The Brief Relationship Checkup: A 3-Session Program to Support Veteran Relationships

Funding Agency: VISN 2 Center of Excellence for Suicide Prevention

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Abstract

Title: The Brief Relationship Checkup: A 3-Session Program to Support Veteran Relationships

Purpose: Relationship distress is a common problem for Veterans with mental health concerns and is in turn a risk factor for suicide. In the proposed study, we aim to explore the Brief Relationship Checkup (BRC) model as a possible treatment for Veterans and their partners.

Research Question: We aim to inform the development of a larger randomized control trial (RCT) of a refined, Veteran-specific BRC model by (1) evaluating the feasibility of conducting BRC in our target sample, (2) piloting outcomes to evaluate BRC in a larger trial, and (3) adapting BRC to best serve the unique relationship needs of Veterans and their partners.

Aims:

Aim 1: Evaluate feasibility of conducting a BRC trial in Veterans with mental health concerns.
- Sub-aim 1-1 Calculate recruitment rate (# couples with both partners consenting/30-day period)
- Sub-aim 1-2 Calculate completion rate (# completing all activities/couples initiated)
- Sub-aim 1-3 Evaluate providers' adherence to treatment protocol within this population.

Aim 2: Pilot outcomes that can be used to evaluate pre-post change in future studies of BRC.
- Sub-aim 2-1. Calculate change in relationship functioning (i.e., relationship satisfaction, intimacy).
- Sub-aim 2-2. Calculate change in suicide risk (i.e., depression, interpersonal needs, presence and intensity of ideation).
- Sub-aim 2-3. Calculate change in treatment utilization (i.e., Veterans in treatment via chart review; Supporting Partners reported efficacy in discussing treatment/mental health).

Aim 3: Inform continued refinement of BRC to be suitable to the needs of Veterans and their partners.
- Sub-aim 3-1. Evaluate acceptability of current BRC format (i.e., client satisfaction and working alliance).
- Sub-aim 3-2. Identify areas for refinement using open-ended interviews.

Design Overview: We will conduct a single arm, open-label pilot trial of BRC in 20 couples.

Methodology: *Criteria:* We will recruit couples where the Veteran partner is positive on VA primary care mental health screens who self-identify as in a committed relationship where one partner demonstrates significant relationship dissatisfaction. We will exclude partners with common contraindications for couples therapy or who are already engaged in family services. *Evaluation:* Partners will provide initial ratings of outcomes in separate baseline sessions. *Intervention:* Then couples will complete BRC in three 30-minute couple sessions. *Follow-up:* Partners will complete post-treatment assessments separately that include outcome measures packet and an open-ended interview.

Data Safety Monitoring Plan: This is a small pilot trial that will not use a data safety monitoring board. Safety will be monitored by the PI, Syracuse VA IRB, and Canandaigua Research Compliance Office (RCO) in consultation with the Information Security Officer (ISO).

Data Analysis: We will use descriptives (e.g., frequencies; means) and repeated measures ANOVA to analyze quantitative data. We will use framework-guided rapid analysis to analyze open-ended qualitative data.

List of Abbreviations

AUDIT-C – Alcohol Use Disorders Identification Test Consumption Questions
BRC – Brief Relationship Checkup
CDGA- Canandaigua VA Medical Center
C-SSRS – Columbia Suicide Severity Rating Scale
Doc # - Reference document Attached to IRB Application Package
EBP – Evidence Based Program
IBCT – Integrative Behavioral Couple Therapy
IPV – Intimate Partner Violence
ISO – Information Security Officer
MI – Motivational Interviewing
PC-MHI – Primary Care Mental Health Integration
PC-PTSD-5 – Primary Care PTSD Screener for DSM-5
PC-Screen – Primary Care Mental Health Screen (i.e., PHQ-2; PHQi9; AUDIT-C; PTSD-PC-5)
PHQ-2 – Physician Health Questionnaire 2-item Depression Screen
PHQi9 – Physician Health Questionnaire, Item 9 Suicide Ideation Screen
RC Questionnaire – Relationship Checkup Questionnaire
RCT – Randomized Control Trial
ROPC- Rochester Community Based Outpatient Clinic
VINCI – VA Informatics and Computing Infrastructure (VINCI)
VVC – VA Video Connect

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1.0 Study Personnel

Principal Investigator:

Peter Britton, Ph.D. (Peter.Britton@va.gov; x3-7926)
Researcher, Center of Excellence for Suicide Prevention

Co-Investigators:

Dev Crasta, Ph.D. (Dev.Crasta@va.gov; x3-7537)
Postdoctoral Fellow, Center of Excellence for Suicide Prevention (Note: Grant PI under supervision of Peter Britton)

Jennifer Funderburk, Ph.D. (Jennifer.Funderbruk@va.gov; x5-4703)
Clinical Research Psychologist, Center for Integrated Healthcare

Staff:

Carley Anderson, M.P.H. (Carley.Anderson@va.gov; x3-7724)
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Program Analyst, Center of Excellence for Suicide Prevention

Collaborators:

2.0 Introduction

Background and rationale for study

Relationship distress is a risk factor for Veteran suicide, especially through middle age. For Veterans aged 18-45, relationship problems were more likely to precede suicide deaths than substance use, depressed mood, or reports of recent non-relationship "crisis."[1] These findings are explained by a growing literature identifying relationship distress as a correlate of depressive symptoms ($r_{\text{Meta-Analytic}}$= .37-.42),[2] a driver of key interpersonal risk factors for suicide including thwarted belongingness,[3,4] and even a potential trigger for suicidal behavior.[5] Despite this, there is a dearth of research investigating relationship treatment as a tool for suicide prevention.

Relationship interventions are effective but underutilized by Veterans. Couple therapies show moderate efficacy in reducing relationship distress[6,7] and are comparable to individual therapy for treating depression.[8,9] The VA has disseminated Integrative Behavioral Couple Therapy (IBCT[10]), as an evidence based program (EBP) for treating relationship distress.[11] Unfortunately, its length (12+ sessions) leads to 50-80% of Veteran couples terminating prematurely.[12] Even more concerning, between 19-36% of Veteran couples drop out in the first 2-3 sessions.[13,14] This suggests Veterans could benefit from treatment that (1) demonstrates efficacy over a brief window and (2) increases engagement when intensive treatment is needed.

Relevant data, knowledge gaps, and potential to improve Veteran care:

VA can better address relationship distress through Brief Relationship Checkups (BRC). BRC is a three 30-minute session relationship treatment that uses joint motivational interviewing (MI) to help couples commit to concrete steps they can take to improve their relationship.[15] It was designed for Air Force primary care and may be ideal for delivery in VA primary care mental health integration settings (PC-MHI). Its "checkup" model attracts couples earlier in the deterioration process, leading to immediate modest improvements in relationship quality.[16-18] For couples with more significant problems, BRC has also been shown to increase subsequent therapy enrollment.[19] BRC's short format means it can be used adjunctively by Veterans already engaged in long-term therapy. It can thus occupy the same role in PC-MHI as other brief treatments for transdiagnostic issues like alcohol misuse,[20,21] poor sleep,[22] and mood issues.[23]

Rationale for including & excluding populations

We are evaluating BRC as a potential service in PC-MHI or General Mental Health. In a study of OEF/OIF Veterans screening positive on primary care mental health screens (PC-Screens), 57.8% of married Veterans reported they had a "troubled relationship" during a follow-up evaluation,[24] underscoring the potential value of BRC for individuals with mental health symptoms. However, BRC has never been tested in Veterans and has never been tested in samples where one or more partners have significant mental health concerns. Thus, the inclusion criteria for this study was designed to mimic the PC-Screen requirements that may result in a referral to PC-MHI or General Mental Health and the level of relationship distress where providers would choose to address relationship problems over other concerns.

BRC is not being evaluated as a crisis management tool. We will exclude couples reporting common contraindications for outpatient couple therapy including severe intimate partner violence (IPV; e.g., behaviors resulting in injury, sexual coercion), suicidal intent, or current mania/psychosis and will refer to appropriate providers for evaluation.

3.0 Objectives

Insights from the present study will inform the feasibility of a randomized control trial (RCT) of a refined, Veteran-specific Brief Relationship Checkup (BRC)[15] by pursuing following aims:

Aim 1: Evaluate feasibility of conducting a BRC trial in Veterans with mental health concerns.

Sub-aim 1-1 Calculate recruitment rate (# couples with both partners consenting/30-day period)

Sub-aim 1-2 Calculate completion rate (# completing all activities/couples initiated)

Sub-aim 1-3 Evaluate providers' adherence to treatment protocol within this population.

Aim 2: Pilot outcomes that can be used to evaluate pre-post change in future studies of BRC.

Sub-aim 2-1. Calculate change in relationship functioning (i.e., relationship satisfaction, intimacy).

Sub-aim 2-2. Calculate change in suicide risk factors (i.e., depression, interpersonal needs, presence and intensity of ideation).

Sub-aim 2-3. Calculate change in treatment utilization (i.e., Veterans in treatment via chart review; Supporting Partners reported efficacy in discussing treatment/mental health).

Aim 3: Inform continued refinement of BRC to be suitable to the needs of Veterans and their partners.

Sub-aim 3-1. Evaluate acceptability of current BRC format (i.e., client satisfaction and working alliance).

Sub-aim 3-2. Identify areas for refinement using open-ended interviews.

4.0 Resources and Personnel

Setting
Procedures will be performed at the Canandaigua VA Medical Center (CDGA) and the Rochester Community Based Outpatient Clinic (ROPC) Study activities at CDGA will utilize CoE onsite offices. Study activities at ROPC will use the CoE/CIH shared office or will occur in open exam rooms when needed.

Personnel
Peter Britton (Study Chair/Principal Investigator; 15%)
Role. Dr. Britton will oversee all study activities and provide clinical coverage. He will provide clinical supervision of all assessments and intervention sessions. He will also ultimately review and co-sign all study documentation.
Access to PHI. Yes.

Dev Crasta (Co-I; Study Coordinator; 50%)
Role. Dr. Crasta will coordinate all study activities under direct mentorship of the PI. Additionally, he will obtain consent and conduct screening, assessment, or intervention sessions when needed. He will both prepare data for analysis and conduct all quantitative and qualitive analyses.
Access to PHI. Yes.

Jennifer Funderburk (Co-I; 5%)
Role. Dr. Funderburk will provide back-up clinical coverage as needed. Dr. Funderburk will support participant identification/screening efforts to help achieve recruitment targets by supervising the initial subject identification process, the implementation of screening efforts, and outreach to primary care providers (PCP) to obtain referrals.
Access to PHI. Yes.

Carley Anderson (Staff; 25%)
Role. Ms. Anderson will help with recruitment and assessment activities by helping with participant identification by providing list of recently-pulled participants to PCPs for review, consenting participants, and administering verbal and paper assessments. Ms. Anderson will help with qualitative analysis by both helping manage recording data and participating in coding.
Access to PHI. Yes.

Cathleen Kane (Staff; <1%)
Role. Ms. Kane will help with identification of potentially eligible subjects for recruitment by providing consultation on appropriate datasets and variables to use in the data pull process and consulting on development of the code to accurately and reliably pull these data.
Access to PHI. Yes.

John Klein (Staff; 2%)
Role. Mr. Klein will help with identification of potentially eligible subjects for recruitment by writing the code to accurately and reliably conduct a data pull and running this code each month to generate new lists of potential participants.
Access to PHI. Yes.

5.0 Study Procedures

5.1 Study Design

Overview

This study employs an open-label, pre-post design. There is NO randomization and all interested and eligible couples will be scheduled to complete all study activities described below. Study activities can be completed in as little as 1-month but can take up to 3 months from baseline to finish depending on participant scheduling difficulties. To address public health concerns during the COVID-19 outbreak, the protocol has been designed so that all sessions can occur in person or remotely. This way, participants with relationship distress who are seeking support can still engage in the program without increasing risk to health (e.g., unnecessary exposure to infection during period of containment protocols) or increasing discomfort/distress (e.g., anxiety about exposure even after outbreak is resolved). Remote options include completing a session by VA Video Connect application (VVC) or by phone. VVC uses encryption to provide a secure and private session and is routinely used in VHA behavioral health to deliver the experience of a face-to-face intervention to Veterans and their families at home. Phone calls will be used for when couples have difficulties using the VVC service (e.g., VVC connectivity issues; couples without access to a video-enabled device). For the remainder of the study procedures section, we will use the term "remote" to refer to participating in the session either by phone/VVC, providing information specific to one approach when applicable.

Baseline

After both partners are confirmed eligible and interested in the study through the screening process (see section 5.2), they will be scheduled for separate 2-hour baseline sessions where each partner will complete their paper consents (*Doc#11)*, HIPAA authorization (*Doc#8*) study measures (*Doc#15)*, and interviews assessing intimate partner violence and suicide risk (*Doc#16)*. Non-Veteran partners will also be provided with the notification of Privacy Practices and will sign the Acknowledgment of the Notification of Privacy Practices at this session (*Doc#30)*.

In order to accommodate Veteran preferences/comfort as well as respond to participants' accessibility/health/safety needs, this baseline may be conducted in person or remotely. In a remote session, research staff will mail questionnaires and consent forms to the participant ahead of the session and then discuss the materials with that participant over the phone/VVC. Participants will then be able to return signed forms through self-addressed, pre-stamped envelopes to the VA. To maximize accessibility for participants with reading or writing difficulties, they will have the option to (1) complete the questionnaire packet to mail to staff in pre-stamped envelopes; or (2) use the packet as a reference when completing questionnaires verbally with the staff. Finally, the interviews will be conducted directly over the remote platform (phone/verbally).

By conducting the baseline separately, we will be able to individually screen partners for risk factors and exclusion criteria (e.g., severe IPV, recent suicidal ideation with intent) and initiate appropriate safety planning one-on-one with that partner. This reflects VA couple therapy guidelines as well as recommendations for telehealth with couples, where appropriateness for therapy is evaluated using separate individual sessions with each partner and safety planning is conducted individually to maximize safety and privacy.

Intervention.

The first session can be scheduled as soon as one day after the second partner completes the baseline. Sessions are expected to be scheduled every 1-2 weeks and will ideally occur

over a 30-day window. Treatment will be based on the BRC manual developed for Air Force primary care with modifications noted below (*Doc#18)*. In order to protect Veteran health/safety and accommodate Veteran preferences/comfort, couples may also conduct any and all the joint BRC sessions as a remote session (i.e., by VVC/phone).Prior to each session, participants will complete relevant sections of the Intervention Packet (*Doc#17)* including the "Relationship Checkup (RC) Questionnaire," a list of relationship strengths and concerns used to focus the discussion. For Veterans participating remotely, RC questionnaire packets will be mailed to the couple along with separate self-addressed, pre-stamped envelopes for each partner.

Session 1: Eliciting positive relationship narrative. The therapist will use structured items to ask partners to share stories of positive aspects of their relationship including their first meeting and their decision begin a serious relationship. Then partners review their top nominated relationship strengths from the RC Questionnaire. The therapist integrates these elements to builds a view of the relationship increases efficacy to enact change.

Session 2: Exploring relationship concerns. The therapist will lead the couple through a review each partner's top relationship concern from the RC questionnaire. The therapist utilizes techniques from IBCT to explore ***both*** partners' experiences of the two concerns in a way that models effective communication and promotes a dyadic perspective of the problems. This avoids defensive argumentation and individual resistance.

Report Generation. Between sessions 2 and 3, the therapist will create written feedback report using an automated feedback system developed for the Air Force trial that quickly generates reports by providing pre-written responses to the strengths and concerns highlighted by the partners. In addition to summarizing strengths and areas of concern, the report presents a "menu" of strategies including joint activities, self-help resources, and therapy. We will supplement this feedback with relevant VA Family Consultation Education handouts including psychoeducation regarding common problems in Veterans (i.e., depression; posttraumatic stress disorder) and resources for supporting partners (i.e., Caregiver Support Pamphlets; Coaching into Care guidelines). Additionally, we have created a supplemental list of relevant VA resources to add to the menu of options at the therapist's discretion (e.g., VA parenting website; VA couple therapy; Caregiver Support Program; relevant psychotherapy).

Session 3: Feedback. The final session is framed around a review of the automatically generated report with the couple, addressing history, strengths, and concerns in sequence. The bulk of session time is spent on the "menus" presented for each concern. Using an MI framework, the therapist helps partners select relevant options or generate their own. Throughout the discussion, the therapist will help partners address barriers towards implementation and offer VA resources and referrals to support partners' decisions. For couples completing Session 3 remotely, this report will be mailed at the end of the session along with follow-up questionnaires.

Training & Supervision. All interventionists will be master-level psychology graduates or psychology postdocs and will be trained by consultants James Cordova (BRC developer) and Tatiana Grey (BRC master trainer) in an 8-hour session reviewing the BRC protocol and demonstrating skills for managing couples and encouraging relationship-promoting views of problems.

All study sessions will be recorded using approved digital recorders or secure voice recording software installed on VA computers. BRC delivery will be supervised in weekly meetings with the Peter Britton (PI) and Dev Crasta (Co-I), who are experienced in MI (Britton) and couple therapy including BRC (Crasta) with Veterans. All staff will be trained in risk assessment by Britton and risk management will be supervised by Britton and Jennifer Funderburk (Co-I), licensed psychologists who have served as PIs on high-risk Veteran studies.

Follow-up assessment.

Follow-up Questionnaire Packet (Doc#19). At the end of the final treatment session, staff will hand partners paper copies of the questionnaires (or mail the packet to them in case of remote sessions) to either (1) complete directly after the session if they wish, (2) mail back to study staff with pre-stamped envelopes, or (3) to have as a reference when completing the questionnaires remotely in the final interview. This is designed to maximize convenience for couples. If study staff have not received the packet by 1-week (or after their scheduled final interview), study staff will send reminder calls to participants to remind them to complete the packet or to offer them the opportunity to complete these questions by phone.

Follow-up Semi-structured Interview (Doc#20). After the final treatment session, partners will be asked to schedule separate follow-up interviews with study staff between within 30 days of the final treatment session. Interview will consist of an open-ended treatment evaluation, suicide ideation assessment, and IPV assessment (modified to a 1-month timescale). As above, this can be completed remotely or in-person based on participant convenience

After completing the final interview and questionnaire, participants will be thanked, final payments will be made, and no further contacts will be scheduled. Participants who request further treatment will have any requested consultations scheduled. Participants that share any risk concerns (i.e., new violence over the prior month; any ideation with intent over the prior month) will be immediately referred to appropriate resources for follow-up.

Risk benefit analysis

Anticipated benefit. Participants may experience indirect benefits of study participation. As part of the check-up process, participants will be thoroughly screened for individual mental health concerns and relationship concerns and will be offered treatment recommendations and referrals, which may lead to concerns being addressed in treatment.

Prior research in civilian couples and active duty Airmen suggest that participating in the BRC intervention sessions may lead to direct improvements for relationship quality for some couples, however we cannot guarantee that any direct benefit will be experienced by the couples in our study.

Dissemination of the findings from the study will contribute to the extant literature, provide data to guide a larger trial, and may contribute to knowledge about ways to better support well-Veteran relationships.

Population risk. The purpose of this project is to pilot a brief intervention with Veterans screening positive for known suicide risk factors (i.e., depression, alcohol use, PTSD, suicide ideation) and known IPV risk factors (i.e., relationship distress, alcohol use, PTSD). Thus, participants will be at a somewhat elevated risk for suicidal crises, intimate partner violence, and other negative outcomes.

Participation risk. Study procedures do not expose the participants to physical risk beyond those encountered in daily life but may expose them to psychological distress and fatigue. The assessments, semi-structured interviews, and intervention sessions encourage participants to recall personal events, life stressors, and suicide-related issues that may evoke distress. Discussion of these topics in front of a partner during couple therapy sessions may lead to additional stress or increased conflict.

Confidentiality risk. The sharing of personal and sensitive information increases the potential that research staff may need to break confidentiality in the event that a participant is determined to be a risk to self or others, or child abuse or neglect is revealed.

Measures to Protect from Risk

Protections to minimize population risk. Exclusion criteria will ensure that participants at highest likelihood for a negative response to treatment (i.e., those reporting severe IPV such as IPV with injury or sexual violence in the year prior to the study; those reporting ideation with

intent or attempt in the month prior to the study) and those unlikely to benefit from treatment (e.g., lack of comprehension of consent; psychosis; mania) will be excluded from the study. Additionally, all staff will be trained in the semi-structured IPV interview, C-SSRS, P4, and MINI psychosis and mania scales to be used at any time they are concerned about individual functioning during either in-person sessions or phone sessions.

Protections to minimize participation risk. Recruitment and informed consent procedures were designed to ensure patients do not feel like participation is required and feel able to discontinue at any time, including if they find themselves unduly stressed by participation. Participants will be explicitly reminded about their right to withdraw participation during verbal consent to initiate screening, after completion of screening but before engaging in baseline, and upon completing full consent form during baseline. Patients unable to understand the informed consent process will be excluded from participating. Participants demonstrating active psychosis or mania will be excluded due to potential that participation in couples treatment could increase distress.

If participants appear to be distressed during outpatient sessions or on the phone, researchers will stop asking questions and provide support, only re-starting if the participant is willing to continue. If distress persists, researchers will suspend the interview and reschedule. If the participant's distress remains unresolved, researchers will provide the phone number of the Veterans Crisis Line or schedule an appointment at a local facility based on the patient's preference. Participants will be informed that discomfort may arise after assessments and sessions and, if it does, to contact the researcher, other research staff, or a local healthcare provider who will connect them to the necessary care. Researchers reserve the right to withdraw patients from participating if they are concerned for the patient's safety, and participant will be informed of such decisions.

Some couples may not be able to attend joint sessions at a VA due to health/accessibility concerns while others may be uncomfortable or anxious about attending couples sessions in a medical setting. In order to accommodate these needs, minimize discomfort, and maximize convenience, couples will also be offered the opportunity to engage in the joint BRC sessions remotely (i.e., VVC or by phone). VVC is routinely used in behavioral health teams to offer services remotely that are typically face-to-face format (including couple/family services). Staff will follow established procedures for VVC services to maintain safety and confidentiality, including confirming with participants that they are in a private location (e.g., room by themselves where other family members are not in earshot), confirming alternate contact strategy (e.g., phone number) to establish contact in case of technical difficulties, and locking the conference room after both participants are confirmed so that nobody else can join using the link. For phone sessions, staff will similarly ensure that participants are in a private location (i.e., with family not in earshot) and encourage participants to use a landline or plug their phone into a charger to minimize likelihood that the call is dropped.

Protections to minimize suicide risk. This study will provide participants with a formal assessment of suicide risk. Therefore, participation in the study would lead to providing more information about a patient's suicide risk and equip patients with additional precautions than would otherwise be available. If participants screen positive for suicidal ideation or researchers become aware that a participant might be thinking about suicide, researchers will assess risk using the P4 screener, a screening form that was developed to help non-mental health practitioners and researchers assess for suicide risk. Note that if researchers become aware that a participant is thinking about suicide during a joint treatment session, this participant will be taken to a private location to continue the assessment. This will improve the reliability of assessment, protect participant confidentiality, and allow for collaborative risk management process should the need arise. All study staff will receive adequate training in suicidal ideation and risk assessment, and all work will be supervised by the Drs. Britton or Funderburk, both are licensed clinicians who have supervised studies of high-risk populations.

If the participant is determined to be at higher risk, an appropriate safety plan will be initiated. Such plans will depend on the setting (i.e., outpatient or telephone assessment) but may include a walk to the ED, warm transfer to the National Veterans Crisis Line (1-800-273-TALK), an in-person appointment with a local provider, or emergency services such as 911, among other options.

If the interviewer is concerned about imminent risk during in-person sessions (e.g., Baseline, Treatment sessions), the interviewer will utilize available resources to ensure that their risk is adequately addressed (i.e., walk-in clinics, ED, etc.). Participants will be informed that the interviewer is concerned about their risk level and believes that steps need to be taken to ensure their safety. To aid in the protection and treatment of participants, interviewers will try to elicit agreement for necessary services, and will always inform patients that they are seeking additional care if the patient refuses to cooperate. The persons to contact will be clarified with program administrators prior to implementing the study, and information that bears directly on risk (e.g., level of risk, suicide plan, access to a weapon, prior attempts, etc.) will be disclosed. For research staff who are not clinicians, study clinical staff will be accessible to provide guidance as to appropriate risk determination as well as treatment. If clinical staff desires, interviewers will serve as a resource to treatment staff, providing guidance and consultation. Emergency care will be provided by the site clinical staff, and research staff will in no way usurp their authority.

If the interviewer is concerned about imminent risk during a telephone assessment (e.g., during screenings, a phone baseline, phone treatment session, or follow-up assessments), we will enact our Center's telephone emergency procedures. Participants determined to be at imminent risk will be asked if they are willing to be transferred to the Veteran Crisis Line. Veteran Crisis Line responders are well trained in emergency procedures and have working protocols for locating callers and initiating rescues. All telephone sessions will be conducted on site to ensure that the research staff's telephones are set up for transfers to the crisis line. Participants often refuse to be transferred to the crisis line but are amenable to research staff contacting mental health care providers to share their concern or advocate for additional care. In prior studies we have never had a hang-up after disclosure of imminent risk, but a plan is set up in case of such an event. Research staff will begin each assessment by asking participants for the address from where they are calling so that help can be sent if it is needed. In the case of a false address, clinicians will provide a crisis line responder with the cell or telephone number, as the crisis line has a protocol for emergency responses for cell phone callers.

If study staff are concerned about risk during a VVC session (e.g., VVC baseline; VVC treatment sessions; VVC follow-up assessment), we will enact risk management procedures consistent with national telehealth guidelines. Specifically, these guidelines require that study staff will verify and/or update necessary patient information at the beginning of each telehealth session (i.e., current location, patient's phone number; contact information of emergency support if available; and local emergency # if different than 911). This will allow the interviewer to both develop technology contingencies with the couple (e.g., in case of poor connection) or respond to physical or mental health emergencies. The VVC service includes a specific enhanced-911 service (E911) that is prepared to respond to medical emergencies or mental health emergencies occurring during telehealth sessions. If patients are determined to be at imminent risk for suicide during a session, the interviewer will utilize this E911 service, which has established procedures for locating callers and initiating rescues in collaboration with local emergency services. E911 also has mental health responders trained to respond to suicidal crises. Interviewers will try to elicit agreement for necessary services and will always inform patients that they are seeking additional care if the patient refuses to cooperate. We will disclose to the responder any information that bears directly on risk (e.g., level of risk, suicide plan, access to a weapon, prior attempts, etc.). As with in-person sessions, study clinical staff

will be accessible to provide guidance to research staff and interventionists about appropriate risk determination as well as treatment.

Protection against IPV risk. Our IPV risk management procedure is consistent with VA guidance for couples therapy (which advises that the best time to initially screen for IPV is during individual in-person sessions and then every subsequent contact) IPV Assistance Program guidelines (which takes a person-centered approach to deciding on the next course of action). Accordingly, violence will first be systematically assessed during the Baselines, which are conducted separately and maximize each partner's assurance of privacy and confidentiality. After that, all sessions will contain the 1-item self-report IPV screen used as a default in session packets in VA couples therapies.

If the interviewer is concerned about severe IPV during an individual assessment (e.g., volunteered by participant during Phone Screen, stated in response to IPV screening instruments in baseline), that interviewer will provide contact information to the Finger Lakes Healthcare System IPV coordinator and the National Domestic Violence Hotline for support if needed and will further offer It is possible that participants may refuse to be transferred or hang up. By IPV Assistance Program guidance, clinicians are encouraged to support and validate these choices and simply provide education and contact information without insisting they are used. This will increase the likelihood of subsequent contacts to IPV coordinator and will allow participants to determine the best time for outreach based on their own considerations (e.g., privacy; safety from the partner; etc.).

Participants who screen as ineligible for participation in the study due to severe IPV in the last year (i.e., IPV with injury; sexual violence; fear of violent reprisal) during the baseline interview will be further offered the opportunity for a warm hand-off to the IPV Coordinator or National Domestic Violence Hotline using the same process described above.

5.2 Recruitment Methods

Subject Identification

Potential subjects will be identified and sent a letter through two approaches outlined below in primary care (see letter of support, *Doc#26*) and behavioral health (see letter of support, *Doc#27*). Study personnel will call all patients who receive a letter unless the Veterans opt out by contacting staff and declining participation using the process detailed on the letter. Veterans who wish to initiate the process sooner may also call study staff directly using contact information on the letter.

Letters from providers to patients who have recently screened positive on PC Screens. Outpatient Veterans who have had a positive PC screen (i.e., PHQ-2 ≥3, PHQi9≥1, AUDIT-C≥5, OR PC-PTSD-5≥4) during a past month primary care visit will be identified via monthly data pull by CoE Program Analyst. We are requesting a HIPAA waiver for the data pulls (*Doc#4*), which will be conducted by an information technologist within VISN 2 or will be requested and extracted from the VA Corporate Data Warehouse (CDW) and placed within VA Informatics and Computing Infrastructure (VINCI). Information will include Veteran Name, Social Security Number, Screen Scores, PCP Name, Phone Number, and Mailing Address. We will do an initial data pull or chart review in the case data pull is delayed due to technical difficulties at the beginning of the study and repeat every month as necessary until enrollment goals are met. This list will then be presented DIRECTLY to the PCP for review and approval. We will then send approved patients the Recruitment Letters from Providers (*Doc#13*) that describes the study, alerts patients that a member of the research staff will be calling them about the study, and provides ways to opt out of being contacted. We will call the Veteran 1-2 weeks after the date the letter is sent.

Direct provider referral: Referrals for potential participants at each site will come from providers in behavioral health (including suicide prevention coordinators, VA LGBTQ coordinators, IPVAP coordinator) and primary care. VA healthcare providers will be able to refer potentially eligible participants by distributing the same Recruitment Letter (*Doc#13*) and/or Recruitment Flyer (*Doc#32*) directly to the Veteran. Providers may directly hand the letter or flyer to patient, may mail letter to patient, or request that our study team send a letter on their behalf based on clinical judgment and preference. Providers will inform study coordinator that a referral has been made through secure communication. We will call the Veteran 1-2 weeks after the date the provider informs study staff that the referral has been made. Dr. Crasta (Co-I) also provides couples/family services as part of his clinical responsibilities. In this role, he may receive referrals for Veterans who are potentially eligible for the study. As he typically respond to referrals by reviewing different treatment options with the Veteran, Dr. Crasta will ask the referring provider if it would be appropriate to include the study as one of the options. If the provider approves, Dr. Crasta will discuss study with the Veteran. All Veterans will be informed that they can still receive the intervention if they decline to participate in the study.

Screening Process

Veteran screens. Screens will occur by telephone and be conducted by research assistants trained in this procedure; any Veteran may request to be seen in person. During the initial assessment, the research assistant conducting the screening will describe the study and all aspects of consent to the patient and evaluate comprehension of consent using two comprehension questions. Following verbal consent, Veterans will be asked to complete the *Phone Screen Interview Measures (Doc#14*).

If the Veteran is ineligible to participate in our study or is eligible for other studies, we would like to be able to ask them if they are interested in hearing about other research studies going on at their local VA if they are interested in participating. If interested, we would help connect that participant and the research team with them to obtain additional information.

Supporting partner screens. If a Veteran Partner is eligible and interested, we will request their permission to contact the supporting partner using contact information they provide. We are requesting a *second HIPAA waiver (Doc#6)* to request this contact information (Name, Phone Number) from the Veteran partner as it is the only way to feasibly contact the second partner in a way that maximizes their convenience and gives them privacy to accept or decline the study without their partner present. The approach of having the initial partner provide contact information for their partner is standard practice in both longitudinal surveys of couples/families and couples intervention studies in academic medical centers and research universities. It does not require greater disclosure than expected in daily life (e.g., providing partner's information to a gym for a referral bonus; providing partner's contact when scheduling family services), and has not to our knowledge ever resulted in partners from romantic relationships feeling that their privacy has been violated.

Supporting Partner will be scheduled to provide consent and answer questions in a separate screen containing eligibility questions. As a majority of Veterans are in relationships with non-Veterans, we have submitted a Memorandum for Recruitment of Non-Veterans (*Docs#28&29).*

This will provide a separate opportunity to ask questions about the study, screen for intimate partner violence, and provide resources as necessary

Screens Needed. Using previously collected data, we calculated that approximately 40% of Veterans screening positive on PC Screens will be in a current romantic relationship and remain eligible we further expect that approximately 50% of eligible Veterans and 50% of partners would still decline to participate in our study. Thus, to reach our target enrollment of 20 couples, we expect we need to screen 240 participants, or approximately 200 Veterans and 40 partners.

Participant Recruitment Incentives

Participants will receive compensation for their participation in the study. This compensation will be in the form of electronic funds transfer (EFT) or a Direct Express prepaid debit card, per Department of Treasury regulation. For those participants not currently enrolled in EFT or the Direct Express debit card, research staff will inform that participants on the information required for enrollment in EFT or the Direct Express debit card and that the appropriate forms (two copies) were sent to the Veteran participant along with the recruitment letter. Participants may also request that extra copies be sent to their address. Once the Veteran completes the enrollment paperwork, they will be able to send the form to the Canandaigua VA agent cashier.

Each *individual participant* will be compensated up to $115 for their participation according to the following schedule:

Phone Screening	$15
Baseline Assessment	$50
Follow-up Assessment (post-treatment)	$50

Note that while this means each couple can earn up to $230 total, emphasizing separate payments for completion of each study activity by each individual participant ensures participants will be paid for that activity regardless of whether their partner has participated in that activity (e.g., Veterans will be paid for their screen even if they are not enrolled in the larger study due to ineligibility or if their partner subsequently declines their screen). This also serves to maximize confidentiality as study staff will not need to discuss information about a partner's participation in order to resolve an individual's compensation issues.

If there are any issues with enrollment or receipt of compensation, research staff will contact the specific participant over the phone or that participant may call the research staff to communicate about the issues and work toward a resolution. Since this often requires a lot of information to be conveyed over the phone (i.e., research staff contacting the fiscal office for information for the participant) a follow-up letter with this information may also be sent to that participant in order to assist in the resolution of the payment issues. No identifiable data or sensitive payment information will be included with these payment letters.

5.3 Informed Consent Procedures

Consent will occur in two phases: Initial verbal consent for telephone screens. Full written informed consent during baseline assessment.

Verbal consent during phone screen. At the beginning of the phone screen for each partner, the research assistant conducting the screening will describe the study and all aspects of consent to the patient and evaluate comprehension of consent using two comprehension questions (*Doc#10)*. Conducting this first assessment separately allows each partner to ask individual questions of the researcher without concern for embarrassment in front of their partner in addition to increasing privacy/confidentiality during the actual screening process.

For participants who are mailed recruitment letters, the mailer will include a sample of the consent form as well as the Notification of Privacy Practices for non-Veteran participants so that they will additionally be able to review these documents. Participants who receive a recruitment letter from their provider directly will be able to request a copy of the letter during their phone interview and will be able to request a call back at a later date to give them time to review the information.

We are requesting a waiver of consent documentation for this phone screening (*Doc#11*); full written informed consent will take place at the Baseline Assessment for those participants who are eligible following the phone screen and wish to participate in the Baseline Assessment.

Full consent during baseline assessment. At the beginning of the baseline assessment for each partner, the research assistant conducting the assessment will review the written consent document with the participant (*Doc#12*), describing all aspects of consent. We will evaluate comprehension of consent using additional comprehension of consent questions. As couples psychotherapy requires full involvement of all participants, potential subjects who appear to have impaired decision-making ability or difficulty comprehending the consent will not be enrolled in the study. Concerns will be discussed with Drs. Britton or Funderburk, licensed psychologists who will integrate findings to determine whether exclusion criteria are met.

During the non-Veteran partner's consent process, they will additionally be presented with a notification of Privacy Practices and will be asked to sign the acknowledgment of Notification of Privacy Practices (*Doc#30*).

Participants completing the baseline over the phone will be asked to provide verbal consent, as well as complete the required baseline documents (consent; HIPAA authorization; and notice of privacy practices for partners without a VA record). The interviewer will document the verbal consent as well as satisfactory demonstration of comprehension of consent on the new Baseline comprehension of consent document (*Doc#33*). We will continue with the baseline questionnaires and interview upon receiving verbal consent. However, no follow-up activities (chart review; documentation in the medical record; scheduling sessions) will occur until we have received fully signed consent forms, HIPAA authorizations forms and acknowledgment of Notification of Privacy Practices from any non-Veteran partners in the mail.

Training. All staff obtaining consent have completed required CITI trainings regarding human subjects requirements. Staff obtaining and documenting informed consent (1) will be trained by the PI and study-coordinator, (2) will roleplay the consent process with the PI and study coordinator, and (3) will be observed in their first phone assessments and baseline assessments until the PI is satisfied that they can independently describe all aspects of consent and adequately assess comprehension of consent.

5.4 Inclusion/Exclusion Criteria

List of criteria for inclusion

1) *Both partners* must be age 18 or over
2) *Both partners* must demonstrate sufficient knowledge of English and cognitive capacity to understand the study through comprehension of consent questions
3) *Both partners* must self-identify as "in a committed relationship" with their partner for at least 6-months.
   Note: Eligibility will NOT be based on marital/cohabitation status or sexual orientation to remain consistent with VA priorities of offering inclusive family services.
4) *At least one partner* must report at least mild relationship distress on a satisfaction screen (CSI-4<13.5)
5) *At least one partner* must have Veteran status
6) *The Veteran partner* must screen positive on at least one PC-Screen (i.e., PHQ-2 ≥3; PHQi9≥1; AUDIT-C≥5; OR PC-PTSD-5≥4)

List of criteria for exclusion:

1) *Either partner reports* that they are engaged in ongoing couple or family therapy (via brief questions during Telephone Screen).
   Note: Any new couple/family therapy scheduled *after* screening will not impact eligibility and will be evaluated as an outcome.
2) *Either partner reports* severe intimate partner violence in the last year (via semi-structured interview during the Baseline session).
3) *Either partner reports* experiencing suicidal intent / attempts in the last month (via C-SSRS in Baseline session).
   Note: Participants will NOT be excluded based on suicidal ideation or plan alone.
4) *Either partner experiences* current psychosis (via chart review, presentation during session, or MINI psychosis scale).
5) *Either partner experiences* current mania (via chart review, presentation during session, or MINI mania scale).

All staff will be trained in the semi-structured IPV interview, C-SSRS, P4, and MINI psychosis and mania scales to be used at any time they are concerned about individual functioning during either in-person sessions or phone sessions. Veteran charts will be reviewed prior to any Veteran-participants' to check for any indications of hospitalization or records flag. Results will be discussed with Drs. Britton or Funderburk, licensed psychologists who will integrate findings to determine whether exclusion criteria are met.

5.5 Study Evaluations

Questionnaires

See Table 1 for full list of measures. Except for newly developed measures, all measures have established reliability/validity and were selected with preference for measures used in VHA care.

Inclusion/Exclusion. The listed measures will assess eligibility (per Section 5.4). The relationship quality screen and PC-Screens are established short forms used in VA practice.

Safety. In addition to routine use to evaluate exclusion measures

Outcomes (Aim 2). We selected measures of relationship quality and depression used in weekly assessments for VA EBPs.[26] Intimacy and interpersonal risk will be assessed using well-validated measures. We are piloting new measures about communication around mental health.

Evaluation (Aim 3). The well-established acceptability measures are supplemented with open-ended interview questions to identify unique strengths and weaknesses of the program

Risk. Measures assess shared risk factors for suicide and divorce to contextualize findings.

Table 1*List of Measures used in Study*

Construct	Measure	Items	Purpose	Screen	Base	Tx	Post
Demographics	Standard Items	8	Inclusion	X			
Relationship Status	Made for Study	4	Inclusion	X			
Tx Engagement	Made for Study	6	Exclusion	X			
Veteran Status	Standard Items	5	Inclusion	X			
IPV Assessment	VA IPV Screen	8	Safety		X		X[a]
Severe IPV Behaviors	IPV Interview	8	Exclusion/Safety		(X)	(X)	(X)[a]
IPV Monitoring	IPV Session	1	Safety			X	
Mania/Psychosis	MINI[25]	20	Exclusion		(X)	(X)	(X)
Last Month Suicide Ideation Severity	C-SSRS[27]	5	Exclusion/ Safety		X		X
Suicide Risk Eval	P4 Screener	4	Safety	(X)	(X)	(X)	(X)
Relationship Quality	CSI[28]	4/32	Aim 2-1	X[b]	X		X
Intimacy	PRI	16	Aim 2-1		X		X
Recent (2-Week) Depression	PHQ-9[29]	2/8	Aim 2-2	X[b]	X		X
Recent Suicidal Ideation	PHQ-i9[29]	1	Aim 2-2	X	X		X
Last Month Ideation Intensity	C-SSRS[27]	5	Aim 2-2		X		X
Interpersonal Connection	INQ[30]	15	Aim 2-2		X		X
Discussing Mental Health	Made for Study	18	Aim 2-3		X		X
Service Utilization	Chart Review	N/A	Aim 2-3				X
Perceived Quality of Service	CSQ-18[31]	8	Aim 3-1				X[a]
Quality of Alliance w/ Provider	WAI-SR[32]	12	Aim 3-1				X[a]
Semi-Structured Interview	Made for Study	15	Aim 3-2				X
Potential PTSD	PC-PTSD-5[34]	6	Inclusion	X			
Trauma Exposure	LEC-5[35]	17	Risk		X		
Childhood Adversity	ACES[36]	17	Risk		X		
PTSD	PCL-5[37]	20	Risk		X		X
Lifetime suicide ideation, lifetime/last-month attempts	C-SSRS[27]	20	Risk/Safety		X		X
Disordered Drinking	AUDIT[33]	3/10	Inclusion/Risk	X[b]	X		
Drug Abuse	DAST-10[38]	10	Risk		X		
Last month alcohol / drug use	AUDADIS[39]	20	Risk		X		X

[a]Modified for study. [b]Phone screen will use established short-form versions.

Chart Review

A post-treatment chart review of a Veteran partner's chart will be used to evaluate engagement in mental health services over the following windows: 1) 90-day period prior to the baseline session; 2) during the treatment period from baseline to the day of the final feedback session, 3) the 90-day period after the final intervention session. Over each window, staff will review treatment appointments (e.g., individual, group, assessments), consults placed (e.g., General Mental Health; MST coordinator); and new prescriptions (e.g., Naltrexone; SSRIs).

5.6 Data Analysis

Sample Size Determination

As the purpose of the present study is to primarily pilot the BRC intervention, we selected our target sample size based on our maximum expected capacity to run subjects through the protocol given our limited staff (2 couples/month) and the limited time in which to run the study (1 year).

Expected study continuation/lost to follow-up rate. We project 75% retention based on prior VA RCTs with couples.[39,40] Thus, if we successfully recruit 20 couples, we expect to obtain complete data from 15 couples at follow-up.

Expected screen failures. As noted above, we expect that only 20% of Veterans screened will be both eligible and interested in participating in the larger study and that only 50% of partners will be eligible and interested. Thus, we are expecting 200 screen failures (i.e., approximately 160 Veterans and 40 Non-Vet partners).

Analytic Strategy by Aim

The Drs. Britton and Crasta will maintain the database and conduct all analyses. Findings will be used for the preliminary study sections of a grant and, depending on data, in presentations or publications.

Aim 1: Evaluate the feasibility of BRC. Frequencies will be used to calculate the recruitment rate (i.e., # couples where both agree to attend the baseline/30-day period; Sub-aim 1-1) and completion rate (i.e., # completing all sessions/those completing baseline; Sub-aim 1-2). The above metrics will be calculated both across the sample and within recruitment source to estimate the feasibility of conducting a large-scale RCT in that population. To evaluate protocol adherence (Sub-aim 1-3), staff other than the therapists will evaluate randomly selected digital session recordings from each therapist using established criteria that rates elements of BRC delivery on a 1-5 scale.[26] Sufficient adherence is defined as 75% of elements rated at 4 or higher.

Aim 2: Pilot outcomes. As relationship quality and emotional intimacy are dependent between partners, we will calculate effect size dyadically using a repeated measures ANOVA with Partner (Veteran-Supporting) and Time (pre-post) as within "subjects" factors to generate partial-η^2 (Sub-aim 2-1). In contrast, differential recruitment criteria will create baseline differences in suicide risk factors (Sub-aim 2-2) and efficacy discussing mental health (Sub-aim 2-3). Thus, we will calculate separate Cohen's *d* estimates for Veteran and Supporting partners. Effect sizes will then be contrasted with 1-month change in the above outcomes observed in past waitlist control studies of Veterans to inform power analysis. Finally, we will examine chart review data to investigate change in proportion of Veterans engaged in mental health services (Sub-aim 2-3). In cases where specific referrals were made in the final session, we will also assess the proportion utilizing those services.

Aim 3: Explore suitability of BRC. Mean scores will be calculated for each participant on the CSQ-8 and the WAI. Acceptability (Sub-aim 3-1) is defined as *75% of participants* scoring ≥3 on both measures. We will use framework-guided rapid analysis (RA) to evaluate semi-structured interviews.[58] Transcription services will be provided through VA HSR&D's Centralized Transcription Service Program (CTSP). The audio recordings to be transcribed by CTSP staff will not contain any identifiable information and will only be labeled with a study identification number. They will be saved in a project folder shared between IRB-approved study staff and CTSP transcription staff that is located on the VA secure V: drive. IRB-approved study staff will place the audio files into the shared folder for a CTSP transcriptionist to have access for the purposes of transcription. Once the audio file is transcribed, the transcriptionist will save the completed transcript in the same shared folder using the same identification number. No data (audio files, in process transcripts, or completed transcripts) will leave the VA secure server. As

completed transcripts become available, approved study staff will move these files from the transcription folder into another folder that is only accessible to IRB-approved study staff and password protected, where they will be stored for qualitative analysis. RA templates will summarize transcripts on specific BRC elements. These will be consolidated into themes that can inform BRC refinement (Sub-aim 3-2). RA yields insights comparable to more intensive coding using less staff resources.[58]

Exploratory analyses. Due to a lack of prior literature on relationship-focused interventions impacting risk factors beyond depression, we do not have any specific aims or directional hypotheses. However, we will calculate separate Cohen's *d* estimates by partner using the same analytic approach seen in Sub-aim 2-2. Additionally, we will compare outcomes across higher and lower-functioning couples. The analyses will help evaluate the BRC's tolerability and safety, adding additional considerations for changes in the RCT.

5.7 Withdrawal of Subjects

Voluntary withdrawal

Process for withdrawal. All couple-based treatment sessions will require consent from both partners before proceeding. Individual participants may request to withdraw from participating in the study at any time by contacting study staff. Study staff will ask for a brief reason for voluntary withdrawal to monitor for potential adverse events. If staff is concerned about safety, they will conduct follow-up assessments as appropriate based on their concerns (e.g., IPV interview, P4 suicide risk screener, MINI mania/psychosis screen) and follow the appropriate protocol.

Withdrawal of one partner during treatment. As this is a pilot of a couples treatment, if either partner withdraws during the treatment process, then the other partner will not be able to complete the treatment. Partners will be reminded of this fact and will be offered the opportunity to withhold their decision to withdraw if they would like to discuss their choice with a partner first (with a member of study staff following up after participating). However, partners are NOT REQUIRED to take this time in order to withdraw.

If a participant withdraws while the couple has an in-person session scheduled, study staff will explain that they need to notify the partner of this decision and the cancellation of ongoing appointments. Withdrawal from the intervention will not impact either participant's ability to participate in the follow-up assessment, which will allow either partner to give feedback on what was appealing,

If a participant withdraws *after* completion of the treatment process (i.e., not wishing to participate in the follow-up assessments), the partner will not need to be informed, as all remaining study activities (assessment packet, interview process) are completed individually.

Involuntary withdrawal

Safety of participants/couple. Exclusion criteria was selected to minimize the likelihood that the intervention would negatively impact either partner. However, consistent with standard approaches in VA intervention research, we will withdraw participants due to unanticipated circumstances, such as extreme distress from participating in the intervention or if we judge the participation of the couple is not in their best interest. Any such decisions will be documented using the reporting guidelines (Section 6.0).

If this occurs while the couple has an in-person session scheduled (baseline or joint checkup session), study staff will withdraw both partners from the study and will notify both partners of this decision and the cancellation of ongoing study activities.

If a participant withdraws ***after*** completion of the treatment process (i.e., a situation where the follow-up interviews may be contra-indicated), decisions about withdrawal will be made separately for each partner as all remaining study activities (assessment packet, interview process) are completed individually. Participants will not need to be informed of whether or not their partner was withdrawn from the study in this manner.

6.0 Reporting

Unanticipated problems

Study staff will report any unanticipated problems to the PI and study coordinator via encrypted e-mail and/or phone call. All problems will be documented using internal logs saved locally behind the VA firewall.

Unanticipated problems that do not significantly impact the experience of participants or result in a deviation from the study protocol will be noted and provided to the IRB in annual report. Recurring problems will form the basis for amendments in order to improve Veteran and family member experiences, improve data quality, and/or minimize the impact on clinical care activities within referring clinics.

Per IRB regulations, problems or events resulting in a deviation from the study protocol (e.g., emergency hospitalization to address suicidal behaviors) will be reported to the PI within 24 hours and to the IRB in 48 hours using required IRB forms.

Adverse events

All internal serious adverse event reports will be sent via encrypted e-mail to the PI and Study Coordinator. Copies of all SAE reports (both IRB forms and internal study forms) will be saved locally behind the VA firewall. No paper copies will be saved. Adverse events will include all suicide attempts, reports of new intimate partner violence behaviors (of any severity) after the initial screening, and occurrences of imminent risk. Per IRB regulations, any serious adverse event, any event resulting in a deviation from the study protocol (e.g., emergency hospitalization to address suicidal behaviors) or death will be reported to the PI within 24 hours and to the IRB in 48 hours. This will be completed in order to assess significance and determine an appropriate response. Adverse events that involve temporary distress will be noted by interviewers and provided to the IRB in an annual report.

7.0 Privacy and Confidentiality

Confidentiality and limits of confidentiality. All participants will be instructed in the informed consent and at the initiation of treatment the limits of confidentiality and the fact that if we feel they may be in imminent danger of harming themselves or others that we will involve other medical providers/emergency staff to protect their safety. Additionally, if we are concerned about the safety of a child, we will inform relevant authorities consistent with VA law. Participants will further be informed that the Veteran's Baseline assessment, treatment sessions, and follow-up contacts will be documented in the medical record of the Veteran's charts using study participation notes.

Documentation in the Veteran's chart. Study participation notes will notify other VA providers only that the Veteran is participating in the study and receiving an intervention for relationship concerns (see *CPRS Note Templates, Doc#31*). No other components will be documented unless clinically necessary.

Creation of Collateral Charts. Contacts with non-Veteran partners during the couples sessions will generally be documented VETERAN'S chart only. Collateral charts will NOT be routinely created. In situations when non-Veteran partners indicate a personal problem or concern (e.g., imminent suicidality, imminent homicidality, severe intimate partner violence, medical event during session) that is serious enough to warrant its own disposition and documentation, we will follow established clinic procedures for creating a collateral chart. This is consistent with the approach used in couples-therapy research in Austin VA, documentation of partner contacts as part of collateral assessments during VA IPV programs, and VA guidance for family clinics (e.g., VHA Directive 1603.04 Appendix A.6, "Documentation of Services to Relatives as Part of Family Services").

Documentation when Both Partners have Separate Charts. In couples where both partners already have separate charts (e.g., both partners are Veterans; partner already has collateral chart due to already existing receipt of services through the VA) each partner's participation will be documented in their OWN respective medical record using the note template. To maximize privacy, notes are designed to minimally describe the other partner's experience. The only exception is noting that the partner has completed the Baseline and that the couple will be enrolled in the intervention.

Data flow and data storage. Recorded interviews and intervention sessions and all informed consent forms will contain identifying information. In order to maximize confidentiality, signed forms (e.g., consent forms; signed acknowledgment of privacy practices) will be stored in separate double-locked files from other study materials (e.g., questionnaire data; digital recorders). As noted in our Data Transport memo (*Doc#23*) locked courier bags will be used to transport any sensitive study information (e.g., consents, audio recorders) outside VA property from ROPC to storage in the CoE. To maximize confidentiality, identifiable information will be transported in separate locked bags from de-identified questionnaires.

Digital recordings of interviews will be recorded under the unique participant ID number (no names will be used to label these recordings). Recordings on digital recorders, transported from interview sites in locked bags, will be promptly uploaded to the local site's secure server and deleted off the digital recorder. This action will be logged in the local site's audio recorder file deletion log. Recordings made using VA software will be saved directly to the secure server. Any identifiable paper data will be stored in two separate locked file cabinets (one for informed consents and the other for paper questionnaire data) in the offices of the CoE. After a participant completes the study, any identifiers will be removed from the paper questionnaire data and will be replaced with their numeric identifier.

CoE servers are password protected and has regular backups, and to which only IRB approved VA research personnel have access. Should any identifiable information need to be

shared between research sites, research teams will utilize a secure, SharePoint site or electronic communication with PKI encryption. Data will not be stored directly onto the hard drive of a PC or laptop.

VINCI will be used for the long-term storage of study data. VINCI is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the VHA Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources. VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC), located in Austin, Texas. This secure enclave with 105 high-performance servers and 1.5 petabytes of high-speed data storage has multiple layers of security and disaster recovery to prevent data loss. VINCI is equipped with secure download and upload utilities which will be used to move PII and PHI between VINCI and other VA systems. Questionnaire Data analysis will occur in the VINCI framework using approved software.

Read and write access to VA servers, VINCI project files, or SharePoint will be restricted to IRB approved VA research personnel. When study personnel are no longer part of the research team, we will terminate data access using appropriate procedures.

Data will not be disclosed to any other person or entity except as required by law for authorized oversight of the research study.

Data disposition. Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1 (RCS 10-1). If and when it is deemed appropriate to destroy data according to RCS 10-1, we will consult with the ISO on current standards and process for destruction. Storage and transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) must be done in accordance with applicable VA and VHA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability Act (HIPAA). Unless explicitly requested and approved by data stewards, all sensitive patient data must remain on VINCI project servers and only aggregate data without PII / PHI may be transferred from VINCI.

Publication and Reports. All data will only be used for scientific research purposes. No personnel will directly (e.g., through name or recognizable audio) or indirectly identify any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.

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