Healing Touch With Guided Imagery for PTSD in Returning Active Duty Military: A Randomized Controlled Trial

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ABSTRACT Post-traumatic stress disorder (PTSD) remains a significant problem in returning military and warrants swift and effective treatment. We conducted a randomized controlled trial to determine whether a complementary medicine intervention (Healing Touch with Guided Imagery [HT+GI]) reduced PTSD symptoms as compared to treatment as usual (TAU) returning combat-exposed active duty military with significant PTSD symptoms. Active duty military (n = 123) were randomized to 6 sessions (within 3 weeks) of HT+GI vs. TAU. The primary outcome was PTSD symptoms; secondary outcomes were depression, quality of life, and hostility. Repeated measures analysis of covariance with intent-to-treat analyses revealed statistically and clinically significant reduction in PTSD symptoms (p < 0.0005, Cohen's d = 0.85) as well as depression (p < 0.0005, Cohen's d = 0.70) for HT+GI vs. TAU. HT+GI also showed significant improvements in mental quality of life (p = 0.002, Cohen's d = 0.58) and cynicism (p = 0.001, Cohen's d = 0.49) vs. TAU. Participation in a complementary medicine intervention resulted in a clinically significant reduction in PTSD and related symptoms in a returning, combat-exposed active duty military population. Further investigation of GT and biofield therapy approaches for mitigating PTSD in military populations is warranted.

INTRODUCTION

Post-traumatic stress disorder (PTSD) is a common and persistent problem in military populations that warrants swift and effective treatment. Recent estimates suggest that among recent Iraq and Afghanistan veterans, 21.8% are diagnosed with PTSD, with prevalence rates increasing 4 to 7 times after the invasion of Iraq.¹ Substance use disorders, depression, and interpersonal conflicts also substantially increase in these soldiers,^{1,2} and physical health-related consequences such as increased risk for hypertension and diabetes have also been noted.^{3,4} Not surprisingly, the incidence of PTSD appears to increase with combat exposure.^{5–7}

Despite all best efforts to treat PTSD in our military, it remains untreated in a substantial number of those on active duty and/or recently deployed. These soldiers are more likely to report mental health issues compared to their reserve comrades,⁸ and yet are significantly less likely to engage in mental health services.^{8,9} In general, the younger cohort of Operations Enduring Freedom/Iraqi Freedom veterans are notably loathe to seek conventional PTSD treatment, in part, because of perceived stigmatization and negative beliefs about conventional mental health care (i.e., psychotherapy and medications^{9–12}). Even for those who may be open to seeking treatment, data suggests there are large numbers of military personnel who may not meet clinical cutoffs for PTSD immediately upon return from deployment, but whose symptoms escalate to clinical levels even up to 12 months postdeployment.^{2,13} These findings suggest a need for swift, effective, and nonstigmatizing treatment of PTSD symptoms in postdeployment active duty personnel, as well as speak to the need to address PTSD symptoms for active duty military in general health care settings as opposed to providing PTSD treatment solely in mental health care settings.

Complementary Medicine: Approaches and Use in the Military

Similar to civilian populations, complementary and alternative medicine (CAM) approaches are often sought out by military personnel, for a variety of health conditions. Recent studies estimate CAM use in U.S. Military populations to range between 39.3 and 50.7%.^{14–16} The largest epidemiological study reported that 41% of military personnel had reported CAM use in the past year, with 27% reporting use of practitioner-assisted CAM therapies (such as acupuncture, biofeedback, and biofield/energy healing¹⁴). Interestingly, the study reported that use of CAM was nearly doubled compared to no CAM use for those with a PTSD diagnosis, suggesting that military personnel with PTSD are relatively high users of CAM.

Study Purpose and Hypotheses

Given the high prevalence of PTSD symptoms in active duty personnel, a noted lack of initiation and/or adherence to mental health treatments for PTSD in this population, and supporting literature suggesting a potential openness to

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CAM approaches in those with PTSD symptoms, we conducted a pilot, two-armed randomized controlled trial (RCT) of a CAM intervention (Healing Touch with Guided Imagery [HT+GI]), compared to treatment as usual (TAU), in 123 active duty military personnel at Camp Pendleton, California. We hypothesized that this intervention would be effective in reducing PTSD symptoms (primary outcome) as well as depression, health-related quality of life, and hostility (secondary outcomes).

METHOD

Recruitment, Eligibility, Screening, and Enrollment

The study took place at the Marine Corps Base Camp in Camp Pendleton, California and was approved by the Clinical Investigation Department, Naval Medical Center San Diego and Scripps Office for the Protection of Research Subjects. Recruitment and enrollment took place from July 2008 to July 2010. Flyers announcing the study were posted at the Deployment Health Clinics (DHC) and the hospital mental health department on Camp Pendleton. Health care providers at these locations were introduced to the study by research staff members. During the postdeployment health reassessment for military personnel returning from a combat zone, the Base DHC providers identified potential candidates for the study via screening of PTSD symptoms. To be potentially eligible for the study, participants were identified by DHC providers to be currently experiencing at least one or more of the following hallmark PTSD symptoms: re-experiencing of trauma (via, e.g., flashbacks, nightmares, intrusive thoughts/images, exaggerated physical and/or emotional responses to triggers of trauma), exaggerated arousal (including insomnia and/or sleep disturbance, irritability, exaggerated startle response), emotional numbing, and/or avoidance (i.e., of people, places, or situations that might remind them of the trauma). Potentially eligible participants were then referred to the research staff for further screening via telephone. If the person was eligible, appointments were made to sign consent, complete pretest questionnaires and after completion, obtain randomized group status. Inclusion criteria were as follows: (1) female or male subjects 18 years or older, (2) postdeployment from a combat zone, (3) referred by Camp Pendleton clinician, and (4) identified by postdeployment health reassessment to have PTSD symptoms (as described above). Exclusion criteria were as follows: (1) Currently pregnant or nursing, (2) currently using HT or GI from other sources, and (3) inability to sign informed consent. The study screened 205 potential participants; of these, 123 were eligible and enrolled in the study.

Overview of Research Design

This was a Phase 2, two-armed, RCT with one arm randomized to receive HT+GI and one arm randomized to a TAU control group. Each participant was studied over a 1-month period. Although follow-up assessment was originally planned for this study, it was not possible as the active duty study participants were awaiting further deployment and would not be available for follow-up assessment. Participants were randomized using a computer-generated randomization table by a statistician not affiliated with the study. This table was provided to two study co-ordinators who, each assigned patients to their respective groups upon entry. Both the principal investigator and data analyst were blind to group assignment (group status was coded with study numbers until data analyses were completed, at which point the group assignment was revealed). Those randomized to the HT+GI group received 6 treatments over a 3-week period in addition to any other standard care, and those in TAU continued to receive their standard care for PTSD, which included various forms of psychotherapy (including cognitive behavioral therapy, biofeedback, and relaxation training), as well as in many cases, medications.

Intervention

Participants randomized to the intervention group received a combined intervention of HT+GI. The purpose of combining these interventions was to provide the participant both with practitioner-based treatment (HT) to establish a "safe space" using a nonstigmatizing touch-based therapy aimed at eliciting the participant's own healing response, whereas also engaging in a self-care therapy (listening to GI CD) that helped the patient to work with trauma-related issues including trust and self-esteem. HT is a type of biofield therapy that involves gentle, noninvasive touch by trained practitioners, who utilize specific techniques with the intention of working with the body's vital energy system to stimulate a healing response. Two nurses certified in HT, with several years of experience in using HT with patients, provided the HT intervention. Practitioners met on a regular basis to discuss use of specific techniques and ensure intervention delivery consistency. Practitioners utilized three specific HT techniques: Chakra Connection (involving techniques used along the body, intended to stimulate movement of vital energy through the body), Mind Clearing (techniques performed on the head, intended to stimulate mental relaxation), and Chakra Spread (an advanced technique utilized by HT practitioners and generally reserved for patients with more severe symptoms, intended to promote deep healing for emotional and/or physical pain).

GI is a complementary therapy that utilizes visualization to induce a state of deep relaxation. The GI recording (CD) used in this study was specifically for use in PTSD (Healing Trauma (PTSD)—Healthy Journeys by Belleruth Naparstek). This recording does not utilize imagined exposure but uses imagery and affirmations to enhance relaxation, reduce negative emotions associated with PTSD (such as terror and shame), and promote healthy self-esteem and sense of protection.

Participants randomized to the HT+GI group received 6 sessions of HT over a 3-week period (two sessions per week). Each session was of 1 hour's duration and consisted of the participant lying fully clothed on a massage table, listening to the GI CD, whereas the practitioner provided HT. After the

first HT+GI session, participants were given the GI recording on CD and encouraged to listen to the GI recording at least once daily or more often if desired. Participant's adherence to listening to the GI CD was not assessed.

Outcome Measures

Primary Outcome Measure—PTSD Symptoms (PCL-Military)

The primary outcome examined was PTSD symptoms as indexed by the gold-standard PTSD Checklist (PCL)-Military. This reliable and valid¹⁷ 17-item self-report measure was developed by the National Center for PTSD and measures PTSD symptom severity in reference to stressful military experiences. Scores range from 17 to 85. A clinical cutoff score of 50 has been established as an optimal cut point for PTSD diagnosis using this measure.¹⁸

Secondary Outcome Measures—Depression (BDI), Quality of Life (SF-36), and Hostility (Cook–Medley Hostility Inventory)

Given recent data indicating the clustering of depression and poorer quality of life as well as higher hostility with higher PTSD in military populations,^{19,20} we examined potential changes in depression, quality of life, and hostility as secondary outcomes. Depression was measured via the Beck Depression Inventory (BDI-II), a highly reliable and valid 21-item self-report scale that measures depressive symptomatology including sadness, feelings of guilt, perceptions of self-worth, suicidal ideation, and changes in appetite and body weight, among other characteristics.²¹ Scores range from 0 to 63; scores above 18 indicate likelihood of major depressive disorder (MDD).²² Quality of life was measured using the goldstandard SF-36 measure, which has been found to have high reliability and validity²³ and is widely used to examine both mental quality of life (summated via the mental component score [MCS]) as well as physical quality of life (summated via the physical component score [PCS]). Scores range from 0 to 100 with higher scores representing higher quality of life. Norms for the general U.S. population for the PCS and MCS are 50.²⁴ Finally, we utilized the reliable and valid Cook-Medley Hostility Inventory, to measure the derived scales of hostile affect, cynicism, and aggressive responding.²⁵

Statistical Analysis Strategy

To determine sample size, a power analysis using the program G-Power was performed for the primary variable of interest (PCL-Military), using means and SDs derived from the instrument's standardization report, $\alpha = 0.05$, and a power of 0.90. A mean initial PCL score of 64 was hypothesized based on previous norms. For a hypothesized reduction of ~10% in the mean PCL score from 64 to 58, a total of 126 (63 subjects per group) were needed. Data were analyzed via repeated measures analysis of covariance (RMANCOVA), using SPSS 17.0. Outcome data were examined for potential outliers and verification of normal distribution. Demographic and behavioral characteristics (age, gender, ethnicity, marital status, number of children, years of service, number of times deployed in a combat zone, alcohol use, and PTSD medication use) were examined for potential correlations with outcome variables and entered as covariates in the analysis if associated with the dependent variable at p < 0.05. Intent-to-treat analyses were performed using the last-score carried forward approach; this approach was compared to per-protocol analyses (using casewise deletion) to confirm agreement in results. Alpha was set to 0.05; to avoid Type 1 error with multiple comparisons, alphas for secondary outcome measures comprised of separate subscales (i.e., SF-36 and Cook–Medley Hostility Inventory) were Bonferroni corrected (0.05/2 or 0.025 for SF-36 MCS and PCS scales, and 0.05/3 or 0.016 for Cook-Medley Cynicism, Hostile Affect, and Aggressiveness scales). Effect sizes were calculated using absolute values of Cohen's d, using the standard formula: $d_{IGPP} = (M_{post}, E - M_{pre}, E)/SD$ pre, E - $(M_{\text{post}}, \text{E} - M_{\text{pre}}, \text{C})/SD_{\text{pre}}, \text{C}.$

RESULTS

Figure 1 depicts the Consolidated Standards of Reporting Trials (CONSORT) flow diagram for participants through the study. Of the 123 participants, there were 21 dropouts for a total attrition rate of 17%. Of these dropouts, 15 were in the control group (28.3% attrition rate) and 6 were in the treatment group (12.2% attrition rate). No adverse effects were reported.

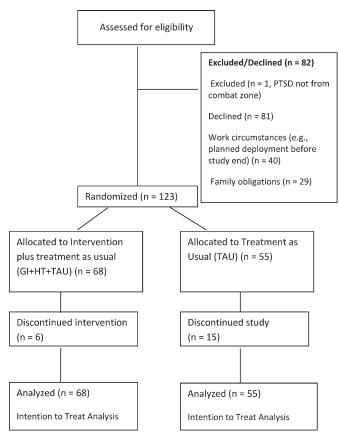


FIGURE 1. CONSORT patient flow diagram.

Demographic/behavioral characteristics of participants are found in Table I. All data were normally distributed with no outliers. Intent to treat analyses based on RMANCOVA were conducted using relevant covariates in each analysis. Means and SDs for primary and secondary outcome measures are depicted in Table II.

Primary Outcome—PTSD Symptoms

PTSD medication use was significantly positively correlated with increased PCL scores and entered as a covariate in analysis. RMANCOVA analysis for PCL scores controlling for medication use indicated a significant group × time interaction ($F_{1,113}$ =

TABLE I. Baseline Medical and Demographic Characteristics of 123 Active Duty Personnel: Means (Range) for Continuous Variables and Percentages for Categorical Variables

	HT + GI + TAU	TAU	
Characteristic	(n = 68)	(n = 55)	p-Value
Age, Years	27.1 (20, 42)	27.9 (20, 48)	0.51
Military Service, Years	7.2	7.9	0.42
Number of	1.9	2.0	0.74
Times Deployed			
Gender			0.75
Male	89.7%	92.7%	
Female	10.3%	7.3%	
Ethnicity			0.29
Caucasian–American	69.8%	67.4%	
Hispanic/Latino	28.6%	23.9%	
African-American	0%	4.3%	
Asian/Pacific Islander	1.6%	4.3%	
Marital Status			0.80
Married	61.2%	63.6%	
Divorced	6.0%	9.1%	
Separated	9.0%	5.5%	
Single	23.8%	21.8%	
Number of Children	0.87 (0, 7)	1.1 (0, 5)	0.20
Currently Use Medications	56.9%	51.9%	0.71
for PTSD (%)			
Currently Drink	74.2%	70.4%	0.68
Alcohol (%)			

23.0, p < 0.0005), with PTSD symptoms markedly declining for the HT+GI group (Cohen's d = 0.85). This group by time interaction is depicted in Figure 2.

Secondary Outcomes—Depression, Quality of Life, and Hostility

Alcohol use was significantly positively correlated with BDI depression scores and was entered as a covariate in RMANCOVA analyses. Results indicated a significant group × time interaction ($F_{1, 117} = 15.3$, p < 0.0005), with the HT+GI group showing notable decreases in depression over time (Cohen's d = 0.70).

For quality of life, PTSD medication use was significantly associated with poorer SF-36 mental health as indexed by MCS scores, and alcohol use was significantly positively correlated with poorer physical health as indexed by PCS scores. These were entered as covariates in subsequent analyses. RMANCOVA for MCS scores indicated a significant group × time interaction ($F_{1, 114} = 10.0$, p = 0.002), with those in the HT+GI group showing increases in mental health quality of life over time (Cohen's d = 0.58). Results for the PCS scores when controlling for alcohol use were not significant when Bonferroni corrected (p = 0.04, Cohen's d = 0.2).

For Cook–Medley Hostility scales, increasing age, years of military service, and number of children were negatively associated with Cynicism; ethnicity was significantly associated with Hostile Affect, and increasing age and number of children were negatively associated with Aggressive Responding. These were entered as covariates in respective analyses. Results indicated a significant group by time interaction for cynicism ($F_{1, 114} = 11.2, p = 0.001$, Cohen's d = 0.49), a trend for hostile affect ($F_{1, 105} = 5.3, p = 0.02$, Cohen's d = 0.58), and no effect for aggressive responding (p = 0.67, Cohen's d = 0.03).

To verify that our use of the last-score carried forward approach for intention-to-treat analyses was appropriate, we conducted per-protocol analyses (RMANCOVA without substitution of missing values using casewise deletion). Results

TABLE II. Means (95% Confidence Intervals) for Outcome Variables by Group

	HT+GI+TAU $(n = 68)$	TAU $(n = 55)$	RMANCOVA <i>p</i> -Value; Effect Size (Cohen's <i>d</i>)
PCL-Military Preintervention	54.0 (50.9, 57.2)	55.6 (52.1, 59.1)	
PCL-Military Postintervention	40.7 (37.0, 44.2)	52.0 (48.0, 56.0)	p < 0.0005; Cohen's $d = 0.85$
BDI Preintervention	25.6 (22.9, 28.4)	26.8 (23.7, 29.8)	
BDI Postintervention	16.4 (13.5, 19.4)	23.9 (20.6, 27.1)	p < 0.0005; Cohen's $d = 0.70$
SF-36 PCS Preintervention	48.5 (46.1, 50.1)	48.0 (45.5, 50.6)	
SF-36 PCS Postintervention	49.9 (47.7, 52.1)	47.2 (44.7, 49.7)	p = 0.04; Cohen's $d = 0.20$
SF-36 MCS Preintervention	30.3 (27.6, 33.1)	30.1 (27.1, 33.3)	
SF-36 MCS Postintervention	39.6 (36.5, 42.6)	32.9 (29.5, 36.3)	p = 0.002; Cohen's $d = 0.58$
CM Cynicism Preintervention	8.1 (7.5, 8.7)	8.3 (7.6, 9.1)	
CM Cynicism Postintervention	7.0 (6.3, 7.7)	8.7 (7.9, 9.4)	p = 0.001; Cohen's $d = 0.49$
CM Hostile Affect Preintervention	3.0 (2.7, 3.3)	3.3 (2.9, 3.6)	
CM Hostile Affect Postintervention	2.5 (2.1, 2.9)	3.3 (2.9, 3.7)	p = 0.02; Cohen's $d = 0.58$
CM Aggressiveness Preintervention	5.0 (4.6, 5.4)	5.1 (4.6, 5.6)	-
CM Aggressiveness Postintervention	4.8 (4.4, 5.2)	5.0 (4.5, 5.5)	p = 0.67; Cohen's $d = 0.03$

CM = Cook-Medley.

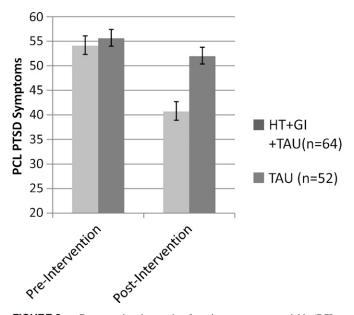


FIGURE 2. Group \times time interaction for primary outcome variable (PCL-Military symptom scores), controlling for the significant covariate of PTSD medication use.

were identical in terms of significance/nonsignificance of outcomes with comparable effect sizes, suggesting that the intention-to-treat analyses in this study were appropriate.

DISCUSSION

This phase 2 RCT examined the effectiveness of a combined complementary medicine intervention (HT+GI) compared to TAU on PTSD and related symptoms in active duty military. Results indicate significant and substantial reductions in PTSD symptoms, depression, and cynicism as well as improved mental quality of life for those receiving the intervention. Clinical cutoffs for PTSD diagnosis using the PCL are 50,¹⁸ and changes of 10 to 20 points are considered to be clinically significant.²⁶ The drop in PTSD symptoms for the intervention group by 14 points (from 54.7 to 40.7) thus has clinical as well as statistical significance. A score of 18 on the BDI has been found to be optimal in predicting major depressive disorder²²; thus, the pre-post drop from 26.1 to 16.4 for the intervention group also suggests a clinically meaningful reduction in depression. Although these results may generalize to other active duty military with combat-related PTSD symptoms, it is unclear how these results may generalize to other military populations (e.g., veterans with continued PTSD).

The decrease in cynicism (with a medium effect size), for participants receiving the intervention, is particularly noteworthy. Reports of higher cynicism are common among active duty combat soldiers and likely relate to issues of perceived stigma and negative beliefs about traditional mental health care (i.e., clinical psychology and psychiatry) that appear to hinder these soldiers from seeking help from mental health sources for PTSD. Our data support the notion that engagement in a complementary medicine approach that is less explicitly focused on "mental disorder" may serve to reduce soldiers' potential stigmatizing beliefs about mental health care (ostensibly through the positive perception and development of a patient-practitioner relationship) and possibly provide them with tools to better cope with PTSD symptoms as they emerge (potentially through enhancement of the relaxation response and increased sense of safety). However, specific dose-response effects and the potential longterm effectiveness of this intervention on maintaining reductions in PTSD symptoms are unclear. In contrast, the short- and long-term efficacy of gold-standard approaches (such as exposure, cognitive behavioral therapy, and eye movement desensitization and reprocessing) to reducing and preventing relapse of PTSD has been demonstrated.^{27,28} However, initiation of treatment and adherence to these therapies is noted to be problematic in this population.²⁹ A future direction for studies in this area may be to directly examine the effectiveness of complementary medicine interventions on increasing adherence and positive clinical outcomes in response to other gold-standard treatments for PTSD and/or depression. One might examine the potential mediating roles of decreased stigmatizing beliefs and enhanced sense of safety, on complementary medicine interventions' effects on adherence and outcomes to gold-standard approaches for eliminating PTSD.

There are notable limitations to this study, including lack of follow-up (which was not feasible for this studied population), lack of adherence monitoring (for listening to the GI recordings outside of sessions), and lack of an active comparison group. The study also had notably low representation among certain ethnic minority groups; although, this may be partly because of the lack of representation of these groups in the geographical area, it may also be due to selection bias. Some may point to the combining of the interventions of HT and GI as a limitation. However, this study was aimed at determining feasibility and effectiveness of the combined intervention, not mechanisms of action for each component. The decision to combine the two complementary medicine interventions was based on consultations with expert practitioners who, based on prior experience with similar populations, suggested that the combination of both biofield healing and GI would synergize to provide maximum effectiveness in reducing PTSD symptoms in the following manner: the GI, which focuses on creating a sense of spiritual safety and deep relaxation, provides an atmosphere where the participant could allow him or herself to safely and deeply engage into a relaxation response and therefore also gain maximum benefit from the interaction with the HT practitioner. The continued pairing of this relaxation response with the positive and trusting interaction with a health care professional and invitation for spiritual grounding and selfconnection would further the possibility of the mind-body to "let go" of the residual conditioning of previous trauma, and thus reduce PTSD symptoms. The underlying rationale for combining the two techniques is not unlike the underlying rationale for many psychotherapeutic approaches, where it is

understood that establishing trust, rapport, and often also a sense of relaxation are fundamental to the therapy processit is thought that with this foundation, the engagement in cognitive or behavioral processes to "process and let go" of traumatic experiences for symptom reduction is more effective. Thus, it may be argued that the main difference between these so-called "traditional" psychotherapeutic approaches and these "complementary medicine" approaches are simply the explicit foci of the therapies (i.e., practitioner focus on cognitive or behavioral techniques vs. practitioner focus on spiritual-energetic techniques). Whether the actual underlying mechanisms surrounding current psychotherapeutic approaches and many practitioner-assisted complementary medicine approaches are different remains to be elucidated. In conclusion, this study reports substantial reductions in PTSD symptoms, depression, cynicism and improvements in mental quality of life for active duty military receiving HT+GI vs. TAU. Effect sizes found for this intervention are comparable and sometimes superior to those reported in the literature for first-line pharmacological and psychological treatments, 28,30,31 with notably lower attrition rates. The attrition rate for participants in the active arm was quite low (12.2%), particularly when compared with attrition rates for other empirically supported treatments for PTSD, which have been reported to range from 20.5 to 54% and often also have significant nonresponse rates.^{32,33} Thus, this intervention appears effective both in reducing targeted symptomatology within the military health care setting and in soliciting receptivity and engagement from both the soldiers and their health care personnel. This indicates the potential in implementing such interventions in military health settings to help swiftly reduce the suffering of returning active duty military who suffer from combat-related PTSD and depression. However, the long-term follow-up effects of this type of approach on PTSD are yet unknown, and the potential value of this approach for potentially reducing treatment-discouraging beliefs and increasing the likelihood of further engagement in health-promoting services (including mental health services) needs to be evaluated. Future studies examining the impact of this intervention as a complementary treatment to help eliminate PTSD and depression in our military are warranted.

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