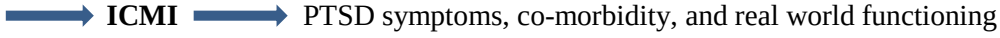
Title: Spiritually Oriented Cognitive Processing Therapy for Inner Conflict in Soldiers/Veterans with PTSD and Physical Injury

Research Aims & Objectives: Spiritual beliefs are important to many soldiers/veterans, are often used to cope with the stress of war/trauma, and predict faster recovery from PTSD. In contrast, spiritual struggles and moral injury are associated with prolonged recovery and persistent need for mental health services. A therapy (SOCPT) that utilizes the spiritual resources of Soldiers/Veterans and addresses spiritual and moral struggles may be more effective in relieving PTSD symptoms than conventional CPT (CPT) that does not always specifically and intentionally address them.

We are currently conducting surveys at four sites (two active duty Army [Fort Gordon, Fort Bragg] and two VA [Charlie Norwood and Durham], n=100 each site) to assess Soldiers/ Veterans with PTSD symptoms in order to (1) determine the prevalence of inner conflict/moral injury (**ICMI**) (i.e., guilt, shame, self-condemnation, spiritual struggles, difficulty forgiving, feeling betrayed, loss of trust, and loss of meaning, purpose, hope and faith); (2) develop and test the psychometric properties of a multi-dimensional symptom measure of ICMI (a mutable target for intervention that we think lies along the etiologic pathway to PTSD); (3) identify spiritual resources of Soldiers/Veterans that can be utilized to address ICMI; (4) determine receptivity of Soldiers/Veterans to a spiritually-oriented intervention for ICMI; (5) determine the interest level of Soldiers/Veterans in participating in a study that examines SOCPT for ICMI; and (6) examine the relationships between ICMI, spiritual resources, and PTSD symptoms and comorbidities such as depression, anxiety, physical pain, insomnia, relationship dysfunction, and substance abuse. Informed by these pilot data and following an experimental therapeutic approach, we propose here a proof of concept clinical trial to (1) determine the feasibility and acceptability of a *manual-based* SOCPT for engaging the ICMI target; (2) identify dose and duration of treatment necessary to engage the target (reduce ICMI); and (3) detect an initial signal of efficacy in terms of positive effects on PTSD symptoms, co-morbidities, and real world functioning (mental, physical, social) demonstrating an impact on therapeutic need. The ultimate goal is to develop a treatment that is more effective than current treatments for PTSD, increases overall functioning, and increases accessibility and acceptability of treatment to those who are at least somewhat S/R (most Soldiers/Veterans). This study will support the "go/no go" decision regarding further development/testing of SOCPT.

Specific aims:
1) Develop a *manual-based* SOCPT for engaging the ICMI target
2) Determine receptivity of Soldiers/Veterans to SOCPT for ICMI (i.e., recruitment & retention)
3) Determine if SOCPT is superior to conventional CPT in relieving ICMI
4) Determine if SOCPT is superior to CPT in relieving PTSD symptoms via reduction in ICMI
5) Determine if SOCPT is superior to CPT in relieving co-morbid depression, anxiety, substance abuse, sleep problems, pain, and improving overall functioning via reduction in ICMI



Study Rationale/Research Gap: PTSD is the most common mental disorder among Iraq and Afghanistan veterans **[1]** and is a major risk factor for suicide **[2]**. The risk of PTSD is much higher in those with physical injury or health problems, in whom PTSD symptoms are known to increase over time **[3]**. Inner conflict (sometimes called "moral injury") and spiritual struggles

are also common in PTSD, and if not addressed, may explain why PTSD is so resistant to treatment **[4,5]**.

Inner Conflict/Moral Injury (ICMI). Since the 1980's, war-time experiences such as violence, direct or indirect killing of enemy combatants and non-combatants (innocents), observing the death of fellow soldiers, and surviving when others have died, have been known to cause internal ethical conflict, guilt, self-condemnation, feelings of betrayal, difficulty forgiving, loss of trust, meaning and purpose, and spiritual struggles **[6]**. Only within the past 5-10 years, however, has the concept of moral injury received serious attention or been connected with PTSD (partly because of the resistance of PTSD to current treatments) **[4,7,8]**. Those with moral injury view themselves as immoral, irredeemable, and un-repairable, or struggle with their faith and believe they live in an immoral world – beliefs which may interfere with PTSD treatment unless addressed **[5]**. Soldiers/veterans raised in a religious environment may be particularly vulnerable to moral conflicts **[9]**.

Soldiers/Veteran Spirituality. Among active duty Soldiers in general, a 2011 survey of 34,416 military personnel in the DoD and 5,461 personnel in the Coast Guard found that nearly two-thirds (63.6%) classified themselves as medium (35.3%) or high (28.3%) on spirituality/religiosity (S/R) **[10]**. Soldiers reporting higher S/R had less heavy alcohol use (4.8% vs. 8.4%), less cigarette smoking (15.9% vs. 24.0%), less drinking and driving (4.0%), and less negative affect (6.7% vs. 9.6%) compared to those reporting lower R/S. According to a recent survey of 528,070 active duty Army personnel in 2013, 74.6% indicated a religious affiliation, 72.1% Christian (i.e., 97% of those indicating a religious affiliation) **[11]**. Many retired Veterans are likewise S/R. One study found that more than 80% of Veterans with severe PTSD at a residential treatment facility on the West Coast were at least somewhat S/R and nearly 70% believed in God as a "heavenly father who can be reached by prayer," **[12]** which is consistent with studies in Veterans on the East Coast **[13]**. Ethnic minority Soldiers/Veterans (Black Americans, Hispanics, etc.) have historically been particularly receptive to spiritual approaches.

Psychological Therapies for PTSD. Cognitive Processing Therapy (CPT) and prolonged exposure therapy (PE) are the primary evidence-based treatments for PTSD **[14]**. More than 2,300 VA clinicians have been trained in CPT and 1500 in PE **[15,16]**. Although the VA has mandated that Veterans with PTSD receive CPT or PE **[17]**, less than 10% have completed a course in either modality **[18-20]**. These therapies do not typically **focus on** moral injury, spiritual struggles, loss of faith, or actively utilize spiritual resources as part of the treatment. To fill this gap, we will develop and test a spiritually oriented version of CPT (SOCPT) for Soldiers/ Veterans with PTSD and co-existing physical injuries/illness. SOCPT will be *tailored to the specific spiritual/religious beliefs of each Soldier/Veteran*, as in our previous research testing spiritual cognitive approaches in those with physical health problems **[21]**.

Rationale for a Spiritually Oriented CPT. While there are many reasons why Soldiers/Veterans with PTSD are failing to complete CPT, one reason may be that those who are S/R perceive these therapies as inconsistent with their beliefs. Religious professionals are often reluctant to refer members of their congregation to mental health professionals, especially for psychotherapy that seeks to alter beliefs and attitudes. Since clergy represent a major first line treatment for mental health problems in the community, the failure of clergy to refer may prevent many Soldiers/Veterans from receiving treatment. If military personnel or family are members of a faith community, and that community does not support (or counteracts) the gains made in therapy, those gains may not last or treatment may be discontinued prematurely. Therefore, an evidence-based psychotherapy for PTSD that utilizes Soldiers'/Veterans' spiritual beliefs as part of the therapy may open the door to treatment for many military personnel with PTSD, especially

if delivered by chaplains or trained clergy. A spiritual form of CPT that targets ICMI may also be particularly effective in relieving PTSD symptoms, as inner conflicts and spiritual struggles tend to be widespread among those with combat-related PTSD **[4,22-24]**.

Greater S/R has also been shown to predict a faster resolution of depressive symptoms over time in those with physical health problems, including U.S. Veterans (increasing speed of remission by 50-70%) **[13,25-27]**. S/R involvement distinguishes resilient from non-resilient Veterans by increasing emotional stability, serving as a protective psychosocial factor, and increasing social connectedness **[28]**. As noted above, however, spiritual struggles are common in Veterans with PTSD, and PTSD symptoms have been significantly and positively associated with alienation from God, religious rifts, religious fear, and religious guilt **[24]**. In contrast, post-traumatic growth (PTG) in Veterans is significantly and positively associated with spiritual practices **[29]**. Studies reported this year (2015) reinforce these earlier findings. For example, a survey of 3,157 Veterans found that S/R was the second strongest predictor of overall PTG, stronger than any other psychological or social measure **[30]**. A second prospective study of 532 Veterans with severe PTSD found that those with spiritual resources had better outcomes during an inpatient treatment program **[5]**. In contrast, spiritual struggles in that study were associated with worse PTSD outcomes, as reported by others **[23,24,29]**.

Spiritually-integrated Therapies. Spiritually-integrated CBT (SICBT) has been shown to increase the speed of remission in depressed S/R patients over that achieved by conventional CBT **[31,32]**. Likewise, a number of studies utilizing patients' spiritual beliefs in psychotherapy have reported results superior to secular treatments or usual care **[33]**. Our research team recently reported that SICBT was effective in treating major depression in 132 persons with a wide range of physical health problems. This was particularly true in more S/R clients, in whom treatment adherence and depression outcomes in those receiving SICBT were superior to those receiving conventional CBT **[34]**. A spiritual form of psychotherapy targeting ICMI in Soldiers/Veterans with PTSD, however, has yet to be developed or tested.

Research Methods: In collaboration with Eisenhower (EAMC), Womack (WAMC), Charlie Norwood VA (CN-VAMC), and Durham VA (DVAMC) we propose a pilot randomized clinical trial of SOCPT vs. conventional CPT for ICMI in active duty soldiers and veterans with PTSD and co-morbid combat-related physical injuries or illness. For this pilot trial, while power is not an issue, a sample of 25 in each group (n=50) is needed to have 80% power to detect a moderate to large difference in treatment effect (d=0.70) at p=0.05 (2-tailed test) on the target (ICMI). Soldiers/Veterans will be enrolled if they (1) are at least somewhat S/R, (2) have PTSD diagnosed with the SCID5 (subthreshold PTSD, PTSD without complications, PTSD with complications), (3) score 27 or higher on the PCL-5, and (4) have one or more co-morbid physical injuries/illnesses lasting at least 1 month or longer. Participants will be randomized to twelve 50-min sessions over 6 weeks of either SOCPT or CPT, and randomly assigned to therapists trained to deliver both treatments. The type of therapist (psychologist vs. chaplain) for this pilot trial will depend in part on the results of our surveys above, which are asking Soldiers/Veterans what professional they prefer to work with on ICMI issues. Participants will be assessed blind to treatment group at baseline, 3, 6, and 12-weeks using PCL-5, Pittsburgh Sleep Index, Brief Pain Inventory, Hospital Anxiety/Depression Scale, the ASSIST, and the newly developed multi-dimensional ICMI scale (target), along with standard measures of spirituality (a possible moderator) and post-traumatic growth (a secondary outcome).

Description of Intervention. While still being conceptualized, we anticipate that SOCPT will target ICMI by addressing erroneous interpretations of trauma using cognitive restructuring that utilizes Soldiers'/Veterans' spiritual resources (i.e., spiritual beliefs, practices, values, and motivations) to challenge maladaptive thinking patterns. Spiritual concepts of mercy, grace, repentance, forgiveness, spiritual surrender, prayer/contemplation, divine justice, hope, and divine affirmations will be discussed as means to reverse ICMI having to do with guilt, shame, self-condemnation, spiritual struggles, feeling betrayed, loss of meaning, trust, and hope, and loss of faith. These techniques will be supplemented by powerful rituals involving confession and forgiveness, scripture memorization, and emersion within a spiritual community.

Research Performance Site: We will choose the particular site for this pilot trial based on the results of the surveys cited above and level of cooperation at each of the sites.

Personnel: Harold G. Koenig, M.D., (PI) is professor of psychiatry and associate professor of medicine at Duke University and is a WOC at the DVAMC. He is experienced at conducting randomized clinical trials, and has nearly 400 peer-reviewed publications on mood/anxiety disorders and spirituality. He heads a team of health professionals skilled in the treatment of PTSD in Soldiers/Veterans and in developing spiritually-integrated cognitive interventions. Almost all team members have DoD or VA appointments. They include *Scott Mooney, PhD*, lead neuropsychologist in Rehabilitation at EAMC; *Jay Earles, PsyD*, director of Behavioral Health at WAMC; *Nagy Youssef, MD*, director of inpatient psychiatric services at CN-VAMC; and *John Oliver, D.Min.*, chief of chaplains at the DVAMC. *Patricia Resick, PhD*, was Director of the Women's Health Sciences Division of the National Center for PTSD at the Boston VA before coming to Duke, and is the original developer of CPT for PTSD. No collaboration with Cores is planned, but we are open to this.

Innovation: Many psychotherapy patients (55% to 74%) express a desire to discuss spiritual issues during therapy **[35,36]**, and we expect this will be true for Soldiers/Veterans frustrated over symptoms not responding to traditional treatments (only 20-30% of those with PTSD experience improvement that could be characterized as remission **[37]**). If the efficacy of SOCPT is established, the plan is to train military chaplains (and/or psychologists) on how to administer it both in the treatment and the prevention of PTSD. The significance of this research program is that it may help Soldiers/Veterans use existing spiritual resources to recover from (or avoid) the psychological trauma of war and provide a transformative experience resulting in greater resilience while on active duty and throughout the rest of their lives.

Pre-Proposal Estimated Budget (January 1, 2016-December 31, 2016):

Direct costs	
Personnel:	236,951
Therapist and training costs:	56,500
Participant reimbursement:	5,000
Supplies (including licensing fees):	17,250
Subtotal DC:	315,701
Matching (by Duke CSTH)	29,570
Total DC:	**286,131**

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