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Multifamily Group to Reduce Marital Conflict and Disability in Veterans with mTBI

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Abstract

Mild traumatic brain injury (mTBI), an injury or concussion associated with brief loss of consciousness or altered mental state, has affected as many as 35% of soldiers wounded during recent military actions in Iraq and Afghanistan. Up to 30% of those injured report persistent somatic, emotional and cognitive post-concussive symptoms (PCS) which may adversely impact family life and community re-integration. Marital conflict and intimate partner violence, reported by 54% of OEF/OIF/Persian Gulf couples, and co-occurring mental health problems may exacerbate cognitive dysfunction and delay rehabilitation. A key contributor to marital conflict is a lack of knowledge about the Veteran's condition and the skills needed to help him compensate for common deficits in memory and planning which create challenges in household management. Despite a growing evidence base for couples treatment for PTSD, there is no established family-based treatment for OEF/OIF/Persian Gulf Veterans with mTBI, creating a critical research and services gap. The proposed research aims to fill this gap by evaluating a novel form of multi-family group treatment designed to improve community integration (CI) among married/cohabiting OEF/OIF/Persian Gulf Veterans with mTBI and/or significant posttraumatic stress (PTS) or combat-related stress (CS) by training spouse/partners to aid with rehabilitation and employing disability-adapted communication and problem-solving skills to reduce marital conflict and improve marital satisfaction.

Veterans (N=150) with a positive DVBIC screen for mTBI sustained during the OEF/OIF/Persian Gulf era, confirmed by the VA Identification Clinical Interview and a Montreal Cognitive Assessment (MoCA) score ≥ 19 or if they either meet diagnostic criteria for PTSD or have trauma- or CS of at least *moderate* severity, as defined by either a) PCL score >34 or b) CES score of >23, will be randomized to receive either: 1) Multifamily Group for TBI for Couples (MFG-mTBI-C), a psychoeducational, rehabilitation and skills-building intervention consisting of a 2-session multifamily educational workshop providing information about TBI and 12 bi-monthly multifamily group meetings providing skills training in problem-solving and communication related to cognitive/emotional deficits; or 2) 14 bi-monthly multifamily group sessions delivering health education without skills training. Both treatments will be preceded by 2-3 individual couples sessions. Participants will be assessed pre- and post-treatment and 6 months post-treatment. Data will be analyzed using an intent-to-treat analysis with paired comparisons between treatment groups on primary (Veteran CI, caregiver burden) and secondary (anger management, use of social supports) outcome variables using mixed effects regression models. It is hypothesized that: 1) Veterans treated with MFG-mTBI-C will show improved CI, anger management and use of social support, and spouse/partners will show reduced burden compared with those treated in the health education group; 2) that improvement in CI will be mediated by improvement in marital satisfaction and Veteran anger management and social support; 3) that Veterans with more intact cognitive functioning at baseline will show greater improvement in CI, anger management, social support and marital satisfaction. If efficacious, MFG-mTBI–C has the potential to assist Veterans with mTBI and their partners throughout the VA Health Care System.

List of Abbreviations

CI = Community Integration

CS = Combat-related Stress

DoD = Department of Defense

DVBIC = Defense and Veteran Brain Injury Center

GHE = Group Health Education

JJP VAMC = James J. Peters VA Medical Center

MFG = Multifamily Group

MFG-mTBI-C = Multifamily Group for Traumatic Brain Injury for Couples

MIRECC = Mental Illness Research, Education, and Clinical Center

mTBI = Mild Traumatic Brain Injury

OEF/OIF = Operation Enduring Freedom/Operation Iraqi Freedom

PTS = Posttraumatic Stress

PTSD = Posttraumatic Stress Disorder

SMI = Serious Mental Illness

TBI = Traumatic Brain Injury

VAMHCS = VA Maryland Healthcare System

VANYHHS = VA New York Harbor Healthcare System

VISN = Veterans Integrated Services Network

DCVAMC = Washington DC VA Medical Center

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2.0 Introduction

Veterans surviving an mTBI potentially face a variety of physical, cognitive, behavioral, personality and emotional problems, with consequent barriers to productive living and community reintegration (Hoge et al., 2008; Lew et al., 2006). Although the cognitive, behavioral and somatic problems and complaints experienced by those with a history consistent with mTBI often cannot be specifically attributed to the TBI due to their association as well with common co-occurring conditions such as PTSD and depression (Hoge et al. 2008; Lew et al., 2009; Adams et al., 2012), they nonetheless dramatically impact the lives of Veterans' spouses who must learn to cope with changes in the Veterans' behavior and role functioning. Yet, spouses frequently lack important information about the Veteran's condition, prognosis, treatment and home assistance needs, contributing to misguided expectations, disappointment, frustration, family conflict and child distress (Cozza et al., 2010; Perlick et al., 2011). Although decades of research and meta-analytic studies have demonstrated that education and involvement of primary caregivers in the treatment of persons with serious mental illness (SMI), alcohol abuse and other disorders has resulted in improved symptom and community outcomes relative to those observed for individual treatment or treatment as usual (e.g., Pilling et al., 2002; Mueser et al., 2003; Glynn et al., 2008), no systematic effort to involve family members in interventions aimed at improving community integration of Veterans with a history of mTBI has emerged to date, creating a serious gap between accumulated knowledge about effective, family-based treatment strategies for improving consumer outcomes and the urgent rehabilitation needs of these Veterans. This gap is particularly striking in view of the growing evidence base supporting the benefits of involving partners in the treatment of Veterans with post-traumatic stress disorder (PTSD) (Sautter et al., 2009, 2011; Glynn et al. 1999; Monson et al., 2004, 2012), a common co-morbid condition (Hoge et al., 2008). The proposed research aims to fill this gap by evaluating the efficacy of a manualized adaptation of an evidence-based treatment for SMI (McFarlane et al., 2002) for the treatment of Veterans with a history of mTBI. This model, Multifamily Group for Veterans with mTBI for couples (MFG-mTBI-C) builds on both an earlier adaptation of the MFG model for civilian TBI (Rodgers et al., 2007) as well as pilot data from a recently completed open trial of MFG-mTBI (Perlick et al., 2011) described under Preliminary Studies. Our model of the impact of combat-related mTBI on Community Integration (Figure 1 below) is informed by stress-appraisal-coping theory and overlaps with other models generated to describe stress and coping among families with a member with TBI reviewed by Blais & Boisvert (2005). Figure 1 hypothesizes both direct and indirect paths of mTBI impacting Veteran re-integration: 1) the direct effects of mTBI-associated cognitive and social cognitive deficits and co-morbid conditions on reintegration (a); 2) the indirect effects of mTBI and co-morbid conditions on reintegration through their impact on the Veteran's partner and couples' functioning (b,c,d,e). Figure 3, presented in conjunction with the intervention description in 2aix below, describes the components and hypothesized change mechanisms of MFG-mTBI-C. Because the literature on mTBI in OEF/OIF/Persian Gulf Veterans is relatively new, and does not encompass

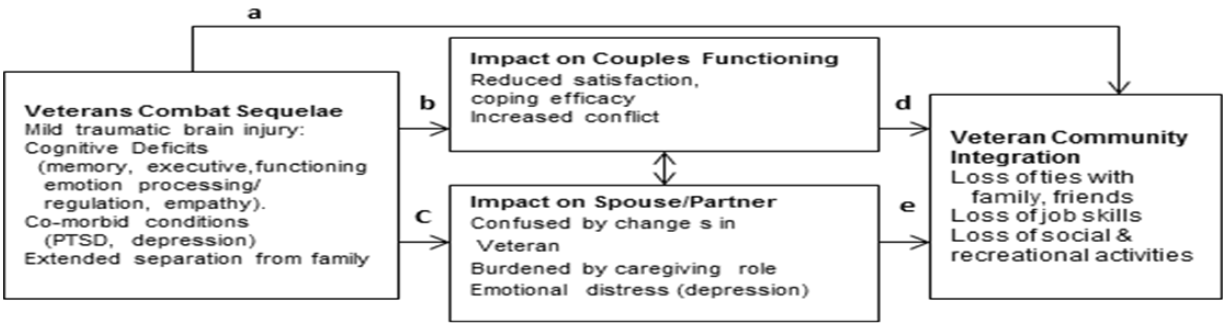

Figure 1: Impact of mild traumatic brain injury and co-morbid conditions on couples functioning and Veterans' Community Integration

all relevant constructs, we have selectively included some studies of non-Veterans and moderate TBI in the following review, with the caveat that findings may differ for Veterans with a history of mTBI associated with blast injuries. Where relevant we have also incorporated findings from the literature on PTSD and family functioning. We begin our review by defining mTBI and its prevalence.

Definition and Prevalence of mTBI: Combat-related traumatic brain injury (TBI) has been referred to as a signature injury of recent military operations in Iraq and Afghanistan. Studies indicate that between 12% and 35% of recent combat Veterans have experienced at least one TBI (Rigg & Mooney, 2011), with 80-90% of these classified as mild TBIs based on symptoms at the time of injury (Schwab et al., 2007). mTBI is defined by the VA/DoD Clinical Practice Guideline for Management of Concussion/Mild Traumatic Brain Injury (Concussion/mTBI Guideline Working Group, 2009) as an injury or concussion associated with at least one of the following: brief (< 30 minutes) loss of consciousness, altered state of consciousness or post-traumatic amnesia for < 24 hours following the injury. The neuropsychiatric sequelae of mTBI may include cognitive dysfunctions (problems in memory, attention, executive functions, affect recognition, empathy, self-awareness) as well as co-morbid mood, posttraumatic stress and other neurobehavioral disorders, somatosensory disruptions and somatic symptoms (Halbauer et al., 2009; Cicerone et al.,2006; Wehman et al.,2009; Huckans et al., 2010). While studies of civilian mTBI have found the majority of cases improved by 3-6 months post-injury (e.g., Belanger et al 2005), up to 30% suffer persistent sequelae and up to 20% are unable to return to work (Lipton et al., 2008; Nolin & Heroux, 2006). There is evidence for delayed development and recognition of cognitive deficits (Nortje et al., 2004). It is not uncommon for persons with mTBI to first seek evaluation/treatment for neurocognitive impairment months or years after the injury (Lipton et al., 2008; CDC, 2003). For example, Lipton et al (2008) observed occult white matter brain changes in mTBI patients who sought treatment for neurocognitive deficits up to 3 years post-injury, and Konrad et al (2011) found significant deficits in memory, attention and executive function in individuals who had sustained an mTBI on average 6 years earlier. An NIH Consensus Panel (1998) found that “Mild TBI is significantly underdiagnosed and early intervention is often neglected”, in part perhaps because standard neuropsychological tests may not detect subtle neurocognitive disorders which can influence neurocognitive functioning on a day-to-day basis (Geary et al., 2010). Among OEF/OIF Veterans with a history of mTBI, the presence of PTSD and other common co-morbid psychiatric disorders, sleep problems/disorders (Orff et al., 2009; Capaldi et al., 2011), substance and alcohol use/misuse (Adams et al., 2012) and chronic pain (Lew et al., 2009) as well as environmental stress may increase the likelihood of, and help maintain, PCS (Schneiderman et al., 2008; Wehman et al., 2009) and/or specific components of PCS such as memory impairment (Mateer & Sira, 2006). The pattern of multiple deployments in the post-911 conflicts in Iraq and Afghanistan has placed Veterans at risk for sustaining repeated injuries over a relatively short time frame, increasing the

likelihood of persistent cognitive deficits (Huckans et al., 2010). Recent findings of decreased cerebral metabolic glucose rates in subcortical and medial temporal regions on FDG-PET imaging in OIF combat Veterans with repetitive blast-trauma mTBI 3.5 years after the final exposure are suggestive of a specific neurobiological substrate for chronic PCS characterized by hypometabolism and accompanied by subtle impairments in cognitive processing (Peskind et al, 2010).Lew et al (2009) reported that persistent post-concussive syndrome (PPCS) characterized 66.8% of Veterans seen in a DVA Polytrauma Network Site, demonstrating that mTBI and related cognitive and affective impairments represent a sizeable and enduring challenge to reintegration.

Impact of mTBI on Community Integration (a): As noted above, up to 30% of mTBI patients suffer long-term sequelae of their injury (Alexander, 1998; Niogi et al, 2010; Shenton et al, 2012), leading to substantial morbidity and disability (Kushner, 2003). Impairment following TBI has been described in multiple aspects of daily functioning including impaired social and work relationships, resulting in loss of social support and/or employment, economic strain, divorce, poor quality of life and increased risk of suicide (Halbauer, 2009; Nolin & Heroux, 2006; NIH Consensus Panel, 1999). Loss of social support may be related to deficits in emotion processing/empathy which impact the ability to recognize and respond appropriately to social cues needed to maintain interpersonal relationships (Halbauer, 2009). In support of this line of reasoning, recent studies have found that lower scores on various measures of emotion recognition, including facial emotion recognition, vocal emotion recognition (prosody) and ability to infer intentions (theory of mind) were associated with “less effective communication” and higher problem behavior ratings by relatives of survivors (Milders et al., 2008, 2010) and with poorer occupational and social integration outcomes on standard measures (Struchen et al. 2008).

Impact of mTBI on Partner and Couples Functioning (b,c):Partners (b): There is abundant literature documenting that between 23-73% of caregivers of individuals with a TBI report both significant symptoms of psychological distress such as depression and anxiety (e.g., Blais & Boisvert, 2005), as well as what is commonly referred to as caregiver burden in relation to both demands on the caregiver’s finances and time, and a loss of emotional support, sexual intimacy and companionship (Novak & Guest, 1989). A key source of stress for caregivers is lack of information about the Veteran’s condition, prognosis and family assistance needs (Perlick et al., 2011). The VA Rapid Assessment Process (RAP) study identified the need for information by families and caregivers of Veterans with a TBI as one of two significant needs to better serve families (Friedemann-Sanchez et al 2008).

Couples (c): Studies suggest that TBI has a more negative impact on spouses than on other caregivers, supported by data that 30-50% of marriages end in divorce within 10 years after a TBI (Blaise & Boisvert, 2005; Griffen et al., 2009). Studies of combat veterans have found high rates of marital distress and intimate partner violence reported by 54% of OEF/OIF couples (Dekel, & Monson, 2010). Reintegration of OEF/OIF Veterans following multiple deployments and extended absence presents numerous challenges for both the Veterans and their families, including re-establishing family routines, reallocating household responsibilities, renegotiating parental roles in caregiving and discipline, financial strain and reconnecting emotionally (Gerwitz et al., 2010). Reconnecting as a couple is complicated by both TBI sequelae and co-morbid mental health problems. Low spousal relationship satisfaction has been associated with poor socio-emotional skills, particularly empathic ability, a common sequela of TBI (Burridge et al., 2007). Veteran depression has been linked to role uncertainty, and PTSD symptoms have also been associated with poor marital adjustment and disturbed family functioning (Dekel & Monson, 2010). As a result of the Veteran’s impaired interpersonal skills and/or PTSD

avoidance symptoms, both those with TBI and their family members experience a “shrinking of support networks” (LoBello et al., 2003), reducing the couple’s ability for enjoyment and companionship which might provide a buffer against the challenges of reintegration.

Impact of Partner and Couples Functioning on Veteran Community Integration: Studies of family functioning and rehabilitation outcomes in TBI have shown family support can promote successful rehabilitation while poor family functioning can impede it (e.g., Griffin et al, 2009). For example, Lobello et al (2003) found that family satisfaction, assessing dimensions of cohesion and adaptability, was significantly associated with higher levels of social integration of TBI survivors five years post-injury.

Proposed Treatment Model: Multi-Family Group for mTBI for couples (MFG-mTBI-C) uses a structured problem-solving and skills training approach to provide Veterans and partners with tools and information to improve coping and help couples reconnect through positive behavioral exchanges. MFG-mTBI-C consists of three sequential phases: 1) a “Joining” in which educators meet with each individual family for 2-3 sessions to evaluate ongoing problems and define treatment goals; 2) a 2-session Educational Workshop which provides information about TBI to all Veterans and families; 3) bi-monthly multifamily group meetings for 6 months (12 sessions) which provide a structured format for building problem-solving and communication skills while receiving social support. Through teaching a systematic approach to solving everyday problems related to cognitive deficits and marital conflict through use of compensatory strategies and communication training, it aims to reduce emotional distress and dysfunctional interaction patterns and behavior and to enlist the spouse’s practical and emotional support for the Veteran’s rehabilitation program. Dyck and colleagues (2007) adapted the McFarlane model for survivors of civilian TBI and collaborated with the PI in a preliminary adaptation for military TBI (Perlick et al., 2011), described below.

Contributions of Proposed Research: The proposed research relates to RR&D priority areas for TBI in that it: 1) tests an innovative manualized rehabilitation model for TBI using random assignment to evaluate clinical and reintegration outcomes; 2) compares the efficacy of different intervention strategies for caregivers (health education group vs. multifamily group with skills training); 3) advances knowledge of rehabilitation by assessing the benefits of family involvement and evaluating the associations between and relative contributions of partner support and cognitive deficits to Community Integration. Results showing superior efficacy for MFG-mTBI-C vs. an education group would support the adoption of this intervention throughout VA, potentially benefiting thousands of Veterans through training in interpersonal and organizational skills needed for community Integration and return to work (RTW). The recent enactment by Congress of legislation providing tax incentives to corporations employing Veterans increases the timeliness and urgency of evaluating and implementing effective rehabilitation strategies targeting community integration. Huckans et al (2010) note that rehabilitation research for mTBI is in a very early stage, with most studies focused on civilian populations and few controlled trials. Although a large meta-analytic study concluded that compensatory approaches work best “when the teaching of adaptive cognitive strategies is emphasized and offered within a naturalized context (including caregiver training and community follow-along)” (Cicerone, 2007), and the NIH Consensus Panel (1999) recommended that “Persons with TBI, their families, and significant others are integral to the design and implementation of the rehabilitation process and research”, to our knowledge there are no data-driven reports of an intervention targeting community integration or rehabilitation for OEF/OIF/Persian Gulf or any era Veterans with TBI that involved family members. Griffin et al. (2009) identify development of training programs for family members as a gap in the VA spectrum of services for TBI and a direction for future research.

By contrast interventions for couples with a member suffering from combat-related PTSD are accumulating an evidence base. Improved symptom and relationship outcomes from couples-based treatments for PTSD (e.g., Cognitive- Behavioral Couples Treatment (CBCT)-Monson et al., 2004, 2012; Structured Approach Therapy (SAT)-Sautter et al., 2009) lend support to involving partners in an intervention that aims to rehabilitate Veterans with [a history of] mTBI given the comorbidity between these two conditions. Our treatment model in fact shares common elements with CBCT and SAT including psychoeducation, enlisting the support of the partner in rehabilitation and a focus on communication. However, whereas the PTSD treatments focus on strengthening the marital relationship as a foundation for exposure exercises aimed at symptom reduction, MFG-mTBI-C promotes empathic acceptance of and helping to compensate for the Veterans' cognitive limitations. Communication skills training (CST) in CBCT and SAT assumes intact cognitive functioning in emotion recognition and processing, whereas CST in MFG-mTBI-C starts by developing strategies to assess and compensate for deficits in emotion processing as a prerequisite to learning more advanced skills: The unique challenges that Veterans with a history of mTBI confront in developing skills to communicate with their spouses/partners underscores the need for couples' interventions addressing the specific rehabilitation needs of these Veterans. The proposed research aims to fill this critical gap in research on interventions targeting Community Integration among OEF/OIF/Persian Gulf Veterans with a history of mTBI and their families. Finally, in addition to promoting community integration, if effective, this intervention could help stem the tide of intimate partner violence, hazardous drinking and divorce that is threatening this country's Veterans and their families.

3.0 Objectives

The proposed RCT evaluates a novel form of multi-family group treatment designed to improve community integration (CI) among married/cohabiting OEF/OIF/Persian Gulf Veterans with mTBI, a diagnosis of PTSD, and/or moderate-severe PTS or CS by training spouse/partners to aid with rehabilitation and training both partners to use disability-adapted communication and problem-solving skills to reduce marital conflict and improve marital satisfaction. This intervention, Multifamily Group for Veterans with mTBI for couples (MFG-mTBI-C) builds on an evidence-based treatment for SMI (McFarlane, 2002) by incorporating training on compensatory strategies for cognitive deficits and communication training into the basic problem-solving model. Our specific aims are:

Primary Aims:

1. To evaluate the efficacy of MFG-mTBI-C in improving community integration *(primary outcome)*, and interpersonal skills, i.e., anger management, use of social support *(secondary outcomes*) among OEF/OIF/Persian Gulf Veterans with mTBI relative to improvements observed among Veterans participating in a health education group with their partners.

2. To evaluate the efficacy of MFG-mTBI-C in reducing caregiver burden (*primary caregiver outcome)* among the spouses/partners of OEF/OIF/Persian Gulf Veterans with mTBI relative to improvements observed for spouses/partners participating in a health education group with the Veteran.

Secondary and Exploratory Aims:

3. To evaluate the role of gains in Veteran marital satisfaction and emotion regulation and interpersonal skills in mediating improvement in community integration for Veterans participating in MFG-mTBI vs, those participating in a health education group with their partners.

4. To evaluate the role of neurocognitive functioning in moderating improvement in community integration for Veterans participating in MFG-mTBI vs, those participating in a health education group for with their partners.

5. To evaluate the efficacy of MFG-mTBI-C in reducing PTSD and depressive symptoms relative to reductions observed among Veterans participating in a health education group with their partners.

6. To evaluate comparisons between mTBI + PTSD/CS and PTSD/CS 'only' samples,

5.0 Study Procedures

5.1 Study Design

Overview:150 Veterans with a positive DVBIC screen for deployment-related mTBI sustained during the OEF/OIF/Persian Gulf eras confirmed by Parts A-C of the VA TBI Identification Clinical Interview (Vanderploeg et al, 2012), with reported loss of consciousness < 30 minutes or *if* they *either* meet diagnostic criteria for PTSD based on the Mini International Neuropsychiatric Interview (MINI) *or* have trauma- or combat-related stress (CS) of at least *moderate* severity, as defined by either a_ PTSD Checklist (PCL) score >34 (Kimerling, 2009) or Combat Exposure Scale (CES) score >23 (Keane et al., 1989), a consenting spouse/cohabiting partner and a Montreal Cognitive Assessment (MoCA) (Nasreddine, 2005) score ≥ 19 will be randomized to receive either: 1) six months (12 bi-monthly sessions) of MFG- mTBI-C, a psychoeducational rehabilitation and skills-building intervention after 2-3 individual couples "Joining" sessions; or 2) six months (12 bimonthly sessions) of Group Health Education (GHE), a structured didactic intervention delivering information and general recommendations to address health problems common in the OEF/OIF/Persian Gulft cohort. Participants will be assessed pre-treatment, immediately post-treatment, and 6 months post-treatment. A Diversity Committee will ensure representative ethnic/racial enrollment and cultural competence. The Diversity Committee will be chaired by Dr. Lisa Dixon and will additionally comprise a member from each site with expertise in ethnicity/racial issues, including treatment, recruitment and retention in clinical research (Dr. Shirley Glynn, JJP VAMC and Dr. Patricia Ryan, VAMHCS). Prior to enrollment, the committee will help each site develop a diversity recruitment plan, individualized to the local catchment area, participating facilities and support groups. Weekly coordinator calls throughout the study will include a discussion of ethnic minority enrollment rates for each site. A committee member will attend a call monthly to review enrollment, retention and develop enhanced outreach strategies if goals are not being met.
Data will be analyzed using an intent-to treat analysis with paired comparisons between treatment groups on primary (Veteran community integration) and secondary (Veteran interpersonal skills, marital adjustment, caregiver burden) outcome variables using mixed effects regression models. The study research tasks and our timeline to achieve them are presented in ***Table 4*** below.

Table 4: Timeline of Research Tasks

Months	Research Task
0-5	Refine manual, develop adherence scale for control condition, Train educators and research assistants, IRB submission, approval
4-5	Specify procedures for random assignment; blinding assessors, develop databases, refine recruitment procedures with study and facility staff

5-38	Enroll and study 150 cases (75 treatment, 75 control); Follow-up assessments
39-44	Complete follow-up on last cohorts' cases for 6 months
44-48	Analyze, disseminate data

Tempo: In order to study 14 groups of 3-5 couples each (7 treatment, 7 control) per VISN (3 and 5), each VISN will begin recruitment and individual sessions for two groups, one treatment, one control in study month 5, and continue to enroll and initiate treatment for two additional groups, one in each study condition, every 4-5 months until all groups have been completed and followed, in study month 44. This design will in most cases avoid a long wait for participants between randomization and starting treatment. In cases where one treatment condition becomes "filled", in order to avoid long delays and possible attrition before starting treatment, and permit both interventions to be conducted in tandem, we will allow groups with as many as 8 and as few as 3 couples. The protocol also permits an additional "Joining" session to keep early enrolled couples engaged while later-enrolled couples are being assessed and 'joined". In terms of workload, although there will be overlap between groups, the more labor-intensive work of recruiting, consenting and meeting with individual couples will overlap with the less intensive bi-monthly group meetings for the previously-enrolled two groups and will therefore be feasible**.**

Assessment*:* Participants will be assessed pre- and post-treatment and 6 months post-treatment ***(Table 5 below***). Partners will be assessed within 2 weeks of the corresponding Veteran assessment. Assessors will be trained to reliably administer all clinical instruments, using the PI, a psychologist or psychiatrist experienced with these measures, as a 'gold standard.' Dr. Patricia Ryan, neuropsychologist based at the VAMHCS's, will establish reliability on the VA TBI Identification Clinical Interview through independent ratings of 10 interviews and will then supervise the RA at their site on administration and scoring of this interview and other neurocognitive measures on a weekly basis. An *Assessment Committee* comprised of Drs. Drapalski, and Ryan will meet bi-weekly to plan and implement training, monitor reliability via periodic checks, and implement corrective procedures as needed.

Table 5: Veteran and Partner Assessment

Veteran Assessment	Pre-treatment	Post-treatment	6-month
Community Integration			
Sydney Psychosocial Reintegration Scale and CRIS-CAT*	X	X	X
Emotion Regulation/Interpersonal Skills			
DERS (emotion regulation)	X	X	X
Duke Social Support Scale (use of supports)	X	X	X
Health Behavior	X	X	X
CES-D-10 (depression) [a]	X	X	X
PCL-M (PTSD) Checklist [a]	X	X	X
Combat Exposure Scale [a]	X		
PROMIS-PI (pain)	X	X	X
ISI (insomnia)			
Service Use Checklist [a]	X	X	X
Addiction Severity Index [a]	X	X	X
Memory Compensation Questionnaire [a]	X	X	X
BSI Anxiety subscale	X	X	X
MINI (Axis I Disorders)	X	X	X

Life Satisfaction Scale	X	X	X
Health Risk Behavior Scale	X	X	X
Neuropsychological			
Rey Auditory Verbal Learning test *	X	X	X
Trail Making Test A,B *	X	X	X
MASC (theory of mind)	X	X	X
Couples Functioning			
Dyadic Adjustment Scale*	X	X	X
IRI	X	X	X
CPQ	X	X	X
PACT (coping flexibility)	X	X	X
Post Traumatic Growth Inventory – Short Form	X	X	X
CARE (relationship skills)	X	X	X
Spouse/Partner Assessment			
Emotion Regulation/Interpersonal Skills			
DERS (emotion regulation)	X	X	X
Duke Social Support Scale (use of supports)	X	X	X
Neuropsychological			
MASC	X	X	X
Caregiver Burden/Health	X	X	X
Caregiver Burden Inventory			
CES-D-10 (depression) [a]	X	X	X
PCL-C (trauma)			
ISI (insomnia)	X	X	X
SF-8 (health) [a]	X	X	X
Service Use Checklist [a]	X	X	X
BSI Anxiety subscale	X	X	X
MINI (Axis I Disorders)	X	X	X
Life Satisfaction Scale	X	X	X
Health Risk Behavior Scale	X	X	X
Couples Functioning			
Dyadic Adjustment Scale	X	X	X
IRI	X	X	X
CPQ	X	X	X
PACT (coping flexibility)	X	X	X
Post Traumatic Growth Inventory – Short Form	X	X	X
CARE (relationship skills)	X	X	X

Bolded measure indicates primary outcome measure. [a] covariate in model * NINDS core test for TBI. Screening measures are described under 2avi above.

*Subject to re-administration (Veteran only) before start of groups to control for any changes that may occur during a particularly long interim between baseline assessment and start of the group.

We have organized the assessment schedule to correspond to our conceptual and measurement models, leading with the primary study outcome, Veteran community integration, followed by measures of the secondary Veteran outcome, emotion regulation and interpersonal skills, measures of potential covariates, i.e., measures of mental health and health behavior, and measures of Veteran neuropsychological functioning hypothesized to moderate outcomes. We have followed the same organization for caregivers, ending with our measure of couples functioning, hypothesized to mediate improvement community integration

Intervention Testing Procedures-Randomization and Maintaining Blind: Following informed consent enrollment, couples will be randomized to one of two treatment conditions (75 to each condition) within each VISN: 1) MFG-mTBI-C, or 2) GHE. To maximize adherence to intervention protocol and avoid inadvertent cross-contamination, each of the two educators at each site will conduct only one intervention, either MFG-mTBI-C or GHE. We will take precautions to ensure the RA's performing outcome assessments and other relevant persons are blind to study condition: 1.Subjects will be randomized to treatment condition using Proc Plan in SAS by an independent research staff member from another project who will place treatment assignments in separate envelopes according to the randomization sequence. To avoid recruitment and/or assessment bias, envelopes will be opened by the independent researcher after informed consent procedures in sequence, and assigned participants will be given a new # according to the randomization schedule; 2.The list linking participant code with treatment assignment will be maintained in a locked cabinet by the PI (who will not perform assessments) and by the study biostatistician (who is in a different location); 3. RA's performing assessments will be blind to educator assignment to treatment condition and will additionally be unaware that each educator is delivering only one treatment. 4. To make # 3 plausible, all educators (and other research staff) will participate in the initial training for both treatments. 5. The PIs will convey new assignments to the appropriate educator who will initiate contact to schedule Joining sessions. 6. All educators will deliver both treatments in closed rooms; 7.The rooms will be equipped identically, with a digital tape recorder; 8.The number and length of sessions will be standardized across conditions; 9. Both MFG-mTBI-C and GHE sessions will be recorded for adherence monitoring so that all participants will have identical files; 10. All data pertaining to session material (e.g., treatment notes) will be stored by educators in a locked or password-protected file separate from that used for assessment data; RA's will not have access to the session files. 11. Participants will be trained not to discuss study procedures except with their study educator or the PI, and study staff (educators and RA's) will only discuss study procedures and assignments with the PI or during supervision. 12. Veterans' VA clinicians will be blind to their treatment assignment; 13. Prior to data analysis, the biostatistician will add an electronic field for treatment group to the data base and the data analyst will be trained not to link assignment with ID code. Thus although RA's will be able to link participant names with ID codes needed for labeling and entering data, etc., they will be blind to treatment assignment using the above measures.

Treatment*:* Multi-Family Group for mTBI (MFG-mTBI-C) consists of three sequential phases: 1) "Joining" in which the educator meets with each individual family for 2-3 sessions to evaluate ongoing problems and define treatment goals; 2) An Educational Workshop which provides information about TBI to all Veterans and families; 3) bi-monthly multifamily group meetings for 6 months (12 sessions) which provide a structured format for building problem-solving and communication skills. The educator joining with each couple also leads the group. The first two phases take approximately 2 months, for a total of 8 months of intervention. The group sessions consist of 3 components: (1) A brief (15-minute) period for socialization, unwinding and "small talk"; after 15 minutes the educator starts the "Go Round" (2) in which each couple relate briefly how the past two weeks have gone for them, including follow-up on homework or problem-solving recommendations. The educators take this opportunity to amend plans which have not been successful, offering a modification of the original or an alternative solution. Based on the Go Round, a problem or goal is selected for the current week's group exercise. Thirty-five minutes are allotted to the Go Round, including problem selection. (3) The educators then lead the group in formal problem solving, using a six step process based on brainstorming methods from organizational and business practices. Approximately thirty-five minutes are allowed to complete this process, specified below. The proceedings should be recorded on a whiteboard, to facilitate group participation and record the results.

Step 1. Define the problem or goal. (MFG members & educators);

Step 2. List all possible solutions. (All MFG members);

Step 3. Discuss advantages and disadvantages of each in turn. MFG members & educators);

Step 4. Choose the solution that best fits the situation. (Family);

Step 5. Plan how to carry out this solution. (Family & educators); and

Step 6. Review implementation. (Educators).

After the problem-solving exercise, 5 minutes are reserved for a wind-down before ending. This treatment approach differs from those that deliver information or skills in a planned sequence. Instead problems with reintegration are addressed as they occur in the course of participants' daily lives. Solutions to real time problems are generated both by the group and by the educators, drawing on their knowledge of general problem-solving and compensatory strategies keyed to specific deficits, using the rehabilitation specialists (Drs. Klingbeil and Ryan) as consultants. The solution is then implemented as homework, with assistance from the caregiver and reviewed in the next session. This approach has the advantage of ecological validity, a key aspect of rehabilitation often lacking in more formulaic interventions (Cicerone et al., 2006). To accommodate difficult schedules that often include work, school, and/or childcare, we offer participants to call-in to groups from a private space, such as a bedroom or private office, to maintain confidentiality.

Figure 3 below describes our hypothesized model of the how participation in MFG-mTBI-C leads to improved rehabilitation outcomes both directly, and indirectly through the effects of MFG-mTBI-C on couples coping and Veteran emotion regulation and interpersonal skills. We describe below four core components of MFG-mTBI-C that are hypothesized to enable the couple to begin to reverse the multiple, adverse sequelae of combat-induced mTBI described in ***Figure 1*** and present selected research supporting the hypothesized direct and/or indirect paths.

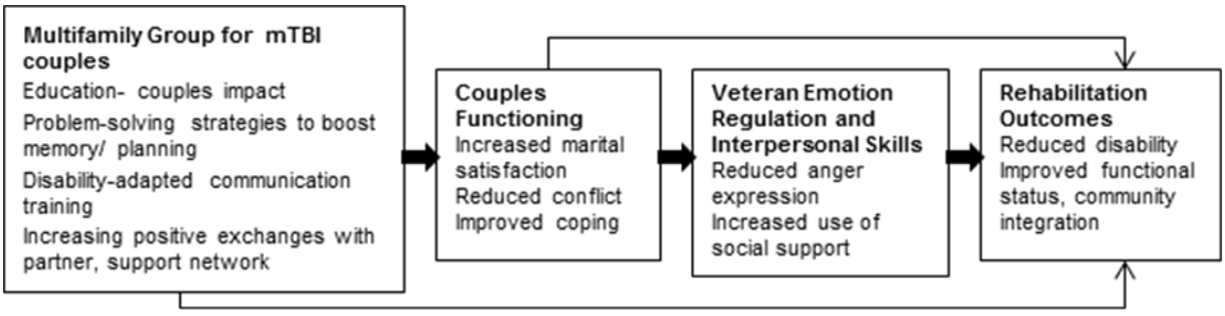

Figure 3: Hypothesized Direct and Indirect Effects of Multifamily Group Treatment for Veterans with mild Traumatic Brain Injury on Couples Functioning, Veteran Social Behavior and Rehabilitation outcomes

Education: Seeking and receiving disorder-specific information and coping/management strategies helps to reduce family stress and anxiety, and family stress has been associated with patient quality of life and health in dementia, and is anticipated to have similar effects for families of Veterans with polytrauma (Griffin et al., 2009). Our work to date indicates that education about mTBI and its impact on the Veteran and the family also alters the couples' shared understanding about the cause of illness-related behaviors that spouses in particular may have previously attributed to negative, personal traits of the Veteran. For example, gaining

an appreciation of the Veteran's memory and organizational deficits may cause his spouse to alter her belief that the Veteran's forgetting to pick up the children is due to careless, inconsiderate behavior, attributing it instead to his mTBI and leading to reduced spousal criticism and arguments. With this education-induced attributional shift, the spouse is able to be more supportive and the couple can renegotiate their child care arrangements or work out a reminder system. As one male partner put it, "It takes patience, and the more educated we get the more patient we are". Education also alters caregivers' emotional appraisal and beliefs, which in turn impact their relatives' clinical outcomes (Griffin et al., 2009).

Social support: Social support from other military couples is hypothesized to help normalize the life stressors and marital tensions that OEF/OIF/Persian Gulf couples experience through a cognitive reframing that attributes these stressors/tensions to external, i.e. post-deployment strains that other couples share. Negative emotional states such as depression, present among both Veterans and spouses, have been associated with a tendency to make more person vs. situational attributions for behavior, (i.e. blaming the other person) among couples (Tashiro & Frazier, 2007), a potential explanation for the high rates of conflict among OEF/OIF/Persian Gulf couples. Social support, which has been repeatedly demonstrated to have a buffering effect on depression, may foster a more positive emotional climate that enables cognitive reframing to occur. Becoming aware that other couples are experiencing the same relationship strains is enormously relieving and reassuring to both members. As one partner put it, "Just the fact that there are other couples here helped, just to know that I'm not the only one." The presence of other Veterans in the room appears to be a critical component enabling Veterans to begin to share with their spouses what they had not felt able to share previously. As one Veteran put it, "One of the comforting things is being a Veteran and knowing that person's a Veteran… you know they are not judging you at all, because they've been there." Social support may also promote greater acceptance of mTBI and associated challenges for couples; acceptance has been described as a critical component in couples interventions, including couples with PTSD (Erbes et al. 2008). In one study of mTBI, initial level of social support predicted consumer outcomes 8 years post-injury (Luis et al., 2003).

Problem-solving*:* MFG-mTBI-C provides, and models, group problem-solving focused on learning how to navigate around a deficit with minimal friction for both partners. This problem-solving approach is consistent with the approach employed in a number of interventions for TBI focusing on problem solving, reviewed by Cicerone et al., 2006. Specific solutions introduce strategies targeting specific deficits. For example, to address a Veteran's problem identified as "Remember to order prescription refills," the group generated a solution including the following items: (1) use multiple reminders, such as a white board, (2) use the "snooze" or "later" option when dismissing PDA reminders, and (3) use a pillbox. In a subsequent session, the Veteran reported no longer dismissing PDA reminders and using the whiteboard for other reminders. The educators are trained to define problems as concrete intervention targets that are attainable. Success or even partial success in compensating for a deficit can begin to alter both primary and secondary appraisal: stress-generating problems are now viewed as potentially manageable and participants gain increased confidence in their ability to learn to manage the stressful situations they confront on a daily basis—both related to the Veterans' TBI, and/or stressful life events. This shift in appraisal helps to reduce marital conflict relating to problems that were formerly appraised as unsolvable.

Skills building-disability-adapted communication training*:* Emotion recognition in TBI has been studied only relatively recently, yet family complaints that the Veteran is "not the same", relating to feeling a lack of affective connection are common and can lead to marital dissatisfaction and/or divorce (Halbauer et al., 2009; Burridge et al., 2011). A novel contribution

of this study is the modification of standard Communication Training skills, commonly employed in behavioral family or couples interventions (e.g. Behavioral Family Therapy, Mueser & Glynn, 1999) to address potential impairment in emotion processing that may lead to miscommunications and arguments as well as to lack of positive behavioral exchanges and reduced intimacy. Strategies will be tailored to the particular couple, but will typically include one or more of the following tasks for the couple: 1) perform basic exercise, e.g. give positive feedback with/without appropriate nonverbal cues (vocal inflection, facial expression, eye contact) and describe the impact of the received message under each condition; 2) role-play/replay a recent dispute stopping after each meaningful phrase(s)(as directed by educator) so that each member can recount his/her understanding of both the spoken and intended message, and the emotion communicated. The other member then validates or corrects his/her partner's perceptions; 3) if these exercises are judged to be too difficult, i.e., without observable improvement over several trials, more basic techniques such as those described in Bornhofen & McDonald (2008) will be used, e.g. practice on tasks decoding emotional stimuli (photos, voice cuts) and rehearsal of different modes of expression using a mirror and role-playing to increase appropriate responding. Strategies chosen will be based on neuropsychological test performance and clinical judgment. It should be noted that information is lacking about the prevalence or severity of emotion processing deficits in OEF/OIF/Persian Gulf Veterans with mTBI, nor is it known if these problems contribute to marital conflict or dissatisfaction in this cohort. However, even where specific deficits in emotion expression are not observed, deficits in speed of processing or memory may result in miscommunication and frustration among OEF/OIF/Persian Gulf couples where the Veteran has an mTBI. The proposed research represents an opportunity to examine potential emotion processing deficits in mTBI in relation to marital adjustment.

Impact of Couples Functioning on Veteran Emotion Regulation, Interpersonal Skills and Community Integration: A recent study found that 42% of Veterans report marital problems persisting 3 years after homecoming (Sayers et al., 2010) and chronic stress has been found to erode social support (Kaniasky & Norris, 1993). Studies of family functioning after TBI have found that more effective family coping was associated with better ability to regulate mood and other indices of emotional distress among survivors (Leach et al., 1994; Kreutzer et al., 1992). Finally couples functioning has been found to directly impact both Veteran Community Integration both directly (Cifu et al., 2007, Wehman et al., 2009; Griffin et al., 2009) and indirectly, through the impact on Veteran functioning.

Comparison Condition: Group Health Education: The Group Health Education (GHE) condition is a 14-session, highly structured educational intervention providing general information on health problems that are common among the general OEF/OIF/Persian Gulf cohort including sleep and sleep problems, physical activity and exercise, and alcohol and drug use, as well as general guidelines for improving health behavior in these areas. ***Areas of focus in MFG-mTBI-C such as coping with Veterans' memory problems or couples and family readjustment issues are explicitly not addressed in GHE.*** Each session follows the same structure, beginning with a presentation of the objectives for the current session and a brief review of material from the previous session before introducing the session's topic and presenting information on two to six major points. In order to limit opportunities for group interaction and development of group cohesion, GHE utilizes a traditional didactic model with information delivered by the educator in a classroom or lecture setting (where all chairs face the educator), where the information provided is general and broad-based rather than focused on individual participants' concerns. To avoid overlap with MFG problem-solving skills training, individual health problems will not be discussed: participants will be referred to their provider or supplied with a referral as needed. By contrast, MFG-mTBI-C delivers skills training in a round-

table setting where all group members are encouraged to join in problem-solving exercises, the educator's approach is collaborative and materials are drawn from the everyday problems brought in by members, designed to foster group cohesion and support. Consistent with an educational model, handouts summarizing session material are provided in GHE-C but homework is assigned only in MFG-mTBI-C, as an integral feature of skills training and of our adaptation of multifamily group for mTBI where rehearsal and repetition are critical components of skills acquisition. ***Table 6*** shows the key structural-conceptual differences between conditions, while ***Table 7*** summarizes the overall structure of the two conditions, including the different phases, components and basic material delivered in each intervention. ***Table 7*** demonstrates the 2 conditions are identical in # sessions and overall structure (multifamily group sessions following individual couples "Joining" sessions), but differ in treatment strategies (skills training vs. general education without reference to or problem-solving about participants' individual health concerns/behavior. As with MFG-mTBI-C, the educator joining with the couple is also the group leader. To accommodate difficult schedules that often include work, school, and/or childcare, we offer participants to call-in to groups from a private space, such as a bedroom or private office, to maintain confidentiality.

Table 6: Comparison of MFG-mTBI-C and Control Treatment (GHE)

Treatment Component	MFG-mTBI-C	GHE (Control)
Therapeutic Strategy	Skills training	Information only
Contents	Compensation for TBI-related deficits in emotion processing, memory/planning	Building a healthy lifestyle
Target Group	OEF/OIF/Persian Gulf Veterans with TBI/partners	All OEF/OIF/Persian Gulf Veterans/partners
Use of Group Dynamics/ Cohesion	*Social support promoted*: Entire group participates in problem-solving for each couple and gives support and encouragement	*Social support minimized:* Because individual health issues are not discussed, education is general and group interaction minimized
Therapeutic Stance	Educator stance is collaborative	Educator stance is didactic
Room Set-up	Round table	Lecture style (all chairs face forward)
Source of Material	Drawn from everyday problems brought in by group members	Supplied by educator
Homework	Assigned and reviewed and the start of the following session	Handouts but not homework provided

Table 7: Comparison of MFG-mTBI-C and Control Treatment (GHE)

Treatment Component	MFG-mTBI-C	# sessions	GHE (Control)	# sessions
Joining	*Couples-tailored Education*:* Normalization of couples conflict, misattribution of TBI deficits corrected. *Skills Training*: Recommend 1+ compensatory strategies, basic communication training exercise. *Formulation* of problems in coping & communication patterns	2(3)**	*Standard Couples Intake:* History of Veteran, partner and couple, focusing on current health, activities, sleep patterns, diet, medications and other health behaviors. No skills training, cognitive interventions or formulation of couples' functioning.	2(3)**
Multifamily Group Sessions	*Educational Workshop:* TBI: pathogenesis, behavioral sequelae, comorbidities, treatment, prognosis and family impact. Structure and function of multifamily group, how it can help.	2	*Health Education Introduction:* Structure and rationale for intervention. Rules of conduct. Overview of topics to be covered.	1
	Problem-solving Sessions: Skills training: Problem-solving designed to address specific problems associated with mTBI. Compensatory strategies for memory problems, planning. Disability-adapted communication training.	12	*Group Health Education:* Information provided to promote healthy living in areas relevant for Veterans and partners (sleep hygiene, nutrition, use of alcohol, drugs, safe exercise). Personal health concerns not discussed-referred to provider.	13
Total		16		16

*In addition to basic intake. **The default is 2 sessions, an optional 3rd session may be used to maintain contact with group members recruited early, or where the couple are uncertain about continued participation.

Participant Retention and Tracking Strategies: Although as noted above retention in our pilot study was good, with 92% of Veterans who started treatment completing it, retention may be more challenging in a larger study. Our retention plan has 3 core components: educator outreach, systematic tracking/follow-up and routine intersession outreach. ***Educator outreach:*** We have allocated 25% of educator effort to the more 'clinical' aspects of retention at each site during the 36 months of treatment/follow-up, including calling participants who miss a meeting, problem-solving barriers to participation, use of motivational enhancement strategies. To equip educators with skills to promote participation our initial training and supervision will focus on promoting working alliance, group cohesion and motivational enhancement/problem-solving. Telephone motivational interviewing enhanced engagement in mental health treatment (Seal et al, 2012) and may help with continuation as well. ***Systematic tracking:*** 1) At consent, participants will complete a locator form authorizing staff to contact them at their preferred address and telephone number(s) and to send email alerts through the VA's MyHealtheVet portal, the only approved vehicle for email correspondence between Veterans and VA staff. We will also request that participants provide information for a third party (staff, friend or family) who can be contacted if we are unable to reach them directly. Attendance at group and assessment

sessions will be monitored through a password-protected Access database developed for tracking participants during the DoD-funded open trial of MFG-TBI which provided pilot data for the proposed research. This data base includes fields for noting attendance at up to 20 joining and group couples' sessions and follow-up assessments, and drop-down menus for specifying reasons for missed sessions and dates/type of effort made to contact participants. It is programmed to generate weekly reports relevant to each phase of study. For the treatment phase, the site RA's will generate reports specifying the number of active groups, and for each group, # of sessions completed, # active couples and the ID of any couples whose attendance record falls below a pre-determined threshold or who missed the last session, to be reviewed with the Project Director at a weekly cross-site meeting. This method will permit rapid identification of couples with missed group or assessment visits and ensure and evaluate the impact of follow-up procedures in time for additional strategies to be applied if warranted (e.g., individual couples session, meeting with PI, or with a Veteran or partner 'alumna' volunteer, as suggested by pilot study participants). To maintain the blind, the reports and discussions will avoid reference to treatment assignment. Use of similar methods in prior studies has enabled us to effectively track the overall progress of the study as well as identify and address emerging problems with individual participants. In an RCT for caregivers of both Veterans and non-Veterans with bipolar disorder, 93% of caregivers *randomized* completed the 12-15 session trial. Retention rates for *follow-up assessments* were 93% for the caregiver and 89% for his/her relative immediately post-treatment, and 89% and 85% for the caregiver and relative, respectively, at the six-month follow-up. In a multi-site interview study, 426 or 85% of 500 family members enrolled completed a 12-month assessment. ***Intersession Outreach****:* Based on recommendations of Veterans and partners in our pilot study, we plan to incorporate more contact with group members between group meetings. This will include posting homework and reminders for group meetings securely through the VA's MyHealtheVet portal. Because the MFG meets bi-monthly, maintaining continuity between meetings may be particularly important for promoting retention.

Training of Educators: Intervention training, supervision and adherence and competence monitoring of the MFG-mTBI-C and GHE interventions will be the focus of the Treatment Committee (Drs. Glynn, Dyck, and Drapalski), which will meet bi-monthly to ensure the integrity and consistency of psychosocial protocols across sites, including monitoring the comparability of Treatment Competence and Adherence Scales (TCAS) ratings across sites and introducing additional training and supervision if ratings fall short of standards. The training protocol for new educators will include reading the manuals, a 2-day in-person training session led by Drs. Perlick, Glynn, Dyck, Dixon and Taber in New York, and weekly, individual site supervision on the first two groups conducted by Drs. Perlick and Glynn or Drapalski. All MFG-mTBI-C educators will be masters' or doctoral level and have experience with OEF/OIF Veterans and families. Educators must achieve average TCAS ratings of "2" or good adherence or above on all sessions from two groups before working independently as an educator. This training protocol is consistent with that used in large-scale intervention studies. Educators who have met this criterion will participate in weekly group supervisory phone supervision across sites conducted by Dr. Drapalski, as well as a monthly consultation with Dr. Glynn or Dr. Dyck focused on complex cases.

Treatment Competence and Adherence Scale (TCAS). Two aspects of each session are rated: educator adherence to the prescribed treatment interventions, and educator competence, which encompasses attributes/skills such as empathy and warmth. Adherence includes omission of proscribed interventions, such as use of problem-solving or other skills-based interventions within the GHE condition.

Cross-Site Fidelity Monitoring of Educators. In Stage I of fidelity monitoring, the most experienced raters, Drs. Glynn or Drapalski will rate every fourth MFG-mTBI-C session, for each of the first two groups at each site using the TCAS scale (5 ratings on each of 4 groups=20 tapes) to establish inter-rater reliability. They will also rate the first GHE session and two additional randomly selected sessions for the first two GHE groups at each site, to establish inter-rater reliability. In Stage II of monitoring, (i.e. after the educators have established good adherence and reliability with our expert raters), study educators will rate two randomly selected sessions from each of the 5 subsequent MFG and 5 GHE groups at each site, with each educator rating sessions from the other site (i.e., the JJP educator will rate VAMHCS sessions and vice versa). In cases where a rater observes significant departures from the MFG-mTBI-C or GHE protocols, he/she will inform Dr. Drapalski and the Treatment Committee. Intraclass correlations between TCAS raters will be computed at the end of years 2 and 3 on at least 10 tapes per year.

5.2 Recruitment Methods

Veteran participants (n=150) will be identified in one of two ways. Study staff will work closely with the clinics and programs within the site hospitals (JJP VAMC, VANYHHS, VAMHCS, DCVAMC), such as poly trauma, PTSD and mental health clinics, primary care, caregiver support programs, OEF/OIF/OND services, and other relevant clinics. Potential participants will be identified based on deployment history to Iraq/Afghanistan, a positive DVBIC screen or if they either meet diagnostic criteria for PTSD or have trauma- or CS of at least *moderate* severity, and cohabitation with a spouse/partner. Clinicians will then discuss study participation with identified study candidates during a routine clinical visit. Clinicians who obtain verbal consent from Veterans during a routine clinical visit may contact research staff by page to effect an in-person introduction if the clinician and the Veteran agree to this method. As an alternate method, for Veterans who agree to be contacted by the study team, the clinician will hand deliver identifying and preferred contact information to approved research staff. Research staff will then attempt to contact the Veteran using his/her preferred phone number. Veterans will also be recruited within the site hospitals via study fliers and study pocket cards posted/distributed around the site hospitals. Veterans who initiate contact do not need clinician approval but study staff will contact the Veteran's provider with his/her consent to ensure participation would not compromise healthcare. In addition, we will conduct community outreach efforts to Vet Centers, local universities and colleges, and local Community Based Outpatient Centers (e.g., White Plains CBOC), which we will visit in-person to present the study and to supply the relevant contacts persons our study fliers/pocket cards to distribute to potential candidates. All referrals made from non-VA settings will have to be enrolled at VA; otherwise, we will not consider them as eligible participants. No referrals will be made via email. All Veterans referred who express interest in the study will be asked for consent to invite their spouse or partner to participate in an information session about the study. The spouses or partners of consenting Veterans will be approached in one of two ways: 1) the Veteran may either describe the study to their spouse/partner with the assistance of the IRB-approved flier (attached as a supplement), or, 2) if the Veteran prefers, an appointment can be made for the research staff to contact the Veteran and his/her spouse/partner at a convenient time during which the staff member will describe the study and determine interest in participation. The pilot study's initial protocol left the full responsibility of describing the study to the caregiver to the Veteran. However, we discovered that using this method Veterans reported difficulty and/or burden due to the cognitive limitations and disabilities associated with mTBI. The Veterans expressed a preference for the research staff to describe the study in a consultation with their spouse partner. Based on this feedback, we amended our IRB protocol in the pilot study to allow study staff to describe the study to the spouse/partner and the Veteran in an information session at the couple's convenience. We therefore propose to provide Veterans with the two

aforementioned options. There will be no cold-calling. Any calls will be approved by the Veteran for a time where he/she and/or the spouse/partner can be present. This procedure will be followed in order of referral until the target number of cases have been consented and enrolled. Pooling data from 2010 OEF/OIF intake in VISN 2 South and the current poly-trauma clinic census in VISN 5, the estimated ethnic/racial breakdown of the study sample is 53% Caucasian, 30% African American, 15% Hispanic and 2% Asian/Pacific Islander. The Diversity Committee will recommend and help implement novel recruitment and outreach strategies to ensure overall diversity and increase the numbers of Hispanic Veterans and families seen, in particular. Participants will each be paid $45 each time they complete an assessment (pre-treatment, post-treatment, and 6 months post-treatment).

5.3 Informed Consent Procedures

Consent will be obtained at the mental health clinic of the three participating sites after the clinician and the participant have agreed to participate in the research study. After a Veteran has indicated their willingness to participate in the study, he or she will be shown the informed consent form. The reason for obtaining audio/video recording will be explained, i.e., to assure that group facilitators follow correct procedures as judged by more junior facilitators who will listen to randomly selected session tapes and give feedback to facilitators. It will be emphasized that the focus of this exercise is to ensure appropriate conduct of the facilitators and that the participants' PHI will remain anonymous. Tapes will be promptly uploaded as a secure computer file, transcribed, and then the digital record will be erased Digital recording devices will be transferred across study sites via a secure carrier with a chain of custody, i.e. FedEx. Recordings will always be encrypted. The forms will be explained, and the individual will be encouraged to ask questions if anything is not clear. The individual will then be given a brief quiz about the nature of the study (to be forwarded as an appendix). This process will be reiterated until the individual answers all questions on the quiz correctly, and then he or she will be asked to sign the consent form and HIPAA authorization. Veterans will be excluded if they do not understand the study, or cannot answer all questions correctly on the quiz. The quiz will include questions that will assess whether the Veteran understands that his/her partner will attend the multifamily group. The research assistant will then seek permission to contact the Veteran's partner. After the Veteran gives informed consent and permission to contact his/her partner, we shall first screen them to determine eligibility. Once eligibility has been confirmed, the RA will contact the partner by telephone to describe the project, answer questions, and invite them to meet with him/her to explain the study.

The initial interview will begin with the interested partner, to describe the project, and to determine whether the partner meets study criteria of primary caregiver. We shall use a self-rating scale that asks about frequency of contact, involvement and care-giving responsibility for this purpose. Informed consent will then be sought from this person as well as consent for use of picture and/or voice. He or she will be shown the informed consent form. The reason for obtaining audio/video recording will be explained, i.e., to ensure that group facilitators follow correct procedures as judged by more junior facilitators who will listen to randomly selected session tapes and give feedback to facilitators. It will be emphasized that the focus of this exercise is to ensure appropriate conduct of the facilitators and that the participants' PHI will remain anonymous. Tapes will be promptly uploaded as a secure computer file, transcribed, and then the digital record will be erased Digital recording devices will be transferred across study sites via a secure carrier with a chain of custody, i.e. FedEx. Recordings will always be encrypted. All eligible participants may take as much time as needed to discuss the study with study staff, to review and discuss the consent, and to decide whether or not to participate. All members of the study staff who conduct informed consent interviews will have received appropriate training in administering the informed consent protocol. The training will emphasize

that exculpatory language is not to be used. The individuals communicating information to the participant or the legally authorized representative during the consent process will provide that information in language understandable to the participant or the representative. Given possible cognitive impairments in this population, the research staff will use proven informed consent procedures. Specifically, after a Veteran has indicated willingness to participate in the study, the Veteran will be shown the informed consent form. The form will be explained, and the Veteran will be encouraged to ask questions if anything is not clear. The Veteran will then be given a brief quiz about the nature of the study. This process will be reiterated until the Veteran answers all questions on the quiz correctly and only then will the Veteran be asked to sign the consent form. Veterans will be excluded if they do not understand the study, or cannot answer all questions correctly on the quiz.

All study procedures, including consent, assessments, and intervention procedures may now be performed at the performance sites' affiliated CBOCs, in the Veteran's home, or in a neutral location, e.g., at a school library.

5.4 Inclusion/Exclusion Criteria

Inclusion criteria-Veterans: Eligible Veterans must have a diagnosis of mTBI in accordance with the VA/DoD Clinical Practice Guideline for Management of Concussion/Mild Traumatic Brain Injury: injury or concussion associated with at least one of the following: brief (< 30 minutes) loss of consciousness or altered state of consciousness or post-traumatic amnesia for < 24 hours following the injury, or they *either* meet diagnostic criteria for PTSD based on the MINI *or* have trauma- or CS of at least *moderate* severity, as defined by either: a) PCL score >34; or b) CES score of >23. Although mTBI-related referrals will be based on a positive DVBIC screen, the diagnosis must be confirmed by Parts A-C of the VA TBI Identification Clinical Interview (Vanderploeg et al., 2012). The TBI must be either blast-related or attributable to another discrete event (e.g., fall, fight, injury) sustained during deployment in the OEF/OIF or Persian Gulf War eras. Post-concussive symptoms (e.g., sleep or memory problems, headache) must not be attributable to a subsequent injury or other pre-existing or concurrent neurologic disorder: Veterans with pre-existing or concurrent neurologic conditions (head trauma, seizures, strokes, neurosurgery, other neurologic impairments based on medical record or self-report) will be excluded. Eligible Veterans must also have a consenting, qualifying spouse/cohabiting partner and a Montreal Cognitive Assessment (MoCA) (Nasreddine,2005) score ≥ 19.The 30-item MoCA screens for impairment in specific areas of cognitive functioning deemed necessary for participation in a 90-minute, structured group including attention and concentration, executive functions, language and conceptual thinking. We have specified a MoCA cut-off at the lower end of the range for mild cognitive dysfunction (≥ 19), in order to exclude Veterans with severe memory and/or other cognitive deficits, while admitting those with more mild deficits, as these represent our target population, i.e., Veterans with a history of mTBI, PTSD, and/or moderate-severe PTS or CS.

Inclusion criteria-partners: Legally married to or co-residing with Veteran for at least 6 months, with no plans for divorce or separation.

Exclusion criteria for Veterans and partners:1) a lifetime diagnosis of a major psychiatric disorder (schizophrenia, schizoaffective or bipolar disorder) or active psychosis based on the Structured Clinical Interview for DSM-IV-TR (SCID-L) (First et al., 2007); 2) alcohol or drug abuse or dependence within the past three months defined by a Short Michigan Alcoholism Screening Test (SMAST) (Selzer, 1975) ≥ 3, based on the recommended cut-off for TBI survivors (Gentilello et al.,1995) or a Drug Abuse Screening Test-10 (DAST-10) (Skinner, 1982) ≥3; 3) "severe" inter-partner violence as defined by the revised 20-item Conflict Tactics Scale

Short Form (CTS2S) (Straus & Douglas, 2004);4) a suicide attempt (actual, aborted, or interrupted) within the past six months indicated on the Columbia Suicide Severity Rating scale (C-SSRS); 5) medical condition or life event (e.g., ongoing or pending legal action in another state) that would compromise participation; 6) participation of either the caregiver or Veteran in another psychosocial intervention trial for couples six months prior to or during study or follow-up. Participation in individual psychotherapy, individual couple's psychotherapy, and pharmacotherapy are permitted: use of and starting/stopping these services will be tracked. Participants will be screened for inclusion/exclusion as described above immediately after giving consent.

5.5 Study Evaluations

Veteran Assessment

Primary Outcome: Veteran Community Integration. Our original measure, the Sydney Psychosocial Reintegration Scale (Tate et al., 2011), normed for non-military TBI survivors in Australia, will be supplemented by the computer adaptive test version of the Community Reintegration of Injured Service Members (CRIS-CAT) (Resnik et al., 2012), developed and normed specifically for the OEF/OIF cohort. Due to a recently developed computer adaptive format, the CRIS-CAT is now a feasible measure, requiring only 10 minutes to complete.

Secondary Outcome: Veteran Emotion Regulation and Interpersonal Skills. Two measures will be used to assess change in the Veteran's use of adaptive social behaviors needed for community reintegration. Emotion regulation, currently assessed by the AX scale of the State-Trait Anger Expression Inventory (Spielberger & Sydeman, 1994), will be evaluated more directly by the Difficulties in Emotion Regulation Scale (DERS) (Gratz & Roemer, 2004), which is comprised of six orthogonal factors (nonacceptance, goals, impulse, awareness, strategies, and clarity), that together explain 56% of the variance in emotion regulation and has a Cronbach's alpha = .85 (Gratz & Roemer, 2004). In addition, the Abbreviated Duke Social Support Scale (ADSSI) (Koenig et al., 1993) will be used to measure both subjective support and social network interactions. To measure social interaction, Veterans are asked to describe their telephone and face-to-face interaction patterns and attendance at clubs and religious events during the past week outside of work. To measure subjective support, they are asked to respond to questions such as "Does it seem that your family and friends understand you most of the time, some of the time, or hardly ever?"

Mental Health/Health Behavior. Although Veteran mental health disorders/symptoms are not treatment targets in MFG-TBI, the presence/degree of PTSD or depressive symptoms, medication, substance use, physical problems and use of mental health and/or medical services may influence benefits derived from treatment. The Post Traumatic Stress Disorder Checklist-Military (PCL-M) (Weathers et al., 1996) will quantify level and type of PTSD symptoms. The 7-item Combat Exposure Scale (CES) (Lund et al., 1984) will quantify level of war-zone exposure to violence, wounding and other wartime events. The 10-item form of the widely-used, reliable Center for Epidemiologic Study of Depression (CESD-10) (Irwin et al., 1999) will assess level of current depressive symptoms. The Addiction Severity Index-Lite-Veterans Administration Version (ASI-L-VA) (Cacciola et al., 2007) will evaluate alcohol and substance use and related problems. The ASI-L-VA is a widely-used semi-structured interview with well-established psychometric properties and alternate versions for baseline and follow-up administrations; scales that overlap with other measures (e.g., medical and mental health) will be eliminated. The 6-item Pain Inference Short Form (Amtmann et al., 2010) from the Patient-Reported Outcomes Measurement Information System (National Institutes of Health Roadmap initiative) and the 7-item Insomnia Severity Index (ISI) will be used to assess important Veteran health

domains not addressed by the sole current measure, the SF-8, an 8-item measure of general health. Internal consistency and reliability for the ISI is high; Cronbach's alpha = .91 (Morin et al, 2011). The Service Use Checklist (Perlick et al. 2005) will document reported use and frequency of a comprehensive list of inpatient and outpatient services, as well as instances of starting/stopping psychosocial or pharmacologic treatment during the trial. For Veterans enrolled in mental health services at VA, medication and mental health service use will also be examined through the VA medical record, and we will use VA medical record data to validate the Service Use Checklist with respect to medication and mental health services in a subgroup of 60 Veterans (20 per site). Based on examination of the range and frequency of use of different medications and medication classes, we will create summary variables for use in analyses (e.g., hypnotics, antidepressants). These variables will then be evaluated for inclusion as covariates in primary analyses as articulated under "General Approach" in section 2axiv.The Memory Compensation Questionnaire (MCQ) (Dixon et al., 2001) which assesses use of compensatory strategies in daily life, will be administered to MFG-mTBI-C Veterans to monitor utilization of the strategies learned in MFG-mTBI-C. The Brief Symptom Inventory – Anxiety Subscale (BSI – Anxiety) will be given to assess for symptoms of anxiety experienced within the past week. The Axis I Disorder symptomatology interviews from the Mini International Neuropsychiatric Interview (MINI) will be given to assess for current and past episodes of major psychiatric illnesses for diagnostic purposes. The Health Risk Behavior Scale (HRBS) will be administered to measure current health behaviors such as medication adherence, hygiene, and putting off medical appointments. Finally, a Life Satisfaction question will be asked to capture the participant's current quality of life and life satisfaction in general. The CESD-10, PCL, ISI, BSI, MINI, HRBS, and Life Satisfaction Scale will be given to both the Veterans and partners.

Veteran Neuropsychological Functioning will be evaluated by 3 core (Rey Auditory Verbal Learning Test (RAVLT-Vakil Blachstein,1993), and the Trail-Making Test (TMT- Bowie & Harvey, 2006) A& B, measures from the NINDS Common Data Recommendations for Neuropsychological Impairment in TBI. The Movie for the Assessment of Social Cognition (MASC) (Dziobek et al., 2006) will replace The Awareness of Social Inference Task (TASIT) (McDonald et al., 2006) as our evaluation of awareness of social inference measure. While the 2 measures are virtually identical, our research group has considerable experience with the MASC, ensuring more accurate administration and scoring.

Partners will also be administered the MASC in order to provide a control sample with which to compare the Veteran MASC data.

Spouse/Partner Assessment:

Primary Spouse/Partner Outcome: The Caregiver Burden Inventory (CBI) (Novak & Guest, 1989), a 24-item scale will evaluate caregiver burden in four areas: physical, social, emotional and time dependence burden. The CESD-10, PCL-C, SF-8, ISI, BSI, MINI, Life Satisfaction Scale, and Service Use Checklist will be used to evaluate depressive symptoms, trauma symptoms, mental and physical health and service use during the past 6 months. The DERS and ADSSI will also be administered to the spouse/partner.

***Couples Functioning*:** Marital satisfaction and conflict will be evaluated by the Dyadic Adjustment Scale (DAS) satisfaction subscale (Spanier,1976), chosen over the DAS-7 (Sharpley & Rogers, 1984) as evaluating conflict as well as satisfaction (Hunsley et al.,1995). The Interpersonal Reactivity Index (IRI) (Davis, 1980) will replace the Family Crisis Oriented Personal Evaluation Scales (F-COPES) (McCubbin et al., 1985) in evaluating couples coping efficacy. Whereas the F-COPES assesse coping of the family unit (including children), the IRI assess dyadic coping with interpersonal stress and empathy, and is thus more relevant to

couples coping. It has 28 items and 3 subscales (empathic concern, personal distress, and perspective-taking). The IRI will be supplemented by the Perceived Ability to Cope with Trauma (PACT) scale (Bonanno et al., 2011) in evaluating the Veteran and partner's resilience and coping flexibility. In addition, we will administer the Post Traumatic Growth Inventory – Short Form (PTGI-SF) (Cann et al., 2010) and the Couples Assessment of Relationship Elements (CARE) (Worthington et al., 199&) to both the Veteran and partner. The IRI will be also supplemented by The Communication Patterns Questionnaire (CPQ) (Christensen & Sullaway, 1984), a self-report measure designed to assess the extent to which couples make use of various interaction strategies during conflict. Subjects are instructed to rate the use of each of 25 items, allowing researchers to "type" couples as high in demand/withdrawal, avoidant, and mutual constructive or destructive communication patterns. These typologies will be shared and discussed with couples in the individual joining sessions in order to develop individual goals for each couple. These measures will be administered to both partners. The Veteran assessment takes 120-150 minutes at baseline, and 80-95 minutes at post-treatment and 6-month follow-up**.** While most Veterans tolerate comparable assessments administered by skilled examiners, the assessment can be divided into 2+ sessions as needed. The spouse/partner assessment takes about 80-90 minutes to complete at baseline and 75 minutes for follow-up assessments*.* Well-known measures such as the SCID-L have not been reproduced.

5.6 Data Analysis

All data will be entered into an SPSS database at the individual sites; de-identified data will be transferred electronically bi-weekly to the Data Coordinating Center (DCC) at the JJ Peters VAMC where it will be merged into a master database constructed by the data manager with input from the biostatistician, Dr. Luo. Tenets of our data system include double data entry, range checks and exclusion of identifiers that can be directly traced to individuals. Data are backed-up bi-weekly onto Zip drives and saved. Our computers are accessible only to authorized study personnel and are protected by a firewall and Norton antiviral software. All original forms and backup-up data will be saved in locked cabinets in locked rooms. Data analysis will be done in SPSS or SAS. Preliminary analyses will be performed by the project director, in collaboration with Dr. Goetz, who will perform the final runs for complex analyses such as mixed models.

General Approach:

Preliminary analyses including computing descriptive statistics and inspecting features and patterns of data to determine whether data transformations are necessary will be performed. We will test whether clinical characteristics of the study population, (e.g., age, sex, race, PTSD comorbidity), and other variables known to be prognostically related to the primary outcomes, are comparable between two treatment groups at baseline, using t-tests or Wilcoxon rank-sum for continuous variables, and chi-square or Fisher's exact tests for categorical variables. Groups will be considered imbalanced on variables that differ between them at $p < .10$ and all such imbalanced baseline prognostic factors will be included in primary analyses as control variables. Psychometric analyses will be conducted to check the properties of the scales for this sample. Outcome variables such as the Sydney and CBI will be measured at three time points for each participant. Because repeated measurements on individual subjects tend to be correlated and in some cases, the number and spacing of observations may vary among subjects, we will examine these data by graphic displays of outcome variables versus time and individual subject and mean profiles to assess the mean structure for modeling fixed effects and to examine whether there are heteroscedasticity and/or curvature in the data. Linear mixed models (LMM), generalized linear mixed models (GLMM) or generalized estimating equations (GEE) will then be used to account for dependence of repeated measures and to accommodate correlated errors, unequal correlations among time points, unbalanced data resulting from

missing data points and unequal intervals between testing occasions. Choices of variance-covariance structures to account for within-subject correlation will be made based on the AIC, BIC, or likelihood ratio statistic. All principal analyses will be conducted based on the intention-to-treat principle in which any participant randomized to a treatment arm remains in it regardless of adherence to or completion of treatment. We will measure the level of participation, and will conduct a sensitivity analysis that assesses the stability of the conclusions from this study with an intention-to-treat analysis versus an analysis that takes into account level of adherence. With multiple time points and variables representing outcomes at both the individual and couples level, the planned analyses involve multiple comparisons raise concerns about the increased likelihood that any single outcome will be found to be statistically significant based on chance alone. In order to minimize this risk, we have carefully selected a limited number of outcomes and clearly designated primary, secondary and exploratory outcomes. Our primary outcomes for the Veteran and for the caregiver are each represented by a single measure. For models evaluating the effect of treatment assignment on constructs represented by more than one measure, e.g., Veteran Emotion Regulation and Interpersonal Skills, we will employ Bonferroni's correction to adjust each observed p-value by the number of tests performed and have calculated power on this basis (see power calculations below).

Tests of Specific Study Hypotheses:

Primary Hypotheses:

Hypothesis 1: ***Veterans with mTBI treated with 6 months of multi-family group for couples (MFG-mTBI-C) will show improved community integration (primary outcome), and improved anger management and use of social support (secondary outcomes) compared with those treated in a health education group without training in communication skills or compensatory strategies***; Changes in the primary study outcomes (Sydney Psychosocial Reintegration Scale) from baseline for each treatment group at each time point will be examined using paired t-tests or Wilcoxon signed-rank tests as appropriate. Differences in changes in mean Sydney scores from baseline between two treatment groups will be compared using t-tests or Wilcoxon rank-sum tests as appropriate at each time point. Linear mixed models will be used to examine changes in scales over time and to examine whether the effects of MFG-mTBI-C on the Sydney and secondary Veteran outcomes (DERS and social support scales) vary with time and study sites adjusted for the time-dependent treatment, imbalanced baseline prognostic factors (if applicable), and control variables relating to combat/ injury exposure (mechanism of injury (blast vs. other), # deployments, # TBI's and degree of exposure to war zone violence/threats). In addition, Spearman correlation coefficients will be used to assess associations of changes in the Sydney with changes in Veteran symptoms from baseline at each time point and to examine whether degree of associations increases over time among Veterans treated with MFG-mTBI-C. If significant patterns over time are observed in any of these variables, mixed models will then be used to examine the effects of the variables identified on CI change over 6 months post treatment.

Hypothesis 2: Caregivers whose Veteran spouse/partners are treated with MFG-mTBI-C will show reduced burden (primary caregiver outcome) over the course of treatment and in the 6-month follow-up period relative to caregivers whose Veteran partners are treated in a health education group. The analytic plan proposed in Hypothesis 1 will be used for assessing effects of MFG-mTBI-C on changes in the CBI.

Secondary Hypotheses:

***Hypothesis 3:* Improvement in community reintegration will be mediated by improvements in Couples Functioning and Veteran emotion regulation and interpersonal skills.** An aim of this study is to develop a conceptual model of the therapeutic action of MFG-mTBI-C. We will conduct exploratory analyses to evaluate the potential mediating role of hypothesized mediators, marital satisfaction/conflict assessed by the DAS, and Veteran emotion regulation and interpersonal skills, assessed by the DERS and Duke scales, following the approach described by Baron & Kenney (1986), which entails evaluating the bivariate associations in the model prior to multivariate modeling. If the bivariate associations between the predictor, outcome and potential mediating variable are all significant, a mediational hypothesis will be evaluated using hierarchical linear models or random effects models. For example, to evaluate the potential role of marital satisfaction in mediating improvement in community integration among couples treated with MFG-mTBI-C vs. GHE, we would enter treatment assignment and time effects in Step 1, followed by marital adjustment (DAS) efficacy in Step 2, and the interaction between marital adjustment and treatment group in Step 3. A significant main and group interaction effect for marital satisfaction would support a mediational hypothesis (Kraemer et al., 2002).

***Hypothesis 4*: Veterans with more intact baseline cognitive functioning will show greater improvement in community integration, emotion regulation and interpersonal skills and marital satisfaction.** In order **to evaluate the potential role of baseline neurocognitive status in moderating the effects of treatment, we will evaluate the interaction of baseline levels of impairment with treatment group in predicting treatment response, after controlling for imbalanced** baseline prognostic factors. Preliminary analyses will be conducted to evaluate the bivariate associations between baseline neurocognitive test scores and change in primary and secondary outcomes over treatment, and multivariate—level analyses will be conduct only outcome variables with an association of at least .5 for 1+ of the neurocognitive measures, using mixed models to examine the moderating effect of neurocognition on CI and other secondary or intermediate outcomes.

Exploratory Hypotheses:

Using the same analytic approach outlined for Hypothesis 1, we will explore the hypotheses that ***Veterans with mTBI treated with 6 months of multi-family group for couples (MFG-mTBI-C) will show improvement in PTSD and depressive symptoms relative to Veterans treated with group health education (GHE) with their partners, in separate analyses. Power calculation:*** Our power calculations are based on pilot data from our open trial of MFG-mTBI for the primary study outcome, Veteran community integration, assessed by the Sydney Psychosocial Occupational Activity scale, and for the primary spousal outcome: caregiver burden. As we have no control group to allow us to calculate an effect size for differences in pre-post-treatment change between treatment groups, we have based our calculations on available data and calculated a range of scenarios. Our calculations assume the same mean pre-post-treatment changes on the Sydney (3.9) and Caregiver Burden Inventory (CBI) (18.0), as observed in the pilot study, and further assume that the standard deviation for the change in the control group is identical to that observed in the treatment group. The effect size is defined as (mt-mc)/mc, here mt and mc are the mean changes in the treatment and control groups respectively. The correlation between the baseline score and the follow-up score (rho) is also a factor impacting the standard deviation of the mean change, which in turn impacts the effect size associated with treatment group assignment. From the pilot study, these correlation coefficients are 0.83 and 0.84 for the Sydney and CBI. Using these data we are able to calculate power for a range of clinically significant (i.e., medium to large) effect sizes. ***Tables 8***

and ***9*** below present the power calculations for each of the two outcomes based on the above assumptions for a two- sided, two-sample

Table 8: Power estimate-Veteran occupational activity

Effect Size	Attrition	N per cell pre/post attrition	α	1-β
.5	15%	90/76	0.05	.87
.5	20%	90/72	0.05	.85
.5	25%	90/67	0.05	.83
.6	15%	90/76	0.05	.94
.6	20%	90/72	0.05	.92
.6	25%	90/67	0.05	.91
.7	15%	90/76	0.05	.97
.7	20%	90/72	0.05	.96
.7	25%	90/67	0.05	.95

Calculated for rho = .5; Pilot rho = .833

Table 9: Power estimate-Caregiver burden inventory

Effect Size	Attrition	N per cell pre/post attrition	α	1-β
.5	15%	90/76	0.05	.84
.5	20%	90/72	0.05	.81
.5	25%	90/67	0.05	.79
.6	15%	90/76	0.05	.91
.6	20%	90/72	0.05	.89
.6	25%	90/67	0.05	.87
.7	15%	90/76	0.05	.95
.7	20%	90/72	0.05	.94
.7	25%	90/67	0.05	.93

Calculated for rho = .5; Pilot rho = .839

t-test, with alpha=0.05, rho=.50 and effect sizes ranging from .5 to .7. Although attrition in the pilot study was relatively low: 10%, we have conservatively calculated power for higher rates of attrition that that observed in our pilot work: 15%, 20% and 25%, at effect sizes lower than the 1.03 effect size observed for both measures. For the Sydney, we have good power to detect an effect of .5 for Occupational activity, assuming a correlation coefficient of .5, lower than the correlation observed in the pilot study of .83 even with 2.5 times the attrition observed in the pilot study. For the CBI we have good power to detect an effect of .5, lower than the correlation observed in the pilot study of .84, even at 20% attrition, and more power at higher effect sizes or lower levels of attrition. In the unlikely scenario that a substantially lower correlation is observed (.3) along with an effect size half that observed, our power falls somewhat short of conventional standards at higher levels (25%) of attrition (i.e., .70 for Sydney and .68, with a higher correlation coefficient, lower attrition or a larger effect size we have good power to detect a medium to large effect size.

We note that a larger sample size and repeated measures at follow-up will tend to increase the correlation coefficients and reduce the variance of the change over time, most likely resulting in an increase in power. The above power calculation is based on a two-sample t-test which is the simplest form of LMM (with random intercept only) and GEE. If the imbalance between groups on key participant characteristics is minimal, as we anticipate in this randomized trial, this calculation is justified. We chose the more robust approach of using the simpler model and powering our study for a worst case scenario (compared to the effect sizes and correlations

observed in our pilot data) to cover the possibility of a more substantial imbalance, rather than basing our calculations on a more sophisticated model involving many assumptions.

Secondary Outcomes: We calculated power for the Veteran secondary outcomes, AX (anger expression) and Duke (social support) scales for a two-sided, two-sample t-test, using the same assumptions for calculating primary outcomes and the observed correlation coefficients of .90 and .72, respectively for a two sample t-test, with alpha=0.025. Based on these assumptions, we have 94% power to detect an effect of .5 on the AX scale and 81% power to detect an effect of .5 on the Duke scale. *Covariates*: Due to the high degree of comorbidity in this cohort of Veterans, we have specified a number of variables for potential inclusion as covariates in our analytic models, should randomization result in an imbalance. These include Veteran (and where appropriate caregiver) physical health, substance use, service use (including starting and stopping treatment), level of depressive and post-traumatic stress symptoms, as well as usual sociodemographic (race/ethnicity, gender, age, SES) and military (e.g., number of deployments) variables. As noted above under General Approach, we will employ t-tests or Wilcoxon rank-sum for continuous variables, and chi-square or Fisher's exact tests for categorical variables at baseline to identify any imbalance between groups on these variables, and will control for any imbalance by including variables that differentiate groups at conventional levels by including them in our analyses as covariates. However, as discussed, given random assignment of a sample of 180 to one of two treatment groups, we anticipate that few if any variables will differentiate between groups, and that our power analyses are conservative enough to accommodate inclusion of a limited number of covariates if necessary. Potential inclusion of covariates as "control variables" should be distinguished from inclusion of covariates for the purpose of testing exploratory mediating/moderating hypotheses as described under hypotheses 3 and 4 above.

Analyses to Determine Generalizability of Results: Although the rate of refusal in the pilot study was relatively low (28.6% of caregivers of consenting patients), we will compare the baseline characteristics (e.g., age, sex, education) of the study caregiver population to those that declined participation, and will evaluate reasons for refusal using questions adapted from our Family Service Needs and Treatment Preferences Scale (FANS-Perlick et al., 2009, Appendix A). ***Missing data and loss to follow-up*** are usually concerns in longitudinal studies presenting problems in interpretation with any approach. The validity of the resulting inferences depends critically on the underlying mechanism that generates the missing observation. If the mechanism for missing data is not a function of the underlying missing data, then no adjustment is necessary. Data that are missing at random will yield estimates from the likelihood-based methods that are valid and efficient, provided the model assumed for the data distribution is correct. However, when missing data are related to study treatment or outcomes of interest, parameter estimates and resulting tests on hypotheses will be biased without further adjustment. In this study, data will be stratified according to their missing pattern (e.g., early termination, late termination, and complete follow-up); variables based on these groups will be used as model covariates, allowing us to examine the effects of missing-data patterns on out-outcome measures. Overall estimates can be obtained by averaging over the missing patterns. Multiple imputations will be used if missing data rates are observed to differ across observed covariates.

5.7 Withdrawal of Subjects

Participants can refuse to participate in the study initially or can withdraw from the study at any time after giving consent, which will not interfere with treatment if they are a patient. Subjects that withdraw will be asked for permission to contact them to complete assessments remaining in the study. Any participant (whether a Veteran or spouse/partner) found to have violated the

confidentiality of the group or who causes distress to others, e.g., through verbal aggression or repeated and deemed irremediable disruptions to the group activity after clinician intervention, will be excluded from the intervention and from the study.

6.0 Reporting

This project will be monitored by a Data and Safety Monitoring Board (DSMB) because the Veterans have either been diagnosed with mTBI, a mild cognitive impairment, PTSD, and/or have reported moderate-severe PTS or CS. Thus, while the risk in this study is minimal, these Veterans can be considered a vulnerable population. The board will be composed of persons not affiliated with this pilot intervention who are experienced in various aspects of the conduct of clinical trials for persons with mTBI, or with research on PTSD or associated conditions. Because the safety risk is judged to be minimal, we propose to submit a quarterly report of aggregate data to DSMB members rather than attempt an interim analysis of efficacy and safety data by treatment assignment. The report will contain screening data, baseline demographics, retention data, number of participants removed due to clinical deterioration, serious adverse events data, as well as accruable status including projections and times to milestones. Based on this report, each DSMB member will complete a form making one of two recommendations: 1) continue recruitment as planned; or 2) schedule formal DSMB meeting immediately. If any DSMB member recommends a meeting, this will be scheduled within one week, minutes will be kept, the report will be reviewed with the PI, and the committee will vote on whether the study should: 1) continue recruitment unchanged; 2) continue with a protocol amendment; 3) stop recruiting pending further investigation. If, after this meeting, any DSMB member votes to stop recruitment, each site's IRBs will be informed. All SAEs will result in completion of an SAE reporting form and a verbal report to the Principal Investigators (Dr. Drapalski). Within 24 hours, the following additional individuals will be notified: 1) all Consulting Investigators and Senior Clinicians; 2) all Core Clinical Investigators; 3) The VA Institutional Review Board; 4) the DSMB. These same individuals will receive a copy of the SAE form within one week at which point a decision will be made whether to convene a meeting of the DSMB. Communication of recommendations and decisions from all parties are made back to the investigator in a timely manner. We will report all protocol amendments or changes in the informed consent to the VA IRB, as well as any temporary or permanent suspension of participant accrual.

Dr. Drapalski will chair the Advisory Board and Treatment Committee. She will supervise and meet with the VISN 5 study staff weekly and will participate in weekly conference calls with the VISN 2 South study sites to assess and report any unanticipated problems, serious adverse advents, or protocol deviations.

7.0 Privacy and Confidentiality

Once a Veteran consents to participate in the study, the research assistant will then seek permission to contact the Veteran's spouse/partner. After the Veteran gives informed consent and permission to contact his/her spouse/partner, we shall first screen them to determine eligibility. Once eligibility has been confirmed, the RA will contact the spouse/partner by telephone to describe the project, answer questions, and invite them to meet with him/her to explain the study. The initial interview will begin with the interested spouse/partner, to describe the project, and to determine who is eligible for the study as the primary caregiver. We shall use a self-rating scale that asks about frequency of contact, involvement and care-giving responsibility for this purpose. Informed consent will then be sought from this person. We are only enrolling Veterans who regularly receive services from or work at the JJP VAMC, VAMHCS, or VA NYHHS mental health clinic, so the environmental experience will not differ

from their usual routine. The individual and group sessions will be conducted in the private setting of a closed office or group room. Any participant (whether Veteran or spouse/partner) found to have violated the confidentiality of the group or who causes distress to others, e.g., through rudeness or verbal aggression, will be excluded from the intervention and from the study.

Privacy during interviews of patients and caregivers will be maintained by using offices that are not shared and by keeping the door closed. Questionnaires can be administered over the phone only if the Veterans or spouse/partner is alone in a private room at his/her residence, and the research staff member is in a private office or room.
All investigators, the project coordinator and research assistants will be eligible to review individuals' paper research records at the study sites. However no individual's paper research records will be transferred from the study site where the data was collected. Representatives of the USAMRMC are eligible to review research records.
The research team will follow the same reporting requirements as the clinicians providing the research intervention regarding sensitive information to be reported to New York State authorities. Any information on child abuse provided to a research assistant during interviewing or to other research team members will be reported to Child Protective Services within 24 hours.

Signed consent and HIPAA authorization forms will be kept in locked file cabinets in the office of the PI for each site. Data collection forms will not include names and a code will be used instead (see above under Volunteer Identification), and will be kept in the office of the research assistant. The list of names and codes will be kept electronically behind the VA firewall on a drive accessible only to the PI and research assistant. Data entered electronically for analysis will use the code and no HIPAA identifiers will be included. The datasets thus created will be sent to the study PI using PKI encrypted email, in order to be able to retain the code used on the subjects' research records.

Research Investigator files will be destroyed six years after the end of the fiscal year when the research project has been completed per Records Schedule DAA-0015-2015-0004-0032, Section 7.6, Research Investigator Files.

8.0 Communication Plan

All sites will have weekly meetings, will cover as agenda items: approvals, productivity, changes in protocol, SAEs, unanticipated problems, interim results. We will review and check for any protocol deviations and, if any, take appropriate steps to remedy them. In addition, at each site the PI will hold weekly meetings within each site and go over all activities that occurred that week to ensure that the protocol was adhered. There will be formal adherence monitoring as outlined in the study procedures.

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