THE BRIDGE BACK PROJECT: RESEARCH PROPOSAL

TITLE
Counterstrain Manual Therapy and its impact on Trauma exposed First Responders, Active Duty Military and Veterans.

BACKGROUND
First responders and Active Duty Military often experience trauma while serving. Over 250,000 Vietnam theater veterans have Post Traumatic Stress Disorder (PTSD), 40 or more years after the war[i]. An estimated 10% of First Responders world-wide experience PTSD[ii]. They can experience recurring memories, insomnia, nightmares, apathy, emotional lability, physical pain, constant vigilance, and an inability to effectively and calmly deal with stress [iiiivvvi]. These symptoms can interfere with their activities of daily living (ADL's) and can surface months or even years after the traumatic event occurred.

People who have served and protected us frequently use coping mechanisms such as drug and alcohol abuse to help them cope[vii]. They often pull away from others and isolate themselves. The suicide rate in this population is high: In 2014, an average of 20 Veterans died by suicide each day, and 6 of the 20 were recent users of VHA services in 2013 or 2014[viii].

Counterstrain Manual Therapy (CMT) offers a new treatment option to address this problem. CMT is an advanced manual therapy technique designed to relax the tension in the connective tissue surrounding every tissue in our bodies. To date, clinical data has demonstrated significant changes in the population we wish to study: CMT has measurably relieved the symptoms associated w/ trauma exposure, i.e. recurring memories, insomnia, nightmares, apathy, emotional lability, physical pain, constant vigilance, and an inability to effectively and calmly deal with stress.

Fascia reflexively contracts around offended structures (e.g. epineurium, adventitia, dura, etc) and, through a reflex arc, controls nearby muscles to contract and protect the offended tissue in response to mechanical, chemical or temperature threat[ix]. When reflexive guarding sets in, dysfunction occurs, causing aberrant behavior in the affected structure.

With CMT, we are able to use manual therapy to physically relax the fascia surrounding vital tissues in the body, effectively normalizing the protective reflex spasms that occur in all fascial systems of the body: vascular, visceral, neural, musculoskeletal, thereby restoring full physiological function.

Type III and IV neuron receptors, found in muscle and connective tissue, are known to connect to the autonomic nervous system and have been shown experimentally to change heart rate, blood pressure and respiration[x xi]. This explains the autonomic arousal associated with chronic somatic dysfunction and the observed viscerosomatic effects of CMT. These neurons connect in the spinal cord to motor neurons in the ventral horn, and to preganglionic neurons of the autonomic nervous system, thus can trigger nocifensive and nociautonomic reflexes [8,xii]. These primitive reflexes play a central role in trauma exposed individuals. With CMT, we are able to turn off the reflex arc which directly stops the autonomic arousal cycle.

When a manual CMT release is performed, the involved fascial tissues are physically slackened, including the embedded Type III and IV neurons. Thoeretically, this "decompression" of the free nerve endings mechanically deactivates the local noci/mechanoreceptors, silencing the associated nociautonomic and nocifensive reflexes, thus calming a hyperactive response in

the offended nerve. CMT also has an immediate impact on local inflammatory metabolites. As the involved tissues are decompressed, local venous and lymphatic vessels open and drain inflammation from the region. This eliminates the chemical irritation of the local type III and IV neurons which also silences the nociautonomic and nocifensive reflexes. This can occur in muscular, vascular, neural and visceral structures since they all have their own lymphatic / venous drainage systems (e.g. vasa vasorum, vasa nervorum).

PTSD may be understood as a deficit in autonomic adaptation that is often expressed as an incongruity between physiological state and environmental demands. For example, Heart Rate Variability (HRV) is a measure of the autonomic nervous system functioning and reflects an individual's ability to adaptively cope with stress. Patients with PTSD have decreased high-frequency heart rate variability, likely indicative of an autonomic state that would support the mobilization necessary for fight or flight behaviors and resulting in lower vagal tone to the heart, perhaps due to the perception of a threat condition manifesting as a combination of increased sympathetic drive and/or parasympathetic withdrawal[xiii]. Polyvagal theory argues that risk evaluation is not within our volitional control, but is instead a system of autonomic controls described as neuroception, which is defined as humans' ability to engage in social interactions, or withdrawal from them, based upon the ability to assess threat properly[xiv]. Neuroception, although functioning outside of human awareness, may manifest reactions that are felt consciously, since they shift the autonomic state and create symptoms such as palpitations, elevation in heart rate, vasovagal syncope, and other psychophysiological measures. PTSD is linked with hyperactivity of the sympathetic branch of the autonomic nervous system, which causes the aforementioned symptoms[xv]. Polyvagal theory provides a viable explanation for the reported covariation between atypical autonomic regulation (eg, reduced vagal and increased sympathetic influences to the heart) and psychological and behavioral disorders that involve difficulties in regulating appropriate social, emotional, and communication behaviors, as seen in those with PTSD[xvi]. Normalization of nerve conductivity is theoretically restored following theses releases. In clinic, patients who've been exposed to trauma have experienced a significant relief in physical, emotional and mental symptoms after treatment.

A common way of assessing how subjects improve from treatment is to administer psychological outcome measures. Clinician Administered PTSD Scale for DSM-5 past month version (CAPS-5) is the gold standard psychometrically sound measure of DSM-5 PTSD diagnosis and symptom severity[xvii]. We will utilize this, as well as up to 11 other outcome measures pre and post CMT treatment.

OBJECTIVE

To determine if CMT manual therapy has a positive impact on the quality of life and activities of daily living in Active Duty Military, Veterans and First Responders exposed to traumatic stress.

HYPOTHESIS

Based on our clinical data, patient reports, and previously demonstrated changes made with CMT, we project a statistically significant improvement in CAPS-5 scores, psychological outcome measures post-CMT therapy. In a second study or second phase of this study, we would like to use brain imaging to demonstrate an improvement in rCBF post-CMT therapy.

METHODS

Screening procedure

Subjects' trauma history will be assessed using the Life Events Checklist for DSM-5 (LEC-5), a 17-item self-report questionnaire developed to screen for lifetime trauma experiences[xviii]. The LEC-5 will be a self-administered checklist to identify the nature and extent of trauma experiences.

To determine the focus of the CAPS-5 interview, subjects must identify an index trauma, being a single or group of closely related events which will be the traumatic event (PTSD criterion A).

Each subject will complete a CAPS-5 interview and psychological outcome measures before as well as at 1, 3 and 6 months following CMT treatment to track the subjective improvements made post CMT therapy. Our first phase goal is to track the progress and improvement of patients using these tools.

We will be using the following psychological outcome measures

- BDI - (Beck Depression Inventory) The most trusted, tested, and reliable measure for depression symptomology.
- PHQ-9 - (Patient Health Questionnaire-9) Measure of depressive symptom severity.
- PHQ-15 - (Patient Health Questionnaire-15) Assesses somatic symptom severity.
- GAD-7 - (Generalized Anxiety Disorder -7) Measure for anxiety
- SWLS - (Satisfaction With Life Scale) Measure of subjective happiness.
- BPI - (Brief Pain inventory) Assesses how much pain is interfering with life tasks.
- PSEQ - (Pain Self-Efficacy Questionnaire) Assesses confidence in ability to do tasks and activities despite pain.

For patients taking opioid medications:

- Opioid Craving. Rates craving for opioids in the past week
- PODS - (Prescription Opioid Difficulty Scale) Measures the side effects of opiate medication.

For 1, 3 and 6 month follow up interviews, add:

- PGIC - (Patient Global Impression of Change) Measures if patient feels treatment was useful, have symptoms improved, etc.

To do all of above questionnaires: 15 minutes minimum up to 25 minutes.
CAPS-5 interviews take 30-60 minutes to complete.

Delayed treatment controls: Instead of a "sham" treatment, our control group will be randomly assigned to receive delayed treatment after the 6 month psychological outcome measures interview.

We will be using REDCAP to track the data from above questionnaires and CAPS-5 interview from the before and at 1, 3 and 6 month intervals. Each subject, whether in the immediate or delayed treatment groups, will be asked to voluntarily submit to the psychological outcome measures interview 4 times total. The data we collect will determine if the immediate treatment group's outcome measures were significantly more improved than the delayed treatment group's.

Randomization - Will be done by computer after first interview and without stratification.

CMT treatment will include treatments to calm the sympathetic nervous system, optimize adrenal gland function, centrally stimulate the vagus nerve and treat targeted brain structures. The brain structures will have treatments to address dysfunction in the arterial supply, the sinus/venous drainage, neural structure (including dura, rami communicantes, pre and post ganglionic nerves) and musculoskeletal impact (including torsions in cranial bones, and structural/ligamentous dysfunction related to dural connections of C1, C2, T1 and T2, as well as peripheral impacts). We are theorizing that by deactivating the proprioceptive impact and metabolite drainage in tissues in the affected structures with CMT, we are effectively changing the dynamics of blood flow and function in the brain itself, which can potentially impact all other systems of the body.

Possible negative outcomes: We realize that our subjects have all been exposed to trauma and that they may have negative memories, flashbacks, feelings of anxiety or stress come up during the psychological outcome measures interviews or even during the manual therapy sessions. All therapists are informed about the possibility of such an outcome and how to calmly handle such situations as they arise. All subjects are informed that they are in control of every session and can decline to be interviewed or treated at any time.

POSSIBLE FOR DISCUSSION SECTION:
With CMT, clinical data has shown that we are able to effectively dampen the hyperactivity of the sympathetic nervous system by physically relaxing the nocifensive contraction of the perineureum of the affected nerves. We also stimulate the vagus nerve by improving blood flow to it by physically relaxing the nocifensive contraction of the tunica adventitia of the posterior inferior cerebellar artery. Many other structures need to be cleared of dysfunction in order to normalize function in a subject with trauma exposure. For example, CMT manipulation of cranial bones, C1, C2 and T1 and T2 will affect sympathetic nervous system activation (SNA), as these all have direct impact into the brain and spinal cord through their attachments to the dura. Periosteum, bone marrow, compact and trabecular bone all are extensively innervated by type III and type IV neurons[xix]. In addition to nocifensive neurons, there are also nociceptors releasing neuropeptides that could be nociautonomic and thus related to bone vasculature .

DISCUSSING FUTURE:

In a future study, or second phase of this study, we would like to use imaging to evaluate if cerebral blood flow irregularities can be restored with CMT to the structures affecting the amygdala, hippocampus and cortical regions, e.g., cerebral and cerebellar arteries, ventricles, brain sinuses, vertebral vein, cranial bones and other associated musculoskeletal structures.

Currently, there are several studies looking at how to actively measure regional cerebral blood flow (rCBF). Single photon emission computed tomography (SPECT) scans have shown irregularities in subjects with PTSD. SPECT is a functional neuroimaging technique that uses γ emitters to measure rCBF changes in the brain. PTSD is positively correlated Anterior cingulate, cerebellar, limbic and extrastriate rCBF, while being negatively correlated with rCBF in the superior frontal gyrus, parietal and temporal regions[xx,xxi]. The main output center for the response to fearful stimuli is the central nucleus of the amygdala, which mediates responses (autonomic, behavioral, and endocrine) related to fear[xxii]. The dysregulation of the fear responses in those with PTSD worsens subjective experiences by causing a disparate reaction to possible fear stimuli in the environment.

Other imaging has been used to study rCBF in subjects with PTSD. In one study, positron emission tomography (PET) of subjects with PTSD showed that symptom severity was positively related to rCBF in the right amygdala and negatively related to rCBF in medial frontal gyrus[xxiii]. MRI studies in Vietnam veterans with PTSD have also shown a decrease in hippocampal volume[xxiv]. The hippocampus is implicated in the control of stress responses, declarative memory, and contextual aspects of fear conditioning.
In our second phase, should we have positive outcomes in phase one, we will include functional neuroimaging to determine post-CMT improvements in blood flow. Subjects will have functional neuroimaging before and at 3 and 6 month intervals following treatment with CMT. We have yet to determine if we will be using PET, SPECT or fMRI.

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