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**Invited Testimony**

**United States Senate  
Committee on Veterans' Affairs  
Senator Bernie Sanders, Chairman  
Senator Richard Burr, Ranking Member**

**April 30, 2014**

Chairman Sanders, Ranking Member Burr and Members of the Committee:

Thank you for the honor to testify before this distinguished body regarding how best to serve our veterans, who as we all know, face enormous physical and emotional challenges. The issue that prompts this hearing, overmedication of our veterans, as well as active duty service members and civilians, particularly overuse of opioids for pain management, is a critical one. I have been asked to share my understanding of what integrative healthcare approaches might offer to people in pain.

By way of background, I am a social scientist, a medical sociologist. For the past 30 years my research and policy-oriented work have focused on integrative health care. I am also a clinician – a massage therapist, and an instructor in meditation and somatic awareness. For these same thirty years, in the treatment room, I have sought to understand what helps people move from illness to wellness, from pain to ease; and how a nervous system that has become stuck in a fight or flight or freeze response, can reset itself for optimal functioning.

For the past five years I have worked with Veterans of OIF/OEF/OND and their partners. I have seen them in my private practice, and with my research partner, William Collinge, have developed a program called Mission Reconnect. This is a self-directed, home use, web and app-based program, offering instruction to both veterans and their partners in a number of mind-body practices that support mental, physical and relationship health. Preliminary research, conducted with Veterans from Vermont and Oregon National Guard units showed 8-weeks of this program to be effective in decreasing pain, anxiety and PTSD scores.<sup>1</sup> We are now conducting an NIMH-funded large randomized clinical trial in four cities, with veterans from all branches of the military.

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<sup>1</sup> Collinge W, Kahn J, Soltysik R. Promoting Reintegration of National Guard Veterans and Their Partners Using a Self-Directed Program of Integrative Therapies: A Pilot Study. *Military Medicine*, December 2012, vol. 177, no. 12, pp. 1477-1485(9)

The United States has a drug problem. In our veteran, active duty and civilian populations we face an enormous public health crisis of chronic pain, which must be addressed without creating a second problem of overuse of prescription and over the counter medications. Many have noticed this problem. The 2010 report of the Army Pain Management Task Force, chartered by Army Surgeon General Schoomaker, and the 2012 Institute of Medicine (IOM) report entitled “*Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*” each in their own way call for a cultural transformation in our understanding and treatment of pain. The Task Force Report specifically called for first, an unprecedented level of coordination between the Military Health System and the Veterans Health Administration; and secondly, for the use of complementary and alternative therapies along with conventional medical approaches.

I join that call for a comprehensive change in how we think about and treat pain, beginning with the understanding that our job is to treat people, whole people in all their complexity – pain being part of what they bring to the picture. I support the broad implementation of patient-centered integrative health care, by which I mean team-based coordinated use of the most appropriate proven therapies, products and approaches from across the conventional, complementary and alternative medicine spectrum, including a strong focus on interventions that educate and engage the patient and his or her family members. That is the summary statement. Now a few words on why we need integrative health care and some challenges to its implementation.

We have a tsunami of need returning home from these wars - young people with multiple wounds – injuries to their bodies and their brains, as well as to their minds, hearts and spirits. The veterans I see need not just to be fixed up and have their symptoms quieted. They need help to heal, to live fulfilling lives. They have decades ahead of them. A reductionist approach of addressing each specific injury, each location of pain, each troublesome symptom, will not do. Thinking of each source of pain in isolation and prescribing a drug specifically for it, too easily leads to polypharmacy effects beyond our capacity to predict or manage. These people have already been asked to carry and maneuver with more weight in their pack than their bodies were designed for; they have already experienced more stress than their nervous systems can manage and we see the results of that every day. Overmedicating them is no solution. I hear from veterans increasingly, their suspicion that the suicides of their friends are at least in part a result of depression and confusion arising from too many medications. I don’t know if they are right.

I do know that emotional and physical pain are inter-related in people, and that there are evidence-based non-pharmaceutical ways to address these that we should deploy. Wayne Jonas and colleagues at the Samueli Institute have coined the term “war-related trauma spectrum response” to capture the reality that veterans’ experience of the impact of their multiple injuries cuts across the boundaries of anatomy, biology, neurology, psychology, and that our responses to them must be comparably holistic and integrative.<sup>2</sup>

Many complementary and alternative medicine therapies also cross these boundaries in their effects. Acupuncture used to be spoken of entirely in terms of energy or chi. Yet, research by my colleague at the University of Vermont, Dr. Helene Langevin, has shown that when a thin acupuncture needle is inserted, collagen fibers from the connective tissue adhere to the needle, which prompts a stretch in the fascia, which in turn, prompts certain gene expression, and the

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<sup>2</sup> Jonas W, et al. Acupuncture for the Trauma Spectrum Response: Scientific Foundations, Challenges to Implementation, *Medical Acupuncture*, 2011, vol.23, no. 4, pp.249-262.

chain of effect continues leading to effects that touch many aspects of the person and endure well beyond the duration of needle insertion.<sup>3</sup> Therapeutic massage is often regarded as a physical medicine, but research shows that it produces EEG changes, specifically increased frontal delta power and decreased frontal alpha and theta power – a combination correlated with simultaneous relaxation and alertness – a relatively pleasant and helpful state of mind.<sup>4</sup>

We need to re-orient toward a positive vision of health and wellness for our veterans, not just approach them with a problem-fixing mentality. Sufficient high-quality sleep, appropriate nutrition, compassionate touch whether from a human friend or a therapy dog, experience of community and a sense of purpose are all factors in human well-being. Lack of sleep, emotional stress, and the inability to take a deep breath – these things exacerbate our experience of physical pain. They literally make pain hurt more. Addressing these building blocks of wellness can reduce the need for pain medication. Research clearly indicates that massage, acupuncture, yoga and other mind-body therapies can significantly enhance sleep quality, help the nervous system rest down, and thus reduce physical and emotional pain. Educational interventions that include family members or groups of veterans can impart needed skills at the same time that they build community. Loss of community is a real source of pain for many veterans post-deployment.

There will be challenges in making this change. I will name three. First is the hegemony of pharmaceuticals in conventional medicine's approach to pain treatment and in the US in general. The pharmaceutical industry is heavily invested in drugs being the first thought of every provider and patient, and thus we see them advertised on television every day. It will take a conscious decision to bring other proven approaches into the mix. In contrast, educational tools offering veterans a lifetime of help in their own self-care cost very little to put into every home. No one profits from them financially. Thus they are not advertised as are pharmaceuticals. It is our responsibility to bring them prominently into the picture.

Second, we all need a big dose of humility, and support in relinquishing professional territoriality. If any health care profession were already responding satisfactorily to the multi-dimensional needs our veterans are living with, you would not have called this hearing. Integration requires real teamwork. Teamwork requires humility and mutual respect. We must respect not only one another's therapies, but also the fact that both reductionis and holistic thinking will contribute to best care.

Third, the VA is a big system and big systems are hard to change. But the VA also has a compelling purpose, strong leadership and a stated commitment to patient-centered care and cultural transformation. It is also a true single system – unlike the rest of US healthcare, so it is ideally suited to lead the way.

People are complex, integrated, and highly individual beings. Our treatment approaches need to match this. On top of all they have already offered this country, veterans are offering us the opportunity to embrace a wellness approach to the care of people who have incurred complex trauma, to kick our pharmaceuticals only habit of medicine and to learn to collaborate across

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<sup>3</sup> Langevin HM, The Science of Stretch, *The Scientist*, May1, 2013

<sup>4</sup> Field T, et al; Massage therapy reduces anxiety and enhances EEG pattern of alertness and math computations, *Int J Neurosci*. 1996 Sep;86(3-4):197-205.

disciplines, on their behalf. We should recognize this as one more gift from them and move forward as quickly as we responsibly can.



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## Promoting Reintegration of National Guard Veterans and Their Partners Using a Self-Directed Program of Integrative Therapies: A Pilot Study

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### Abstract

This article reports pilot data from phase I of a project to develop and evaluate a self-directed program of integrative therapies for National Guard personnel and significant relationship partners to support reintegration and resilience after return from Iraq or Afghanistan. Data are reported on 43 dyads. Intervention was an integrated multimedia package of guided meditative, contemplative, and relaxation exercises (CD) and instruction in simple massage techniques (DVD) to promote stress reduction and interpersonal connectedness. A repeated measures design with standardized instruments was used to establish stability of baseline levels of relevant mental health domains (day 1, day 30), followed by the intervention and assessments 4 and 8 weeks later. Significant improvements in standardized measures for post-traumatic stress disorder, depression, and self-compassion were seen in both veterans and partners; and in stress for partners. Weekly online reporting tracked utilization of guided exercises and massage. Veterans reported significant reductions in ratings of physical pain, physical tension, irritability, anxiety/worry, and depression after massage, and longitudinal analysis suggested declining baseline levels of tension and irritability. Qualitative data from focus groups and implications for continued development and a phase II trial are discussed.

### INTRODUCTION

Psychological distress and adjustment difficulties among military veterans returning from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) and their relationship partners are well documented.<sup>1–3</sup> Screening efforts suggest that up to 42% of National Guard veterans and roughly one-third of all returning veterans have problems that warrant mental health treatment, yet most are not receiving treatment. Many returnees express concerns about interpersonal conflict, highlighting the potential impact of deployment-related psychological distress on the well-being of veterans' family members, friends, and coworkers.<sup>3,4</sup>

Perceived stigma associated with seeking behavioral health services remains a barrier to needed treatment.<sup>5</sup> Sayer et al<sup>6</sup> reported both individual and sociocultural barriers cited by veterans as reasons for not seeking treatment. With the numbers of veterans that will be reintegrating into community life in the coming years, the long-term impact of untreated or undertreated mental health problems is expected to impact communities for years to come.

As a distinct population, members of the National Guard face circumstances different from those of veterans of other branches of the military in terms of access to services during reintegration. Rather than returning to a base that may offer a comprehensive range of

services and the camaraderie of others who have shared their experiences, they return to their home communities as “citizen soldiers.” Although eligible for Veterans Administration (VA) benefits, distance to VA facilities and Vet Centers may pose an obstacle that limits their use of those opportunities, particularly in rural states. Although other veterans who return to a base spend their days among those who recognize their service, rank, and experiences, and may also be alert to signals of mental difficulties, National Guard veterans returning to prior jobs may well be earning less pay, having less responsibility, and receiving less respect from coworkers who have never experienced them in their military capacities. From a community health perspective, National Guard veterans are a population at significant risk of being underserved in terms of mental health needs. Thus, innovative interventions that overcome the psychological, geographical, and financial obstacles to accessing formal services and help this population reintegrate and adjust to community life in the long term are needed. Of particular interest are interventions that target maladaptive coping strategies commonly addressed in cognitive behavioral interventions such as worry, self-punishment, and social avoidance, and that bolster social support as these may reduce combat-related symptoms in this population.<sup>7</sup>

This article reports pilot data from a phase I National Institute of Mental Health–funded study of a behavioral health intervention designed for autonomous use at home by National Guard veterans and partners of their choice to promote reintegration and well-being. The project is entitled “Mission Reconnect: Promoting Resilience and Reintegration of Post-Deployment Veterans and Their Families.” The intervention, delivered by CD, DVD, and print, integrates instruction in evidence-based complementary therapies supporting both individual and relationship well-being. The program is designed to be self-directed with its different elements used at home, at work, or anywhere the participant finds them helpful. People may use each element of the program as frequently or infrequently as they like. Using it requires neither travel to VA or other facilities nor labeling oneself as in need of mental health care. The wellness-oriented techniques in this program are appropriate for people across a broad spectrum of mental health status and may be used by themselves or as an adjunct to individual or group therapies. Thus, the program may be able to reach people who are geographically isolated from services as well as people who are reluctant to use mental health services.

Mission Reconnect includes meditative, contemplative, and relaxation techniques and use of touch with a partner in the form of simple massage. Hundreds of small clinical trials indicate that mindfulness-related practices may offer significant benefits for a broad spectrum of health and mental health outcomes including stress, depression, and post-traumatic stress disorder (PTSD), including with military populations.<sup>8–10</sup> However, given the size and quality of these studies (many, for instance, lacked plausible comparison groups), their findings must be taken as suggestive rather than definitive. A recent systematic review of complementary and alternative medicine (CAM) therapies for depressive and anxiety disorders concluded that “For anxiety disorders, there is limited evidence on the effectiveness of meditation (n = 2 studies). . . . Relaxation and/or breathing retraining show promise as a CAM therapy. . . . Mindfulness-based stress reduction has shown positive effects on anxiety and depressive symptoms. However, studies are poor to fair quality.”<sup>11</sup> Other systematic reviews have drawn similar conclusions.

The literature on massage is somewhat stronger, with massage methods, including simple relaxation massage, having been established as beneficial for a broad spectrum of conditions, with reductions in anxiety and pain among the most common benefits.<sup>12–18</sup>

While using these often-studied techniques, this investigation breaks new ground in part by delivering the instruction solely through self-directed media. In our own prior research, we

found not only that people are able to learn simple touch and massage techniques from video with no personal instruction but also that the resulting massages produced reductions of pain, fatigue, anxiety, and depression, on a par with those of professional massage therapists.<sup>19</sup> Although mind–body techniques are now taught in many medical schools,<sup>20</sup> and their use is fairly widespread, we found no research on the effects of these techniques when taught exclusively by CD and/or audiotape even though tapes and CDs teaching mind–body techniques are ubiquitous. Although both massage and mind–body techniques are increasingly used in VA and Department of Defense sites around the country, our program’s emphasis on self-directed media delivery of instruction is, to our knowledge, novel for the military population.

A key aspect of this program is targeting the dyadic system of a veteran and trusted partner for intervention. As stated in the Iraq War Clinician Guide, “The primary source of support for the returning soldier is likely to be his or her family. We know from veterans of the Vietnam War that there can be a risk of disengagement from family at the time of return from a war zone. We also know that emerging problems with ASD (acute stress disorder) and PTSD can wreak havoc with the competency and comfort the returning soldier experiences as a partner and parent.”<sup>21</sup>

Although it is clear that formal mental health support is warranted for a large number of returning veterans, the people in their significant relationships are seriously affected as well.<sup>22–27</sup> Early support for both the veteran and family may increase the potential for successful reintegration and family cohesion and reduce the likelihood or severity of future problems. Thus, the goal of Mission Reconnect is to offer an integrated program that leverages the relationship bond to encourage compliance, teaches stress-management skills to both the veteran and partner, and strengthens the relationship through joint use of wellness-related practices and guidance in generating compassion and appreciation for self and partner. This article reports on a phase I feasibility study of the approach.

## METHODS

### Recruitment and Sample

Recruitment was conducted with the cooperation of the Family Support and Assistance Programs (FSAPs) of the Army National Guard in both Vermont and Oregon. Subjects were recruited through presentations at postdeployment Yellow Ribbon events and through announcement in FSAP e-newsletters. Subjects were consented in person or by phone by the first author, and institutional review board oversight was provided by the New England Institutional Review Board, Newton, Massachusetts.

### Baseline Phase

Subjects completed a 30-day baseline phase (no intervention) with survey data (described below) collected at the beginning (baseline 1) and end of the 30 period (baseline 2) to establish stability of baseline levels on standardized instruments (see the section “Data Collection”).

### Intervention Phase

Intervention began with a 2-hour orientation meeting in which subjects were given the intervention package (CD, DVD, manual, described below), viewed the materials as a group, and received instructions for home practice and data collection.

Intervention activities were of two types: (1) mind/body practices (meditative, contemplative, and relaxation techniques) taught by audio CD and print instruction and (2)

massage for stress reduction (taught by video DVD and print/photographic instruction). Subjects were instructed to practice their choice of practices at least 3 to 4 times per week for 8 weeks and to try them all at least once during the course of the 8-week intervention period.

For massage, we instructed the subjects to practice massage techniques of their choice as often as they mutually agreed each week, suggesting that they may benefit from sessions of just a few minutes on up to 30 minutes or more. This would allow us to collect data on preferences and utilization patterns. In addition to these general instructions, we asked all dyads to do one 20-minute session per week as a “massage reporting session.” This would allow us to collect data on change in veterans’ symptoms after a uniform dose of partner-delivered massage across the sample. (This weekly reporting session was not assumed to be representative of all sessions because of expected variations in duration.) We used this approach successfully in a prior study for assessing the ability of caregivers to provide relief through massage at home.<sup>19</sup>

### Data Collection

All data were collected online via PsychData.com. Data were collected both monthly and weekly. The monthly survey package was administered to both veterans and partners at baselines 1 and 2 (30 days apart), 4 weeks after beginning intervention, and again at 8 weeks (end of intervention). We used the PTSD Checklist—Civilian Version (PCL-C)<sup>28</sup> for both the veteran and the partner. The PCL-C is a 17-item self-report scale that assesses the Diagnostic and Statistical Manual for Mental Disorders (Edition 4) diagnostic symptoms of PTSD using a Likert-type response format. It has demonstrated excellent internal consistency and test-retest reliability and correlates highly with other measures of PTSD.<sup>29</sup> The PCL-C is used rather than the PCL-Military because it is important to assess veterans’ responses to military and nonmilitary traumatic events. The PCL-C was used with partners and veterans since partners of veterans with PTSD may experience secondary trauma stress,<sup>30,31</sup> veterans with PTSD have increased tendency toward intimate partner violence,<sup>32</sup> and women who have experienced intimate partner violence have increased incidence of PTSD.<sup>33,34</sup> The incidence of PTSD among partners of OIF/OEF veterans remains understudied.

To assess depression, we used the Beck Depression Inventory II (BDI-II). This is one of the most widely used instruments for measuring depression and uses a 21-item scale with reliability and validity established in numerous studies. Respondents are asked to rate their symptoms and attitudes using a 4-point scale. Normative values for a variety of patient populations are available as reliability figures,<sup>35</sup> and comparison data on OIF veterans are provided in the section “Results.”

Subjects completed the Perceived Stress Scale (PSS-10), a 10-item Likert-scaled instrument to determine perceived stress levels over a 1-month recall period. The PSS is a validated and widely used scale for community samples with at least a junior high school education. The items are general in nature and free of content specific to any subpopulation group.<sup>36</sup>

To assess capacity for compassion toward others, we used the Compassionate Love Scale (“Close Other” version), 21 items with a single score that assesses compassionate or altruistic love. Studies with three samples ( $N = 529$ ) were used to create the scale that was tested in three new studies ( $N = 700$ ) for validation and to identify correlates of compassionate love. Correlates were seen with indices of prosocial behavior such as helping others, social support to close others, and empathy with others ( $\alpha = 0.95$ ).<sup>37</sup>



We also used the Self-Compassion Scale, a 26-item, 5-point Likert measure of 6 different aspects of self-compassion: self-kindness, self-judgment, common humanity, isolation, mindfulness, and overidentification. The scale has an appropriate factor structure and demonstrates concurrent validity (e.g., correlates with social connectedness), convergent validity (e.g., correlates with lower anxiety, depression, and perfectionism, and greater satisfaction with life), discriminant validity (e.g., no correlation with social desirability or narcissism and appears to promote better coping than self-esteem),<sup>38,39</sup> and test-retest reliability ( $\alpha = 0.93$ ).<sup>40</sup>

To assess quality of life, we used the Quality of Life Inventory (QoLI),<sup>41</sup> a 32-item questionnaire with evidence for concurrent, discriminant, predictive, and criterion-related validity. It includes subscales for health, self-esteem, goals and values, money, work, play, learning, creativity, helping, love, friends, children, relatives, home, neighborhood, and community and an overall score. It was validated in a study involving 3,927 clients from various clinical settings and has been found sensitive to treatment-related change in naturalistic clinical settings and samples.<sup>42</sup>

In addition to the above monthly survey instruments, both veteran and partner submitted a weekly report online each week during the 8-week intervention phase. The weekly reports recorded (1) frequency and duration of use of each intervention method offered plus (2) data from both the veteran and partner specific to the massage reporting session. Massage session data for the veteran comprised pre- and postsession ratings (recorded at time of massage on a two-sided, 5 × 8-inch session card) for levels of physical pain, physical tension, irritability, anxiety/worry, and depression, each rated for severity on a 0 to 10 scale. Massage data for the partner comprised areas of the body massaged and duration of the reporting session. All session card data were later entered by the subjects individually on their online weekly report.

Subject compensation was \$20 for each weekly report and \$25 for each monthly survey.

### Instructional Materials

**Video Instruction**—A DVD was professionally produced with the following contents: (a) Introduction to Mission Reconnect by LTC Wayne Jonas, MD (Ret.), U.S. Army Medical Corps (welcoming and endorsing the program, 2:15), (b) Overview of the Project (W.C., purpose and goals, 1:45), A Word on PTSD (W.C., responding if symptoms arise during exercises, 1:21), How to Participate (W.C., setting aside time daily for wellness practices, willingness to test practices, 0:50), The Tools (W.C., types of practices, frequency and duration of use, 1:05), and (c) Instruction in Massage for Stress Reduction (J.K., overview, communication, preparation, affirming nonsexual intention; instruction in light massage techniques for the head and face, neck, shoulders, back, feet, and hands, using home furniture, 29:00).

**Audio Instruction**—The first two authors (W.C., J.K.) produced and recorded an audio CD with the following guided mind/body practices: “Centering” (basic mindfulness meditation instruction, 11:36, male and female voice versions), “Connecting” (contemplative guided meditation to encourage appreciation, compassion, and well-wishing for the partner and self, 7:03, male and female voice versions), “Deep Relaxation” (progressive relaxation through the body, 20:12, male voice), “Sound Into Silence” (following the tone of a struck chime into silence to facilitate meditative state, 4:16, female voice), “Movement Into Stillness” (seated, gentle rocking in progressively reduced movements until still, 5:32, female voice), and “Therapeutic Yawning” (evocation of the yawning reflex for a series of six to twelve yawns, 3:16, female voice). Subjects were

encouraged to download the exercises to their mobile devices for practice any time of day they wished (though we did not collect data on devices used).

**Printed Manual**—The project manual (47 pages) includes the text of the introductory DVD material, descriptions and specific instructions for each of the guided mind/body exercises, and instructions for the massage techniques accompanied by photos.

### Follow-Up Focus Groups

A convenience sample of 12 dyads (self-selected), who were able to attend at the scheduled meeting times, participated in two 90-minute follow-up focus groups after the completion of intervention. The purpose was to provide qualitative data on perceived impact of the program, usability of the materials, and recommendations for future development. The meetings were recorded, transcribed, and analyzed using QSR NVivo software for thematic analysis and coding of participant comments. Participants were compensated \$50 for attendance.

### Deployment-Related Interruption

Hurricane Irene struck New England roughly midway through the intervention phase for the Vermont cohort, requiring temporary deployment of some subjects. Given study's primary goal of assessing feasibility of the instructional approach, we decided to accommodate this by instructing affected dyads to pause their weekly reporting regimes until after the soldier returned so as to have 8 weeks of complete data from participating dyads. We address this further in the section "Discussion."

## RESULTS

### Sample

Forty-three dyads were consented (27 Vermont, 16 Oregon). Of these, 23 veterans had 1 deployment, 18 had 2 deployments, and 2 had 3 deployments; 8 were OIF only, 20 OEF only, and 15 had been in both OIF and OEF. The sample includes service members with return dates ranging from 2002 to 2011. As seen in Figure 1, of 43 consented dyads, 41 provided baseline data, 38 began intervention, and 32 completed the final follow-up (84% of intervention starters). Demographics of the sample are shown in Table I. In all cases of dropout for which we were able to attain information, reasons given were related to time commitment involved to do project activities.

### Fidelity

Subjects averaged over six times per week using one or more of the mind/body exercises and more than 2.5 times using massage (Table II); thus, for both modalities, fidelity exceeded the minimum instructions. Minutes per week devoted to both modalities combined averaged 61 for veterans and 63.3 for partners.

### Mind/Body Practices

Of mind/body exercises, the Therapeutic Yawning, Centering, and Deep Relaxation exercises were most used. Subjects reported using the mind/body practices an average of 6.3 times per week; veterans averaged 27 minutes (SD 17.6), and partners 27.6 minutes (SD 15.6).

### Massage Data

Mean duration of the 136 massage reporting sessions conducted was 22.7 minutes (SD 5.5), and the most prominent areas massaged were shoulders (75%), neck (72%), back (68%),

head (36%), and feet (27%). Veterans reported highly significant reductions after massage for physical pain, physical tension, irritability, anxiety/worry, and depression (Table III). Change over time in veterans' pre-session ratings of symptom levels was analyzed by splitting each veteran's weekly reporting sessions into an early series and a late series, and then comparing the two series using Kendall's tau-b (Table IV). Significant declines were seen over time in pre-session ratings for "physical tension" and "on edge/irritable."

### Survey Data

For all survey instruments, two baseline testings showed no significant differences; thus, the mean scores of two baseline testings were calculated for each subject for reporting as their "baseline" (Table V).

**Post-Traumatic Stress Disorder**—Baseline scores for veterans on the PCL-C (mean 34.7, SD 13.6) were close to those of a study of 355 OIF veterans by Erbes et al<sup>43</sup> (mean 35.5, SD 13.6, using the Military version of the PCL). The VA National Center for PTSD suggests cutoffs for screening and diagnostic purposes,<sup>44</sup> with a screening cutoff of 25 for both active duty OIF/OEF veterans and civilians and diagnostic cutoffs of 28 and 30 to 38, respectively.<sup>45-47</sup> Thus, there appeared to be substantial risk of PTSD in both veterans and partners in our sample, and both veterans and partners showed significant, though modest, improvements at both follow-ups.

**Depression**—Baseline depression scores for veterans (mean 12.6, SD 11.5) were higher than that of Erbes et al sample (mean 9.78, SD 7.95). The cutoffs used for the BDI-II are 0 to 9 for minimal depression, 10 to 16 for mild, 17 to 29 for moderate, and 30 to 63 for severe. Both veterans and partners showed significant reductions from the mild range to the minimal range at follow-up.

**Other Scales**—The PSS-10, Compassionate Love Scale, and Self-Compassion Scale are not diagnostic instruments, so there are no cutoffs. Partners showed significant reductions in perceived stress, and both partners and veterans had significant improvements in self-compassion at first follow-up and a trend at second follow-up. There were no significant changes on the Compassionate Love Scale, although over half of the subjects improved their scores at both follow-ups. The QoLI showed no significant outcomes on any subscales or total score. Those data are not presented here but are available on request.

### Qualitative Data (From Focus Groups)

Participants reported practicing the exercises at home, at work, and in their vehicles. They viewed the project and each of its elements as well designed and beneficial. They endorsed the inclusion of all the elements even though they individually selected elements that best suited their personalities and/or life circumstances: "Regardless of where I was during the day, I felt like I could use Centering when I felt things getting kind of edgy and unsettled." The overall program was described as providing useful ways of managing stress and improving their couple relationship: "...the Connecting, with thinking about what I appreciated in him, that was nothing new, but sharing it with him was a new piece and it helped me to open up more", and "I think it's a great post-deployment type thing, because you are so separate for so long, it definitely did draw us back towards each other..." The participants strongly endorsed the program and proposed its broader availability to veterans and families: "...the guys are under a lot of stress, and we are under a lot of stress at home, even without the deployment. The military world is a different world, so anything from this aspect of empowering themselves and couples is just great, so thanks for bringing it to us."

## DISCUSSION

As noted in the section “Methods”, some dyads had data collection interrupted for emergency deployment during Hurricane Irene. Given our primary goal of evaluating feasibility of the instructional approach, we deemed delayed reporting to be an appropriate, though imperfect, solution to obtain a full 8 weeks of “normal use” data. Nine dyads were affected. These partners and some veterans were free to practice to the extent they could during nonreported weeks (though some veterans were working 18–20 hours per day). Four dyads required an additional 2 weeks, 3 an additional 4 weeks, and 2 an additional 5 to 7 weeks to achieve 8 weeks of reporting. For these 9 dyads, we cannot rule out potential historical confounds, either negative (e.g., greater stress) or positive (e.g., more practice, maturation), affecting their monthly survey data.

One of the most important findings of this pilot study concerns compliance/fidelity. We found that postdeployment National Guard veterans and their partners were able and willing to follow the recommended utilization of the proposed health promotion activities. Williams et al, in a review of CAM therapies that they conducted for the VA, found that the studies they reviewed often reported high rates of dropout. From this, they concluded that adherence to meditation may be problematic in a clinical setting. Although our methods do not allow a direct comparison to these studies, it appears that our adherence may have been higher, perhaps because of the support of the partner relationship.

This also contrasts with the often-lamented avoidance of help seeking or self-help commonly attributed to the military population. We observed during recruitment that most dyads entering the study were led by the partner initiating the contact (e.g., bringing the soldier to our table at a Yellow Ribbon event or telling their soldier “we need this” in response to a newsletter announcement). This affirms the viability, indeed the importance, of leveraging an existing trusted relationship as a strategy for engaging the veteran in health-promoting reintegration activity. Also, although we offered the project to veteran/partner dyads of all kinds, including parent/adult, child, sibling or friend, only one dyad entered the study that was not a spouse/life partner relationship. It appears that inclusion of massage, although deemed very helpful by those who participated in Mission Reconnect, calls for a level of intimacy that may not be seen as suitable by this population for other types of relationships. A somewhat different approach needs to be explored for nonpartnered veterans.

The data on massage for veterans suggest that partners may achieve significant acute effects for veterans’ stress-related symptoms with minimal instruction in very basic massage techniques. Perhaps, more striking was the finding that pre-session levels of most symptoms declined over time, suggesting declining background levels of most symptoms over the intervention period for veterans. Although post-massage ratings can be attributed to the massage, change in pre-massage ratings over time cannot be attributed to a single source with confidence. Participants reported during focus groups that they felt the whole program was beneficial in symptom reduction and relationship strengthening, but with no comparison group, we cannot be certain how much of their increased comfort is program effect or simply a matter of time and settling in, so to speak. This will be tested in phase II.

Although data were not collected on effects of veteran-delivered massage on partners in follow-up focus groups, there was consensus that partners wanted and appreciated receiving massage and that veterans found satisfaction in providing it. This was an unanticipated finding that we will explore further in phase II as potentially supportive of reintegration and relationship quality.

The survey data suggest that the intervention approach may yield significant reductions during the reintegration process, for both veterans and their partners, in measures of PTSD, stress, depression, and self-compassion. Depression scores (BDI-II) for both veterans and partners dropped from the mild range to the minimal range during intervention. Mean PTSD scores were below the threshold for the clinical diagnosis (50) from baseline onward, though a substantial range in scores was seen. The change in self-compassion scores is of particular interest in light of the concept of “moral injury” as related to PTSD in OIF/OEF veterans.<sup>48</sup> The absence of significant change on the Compassionate Love Scale may be because of a ceiling effect, given that baseline scores were relatively close to the maximum possible score (105). The lack of significant effects on the QoLI may be a function of insufficient sensitivity of the instrument or too small a sample.

Finally, we recognize that reintegration and resilience are multifaceted constructs. In this feasibility study, we sought to assess potential for impact of the intervention on some variables that theoretically contribute to those broad constructs. In phase II, with feasibility established, we will focus more directly on measures of both reintegration and resilience, as well as sleep and relationship quality, in a four-armed randomized controlled trial. We plan to refine the intervention approach based on phase I data; use web-based delivery to computers and mobile devices so that it can be a fully autonomous, self-directed intervention; and then compare outcomes to a standard of care in-person program currently being used in the military to promote reintegration and resilience.

## CONCLUSIONS

Veterans and their partners in this sample showed willingness to engage and use the mind/body practices and massage methods offered in Mission Reconnect and appeared to benefit from them. This study suggests that leveraging a trusted relationship may offer a viable approach to implementing self-directed interventions such as this for promoting well-being during postdeployment reintegration. Given that members of this branch of military are at particular risk for being underserved, in both short-term and long-term mental health service needs, autonomous and self-directed interventions may play an increasingly important role over time.

These pilot data encourage further development of the approach followed by testing with a larger and more diverse sample as is planned for phase II. Questions remaining to be answered include optimal duration of intervention period, longevity of effects, usability of the intervention by more ethnically diverse populations, and effects for veterans from various branches of the military.

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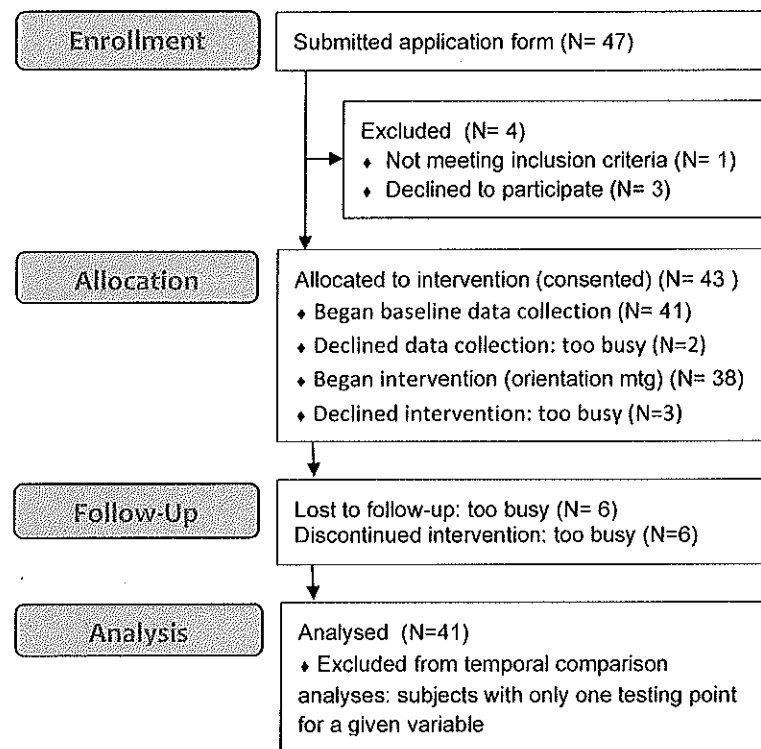
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**FIGURE 1.**  
Subjects flow diagram (N refers to dyads).

TABLE I

## Demographics

	Veteran	Partner
Age (Years)		
Mean	34	29.3
Median	36	31.5
SD	6.7	6.9
Sex (N)		
Male	38	4
Female	5	39
Ethnicity (N)		
White	37	37
Black	1	2
Hispanic/Latin	2	3
Native American	3	1
Education (N)		
Some High School	1	0
High School Graduate	13	9
Some College	14	18
Technical School	1	3
BA	13	12
MA	1	1

TABLE II

Weekly Frequency and Duration of Project Activities ( $N=43$  Dyads)

Activity	Veterans (168 Reports)		Partners (176 Reports)	
	Frequency Mean (SD)	Minutes <sup>a</sup> Mean (SD)	Frequency Mean (SD)	Minutes <sup>a</sup> Mean (SD)
Centering Exercise	1.2 (1.9)	9.0 (3.1)	1.4 (1.9)	8.8 (2.3)
Connecting Exercise	0.7 (1.0)	9.3 (3.4)	0.8 (1.1)	8.9 (2.7)
Deep Relaxation Exercise	1.3 (1.7)	12.8 (5.5)	1.1 (1.7)	12.5 (5.1)
Movement Into Stillness	0.5 (1.0)	9.1 (3.4)	0.6 (0.9)	8.7 (2.0)
Sound Into Silence	0.5 (1.1)	9.5 (3.1)	0.5 (1.0)	8.7 (2.1)
Therapeutic Yawning	2.2 (2.8)	8.2 (1.6)	1.9 (2.6)	8.5 (2.2)
Cumulative Mind/Body	6.3 (5.7)	27.0 (17.6)	6.3 (5.6)	27.6 (15.6)
Used Any of the CD	1.5 (2.0)	11.9 (5.8)	1.9 (2.4)	10.4 (4.7)
Watched Any of the DVD	0.6 (1.3)	12.5 (5.7)	0.6 (1.2)	12.4 (6.4)
Looked at the Manual	0.6 (1.2)	9.7 (3.9)	0.9 (1.4)	8.8 (2.8)
Gave Massage	1.3 (1.5)	15.6 (6.6)	1.4 (1.3)	19.4 (6.1)
Received Massage	1.5 (1.6)	18.4 (5.9)	1.1 (1.3)	16.3 (6.5)
Cumulative of All Activities	11.9 (9.2)	66.0 (38.1)	12.2 (8.8)	67.9 (31.6)

<sup>a</sup>For sessions performed, cumulative is total minutes reported per subject.

**TABLE III**  
Symptom Ratings Pre- and Postmassage (Veterans)<sup>a</sup> (Wilcoxon Signed-Rank Tests)

Symptom	Before		After		N	S	P
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)			
Physical Pain	3.35 (2.11)	2.36 (1.46)	2.11	3933.5	211	3933.5	<0.001
Physical Tension	4.12 (2.09)	2.30 (1.37)	212	8382.5	212	8382.5	<0.001
On Edge/Irritable	3.97 (2.22)	2.06 (1.21)	212	8,055	212	8,055	<0.001
Anxiety/Worry	3.63 (2.21)	2.12 (1.30)	206	5,975	206	5,975	<0.001
Depression	2.59 (2.06)	1.77 (1.24)	212	2232.5	212	2232.5	<0.001
Other	1.65 (2.01)	1.34 (1.11)	119	28	119	28	<0.010

<sup>a</sup>Self-ratings from 0 (not at all) to 10 (worst imaginable).

TABLE IV

Change in Premassage Symptom Ratings Over Time: Kendall's tau-b Results ( $N=215$  Session Reports)

Symptom	<i>t</i>	<i>p</i>
Physical Pain	-0.023	<0.665
Physical Tension	-0.124	<0.017
On Edge/Irritable	-0.111	<0.032
Anxiety/Worry	-0.048	<0.359
Depression	-0.029	<0.587
Other	-0.043	<0.536

TABLE V

Survey Data: Baseline vs. 4-Week and 8-Week Follow-Up (N = 41 Veterans, N = 41 Partners, Wilcoxon Signed-Rank Tests)

Instrument	Subjects	Baseline			4-Week Follow-Up			8-Week Follow-Up		
		Mean (SD)	Mean (SD)	Mean (SD)	Percentage Improved (%)	S	p	Mean (SD)	Percentage Improved (%)	S
PCL-C	Veterans	34.7 (13.6)	29.0 (9.6)	72.4	106.5	<0.003	29.8 (12.5)	73.3	139.5	<0.003
	Partners	31.8 (11.1)	27.5 (8.4)	59.3	81	<0.026	27.1 (10.8)	67.7	111.5	<0.009
PSS-10	Veterans	26.5 (6.8)	24.6 (6.8)	62.1	59	<0.201	25.2 (7.0)	60	83	<0.088
	Partners	26.7 (6.6)	23.2 (6.3)	66.7	97.5	<0.006	23.6 (6.9)	58.1	103	<0.016
BDI-II	Veterans	12.6 (11.5)	9.0 (7.7)	69	113	<0.008	9.6 (9.0)	66.7	129	<0.006
	Partners	10.1 (7.8)	6.3 (7.2)	66.7	88	<0.015	7.5 (9.4)	67.7	88	<0.032
Compassionate Love Scale	Veterans	83.5 (12.1)	88.1 (14.5)	72.4	58.5	<0.212	84.1 (14.4)	66.7	-35.5	<0.453
	Partners	91.1 (10.6)	91.4 (12.5)	77.8	-25	<0.513	87.2 (15.6)	64.5	-58	<0.216
Self-compassion Scale	Veterans	3.0 (0.6)	3.4 (0.7)	75.9	130.5	<0.003	3.2 (0.9)	70	84	<0.069
	Partners	3.0 (0.8)	3.3 (0.7)	63	100.5	<0.013	3.2 (0.7)	67.7	92	<0.057

# Acupuncture for the Trauma Spectrum Response: Scientific Foundations, Challenges to Implementation

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## ABSTRACT

The long wars in Iraq and Afghanistan have produced extensive and often repeated trauma to United States service members and their families. These injuries occur to the mind, the brain, the body and the soul. The current approach to management of these injuries follows the standard medical model that attempts to isolate the pathophysiological locations and processes affected by the injury and provide specialized care for that part of the person—psychological treatment for mind injuries, neurological treatment for brain injuries, and surgical and rehabilitation approaches for body injuries. This model is overwhelmingly dominated by the use of drugs for symptom management. Yet, research has shown that, no matter where an injury is located, its impact and the healing responses to it cut across these boundaries resulting in a common symptomatic and functional spectrum. The authors of this article have called this the war-related trauma spectrum response (wrTSR) and propose a better approach to this spectrum, which is to induce whole-person healing responses not specialized to addressing the injury cause or location. Acupuncture appears to be such an approach. This article reviews the conceptual and scientific foundations of wrTSR, makes the case for managing it in a holistic manner, and reviews the evidence for using acupuncture as a treatment across the trauma response spectrum. This article then discusses the challenges to implementing of acupuncture in the military and veterans' systems and proposes direct comparative effectiveness, health services, and program evaluation approaches to providing the evidence needed to broaden acupuncture's use.

**Key Words:** Acupuncture, Military, Pain, Trauma Spectrum Response, TBI, PTSD, Depression, Anxiety, Moral Injury, Integrative Medicine

## INTRODUCTION

**T**HE CURRENT WARS in Iraq (Operation Iraqi Freedom, OIF) and Afghanistan (Operation Enduring Freedom, OEF) are returning thousands of warfighters with psychological mind injuries, such as post-traumatic stress disorder (PTSD), and physical mind-body injuries such as traumatic brain injury (TBI), many with long-term symptomatic and

functional consequences.<sup>1,2</sup> The multicomponent and overlapping nature of injuries in returning warfighters are appropriately considered as war-related, trauma spectrum responses (wrTSR) and may be of a different character and require a different approach than the civilian trauma stress response (TSR). Trauma to the head and neck occurs in 15%–20% of all battle injuries, and mild TBI (mTBI) may afflict up to 28% of all deployed warfighters.<sup>3,4</sup>

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More than 46% of blast patients and 55% of amputees at Walter Reed Army Medical Center (WRAMC) have sustained comorbid brain injuries. Nearly 20% of soldiers returning from the wars in Iraq and Afghanistan suffer from diagnosable post-traumatic stress disorder (PTSD),<sup>5,6</sup> and nearly 40% report stress-related symptoms and dysfunctions that significantly prevent reintegration into a full, productive life. As stated by Potash, the wounded veteran presents the health care system with “new challenges” not the least of which is the “growing number of patients with co-morbid chronic pain...brain trauma and...attendant cognitive issues.”<sup>7</sup>

Triggered by combined mind-brain/body injuries (MBIs), the various manifestations of wrTSR share many common pathophysiological and recovery mechanisms. Evidence supports the potential for the development, expression and durability of certain types of pain and psychopathologies in which genotypic factors could be either latent or code for phenotypes (e.g., of ion channels, neurotransmitters, receptors and synaptic elements) that are differentially expressed from factors from the internal and external environments. In such genotypically predisposed individuals, environmental and/or psychosocial insult can induce a core constellation of common symptoms that includes: (1) psychological and emotional distress (e.g., depression, anxiety, or anger); (2) cognitive impairment; (3) chronic and, often refractory, pain of organic and psychosomatic origins; (4) drug/opioid desensitization (with abuse potential); and (5) somatic (sleep, appetite, sexual, and energy) dysfunction.

Best estimates suggest that multiple comorbidities after exposure to trauma may be present in a substantial percent of wounded military personnel. Villano et al.,<sup>8</sup> and Shipherd and coworkers<sup>9</sup> have shown that psychiatric conditions, such as depression and anxiety, appear to be responsible for the co-occurrence of a syndrome of chronic pain and heightened stress-reactivity, including frank presentation of PTSD, in between 24% and 66% of combat-wounded veterans of OIF/OEF. The impairment of cognitive abilities in patients with chronic pain and PTSD, and the reported incidence and prevalence of chronic pain, PTSD, other neuropsychiatric conditions, and cognitive deficits in wounded OIF/OEF troops has also been described by Beck and colleagues.<sup>10,11</sup> These results are strengthened by the report that more than 60% of these soldiers have been diagnosed with some form of brain-injury condition or apparent constellation of cognitive, emotional, and behavioral features resulting from neural insult.<sup>9</sup> When induced by exposure to deployment and battle, we refer to this constellation of trauma-related manifestations as wrTSRs (Fig. 1).

The current authors hypothesize that the effects of mind-brain injury are approached better by assessing the full spectrum of trauma-related morbidities—rather than dividing them into subcomponents—and then treating the whole person with an approach that enhances the patient’s inherent

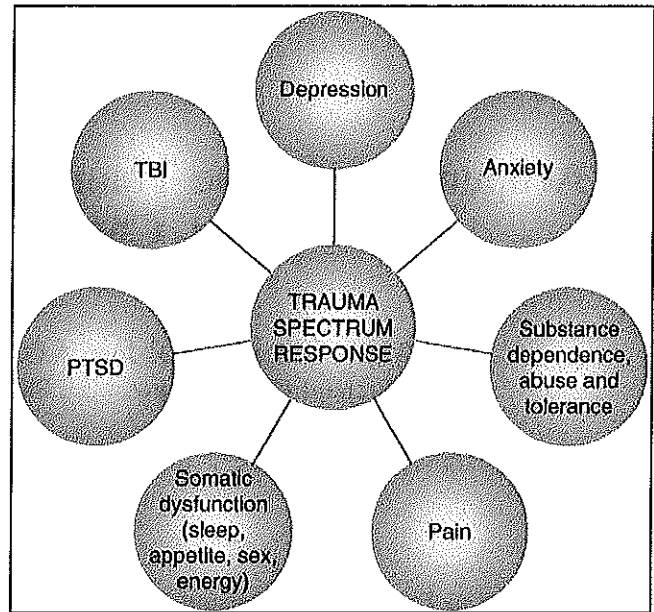


FIG. 1. Trauma spectrum response components. TBI, traumatic brain injury, PTSD, post-traumatic stress disorder.

healing mechanisms and capacities.<sup>12</sup> The current authors hypothesize that this can be done with a standardized acupuncture method. Using this approach, the authors will test the efficacy of acupuncture on Health Related Quality of Life (HRQoL) and wrTSR comorbidities in service members with TBI and PTSD drawn from several Department of Defense (DoD) and Veterans Affairs (VA) sites across the country.

## PTSD AND wrTSR

### PTSD as a Component of wrTSR

PTSD (from psychological or mind injuries) is a widely recognized consequence of combat trauma and frequently accompanies wrTBI and bodily injury. The PTSD prevalence rate in OIF/OEF active duty, deployed service members is estimated to be between 15.6% and 17.1%.<sup>13</sup> A more-recent study by the RAND Corporation put this rate at nearly 20%.<sup>6,14</sup> Likewise, the National Vietnam Veterans Readjustment Study (NVVRS<sup>15</sup>) found that more than 15% of male Vietnam theater veterans (VTVs) met criteria for current PTSD, and 30% met diagnostic criteria for lifetime PTSD, while 9% of female VTVs met current PTSD criteria and 27% met lifetime criteria for PTSD related to Vietnam combat trauma. High rates of PTSD and depression (ranging from 9% to 31%, depending on the level of functional impairment reported) are accompanied in nearly half the cases by alcohol abuse or aggressive behavior comorbidity.<sup>14</sup> According to the official report of the Joint Mental Health Advisory Team 7 (J-MHAT 7),



2010 prevalence rates of acute stress, depression and anxiety among deployed OIF/OEF service members are 17.4%, 7.9%, and 8.8%, respectively.<sup>16</sup>

PTSD (especially combat-related PTSD) commonly co-occurs with other psychiatric disorders. In fact, the majority of individuals with PTSD meet criteria for at least one other psychiatric disorder and many for three or more<sup>17,18</sup> including: depression,<sup>19,20</sup> suicide,<sup>21–23</sup> substance abuse disorders,<sup>15,24</sup> anxiety disorders,<sup>18</sup> and chronic pain.<sup>25–28</sup> Comorbid diagnoses are particularly common among people suffering from combat-related PTSD with many in more than 50%.<sup>29,30</sup> Any additional disorders in the presence of PTSD complicates the treatment process and weakens the prognosis for recovery.<sup>17,31,32</sup>

### **Injury and Trauma to the Soul**

In combat, perpetrating, failing to prevent, or witnessing acts that transgress deeply held values can shatter an individual's beliefs about the purpose and meaning of life, challenge belief in God, induce moral conflict, and even precipitate an existential crisis.<sup>34</sup> In December 2009, Veteran's Administration mental health professionals described a new concept of the consequences of spiritual and psychological trauma: "moral injury," defined as "perpetrating, failing to prevent, or bearing witness to acts that transgress deeply held moral beliefs and expectations."<sup>35</sup> Clinicians have observed that moral injury is a significant contributor to clinical depression, addiction, violent behavior, and suicide, and that the current wars create conditions that increase the exposure to moral injury.<sup>36</sup> Signs and symptoms of moral injury include misconduct, violence, other disciplinary problems, social alienation, alienation from self, loss of faith, and loss of meaning.<sup>37</sup>

Prevalence rates for moral injury are not yet available, because it is a relatively new construct, and a well-validated metric is lacking. (A 14-item Moral Injury Scale [MI Scale] has been developed as part of the Marine Resiliency Study [MRS]<sup>38</sup> but this scale has not yet been validated in the military.) However, surrogate statistics can be used to estimate the magnitude of the problem. The 2010 MHAT-VII survey found that < 15% of soldiers report high or very high individual morale, and 13% report suicidal ideation. Suicide rates among active duty military and veterans are currently alarmingly high and rising.<sup>39</sup> Suicide rates have doubled among Marines in the last 3 years, and these rates remain more than double the national average among Army personnel.

### **PTSD and Substance Abuse**

Substance-use disorders (including alcohol and drug abuse, and dependence) represent another class of disorders commonly co-occurring with PTSD. In two community studies of Vietnam veterans with PTSD, 22%<sup>33</sup> and 39%<sup>24</sup> also had current alcohol abuse or dependence. One hy-

pothesis for this phenomenon is that people with PTSD use alcohol and drugs as a means of self-medicating to relieve their debilitating symptoms.<sup>18</sup> This hypothesis is supported by the finding that a diagnosis of PTSD increases a person's risk of developing an alcohol and drug use disorder. However, research has also demonstrated that people with PTSD (particularly males) are more likely than others with a similar background to have an alcohol use disorder that preceded PTSD.<sup>40,41</sup>

Whatever the cause of comorbidity between PTSD and alcohol/drug use disorders, it is clear that excessive use can worsen the symptoms related to PTSD, including sleep disturbance, difficulty in concentrating, emotional numbing, social isolation, anger and irritability, depression, and hypervigilance. Alcohol can also reduce a person's ability to cope with traumatic memories and stress. A number of factors complicate the treatment of comorbid PTSD and alcohol-use disorder. While, to a patient, alcohol use may appear to help symptoms of PTSD by decreasing the severity and number of nightmares, alcohol may also exacerbate the cycle of avoidance that occurs in PTSD.<sup>42</sup> Furthermore, people with comorbid PTSD and alcohol abuse/dependence are at increased risk for premature termination of therapy, and take a longer time to remit from an episode of chronic PTSD.<sup>31,32</sup>

### **PTSD and Pain**

A number of studies have been conducted to assess the co-occurrence of PTSD and chronic pain symptoms. Benedikt and Kolb reported that 10% of 225 patients referred to a VA pain clinic met criteria for PTSD.<sup>25</sup> Muse reported that 9.5% of a sample of patients attending a multidisciplinary chronic pain center met criteria for "posttraumatic pain syndrome."<sup>43</sup> Patients referred for assessments of chronic pain resulting from a traumatic event have an even higher prevalence of PTSD. In a study conducted to determine the extent to which work-related injuries were associated with PTSD, assessments of 139 injured workers with chronic pain referred to a rehabilitation program indicated that 34.7% reported symptoms consistent with PTSD.<sup>44</sup> Rates of PTSD in patients for which pain is secondary to a motor vehicle accident range from 30% to 50%.<sup>45–47</sup> Geisser et al. examined self-reports of pain, affective distress, and disability in pain patients with and without PTSD symptoms.<sup>48</sup> The results of this study indicated that patients with accident-related pain and high PTSD symptoms reported higher levels of pain and affective distress, compared to patients with accident-related pain who did not have PTSD.

Studies examining the prevalence of chronic pain in patients with a primary diagnosis of PTSD have reported even higher rates of other comorbid conditions. McFarlane et al. reported that pain was the most common physical complaint (45% back pain and 34% headaches) in a sample of PTSD patients reporting physical symptoms.<sup>26</sup> Beckham et al.

performed a study to investigate chronic pain patterns in Vietnam veterans with PTSD<sup>27</sup> and found that 80% reported the presence of a chronic pain condition. In addition, increased levels of PTSD involving reexperiencing of symptoms were associated with increased pain levels and pain-related disability. White and Faustman reported that 60% of 543 veterans treated for PTSD had an identified medical problem and that 1 in 4 had signs some type of musculoskeletal or pain problem.<sup>28</sup>

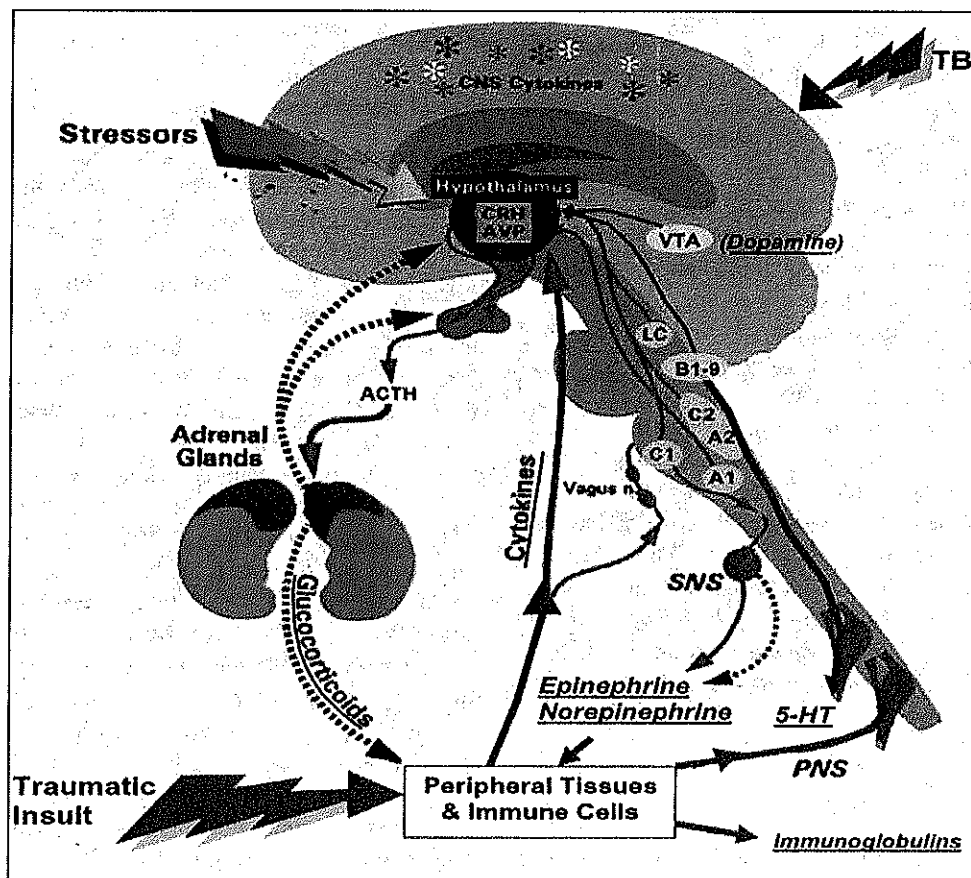
The co-occurrence of pain and PTSD may have implications for both conditions. Patients with chronic pain related to trauma and PTSD experience more intense pain and affective distress,<sup>48,49</sup> higher levels of life interference,<sup>50</sup> and greater disability than pain patients without trauma or PTSD.<sup>51</sup> Chibnal and Duckro found that patients with PTSD and traumatic headache pain had higher levels of depression and suppressed anger than non-PTSD traumatic headache pain patients.<sup>46</sup> In addition, patients with post-traumatic headache reported more frequent pain and had a poorer prognosis than did nontraumatic headache patients.<sup>52</sup> Thus, the presence of both PTSD and chronic pain may increase the symptom severity of either condition. In the proposed

study, acupuncture treatment in combat-injured soldiers is intended to improve recovery from both conditions and interrupt the trajectory of chronic PTSD and pain symptoms.

### Traumatic Brain Injury and wrTSR

TBI is a major cause of death and disability in young people, involving more than 5 million Americans and an annual cost of nearly \$50 billion.<sup>53–55</sup> More than 7000 noncombat patients are admitted to VA and military hospitals for TBI annually, with an additional 1700 resulting from problems related to the recent wars in Iraq and Afghanistan.<sup>3,4</sup> Approximately 28% of service members (SMs) with battle injuries requiring evacuation to WRAMC have had TBI.<sup>4</sup> Trauma to the head and neck occurs in 15%–20% of all SMs with battle injuries and mild TBI (mTBI) may afflict up to 28% of all deployed warfighters.<sup>3,4</sup> More than 46% of blast patients and 55% of amputees at WRAMC have sustained comorbid brain injuries.<sup>56,57</sup>

Symptoms and dysfunction, from mild-to-moderate TBI cross the spectrum of dimensions in wrTSR and may include physical symptoms (headache, dizziness, balance, visual



**FIG. 2.** The hypothalamic–pituitary–adrenal (HPA) axis. Dotted lines represent negative regulatory pathways, solid lines represent positive regulatory pathways. Reprinted with permission from *Annual Review of Immunology*, Volume 20, 2002 by Annual Reviews ([www.annualreviews.org](http://www.annualreviews.org)). TBI, traumatic brain injury; CRH, corticotrophin releasing hormone; AVN, arginine vasopressin; ACTH, adrenocorticotrophin hormone; SNS, sympathetic nervous system; PNS, parasympathetic nervous system.

changes, and pain), cognitive dysfunction (memory, attention, and concentration difficulties), and psychological or behavioral problems (depression, anxiety, anger, mood swings, social and family dysfunctions).<sup>58</sup> Patients admitted to the hospital for other injuries may have sustained previously unrecognized brain injuries or suffer from psychological and stress traumas. The mechanisms and manifestations of TBI from combat blast injuries may have different and more complex characteristics than civilian blunt head injuries.

Wounded military personnel also have unique demographic factors that cause trauma-related physical and psychological injuries to manifest in a particular way. First, this patient population may be comprised of young(er) individuals with characteristically multiple, compound traumas that involve substantial alterations in physical and mental status, and which require acute, subacute, and long-term therapeutic support in both curative and palliative domains.<sup>59</sup> Second, the personal protective equipment that is currently used by the military has undergone significant improvement over its iterations in previous wars. But while such gear has proven to reduce combat-related mortality, the enhanced survival afforded by Kevlar head and torso equipment has led to an increased morbidity of IED-induced injuries, including blast-generated appendicular fractures, projectile wounds, traumatic amputation(s), and compression wounds as well as concussive (and cerebral contusive) insults.<sup>4</sup>

Finally, such external-blast TBI (ebTBI) is more often accompanied by skull fractures, seizures, and limb amputations. (For a summary, please see Warden and French 2005 and Warden 2006.<sup>3,4</sup>) Rates of post-concussive symptoms (PCS) may occur at increased frequency than found in civilian populations.<sup>4</sup> MTBIs sustained in battle may be difficult to distinguish from, and are often accompanied by, PTSD. Thus, both MTBI and PTSD often manifest with similar sets of symptoms and dysfunctions.<sup>60</sup>

### Converging Mechanisms of wrTSR

As illustrated in Figure 2, there are interactive peripheral and central mechanisms that affect the progression of the constellation of features representative of wrTSR. Both physical insult to peripheral tissues and the concomitant stress that such an injury evokes induce this cascade of events to produce early and late effects across the trauma spectrum. These interacting mechanisms produce high levels of inflammatory mediators, including the cytokines (most notably interleukins [IL]-1 and -6), tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), neurotropic factors and the tachykinins (including substance P).<sup>61</sup> These “bottom-up” mediators can affect the central nervous system (CNS), both by engagement of the peripheral nervous system and by accessing the CNS via altering the vascular integrity and permeability of the brain, to evoke neuroinflammatory changes within the brain parenchyma. The cytokines and tachykinins affect glial metabolism and disrupt glial-neuronal calcium

regulation, leading to increased neural uptake and endocellular release of calcium.

Acting as an intracellular messenger, calcium produces “downstream” effects to induce early and late-stage transcriptional factors and promotes translation of ion channel, synaptic, enzymatic, and receptor proteins that can lead to disrupted neural function in several brain areas (for a summary see Carofoli and Klee, 1999).<sup>62</sup> This aberrant neural and glial activity is manifested in alteration of both neurochemistry (of neurotransmitter and metabolic systems; for example, epinephrine, norepinephrine, serotonin [5-hydroxytryptamine; 5-HT], and dopamine, as well as other peptidergic and amino-acid transmitters) and of more global network properties to produce “top-down” brain-mind effects that induce pathological change(s) in mentation, cognition, and psychological states (see Fig. 2). Thus, while initial effects may be transitory, more durable sequelae are evidenced in those systems with the highest “vulnerability,” namely, those neural networks and systems that have sustained direct neurological damage and those with genetic-phenotypic predispositions. These factors are strong predictors of the development of chronic pain, pain syndromes, and psychopathology following trauma.<sup>63</sup>

Some of these effects are overt and acute, while others are more subtle and delayed, reflecting the slower changes that occur as a central consequence of inflammatory processes, with resultant alterations in neural and glial function, and disruption and/or remodeling of neurological networks. The lack of explicit, first-order signs and symptoms may result in a return to combatant status, or, if other wounds are sufficiently grave, triage to a secondary- or tertiary-care facility. Often, it is in these settings—or in the home—that the signs and symptoms reflective of progression along the pain and neuropsychopathologic spectrum of wrTSR (i.e., co-occurrence of depression and anxiety—including PTSD—disorders) are more saliently expressed and in evidence. This is not incidental; rather, it may at least partially be the result of the psychophysiological effects of increased allostatic loads incurred by social, familial, occupational, and/or economic stressors.<sup>64</sup> The reciprocity and cyclicity of these events are such that:

1. Large-scale peripheral injury augments the inflammatory effects within the CNS.
2. Geno- and phenotypic factors are induced/provoked that are ultimately expressed as pain and psychopathology.
3. These pathologies become chronic, with possible functional and structural remodeling of CNS micro-networks
4. These networks mediate dysfunctional responses and reactions to environmental factors.
5. This adaptational dissonance enhances stress loads.
6. The condition(s) may worsen as discordant interactions between the underlying neural state and environmental factors become increasingly synergistic (Fig. 2).<sup>12,65</sup>

While symptomatic assessment is important, if not essential, to diagnose syndrome expression accurately within this spectrum disorder, and, ultimately, to determine the best type(s) of care, it is equally important to attempt to identify peripheral and central biological markers (e.g., IL 1 and 6, immunoglobulin G, cortisol) and endproduct metabolites of adrenergic (i.e., 3-methoxy, 4-hydroxy phenylglycol [MHPG]), dopaminergic (i.e., homovanillic acid [HVA], dihydroxyphenylacetic acid [DOPAC]), and serotonergic (i.e., 5-hydroxyindole acetic acid [5-HIAA]) neurotransmission (see below, also Fig. 2) that reflect particular syndromes or subsyndromes of the TSR continuum, and physiologic effects of both pathological variables and those of various treatments.

This pathological progression advances many patients to treatment failure, symptomatic worsening, chronic illness, psychosocial stress, and family and life disruption. As described below, there is good evidence to believe some integrative medicine approaches, especially acupuncture, can disrupt this pathological progression and offer an opportunity to reverse this cycle and lead to enhanced recovery, quality of life and function.

## PTSD, wrTSR, RESEARCH, AND THE HEALTH CARE SYSTEM

### Failure to Address the Full wrTSR and the Overuse and Underuse Burdens on Health Care

The expression of wrTSR complex often manifests following treatment of the acute neuropsychological symptoms caused by in-theater trauma, with signs and symptoms reflective of progression along this neuropsychopathological spectrum in these wounded military personnel.<sup>61</sup> This pathological progression may be the result of psychophysiological effects of increased allostatic loads incurred by social, familial, occupational, and/or economic stressors, and it advances many patients down the slippery slope of treatment failure, symptomatic worsening, psychosocial stress, and life disruption.<sup>62</sup>

These patients are classified into categories based on mind, brain, or bodily damage and sent to specialty clinics (psychiatry, neurology, rehabilitation medicine, etc.) that address selected components of the wrTSR (psychological, neurological, or physical). Often, these SMs simply do not show up for care (avoiding treatment altogether for symptoms that carry a social stigma) or show up repeatedly at a later time in primary care clinics with a variety of somatic complaints involving dysfunctions in sleep, appetite, energy, and/or sexual activity. The former results in underdiagnosis and treatment, and the latter increases the burden on primary care resulting from chronic, unremitting illness. The latter may arise from so-called "subthreshold" PTSD or "mild-to-moderate" TBI, which often goes undiagnosed

or is treated ineffectively.<sup>63</sup> These patients present weeks to months after trauma exposure with symptoms and dysfunctions that chronically burden the DoD or VA health care delivery systems.<sup>7,63</sup> Clearly, the zero-sum nature of this situation is opprobrious to the sound practice of medicine—both technically and ethically—and calls for a more innovative and comprehensive approach to addressing the full consequences of mind–brain/body injuries (MBI).

### The Need to Focus Research on the Whole Person wrTSR Response

Clearly, these epidemiological and mechanistic data indicate a large and growing clinical problem (with recent estimates of this pattern of comorbidity within this population of wounded at as much as  $n=10,000$ )<sup>66</sup> and suggest that these patterns of comorbidity may reflect underlying, common patho-etiological variables and mechanisms; compel the need for additional research to define these variables and mechanisms more fully; and equally compel and sustain the need for "the development of intervention based on a new integrated care model."<sup>9</sup> In addition, the long-term impact of MBI goes far beyond individuals and affects their families and communities, which, too often, go unaddressed by the health care system.<sup>67</sup> Thus, from the perspectives of the person, family, and community, there is good reason to consider the full wrTSR (rather than individual components) and to investigate integrative, multidimensional (mind, body, symptom, function) approaches to classification and treatment.

Because of this complex nature of the trauma response, the current standards of care for wrTSR are probably not maximally effective, nor do they address fully the biopsychosocial aspects and spectrum effects of wrTSR. Thus, there is a need for additional research to define and understand TSR more completely so as to develop interventions based upon both neuroscientific information and new integrated care models. Such care should address the whole-person experience of wrTSR and seek to facilitate prevention, cure, and healing as an integrated paradigm that includes contextual understanding of patient-specific variables, uses innovative therapeutic approaches based on rigorous methods of empirical evaluation, and narrows the gap between research and clinical practice.<sup>8</sup> Complementary and integrative approaches, and acupuncture in particular, may be able to address many of these challenges to wrTSR treatment.

### Complementary and Integrative Practices

Complementary and integrative medicine (CIM) refers to a family of holistic practices used in conjunction with conventional medicine to enhance health, stimulate recovery, and reduce side-effects. CIM therapies are being increasingly utilized within comprehensive care models<sup>68</sup> and may provide major contributions to patient recovery. Local

surveys in military treatment facilities have shown that more than 70% of DoD beneficiaries may use CIM at certain sites.<sup>69</sup> A large survey conducted by the Samueli Institute (Alexandria, VA) in conjunction with the DoD Health Behaviors Survey showed that more than 45% of active duty military members have used CIM and more than two thirds used dietary and nutritional supplements in a 12-month period. Surveys, such as the Klemm Analysis Group<sup>70</sup> and Healthcare Analysis and Information Group<sup>71</sup> reports, showed extensive use of CIM practices by Veterans Health Administration (VHA) health care practitioners.<sup>62</sup> The wide acceptance of CIM for addressing various health issues suggests that, were a CIM approach to prove effective for treating PTSD, many people who have mixed feelings about psychiatric treatment might use CIM.<sup>73</sup> Current research is shifting its primary focus from managing and mitigation of PTSD to one that also promotes post-traumatic adaptation, development, and resurgence. Ai and Park<sup>74</sup> describe three interrelated trends in mental health research that are based on a broader view of (1) the positive psychology movement, (2) the recognition of the role of spirituality and religion in health and well-being, and (3) stress-related growth.<sup>74</sup> Similarly, research on the use of optimal healing environments for the treatment (and possible prevention) of the negative effects of PTSD is emerging.<sup>75</sup>

For the treatment of wrTSR, CIM approaches fall into two basic categories:

1. Actions people do for themselves that enhance self-care and self-treatment skills, such as mind-body practices<sup>76</sup> (imagery, relaxation response,<sup>77</sup> mindfulness training,<sup>78</sup> and yoga<sup>79</sup>), self-care skills (community self-care practices, diet, and exercise training), device-assisted biofeedback (heart-rate monitoring, breathing, and virtual reality), and diet and supplements for enhancing cognitive/physical fitness and psychological resilience
2. Nondrug and nonpsychiatric approaches used by CIM professionals to complement conventional treatments and facilitate healing, such as acupuncture,<sup>80,81</sup> Reiki, osteopathic manipulation,<sup>82</sup> chiropractic, and integrative medicine team approaches.

## RESEARCH ON ACUPUNCTURE FOR PTSD AND wrTSR

### Preliminary Data for the Effectiveness of Acupuncture for HRQoL and wrTSR Comorbidities

Arguably, the most promising CIM intervention for TSR is acupuncture. Originating in China, acupuncture has been used as a medical treatment modality for more than 2500 years, but only relatively recently has it received attention in the United States. It is based on a

concept of health and disease that is very different from conventional Western scientific thinking. Acupuncture theory holds that energy, called Qi, travels along pathways (meridians) within the body. Disease states result from disruption or blockage of proper Qi flow. To influence this energy flow, thin metal acupuncture needles are inserted at specific points along the meridians. The stimulation of those points may also be accomplished by other techniques, such as electrical stimulation, laser, moxibustion, and pressure.<sup>83,84</sup>

Acupuncture is used to treat many conditions. Even as far back as 1998, it was estimated that more than 1 million people in the United States collectively received 10 million acupuncture treatments.<sup>85</sup> Treated disorders included acute and chronic pain of various etiologies, nausea, stress and anxiety states, depression, substance abuse, allergic rhinitis, asthma, gastrointestinal disorders, infectious disease, and brain injury from stroke.<sup>84</sup> Overall studies show that acupuncture helps reduce stress, anxiety, and pain, and is effective for treating depression and insomnia, which are all symptoms with diagnostic groups that are part of the complex of the trauma spectrum.<sup>86-91</sup> The relevant studies are summarized next.

### Controlled Clinical Studies of Acupuncture

There is evidence, demonstrated via controlled clinical trials, that acupuncture can be effective for treating many of the specific comorbidities that comprise wrTSR in TBI and PTSD. Recent randomized, controlled, blinded studies support the efficacy of acupuncture for treating pain associated with fibromyalgia, knee arthroscopy, and labor.<sup>92-94</sup> These findings are consistent with many prior investigations showing the amelioration of pain caused by diverse conditions in both humans and animals.<sup>95</sup> Strong evidence also exists for treating postoperative nausea and vomiting with acupuncture, resulting in minimal side-effects.<sup>96</sup> Several clinical trials have demonstrated acupuncture's effectiveness for ameliorating stress and anxiety and for facilitating a mentally relaxed state.<sup>97-106</sup> Studies in healthy volunteers have demonstrated reduction in stress scores and levels of subjective stress achieved by acupuncture,<sup>107,108</sup> while another study showed an increase in vagal tone, with suppression of sympathetic tone in healthy volunteers, suggesting a direct effect on CNS control.<sup>109</sup> Acupressure has reduced anxiety and stress as well as perceived pain of treatment in emergency patients being transported to the hospital via ambulance.<sup>101</sup> Electrical stimulation of acupuncture points has been shown to increase "mental relaxation" in patients with chronic physical disorders,<sup>110</sup> and, in another controlled study of acupuncture, muscle sympathetic nerve activity was reduced in heart failure patients undergoing mental stress testing.<sup>111</sup>

Furthermore, acupuncture is effective for addressing other symptoms that comprise wrTSR, including insomnia<sup>112-115</sup> and somatic and postoperative pain.<sup>95,116-121</sup>

While research results for the effectiveness of acupuncture for treating drug addiction is mixed, there are national standards for using ear acupuncture in drug addiction, with reported effectiveness, and several states mandate a trial of acupuncture for treating drug addiction.<sup>122</sup> Several studies in patients with stroke have found that acupuncture can enhance cognitive and physical functioning in patients with brain damage above and beyond conventional rehabilitation approaches.<sup>123</sup> In a study by Hollifield (the acupuncture trainer and consultant on this project) and colleagues, acupuncture was as effective as cognitive behavioral therapy and markedly more effective than a wait-list control for alleviating symptoms of PTSD in veterans.<sup>124</sup> In addition, large randomized controlled trials of acupuncture for treating various chronic pain conditions have shown acupuncture to be more effective than guideline-based standard therapy.<sup>125,126</sup> Finally, numerous case reports, case series, and observational studies have reported benefits in patients after surgery and head trauma.<sup>126-131</sup>

Acupuncture studies frequently use the Short Form (SF)-36/SF-12 for measurement of HRQoL, which will be the primary outcome measure for this study. Across heterogeneous populations, acupuncture consistently improves SF-36 scores by 5–7 points,<sup>132-135</sup> a change that is considered to be clinically significant.

### Acupuncture Research in the Military

Several studies overseen by the primary author of this article have been done on acupuncture use in the military for the comorbidities of trauma response. These include studies on acute pain,<sup>73</sup> chronic and refractory pain,<sup>127</sup> and PTSD.<sup>128</sup> The authors are currently testing a simplified field deployable acupuncture technique to be used for headache called Battlefield Acupuncture (BFA), also known as Auricular Stimulation Procedure (ASP), previously tested for pain.<sup>81</sup> This simple Five Point ear acupuncture technique reduced pain by 23% over controls.<sup>81</sup> The authors of the current article have recently completed two studies at WRAMC using acupuncture. One in the Deployment Health Clinical Center found that acupuncture over 12 weeks was acceptable and effective as an adjunct in OIF/OEF patients being treated for PTSD.<sup>†</sup> A second study done in the rehabilitation clinic examined the effect of scalp acupuncture for treating phantom-limb pain in amputees from the war.<sup>‡</sup> In a pilot study, Niemtzw et al.<sup>130</sup> and Gambel et al.<sup>¶</sup> found acupuncture effective for addressing this otherwise refractory pain condition. A follow-up study is being planned that will parallel and coordinate data collection with this proposed study. The current authors have also conducted a

Rapid Evidence Assessment of the Literature (REAL©; which is also reported in this special issue by York et al., pages 229–236). The REAL was conducted to survey the literature on acupuncture research conducted in the military population and to evaluate the quality of the research available—there is a paucity of published reports in this area and further research is necessary, as acupuncture is becoming more readily chosen for military populations in the field for treating various conditions.

Translation of effective therapies is of prime importance for the military. The current authors are currently evaluating the feasibility of training Air Force physicians in the BFA technique for possible widespread use as a pain treatment modality in military primary care. The current study will use an approach recently shown by Hollifield et al. to be effective for trauma spectrum comorbidities in veterans with PTSD. Hollifield et al. used a semi-standardized acupuncture technique that was carefully developed from Traditional Chinese Medicine and matched to trauma response syndromes. In a randomized controlled trial, this approach was found to be easily teachable, as effective as cognitive behavioral therapy, and markedly more effective than a wait-list control for alleviating symptoms of PTSD in veterans.<sup>124</sup> Hollifield also found that this approach was effective for addressing other trauma comorbidities, including pain, insomnia and quality of life.<sup>§</sup>

### Common, Interacting Mechanisms of Acupuncture in wrTSR Conditions

Acupuncture may have such ubiquitous effects because it appears to simultaneously influence several common, interacting mechanisms involved in trauma response and recovery. Acupuncture is known to have effects on the autonomic nervous system and the prefrontal cortex—systems that are involved in the pathophysiology of the emotional, pain, and cognitive dysfunctions of TSR.<sup>136-138</sup> It has been established that acupuncture stimulates the release of endogenous opioids and that analgesic effects are blocked in a dose–response manner by naloxone, an opioid antagonist.<sup>95</sup> Cho et al. have demonstrated specifically that the cingulate gyrus and the thalamic areas, activated in the presence of applied pain stimulation, show brain activity that correlates with decreased pain sensation in human subjects.<sup>139</sup> There is evidence that electroacupuncture may affect the pressor response, resulting in decreased oxygen demand in the presence of myocardial ischemia<sup>140</sup> and cardiovascular reactivity and hypertension.<sup>141</sup> Thus, acupuncture appears to cause a broad matrix of CNS responses involving the amygdala, hippocampus, hypothalamus,

†Cooper J, Walter J, Ader D, Niemtzw RC. Outcomes and Cost Assessment of Acupuncture in the Treatment (OCAT) of Pain Patients at Malcolm Grow. Unpublished.

‡Engel C, Benedek D, Armstrong D, Osuch E, et al. Acupuncture for the Treatment of Trauma Survivors. Unpublished.

¶Gambel J, Niemtzw RC, Burns SM, Penhollow T, et al. Acupuncture for Post Amputation Limb Pain. Unpublished.

§Jonas WB and Hollifield M. Personal communication about acupuncture techniques effective for trauma. Washington, DC, 2008.

cerebellum, basal ganglia, anterior cingulate, insula, and other limbic structures, as evidenced by functional magnetic resonance imaging, positron emission tomography, and electroencephalographic studies.<sup>136</sup> Responses by the CNS may be dependent on the type and frequency of acupuncture treatment.<sup>136,142,143</sup> In this proposed study, the authors will use an acupuncture approach previously developed and found to be effective for addressing TSR.<sup>124</sup>

### Specific and Nonspecific Effects of Acupuncture

The many potential mechanisms for the efficacy of acupuncture on the trauma recovery spectrum has both pros and cons for testing its efficacy. The apparent “multimechanism” whole-person’s response acupuncture seems to provide a compelling rationale for testing acupuncture effects on quality of life and function in two heterogeneous populations—the authors expect both to improve significantly. The down side for collecting evidence about acupuncture efficacy is that it becomes difficult to select an appropriate control procedure without knowing its precise mechanism. Three competing mechanisms exist: (1) the traditional Chinese theory of “point specificity”; (2) the more Western explanations related to fascia and the induction of fascia/neural/inflammatory “matrix” responses; and (3) the “therapeutic meaning and expectancy” theory of acupuncture as a placebo. While all three of these potential mechanisms cannot be disentangled in a single clinical trial, the acupuncture control methods will be specifically selected to control for all three mechanisms simultaneously in the following manner.

Clinical trials testing the therapeutic claims of acupuncture have focused on the efficacy of needling at specific sites on the body surface (acupuncture points), using selected needling techniques. The choices of acupuncture points and needling techniques are guided by traditional and modern theories and diagnostic procedures. However, insertion of needles into the body can also induce a range of physiological effects that are not dependent on the location of stimulation and are thus considered nonspecific.<sup>144,145</sup> Among these nonspecific effects likely to be associated with the microtrauma of acupuncture are stimulation of cutaneous microcirculation,<sup>146,147</sup> heterosegmental analgesic mechanisms (i.e., diffuse noxious inhibitory control),<sup>148,149</sup> and aspects of the relaxation response.<sup>150,151</sup> Even “needle grasp”—a biomechanical phenomenon traditionally associated with acupuncture, needle insertion, and manipulation—has been shown to occur to a marked, albeit lesser, extent at control points relative to acupuncture points.<sup>152</sup> The realization that acupuncture treatment elicits nonspecific and specific effects has led to adoption of the term “sham acupuncture” for control needling procedures in randomized controlled trials (RCTs) of acupuncture, because the term “placebo” is generally applied to control procedures that are believed to be inert.

Nonspecific effects of needling may well have contributed to the outcomes of recent large-scale German trials of acupuncture (involving several hundred to several thousand patients per trial) in which sham acupuncture, delivered as superficial needling at non-acupuncture points with no needle manipulation, was found to be as effective as true acupuncture for treating low-back pain<sup>132,153</sup> and migraine.<sup>135,154</sup> Invasive sham acupuncture cannot be discarded as a control procedure in acupuncture trials, however, in part because another of the German trials, one on osteoarthritis of the knee,<sup>133</sup> found acupuncture to be statistically superior to the same type of “minimal acupuncture” provided in the low-back pain and migraine trials cited above.

The likelihood that invasive needling at non-acupuncture points induces some level of nonspecific healing has led to the development of an alternative type of sham acupuncture involving noninvasive needling.<sup>155,156</sup> This procedure utilizes needles with blunted tips, designed such that contact with the skin leads to retraction into the shaft instead of penetration of the skin. Despite nonpenetration, the sham needle is held “upright” because it perforates the tape used to hold a small O-ring in place that surrounds the needle placement site<sup>155</sup> or the sham needle perforates a small square of Styrofoam that is attached at the site of “needling.”<sup>156</sup> In either procedure, the patient sees the needle shorten and believes that true acupuncture has occurred—an expectation that has been confirmed by questionnaires. A review of the literature over the period since these nonpenetrating sham needles were introduced in 1999 reveals 19 RCTs that utilized a sham needling telescoping device, of which 8 trials were positive, 9 negative, and 2 mixed with regard to their authors’ stated primary outcomes. The summative situation with respect to trial results is similarly inconclusive in acupuncture trials that used invasive needling as a sham control procedure.<sup>157</sup>

At this stage in the development of acupuncture research methodology, it seems clear that an appropriate sham procedure cannot be designed or agreed upon until a clearer understanding emerges regarding the mechanism by which the acupuncture needle elicits its response.<sup>158</sup> Given the present dilemma, the current authors have chosen to utilize a noninvasive needling procedure for a sham control in the present 3-arm trial of acupuncture for HRQoL in TBI and PTSD. This procedure will be designed to control for the “meaning responses” (placebo)<sup>159</sup> associated with the delivery of acupuncture and, when compared to true acupuncture, will allow an assessment of the treatment benefit that results from acupuncture needling-related responses.

### CONCLUSIONS

There is a need for new approaches for treatment of trauma that induce a whole-person healing response. The current medical approaches that divide an individual into

subspecialties increase the precision of diagnosis and treatment but create complicated management approaches, which are, in some cases, counterproductive. Healing approaches such as acupuncture provide an alternative model to the current biomedical model and provide an opportunity for widespread healing with fewer medications and subspecialty oversight, and are nonstigmatizing.

However, the costs of differing strategies for delivery of acupuncture may vary substantially. Little research has evaluated the cost effectiveness of acupuncture treatment or determined which strategies are optimal for adoption. A recent panel conducted by the RAND–Samueli Program on Integrative Medicine Policy focused on economic analysis issues in CIM, which will help inform the DoD about the best approaches for evaluating these differing strategies. The report and toolkit from that panel should be out before the end of 2011. Given the growing interest in acupuncture and integrative approaches for treating wrTSR, such as that incorporated to the recent DoD Pain Task Force Report, and given the increased suffering likely to emerge as warriors return from the battlefield with the coming drawdown, it would behoove the military and the VA to substantially accelerate the development and evaluation of programs delivering acupuncture. SMs and families who are suffering the consequences of these long wars deserve nothing less than the optimal healing environments we can provide.

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