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Study Title:
Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD

Combined documents include:

- Protocol V18_06.13.2023
- Verbal Consent for Veteran V10_01.11.2021
- Verbal Consent for Partner V10_01.11.2021
- Social Consent for Veteran V9_01.11.2021
- Social Consent for Partner V9_01.11.2021

RESEARCH PROTOCOL

Protocol Title:

"Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD"

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ABSTRACT

OBJECTIVES: The VA Secretary of Health Strategic Priorities and the emerging VA Whole Health Program identify access to complementary and integrative health (CIH) for pain and self-care management as a priority to achieve optimal Veteran health. To be responsive to these priorities the 2016 VA State-of-the-Art Conference (SOTA) and Comprehensive Addiction Recovery Act (CARA) mandated VA's commitment to conduct rigorous research to integrate non-pharmacological and CIH approaches into care, with emphasis on pain management. This proposal is also responsive to the VA's Opioid Safety Initiative (OSI) and Pain Care Mission which prioritize the need for nonpharmacological treatment options for pain.

This project is specifically responsive to RR&D's current special areas of interest for non-pharmacological activity-based interventions for chronic pain impacting pain reduction, function and quality of life. This project aligns with the VA mandate for complementary and integrative health (CIH) care for Veterans and their families. CIH complements traditional care for Veterans managing chronic conditions, such as chronic pain and PTSD. *Mission Reconnect* (MR) is a user-driven, dyadic, CIH self-care management program delivered remotely that teaches techniques that Veteran/partner dyads can use to reduce pain, anxiety and stress, promote well-being and improve relationship quality. The research goal is to evaluate MR as an approach to manage chronic pain and PTSD symptoms, for potential subsequent implementation. The **short-term** goal of this study is to determine the effects of MR on (1) chronic pain, PTSD and related outcomes and (2) relationship outcomes for Veterans and their partners. The **long-term** goal is to determine the effectiveness and sustainability of using CIH self-care management programs like MR to improve outcomes for Veterans with chronic pain and PTSD, and their partners. This study will possibly provide a model for establishing remote access and sustainable implementation of CIH within VA.

RESEARCH DESIGN: This study is a four-year mixed-methods randomized controlled trial of MR with two arms (treatment intervention arm & wait-list control arm) in a clinical sample of Veterans with comorbid pain and symptoms of PTSD, and their partners (e.g., spouse, significant other, caregiver, friend, or family). The study will evaluate the effectiveness and perceived value of the MR program in relation to physical and psychological symptoms, global health, and social outcomes.

METHODOLOGY: The specific aims are to: **(Aim 1)** Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological (depression, stress, anxiety) symptoms, and global health (quality of life); **(Aim 2)** Determine MR effectiveness for social (relationship satisfaction, compassion for self/others) outcomes among Veterans and their partners; and **(Aim 3)** Describe Veteran and partner perceived value of MR in a sub-sample of participants. The sample will consist of Veteran and partner dyads (N = 600). **Aim 1 & 2** data collection will include self-report assessment of 4-data points over a 4-month period to evaluate physical, psychological, and social outcomes. Eight weekly reports will also be collected for the first two months of MR use to assess MR utilization, and pain and stress levels. **Aim 3** data collection will include telephone interviews from a selected sub-sample of 84 individuals to examine MR user experiences, study experiences, and to collect their suggestions for making MR useful for Veterans and their partners.

CLINICAL RELEVANCE: In a community-based trial in a non-clinically defined sample of Veterans, MR was associated with significant reductions in pain and PTSD-related symptoms. In the proposed study we will test MR's effects in a clinically defined population as a complement to clinical services. This program evaluation is needed to determine MR's appropriateness for implementation within the VA for clinically defined populations.

Aim 1: Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological symptoms (depression, stress, anxiety), and global health (quality of life).

H1.1. Veterans who use MR will report significantly greater improvement in physical pain compared to those in the control group. (Primary Outcome)

H1.2. Veterans who use MR will report significantly greater improvement in PTSD and psychological symptoms, sleep and quality of life compared to those in the control group. (Secondary Outcomes)

Aim 2: Determine MR effectiveness for social (relationship satisfaction, compassion for self/others) outcomes among Veterans and their partners.

H2.1. Veterans and partners who use MR will report significantly greater improvement in social outcomes compared to the control group. (Secondary Outcomes)

Aim 3: Describe Veteran and partner perceived value of MR in a sub-sample of participants.

RQ3.1. What are the experiences of participants and their partners using MR?

RQ3.2. What recommendations do participants have for promoting use of MR?

Impact. Currently there is no self-directed evidence-based CIH mobile application for a clinically defined population of Veterans and their partners to improve outcomes. This study will catalyze a program of research focused on MR, a multi-dimensional non-pharmacological intervention, to allow potential subsequent evaluation of service utilization, cost, outcomes (e.g., opioid use and suicide risk) and implementation. This study will also potentially provide a model for establishing remote access and sustainable implementation of CIH within VA.

Contents

ABBREVIATIONS

AE	Anticipated Event
AMSUS	Association of Military Surgeons of the United States
ANCOVA	Analysis of Covariance
BDI	Beck Depression Inventory
CARA	Comprehensive Addiction and Recovery Act
CARF	Commission on Accreditation of Rehabilitation Facilities
CBOC	Community Based Outpatient Clinic
CCO	Connected Care Office
CIH	Complementary and Integrative Health
CLC	Community Living Center
COS	Compassion for Others Scale
CSS	Compassion for Self-Scale
DART	Data Access Request Tracker
DCG	Diagnostic Cost Group
DOD	Department of Defense
DSS-NDE	Decision Support System – National Data Extracts
DV	Dependent Variable
HCC	Hierarchical Condition Category
HIT	Health Information Technology
HSR&D	Health Services Research and Development Service
IV	Independent Variable
IRB	Institutional Review Board
JAH	James A. Haley Veterans' Hospital
LL	Log Likelihood
LR	Likelihood Ratio
MedSAS	VHA Medical SAS Datasets
MR	Mission Reconnect
NRS	Pain Numeric Rating Scale
NSI	Neuro-behavioral Symptom Inventory
OEF/OIF/OND	Operation Enduring Freedom/ Operation Iraqi Freedom/Operation New Dawn
OPCCCT	Office of Patient Centered Care and Cultural Transformation
OSI	Opioid Safety Initiative
P	Partner
PCL-C	Posttraumatic Checklist-Civilian
POQ-VA	Pain Outcomes Questionnaire – for Veterans

ABBREVIATIONS CONTINUED

R&DS	**Research and Development Service**

Rationale

The VA Secretary of Health Strategic Priorities and the emerging VA Whole Health Program identify access to CIH for pain and self-care management as a priority to achieve optimal Veteran health. To be responsive to these priorities the 2016 VA State-of-the-Art Conference (SOTA) and Comprehensive Addiction Recovery Act (CARA) mandated VA's commitment to conduct rigorous research to integrate non-pharmacological and CIH approaches into care, with emphasis on pain management. This proposal is also responsive to the VA's Opioid Safety Initiative (OSI) and Pain Care Mission which prioritize the need for nonpharmacological treatment options for pain.

This project is responsive to RR&D's current special areas of interest for non-pharmacological activity-based interventions for chronic pain impacting pain reduction, function and quality of life. This project aligns with the VA mandate for complementary and integrative health (CIH) care for Veterans and their families. CIH complements traditional care for Veterans managing chronic conditions, such as chronic pain and PTSD. *Mission Reconnect* (MR) is a user-driven, dyadic, CIH self-care management program delivered remotely that teaches techniques the Veteran/partner dyad can use to reduce pain, anxiety and stress, promote well-being and improve relationship quality. The research goal is to evaluate MR as an approach to manage chronic pain and PTSD symptoms, for potential subsequent implementation. This study will possibly provide a model for establishing remote access and sustainable implementation of CIH within VA.

The **short-term** goal of this study is to determine the effects of MR on (1) chronic pain, PTSD and related outcomes and (2) relationship outcomes for Veterans and their partners. The **long-term** goal is to determine the effectiveness and sustainability of using CIH self-care management programs like MR to improve outcomes for Veterans with chronic pain and PTSD, and their partners. We propose a four-year mixed-methods randomized controlled trial of MR with two arms (treatment & wait-list control) in a clinical sample of Veterans with comorbid pain and PTSD, and their partners (e.g., spouse).

The specific aims are to:

Aim 1: Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological symptoms (depression, stress, anxiety), and *global health (quality of life).*

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Aim 1 & 2 data collection will include self-report assessment of 4-data points over a 4-month period to evaluate physical, psychological, and social outcomes. Eight weekly reports will also be collected for the first two months of MR use to assess MR utilization, and pain and stress levels.

Aim 3 data collection will include telephone interviews from a selected sub-sample of 84 individuals to examine MR user experiences, study experiences, and to collect their suggestions for making MR useful for Veterans and their partners.

Background

The impact of chronic pain. Chronic pain is a highly prevalent condition among Veterans (81.5%).[1] Musculoskeletal ailments are some of the most frequent reasons that Veterans seek care at the VA.[2] In addition to discomfort and mood and sleep disturbances associated with pain, Veterans with chronic pain have a high co-prevalence of medical, mental health and substance use disorders.[3] Veterans with pain have higher prescribed opioid doses which is associated with risk of accidental poisoning death and suicide death.[4] In sum, chronic pain is a high priority area in the VA due to its prevalence and severity of impact on quality of life for Veterans and their families.

The compounded impact of chronic pain and comorbid PTSD on outcomes. We chose to address chronic pain and PTSD due to their prevalence, compounded impact, and their priority in the VA. As many as 70% of Veterans with chronic pain treated in the VA have PTSD, and up to 80% of those with PTSD have pain.[2] Prevalence of PTSD is higher in patients with chronic pain.[5,6] Patients with both PTSD and chronic pain generally present with more complicated clinical profiles[7] and patients with these comorbidities report lower quality of life than their Veteran counterparts.[8] Chronic pain and PTSD are associated with high rates of depression, anxiety and fatigue, [9–13] which detrimentally impact work, social functioning, relationships, independent living, and ability to enjoy life.[14–16] Effectiveness of pharmacotherapy is limited and can result in other negative consequences, such as substance use disorders.[17] Further, Veterans with PTSD receive more frequent and higher-dose opioids for pain diagnoses than Veterans without PTSD.[4] Innovative CIH approaches are needed to help Veterans and their families cope with chronic pain and PTSD without the side effects and adverse events associated with pharmacological management.[18–20]

Theoretical Mechanisms Connecting Pain and PTSD. The biopsychosocial model represents the complex inter-relationships between physical, psychological, and social factors.[21,22] Within the context of our research, the application of the biopsychosocial model will center around the bi-directional relationship between pain and PTSD. Psychological trauma induces change in biological substrates, which in turn alter pain transduction pathways and pain processing mechanisms in the brain, intensifying pain experience in individuals with PTSD.[2] Neurologically, PTSD is characterized by hyperactivation of the amygdala and hippocampus, and lower activation and imbalance in the medial prefrontal cortex. The amygdala integrates nociceptive information and plays a dual faciliatory and inhibitory role in the modulation of emotional pain behavior.[2] Therefore, interventions that ameliorate pain may be expected to reduce symptoms of PTSD[23] and vice versa.[2] On the basis of this bi-directional biopsychosocial model, we propose a multi-dimensional CIH intervention to support positive multi-factorial outcomes associated with comorbid chronic pain and PTSD.

Veterans' chronic conditions can affect their families' well-being. In alignment with the biopsychosocial model we contend the complexity of comorbid chronic pain and PTSD does not end with the Veteran. We recognize the critical role of the Veteran's family in supporting Veterans' well-being. Chronic conditions, such as comorbid pain and PTSD, can have substantial impacts on personal relationships. Studies have linked unhealthy family responses to poorer outcomes in the person with pain.[24] Maladaptive patterns of interaction may reinforce disability, fear of activity, and dependency in the patient, thereby inhibiting their recovery, rehabilitation and treatment outcomes. Family members or other support partners may respond in a manner that is solicitous, thereby unintentionally reinforcing the sick role and disabled lifestyle of the person with pain.[24] Though partners often serve as a protective factor through social support and advocacy, problematic effects of caregiver burden are common.[25,26] Family/loved ones' involvement in treatment can help to support positive outcomes.[27,28]

Partner-family-assisted interventions. Including partners-family in treatments has been conceptualized in four ways: (1) partner-assisted interventions, (2) disorder-specific interventions, (3) general therapy, and (4) education facilitated engagement.[29,30] MR qualifies as a partner-family assisted intervention, as MR is not disorder-specific, nor a focused couples therapy, nor primarily educational; rather it involves providing guidance and encouragement to the partners or family members so they can support the Veterans' engagement in and experience of MR. The majority of family-partner focused interventions focus on mental health and couples-family therapy. [29,30] MR is unique in its conjoint approach to supporting the Veteran through the use of partnered CIH. A Veteran-partnered sample participated in a multimodal intervention to address PTSD symptoms using CIH modalities for stress reduction and resource building; findings indicate significant reduction in PTSD symptoms and benefits to their family members.[31] Though current research in partner-assisted CIH based programs is limited, these programs hold potential for supporting Veterans with chronic conditions and their partners/families.

Introduction of an Innovative Partnered-family-assisted CIH Intervention. Mission Reconnect (MR) provides a novel CIH approach that supports Veterans' symptom management using evidence-based CIH modalities (i.e., massage, meditation, positive psychology) presented in a self-paced partnered-family-assisted program that can be accessed remotely.

MR is distinctive in its:

(1) Approach to treating chronic pain using a non-pharmacological CIH approach to managing chronic pain that has been shown successful in a community-based non-clinically defined cohort.[32]

(2) Use of CIH therapy skills education teaching massage techniques as a home-based, interpersonal skill between Veterans and their selected partners.

(3) Focus on the Relationship dyad as the unit of intervention. The proposed *partner-family-assisted intervention* directly applies the biopsychosocial model, engaging Veterans in their natural social contexts rather than relying solely on a clinical setting. Targeting the dyad leverages the natural resources of the relationship—trust, commitment, compassion, and mutual reinforcement of participation.

CIH impact on pain and PTSD outcomes. Massage is the most preferred CIH modality of all complementary health approaches, indicating broad appeal among Veterans.[33] Research indicates 82% of Veterans with chronic pain reported use of at least one CIH therapy and nearly all (99%) were willing to try such approaches.[33] These findings are consistent with military treatment facilities that report CIH is most often used use for pain and mental health conditions.[34] The preference for massage is intuitive given evidence suggesting the therapeutic benefits of massage including reduction of pain, stress, depressive symptoms, anxiety and improvement of sleep across diverse populations.[32,35–39] A 2016 VA Evidence-based Synthesis report identified 21 high-quality systematic reviews on massage for pain. Findings described potential benefits of massage, but evidence strength is limited due to methods used in reviewed studies.[40] An independent meta-analysis of RCTs addressing pain concluded massage effectively reduced pain compared to sham, and active comparators, and improved mood and health-related quality of life compared to active comparators, and concluded massage is a viable pain management option.[41] A limited number of massage studies have shown results on PTSD, but many studies have demonstrated results on related symptoms such as anxiety, stress, and depression.[42,43,36,44,38]

Though limited research connects the impact of massage on PTSD outcomes, a secondary analysis of four trials with Veterans with PTSD suggests mindfulness based stress reduction, another MR component, is a viable mechanism of treatment.[45] Mindfulness reduces pain for Veterans with chronic pain,[46] and improves anxiety, depression and suicidal ideations.[47]Based on a VA review of the current evidence and best practices, VA/DOD PTSD clinical practice guidelines suggest though CIH is not indicated as primary treatment it holds promise to improve wellness and promote recovery.[48]Even with these clinical guidelines, it is noted that study limitations leave current evidence inconclusive.[48]

Another systematic review of CIH among veterans and military personnel indicated benefits from mind-body modalities; however the quality of most RCTs was rated poorly.[49] The evidence base regarding the effectiveness of CIH interventions[40] for reducing pain and PTSD symptoms in Veterans is inconclusive; this study will fill this gap in this area of research.[50]This project will contribute to the knowledge base of this field of research by using strong methodology related to sample size, contextual specificity of the target population, RCT design and measurement of long term outcomes.

Research Plan (work proposed)

Conceptual Framework

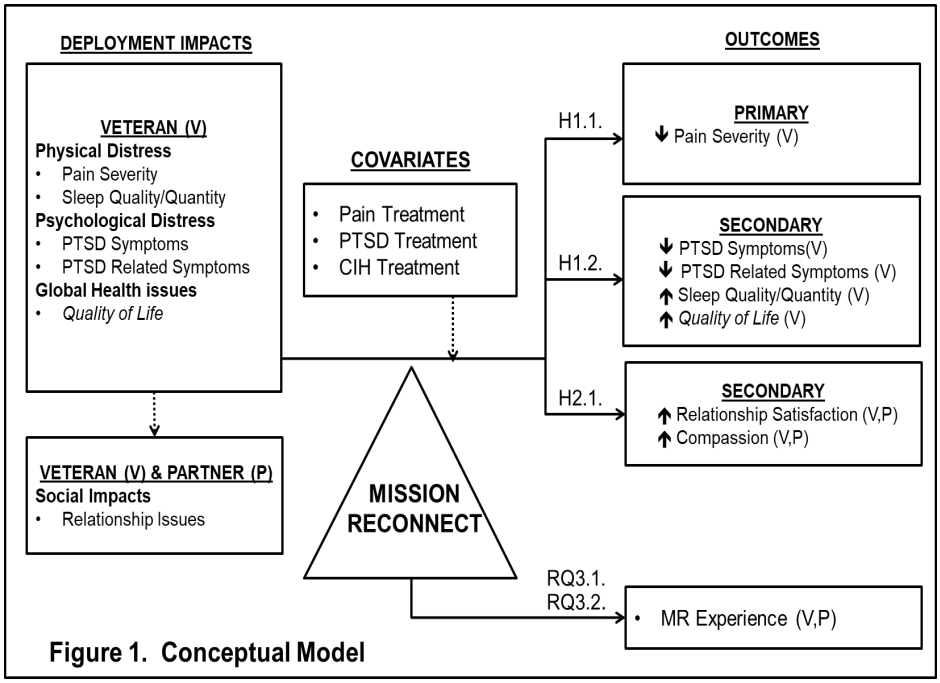

Figure 1. Conceptual Model

In our conceptual model (Figure 1), deployment impacts on Veterans and their families are summarized in the left box while target biopsychosocial outcomes in the boxes on the right are the expected effects of the proposed MR intervention, while controlling for previous and current treatment history (non-MR). MR has potential to provide a critically needed CIH option to manage deployment-related impacts, such as pain symptoms, sleep issues, and relationship issues.

Hypothesized Mechanisms of Mission Reconnect. The biopsychosocial model was proposed to encourage exploration into categories of human distress that did not neatly fit the physiology only biomedical concept of disease, and the processes by which disease developed.[51] Now, the biopsychosocial view is accepted, which provides mechanisms that account for interactions between the comorbid physical, emotional and cognitive symptoms that appear in patients, particularly those with pain.[22] The biopsychosocial model supports interdisciplinary programs that combine intervention components at the biological, psychological and social levels.[21,22] MR leverages the mechanisms of action of multiple evidence-based CIH approaches, offering users multiple pathways to achieve clinical benefit. Users can benefit from the discrete therapies themselves but also the synergy of diverse therapies that mutually reinforce each other's effects. The primary modalities taught in MR - cognitive and behavioral approaches such as activation of mindfulness, gratitude and compassion, and massage - have very rich evidence bases for

reducing pain and anxiety. Finally, the interpersonal support conferred by collaborative participation in MR makes possible the buffering effects of social support while reinforcing practice activities.[52] Impacts of MR participation on pain have been demonstrated in both the Phase I and Phase II trials.[53]

Study Context

The primary site is James A. Haley VA Hospital in Tampa, FL and is one of the largest VHA hospitals. The Tampa VA system includes one hospital and four CBOCs. Furthermore, the Tampa system includes urban and rural facilities to provide diversity based on geographic locality.

Significance

Chronic pain and PTSD are highly prevalent comorbid conditions in the Veteran population, and present a challenge for traditional interventions.[1,54] Pharmacological options have potential consequences of opioid use disorder and overdose.[4] The VA's Opioid Safety Initiative (OSI) and the U.S. Department of Health and Human Services 2016 National Pain Strategy prioritize the need for nonpharmacological pain treatment options that leverage self-management.[17,55] The VA is invested in providing virtual services to improve Veteran and family member access to care that promotes self- management and improves patient outcomes. The VHA currently views touch-based therapies as interventions requiring professional delivery. Massage costs approximately $60/hour,[56] its primarily an out-of-pocket expense, and is often not affordable. Massage is not currently widely available in the VA, however with the emerging Whole Health initiative, massage and other mind-body modalities will be in increasing demand. Simply put, the VA will not be able to meet the increasing demand for massage services. MR provides a potentially low cost, accessible and sustainable intervention for Veterans in home settings. Need for low-cost interventions to support well-being and optimal functioning among Veterans and their families is clear.[3] Furthermore, the VHA's Secretary for Health's Critical Priorities for Strategic Action identified access, pain management, and putting Veterans first to achieve Veteran health. To be responsive to these priorities the 2016 VA State-of-the-Art Conference (SOTA) and VA CARA mandate,[50] indicate VA's commitment to conduct rigorous research to integrate non-pharmacological and CIH approaches into care at every level, with emphasis on pain management. To support these priorities, the Office of Patient Centered Care and Cultural Transformations' (OPCCCT) Whole Health Program, provides an innovative approach to integrative care that leverages CIH and family participation. Finally, the Connected Care Office (CCO) seeks to support self-care management and health care using mobile technology.

Severity of outcomes, cost of care, and initiatives prioritizing access to CIH and whole health care warrant the need for a multi-dimensional approach, such as MR. The proposed research will advance science by: (1) testing a safe self-directed sustainable CIH approach for treating a clinically defined high-risk population of Veterans diagnosed with chronic pain and PTSD-related symptoms to improve psychological and physical outcomes; (2) introducing a non-pharmacologic chronic pain management program option for Veterans;

(3) testing the usefulness of MR as a remotely delivered internet/mobile program delivered in the users' natural environment; (4) leveraging a partnered approach (e.g., spouses or family members) to implementing interventions that address the biopsychosocial aspect of wellness; and (5) conducting longitudinal repeated-measures analyses, which are not common in CIH research.

Research Design and Methods

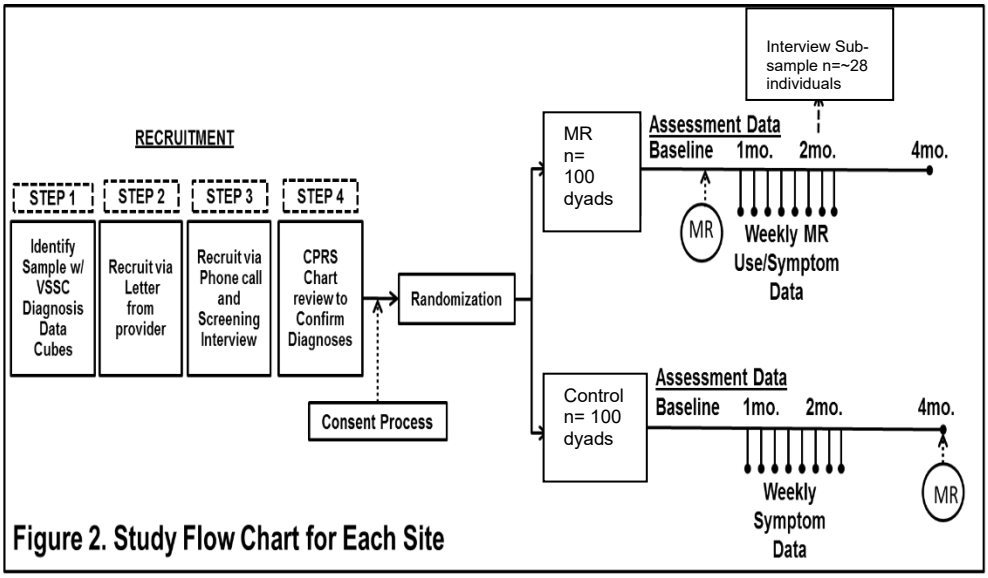

Figure 2. Study Flow Chart for Each Site

Study Design and Overview. This four-year randomized controlled trial with one intervention arm and one wait-list control arm will utilize mixed methods to evaluate the effectiveness and perceived value of the MR program in relation to physical and psychological symptoms, global health, and social outcomes. An underpinning of the MR program is that it is intended to be adjunctive (complementary) to conventional evidence-based modalities for treatment of pain and PTSD (i.e. usual care). This is consistent with the previous MR trial conducted in a non-VA setting and different patient population whereby usual care served as the comparator group.

Therefore, a waitlist control condition has been selected as the comparator for the proposed trial. This will allow assessment of the MR program above and beyond the effects of usual care being received. In addition, the relatively brief waitlist control period insures that all subjects will ultimately be offered the MR program. We believe this will be an incentive for both recruitment and retention of study subjects for this new recruitment setting. We will test MR using a randomized control trial with concurrent mixed methods data collection. We will recruit Veteran and partner (e.g., spouse or family member) dyads. Study flow for each site is shown in Figure 2.

Aim 1 & 2 assessment data will be collected from 600 Veteran/partner dyads (up to 200 per site, 100 dyads per arm) *via* a secure project website at baseline, 1, 2, and 4 months to assess primary and secondary outcomes. MR utilization and pain ratings will be assessed weekly for the first eight weeks of the intervention. This data collection plan will allow assessment of acute changes, rate of change with repeated measures over two months and sustained changes.

In **Aim 3**, a sub-sample of 84 individuals assigned to the intervention arm (n= 84 individuals, approximately 28 individuals/site) will be purposively selected (e.g., high or low MR utilization groups) to participate in telephone interviews to evaluate their experiences using the program. All consenting participants will be randomly assigned in a 1:1 ratio *using a permuted variable block design* to one of two arms (treatment vs. control). Participants will receive study information, instructions on how to complete the online data collection, and contact information in case they experience an adverse event. Participants will provide preferred contact information for data collection reminders. We will have contact information for each participant's primary care provider to ensure contact in the case of an adverse event and follow our established protocol for such events.

Treatment Arm: MR is a user-driven, dyadic, self-care management program developed with NIMH funding (R43/44) for use by Veterans and their selected partners, individually or together, to reduce pain and distress and support physical, mental, and relationship health. MR was designed for Veterans who face obstacles accessing formal mental health services. It can also be used to complement formal services. MR is a patient-centered intervention, allowing users to determine the pace at which to proceed in each program component.

MR Content The program provides video and audio instruction in a set of 11 evidence-based wellness activities in three thematic categories: *Connecting with Yourself*, *Connecting with Quiet*, and *Connecting with Your Partner*. All instruction is accessible via the program website (MissionReconnect.com) and mobile device apps. Video content totals 91 minutes and was produced by filming two days of workshops to teach the practices to Veteran/partner dyads. The *Program Overview* video (54 min.) introduces the MR instructional sequences accompanied by commentary by workshop participants. Detailed massage instruction is presented in the separate *Massage Instruction* video (34 min.) and *Massage Video Supplement* (3 min.) addressing use with home furniture. Users are encouraged to give and receive at least one massage per week. Audio content totals 67 minutes and was recorded in studio, with *nine instructional audios* ranging from one to 22 minutes. Users are encouraged to listen, learn the practices, and then use each technique with or without the guided instruction as they wish. Support materials. A *Massage Instruction Booklet* and illustrated *Massage Reminder Handout* are downloadable from the website. A *What if?* feature enables users to access advice on how to apply program techniques in challenging situations such as experiencing problems with sleep, focus and concentration. Users can submit questions and suggestions for future content through the *What if?* interface. *Optional Audios* give users choice of audio gender voice. A *Resources* section provides links to hotlines, Vet Centers and VA Facilities.

Users will be instructed to (1) try all the practices at least once during the first two weeks, and thereafter (2) do at least one exchange of massage per week with their partner, and (3) practice other methods of their choice at least 3 to 4 times per week. Dyads will be informed that greater use may result in greater benefit to reinforce practice.

Usual Care Waitlist Control Arm: For ethical reasons, this study will use a waitlist control

arm to ultimately offer all participants exposure to the MR intervention. Dyads in the control arm will participate in all assessments like those in the intervention group, however, they will be asked to agree to not access the public web site during their participation. Wait-list control participants will be instructed to seek advice about treatment from their providers. Other than this initial advice, there will be no attempt by study personnel to influence condition management unless an issue (i.e., suicidal ideation) arises. The control condition will account for potential temporal effects that occur from passage of time (brief), and expectation effects associated with anticipation of MR participation. While dyad randomization suggests primary physicians will have intervention and control patients in their practices, numerous effectiveness trials have shown there is little spillover of the intervention to usual care patients. The control group will receive access to MR after they complete data collection.

Sampling: We will use a four-step process to purposively recruit study participants (see Figure 2). First, using an IRB approved procedure with a waiver of consent process; a secondary administrative data query of the ICD-9-10 conditions for chronic pain and PTSD will identify a sample pool of Veterans in the previous fiscal year. Cross-examination of the pain and PTSD cohorts for FY 2016 indicates a sample of 5,508 in Tampa who will be potential participants [Source: VSSC, Diagnosis Pyramid Analytics Report: Accessed 08/27/2017]. With our access levels and expertise, this process should take two weeks. Second, we will recruit from providers using signed letters from the PI. The provider will give the recruitment letter to the patient for him/her to follow up with the study team member to inquire about participating in the study. Study team members will mail the same recruitment letters to cohorts who have been identified in step one of the recruitment process to reduce burden of clinical partners and to reach those Veterans who don't often attend VA medical appointments. This helps provide a way to reach out to those Veterans with this type of diagnoses who are less likely or don't regularly receive care intervention. Potential participants who contact study staff after receiving a recruitment letter will be presented with information about the study to help them determine whether they'd like to participate in the study and provide a verbal consent and HIPPA authorization. Potential participants who have not responded to the letter may be contacted by their healthcare team for follow-up. Based on our previous projects the process from initial sampling to recruitment and randomization should conservatively take three months.

Screening interviews will assess the occurrence of chronic pain (pain for 6 months or more during the prior year) and symptoms of PTSD (diagnosed, treated or experienced symptoms of PTSD in the past 6-months); assess if they have visual, hearing, or other cognitive impairments; assess for previous diagnosis of moderate or severe TBI; recent history of psychosis; and determine availability of a partner and the dyad's interest in participation. Additional details on pain treatment history, severity and treatments of PTSD symptoms, potential TBI exposure, and recent use of complementary and alternative therapies for pain will be captured from the baseline data collection forms. In tandem, the fourth step (with waiver of consent) will allow chart review if needed for interested potential participants to: (1) confirm comorbid conditions (chronic pain and PTSD), (2)

determine substance use disorder treatment status, and (3) determine TBI diagnosis and severity to exclude individuals with moderate or severe TBI.

Eligible Veterans will be invited to participate after screening, be consented, and receive information to access the data collection site and determine their group assignment. This information will be provided at the completion of baseline data collection. Veterans and their partners will receive separate stipends for their time.

Sample: The sample will consist of 400 participants drawn from 200 dyads over approximately 4 months (MR Intervention Group) or approximately 4 months for (MR Control Group) at the Tampa VA. Women and minorities recruitment numbers will mirror site distribution based on sex and race, as this study is not powered to examine differences by race and sex. We anticipate considerable racial variability due to having three geographically diverse sites with markedly different census profiles. We anticipate a considerable representation of female participants with our invested partnership with women's physician Dr. Paykel, who has estimated the ability to recruit approximately 10% (n=25) of the overall sample at the Tampa site alone. This will make a considerable contribution to the knowledge of female Veterans which is often lacking in VA studies.

Inclusion criteria will be: 18 years or older, English-speaking Veterans with chronic musculoskeletal pain[57] as initially identified through secondary administrative data query of the ICD-9-10 conditions for chronic pain. In the initial query, musculoskeletal pain is present if the Veteran meets either of two validated criteria (See Appendix 5): (1) 2+ occurrences of any of targeted musculoskeletal ICD-9-CM codes "likely to represent chronic pain" identified by Tian et.al[58] recorded at visits separated by at least 30 days within past six months; or (2) high impact chronic pain = 2+ occurrences of targeted musculoskeletal ICD-9-CM codes (adapted from Goulet et al.[3]) separated by at least 30 days within the past six months previous to study recruitment and two or more pain scores greater than or equal to 4 separated by at least 30 days within past six months.[58] For pain scores, we will use the 0-10 numeric pain rating scale that is routinely collected at the VA. We will count two ICD-9-CM codes or pain scores recorded on the same day as one code/score.

Previous history of PTSD will be present if the Veteran has a flag in medical record indicating confirmed condition by the VA Compensation and Benefits program, has at least two outpatient visits in the year with the primary diagnosis being listed as PTSD (ICD-9-CM code 309.81) and/or had PTSD listed on the problem list.

Confirmation of chronic pain for more than 6-months in the past year and diagnosis, treatment, or symptoms of PTSD in the past 6 months will be confirmed by the telephone screening interview and use of CPRS if needed for further confirmation.

To participate in the study, the Veteran must also have ability to access and use an electronic platform (e.g. Mobile device, internet, DVD) for MR delivery, with a willing partner to participate in the study and MR program.

Exclusion criteria will be: Moderate to severe TBI, diagnosis or documented treatment for psychosis in previous 6 months, currently in high-intensity substance use disorder treatment, non-English speaking; visual, hearing, cognitive impairment that prevent participation or ability to consent, self-report history of partner/family member physical abuse in the past year, and/or lack of access to internet service. These individuals will be excluded due to medical, language, and technology access issues that would prevent safe and full study participation. As stated above, *potential participants who screen for aggression or violence will also be excluded from study.*

Randomization: Participants (dyads) will be randomized to treatment (MR) or control using a per site variable block randomization method (blocks of 6 and 8) to facilitate a balance in treatment and control group sizes per site and over time. Variable blocks of 6 and 8 per site will be randomly used so that no one will know for sure the next random assignment. Dyad is the unit of randomization; this ensures that members of the same couple receive the same intervention. The randomization will be stratified by whether or not the veteran is currently receiving, or has received in the past 2 weeks, a Level 1 evidence-based treatment for pain and/or PTSD, per current VA-DoD treatment guidelines.

This will facilitate subgroup analyses of the effect of the MR intervention in the presence versus absence of concomitant first-line evidence-based treatment for pain and PTSD. A computer-generated random allocation sequence will be generated by the study biostatistician (separately for each site/era of service combination to ensure balance across sites, that is, control for site effects by design). Dr. Alman and Dr. French will be responsible for monitoring participant (dyad) assignment. Participant dyads randomized to the treatment group will receive a link, and PIN to access the MR site and will be instructed to create personal user accounts. Control group members will receive access to MR after completing data collection.

Participants will complete the informed consent and HIPAA authorization for the study either in-person or over-the-telephone. Research team members will review the consent and HIPAA content with participants, to ensure review and comprehension. Since both partners will be full and equal participants in the study, both will be individually screened and consented by individual interview. We will employ three self-report items (Appendix 6) to address physical threat to and by partner, and fear reprisal. We will use a standard protocol advised and utilized in VA Family Services in its couples/family therapy: (1) Initial brief – individual consent/self-report; (2) Identify urgent need; (3) provide follow up call, and referral for community resources; (4) exclude from study.

Participants will be provided an option to receive a printed copy of their informed consent and HIPAA authorization for review to ensure their understanding. Communication, such as informed consent explanations, will be supplemented using the telephone to provide respondents opportunities for questions and clarification as needed. This is an effective means of communication for studies evaluating electronic health services such as Mission Reconnect. These remote methods of communication and consent have been effectively used in other studies conducted by the PI. These forms of communication: (1) reduce

participant burden; (2) conserve resources; and (3) leverage electronic communication devices which support and promote virtual care.

Sample Size Power Analysis: **Aim 1&2, H1.1-H1.2 & H2.1** estimates of statistical power are based on Aim 1 and initially the primary outcome of pain. Whereas dyad is the unit of randomization, we assess power based on separate analyses for Veterans and partners (one approach used). There are 4 major intervals of assessment (baseline, 1, 2, and 4-months). At the beginning of this study, we estimated attrition based off of a previous MR trial that had less than 5% attrition. Based on early recruitment at the primary site, we have adjusted recruitment goals to allow for approximately 33% attrition, and uneven recruitment across the three study sites. Assuming within-subject (outcome measurement) correlation of 0.5, the proposed sample size will provide 80% power (2-sided type I error rate of 0.05) to detect a "small-to-medium" effect size of 0.38 (Cohen's *d*). For analyses stratified by site (in addition to evaluation by random effect assessment), the study will provide 80% power to detect a "medium-to-large" effect size of 0.66. By way of comparison, the pilot data presented above describes large effect sizes (*d* = 0.81 for pain symptom reduction). While this effect size was based on a relatively small sample of comparable patients (n<15) and within-subject assessment (paired *t*-test), it provides good assurance that the proposed sample size is sufficient to detect realistic, medium size effects should they exist with the MR program. For secondary outcomes, we will use a type I error rate of 0.01 for multiple comparisons. For the sample and our described assumptions, this will provide 80% power to detect a "medium" effect size of 0.45.[59]

Sample Size: **Qualitative- Aim 3** sample size relies on the quality and richness of information obtained.[60] Conceptual saturation is the goal of qualitative research, and depends on data to support interpretations. Saturation has been noted to occur within the first 12 interviews.[60,61] Our team has extensive experience in evaluating electronic technologies, and have found recruiting high and low volume users provides the richest dataset. To ensure representative data, we will conduct telephone interviews with a purposive (e.g., high or low MR utilization group) sub-sample of up to 84 individuals to achieve representation at each site (approximately 28 individuals/site).

Data Collection Procedures. Data will be collected using (1) self-report surveys; and (2) telephone interviews.

(1) *Self-reported Survey Data*.

To test **Aim 1 & Aim 2,** survey data will be collected using Qualtrics, a resource that has demonstrated capacity for remotely and securely collecting participant data in other studies conducted within the VA system. Qualtrics is a secure platform for the creation and distribution of online surveys and recording of response data, including quality control features such as range checks, skip patterns, and completeness of data entry. Qualtrics ensures protection and reliability of client data with high quality firewall systems, regular vulnerability scans, nightly complete backups, and annual complete

penetration tests. Qualtrics services will allow control of individual permissions for accounts and surveys. Qualtrics accounts are password protected, and all data are replicated in real-time. The participants will be assigned a unique PIN and will receive email messages with a link to prompt participant dyads to access the site and complete data collection. Upon access to Qualtrics, participants will be required to enter their PIN as the first entry into the system. Similarly, access to the online Mission Reconnect content will require entry of the same PIN. The PIN selected by each participant will be maintained in a cross-walk file with their randomly assigned study ID number. The Qualtrics measures will be compiled into a single survey format and collected at baseline, 1, 2, and 4 months. The rationale for this schedule is to formally assess initial, short-term, and sustained effects that may occur with the MR intervention. MR will utilize an outcome measure named *Self-Assessment of Change*[62,63]. This tool was uniquely designed to assess a wide range of shifts in well-being across complementary and alternative medicine (CAM), therapeutic modalities and conditions. MR use and satisfaction, pain, tension and stress items will be conducted weekly for the first 8-weeks of data collection. This more frequent schedule of data collection will permit short-term dose-response analyses (i.e. dose of MR utilization) in relation to major symptoms of pain and PTSD. Measures and psychometric properties are illustrated in Table 1.

Table 1: Veteran and Partner Measures and Psychometric Properties

Construct	Measure	Description	Min.	Time point
Veteran Eligibility Variable				
TBI Exposure	OHIO TBI Exposure Screen[64]	8-items designed to elicit self- or proxy-reports of TBI occurring over a person's lifetime. Can provide measures of the extent of exposure to TBI including the current injury.	5	Pre-screening
Veteran and Partner Independent Variables				
Demo-graphics	Participant Survey	15-items assess age, gender, ethnicity/race, education, income levels, religion, marital status, relationship length, military service/status/grade, deployments, computer/internet use.	5	Baseline
Veteran Independent Variable – Covariate				
Other Treatments	Concurrent treatments	2 items asking Veterans to report concurrent pain and PTSD treatment(s) and CIH modalities to account for dual intervention effects.	1	Baseline, months 1, 2, 4
Veteran Dependent Variables				
Quality of Life	Self-Assessment of Change[62,63]	16-item word pairing scale to assess a variety of shifts in well-being across a broad range of therapeutic modalities and conditions.	5	months 1, 2, 4

Quality of Life	Quality of Life SF12[65]	12-items to assess quality of life using physical status and mental health distress.	3	Baseline, months 1, 2, 4
Pain	Defense and Veterans Pain Rating Scale[66]	10-point scale to measure "usual" pain intensity over the last week and 4 pain functionality (past month) items.	3	
	Pain Outcomes Questionnaire- Short Form VA[67]	20-items assess pain-related domains, including pain intensity, interference with activities and mobility, negative affect, vitality, pain-related fear; and improbable pain-related symptoms.	5	
Pain	Single item scale	One item will assess pain using a 0 to 5-point Likert-type scale.	1	Baseline, weeks 1-8; months 1, 2, 4
Stress and Tension	Single item scales	Two items will assess stress and tension using a 0 to 5-point Likert-type scale.	1	
PTSD & Related Psychological Symptoms	PTSD: Posttraumatic Checklist[68]	20-item measure of the DSM-V PTSD symptoms with scales related to stress, anxiety, & emotional numbing.	4	Baseline, months 1, 2, 4
	Depression: Beck Depression Inventory[69]	21-items, a widely used instrument for measuring depression. Respondents are asked to rate their symptoms and attitudes using a 4-point scale.	5	
	Stress: Perceived Stress Scale[70]	10 Likert-scaled items, validated and widely used, to determine perceived stress levels.	3	
	Sleep Quality: Pittsburg Sleep Quality Index[71]	19 self-rated questions from which 7 component scores are calculated and summed into a global score to assess sleep quality in the past month.	4	
Veterans and Partner Independent Variable – Covariate				
MR Program Utilization (Treatment and Control group)	Utilization survey	Treatment group: weekly report 11-items will assess frequency of use and compliance of the MR mind/body & massage practices. Control group: weekly report 4-items with descriptive activities to obtain descriptive data on their utilization of any personal strategies to address stress coping, physical pain, partner relationship support, and sleep quality.	3	weeks 1-8; months 1, 2, 4
Veterans and Partner Dependent Variables				
Relationship Satisfaction	Revised Dyadic Adjustment Scale[72]- Adapted	14-item Likert-scaled instrument is reliable and valid and contains subscales for dyadic consensus, dyadic satisfaction, and dyadic cohesion.	3	Baseline, months 1, 2, 4

Compassion	Compassion for Self and Others Scales[73,74]	26- (CSS) and 21- item (COS) measures, five-point Likert-scaled measures self-compassion and compassion for others.	5	
Program Satisfaction (Treatment Only)	MR Program Satisfaction Items	11 ten-point Likert-type items assess satisfaction using MR components, whether they would recommend MR, and massage satisfaction.	1	Weeks 1-8; months 1, 2, 4

(2) Telephone interviews.

To address **Aim 3**, telephone interviews (~30 min) will be conducted with a sub-sample of 84 individuals. Only treatment group members will be recruited for this data collection. Prospective interviewees will be purposively selected (e.g., high or low MR utilization groups) to participate in telephone interviews to evaluate their experiences using the program. MR utilization will be calculated at the dyadic level. Both Veteran and partner members of dyads assigned to the treatment arm will be contacted for qualitative interviews, however interviews will be conducted with Veterans and their partners separately. We will explain the interview purpose and ask permission to audio-record and use the interview script to ensure that all topics are covered. An audio voice consent must be completed and voice recorded at the time of the telephone interview process. The participant will be informed they will be recorded and need to state on the recorded telephone interview when asked if they agree to participate prior to the start of the telephone interview.

Interviewers will solicit respondents' attitudes, opinions, and reports about their preferences and the pros and cons of MR and/or participating in the practice groups, including their perceptions of usefulness. We will use standard communication techniques to stimulate discussion, with prompts (e.g., "tell me more"), summarizing statements, and silence. We have used these methods in several previous studies to gather data effectively. Additionally, in an effort to understand the factors that contribute to study attrition, a maximum of ten individuals who did not complete study activities may be contacted for a brief 15-minute voluntary telephone interview. These interviews will solicit respondents' experiences with the study and any difficulties that they experienced. Only participants who were lost to follow up and who had been assigned to the treatment arm will be contacted for these attrition interviews. Participants who officially withdrew from the study will be excluded from the pool of prospective interviews.

A total of 84 interviews (n=84 individuals), including participants lost to follow up and participants who have successfully completed the study, will be performed. We will attempt to interview both members of dyads to obtain conceptual saturation.

Data Analysis: The *intention to treat* principle will be used for all analyses irrespective of the extent of protocol compliance or dropout.[90] Whereas randomization is anticipated to balance both study arms on presenting demographic and clinical characteristics, including

within sites and by concomitant receipt of first line pain and/or PTSD treatment, continuous variables will be compared by student t-tests or Wilcoxon tests (depending on distributional properties); categorical variables will be compared by chi-square analyses.

*Hypotheses Aims 1 & 2***.** All outcome measures *(primary and secondary)* under Aim 1 will be collected at baseline, 1, 2, and 4 months and are continuous variables. Therefore, general linear mixed models will be used with main effects terms for GROUP (MR vs. waitlist) and TIME (4-time points) and a GROUP x TIME interaction term (for rate of change). The models will also include site as a random effect. To assess whether the rate of change is curvilinear (i.e., the rate of change differs between time points), a quadratic parameter will be tested. Different correlation structures and functional forms of the effects of the MR program will be assessed using the information criteria and a final parsimonious model will be determined for final statistical inference. Initial effects of the MR program (baseline to 1-month) will be evaluated by analysis of covariance (ANCOVA). For H1.1, the primary outcome measure for pain will be total score on the 19-item POQ. For H1.2., the primary outcome measure for PTSD will be total score on the 20-item PCL-5. Subgroup analyses will be explored using similar methods and examination of severity of baseline pain and PTSD scores. These analyses will provide insight into subgroups in whom the MR program may be particularly beneficial. In a similar realm, analyses will be stratified by baseline median level of relationship satisfaction, as derived from total score on the 14-item RDAS. This will permit assessment of the effect of the MR intervention on potential improvement in relationship satisfaction among a cohort of dyads with presumably troubled relationships at entry. Moreover, using the weekly reports (8 weeks) of MR use and satisfaction with the MR program, the MR sample will be split above versus below the median for these two measures, and compared separately against the waitlist control condition at 2-months. This approach approximates a "per protocol" analysis in terms of recommended use of the MR program. In addition, especially for Aim 2 outcomes, we seek to examine whether dyads appear to show mutual benefits from the MR program. Therefore, multilevel models will be fit using an over-time dyadic model[78] in which individuals are nested within dyads and time is crossed with dyads (i.e., both Veteran and partner are assessed at the 4 time points). This analysis accounts for the non-independence due to the correlation between dyad members' general levels on outcomes averaged over time, as well as the time-specific correlation between their outcomes (e.g., similarity caused by time-specific events).

Data Management and Quality. All data will be password protected and made accessible only to our research team members. Most consent and data collection will occur on a VA approved secure website (i.e. Qualtrics). However, a secure drive folder will be available to each site team.

Self-reported data: Participants' survey data will be remotely collected using Qualtrics, a VA approved secure survey assessment center and located on a secure VA network server database. Location tracking services will be disabled.

Interview data. Interview recordings will be collected on a VA-approved encrypted recorder with a telephone interview adaptive device. These recordings will be downloaded

and stored on a secure network server at the R&DS. Recorded documents will be remotely retrieved, transcribed and returned for analysis by the Salt Lake City Transcription Center. Interview data will be managed using Atlas Ti[91] and analyzed by at least two experienced qualitative researchers. Transcripts will be time stamped, reviewed, compiled, and standardized.

Research Questions RQ3.1. & 3.2. Interview transcript data will be managed using descriptive content analytical methods to identify domains and taxonomies related to participants' experiences with MR use.[44] Categories will be compared and contrasted, and relationships among them will be identified. As coding schemas are developed to create domains and taxonomies, data samples will be extracted and coded by research team members and evaluated for inter-rater reliability and credibility. Descriptive and comparative matrices, which identify the patterns of regularities (shared) and inconsistencies (unique or varied) will then be constructed for the Veteran and partner participants. Comparative matrices enable identification of the most relevant, shared, and perhaps representative components, thereby enhancing the potential representation of the findings. Finally, a complex cross-case data display or matrix will be developed to summarize the significant taxonomic outcome structures identified within and between Veterans and their partners. This process of descriptive and comparative matrix analysis will allow discernment of the most salient and representative components identified by Veterans and their partners.

Data Use

- Data will be stored and maintained in accordance with the VA approved Record Control Schedule.

- Final de-identified data sets underlying publications resulting from the proposed research will be available outside VA in an electronic format, through email upon request, after results are published. Data sets will be available for collaborators and other investigators upon request prior to publication (expected time period: 30 days post request). The extent of the data will be de-identified aggregate data only.

- De-identified data will be publicly shared through publications and scientific presentations at meetings with adequate detail to permit validation of results. Publications/presentations will be made available to the public through the National Library of Medicine PubMed Central website within one year upon request. The current project will not generate any identifiable human data.

In general, data will be stored on a R&DS secure network server or on a VINCI server.

- De-identified information will be stored and shared in password-protected files and accessible only to research team members with VHA Privacy Policy training on VA approved secure server behind VA firewall.

- Data for means of analysis will be backed up to a hard drive, maintained, and secured in the PI's VA office.

- Interview data will be collected on VA encrypted recorders. After being stored, recorded documents will be remotely retrieved and transcribed for analysis. De-identified interview data will be managed using Atlas Ti[77] by experienced qualitative researchers.

- To ensure quantitative data quality, we will identify and correct errors in coding/data entry. De-identified quantitative data cleaning will begin during data collection to allow detection and correction of systematic errors. Measures of frequency, central tendency, and dispersion will be used to identify errors. Statistical data will be managed using SAS statistical software suite.[78]

Missing data. Missing data will be tabulated by treatment arms and by assessment waves; comparison tests between arms will be conducted to assess potential attrition bias and to examine the missing data mechanism (e.g. missing at random). If missing rate is less than 10%, analyses with list wise deletion (missing values dropped from the analysis) will be performed (due to minimal concern over bias). Participants who are lost to follow-up and missing on post randomization outcome assessments will be included in additional comparison analyses that utilize multiple imputations of missing data to minimize bias due to differences between those with complete and incomplete data.

Dissemination Plan. Dissemination efforts will be led by the PI along with the VA operational (e.g. OPCCCT and CCO), clinical stakeholders (e.g. mental health and pain clinicians), and the Tampa R&DS VEC. We will publish findings in peer-reviewed journals and present findings at national and international meetings including Medicine 2.0, the international conference for internet-based health research (Haun) and Association of Military Surgeons of the United States (AMSUS) Annual Continuing Education Meeting. Dissemination activities will inform VHA operational initiatives and clinical practice (Table 2). The deployment of Whole Health models of care nationally will provide a natural setting for dissemination. The Tampa VEC will support dissemination efforts to Veterans, their families, and to Veteran Service Organizations.

Table 2. Dissemination Plan

Format	Target Audience	Potential Use or Outcomes
1. Mission Reconnect for Veterans and their partners		
Briefing	Clinicians in Mental Health and Pain Clinics, VEC	• MR as an option for non-pharmacological self-care management for chronic pain
2. Linking study findings to operational and clinical initiatives		
Reports/Oral Presentation	Office of Mental Health Connected Care Office Office of Patient Centered Care & Cultural Transformation &	• Guidelines for using MR to support clinical care • Support operational mission and provide insight on usability and application of MR

	Flagships	• Lessons learned and MR use strategies
3. Mission Reconnect in the VA for self-care management		
Marketing Materials	Veterans and family members, Veteran Service Organizations, VEC	• Increased motivation to actively use MR for non-pharmacological self-care management
4. System-wide presentation of in-service and marketing of implementation strategies		
TMS/EES	VHA Employees	• Present findings and increase awareness of MR • Lessons learned, recommendations, and MR use strategies
Presentation	VISN PACT Leads & Virtual Care Coordinators	
5. Cyber Seminar		
Oral Presentation	VA Researchers & Administrators	• Present findings and increase awareness of MR • Lessons learned and MR use strategies

Project Management Plan

This team has established effective mechanisms for communication and collaboration leveraging technology across sites. The Tampa based team, led by Dr. Haun, will direct overall coordination of the project. Dr. Haun will work with co-investigators to refine and implement data collection and analyses, and ensure the project is achieving study benchmarks. Dr. Alman will lead randomization and quantitative data analyses for **Aims 1 & 2**. PI and study team will lead qualitative activities for Aim 3. Drs. Paykel, Scott, and Murphy will provide clinical expertise and recruitment support at the Tampa site.

Table 3. GANTT Chart of Study Benchmarks.

	YEAR 1 (2019-2020)				YEAR 2 (2020-2021)				YEAR 3 (2021-2022)				YEAR 4 (2022-2023)			
Project activity	**Q1 Nov '18**	**Q2 Feb '19**	**Q3 May**	**Q4 Aug**	**Q1 Nov**	**Q2 Feb '20**	**Q3 May**	**Q4 Aug**	**Q1 Nov**	**Q2 Feb '21**	**Q3 May**	**Q4 Aug**	**Q1 Nov**	**Q2 Feb '22**	**Q3 May**	**Q4 Aug**
Start-up	■															
Recruitment Screening and Randomization, Qualtrics development and validation		■														
Recruitment (3-4 dyads/month per site)			■	■	■	■	■	■	■	■						
Primary Data Collection			■	■	■	■	■				■					
Conduct Interviews				■	■	■	■									
Interview Transcription				■	■	■	■	■								
Interview Data Analysis					■	■	■	■	■							
Prepare & Stage Primary Data										■	■	■				
Primary Data Analysis													■	■		
Data Interpretation and Triangulation													■	■	■	
Finalize Data Reports/Manuscripts														■	■	■
Develop Materials for Dissemination															■	■
Prepare/Submit Subsequent Proposal															■	■
Disseminate Materials to Audiences															■	■

Resources and Specific Location of Study

Primary Study Site: James A. Haley Veterans' Hospital, Tampa, FL. James A. Haley Veterans' Hospital (JAHVH) is a tertiary care facility classified as a Clinical Referral Level 1 Facility. It was the first VA hospital—and is one of 342 VA and private hospitals worldwide—to receive the prestigious designation as a Magnet Hospital. JAHVH Main Hospital has 415 beds, with an additional 118 beds in the onsite Nursing Home Care Unit. JAHVH was recently designated the VISN 8 Complementary and Integrative Health (CIH) Center, this designation comes with substantial funding to support CIH implementation and evaluation, to support roll-out efforts throughout VISN 8 and ultimately the VA nationally.

JAHVH is a teaching hospital, providing a full range of patient care services, with state-of-the-art technology as well as education and research. Comprehensive health care is provided through primary, tertiary, and long-term care in areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, spinal cord injury, neurology, oncology, dentistry, geriatrics, and extended care. JAHVH consists of five Veterans Health Administration facilities located in Tampa serving four counties in Central Florida; with four Community Based Outpatient Clinics in New Port Richey, Zephyrhills, Lakeland and Brooksville. The proposed study includes three groups within JAHVH: (1) The Center of Innovation on Disability and Rehabilitation Research; (2) Mental Health Outpatient Clinic; and (3) Polytrauma Rehabilitation Center.

R&DS Resources

Investigators include health services researchers and data managers with experience in measurement, survey and qualitative methodologies, and use of VA administrative databases for research, and five anthropologists with qualitative research expertise. We have dedicated servers located behind the VA firewall. We have developed server technologies to securely host a virtual environment to give researchers the ability to securely access data along with reporting and analysis tools. Resources available in the Tampa server include: computing infrastructure; shared research environment; protected development environment; secure and controlled access to data; and tools for analysis and publication. The Tampa server uses a VMware Server driver model and virtualization components. The virtualized environment allows cluster shared volume support and expanded processor and memory support for host systems. The virtual environment includes two VMware server nodes to be collectively configured as a clustered system hosting all the Tampa servers in a virtual fashion. Utilizing a shared SAN (or Storage Area Network), these hosts are to share storage resources providing failover, disaster recovery, as well as high performance to ensure optimal operability for Tampa server resources. The Tampa computing infrastructure contains multiple servers and more than 1 TB of storage. The virtual system is designed to handle more than 200 concurrent users, with more than 50 users at any given time.

R&DS Veteran Engagement Council

The purpose of the R&DS Veteran Engagement Council (VEC) is to improve rehabilitation research through a trusted partnership among Veterans' communities and R&DS investigators. The VEC mission is to incorporate the Veteran and family voice into all phases of R&DS research projects. The ten Veterans and/or caregivers VEC members represent the Air Force, Marines, Army, Navy, National Guard and the Vietnam, pre-9/11, post-9/11-3, Persian Gulf War and Iranian Hostage conflicts. There are 5 males and 5 females. The race/ethnicity representation is white (50%), African American (40%), and American Indian and Hispanic (10%). The VEC members' role is to bring their unique military background, health conditions, and health consumer perspective to the research arena. At each of the monthly meetings, an investigator volunteers to present their research and ask one to three questions of the members to focus the discussion. By using focusing questions, researchers can engage VEC members at any point of the research process, e.g., from topic generation to data collection, to dissemination of results. R&DS VEC members have the option of working of working on individual R&DS projects. On this proposed project, the VEC has reviewed the proposed project to support recruitment and dissemination activities, to support the successful recruitment of Veteran participants and the spread of study findings.

VA Informatics and Computing Infrastructure (VINCI)
Data analysis for many R&DS projects will be conducted using VINCI. VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration's Office of Research and Development (VHA ORD). Supporting Transformation for the 21st Century Initiative #13, VINCI aims to provide researchers a nation-wide view of high value VA patient data. While VINCI brings together data sources and provides the analytical environment for performing studies, VHA National Data Services (NDS) authorizes research access to patient data. New research projects are granted access to snapshots of data that can be updated as needed. In addition to data storage, VINCI includes a cluster of servers set aside for tasks like analysis, data processing, and information extraction from text. This means VA researchers will have access to the data and applications they need to select, transform, and analyze patient data in a central, secure location accessible from the VA intranet. Data are maintained on the VINCI servers behind the VA firewall.

Use of VINCI is governed by the following practices:

- Data will be accessed by authorized members of the research team via a secured remote computing environment using TLS 1.0 to encrypt the connection between the RDP client and the TS Gateway server. The remote computing environment will enable data analysis to be done directly on CDW-VINCI servers located at the Austin Information Technology Center. The transferred data will not be transmitted to local PC hard drives by any of the participating investigators.
- Data will be retained and destroyed according to VA and VHA policy.
- Database and file monitoring tools and reports will be generated to monitor database and file systems access and use.

(2) Outpatient Mental Health Clinic, Tampa, FL. The off-site mental health service facility at James A. Haley Veterans' Hospital provides consultation, evaluation and treatment for a variety of issues impacting emotional well-being. Staff psychologist Dr. Jennifer Murphy (Co-I), is a research team member and employee of the mental health clinic. Dr. Murphy will act as the primary mental health consultant for any mental health queries that study members may have.

(3) Polytrauma Rehabilitation Center, Tampa, FL. Under the leadership of Dr. Steven Scott (research team Co-Investigator), Tampa has the largest of five designated Polytrauma Rehabilitation Centers in the VHA. The program includes a Polytrauma Network Service, a mild TBI program, a Disorders of Consciousness Program, and a 10-bed transitional living unit. The Tampa VA is one of four VAMCs in the collaborative Defense and Veterans Brain Injury Center (DVBIC), designed to ensure that all military and Veterans receive TBI specific evaluation, treatment, and follow-up, while collecting standardized patient outcome data to compare the relative efficacy of various treatment and rehabilitation strategies. Tampa also participates in the VA/TBI Model Systems collaborative and collects comparable data on Veterans. Researchers at the Tampa R&DS and the clinical staff at the Tampa Polytrauma Rehabilitation Centers (PRCs) have a 10-year history of strong collaboration as evidenced by joint publications and co-investigator status on HSR&D and RR&D-funded studies. Polytrauma Rehabilitation System of Care provides specialized rehabilitation for Veterans and Service Members with polytrauma and TBI to restore multiple skills and facilitates the transfer of those skills from the hospital setting to daily life. VA's PRCs provide the most intensive, specialized and comprehensive rehabilitation care for Veterans and Service members with complex and severe polytrauma. Polytrauma injuries involve more than one physical region or organ system, one of which may be life threatening, and which results in physical, cognitive, psychological, or psychosocial impairments and functional disability. The PRCs embrace an interdisciplinary team approach to plan and administer an individually tailored rehabilitation plan to help the patient recover to the fullest extent possible. Each PRC is accredited by the Commission on Accreditation of Rehabilitation Facilities and serves as a resource to develop educational programs and best practice models for other facilities across the system.

Probable Duration of the Project

The projected study period to complete this research is four years. The anticipated start date will occur by November 1, 2018. The PI and study team will conduct a continuing review for approval annually and comply with required reporting based on risk associated with the study. See Table 3 for the GANTT study timeline.

Privacy and Information Security Information

1. Risk to Subjects

A) Human Subjects Involvement and Characteristics

In Aims 1-2 we estimate a recruitment sample size of 600 dyads, with approximately 33% over-sampling for attrition. We will recruit a sample of up to 200 Veteran/partner dyads (total 600 dyads) at each of the three sites to allow even numbers of dyads to be assigned to treatment and control arms. We will use a four-step process to purposively recruit study participants (see Figure 2). First, using a standard IRB approved procedure with a waiver of consent; a secondary administrative data query of the ICD9/10 conditions for chronic pain and PTSD will identify a sample pool of Veterans in the previous fiscal year. Cross-examination of the pain and PTSD cohorts for FY 2015 indicate a sample of 5,508 in Tampa who will be potential participants [Source: VSSC, Diagnosis Pyramid Analytics Report: Accessed 04/27/2017]. With our access levels and expertise, this process should take two weeks. Second, we will recruit from providers using signed letters from the PI. The provider will give the recruitment letter to the patient for him/her to follow up with the study team member to inquire about participating in the study. Study team members will mail the same recruitment letters to cohorts who have been identified in step one of the recruitment process to reduce burden of clinical partners and to reach those Veterans who don't often attend VA medical appointments. This helps provide an effective way to reach out to those Veterans with this type of diagnoses who are less likely or don't regularly receive care intervention. Potential participants who contact study staff after receiving a recruitment letter will be presented with information about the study to help them determine whether they'd like to participate in the study and provide a verbal consent and HIPPA authorization. Potential participants who have not responded to the letter may be contacted by their healthcare team for a follow-up. This procedure has been approved in other studies and provides an effective way to reach out to those Veterans with this type of diagnoses who are less likely or don't regularly receive care intervention. Based on our previous projects the process from initial sampling to recruitment and randomization should conservatively take three months.

Screening interviews will be conducted to assess the occurrence of chronic pain and PTSD; assess if they have visual, hearing, or other cognitive impairments; and determine availability of a partner and the dyad's interest in participation. Fourth, eligibility will be confirmed through review of all questions from the screening interview and use of CPRS if needed for further confirmation. The initial secondary administrative data query of the ICD9/10 conditions will be conducted to: (1) confirm comorbid conditions (chronic pain and PTSD), [Veteran is considered to have chronic pain if he or she has documented chronic pain and/or treatment listed. Veteran is considered to have chronic musculoskeletal pain if he or she meeting either of two validated criteria: (1) Having 2+ occurrences of any of targeted musculoskeletal ICD-9-CM codes "likely to represent chronic pain" identified by Tian et.al63 recorded at visits separated by at least 30 days within past six months; or (2) Having high impact chronic pain = 2+ occurrences of targeted musculoskeletal ICD-9-CM codes (adapted from Goulet et al.19) separated by at least 30 days within the past six months previous to study recruitment and two or more pain scores greater than or equal to 4 separated by at least 30 days within past six months.63 For pain scores, we will use the 0-10 numeric pain rating scale that is routinely collected at the VA. We will count two ICD-9-CM codes or pain scores recorded on the same day as one code/score. Veteran is considered to have previous history of PTSD if he or she has a flag in his/her record indicating confirmed condition by the VA Compensation and Benefits

program, has at least two outpatient visits in the year with the primary diagnosis being listed as PTSD (ICD-9-CM code 309.81) and/or has PTSD listed on the problem list]. After screening, eligible Veterans will be invited to participate and receive information necessary to access the data collection site and determine their group assignment.

Though we have developed a strong recruitment plan that has worked effectively in past studies, in the event we experience recruitment issues identifying eligible participants we will rely on our strong team of collaborators to support recruitment efforts. We will also gain IRB approval to collaborate with the Tampa R&DS Veteran Engagement Council to recruit Veteran participants using other recruitment means such as referrals and advertisements (e.g. poster, brochures, flyers). We will also distribute flyers and brochures in approved VA designated areas of the hospital, outpatient PCA clinic and local Veteran service organizations. Additionally, due to the strong research interest in PTSD populations, we are working with the Tampa VA Physical Medicine and Rehabilitation research committee to support successful recruitment while accounting for dual enrollment in other studies. JAHVAH will not be the data coordinating center.

In Aim 3 we will select a sub-sample of 84 individuals from the intervention arm (approximately 28 individuals per site) to complete a single telephone interview to collect qualitative data about their perceived value of MR and recommendations.

Study Inclusion and Exclusion Criteria. Inclusion criteria will be: Participants must be adults, 18 years of age or older, and English-speaking Veterans with chronic musculoskeletal pain. Veteran is considered to have chronic musculoskeletal pain if he or she meeting either of two validated criteria: (1) Having 2+ occurrences of any of targeted musculoskeletal ICD-9-CM codes "likely to represent chronic pain" identified by Tian et.al recorded at visits separated by at least 30 days within past six months; or (2) Having high impact chronic pain = 2+ occurrences of targeted musculoskeletal ICD-9-CM codes (adapted from Goulet et al.) separated by at least 30 days within the past six months previous to study recruitment and two or more pain scores greater than or equal to 4 separated by at least 30 days within past six months. For pain scores, we will use the 0-10 numeric pain rating scale that is routinely collected at the VA. We will count two ICD- 9-CM codes or pain scores recorded on the same day as one code/score. Presence of chronic pain for 6-months in the past year will be confirmed in the screening interview and use of CPRS if needed.

Veteran is considered to have a history of PTSD if he or she has a flag in his/her record indicating confirmed condition by the VA Compensation and Benefits program, has at least two outpatient visits in the year with the primary diagnosis being listed as PTSD (ICD-9-CM code 309.81) and/or had PTSD listed on the problem list], Veteran must also have PTSD (defined by PTSD diagnosis-ICD-9-CM 309.81). Presence of diagnosis, treatment, or symptoms of PTSD in the past 6-months will be confirmed in the screening interview and use of CPRS if needed.

All participants must have, the ability to access and use an electronic platform (e.g. Mobile device, internet, DVD) for MR delivery, with a willing partner to also participate in the

study and MR program. Exclusion criteria will be: Moderate to severe TBI, diagnosis or treatment for psychosis in previous 6 months, currently in formal substance use disorder treatment program, non-English speaking; visual, hearing, cognitive impairment that prevent participation or ability to consent, and/or lack of access to internet service. These individuals will be excluded due to medical, language, and technology access issues that would prevent safe and full study participation. Potential participants who screen for aggression or violence will also be excluded from study.

B) Sources of Materials

We will not collect any specimens or biological samples. We will collect data during assessments at baseline and follow-up. Data will be collected for research purposes and stored, per VA protocol, behind the VA firewall and on the secure VA server as data is entered. Data collection for this project will include: (1) self-report survey assessment data; and (2) telephone interview data.

For Aims 1 & 2, Self-report survey assessment data and weekly reports will be collected using Qualtrics, a secure electronic survey data collection service. Weekly reports about MR use and pain and stress outcomes will be collected weekly for the first eight weeks. Full assessment data measures will be compiled into a single survey format and collected at baseline, 1, 2, and 4 months.

For Aim 3 we will audio-record telephone interviews with Veterans and their partners to identify their views on the value of MR and possible recommendations for implementation in the VA system.

C) Potential Risks

The potential risks for participating in this study are minimal. No pharmacological therapies are used in this study. This study will be approved for adherence to Human Subjects Protection by the Institutional Review Board and R&D committees at both study sites. Subjects will be issued a coded identifier, which will be known only to the PI, project manager, and data manager; all records and the informed consent documents will be retained in locked files in the PI's or project manager's office. All computer data will be encrypted to protect patient confidentiality. HIPAA regulations will be strictly adhered to. Data will be secure on a networked computer system behind VA firewalls, and access will be restricted and password protected.

Participants will be assured that their participation is voluntary and they can choose not to answer any question. Participants will also be assured that they can choose not to participate in the study at any time. There is an intervention being offered in this study; there are no alternative options available for participants beyond standard of care treatment. The proposed study poses minimal risk to participants. As this intervention is palliative in nature with non-intrusive data collection, this is a minimal risk study. There is a risk that some patient participants may:

1. Feel uncomfortable reporting about their comorbid condition symptoms, specifically their PTSD;
2. Emotional and/or physical discomfort as a result of engaging in the MR activities
3. Experience agitation/distress during the intervention and/or data collection.

Unauthorized access to data is also a risk in all research studies. Based on our prior research, we believe that it is unlikely that these adverse events will occur, however we will implement several protective strategies to protect participants and their data. Should any behavioral or relationship issues arise during treatment, participants will have information to contact their providers and the research team for support. The research team will follow up directly with the Veterans' identified provider (at onset of participation) to ensure the Veteran has mental health support. All unanticipated incidents will be documented and reported in alignment with VA and Institutional Review Board regulations.

2. Adequacy of Protection from Risk

All study staff are up-to-date with VA Privacy and Information Security and Rules of Behavior training.

A) Recruitment and Informed Consent and HIPAA Authorization:

Prior to recruitment, we will obtain IRB and VA R&D Scientific Review Committee approval to conduct this proposed research.

Recruitment. We will obtain a HIPAA authorization waiver for recruitment purposes. Identified patients will be sent a letter via mail or from their provider on behalf of the PI explaining the study and asking if patients would be willing to participate in the study. Veteran will contact the study team member by telephone and at that time team member can gauge Veterans willingness and appropriateness to participate. This recruitment method has been successfully used in previous studies conducted by this team and other R&DS projects. Recognizing the potential limitation of this strategy given the inclusion/exclusion criteria we will also gain IRB approval to collaborate with the Tampa R&DS Veteran Engagement Council and co-investigators to recruit Veteran participants using other recruitment means such as referrals and advertisements (e.g. poster, brochures, flyers). As described under Sampling on page 23 of these potential participants who contact study staff or who are contacted by study staff will be presented with information about the study to help them determine whether they'd like to participate in the study and give verbal consent and HIPPA authorization. If we do not get an adequate recruitment response, we will implement the snowball recruitment technique that involves asking participants to inform and encourage friends, colleagues, and other peers to participate.

Informed Consent. A waiver of informed consent process for recruitment purposes (medical record review), and a waiver of consent for a Verbal Consent Document for

participant phone screening will occur. Please note, the study team will also be utilizing a Written Consent Document or verbal consent via telephone. Participants will have an option to complete the informed consent and HIPAA authorization for study, in person or over-the-telephone. During recruitment contact and calls, research team members will review the consent and HIPAA content with participants, to ensure review and comprehension. Since both partners will be full and equal participants in the study, both will be individually screened and consented by individual interview.

We will employ three self-report items to address physical threat to and by partner, and fear reprisal. We will use a standard protocol advised and utilized in VA Family Services in its couples/family therapy: (1) Initial brief – individual consent/self-report; (2) Identify urgent need; (3) provide follow up call, and referral for community resources; (4) exclude from study. When participants go to the study site to join the study, they will be provided an option to print a copy of their informed consent and HIPAA authorization for review to ensure their understanding. Communication, such as informed consent explanations, will be supplemented using telephone to provide respondents opportunities for questions and clarification as needed. This is an effective means of communication for studies evaluating electronic health services such as Mission Reconnect. These remote methods of communication and consent have been effectively used in other studies conducted by the PI. These forms of communication: (1) reduce participant burden; (2) conserve resources; and (3) leverage electronic communication devices which support and promote virtual care.

PTSD Specific Training and Protocol. This study sample is inclusive of Veterans with PTSD, a chronic mental health condition that can put Veterans at risk. As such, at the onset of funding the study team members will receive a formal training session on the risks and outcomes associated with PTSD as well as an in-depth review of the protocol to address the specific needs of Veterans with PTSD and steps to take to be responsive to the behavioral health needs that may arise for Veterans during their study participation. As appropriate, team members will be provided with the action plan to respond to Veterans behavioral health needs in the unlikely event that a participant and/or partner becomes agitated or distressed during the intervention or data collection process. In this case, team members will be directed to contact and inform the project manager, site PI (if in Ann Arbor or Puget Sound) and study PI immediately. They will also be instructed to provide each participant with: (1) the contact information of the participant's provider (collected at onset of study participation for referral as appropriate (i.e., mental health), if indicated; (2) the PI's contact information; and (3) the national crisis hotline number for Veterans. The project manager and or PI/site PI will also follow up personally with the participant to address resolution of the incident. The participant may be formally excluded from further participation to ensure the individual's safety.

Data Collection. Care will be taken to ensure that sufficient backup procedures are in place. To assure intact data files, we will copy the raw data file into a data file for computation and analysis so that if there are computational errors or computer problems, the raw data will remain unchanged. All hard copies of data documents will be kept in a locked file cabinet in the project manager's office that is kept locked when unoccupied. VA

Policy regarding retention of research records will be stored for6 years once the study is completely closed at R&DC and all subcommittees, in accordance with VHA's Records Control Schedule (RCS10-1), applicable FDA and DHHS regulations, or as described in VHA Handbook 1200.5, section 7.j. At the end of the retention period, the hard copy and electronic source data records will be destroyed in accordance with VA Policy. All identifiable computer data will be encrypted to protect patient confidentiality. VA and other Federal privacy, confidentiality and HIPAA regulations will be strictly adhered to. Electronic data will be secured on a networked computer system behind two firewalls, and access to data folders will be password protected and restricted to study personnel who have a need. Self-report survey data will be collected using Qualtrics, a secure electronic survey data collection service. Qualtrics has been successfully used to remotely collect Veteran data in other studies conducted by R&DS. Telephone interview data will be audio recorded with participant's permission. We will ask them to avoid using their names, others' names, and personally identifying information, however, if they divulge such information, we will scrub the transcribed files of personally identifying or sensitive information before data analysis

Data Storage. Original informed consent forms will be stored at the study site and kept in a locked file cabinet in site PI or project manager's office at all times. Electronic survey, audio recordings and electronic files (e.g., assessment data, notes, transcripts, data analyses) will be stored on the secure server behind a VA firewall.

B) Protection Against Risk

Interviews.

In **Aims 3**, interview recordings will be collected on a VA-approved encrypted recorder with a telephone interview adaptive device. These recordings will be downloaded and stored on a secure network server at the R&DS behind the VA firewall. Once the data quality is verified, files on the recorders will be erased. Recorded documents will be remotely retrieved, transcribed and returned for analysis by the Salt Lake City Transcription Center in accordance with IRB regulations. Qualitative data will be transcribed at the Salt Lake City Transcription Center under the supervision of Dr. Zickmund. Lastly, participants will be instructed that they may refuse to answer any question that they are uncomfortable answering. In addition, participants may withdraw from the study at any time without any repercussions to their healthcare.

Interview Field Notes.
In **Aims 1-3**, handwritten interview notes will be transcribed and electronic files will be handled in the same way described for interview transcripts. Electronically recorded field notes will be saved in an encrypted file (either on a VA issued laptop or thumb drive), transported to the R&DS, and entered and uploaded as soon as possible to the secure VA server. Once verified, the original file will be deleted. We anticipate these efforts will provide adequate protection against risk.

Data Storage Location.

In **Aims 1-3**, Original informed consent forms will be stored at the local sites and kept in a locked file cabinet at the R&DS in the project manager's office at all times. Audio recordings and electronic files (e.g., notes, transcripts, survey data, data analyses) will be stored in secure folders on the secure server behind a VA firewall. We anticipate these efforts will provide adequate protection against risk. All paper forms with PII will be stored with R&DS staff at 8900 Grand Oak Way, Tampa, FL 33647, in Room 196.

Audio Recordings and Transcription. Approved Tampa R&DS staff or approved VA staff from the VA HSR&D Centralized Transcription Services Program will transcribe the audio files. Transcription staff will be given access to a sub-folder within study's secure project folder. The transcriptionist will transcribe each interview and save the completed transcript in the sub-folder using the same de-identified code. The audio files and completed transcripts will be maintained and saved behind the VA firewall in the study secure shared project folders. No data will leave the R&DS secured research server.

Secure Messaging Secondary, Interview, and Survey/Evaluation Form Data.

In **Aims 1-3**, care will be taken to ensure that sufficient backup procedures are in place. To assure intact data files, we will copy the raw data file into a data file for computation and analysis to safeguard raw data against computational errors or computer problems. All hard copies of data documents will be kept in a locked file cabinet in the PI's office, which is kept locked office when unoccupied. Retention of research records will be in accordance with VHA's Records Control Schedule (RCS10-1), applicable FDA and DHHS regulations, or as described in VHA Handbook 1200.5, section 7.j. At the end of the retention period, the hard copy and electronic source data records will be destroyed in accordance with VA policy. All identifiable computer data will be encrypted to protect participant confidentiality. We will strictly adhere to VA and other federal privacy, confidentiality, and HIPAA regulations. Electronic data will be secured on a networked computer system behind two firewalls, and access to data folders will be password protected and restricted to study personnel who have a need to review these data. We anticipate these efforts will provide adequate protection against risk.

In **Aims 1 and 2**, survey data will be collected using Qualtrics, a resource that has demonstrated capacity for remotely and securely collecting participant data in other studies conducted within the VA system. Qualtrics is a secure platform for the creation and distribution of online surveys and recording of response data, including quality control features such as range checks, skip patterns, and completeness of data entry. Qualtrics ensures protection and reliability of client data with high quality firewall systems, regular vulnerability scans, nightly complete backups, and annual complete penetration tests. Qualtrics services will allow control of individual permissions for accounts and surveys. Qualtrics accounts are password protected, and all data are replicated in real-time.

3) Potential Benefits of Research to Subjects and Others

Participants may receive direct benefit for participating in this study as a result of engaging in the proposed intervention. Participants randomized to the control group who receive access to MR after they complete data collection, may also receive benefit from engaging in the proposed intervention. Additionally, this research may benefit the Veteran population and their partners in the future if the intervention is found to be effective and subsequently disseminated to Veterans and their partners throughout the VA system. Potential benefits are those anticipated by the completion and dissemination of our research efforts to support Veterans-centered, patient-driven care through the use of CIH.

Compensation
Compensation to participants include reimbursement for their time: Consistent with other funded HSR&D studies, each participant will receive $5 for providing weekly MR reports on utilization and pain ratings for the first 8 weeks of their participation in the study (total, $40). As an incentive to complete the study each participant will also receive $20 each time they provide assessment data at each time point (4) for a 4-month period (total, $80). Individuals participating in the telephone interview will receive an additional $20. Participants will not be paid for surveys that are not completed by the study end period (up to 4 months). These four time-points were selected to collect baseline for comparison, weekly to examine immediate effects, at 2-months to examine post intervention effects, and at 4-months to examine sustained intervention effects. The total possible incentive for participants is up to $140.

4) Importance of Knowledge to be Gained
Advancing the science of implementing complementary and integrative health services into the VA system of care for Veterans and their partners is an important aspect of providing Veteran-centered care. VHA recognizes the need to develop a holistic approach to create a patient-centered experience for Veterans with comorbid conditions such as chronic pain and PTSD. This data will support the development of a Veteran-centric self-management intervention for Veterans and their partners (e.g. spouse, life partner) within the VA system of care.

5) Data and Safety Monitoring Plan
Risk of harm from this study is less than minimal risk. The principal investigator will be responsible for monitoring the safety and efficacy of the study, executing the data and safety monitoring plan and complying with the reporting requirements. The PI and project manager will provide a summary as part of the grant's progress report. The report will include participant's socio-demographic characteristics, expected versus actual recruitment rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events, and any actions or changes with respect to the protocol. The research team will be trained in protecting the safety of the study participants and the scientific credibility of the project. We will also work with VA clinical psychologists, and Chief of PM&R Steven Scott, DO, to ensure our protocol is appropriate for Veterans with comorbid chronic pain and PTSD, as well as other conditions participants might have including substance abuse disorders and TBI. The team will coordinate to respond to any individual needs participants and their partners may present throughout the study.

The team will meet regularly to plan and report on the selection, recruitment and retention of participants, their management, and the procedures for data management and quality control. The PI and team will monitor success of recruitment, assess data integrity, and monitor for adverse events. In the occurrence of adverse events, the team will report to local R&D and IRB within the regulated timeframe. Risks to study participants relate mostly to misinterpretation of what is research and loss of confidentiality. Appropriate measures will be taken to protect participants and their data. All aspects of data collection and data storage will be carefully monitored to ensure rapid detection of errors, inconsistencies or other problems. Study personnel involved in data collection will follow a strict written protocol that describes study measures for protecting data privacy, clearly explains to study participants that they have the right to refuse to participate or refuse to answer any individual question that they wish to not answer and emphasizes reporting as accurately and truthfully as possible. The principal investigator and co-investigators are experienced in training study staff in handling sensitive and confidential data, and in the storage and processing of such data.

Entity conducting monitoring of the study: The Institutional Review Board (IRB) and Tampa, Ann Arbor and Puget Sound R&D committees will review the protocol and procedures for the proposed study prior to implementation. The IRB, Tampa, Ann Arbor and Puget Sound R&D committees and the principal investigator will continue to monitor the project. All changes to the study protocol and procedures will be submitted to the IRB and Tampa, Ann Arbor and Puget Sound R&D committees for approval prior to implementation.

What is monitored: The following aspects of the study and study conduct are monitored: all procedures to ensure conformity with the approved study protocol; unforeseen circumstance that might arise and affect participant safety; all reports of serious adverse events (SAE) as defined in 38 CFR 46 (death, new or prolonged hospitalization, persistent or significant disability or incapacity; congenital anomaly or birth defect); other significant adverse events that lead to participant dropout, participant termination by the principal investigators, or termination of participation in the project activities within the VAMC clinics.

Adverse or Serious adverse events: Any adverse event (AE) that: (1) results in illness or death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) results in inpatient hospitalization or prolongation of existing hospitalization; (4) results in a persistent or significant disability/incapacity; (5) results in a congenital anomaly/birth defect; or (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.
Since the study is utilizing a non-invasive palliative intervention and social-behavioral methods including surveys and telephone interviews, it is unlikely that recruiting participants in the described activities will cause an "adverse event" among the study population. However, it is possible that a Veteran participant and/or partner will become agitated or experience an adverse emotional/psychological response during the intervention and/or the data reporting process. In the event of an adverse event the project

manager and PI will follow regulated protocol. Then they will follow procedure to report the adverse event to the IRB. In anticipation of the unlikely event that a participant and/or partner might become agitated or distressed during the intervention or data collection period, each participant will be provided: (1) the PI's contact information; and (2) the national crisis hotline number for Veterans. The contact information of the Veteran's provider will be collected at onset of study participation for referral as appropriate (i.e., mental health), if indicated.

The participant may be formally excluded from further participation to ensure the individual's safety.

We are including an established process for responding to adverse events of suicide ideation. We provide resources for suicide ideation in all of the surveys that the participants take. Furthermore, when the participant responds affirmatively to the suicide ideation question in the online survey, they are immediately prompted to seek professional help through the VA crisis hotline. The VA crisis hotline provides 24 hour, 7 days a week free and confidential assistance with adverse events.

Additionally, a designated team member will contact the participant's current mental health provider, or, in the case they do not have a mental health provider, their primary care provider in a timely manner to report the incident and request immediate follow-up. The use of a local clinical psychologist will be unfeasible for this nation-wide participant population. Also, the decision to utilize the mental health or primary care provider that the Veteran has an established relationship with is ethical and Veteran-centric.

After participant's provider is notified, a designated study team member will follow up with the provider to ensure communication has occurred. In the case of participants who recurrently experience adverse events (e.g., responding to survey question with suicidal ideation if they 'had a chance') during the data collection period, study team members will continue to notify participant's provider until agreed upon by all parties (i.e., participant, provider, study team member) to desist on notifications.

If the participant does not have a designated mental health provider or primary care provider, we will escalate the issue to the local VA office's Suicide Prevention Team.

We have added language to the verbal informed consent, and also in the copy of the consent that is mailed to the study participants, that in the case of an AE or SAE, confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

Reporting: It is unlikely that any of the study procedures will cause an AE or SAE. Should an AE or SAE occur, study staff is trained to immediately report AEs connected to implementation of the study to the project manager, and Drs. Haun (PI), Alexander (Site PI), and Hebert (Site PI). They will also be escalated, in the case of suicide ideation, to the mental health provider or primary health care provider. The study project manager will keep a log of AEs and SAEs. In the event of an SAE, we will file a report with VA Tampa R&D

and the IRB. As part of this process the IRB will determine if the event is directly related to project procedures, so that It can be determined if project procedures should be modified. Information about all AEs and SAEs will be provided in annual progress reports.

6) Inclusion of Women, Minorities, and/or Children

The proposed study involves a population of: (1) Veteran patients receiving services at the Tampa VA for chronic pain and PTSD; and (2) Veteran participants' selected partners (e.g. spouse, life partner).

Women and minorities recruitment numbers will mirror site distribution based on sex and race, as this study is not powered to look at race/sex issues; however, we anticipate greater racial variability due to having three geographically diverse sites. We also anticipate increased recruitment of females with our focused efforts to recruit within the women's health centers in partnership with Dr. Paykel at the Tampa site.

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Updated Statistical Analysis Plan

Under Aim 1, data for PRO (Patient Reported Outcomes) will be collected at Baseline, Weeks 1, 2, 3, 4, 5, 6, 7, 8, and 16. Pain, Stress, and Tension will be collected as a single-item scale measures, alongside intervention utilization, intervention satisfaction, and waitlist control pain/PTSD symptom mitigation activities weekly. All other PROs will be collected at Weeks 4 (Month 1), 8 (Month 2), and 16 (Month 4) (*see Table 1: Veteran and Partner Measures and Psychometric Properties in Protocol for further details*). General linear mixed models will be used with main effects terms for GROUP (MR vs. waitlist-control), TIME (continuous time measure from days from activation in protocol) and a GROUP x TIME interaction term (for rate of change).

Different correlation structures and functional forms of the effects of the MR program will be assessed using the information criteria and a final parsimonious model will be determined for final statistical inference. For H1.1, the primary outcome measure for pain will be the total score on the 19-item POQ, and its subscales. Additional analyses will be performed on the DVPRS, and the weekly 5-point Likert-scale Pain item. For H1.2, the primary outcome measure for PTSD will be total score on the 20-item PCL-5. For H1.2, the outcome measure for psychological symptoms is PSS; the outcome measure of sleep is PSQI; and the outcome measure for QOL is the SF12 and BDI. For H2.1, the outcome measure for relationship satisfaction is the RDAS. Additional analyses will be performed on the COS and CSS measures, the weekly 5-point Likert-scale Stress item, and the weekly 5-point Likert-scale Tension item.

Qualitative data analysis followed Inductive and deductive coding methods. A qualitative code book, consisting of known constructs from the literature and those that emerged inductively from the data, was created. Two trained qualitative researchers coded the data using the qualitative analysis software program, ATLAS.ti v. 22. To establish intercoder reliability at 80%, two qualitative researchers coded 20% of the interviews (initially every 5th transcript then randomly to ensure coding consistency) separately then compared codes to determine percent of agreement. Coded text in ATLAS.ti v. 22 was exported and further analyzed in Excel spreadsheets to develop themes. To enhance credibility, initial findings were presented during quarterly stakeholder meetings to provide input and facilitate refinement of findings.

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

Hello: My name is_____.

I am a study team member for the research study called: "Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD"?

[Proceed to read consent]

Overview of the Study**:** Researchers at the James A. Haley Veterans Hospital study many topics. We are asking you to take part in "Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD", IRB Study #Pro00035440

Study Staff: This study is being led by Dr. Jolie Haun, Co-Core Director for Implementation & Dissemination, Health Services Research and Development Service, Research & Development Service (R&DS) at the James A. Haley Veterans Hospital (JAHVH), Tampa, FL. This person is called the Principal Investigator or PI. Other approved research staff may act on behalf of the PI.

Study Details: This study is being conducted at JAHVH-Tampa R&DS and is supported by Rehabilitation Research and Development. This project is responsive to Rehabilitation and Research and Development current special areas of interest for non-pharmacological activity based interventions for chronic pain impacting pain reduction, function and quality of life. This project aligns with the VA mandate for complementary and integrative health (CIH) care for Veterans and their families. CIH complements traditional care for Veterans managing chronic conditions, such as chronic pain and PTSD. Mission Reconnect (MR) is a user-driven, dyadic, CIH self-care management program delivered remotely that teaches techniques the Veteran and family-partner can use to reduce pain, anxiety and stress, promote well-being and improve relationship quality. The research goal is to evaluate MR as an approach to manage chronic pain and PTSD symptoms, for potential subsequent implementation. This study will possibly provide a model for establishing remote access and sustainable implementation of CIH within VA.

Inclusion criteria : You must an adult, 18 years or older. English-speaking Veterans with chronic musculoskeletal pain. Musculoskeletal pain is present if the Veteran meets either of two validated criteria (1) two or more occurrences of any of targeted musculoskeletal diagnoses recorded at visits separated by at least 30 days within past six months; or (2) high impact chronic pain (two or more occurrences of targeted musculoskeletal diagnoses separated by at least 30 days within the past six months previous to study recruitment and two or more pain scores (greater than or equal to 4 separated by at least 30 days within past six months).

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

Exclusion criteria : Moderate to severe TBI, diagnosis or documented treatment for psychosis in previous 6 months, currently in substance use disorder treatment, non-English speaking; visual, hearing, cognitive impairment that prevent participation or ability to consent, and/or lack of access to internet service. These individuals will be excluded due to medical, language, and technology access issues that would prevent safe and full study participation. Pain and PTSD treatment will not be factored as an inclusion/exclusion criterion but will be evaluated as covariates. Potential participants who screen for aggression or violence will also be excluded from study.

Participants: You are being asked to take part because you are a patient at JAHVH. You will receive a copy of the full consent form.

You will be asked to spend several approximately 4 months in the study. The study will last that length of time because we want to 1) Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological symptoms (depression, stress, anxiety), and global health (quality of life), 2) Determine MR effectiveness for social (relationship satisfaction, compassion for self/others) outcomes among Veterans and their partners, (ie. spouse, significant other, caregiver, friend or family member) 3) Describe Veteran and partner perceived value of MR in a sub-sample of participants. As a study participant you may be asked to participate in the following activities. You will not necessarily participate in every activity.

Treatment Group: The treatment group will be asked to review all MR content. The MR program provides video and audio instruction in a set of 11 evidence-based wellness activities in three thematic categories: Connecting with Yourself, Connecting with Quiet, and Connecting with Your Partner. All instruction is accessible via the program website (MissionReconnect.com) and mobile device apps. Video content totals 91 minutes and was produced by filming two days of workshops to teach the practices to Veteran/partner dyads. The Program Overview video (54 min.) introduces the MR instructional sequences accompanied by commentary by workshop participants. Detailed massage instruction is presented in the separate Massage Instruction video (34 min.) and Massage Video Supplement (3 min.) addressing use with home furniture. Users are encouraged to give and receive at least one massage per week. Audio content totals 67 minutes and was recorded in studio, with nine instructional audios ranging from one to 22 minutes. Treatment group participants will be instructed to seek advice about treatment from your provider. There will be no attempt by study personnel to contact your provider unless an issue (i.e., suicidal ideation) arises. Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

Usual Care Waitlist Control Arm: Study subjects in the control arm will participate in all assessments like those in the treatment group, however, will be asked to agree to not access the public web site during their participation. Wait-list control participants will be instructed to seek advice about treatment from your provider. There will be no attempt by study personnel to contact your provider unless an issue (e.g., suicidal ideation) arises. Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

the study participant and others. The control condition will account for potential temporal effects that occur from passage of time (brief), and expectation effects associated with anticipation of MR participation. The control group will receive access to MR after completion of data collection.

Data will be collected using (1) self-report surveys; and (2) telephone interviews.

(1) Self-reported survey data will be collected using online surveys. Participants will receive email messages with a link to prompt participants to access the MR website and complete data collection. The survey should take no longer than 30 minutes. Study measures will be compiled into a single survey format and collected at baseline, 1, 2, and 4 months. Survey data will be kept confidential and stored in a secured network for study personnel for the duration of the study.

(2) Telephone interviews will be conducted with only treatment group members. If selected for a phone interview, you may be contacted at a later date after the initiation of the study to participate in the interview. The interview will last no longer than 30 minutes. Interviewers will request respondents' attitudes, opinions, and reports about their preferences and the pros and cons of MR and/or participating in the practice groups, including their perceptions of usefulness. The interviews will be audio recorded with the participant permission on a VA approved digital recorder and will be kept confidential and stored in a secured network for study personnel for the duration of the study. An audio voice consent will be completed and verbal permission at the time of the telephone interview process.

About 400 people will take part in this study at JAHVH.

Participants will receive $5 for providing weekly MR reports on utilization and pain ratings for the first 8 weeks of their participation in the study; a total of $40. Participants will receive $20 each time you provide assessment data over a 4-month period (4 time points); a total of $80. Each treatment group member participating in the telephone interview will receive an additional $20. The total possible incentive for participants is up to $140. To be paid for your participation in the study, you will need to complete Form 1099 which will be provided to you. Please be aware for all surveys not completed by the study end period WILL NOT receive payment.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will be compensated for your participation in the study. This research is considered minimal risk. Minimum risk means that study risks are the same as the risks you face in daily life. Subject participation involves completing interviews over the telephone or in person with no invasive procedures. Although unlikely, protocol will be followed if there is an adverse event. The project manager will report the adverse event to the PI and the event will subsequently be reported to the Institutional Review Board (IRB). If the

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

participant becomes agitated, the research assistant will ask if the participant would like to stop the interview and the assistant will discuss this immediately with the PI to determine if any further action is indicated. The most likely adverse event to occur would be unauthorized access to data.

Participants in the audio-recorded telephone conversations will not be identified by name. The participants will be told in advance of their participation that you may decline to participate at any time.

Again, there are no known risks to those who take part in this study. If you have any study-related problems, please call the PI at 813-558-7622. Throughout the study, the researchers may notify you (via telephone or in person at a scheduled visit) of any new information that may become available and which might affect your decision to remain in the study.

If a participant is deemed at high risk for harm/suicide; the study personnel will do the following:

- Stay with patient until you can be referred to appropriate medical staff member.

- If the patient is an outpatient, this will involve taking the patient to the Emergency Room for evaluation.

- If the patient is an inpatient, this will involve calling the patient's primary treatment team and/or escorting the patient to such providers.

All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been referred to the appropriate staff, the PI will be alerted.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. While we are doing this research, we cannot let you see or copy the research information we have about you. After the research is done, you have a right to see and copy the information about you, as allowed by JAHVH policies.

Confidentiality of data collected by audio recordings, online surveys, and other communication with study participants will be maintained, unless an issue arises that poses a risk to the health or well-being of the study participant or others (e.g., suicidal ideation). Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on

how we protect your information. If you do not have a copy or would like a copy of the Notice, the research team will provide one to you.

Breach of data confidentiality will be minimized by maintaining research records in accordance with VHA's Records Control Schedule (RCS10-1), applicable FDA and DHHS regulations, or as described in VHA Handbook 1200.5, section 7.j. We will strictly adhere to VA and other federal privacy, confidentiality, and HIPAA regulations.

We must keep your study records as confidential as possible. We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are. However, certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the PI, and all other research staff.
- Certain government and university persons who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- The University of South Florida IRB and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
- The Department of Health and Human Services
- RR&D

It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet.

Interviews will be audio recorded using Veterans Health Administration approved equipment. Recordings will be stored on VHA computers behind password protected firewalls in secure password protected folders. Data will be stored for the duration of the study and in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA (PI and/or the VA research team members to access and use your past or present health information in addition to new health

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you agree with this authorization. Your individually identifiable health information used for this VA study includes the information below:

- Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings
- Demographic Information such as name, age, race
- Questionnaire, Survey, and/or Subject Diary

USE OF YOUR DATA FOR OTHER RESEARCH:

- Not Applicable - No Data or Specimen Banking for Other Research

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

- Non-VA Institutional Review Board (IRB): USF
- Study Sponsor/Funding Source: RR&D
- Compliance and Safety Monitors: Research Compliance Officer
- Other Federal agencies required to monitor or oversee research : The Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Research and Development Committee, may look at any portion of your record.

Access to your Individually Identifiable Health Information created or obtained in the course of this research. You will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study PI.

CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Verbal Consent Script for Informed Consent-Veteran

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

CONSENT FOR PRODUCTION AND USE OF VERBAL OR WRITTEN STATEMENTS, PHOTOGRAPHS, DIGITAL IMAGES, AND/OR VIDEO OR AUDIO RECORDINGS BY VA

NOTE: The execution of this verbal consent does not authorize production or use of materials except as specified below. The specified material may be produced and used by VA for authorized purposes identified below, such as education of VA personnel, research activities, or promotional efforts. It may also be disclosed outside VA as permitted by law and as noted below. If the material is part of a VA system of records, it may be disclosed outside VA as stated in the "Routine Uses" in the "VA Privacy Act Systems of Records" published in the Federal Register.

The purpose of this verbal consent is to document your consent to the Department of Veterans Affairs' (VA) request to obtain, produce, and/or use a verbal or written statement or a photograph, digital image, and/or video or audio recording containing your likeness or voice. By verbally agreeing, you are authorizing the production or use only as specified below.

You are NOT REQUIRED TO CONSENT TO VA's REQUEST to obtain, produce, and/or use your statement, likeness, or voice. Your decision to consent or refuse will not affect your access to any present or future VA benefits for which you are eligible.

You may rescind your consent at any time prior to or during production of an audio recording, or before or during your provision of a verbal or written statement. You may rescind your consent after production is complete if the burden on VA of complying with that request is not unreasonable considering the financial and administrative costs, the ease of compliance that number of parties involved.

The audio recording will be produced while you are participant in the study "Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD" USF IRB number #PRO-35440.

If you have any questions about this study, you can contact Dr. Jolie Haun at (813) 558-7622. If you have question about your rights as a research participant please contact the USF IRB at (813) 974-5638 or by email at RSCH-IRB@usf.edu.

Would you like to participate in this study? [PI or study team member will record if verbal consent is given.]

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

Hello: My name is_____.

I am a study team member for the research study called: "Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD".

[Proceed to read consent]

Overview of the Study**:** Researchers at the James A. Haley Veterans Hospital study many topics. We are asking you to take part in "Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD", IRB Study #Pro00035440.

Study Staff: This study is being led by Dr. Jolie Haun, Co-Core Director for Implementation & Dissemination, Health Services Research and Development Service, Research and Development Service (R&DS) at the James A. Haley Veterans Hospital (JAHVH), Tampa, FL. This person is called the Principal Investigator or PI. Other approved research staff may act on behalf of the PI.

Study Details: This study is being conducted at JAHVH-Tampa R&DS and is supported by Rehabilitation Research and Development. This project is responsive to Rehabilitation Research and Development's current special areas of interest for non-pharmacological activity-based interventions for chronic pain impacting pain reduction, function and quality of life. This project aligns with the VA mandate for complementary and integrative health (CIH) care for Veterans and their families. CIH complements traditional care for Veterans managing chronic conditions, such as chronic pain and PTSD. Mission Reconnect (MR) is a user-driven, dyadic, CIH self-care management program delivered remotely that teaches techniques the Veteran and family-partner can use to reduce pain, anxiety and stress, promote well-being and improve relationship quality. The research goal is to evaluate MR as an approach to manage chronic pain and PTSD symptoms, for potential subsequent implementation. This study will possibly provide a model for establishing remote access and sustainable implementation of CIH within VA.

Inclusion criteria: You must an adult, 18 years or older. English-speaking Veterans with chronic musculoskeletal pain. Musculoskeletal pain is present if the Veteran meets either of two validated criteria (1) two or more occurrences of any of targeted musculoskeletal diagnoses recorded at visits separated by at least 30 days within past six months; or (2) high impact chronic pain, two or more occurrences of targeted musculoskeletal diagnoses separated by at least 30 days within the past six months previous to study recruitment and two or more pain scores (greater than or equal to 4 separated by at least 30 days within past six months).

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

Exclusion criteria: Moderate to severe TBI, diagnosis or documented treatment for psychosis in previous 6 months, currently in substance use disorder treatment, non-English speaking; visual, hearing, cognitive impairment that prevent participation or ability to consent, and/or lack of access to internet service. These individuals will be excluded due to medical, language, and technology access issues that would prevent safe and full study participation. Pain and PTSD treatment will not be factored as an inclusion/exclusion criterion but will be evaluated as covariates. Potential participants who screen for aggression or violence will also be excluded from study.

Participants: You are being asked to take part because you are a partner (i.e. spouse, significant other, friend, caregiver, or family member) of a patient at JAHVH. You will receive a copy of the full consent form.

You will be asked to spend approximately 4 months in the study. The study will last that length of time because we want to 1) Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological symptoms (depression, stress, anxiety), and global health (quality of life), 2) Determine MR effectiveness for social (relationship satisfaction, compassion for self/others) outcomes among Veterans and their partners, 3) Describe Veteran and partner perceived value of MR in a sub-sample of participants. As a study participant you may be asked to participate in the following activities. You will not necessarily participate in every activity.

Treatment Group: The treatment group will be asked to review all MR content. The MR program provides video and audio instruction in a set of 11 evidence-based wellness activities in three thematic categories: Connecting with Yourself, Connecting with Quiet, and Connecting with Your Partner. All instruction is accessible via the program website (MissionReconnect.com) and mobile device apps. Video content totals 91 minutes and was produced by filming two days of workshops to teach the practices to Veteran/partner dyads. The Program Overview video (54 min.) introduces the MR instructional sequences accompanied by commentary by workshop participants. Detailed massage instruction is presented in the separate Massage Instruction video (34 min.) and Massage Video Supplement (3 min.) addressing use with home furniture. Users are encouraged to give and receive at least one massage per week. Audio content totals 67 minutes and was recorded in studio, with nine instructional audios ranging from one to 22 minutes.

Usual Care Waitlist Control Arm: Study subjects in the control arm will participate in all assessments like those in the treatment group, however, you will be asked to agree to not access the public web site during their participation. Wait-list control participants will be instructed to seek advice about treatment from their providers. Other than this initial advice, there will be no attempt by study personnel to influence condition management unless an issue (e.g., suicidal ideation) arises. The control condition will account for potential temporal effects that occur from passage of time (brief), and expectation effects associated with anticipation of MR participation. The control group will receive access to MR after completion of data collection.

Data will be collected using (1) self-report surveys; and (2) telephone interviews.

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

(1) Self-reported survey data will be collected using online surveys. Participants will receive email messages with a link to prompt participants to access the MR website and complete data collection. The survey should take no longer than 30 minutes. Study measures will be compiled into a single survey format and collected at baseline, 1, 2, and 4 months. Survey data will be kept confidential and stored in a secured network for study personnel for the duration of the study.

(2) Telephone interviews will be conducted with only treatment group members. If selected for a phone interview, you may be contacted at a later date after the initiation of the study to participate in the interview. The interview will last no longer than 30 minutes. Interviewers will request respondents' attitudes, opinions, and reports about their preferences and the pros and cons of MR and/or participating in the practice groups, including their perceptions of usefulness. The interviews will be audio recorded with participant permission on a VA approved digital recorder and will be kept confidential and stored in a secured network for study personnel for the duration of the study. An audio voice consent will be completed and verbal permission recorded at the time of the telephone interview process. .

About 400 people will take part in this study at JAHVH.

Participants will receive $5 for providing weekly MR reports on utilization and pain ratings for the first 8 weeks of their participation in the study; a total of $40. Participants will receive $20 each time you provide assessment data over a 4-month period (4 time points); a total of $80. Each treatment group member participating in the telephone interview will receive an additional $20. The total possible incentive for participants is up to$140. To be paid for your participation in the study, you will need to complete Form 1099 which will be provided to you. Please be aware for all surveys not completed by the study end period WILL NOT receive payment.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will be compensated for your participation in the study. This research is considered minimal risk. Minimum risk means that study risks are the same as the risks you face in daily life. Subject participation involves completing interviews over the telephone or in person with no invasive procedures. Although unlikely, protocol will be followed if there is an adverse event. The project manager will report the adverse event to the PI and the event will subsequently be reported to the Institutional Review Board (IRB). If the participant becomes agitated, the research assistant will ask if the participant would like to stop the interview and the assistant will discuss this immediately with the PI to determine if any further action is indicated. The most likely adverse event to occur would be unauthorized access to data.

Participants in the audio-recorded telephone conversations will not be identified by name. The participants will be told in advance of their participation that you may decline to participate at any time.

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

Again, there are no known risks to those who take part in this study. If you have any study-related problems, please call the PI at 813-558-7622. Throughout the study, researchers may notify you (via telephone or in person at a scheduled visit) of any new information that may become available and which might affect your decision to remain in the study.

If a participant is deemed at high risk for harm/suicide; the study personnel will do the following:

- Stay with patient until you can be referred to appropriate medical staff member.

- If the patient is an outpatient, this will involve taking the patient to the Emergency Room for evaluation.

- If the patient is an inpatient, this will involve calling the patient's primary treatment team and/or escorting the patient to such providers.

All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been referred to the appropriate staff, the PI will be alerted.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. While we are doing this research, we cannot let you see or copy the research information we have about you. After the research is done, you have a right to see and copy the information about you, as allowed by JAHVH policies.

Confidentiality of data collected by audio recordings, online surveys, and other communication with study participants will be maintained, unless an issue arises that poses a risk to the health or well-being of the study participant or others (e.g., suicidal ideation). Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy or would like a copy of the Notice, the research team will provide one to you.

Breach of data confidentiality will be minimized by maintaining research records in accordance with VHA's Records Control Schedule (RCS10-1), applicable FDA and DHHS regulations, or as described in VHA Handbook 1200.5, section 7.j. We will strictly adhere to VA and other federal privacy, confidentiality, and HIPAA regulations.

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

We must keep your study records as confidential as possible. We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are. However, certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the PI, and all other research staff.
- Certain government and university persons who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- The University of South Florida IRB and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
- The Department of Health and Human Services
- RR&D

It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet.

Interviews will be audio recorded using Veterans Health Administration approved equipment. Recordings will be stored on VHA computers behind password protected firewalls in secure password protected folders. Data will be stored for the duration of the study and in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION:

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA PI and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you agree with this authorization. Your individually identifiable health information used for this VA study includes the information below:

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

- Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings
- Demographic Information such as name, age, race
- Questionnaire, Survey, and/or Subject Diary

USE OF YOUR DATA FOR OTHER RESEARCH:

- Not Applicable - No Data or Specimen Banking for Other Research

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

- Non-VA IRB: USF
- Study Sponsor/Funding Source: RR&D
- Compliance and Safety Monitors: Research Compliance Officer
- Other Federal agencies required to monitor or oversee research: The Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Research and Development Committee, may look at any portion of your record.

Access to your Individually Identifiable Health Information created or obtained in the course of this research. You will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your revocation is effective as soon as it is received by the study's PI.

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study.

CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

CONSENT FOR PRODUCTION AND USE OF VERBAL OR WRITTEN STATEMENTS, PHOTOGRAPHS, DIGITAL IMAGES, AND/OR VIDEO OR AUDIO RECORDINGS BY VA

NOTE: The execution of this verbal consent does not authorize production or use of materials except as specified below. The specified material may be produced and used by VA for authorized purposes identified below, such as education of VA personnel, research activities, or promotional efforts. It may also be disclosed outside VA as permitted by law and as noted below. If the material is part of a VA system of records, it may be disclosed outside VA as stated in the "Routine Uses" in the "VA Privacy Act Systems of Records" published in the Federal Register.

The purpose of this verbal consent is to document your consent to the Department of Veterans Affairs' (VA) request to obtain, produce, and/or use a verbal or written statement or a

Verbal Consent Script for Informed Consent-Partner

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD– VA R&DS

photograph, digital image, and/or video or audio recording containing your likeness or voice. By verbally agreeing, you are authorizing the production or use only as specified below.

You are NOT REQUIRED TO CONSENT TO VA's REQUEST to obtain, produce, and/or use your statement, likeness, or voice. Your decision to consent or refuse will not affect your access to any present or future VA benefits for which you are eligible.

You may rescind your consent at any time prior to or during production of a audio recording, or before or during your provision of a verbal or written statement. You may rescind your consent after production is complete if the burden on VA of complying with that request is not unreasonable considering the financial and administrative costs, the ease of compliance that number of parties involved.

The audio recording will be produced while you are a participant in the study "Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD" USF IRB number #PRO-35440.

If you have any questions about this study, you can contact Dr. Jolie Haun at (813) 558-7622. If you have question about your rights as a research participant, please contact the USF IRB at (813) 974-5638 or by email at RSCH-IRB@usf.edu.

Would you like to participate in this study? [PI or study team member will record if verbal consent is given.]

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD		
Principal Investigator:	Dr. Jolie Haun, PhD, EdS	VAMC:	Tampa-673

Informed Consent to Participate in Research: Social and Behavioral Research

University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital
Information to Consider Before Taking Part in this Research Study

IRB Study #Pro00035440

Researchers at the James A. Haley Veterans' Hospital study many topics. Our goal is to find better ways to help treat patients. To do this, we need the help of people who agree to take part in a research study.

We are asking you to take part in a research study that is called:

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD

The person who is in charge of this research study is Dr. Jolie Haun. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. The person explaining the research to you may be a study staff member other than the Principal Investigator.

The research will be done at James A. Haley Hospital, Primary Care Annex, and the four surrounding Community Based Outpatient Clinics (CBOCs) Brooksville, CBOC, Lakeland CBOC, New Port Richey CBOC, Zephyrhills CBOC.

This research is being paid for by Veterans Health Administration (VHA), Rehabilitation Research and Development (RR&D) Merit grant program.

Should you take part in this study?

This form tells you about this research study. This form explains:

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	**Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD**		
Principal Investigator:	**Dr. Jolie Haun, PhD, EdS**	**VAMC:**	**Tampa-673**

- Why this study is being done.
- What will happen during this study and what you will need to do.
- Whether there is any chance you might experience potential benefits from being in the study.
- The risks of having problems because you are in this study.

Before you decide:

- Read this form.
- Have a friend or family member read it.
- Talk about this study with the person in charge of the study or the person explaining the study. You can have someone with you when you talk about the study.
- Talk it over with someone you trust.
- Find out what the study is about.
- You may have questions this form does not answer. You do not have to guess at things you don't understand. If you have questions, ask the person in charge of the study or study staff as you go along. Ask them to explain things in a way you can understand.
- Take your time to think about it.

It is up to you. If you choose to take part in this study, you will need to sign this consent form. If you **do not** want to take part in this study, you should **not** sign the form.

Why is this research being done?

We want to examine the effects of a Complementary Integrative Health (CIH) intervention using Mission Reconnect (MR), an online self-care management program and mobile application. MR teaches

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

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Principal Investigator:	**Dr. Jolie Haun, PhD, EdS**	**VAMC:**	**Tampa-673**

techniques that Veterans and significant others can use individually, AND together to reduce pain, promote well-being and improve their relationship.

You have been selected for this study (inclusion criteria) because:

- You are at least 18 years old
- You are an English-speaking Veteran with chronic musculoskeletal pain
- You have a diagnosis of Post-traumatic stress disorder (PTSD) in your VA health record

In order to participate, you must also have the ability to access and use the Mission Reconnect program via internet or mobile device.

You are not eligible to take part in this study (exclusion criteria) if:

- You have moderate to severe Traumatic Brain Injury (TBI)
- You have had documented treatment for severe mental disorder in previous 6 months
- You are currently in an in-patient high intensity substance use disorder treatment program
- You are non-English speaking
- You have visual, hearing, or cognitive impairment that prevents participation or ability to consent
- You lack access to internet service

Potential participants who screen for aggression or violence will also be excluded from this study.

Why are you being asked to take part?

We are asking you to take part in this study because you are a patient at James A. Haley Hospital with chronic musculoskeletal pain and PTSD. We want to learn more about your experiences using CIH modalities to improve pain and PTSD-related outcomes.

What will happen during this study?

You will be asked to spend several months in this study, about 4 months (treatment group) or about 4-8 months (control group). The study will last that length of time because we want to 1) Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological symptoms (depression, stress, anxiety), and global health (quality of life), 2) Determine MR effectiveness for social (relationship satisfaction, compassion for self/others) outcomes among Veterans and their partners, (i.e. spouse, significant other, caregiver, friend or family member). 3) Describe Veteran and partner perceived value

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	**Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD**		
Principal Investigator:	**Dr. Jolie Haun, PhD, EdS**	**VAMC:**	**Tampa-673**

of MR in a sub-sample of participants. As a study participant you may be asked to participate in the following activities. You will not necessarily participate in every activity.

Aim 1: screening interview to assess the occurrence of chronic pain and PTSD
Aim 2: self-report survey assessment data and weekly reports collected using electronic survey
Aim 3: complete an audio-record single telephone interview to collect qualitative data

Mission Reconnect: Mission Reconnect (MR) provides support for Veterans' pain and PTSD symptom management using CIH modalities (i.e., massage, meditation, positive psychology) that can be accessed electronically (via Internet or mobile application).

Treatment Group: The treatment group will be asked to review all MR content. The MR program provides video and audio instruction in a set of 11 evidence-based wellness activities in three thematic categories: Connecting with Yourself, Connecting with Quiet, and Connecting with Your Partner. All instruction is accessible via the program website (MissionReconnect.com) and mobile device apps. Video content totals 91 minutes and was produced by filming two days of workshops to teach the practices to Veteran/partner dyads. The Program Overview video (54 min.) introduces the MR instructional sequences accompanied by commentary by workshop participants. Detailed massage instruction is presented in the separate Massage Instruction video (34 min.) and Massage Video Supplement (3 min.) addressing use with home furniture. Users are encouraged to give and receive at least one massage per week. Audio content totals 67 minutes and was recorded in studio, with nine instructional audios ranging from one to 22 minutes. Treatment group participants will be instructed to seek advice about treatment from your provider. There will be no attempt by study personnel to contact your provider unless an issue (i.e., suicidal ideation) arises. Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

Usual Care Waitlist Control Arm: Study subjects in the control arm will participate in all assessments like those in the treatment group, however, you will be asked to agree to not access the public web site during their participation. Wait-list control participants will be instructed to seek advice about treatment from your provider. There will be no attempt by study personnel to contact your provider unless an issue (i.e., suicidal ideation) arises. Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others. The control condition will account for potential temporal effects that occur from passage of time (brief), and expectation effects associated with anticipation of MR participation. The control group will receive access to MR after completion of data collection.

Data will be collected using (1) self-report surveys; and (2) telephone interviews.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD		
Principal Investigator:	Dr. Jolie Haun, PhD, EdS	VAMC:	Tampa-673

(1) Self-reported survey data will be collected using online surveys. Participants will receive email messages with a link to prompt participants to access the MR website and complete data collection. The survey should take no longer than 30 minutes. Study measures will be compiled into a single survey format and collected at baseline, 1, 2, and 4 months. Survey data will be kept confidential and stored in a secured network for study personnel for the duration of the study.

(2) Telephone interviews will be conducted with only treatment group members. If selected for a phone interview, you may be contacted later after the initiation of the study to participate in the interview. The interview will last no longer than 30 minutes. Interviewers will request respondents' attitudes, opinions, and reports about their preferences and the pros and cons of MR and/or participating in the practice groups, including their perceptions of usefulness. The interviews will be audio recorded, and will be kept confidential and stored in a secured network for study personnel for the duration of the study. An audio voice consent must be completed in addition to the verbal and/or written consent documentation.

How many other people will take part?

About 400 people will take part in this study at James A. Haley Veterans' Hospital.

What other choices do you have if you decide not to take part?

If you decide not to take part in this study, that is okay. Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. If you do not want to participate in this study, the rights and health care benefits you are entitled to will not change (i.e., including VA benefits and access to standard medical care). Any new significant findings developed during the study that may change your decision about participating will be provided to you. Instead of being in this research study you can choose not to participate.

Will you be paid for taking part in this study?

Participants will receive $5 for providing weekly MR reports on utilization and pain ratings for the first 8 weeks of their participation in the study; a total of $40. Participants will receive $20 each time you provide assessment data over a 4-month period (4-time points); a total of $80. Each treatment group

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

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Principal Investigator:	Dr. Jolie Haun, PhD, EdS	VAMC:	Tampa-673

member participating in the telephone interview will receive an additional $20. The total possible incentive for participants is up to$140. To be paid for your participation in the study, you will need to complete Form 1099 which will be provided to you. Please be aware for all surveys not completed by the study end period WILL NOT receive payment.

What will it cost you to take part in this study?

It will not cost you anything to be part of the study. As a VA patient, there may be co-payment costs for some of the non-research procedures for which the VA may not pay even if these occur while you are participating in this research. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study and that you would receive as part of your regular medical care.

What are the potential benefits if you take part in this study?

The potential benefits to you are:

Participants may or may not receive direct benefit for participating in this study because of engaging in the proposed intervention. Participants randomized to the control group who receive access to MR after you complete data collection, may also receive benefit from being in the study. Additionally, this research may benefit the Veteran population and their partners in the future if the study is found to be effective and subsequently disseminated to Veterans and their partners throughout the VA system.

What are the risks if you take part in this study?

There are no known risks to those who take part in this study. If you have any study-related problems, please call the PI at 813-558-7622. Throughout the study, the researchers may notify you (via telephone or in person at a scheduled visit) of any new information that may become available and which might affect your decision to remain in the study.

If a participant is deemed at high risk for harm/suicide; the study personnel will do the following:

- Stay with patient until you can be referred to appropriate medical staff member.
- If the patient is an outpatient, this will involve taking the patient to the Emergency Room for evaluation.

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- If the patient is an inpatient, this will involve calling the patient's primary treatment team and/or escorting the patient to such providers.

All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been referred to the appropriate staff, the PI will be alerted.

What if you are injured while you are in the study?

You are participating in a research project approved by a Research and Development Committee and conducted under the supervision of one or more VA employees. Every reasonable safety measure will be used to protect your well-being. If you are injured because of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment.

If you need emergency care:

- **Go to your nearest hospital or emergency room right away. Call 911 or for help.** It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the person in charge of this study as soon as you can. You will need to know that you are hurt or ill. Call Dr. Jolie Haun at 813-558-7622.

If you need emergency care in a private hospital, have a friend or family member contact the VA immediately at (813) 972-2000, extension 6197 or 6198, and your study doctor so that you can coordinate care with a private hospital. If an eligible veteran requires admission to a non-VA hospital because of an emergency, the Department of Veterans Affairs will not be responsible for the cost incurred unless the Department of Veterans Affairs is involved immediately.

<u>If it is not an emergency</u>, and you get hurt or begin to feel bad: Go to your regular doctor. Tell your doctor that you are taking part in this study. If you can, take a copy of this consent form with you.

If you are harmed while taking part in the study:

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Subject's Last 4 digits of SS# required: _____

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If you believe you have a medical concern related to this study, or have been hurt or became sick because of something that is done during the study, you should call the person listed below immediately.

DURING THE DAY:

Dr. Jolie Haun, PhD

Telephone number: 813-558-7622

AFTER HOURS:

Dr. Jolie Haun, PhD

Telephone number: 813-558-7622

Emergency and ongoing medical treatment will be provided as needed.

Compensation for Research-Related Injuries

Financial compensation for research-related injuries, lost wages, discomfort or disability may be available. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

What happens if you decide not to take part in this study?

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study Principal Investigator or the research staff.

If you decide not to take part:

- You will not be in trouble or lose any rights you normally have.

What if you join the study and decide you want to stop later on?

You can decide after signing this informed consent document that you no longer want to take part in this study. **We will keep you informed of any new developments which might affect your willingness to continue to participate in the study.** However, you can decide you want to stop taking part in the study

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for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.

Are there reasons we might take you out of the study later on?

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen.
- You are not coming for your study visits when scheduled.
- Study inclusion/exclusion criteria are not met.

Informed Consent Process for Online Survey Based Research

It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet.

Interviews will be audio recorded using Veterans Health Administration approved equipment. Recordings will be stored on VHA computers behind password protected firewalls in secure password protected folders. Data will be stored for the duration of the study and in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

Confidentiality of data collected by audio recordings, online surveys, and other communication with study participants will be maintained, unless an issue arises that poses a risk to the health or well-being of the study participant or others (e.g., suicidal ideation). Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

Your Rights:

You can refuse to sign this form. If you do not sign this form:

- **You will not be able to take part in this research.**

While we are doing this research, we cannot let you see or copy the research information we have about you. After the research is done, you have a right to see and copy the information about you, as allowed by James A. Haley Veterans' Hospital policies.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy or would like a copy of the Notice, the research team will provide one to you.

Breach of data confidentiality will be minimized by maintaining research records in accordance with VHA's Records Control Schedule (RCS10-1), applicable FDA and DHHS regulations, or as described in VHA Handbook 1200.5, section 7.j. We will strictly adhere to VA and other federal privacy, confidentiality, and HIPAA regulations.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information you may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, if you agree with this authorization. Your individually identifiable health information used for this VA study includes the information below:

- Information from your VA Health Records such as diagnoses, progress notes, medications, labor radiology findings
- Demographic Information such as name, age, race
- Questionnaire, Survey, and/or Subject Diary

USE OF YOUR DATA FOR OTHER RESEARCH:

- Not Applicable - No Data or Specimen Banking for Other Research

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Subject's Name: _____

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DISCLOSURE:

The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

- Non-VA Institutional Review Board (IRB): USF
- Study Sponsor/Funding Source: RR&D
- Compliance and Safety Monitors: RCO
- Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO): The Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Research and Development Committee, may look at any portion of your record.

Access to your Individually Identifiable Health Information created or obtained during this research. You will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION:

If you sign the HIPPA authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study. If you revoke (take back) your permission, you will no longer be able to participate in this

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study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION:

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study.

CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

You can get the answers to your questions, concerns, complaints or issues.

If you have any questions, concerns or complaints about this study, call Dr. Jolie Haun at 813-558-7622.

Subject's Name: _____

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If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

Statement of Participation in Research

It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true.

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

_____

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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Statement of Person Obtaining Informed Consent / Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.
- How the information collected about the person will be used.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

_____ _____

Signature of Person Obtaining Informed Consent / Research Authorization Date

_____

Printed Name of Person Obtaining Informed Consent / Research Authorization

_____

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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Informed Consent to Participate in Research: Social and Behavioral Research

University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital
Information to Consider Before Taking Part in this Research Study

IRB Study #Pro00035440

Researchers at the James A. Haley Veterans' Hospital study many topics. Our goal is to find better ways to help treat patients. To do this, we need the help of people who agree to take part in a research study.

We are asking you to take part in a research study that is called:

Mission Reconnect: Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD

The person who is in charge of this research study is Dr. Jolie Haun. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. The person explaining the research to you may be a study staff member other than the Principal Investigator.

The research will be done at James A. Haley Hospital, Primary Care Annex, and the four surrounding Community Based Outpatient Clinics (CBOCs) Brooksville, CBOC, Lakeland CBOC, New Port Richey CBOC, Zephyrhills CBOC.

This research is being paid for by Veterans Health Administration (VHA), Rehabilitation Research and Development (RR&D) Merit grant program.

Should you take part in this study?

This form tells you about this research study. This form explains:

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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- Why this study is being done.
- What will happen during this study and what you will need to do.
- Whether there is any chance you might experience potential benefits from being in the study.
- The risks of having problems because you are in this study.

Before you decide:

- Read this form.
- Have a friend or family member read it.
- Talk about this study with the person in charge of the study or the person explaining the study. You can have someone with you when you talk about the study.
- Talk it over with someone you trust.
- Find out what the study is about.
- You may have questions this form does not answer. You do not have to guess at things you don't understand. If you have questions, ask the person in charge of the study or study staff as you go along. Ask them to explain things in a way you can understand.
- Take your time to think about it.

It is up to you. If you choose to take part in this study, you will need to sign this consent form. If you **do not** want to take part in this study, you should **not** sign the form.

Why is this research being done?

We want to examine the effects of a Complementary Integrative Health (CIH) intervention using Mission Reconnect (MR), an online self-care management program and mobile application. MR teaches techniques that Veterans and significant others can use individually, AND together to reduce pain, promote well-being and improve their relationship.

You have been selected for this study (inclusion criteria) because:

- You are at least 18 years old
- You are an English-speaking Veteran with chronic musculoskeletal pain*

Subject's Name: _____

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- You have a diagnosis of Post-traumatic stress disorder (PTSD) in your VA health record*

*Veteran partner has diagnosis

In order to participate, you must also have the ability to access and use the Mission Reconnect program via internet or mobile device.

You are not eligible to take part in this study (exclusion criteria) if:

- You have moderate to severe Traumatic Brain Injury (TBI)
- You have had documented treatment for severe mental disorder in previous 6 months
- You are currently in an in-patient high intensity substance use disorder treatment program
- You are non-English speaking
- You have visual, hearing, or cognitive impairment that prevents participation or ability to consent
- You lack access to internet service

Potential participants who screen for aggression or violence will also be excluded from this study.

Why are you being asked to take part?

We are asking you to take part in this study because you are a partner of a patient at James A. Haley Hospital with chronic musculoskeletal pain and PTSD. We want to learn more about your experiences using CIH modalities to improve pain and PTSD-related outcomes.

What will happen during this study?

You will be asked to spend several months in this study, about 4 months (treatment group) or about 4-8 months (control group). The study will last that length of time because we want to 1) Determine MR effectiveness for physical (pain, sleep), PTSD (intrusion, arousal, avoidance, numbing), and psychological symptoms (depression, stress, anxiety), and global health (quality of life), 2) Determine MR effectiveness for social (relationship satisfaction, compassion for self/others) outcomes among Veterans and their partners, (i.e. spouse, significant other, caregiver, friend or family member) .3) Describe Veteran and partner perceived value of MR in a sub-sample of participants. As a study participant you may be asked to participate in the following activities. You will not necessarily participate in every activity.

Aim 1: screening interview to assess the occurrence of chronic pain and PTSD
Aim 2: self-report survey assessment data and weekly reports collected using electronic survey

Subject's Name: _____

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Aim 3: complete an audio-record single telephone interview to collect qualitative data

Mission Reconnect: Mission Reconnect (MR) provides support for Veterans' pain and PTSD symptom management using CIH modalities (i.e., massage, meditation, positive psychology) that can be accessed electronically (via Internet or mobile application).

Treatment Group: The treatment group will be asked to review all MR content. The MR program provides video and audio instruction in a set of 11 evidence-based wellness activities in three thematic categories: Connecting with Yourself, Connecting with Quiet, and Connecting with Your Partner. All instruction is accessible via the program website (MissionReconnect.com) and mobile device apps. Video content totals 91 minutes and was produced by filming two days of workshops to teach the practices to Veteran/partner dyads. The Program Overview video (54 min.) introduces the MR instructional sequences accompanied by commentary by workshop participants. Detailed massage instruction is presented in the separate Massage Instruction video (34 min.) and Massage Video Supplement (3 min.) addressing use with home furniture. Users are encouraged to give and receive at least one massage per week. Audio content totals 67 minutes and was recorded in studio, with nine instructional audios ranging from one to 22 minutes.

Usual Care Waitlist Control Arm: Study subjects in the control arm will participate in all assessments like those in the treatment group, however, you will be asked to agree to not access the public web site during their participation. Wait-list control participants will be instructed to seek advice about treatment from their providers. Other than this initial advice, there will be no attempt by study personnel to influence condition management unless an issue (i.e., suicidal ideation) arises. The control condition will account for potential temporal effects that occur from passage of time (brief), and expectation effects associated with anticipation of MR participation. The control group will receive access to MR after completion of data collection.

Data will be collected using (1) self-report surveys; and (2) telephone interviews.

(1) Self-reported survey data will be collected using online surveys. Participants will receive email messages with a link to prompt participants to access the MR website and complete data collection. The survey should take no longer than 30 minutes. Study measures will be compiled into a single survey

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

format and collected at baseline, 1, 2, and 4 months. Survey data will be kept confidential and stored in a secured network for study personnel for the duration of the study.

(2) Telephone interviews will be conducted with only treatment group members. If selected for a phone interview, you may be contacted later after the initiation of the study to participate in the interview. The interview will last no longer than 30 minutes. Interviewers will request respondents' attitudes, opinions, and reports about their preferences and the pros and cons of MR and/or participating in the practice groups, including their perceptions of usefulness. The interviews will be audio recorded and will be kept confidential and stored in a secured network for study personnel for the duration of the study. An audio voice consent must be completed in addition to the verbal and/or written consent documentation.

How many other people will take part?

About 400 people will take part in this study at James A. Haley Veterans' Hospital.

What other choices do you have if you decide not to take part?

If you decide not to take part in this study, that is okay. Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. If you do not want to participate in this study, the rights and health care benefits you are entitled to will not change (i.e., including VA benefits and access to standard medical care). Any new significant findings developed during the study that may change your decision about participating will be provided to you. Instead of being in this research study you can choose not to participate.

Will you be paid for taking part in this study?

Participants will receive $5 for providing weekly MR reports on utilization and pain ratings for the first 8 weeks of their participation in the study; a total of $40. Participants will receive $20 each time you provide assessment data over a 4-month period (4-time points); a total of $80. Each treatment group member participating in the telephone interview will receive an additional $20. The total possible incentive for participants is up to $140. To be paid for your participation in the study, you will need to complete Form 1099 which will be provided to you. Please be aware for all surveys not completed by your study end period WILL NOT receive payment.

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What will it cost you to take part in this study?

It will not cost you anything to be part of the study. As a VA patient, there may be co-payment costs for some of the non-research procedures for which the VA may not pay even if these occur while you are participating in this research. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study and that you would receive as part of your regular medical care.

What are the potential benefits if you take part in this study?

The potential benefits to you are:

Participants may or may not receive direct benefit for participating in this study because of engaging in the proposed intervention. Participants randomized to the control group who receive access to MR after you complete data collection, may also receive benefit from being in the study. Additionally, this research may benefit the Veteran population and their partners in the future if the study is found to be effective and subsequently disseminated to Veterans and their partners throughout the VA system.

What are the risks if you take part in this study?

There are no known risks to those who take part in this study. If you have any study-related problems, please call the PI at 813-558-7622. Throughout the study, the researchers may notify you (via telephone or in person at a scheduled visit) of any new information that may become available and which might affect your decision to remain in the study.

If a participant is deemed at high risk for harm/suicide; the study personnel will do the following:

- Stay with patient until you can be referred to appropriate medical staff member.
- If the patient is an outpatient, this will involve taking the patient to the Emergency Room for evaluation.
- If the patient is an inpatient, this will involve calling the patient's primary treatment team and/or escorting the patient to such providers.

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All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been referred to the appropriate staff, the PI will be alerted.

What if you are injured while you are in the study?

You are participating in a research project approved by a Research and Development Committee and conducted under the supervision of one or more VA employees. Every reasonable safety measure will be used to protect your well-being. If you are injured because of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment.

If you need emergency care:

- **Go to your nearest hospital or emergency room right away. Call 911 or for help.** It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the person in charge of this study as soon as you can. You will need to know that you are hurt or ill. Call Dr. Jolie Haun at 813-558-7622.

If you need emergency care in a private hospital, have a friend or family member contact the VA immediately at (813) 972-2000, extension 6197 or 6198, and your study doctor so that you can coordinate care with a private hospital. If an eligible veteran requires admission to a non-VA hospital because of an emergency, the Department of Veterans Affairs will not be responsible for the cost incurred unless the Department of Veterans Affairs is involved immediately.

<u>If it is not an emergency</u>, and you get hurt or begin to feel bad: Go to your regular doctor. Tell your doctor that you are taking part in this study. If you can, take a copy of this consent form with you.

If you are harmed while taking part in the study:

If you believe you have a medical concern related to this study, or have been hurt or became sick because of something that is done during the study, you should call the person listed below immediately.

DURING THE DAY:

_____

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	**Delivering a Mobile and Web Based Self Directed Complementary and Integrative Health Program to Veterans and Their Partners to Manage Pain and PTSD**		
Principal Investigator:	**Dr. Jolie Haun, PhD, EdS**	**VAMC:**	**Tampa-673**

Dr. Jolie Haun, PhD

Telephone number: 813-558-7622

AFTER HOURS:

Dr. Jolie Haun, PhD

Telephone number: 813-558-7622

Emergency and ongoing medical treatment will be provided as needed.

Compensation for Research-Related Injuries

Financial compensation for research-related injuries, lost wages, discomfort or disability may be available. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

What happens if you decide not to take part in this study?

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study Principal Investigator or the research staff.

If you decide not to take part:

- You will not be in trouble or lose any rights you normally have.

What if you join the study and decide you want to stop later on?

You can decide after signing this informed consent document that you no longer want to take part in this study. **We will keep you informed of any new developments which might affect your willingness to continue to participate in the study.** However, you can decide you want to stop taking part in the study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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Are there reasons we might take you out of the study later on?

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health mayworsen.
- You are not coming for your study visits when scheduled.
- Study inclusion/exclusion criteria are not met.

Informed Consent Process for Online Survey Based Research

It is possible that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet.

Interviews will be audio recorded using Veterans Health Administration approved equipment. Recordings will be stored on VHA computers behind password protected firewalls in secure password protected folders. Data will be stored for the duration of the study and in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

Confidentiality of data collected by audio recordings, online surveys, and other communication with study participants will be maintained, unless an issue arises that poses a risk to the health or well-being of the study participant or others (e.g., suicidal ideation). Confidentiality may be breached by escalating the issue to the necessary health authorities, in order to protect the safety of the study participant and others.

Your Rights:

You can refuse to sign this form. If you do not sign this form:

- **You will not be able to take part in this research.**

While we are doing this research, we cannot let you see or copy the research information we have about you. After the research is done, you have a right to see and copy the information about you, as allowed by James A. Haley Veterans' Hospital policies.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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Practices (a separate document) provides more information on how we protect your information. If you do not have a copy or would like a copy of the Notice, the research team will provide one to you.

Breach of data confidentiality will be minimized by maintaining research records in accordance with VHA's Records Control Schedule (RCS10-1), applicable FDA and DHHS regulations, or as described in VHA Handbook 1200.5, section 7.j. We will strictly adhere to VA and other federal privacy, confidentiality, and HIPAA regulations.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information you may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, if you agree with this authorization. Your individually identifiable health information used for this VA study includes the information below:

- Information from your VA Health Records such as diagnoses, progress notes, medications, labor radiology findings
- Demographic Information such as name, age, race
- Questionnaire, Survey, and/or Subject Diary

USE OF YOUR DATA FOR OTHERRESEARCH:

- Not Applicable - No Data or Specimen Banking for OtherResearch

DISCLOSURE:

The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

- Non-VA Institutional Review Board (IRB): USF
- Study Sponsor/Funding Source: RR&D
- Compliance and Safety Monitors: RCO
- Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO): The Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Research and Development Committee, may look at any portion of your record.

Access to your Individually Identifiable Health Information created or obtained during this research. You will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION:

If you sign the HIPPA authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study. If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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EXPIRATION:

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will expire at the end of this research study.

CERTIFICATE OF CONFIDENTIALITY:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

You can get the answers to your questions, concerns, complaints or issues.

If you have any questions, concerns or complaints about this study, call Dr. Jolie Haun at 813-558-7622.

If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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Statement of Participation in Research

It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true.

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

_____

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent / Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

_____

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.
- How the information collected about the person will be used.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

_____ _____

Signature of Person Obtaining Informed Consent / Research Authorization Date

_____

Printed Name of Person Obtaining Informed Consent / Research Authorization

_____

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____