RCT Intervention (WEB-ED+) Provider Procedures: once the provider has agreed to participate, they will be sent an email that contains links to 2 short videos about shared decision-making and three brief decision aids (PTSD, depression, substance use disorder).

Using the knowledge both the provider and patient learned from the WEB-ED+ materials, they will discuss treatment options at the patient's appointment.

If subjects do not complete steps in the process, the appropriate attachment (Phase 2 RCT missing VA enrollment, Phase 2 RCT missing MHV premium enrollment, or Phase 2 RCT missing secure messaging) will be sent via email or postal mail if email is not available to support completion of these steps, with a toll free number provided. Further, up to 3 contact calls will be made until the subject is reached, to determine if the participant has discontinued study participation, if the study team can be of further assistance, or to determine the completion barrier(s), and if the Veteran is enrolled- to assist them with MHV barriers by sending the study screening results summary by encrypted email to the participant's preferred or new provider in their stead (eSDM Chart Review-Secure Message) so they are able to progress to their appointment in order to use shared decision-making with their provider about their positive MH screens. Requested Resources Email Scripts will be sent per request of subject as needed. The missing email notice attachment will be used for those in the treatment arm of RCT to encourage them to contact us and update their email address so we can continue their participation with the study. The provider consent notification document will be sent via mail or email letting the participant know that their provider has consented to participate in the RCT.

Those who decline will be thanked again for their participation and contact will be discontinued. We will use adaptive randomization to achieve balance in the assignment of those who consent to WEB-ED+ or Current WEB-ED. Those who are assigned to Current WEB-ED will not be contacted again until Phase 3.

Per VA Research project modification approval received November 2022, we are now able to provide subjects with an additional $30 for already returned signed HIPAA form and consent to participate with this study phase. We will notify previous subjects using attachments (Phase 2 New Reimbursement postal mail and Phase 2 New Reimbursement email), and submit this request, anticipating that they should receive this direct deposit within 4 to 8 weeks. For new RCT recruitments we have edited the Phase 2 RCT recruitment to indicate that if they return their signed HIPAA form and consent to participate in this study phase they will received $50.00 (the same amount as those who have already returned these forms will receive).

Because of new VA research policy changes, we are now also able to provide subjects with an additional $75.00 upon completion of the RCT "intervention group" steps of this research phase that involves seeing their VA provider (as described in the consent and the

encrypted study group assignment email).

We will send the new funding notice to all RCT consenters first by email, followed by postal mail with follow up a week later via telephone using a 3-call protocol.

If subjects do not complete the screening, attachments Phase 2G Incomplete Survey Email and Phase 2H Incomplete Survey Letter will be sent to encourage completion.

A medical chart review will be conducted for the subjects who return the signed HIPAA and consent forms for the RCT and prior to the interview for phase 3. Chart reviews will focus on VA outpatient care the subject received (or not) including medication, therapy, & substance use treatment. We will review the time from post-deployment through 6 months after the subject's initial study participation. We will assess/confirm enrollment status and upcoming appointments of participating Veterans using a combination of national visual chart review using CAPRI/JLV, along with accessing enrollment and appointment data from the CDW.

Phase 3: Post-intervention process evaluation will rely on data collected via Computer-Assisted Telephone Interview (CATI), with which our team has extensive experience. We will recruit 76 Veteran participants, and all Veteran-identified VA providers who agree to participate. We will use 3:1 sampling. It is anticipated that in each of the four groups, we will have appropriate representation of gender and racial/ethnic groups, but we will monitor this and use purposeful sampling if needed. Fewer numbers of those who did not engage in VA care reflects our expectation of less variation in subgroup data. As we do monthly EMR checks of participants, we will be able to identify provider/TPA interface initiated following WEB-ED and attempt to initiate contact within the month following RCT interface or at 6 months post-RCT vs post-WEB-ED if they have not. We will use a convenience sample of those in each identified comparison group, who are first able to be contacted by the study research coordinator or trained research interviewers by telephone.

Semi-structured interviews with qualitative and survey questions will be implemented from Dr. Sadler's CATI laboratory, with established data security and interviewer training/monitoring protocols in place for a decade. These interviews will not be recorded. Guided by CFIR, we hope to understand participants' perceptions of the intervention to which they were assigned with regard to ease and usefulness, need for improvements, and perceptions of barriers/facilitators to VA and MH services receipt or provision. We will interview both those who did/did not subsequently engage in the eHealth process/secure messaging and among these groups those who did/did not engage in VA MH care consequently. WEB-ED+ Veteran Participants will be asked about their use of secure messaging, VA provider engagement, satisfaction with use of WEB-ED results, if their VA provider participated in SDM with them, and satisfaction with the type of care they received. Those not activated to participate in VA care or who did not secure message results will be asked about barriers/facilitators to this process and how we might improve this interface or MH engagement. Current WEB-ED Veterans will be asked the same questions except for those specific to WEB-ED+. Participants from both RCT arms will be asked about satisfaction with process and care (if sought).

A Veteran process map will be developed from the Veteran's perspective to show whether each step of the WEB-ED RCT process helped create a clear value for them as a care customer or not. Provider/TPAs will be asked parallel questions to the Veterans-respective to each treatment arm. A Provider process map will be developed to help us understand the specific roles of individuals in the overall system of care, i.e. the # of teams involved, if there are bottlenecks and delays, rework that occurs in facilitating war Veterans' access to patient-centered MH care, and the potential system impact of WEB-ED+ and perceived value to the provider/TPA.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - those lost to followup will not be recontacted

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
Yes

VII.E.10 ***Cash***
No

VII.E.11 ***Gift Card***
No

VII.E.12 ***Check***
No

VII.E.16 ***Other***
Yes

VII.E.17 ***Describe:***
Subjects will be paid via electronic deposit.

VII.E.19 ***Describe the compensation plan including***

- ***Compensation amount and type per visit***
- ***Total compensation***
- ***Pro-rating for early withdrawal from study***

Phase 1: Providers will receive no financial compensation for their participation.

Phase 2: $30.00 will be compensated for WEB-ED completion, and an additional $20 will be compensated for return of

participant HIPAA and consent forms allowing for consequent VA chart review and with the Veteran's VA provider for all assigned to the RCT portion of Phase 2. Given a recent VA research modification that allows us to reimburse an additional $30 to those who have already returned signed HIPAA and consent forms necessary to be reimbursed will be contacted about this increase in reimbursement as well as the new policy change that allows us to reimburse $75.00 for completion of the "intervention group" requirements. Those in the RCT will be notified about this change and those newly recruited will have this change included in their initial recruitment and consent documents. Participants need to sign and return a bank form to initiate the electronic deposit(s). Those who have already done and are eligible for the additional reimbursement will not need to do so again. The Bad Address Contact Call script will allow the research team to confirm the correct mailing address to send forms to the participant. If the research team is unable to reach the Veteran by phone, the Bad Address Contact Email will be sent. The reimbursement follow up script and email will be used to see if the participant would like reimbursement materials resent so they can be compensated.

In summary: Per project modification approval received November 2022 (attached), we are now able to provide subjects with an additional $30 for already returned signed HIPAA form and consent to participate with this study phase. We will notify previous subjects using attachment (Phase 2 New Reimbursement postal mail and Phase 2 New Reimbursement email), and submit this request, anticipating that they should receive this direct deposit within 4 to 8 weeks.

Because of new policy changes, we are now also able to provide subjects with an additional $75.00 upon completion of the RCT "intervention group" steps of this research phase that involves seeing their VA provider by March 1, 2023 (as described in the consent and the encrypted study group assignment email). Those who have returned consents and HIPAA forms for the RCT will be notified of this change and encouraged to complete their RCT intervention steps if they have not already. Those newly recruited to the RCT will have this included in their updated Phase 2 RCT consent document.

Phase 3: $40 will be compensated for each participant (76) who completes the Phase 3 semi-structured Veteran interviews.

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial
- legal or social
- physical?

We do not anticipate any health risks as a result of participating in this study. We will not ask subjects to share the results of the screening questionnaire during the telephone interviews, but rather provide us with feedback on the currently developed web-based screening and educational materials. Some of the questions we will discuss are of a sensitive nature and participants do not have to answer any questions they do not wish to. Some of the questions posed in the online assessment instruments are of a sensitive nature and participants do not have to answer any questions they do not wish to. It is possible that loss of confidentiality is a potential risk. However, we have used random study numbers to decrease this risk. Follow up phone interviews will query the usefulness of information women received online, their knowledge and current use of VHA care, barriers to use of VHA mental health services, and their perceptions of and willingness to use VHA mental health services. The interview will be tailored so that participants who already access VA primary or mental health services will be queried about their perceptions regarding utilization. This information will be used to expand a subsequent iteration of the online questionnaire with sections designed to reduce barriers (e.g., stigma, disinformation regarding eligibility, confidentiality concerns) and encourage engagement with VA mental health services. For the randomization to the two study interventions, it is possible that during participation, subjects may experience an exacerbation of pre-existing post-deployment mental health or readjustment conditions.

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Dr. Sadler is an experienced clinician trained to assess and address immediate participant reactions. In the unlikely event that a participant expresses significant acute distress and is clinically determined to be at potential risk of harming self or others, Dr. Sadler will facilitate emergent mental health care and transportation to the appropriate resource. At the end of all telephone interviews, veterans will be given the information about care resources for veterans and Dr. Sadler will facilitate their enrollment in care if this is desired or needed. A protocol will be in place to address any mental health emergency or safety issues and Dr. Sadler or her designee will be on call during study implementation. We do not anticipate that this will happen given our experience with studies that require significantly greater sensitive information than this study covers. However, we will make sure that the protocol will provide safety and resources in the unlikely event this does occur. Confidentiality could be considered a concern, but the participant will designate the time of the telephone interview and choose the site they will make it from. All information obtained will be kept behind locked doors, within a locked office within the locked CADRE research area or on VA Servers maintained by Information Resources Management and CADRE data managers. For phase 2 randomization, the same protocol to address mental health emergencies and safety plans will be in place. In addition, Dr. Sadler or her designee will be on call during study implementation to facilitate any access to emergency services as needed. Notably, in our prior research using telephone interviews and web-based screening, we have experienced no adverse subject reactions to participation.

The identifiable information will be stored on servers located behind the VA firewall located in the OI&T server room at the Iowa City VA. Data on the server will be operating within the VA network, which is protected by a firewall maintained by OI&T. There will be no electronic transfer of data through the Internet, e-mail, or file transfer protocols (FTP). All data transfers will occur via VA shared network drives behind a VA firewall. Data containing Protected Health Information (PHI) will not be removed from VA

property; however, letters will be mailed to veterans inviting them to participate in the study. There will be no remote access to the data except through the VA network to access the data on the server. Only identified study personnel will have access to the data.

Identifiable information will not be reused or disclosed to any person or entity outside VHA, except as required by law, for authorized oversight of the research study or as specifically approved for use in another study by an IRB.

For the interviews, audio-recordings, transcripts, and any interviewer notes will use first names only and will not include other identifiable information. These will all be uploaded to the secure drive from the site where the interviews will be held. The consent documents will be scanned and saved to the secure drive. Original copies will also be securely stored at the Iowa City VAHCS.

Study subjects will be assigned a coded number to which all data will be associated. Subjects can then go to web site to complete surveys. Linking information will be behind a fire wall in locked drives. All paper documents containing confidential information will be kept in the secured office space in locked filing cabinets. All study personnel will complete CITI Human Subjects Training and VA confidentiality certifications before starting work. Database security will be maintained by following a confidential system of user identifiers, passwords, and numerous other VA established standard security measures. In order to ensure subjects' privacy, personal information collected will be limited to the minimum necessary to accomplish the goals of this research.

Data are stored on the HSR&D and/or the VINCI server, behind the VA firewall. Data are secured with directory permissions as directed by the PI. Files with identifiable human subject data are password protected. All analysis will occur on VA owned servers and computers. No data will be stored on removable media. Individuals will not be identified in results; aggregate data will be presented. Anyone accessing data must take annual VA Human Subjects, Privacy, and Research Data Security Training.

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
Participants may have no direct benefit but may benefit from knowing that their study participation may help VA care access and/or care engagement of other war Veterans. Some participants might benefit from research staff assistance in enrolling in MHV and attaining the capability (premium status) to secure message information, such as their study results, to an OEF/OIF/OND coordinator or their VA provider to facilitate their communication and potentially access to care. Providers will potentially benefit from awareness that their contributions assist with improving recent war Veterans access to and needed engagement in VA care.

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
This study seeks to develop and test WEB-ED enhancements (WEB-ED+) that integrate a shared decision-making (SDM) process and eHealth interface to assist secure messaging of MH/SDM interfaces with VA providers. Findings are important in helping us to understand WEB-ED+ usability and adaptability for routine use by Veterans and VA practitioners, with the goal to improve VA MH care access and patient-centered care for Veterans.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***
Study subjects will be assigned a random coded number to which all data will be associated. Subjects can then go to a web site and enter this random coded number to complete the online web-based screening and access the tailored educational materials. UI Qualtrics will provide and oversee the online screening for Phase 2/RCT according to an agreement with the VA Health Care System. It will also be used to assist with scheduling for phase 1 interviews. A web link will be created to serve as an electronic form for phase 1 non-veteran participants to indicate best available times for the interview. UI Qualtrics is not a subsidiary or affiliate of the Veteran's Administration. UI Qualtrics collects and stores the answers submitted on-line on their secure server. UI Qualtrics will not have access to any HIPAA identifiable information. Information linking study numbers with personal information and answers will be kept in locked files and databases accessible only to study researchers within the VA. Dr. Sadler will obtain authorization to transport prior to conducting the phase 1 interviews. Notes from the semi-structured interview will be done only with a subject identification number. All paper documents containing confidential information will be kept in the secured office space in locked filing cabinets. Records will be retained as instructed by NARA and published in the VHA Records Control Schedule. Data will remain on the CADRE server in accordance with NARA requirements, at which time the data will be destroyed per Information Resources Management (IRM) and the latest VA Data Security Protocols for secure file deletion. All study personnel will complete CITI Human Subjects Training and VA confidentiality certifications before starting work. The identifiable information will be stored on servers located behind the VA firewall located in the OI&T server room at the Iowa City VA. Data on the server will be operating within the VA network, which is protected by a firewall maintained by OI&T. There will be no electronic transfer of data through the Internet, e-mail, or file transfer protocols (FTP). All data transfers will occur via VA shared network drives behind a VA firewall. Data containing Protected Health Information (PHI) will not be removed from VA property; however, letters will be mailed to veterans inviting them to participate in the study. There will be no remote access to the data except through the VA network to access the data on the server.
Only identified study personnel will have access to the data. Identifiable information will not be reused or disclosed to any person or entity outside VHA, except as required by law, for authorized oversight of the research study or as specifically approved for use in another study by an IRB.
For the interviews, audio-recordings, transcripts, and any interviewer notes will use first names only and will not include other identifiable information. These will all be uploaded to the secure drive from the site where the interviews will be held. The consent documents will be scanned and saved to the secure drive. Original copies will also be securely stored at the Iowa City VAHCS.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***
Yes

X.3 ***Provide the intended usage of SSN:***
- To provide compensation to subjects
- Other - We will use the subject's SSN to complete the chart review. We will use CAPRI/JLV/Vista Web for the national chart review and SSN is the unique identifier nationwide.

X.4 ***How will information/data be collected and stored for this study (check all that apply):***
- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - These notes will have no direct personally identifiable information and the notes will be maintained following the confidentiality system above within locked offices, locked filing cabinets, on a locked research (CADRE) center. Study team members with an approved authorization to transport will temporarily remove hard copies of transcripts off-site for review.
- Electronic records (computer files, electronic databases, etc.) - CADRE project data will be stored on the CADRE server, which is maintained, backed-up, and secured in a locked server room by the Iowa City VA's Information Resources Management (IRM) department, and on VINCI. The server can only be accessed by individual with an IRM-created network account. Data are further secured using network directory permissions assigned by IRM at the direction of the Principal Investigator (PI). This ensures that only study personnel with the approval of the PI (in accordance with IRB requirements) have access to identifiable human subject/patient data. Additionally, files on the network that contain identifiable human subject data are password protected, and individual accessing the server on a client machine are instructed to password protect their screen saver in order to maintain data security. A random, unique identifier will be used to identify patients in electronic study datasets used for analyses. All direct identifiers will be removed from the study datasets before conducting analyses. The linkage between the unique identifier and identifying information resides on a secure VA server and is only available to IRB approved study personnel. Bank information will be collected only for the purpose of compensating subjects. It can be collected in one of 2 ways, whichever the subject prefers. The subject can be mailed a form to fill out and return via pre-paid postal envelope, or via secure fax. This information will be entered into our database which has all of the security measures described above. Any incidents involving loss of data, etc., will be reported immediately to the PI and data manager. Access to data will be terminated when a staff member is no longer on the research team. A HIPAA de-identified dataset will be shared with outside collaborators, all of whom are either covered to carry out the research by their local institutions, or whose local institutions have deemed the work with de-identified data does not constitute human subjects research. All HIPAA 18 identifiers will be removed, and a Data Manager, Statistician and Privacy Officer will review the data to ensure that all identifiable elements have been removed.
  - [redacted]
  - [redacted]
  - [redacted]

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
No

X.6 ***Describe***
A HIPAA de-identified dataset will be shared with outside collaborators, all of whom are either covered to carry out the research by their local institutions, or whose local institutions have deemed the work with de-identified data does not constitute human subjects research. All HIPAA 18 identifiers will be removed, and a Data Manager, Statistician and Privacy Officer will review the data to ensure that all identifiable elements have been removed.

X.7 ***Does your study meet the NIH criteria for a Certificate of Confidentiality or will you be applying for Certificate of Confidentiality?***
No

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
Qualitative Analysis (Aims 1 and 3): CFIR will guide the key domains/constructs queried in Phases 1 and 3 with key informants and in Phase 3 with RCT participants and providers (see below). The initial analytic approach to the interview data will use the constant comparison method, whereby we use open coding to identify salient issues and concerns raised by the participants across all of the groups. These open codes will be examined by the investigators in order to develop themes that pertain to the majority of participants, with a focus on addressing the specific aims of the study (rather than all emergent themes). These themes will also be analyzed for their potential “fit” with the CFIR model, i.e., their relevance to the concepts of intervention, outer and inner setting, individual characteristics, and implementation process. Assuming that there will be some degree of fit between emergent themes and conceptual domains, each conceptual domain will be summarized with reference to its applicability to refinements to the intervention as well as overall implementation processes. MAXQDA v12, a qualitative data analysis software program, will be used to assist this process. The codebook will be developed initially by Dr. Sadler and Dr. Hamilton with subsequent co-investigator and qualitative team independent coding of transcripts. In Phase 3 this will be specific to RCT participation (WEB-ED+ versus WEB-ED).
Aim 2 Analyses: We will begin with bivariate analyses (i.e., chi-square test for proportions) to test significance of differences in care engagement between RCT arms. Care engagement is the primary outcome and will be operationalized by VA MH services receipt (yes/no). Our primary analyses will use logistic regression models to estimate the adjusted ORs for treatment engagement controlling for participant characteristics. The logistics regression models will provide an estimate of the association between health care engagement by RCT arm, controlling for covariates such as Veteran gender, prior VA enrollment, severity [screening scores] and complexity [multiple positive screens], patient-activation scores, and rurality. Potential confounding variables that will be assessed in all hypotheses include socio-economic variables (e.g., age, income, marital status), and military characteristics (e.g., months home

from deployment, rank). In addition, depending on the resulting proportions of Veterans who get care in various VA clinics (i.e., PC, PCMHI, MH), we plan to conduct a multinomial logistic regression, treating RCT-arm as a covariate. We have used multinomial logistic regression previously to examine associations with three levels of VA health care use (all, some, none).

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
We will aim for 2000 Veterans completing WEB-ED, with approximately 1100 completing the RCT. Not all 2000 will be eligible for the RCT. Based on our five prior studies, ~77-85% of WEB-ED participants screened positive on at least one of the MH screens (~70% screened positive on depression, PTSD, or substance use). We will assume that 70% will eligible for the RCT (~1400) and use adaptive randomization to assign positive-screeners to each RCT arm; two-thirds to WEB-ED+ (~950) and one-third to Current WEB-ED (~450). There are no additional RCT participation activities for those in the Current WEB-ED arm, therefore attrition would be minimal. However, we anticipate there may be attrition among those assigned to WEB-ED+. Our CREATE multi-phase study resulted in attrition of ~30%. Therefore, we expect 650 completers for WEB-ED+. We have increased this sample size to have sufficient power to detect differences per RCT arm. This study is powered to detect whether WEB-ED+ increases VA MH care engagement compared to Current WEB-ED. In our prior work, half indicate that as a direct result of WEB-ED, they will follow up with a provider and 38% with a VA provider, although actual follow-up may be lower (our CREATE study is currently validating participant self-report with chart review data). This proposed study will document VA utilization (including VA purchased care) by VA chart review. We estimated the minimum sample size needed to ensure adequate power (80%) for a variety of assumptions (percentage of Current WEB-ED participants engaging in VA MH care, effect (odds ratios), and variance inflation factors (VIF)57, using nQuery 4.0. We anticipate random assignment will result in no statistical differences between RCT arms based on WEB-ED data (e.g., prior enrollment in VA, positive screens). However, covariates will be included (e.g., gender, rurality, patient-activation scores, VA site) in multivariate analyses to control for variation due to these other variables. Any significant covariates may point to sources of variability to explore in future research efforts, but we do not anticipate having sufficient power to conduct subsample analyses by gender or VA site.

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
Yes

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.3 ***List the data or information you will keep:***
Contact information and data from all study phases.

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
No

XIII. Other Mod and/or Comments

XIII.1 ***Most modifications should be made in the appropriate section (see Index) of the project itself. If you need to describe other changes, or wish to add comments about something you changed, please do so here.***
Per VA Research project modification approval received November 2022 (attachment: ORD-ProjectModification_Sadler_IIR_16-096_September2022_ rwob for LC sig-lmc.pdf), we are now able to provide subjects with an additional $30 for already returned signed HIPAA form and consent to participate with this study phase. We will notify previous subjects using attachments (Phase 2 New Reimbursement postal mail and Phase 2 New Reimbursement email), and submit this request, anticipating that they should receive this direct deposit within 4 to 8 weeks. For new RCT recruitments we have edited the Phase 2 RCT recruitment to indicate that if they return their signed HIPAA form and consent to participate in this study phase they will received $50.00 (the same amount as those who have already returned these forms will receive). In the attachments 'RCT Intervention Assignment Letter.rtf' and 'Recruitment Scripts.docx,' we have added text describing the additional compensation we are now able to provide, as well as to let subjects know when activities for the study need to be completed. We updated the text for the Follow up Script Phase 2 RCT – No appointment follow-up call at 6 and 10 weeks, as well as the VA Provider Invitation Script for Teams (information summarized from above telephone script and approved email the provider will have already received) to include responses to frequently asked questions from providers. The reimbursement follow up script has been edited to reflect the increased compensation amount we are now able to provide to subjects.

Because of new VA research policy changes, we are now also able to provide subjects with an additional $75.00 upon completion of the RCT “intervention group” steps of this research phase that involves seeing their VA provider (as described in the consent and the encrypted study group assignment email).

The chart review (as described in section VII.E.6) template has been attached. We have made changes to existing RCT attachments to reflect these changes, and added the chart review template, added Dan Corry to the research team, as well as removed Michala Cox from the research team since she no longer works with VA. We also removed Samantha Solimeo from the research team as she no longer works on the project.

XIII.2. ***Have you permanently stopped enrolling new subjects into this study?***
No

Project Modification Attachments

Attachment Name	Category	Ver	Size	Type	Attached
Phase 2 RCT Informed Consent 12-14-22.rtf	Informed Consent	16	307 k	E	12/19/22
Phase 2A Consent letter - Current Web-Ed.rtf	Consent Letter	9	729 k	E	07/12/21
Phase 2B Consent letter - RCT.rtf	Consent Letter	13	184 k	E	12/19/22
ORD-ProjectModification_Sadler_IIR_16-096_September2022_ rwob for LC sig-lmc.pdf	Funding Source Grant	1	1 M	E	12/14/22
Sadler 2016 IIR Fall Resubmission2.pdf	Funding Source Grant	1	11 M	E	06/22/17
Phase 3 Invitation Letter - Veterans.rtf	Recruitment Script: Mail	8	179 k	E	09/13/21
Phase 1B Email to Leadership.rtf	Recruitment Script: Email	7	271 k	E	03/08/19
Phase 1C Email to Key Experts.rtf	Recruitment Script: Email	13	203 k	E	09/19/19
Phase 2 RCT Provider Recruitment Email.rtf	Recruitment Script: Email	8	217 k	E	08/10/22
no changes made to content. Just a title change.					
Phase 2 encrypted email - treatment arm RCT.rtf	Recruitment Script: Email	1	117 k	E	09/28/21
Phase 2C Email - Current Web-Ed.rtf	Recruitment Script: Email	13	92 k	E	11/08/21
Phase 2D RCT Recruitment Email.rtf	Recruitment Script: Email	13	186 k	E	12/19/22
Phase 1 VA Key Informant Interview.docx	Subject Data Collection Instruments	4	30 k	E	03/08/19
Phase 1 Veteran Consumer Interview Revised 03-06-20.docx	Subject Data Collection Instruments	6	19 k	E	03/16/20
Phase1_Questions_CFIR_Constructs.pdf	Subject Data Collection Instruments	1	171 k	E	08/10/17
Phase3_Process_Eval_Samp_Ques.pdf	Subject Data Collection Instruments	1	34 k	E	08/10/17
Sadler_eSDM 2021_01_08 Programmed.docx	Subject Data Collection Instruments	2	78 k	E	01/14/21
Sadler_eSDM 2021_01_08 Questions.pdf	Subject Data Collection Instruments	1	7 M	E	01/14/21
Non-participant sociodemographic and military characteristics.docx	Screening: Screening Log	1	13 k	E	08/24/17
Anger Educational Module.pdf	Miscellaneous	3	207 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Bad Contact Info Call Script and Email.docx	Miscellaneous	2	19 k	E	02/07/22
CHART REVIEW 12-14-22.docx	Miscellaneous	1	25 k	E	12/16/22
CONTACT INFORMATION FORM - Veterans.docx	Miscellaneous	2	14 k	E	01/14/21
CONTACT INFORMATION FORM.docx	Miscellaneous	4	16 k	E	07/16/19
Crisis Call Procedures-Steps for Managing Crisis Calls + Warm Transfers to VCL 2015.03.docx	Miscellaneous	1	36 k	E	08/10/17
Depression Educational Module updated links 4.20.21.pdf	Miscellaneous	4	155 k	E	05/27/21
This change is to remove broken web links and add current web links.					
Encrypted email notice to Veteran.rtf	Miscellaneous	2	1 M	E	07/12/21
FAQ_eSDM Qualtrics.docx	Miscellaneous	4	17 k	E	07/12/21
FINAL Decision Aid-AUD.pdf	Miscellaneous	1	362 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.					
FINAL Decision Aid-Depression.pdf	Miscellaneous	1	358 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.					
FINAL Decision Aid-PTSD.pdf	Miscellaneous	1	319 k	E	07/02/20
We are modifying to add the final decision aid documents that will be used in the study.					
Follow up script with RCT new reimbursement.docx	Miscellaneous	1	17 k	E	12/14/22
Insomnia Educational Module.pdf	Miscellaneous	1	121 k	E	07/02/20

We are modifying to add the final educational documents that will be used in the study.					
Interview Sign In Sheet (1).doc	Miscellaneous	5	27 k	E	04/03/19
Intimate Partner Violence Educational Module.pdf	Miscellaneous	3	132 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
LMR SIGNED CONCURRENCE -- BY ROY FERGUSON 00240542 19-C-85212 LMR Concurrence signed Online and Shared Decision Making Interventions for Post-Dep.pdf	Miscellaneous	1	213 k	E	06/26/19
Link Email AGS Final 03_16_2020.docx	Miscellaneous	3	37 k	E	03/16/20
Loneliness & Social Isolation Educational Module.pdf	Miscellaneous	1	243 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
MHV_Linkage_Enrollment_Flowchart.pdf	Miscellaneous	1	729 k	E	08/10/17
Military Sexual Trauma Educational Module.pdf	Miscellaneous	3	185 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Missing email notice to treatment arm RCT participants.docx	Miscellaneous	1	24 k	E	04/05/22
NON SDM 121919.docx	Miscellaneous	1	19 k	E	01/21/20
Phase 1 Confirmation Email.docx	Miscellaneous	1	35 k	E	03/06/19
Phase 1 Leadership Thank You Letter.docx	Miscellaneous	1	72 k	E	03/06/19
Phase 1 Web Link_Mailed Scheduling Template.docx	Miscellaneous	1	12 k	E	03/06/19
Phase 1G Key Expert Thank You Letter.docx	Miscellaneous	1	72 k	E	03/06/19
Phase 2 RCT missing VA enrollment reminder.rtf	Miscellaneous	4	1 M	E	09/13/21
Phase 2 New RCT Reimbursement email notification.docx	Miscellaneous	2	24 k	E	12/19/22
Phase 2 New Reimbursment postal mail.docx	Miscellaneous	1	21 k	E	12/14/22
Phase 2 RCT missing MHV premium enrollment reminder.rtf	Miscellaneous	3	1 M	E	09/09/21
Information was added to assist Veterans with enrolling in My HealtheVet secure electronic health record system.					
Phase 2 RCT Provider Instructions Email.rtf	Miscellaneous	4	112 k	E	08/11/22
Phase 2 RCT missing secure messaging reminder.rtf	Miscellaneous	4	1 M	E	09/13/21
Phase 2 Thank you letter-returned forms.rtf	Miscellaneous	4	247 k	E	12/19/22
Phase 2G Incomplete Survey Email.docx	Miscellaneous	2	54 k	E	07/12/21
Phase 2H Incomplete Survey Letter.docx	Miscellaneous	2	53 k	E	07/12/21
Phase 2I Thank you letter.rtf	Miscellaneous	5	1 M	E	07/12/21
Phase 3C Thank you letter.rtf	Miscellaneous	2	1 M	E	05/28/21
Editing changes were made to provide consistent information as given in other documents used in this study and improve readability for the study participants.					
Phase2_RCT_Trmt_Arm_WEBED+_&_SDM.pdf	Miscellaneous	1	494 k	E	08/10/17
Post Traumatic Stress Disorder.pdf	Miscellaneous	3	113 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Postdeployment Family Adjustment Educational Module updated links 5.11.21.pdf	Miscellaneous	4	175 k	E	05/27/21
This change was to remove broken web links. Current web links were added.					
Prescription Drug Misuse Educational Module.pdf	Miscellaneous	3	89 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Protocol_to_address_potential_risks.rtf	Miscellaneous	1	39 k	E	08/10/17
Provider Consent Notification.docx	Miscellaneous	1	16 k	E	04/05/22
Provider Info Sheet to be completed by Veteran.docx	Miscellaneous	3	15 k	E	10/05/21
RCT Control Arm letter.rtf	Miscellaneous	1	109 k	E	09/09/21
This letter informs the Veteran which arm of the study group they have been randomly assigned to and what to expect					
RCT Intervention Assignment Letter.rtf	Miscellaneous	3	187 k	E	12/19/22
REF 10-22 eSDM Summary Report Error Email Notification.docx	Miscellaneous	1	18 k	E	11/01/22
This is the email to be sent notifying subjects of the incorrect blank template that they received in error. This document was also included as an attachment in the reportable event form.					
Recruitment Scripts.docx	Miscellaneous	23	66 k	E	12/19/22
Reimbursement Follow-up Email_Revised - Final.docx	Miscellaneous	3	36 k	E	05/13/22
Requested Resources Email Scripts.docx	Miscellaneous	1	20 k	E	02/07/22
SDM Provider Animation 121919.docx	Miscellaneous	1	14 k	E	01/21/20
SDM Veteran animation 121919.docx	Miscellaneous	1	13 k	E	01/21/20
Sadler HSRD HX002185-01A2- Union Information with interview questions.pdf	Miscellaneous	1	120 k	E	06/26/19
Sample_WEB_ED_Neg_Screen.pdf	Miscellaneous	1	90 k	E	08/10/17
Sample_WEB_ED_Pos_Screen.pdf	Miscellaneous	1	169 k	E	08/10/17
Screening Summary - Secure Message.rtf	Miscellaneous	4	103 k	E	10/25/21
Skype Script.docx	Miscellaneous	1	14 k	E	06/26/19
Social Determinants of Health Educational Module.pdf	Miscellaneous	1	250 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
Study_Q&A - Current Web-Ed.rtf	Miscellaneous	7	87 k	E	12/19/22
Substance & Alcohol Misuse Educational Module.pdf	Miscellaneous	3	151 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					

Suicide Prevention Educational Module.pdf	Miscellaneous	1	158 k	E	07/02/20
We are modifying to add the final educational documents that will be used in the study.					
To share with Provider.rtf	Miscellaneous	1	65 k	E	07/22/21
This form will enable the Veteran to indicate which screening results they are most concerned about and would like to discuss with their health care provider.					
Traumatic Brain Injury Educational Module updated links 4.20.21.pdf	Miscellaneous	5	160 k	E	05/27/21
This change was to remove broken web links and add active links to online information.					
VA10091 05.22.17.pdf	Miscellaneous	1	811 k	E	08/10/17
assurance-document.pdf	Assurance Document	1	39 k	E	08/09/17