

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/jbmt

PTSD PILOT STUDY

Pilot study of the effects of mixed light touch manual therapies on active duty soldiers with chronic post-traumatic stress disorder and injury to the head

Lauren Davis, PhD, LMT, BCTMB^{a,*}, Brenda Hanson, PhD^b, Sara Gilliam, PhD^{b,1}

^a Brain Plus Manual Therapy, USA

^b William Beaumont Army Medical Center, USA

Received 2 October 2014; received in revised form 31 December 2014; accepted 16 March 2015

KEYWORDS

Traumatic brain injury;
Head injury;
Post-traumatic stress disorder;
Headache;
Anxiety;
Pain Interference;
Manual therapy;
Craniosacral Therapy;
Brain Curriculum;
United States Soldiers

Summary This pilot study was designed to examine the effects of mixed Light Touch Manual Therapies (LTMT) on headache, anxiety and other symptoms suffered by active duty United States service members experiencing chronic Post-Traumatic Stress Disorder (PTSD). Ten service members diagnosed with PTSD and having a self-reported injury to the head acquired at least two years prior, were provided with two hour-long sessions of mixed LTMT given a week apart. Data to assess the immediate and durable effects were gathered before and after the LTMT sessions. Results indicate that headache, anxiety, and pain interference were significantly reduced during the course of the pilot study. This suggests that mixed LTMT may be helpful in reducing some of the symptoms of PTSD and injury to the head. Further studies will be needed to determine if LTMT is an effective non-pharmacological treatment for headache, anxiety or other problems associated with PTSD or injury to the head.

© 2015 Elsevier Ltd. All rights reserved.

* Corresponding author. 6329 Falling Star Way, El Paso, TX 79912, USA. Tel.: +1 915 472 1525.

E-mail address: LaurenDavisMT@gmail.com (L. Davis).

¹ WBAMC Affiliation at the time research was conducted.

Introduction

United States service members (SM) who have deployed to Iraq and/or Afghanistan since September 11, 2001 are commonly impacted by problems such as battle injuries, chronic pain, mental health conditions, and impairments in social functioning (Spelman et al., 2012). Among the most common problems afflicting deployed individuals are post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI). PTSD was newly diagnosed in 103,000 individuals in all services between 2000 and 2012 (Fischer, 2013). TBI was newly diagnosed in over 287,861 US military SM between 2000 and 2013 (Defense and Veterans Brain Injury Center, 2014). TBI (Faul et al., 2010) and PTSD (Kessler et al., 2005) are prevalent in the civilian population as well and both PTSD and TBI are often comorbid in military and civilian populations (Stein and McAllister, 2009).

One of the most common problems accompanying TBI is headache (Simons and Wolff, 1946; Walker et al., 2005), with estimates indicating that 30–90% of people sustaining a TBI go on to develop headaches (Lew et al., 2006; Management of Concussion/mTBI Working Group, 2009; Finkel et al., 2012). Chronic posttraumatic headaches often become permanent (Lew et al., 2006) and are considered to be one of the most disabling types of headaches (Theeler et al., 2008, 2012). While headache is only one of many physical symptoms that may accompany TBI in military populations, it is the only problem that has been found to be significantly associated with mild TBI (mTBI) after statistically adjusting for PTSD and depression (Hoge et al., 2008).

Headache pain from a TBI can significantly interfere with an individual's quality of life for years (Ruff, 2005; Channell et al., 2009). Headache management options include a variety of medications but these are often accompanied by significant side effects (Goadsby et al., 2002; Gallagher and Kunkel, 2003) including an increase in headaches (Zwart et al., 2003). Thus, identifying non-pharmacological headache management options is desirable. Some of these options include acupuncture (Melchart et al., 2001; Vickers et al., 2004), a variety of physical therapy techniques (Mills Roth, 2003), biofeedback (Nestoriuc et al., 2008) and massage therapy (Jensen et al., 1990; Hernandez-Reif et al., 1998; Lawler and Cameron, 2006; Kennedy, 2011). Several groups have reported that manual therapies requiring the application of a few hundred grams or less of pressure applied to the patient- such as craniosacral manipulation, Brain Curriculum, Craniosacral Therapy, osteopathic manual therapy, etc. and termed in this article as light touch manual therapies (LTMT)- have been effective in treating individuals with TBI (Greenman, 1991; Jackman, 2007; Arnadottir and Sigurdardottir, 2013), and SM (Kozminski and Kozminski, 2009) or the general population (Chaibi et al., 2011) with headache. Due to the small number of participants and a variety of limitations common to manual therapy research in the studies cited above, this study was designed to further explore the effect of mixed LTMT on self-reported headache, anxiety and other problems suffered by active duty SM.

This pilot study was conducted at an intensive outpatient program (IOP) on a large military installation in the

United States from 2011 to 2012 established to treat active duty SM diagnosed with chronic PTSD. At the IOP, integrative therapies such as medical massage, acupuncture, reiki, and movement therapy were offered together with psychotherapy and psychopharmacology to active duty SM in a six-month full-time therapy program. This pilot study was designed as the first attempt to isolate the effects of one of the medical massage treatments, mixed LTMT, on self-reported headache, anxiety and other problems faced by active duty SM in the IOP program.

Methods

Participants

It was determined that nine participants would be needed to detect a change in participant outcomes. The study sample consisted of all SM (up to a maximum of twelve) who had been accepted into the IOP during the eight months of recruitment for the pilot study but due to scheduling considerations, had not yet begun to attend IOP activities, and who met all of the other inclusion and exclusion criteria listed in Fig. 1. All participants, therefore, had a diagnosis of chronic PTSD, which was a prerequisite for entrance into the IOP. The *Defense and Veterans Brain Injury Center's (DVBIC) 3 Question TBI Screen* (Schwab et al., 2006) was used to screen for an injury that might have resulted in TBI. Twenty-seven SM were screened and eleven participants were accepted into the study. One participant withdrew

Sample size	10 participants
Gender	100% male
Age	27-45 years old at time of consent
Inclusion criteria	Accepted into IOP, but had not yet received treatment*
	Positive screen for TBI
	Self-reported injury to the head at least 2 years prior to start of study
Exclusion criteria	Shrapnel or prosthetics in the spine or cranium
	History of brain surgery
	Fever
	Acute systemic infection
	Previously received Medical Massage (light touch) on scalp
	Unable to tolerate light to moderate pressure on scalp or body
	Lactating or pregnant
Diagnosis of chronic PTSD	100%
Diagnosis of headache	90%
Diagnosis of TBI	80%

Figure 1 Summary of the demographics of the study sample.

* After data collection was completed, it was learned that one participant received one 60-min session of reiki from a provider at the IOP after being accepted into the program and before informed consent for this pilot study was obtained.

prior to the second LTMT session due to work scheduling conflicts and no data from this participant is included in this study. Ten participants completed the study.

It is common for spontaneous recovery from post-concussive symptoms to occur over the first days to weeks following brain injury (Iverson, 2005). Headaches that begin after a brain injury and persist longer than six months are likely to be permanent (Lew et al., 2006). To provide a more rigorous test of the LTMT intervention, a self-reported injury to the head at least two years prior was chosen for this study. This also results in increased homogeneity of the participant pool, since individuals with a more recent injury to the head who might experience spontaneous improvement were not included in the sample.

After all data were collected, a retrospective chart review was conducted to confirm a diagnosis of headaches (migraine headache, chronic post-traumatic headache or headache syndromes) or a diagnosis consistent with TBI (including one or more of the following: late effect of intracranial injury, history of TBI, history of concussion) (see Fig. 1).

Timeline

After IRB approval, screening of all SM accepted into the IOP began. If a SM had a positive screen for the pilot study, an appointment was scheduled with the SM to explain the study. Prior to the initial data collection, informed consent was obtained. Participants received two 60-minute mixed LTMT sessions one week apart (see Fig. 2). The reason for choosing 60-minute sessions one week apart was to replicate conditions in the IOP. Only two mixed LTMT sessions were given to each participant in order to minimize the delay that pilot study participants might have experienced between acceptance into the IOP and actually beginning full-time participation in the IOP.

Data was collected immediately before and after each mixed LTMT session to capture any immediate effects of the LTMT intervention. Additional data to gauge the durability of the LTMT interventions were collected before each LTMT session and ongoing after the second LTMT session on a weekly basis, until the start of participants' treatments in the IOP.

Mixed LTMT protocol

Mixed LTMT was provided according to the same protocol and by the same massage therapist (the primary author) who implemented it at the IOP. Implementation of this technique was ongoing for two years prior with no adverse effects reported. At the beginning of the study, this massage therapist had been certified as a massage therapist for 16 years, was licensed as a massage therapist in Texas, was nationally certified ("NCBTMB") and had obtained advanced training in several specific LTMT techniques, including Craniosacral Therapy (Upledger, 3 levels), Brain Curriculum (Chikly, 3 levels), and Visceral Manipulation (Barral, 5 levels).

Each mixed LTMT session was customized for each participant according to the pattern of tension palpated by the massage therapist in the participant's head and the rest of the body. The primary techniques used during the session included Craniosacral Therapy according to the protocol described by Upledger and Vredevoogd (1996), Brain Curriculum according to the protocols described by Chikly (2004, 2007a, 2007b), and occasional brief petrissage on the neck. All mixed LTMT sessions finished with 2–5 min of energy work (Oschman, 2000) with the intention of helping the participant to ground and integrate the work. The amount of force exerted by the massage therapist onto the participants varied from very light (5 gm) to moderate (a few hundred gms). During each session, the body parts to which mixed LTMT was administered and the amount of time spent on each body part varied according to the needs of the participants. In all cases at least 80% of the time was spent providing mixed LTMT to the participants' heads, 5–15% of the time spent providing mixed LTMT the sacral/low back area, with up to 5% of the time spent on the rest of the body.

Immediate data collection

Self-reported data were collected immediately before and after each session in order to assess any effect the mixed LTMT had on headache or anxiety. Headache was measured

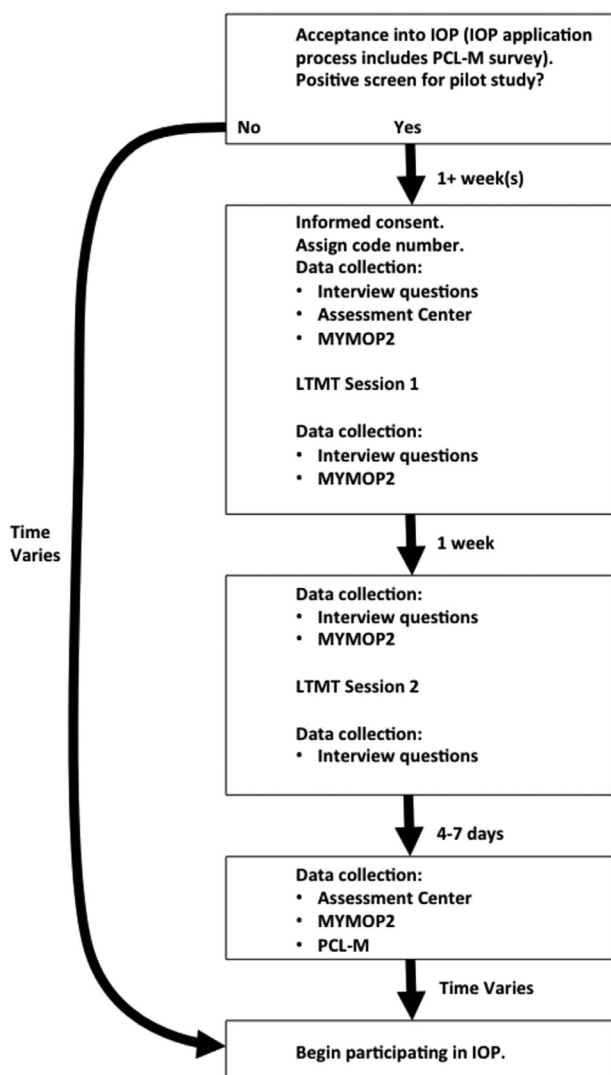


Figure 2 Timeline of study. Arrow indicates time.

by asking “On a scale of 0 (no headache) to 10 (most severe headache that you have experienced), how would you rank the intensity of your headache?” If a participant did not have a headache, headache intensity was scored as zero. Similarly, anxiety was measured by asking the question “On a scale of 0 (not at all anxious) to 10 (extremely anxious), how would you rank the intensity of your anxiety?” If a participant reported no anxiety, anxiety intensity was scored as zero. Anxiety was also evaluated using the validated Anxiety Neuro-QoL Bank v1.0 instrument available from the Assessment Center (www.assessmentcenter.net).

All available validated instruments measuring headache, such as the Migraine Disability Assessment Test (Stewart et al., 2001) and the Headache Impact Test - 6 (Kosinski et al., 2003) ask the participant to reflect on their symptoms over the preceding seven or more days. For example, in a study using classical testing theory versus Item Response Theory to assess fatigue in seven-day or four-week recall periods, Lai et al. (2009) suggests that participants use a much shorter time frame of recall, ‘today’, to answer questions requesting a recall of seven days or more. Similarly, Bennett et al. (2012) reported that recall of symptoms and impacts over seven day and daily diary scores were equivalent in patients with chronic obstructive pulmonary disease. Thus, in an attempt to gather valuable information about changes in major symptoms, such as anxiety and headache, over the course of a LTMT session, these questions were included.

Durable data collection

Four different instruments, the Patient-Reported Outcomes Measurement Information System (PROMIS; www.nihpromis.org), the Quality of Life in Neurological Diseases (Neuro-QoL; www.neuroqol.org), the PTSD Checklist (PCL), and the Measure Yourself Medical Outcome Profile 2 (MYMOP2), were used to collect self-reported data to determine if mixed LTMT provided relief that lasted for days or weeks. The original intent had been to collect data ongoing at weekly intervals for at least one month or more to determine if effects from the LTMT sessions lasted this length of time, and also to determine if the onset of some effects might have been delayed. For example, the developer of Brain Curriculum has indicated that in many individuals there may be a delay of up to two weeks following administration of the technique before the onset of effects (B Chikly, personal communication February 2010). Prior to the study and during initial trials, SM scheduling would have allowed for ongoing data collection most of the time, but because SM began to be processed into the IOP more quickly, most participants were no longer available for extended data collection. Thus, the number of days between intake (pre) data collection and post data collection ranged from 11 to 15.

Assessment Center

Data were collected using the PROMIS and Neuro-QoL libraries available from the Assessment Center. PROMIS and Neuro-QoL are comprised of sets of questions called item banks, which assess the health-related quality of life of adults and children, especially those with neurological disorders. Each item bank tests a unique domain such as anxiety,

fatigue, satisfaction with social roles and activities, pain interference, etc. For example, the Pain Interference PROMIS Bank v1.0 is designed to measure the negative impact or interference that pain has on the lives of people who experience chronic pain (Amtmann et al., 2010). A significant decrease in scores for Pain Interference indicates that participants were not as negatively impacted by pain at the end of the study compared with before the study. Questions in the Pain Interference item bank included, “In the past seven days, how much did pain interfere with your day to day activities?” and “In the past seven days, how much did pain interfere with your ability to participate in social activities?” Pain Interference measurements were calculated using a Likert scale, with the following possible responses: 1-Not at all; 2-A little bit; 3-Somewhat; 4-Quite a bit; 5-Very much. For this study, both PROMIS and Neuro-QoL surveys were presented using the Computerized Adaptive Test feature based on Item Response Theory.

PTSD Checklist

The PTSD Checklist (PCL) was developed and validated as a screening test to identify individuals with PTSD (Weathers et al., 1993; McDonald and Calhoun, 2010). It has moved into common use as a way for individuals to self-report symptoms of PTSD, and for providers to track PTSD symptoms in response to treatment (Berlant and Van Kammen, 2002; Taylor et al., 2008). Several versions of the PCL are available and the one used in this study is the military version (PCL-M) (Monson et al., 2008) in which the questions reference stressful military events. The PCL-M is scored on a five-point scale ranging from 1 – “Not at All” to 5 – “Extremely.” The measure is divided into three subscales (consistent with DSM IV criteria for PTSD diagnosis): Re-experiencing symptoms (items 1–5); Avoidance/Emotional Numbing symptoms (items 6–12); and Hyper-arousal symptoms (items 12–17). The PCL-M score is obtained by summing the results of all 17 questions and can range from 17 to 85. For each subscale and for the measure as a whole, an overall severity score is obtained by summing scores on all items. The items of the PCL have high diagnostic specificity and sensitivity, and have good to excellent concurrent validity (mean $r = .66$) with items of the gold standard of PTSD assessment, the Clinician Administered PTSD Scale (Blanchard et al., 1996; Forbes et al., 2001). According to criteria developed by Hoge et al. (2004), the presence of one re-experiencing symptom, three avoidance and or emotional numbing symptoms, and two hyper-arousal symptoms, along with an overall severity score of 50 or above, indicates PTSD. Not surprisingly, PCL-M scores correlate closely with scores related to other tests of mental health functioning rather than to measures of physical symptoms (Lang et al., 2012).

Whether the PCL underestimates or overestimates treatment-related change in comparison with Clinician Administered PTSD Scale is unclear (Lang et al., 2012). Typically, PCL scores fluctuate from session to session as might be expected with a measure of emotional symptoms in a population diagnosed with PTSD (Forbes et al., 2001; Monson et al., 2008). Additionally, a transient increase (which may last several weeks) in PTSD symptoms, followed by decreases in PTSD symptoms, is typical of the pattern of change seen in PTSD patients undergoing treatment

Variable Name	Desirable Direction of Change (Improvement)	Median (IQR) N = 10 Pre	Median (IQR) N = 10 Post***	p-value*	Effect size (Cohen's <i>d</i>)
Anxiety 1 st massage	Decrease	4.5 (5.5)	0.5 (2.0)	0.016	1.27
Anxiety 2 nd massage	Decrease	4.5 (4.8)	1.0 (3.5)	0.008	1.26
Headache 1 st massage	Decrease	1.5 (4.8)	0.0 (0.3)	0.031	0.82
Headache 2 nd massage	Decrease	2.0 (4.0)	0.0 (2.0)	0.031	0.84
PCL-M	Decrease	64.0** (11.0)	67.0** (14.0)	0.013	1.21
Anxiety Neuro-QoL Bank v1.0	Decrease	1.4 (0.8)	1.2 (0.9)	0.109	1.19
Depression Neuro-QoL Bank v1.0	Decrease	0.8 (0.7)	0.6 (0.8)	0.344	1.81
Emotional & Behavioral Dyscontrol Neuro-QoL Bank v1.0	Decrease	1.6 (0.9)	2.0 (0.6)	1.000	0.88
Fatigue Neuro-QoL Bank v1.0	Decrease	0.6 (1.3)	0.9 (0.9)	0.687	0.84
Pain Behavior PROMIS Bank v1.0	Decrease	1.1 (0.5)	1.1 (0.5)	0.180	0.52
Pain Interference PROMIS Bank v1.0	Decrease	1.4 (0.8)	1.2 (1.2)	0.039	1.11
Sleep Disturbance Neuro-QoL SF v1.0	Decrease	2.0 (1.1)	2.0 (1.2)	0.508	1.31
Stigma Neuro-QoL Bank v1.0	Decrease	0.9 (1.0)	1.1 (0.8)	0.180	0.96
Ability to participate in SRA Neuro-QoL Bank v1.0	Increase	-1.0 (0.3)	-0.9 (0.5)	1.000	1.08
Applied Cognition Executive Functions Neuro-QoL Bank v1.0	Increase	-2.0 (0.4)	-2.0 (0.3)	0.344	1.12
Applied Cognition General Concerns Neuro-QoL Bank v1.0	Increase	-1.9 (0.8)	-2.0 (1.0)	1.000	1.55
Lower Extremity Function- Mobility Neuro-QoL Bank v1.0	Increase	-0.4 (1.4)	-0.9 (0.6)	0.180	1.26
Positive Affect & Wellbeing Neuro-QoL Bank v1.0	Increase	-0.7 (1.3)	-0.6 (1.1)	0.344	2.00
Satisfaction with SRA Neuro-QoL Bank v1.0	Increase	-1.0 (0.4)	-1.0 (0.6)	0.754	1.50
Upper Extremity- Fine Motor Neuro-QoL Bank v1.0	Increase	-0.3 (1.5)	-0.7 (1.4)	0.727	0.95

Figure 3 Results. IQR = Interquartile Range. SRA = Social Roles and Activities. *Wilcoxon signed rank test (2 tailed), Bold = $p < 0.05$. ** $N = 9$. ***Within a day or two before the final data were collected, one participant learned that he would not be able to participate in the IOP.

(Nishith et al., 2002; Gilliam et al., 2011; Keller et al., 2014). A decrease of ten or more points in PCL score indicates a clinically meaningful change (Weathers et al., 1993).

Initial (pre) PCL-M scores were gathered during the intake process by the IOP personnel and these data were shared with the authors of this study. The second (post) PCL-M score was gathered by the research team several days after the second LTMT session. The PCL-M intake score was unavailable for one participant so $N = 9$ in these analyses.

Measure Yourself Medical Outcome Profile 2

To assess changes in the participants' sense of well-being and in the symptoms and activities that participants deem important, the researchers gathered data using the validated self-reported quality of life instrument MYMOP2 (Paterson, 1996). Upon intake into the study and prior to the first LTMT session, participants were instructed to identify the symptom (headaches, back pain, anxiety, depression, etc.) that most bothered them (Symptom 1), a symptom related to the same problem but which was secondary in impact (Symptom 2), an activity made difficult by

the problem causing Symptom 1 (performing their job, working out, being with a lot of people, etc.) and their general feeling of well-being. All questions referenced their feelings over the past seven days. For each symptom, activity or sense of wellbeing, the participant was asked to identify a score on a seven-point Likert scale from 0 (as good as it can be) to 6 (as bad as it can be).

The MYMOP2 test is designed so that a change of at least 1 would be considered meaningful or clinically significant (Guyatt et al., 1998; see <http://www.measuringimpact.org/s4-mymop2>) with a decrease in the score of symptom, activity or wellbeing considered an improvement. Results are presented as the change in score (pre - post) for each variable. In addition to scores for each variable, the change in MYMOP2 profile score is also presented. The MYMOP2 profile score is the average of the summed variable scores for each individual. Mean or median scores for the sample population scores were not calculated since a meaningful aggregate value for a population would require a sample approaching at least 50 individuals (<http://www.measuringimpact.org/s4-mymop2>).

Statistical analyses

The statistical packages SPSS and Minitab as well as commands in Microsoft Excel were used to generate descriptive statistics for the data gathered in the pilot study. Comparisons of data were made using the nonparametric Wilcoxon Signed Rank Test (WSRT) because the sample size was too small to assume they were normally distributed. A two-tailed test was used due to not knowing how participants would respond (e.g. headache symptoms worse or improved) and in order to provide a higher threshold for significance. Effect size for each variable was determined by calculating for Cohen's *d* (Cohen, 1988).

Results

Qualitative observations

During intake and the preliminary data collection, participants typically seemed agitated, fidgety and hyper-alert as did many of their peers beginning the program at the IOP. During the LTMT sessions, participants appeared to relax with their eyes closed and their breathing falling into a slower steady rhythm. Many appeared to fall asleep for most of the LTMT sessions. Following the post-intervention survey, participants often offered unsolicited remarks that they felt very relaxed and in many cases, that the reduction in symptom intensity was profound. For example, one participant said, "I feel normal and I haven't felt like a normal person in years."

Quantitative results

Immediate effects

WSRT of data collected before (pre) and after (post) each LTMT session indicated that both headache and anxiety were significantly reduced (each *p*-value < 0.04) with a large effect size (see Fig. 3). This indicates that immediate

effects from the LTMT sessions included a reduction in head pain and a decrease in anxiety.

Assessment Center

Data collected using the Assessment Center to measure longer-term effects of the LTMT session indicate that Pain Interference was significantly decreased ($p = 0.039$) with a large effect size in the direction of improvement several days after the second LTMT session (see Fig. 3). None of the other comparisons using the Assessment Center yielded significant results in either a positive or negative direction (see Fig. 3). Comparisons of 14 out of 15 variables had a large effect size and the pre - post changes in eight of these variables were in the direction of improvement (Anxiety, Depression, Pain Interference, Ability to Participate in Social Roles and Activities, Positive Affect and Wellbeing) or unchanged (Sleep Disturbance, Applied Cognition Executive Functions, and Satisfaction with Social Roles and Activities). The changes pre - post in six variables (Emotional and Behavioral Dyscontrol, Fatigue, Stigma, Applied Cognition General Concerns, and Upper and Lower Extremity Mobility) were not in the desired direction.

PCL-M

Median PCL-M survey scores significantly increased ($p = 0.013$) (see Fig. 3). Changes in PCL-M scores for individuals were (-1, 2, 3, 3, 6, 10, 12, 14, 20). The change in PCL-M was very small (ranging from -1 to 3) for four participants and if the reliable change index of PCL-M scores is bidirectional, this very small change is unlikely to be clinically meaningful. For four other participants, the change in score ranged from 10 to 20, which may indicate a clinically meaningful change in these participants. The remaining participant's score increased by 6, which may indicate an increase in PTSD symptoms, but which is not clinically meaningful.

MYMOP2

Nine out of ten participants experienced improvement in at least one variable that they considered to be the most affected by their problems (e.g. symptom one, symptom two, wellbeing or an activity). Three participants experienced change in two areas. Only two participants improved in three of the four measures. None of the participants showed improvement on all four measures. Four participants experienced improvements in one or more variables, but no worsening in any variable. One participant experienced worsening in more than one area and no improvements.

Conclusions

This pilot study investigated the effects of mixed LTMT on SM with PTSD and an injury to the head. The results from this pilot study suggest that mixed LTMT are helpful in reducing pain interference, headache and anxiety in the targeted population, as self-reported by participants, and indicates that LTMT may be a non-pharmacological intervention for these problems. Further investigations into

mixed LTMT such as Craniosacral Therapy and Brain Curriculum are warranted by these results.

Limitations

Sample size

While the resulting sample population ($N = 10$) was small, it exceeded the minimum of nine participants we had determined was necessary to detect a change in immediate effects on both headache and anxiety. Sample size was limited by scheduling constraints at the IOP. Future studies of durable effects should include a larger sample size.

Diagnoses

While it is possible that the diagnoses listed in participants' medical charts were inaccurate, headache symptoms were confirmed by participants' responses during data collection. TBI and headaches were relatively common diagnoses among SM being treated at the IOP. Exposure to an injury to the head that could have caused a TBI were reported by the participants during study screening. It was not possible to further confirm diagnoses due to lack of resources for this pilot study.

Control group

Due to limitations in personnel, scheduling, and physical space constraints at the IOP, we were unable to include a control group in this pilot study. Thus, our focus was on determining if there was an effect from mixed LTMT comparing data gathered after the intervention (post) as compared with baseline (pre) data. Future studies should control for exposure to the intervention by providing a sham intervention, wait-list control, or an opportunity for the participants to take a nap on the massage table in the presence of the therapist who is not touching the participant. Inclusion of a group where a standardized intervention protocol is provided could yield important information, although in a clinical setting it is likely that Craniosacral Therapy and Brain Curriculum will be customized for each patient as it was in this study. Additional LTMT therapists should be used to control for effects arising from the use of one individual providing the intervention.

Self-reported data

Due to limitations in resources and personnel availability, all data used in this study were self-reported. A comprehensive analysis of the advantages and disadvantages of self-reported data is beyond the scope of this article and the reader is directed to a discussion of patient-reported outcomes by [Cella et al. \(2012\)](#). Future studies should aim also to collect directly measured data.

Durability of the effect

Personnel and scheduling constraints also impacted the duration of the pilot study, with the final observation collected only four days following the second LTMT session. Anecdotal evidence suggests that the full benefits of these types of LTMT may not manifest for at least two weeks following treatment ([B Chikly, personal communication February 2010](#)). In addition, PTSD symptom exacerbation is not uncommon at the beginning of a treatment program

([Nishith et al., 2002](#); [Gilliam et al., 2011](#); [Keller et al., 2014](#)), which was the situation for all of the participants in the pilot study, none of whom had yet begun the IOP. It is unknown whether other symptoms, such as headache, might be exacerbated at the beginning of a treatment program. Similarly, data from several variables in the Assessment Center that changed in an undesirable direction may be indicative of symptom exacerbation due to the start of a treatment program. For example, participants may have experienced the full extent of their fatigue upon finally relaxing after having been traumatized in combat situations. Also, participants might have felt more stigmatized when they admitted that their problems were bad enough to cause them to seek help at the IOP. Because of these limitations, the durability of the effects cannot be fully gauged from this pilot study and future studies should include an extended period for data collection to gauge durability. Future studies should also include instruments designed to collect long-term data on headache persistence and other symptoms.

Potential mechanism

While it cannot be determined in this pilot study by what mechanism mixed LTMT might alleviate headaches or anxiety symptoms or impact how pain affects a person, there is suggestive literature. Several authors have hypothesized that changes in cell shape and cytoskeleton may underlie the effects of cranial manipulation including LTMT (see [Chaitow, 2005](#); [Swanson, 2013](#) for reviews) with effects on cell function mediated through mechanotransduction ([Chen and Ingber, 1999](#)).

The diversity of neuronal cell types and the presence of specialized microdomains within neurons, such as axons, dendrites and dendritic spines ([Steward et al., 1988](#)), might provide a rich canvas for LTMT-mediated cytoskeletal changes to be expressed in the brain. Several studies have shown that dendritic spines, a postsynaptic structure in some brain neurons, undergo changes in shape and that these shape changes may be correlated with changes in neuronal function such as learning or memory ([Crick, 1982](#); [Segal, 2005](#)). Postsynaptic areas seem to be particularly well designed for regulation via cytoskeletal changes because they are apparently serviced by an active RNA transport system ([Davis et al., 1987](#)) and may be able to regulate protein synthesis autonomously in the local intracellular environment ([Davis et al., 1992](#)). Taken together, these findings suggest that transient changes in neuronal shape, perhaps caused by LTMT, may cause long-term changes in the central nervous system, which in turn may affect headache, anxiety or other physiological processes.

Future directions

To investigate further the effects of mixed LTMT on headache, anxiety and other problems, it would be important to repeat this study in a larger population with appropriate controls. Additional LTMT sessions might help to evaluate the robustness of the effect and explore the dose-response relationship. The durability of the effects would be easier to assess with a longer period of data collection. This

information could establish LTMT as an effective non-pharmacological treatment for headache, anxiety, and other problems.

Identifying the substrate/s by which light scalp pressures, a hallmark of LTMT such as Craniosacral Therapy and Brain Curriculum, may affect physiology would be important to optimize clinical treatment. The use of functional medical imaging to observe neuronal metabolism immediately after LTMT could elucidate the mechanism by which LTMT can affect brain tissue in situ and the ways in which LTMT affects neuronal function. Changes in brain connectivity could be revealed by diffusion tensor imaging after LTMT. Alterations in neuronal cytoskeleton after LTMT could be examined in appropriate animal models. Taken together, future studies could point the way towards safe and effective therapies for problems that are inadequately managed by current medical therapies and may also reveal fundamental biological processes active in a variety of systems.

Role of the funding source

There was no funding for this study.

Conflict of interest

The authors declare that there are no conflicts of interest.

Acknowledgments

Thank you to the staff of the IOP for sharing the baseline PCL-M data, Allwyn Evans for help with screening, Drs. Matt Hayat and Larry Lesser for help with statistical analyses, and to Drs. Matt Hayat and Edith Walsh for discussions on experimental design early in the development of this study.

The views expressed in this document are those of the authors and do not reflect the official policy of William Beaumont Army Medical Center, the Department of the Army, or the United States Government.

References

- Amtmann, D., Cook, K.F., Jensen, M.P., Chen, W.-H., Choi, S., Revicki, D., Cella, D., Rothrock, N., Keefe, F., Callahan, L., Lai, J.-S., 2010. Development of a PROMIS item bank to measure pain interference. *Pain* 150, 173–182. <http://dx.doi.org/10.1016/j.pain.2010.04.025>.
- Arnadottir, T.S., Sigurdardottir, A.K., 2013. Is craniosacral therapy effective for migraine? Tested with HIT-6 Questionnaire. *Complement. Ther. Clin. Pract.* 19, 11–14.
- Bennett, A., Amtmann, D., Diehr, P., Patrick, D.L., 2012. Seven-day recall of COPD symptoms and impacts is most similar to the average of repeated 24-hour recall. *Value Health* 15, 466–474.
- Berlant, J., van Kammen, D.P., 2002. Open-label topiramate as a primary or adjunctive therapy in chronic civilian posttraumatic stress disorder: a preliminary report. *Am. J. Clin. Psychiatry* 63, 15–20.
- Blanchard, E.B., Jones-Alexander, J., Buckley, T.C., Forneris, C.A., 1996. Psychometric properties of the PTSD checklist (PCL). *Behav. Res. Ther.* 34, 669–673.
- Cella, D., Hahn, E.A., Jensen, S.E., Butt, Z., Nowinski, C.J., Rothrock, N., 2012. Methodological Issues in the Selection, Administration, and Use of Patient-Reported Outcomes in Performance Measurement in Health Care Settings: Commissioned Paper #1. National Quality Forum, Washington, DC.
- Chaibi, A., Tuchin, P.J., Russell, M.B., 2011. Manual therapies for migraine: a systematic review. *J. Headache Pain* 12, 127–133. <http://dx.doi.org/10.1007/s10194-011-0296-6>.
- Chaitow, L., 2005. *Cranial Manipulation: Theory and Practice: Osseous and Soft Tissue Approaches*, second ed. Elsevier Churchill Livingstone, Edinburgh.
- Channell, M.K., Mueller, L.L., Hahn, R., 2009. Management of chronic posttraumatic headache: a multidisciplinary approach. *J. Am. Osteopath. Assoc.* 109, 509–513.
- Chen, C.S., Ingber, D.E., 1999. Tensegrity and mechanoregulation: from skeleton to cytoskeleton. *Osteoarthr. Cartil.* 7, 81–94.
- Chikly, B., 2004. *Brain Tissue, Nuclei, Fluid and Autonomic Nervous System (B1) Study Guide*. Chikly Health Institute, Scottsdale, AZ.
- Chikly, B., 2007a. *Brain Tissue, Nuclei, Fluid and Reticular Alarm System (B2) Study Guide*. Chikly Health Institute, Scottsdale, AZ.
- Chikly, B., 2007b. *Brain Tissue, Nuclei, Fluid and Peripheral Nervous System (B3) Study Guide*. Chikly Health Institute, Scottsdale, AZ.
- Chikly, B., 2010. Personal communication by telephone. February.
- Cohen, J., 1988. *Statistical Power Analysis for the Behavioral Sciences*, second ed. Lawrence Erlbaum, Hillsdale, NJ.
- Crick, F., 1982. Do dendritic spines twitch? *Trends Neurosci.* 5, 44–46.
- Davis, L., Banker, G.A., Steward, O., 1987. Selective dendritic transport of RNA in hippocampal neurons in culture. *Nature* 330, 477–479. <http://dx.doi.org/10.1038/330477a0>.
- Davis, L., Dou, P., DeWit, M., Kater, S.B., 1992. Protein synthesis within neuronal growth cones. *J. Neurosci.* 12, 4867–4877.
- Defense and Veterans Brain Injury Center (DVBIC), 2014. DoD Numbers for Traumatic Brain Injury, Worldwide Totals. Accessed at: <http://dvbic.dcoe.mil/sites/default/files/uploads/dod-tbi-worldwide-2000-2013-Q3-as-of-05%20Nov-2013.pdf>. on February 12, 2014.
- Faul, M., Xu, L., Wald, M.M., Coronado, V.G., 2010. *Traumatic Brain Injury in the United States: Emergency Department Visits, Hospitalizations, and Deaths*. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Atlanta (GA).
- Finkel, A.G., Yerry, J., Scher, A., Choi, Y.S., 2012. Headaches in soldiers with mild traumatic brain injury: findings and phenomenologic descriptions. *Headache: J. Head Face Pain* 52, 957–965. <http://dx.doi.org/10.1111/j.1526-4610.2012.02167.x>.
- Fischer, H., 2013. U.S. Military Casualty Statistics: Operation New Dawn, Operation Iraqi Freedom, and Operation Enduring Freedom. CRS Report for Congress February 5, 2013 (accessed February 12, 2014). <http://www.fas.org/sgp/crs/natsec/RS22452.pdf>.
- Forbes, D., Creamer, M., Biddle, D., 2001. The validity of the PTSD checklist as a measure of symptomatic change in combat-related PTSD. *Behav. Res. Ther.* 39, 977–986.
- Gallagher, R.M., Kunkel, R., 2003. Migraine medication attributes important for patient compliance: concerns about side effects may delay treatment. *Headache: J. Head Face Pain* 43, 36–43. <http://dx.doi.org/10.1046/j.1526-4610.2003.03006.x>.
- Gilliam, S., Kuberka, J., Thomas, V., Fu, J., 2011. The Restoration and Resilience Program: an Intensive PTSD Treatment Program (Presented at William Beaumont Army Medical Center's Annual Research Day, Fort Bliss, TX).
- Goadsby, P.J., Lipton, R.B., Ferrari, M.D., 2002. Migraine—current understanding and treatment. *N. Engl. J. Med.* 346, 257–270.
- Greenman, P.E., 1991. *Craniosacral Manipulation in Persons with Traumatic Brain Injury* (Presentation to Symposium on

- Rehabilitation of Traumatic Brain Injury Patients, Kellogg Center, East Lansing, MI February).
- Guyatt, G.H., Juniper, E.F., Walter, S., Griffith, L.E., Goldstein, R.S., 1998. Interpreting treatment effects in randomised trials. *BMJ* 316, 690–693.
- Hernandez-Reif, M., Dieter, J., Field, T., Swerdlow, B., Diego, M., 1998. Migraine headaches are reduced by massage therapy. *Int. J. Neurosci.* 96, 1–11.
- Hoge, C.W., Castro, C.A., Messer, S.C., McGurk, D., Cotting, D.I., Koffman, R.L., 2004. Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *N. Engl. J. Med.* 351, 13–22.
- Hoge, C.W., McGurk, D., Thomas, J.L., Cox, A.L., Engel, C.C., Castro, C.A., 2008. Mild traumatic brain injury in U.S. soldiers returning from Iraq. *N. Engl. J. Med.* 358, 453–463.
- Iverson, G.L., 2005. Outcome from mild traumatic brain injury. *Curr. Opin. Psychiatry* 18, 301–317.
- Jackman, R., 2007. Presentation at army medical center paves way for future collaborations. In: Jackman, R. (Ed.), *Upledger Update Spring: 4*. Accessed at: <http://www.upledger.com/newsletters/UPDSP07.pdf>. on May 18, 2014.
- Jensen, O., Nielsen, F., Vosmar, L., 1990. An open study comparing manual therapy with the use of cold packs in the treatment of post-traumatic headache. *Cephalalgia* 10, 241–250. <http://dx.doi.org/10.1046/j.1468-2982.1990.1005241.x>.
- Keller, S.M., Feeny, N.C., Zoellner, L.A., 2014. Depression sudden gains and transient depression spikes during treatment for PTSD. *J. Consult. Clin. Psychol.* 82, 102–111. <http://dx.doi.org/10.1037/a0035286>.
- Kennedy, A., 2011. Massage can be effective for tension headaches. In: *American Massage Therapy Approved Position Statements*. Accessed at: http://www.amtamassage.org/approved_position_statements/Massage-Can-Be-Effective-for-Tension-Headaches.html. on March 5, 2014.
- Kessler, R.C., Chiu, W.T., Demler, O., Walters, E.E., 2005. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Arch. General Psychiatry* 62, 617–627.
- Kosinski, M., Bayliss, M.S., Bjorner, J.B., Ware Jr., J.E., Garber, W.H., Batenhorst, A., Cady, R., Dahlöf, C.G., Dowson, A., Tepper, S., 2003. A six-item short-form survey for measuring headache impact: the HIT-6. *Qual. Life Res.* 12, 963–974.
- Kozminski, M., Kozminski, T., 2009. OMT as an adjunct therapy for post-traumatic headache in US soldiers: a case series. *Am. Acad. Osteopat. J.* 19, 23–24.
- Lai, J.S., Cook, K., Stone, A., Beaumont, J., Cella, D., 2009. Classical test theory and item response theory/Rasch model to assess differences between patient-reported fatigue using 7-day and 4-week recall periods. *J. Clin. Epidemiol.* 62, 991–997.
- Lang, A.J., Wilkins, K., Roy-Byrne, P.P., Golinelli, D., Chavira, D., Sherbourne, C., Rose, R.D., Bystritsky, A., Sullivan, G., Craske, M.G., Stein, M.B., 2012. Abbreviated PTSD checklist (PCL) as a guide to clinical response. *General Hosp. Psychiatry* 34, 332–338.
- Lawler, S.P., Cameron, L.D., 2006. A randomized, controlled trial of massage therapy as a treatment for migraine. *Ann. Behav. Med.* 32, 50–59.
- Lew, H.L., Lin, P.H., Fuh, J.L., Wang, S.J., Clark, D.J., Walker, W.C., 2006. Characteristics and treatment of headache after traumatic brain injury: a focused review. *Am. J. Phys. Med. Rehabil.* 85, 619–627.
- Management of Concussion/mTBI Working Group, 2009. VA/DoD clinical practice guideline for management of concussion/mild traumatic brain injury. *J. Rehabil. Res. Dev.* 46, CP1 (accessed February 12, 2014). http://www.healthquality.va.gov/mtbi/concussion_mtbi_full_1_0.pdf.
- McDonald, S.D., Calhoun, P.S., 2010. The diagnostic accuracy of the PTSD Checklist: a critical review. *Clin. Psychol. Rev.* 30, 976–987.
- Melchart, D., Linde, K., Berman, B., White, A., Vickers, A., Allais, G., Brinkhaus, B., 2001. Acupuncture for idiopathic headache. *Cochrane Database Syst. Rev. Issue 1*. <http://dx.doi.org/10.1002/14651858.CD001218>. Art. No.: CD001218.
- Mills Roth, J., 2003. Physical therapy in the treatment of chronic headache. *Curr. Pain Headache Reports* 7, 482–489.
- Monson, C.M., Gradus, J.L., Young-Xu, Y., Schnurr, P.P., Price, J.L., Schumm, J.A., 2008. Changes in posttraumatic stress disorder symptoms: do clinicians and patients agree? *Psychol. Assess.* 20, 131–138. [http://dx.doi.org/10.1037/1040-3590.20.2.131](http://dx.doi.org/10.1037/10.1037/1040-3590.20.2.131).
- Nestoriuc, Y., Martin, A., Rief, W., Andrasik, F., 2008. Biofeedback treatment for headache disorders: a comprehensive efficacy review. *Appl. Psychophysiol. Biofeedback* 33, 125–140.
- Nishith, P., Resick, P.A., Griffin, M.G., 2002. Pattern of change in prolonged exposure and cognitive-processing therapy for female rape victims with posttraumatic stress disorder. *J. Consult. Clin. Psychol.* 70, 880–886.
- Oschman, J.L., 2000. *Energy Medicine: the Scientific Basis*. Elsevier Churchill Livingstone, Edinburgh.
- Paterson, C., 1996. Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 health survey. *BMJ* 312, 1016–1020 doi: <http://dx.doi.org/10.1136/bmj.312.7037.1016>.
- Ruff, R., 2005. Two decades of advances in understanding of mild traumatic brain injury. *J. Head Trauma Rehabil.* 20, 5–18.
- Schwab, K.A., Baker, G., Ivins, B., Sluss-Tiller, M., Lux, W., Warden, D., 2006. The Brief Traumatic Brain Injury Screen (BTBIS): investigating the validity of a self-report instrument for detecting traumatic brain injury (TBI) in troops returning from deployment in Afghanistan and Iraq. *Neurology* 66, A235.
- Segal, M., 2005. Dendritic spines and long-term plasticity. *Nat. Rev. Neurosci.* 6, 277–284.
- Simons, D.W., Wolff, H.G., 1946. Studies on headache: mechanisms of chronic and post-traumatic headache. *Psychosom. Med.* 8, 227–242.
- Spelman, J.F., Hunt, S.C., Seal, K.H., Burgo-Black, A.L., 2012. Post deployment care for returning combat veterans. *J. General Intern. Med.* 27, 1200–1209. <http://dx.doi.org/10.1007/s11606-012-2061-1>.
- Stein, M.B., McAllister, T.W., 2009. Exploring the convergence of posttraumatic stress disorder and mild traumatic brain injury. *Am. J. Psychiatry* 166, 768–776. <http://dx.doi.org/10.1176/appi.ajp.2009.08101604>.
- Steward, O., Davis, L., Dotti, C., Phillips, L.L., Rao, A., Banker, G., 1988. Protein synthesis and processing in cytoplasmic microdomains beneath postsynaptic sites on CNS neurons. *Mol. Neurobiol.* 2, 227–261.
- Stewart, W.F., Lipton, R.B., Dowson, A.J., Sawyer, J., 2001. Development and testing of the Migraine Disability Assessment (MIDAS) questionnaire to assess headache-related disability. *Neurology* 56, S20–S28.
- Swanson 2nd, R.L., 2013. Biotensegrity: a unifying theory of biological architecture with applications to osteopathic practice, education, and research—A review and analysis. *J. Am. Osteopath. Assoc.* 113, 34–52.
- Taylor, F.B., Martin, P., Thompson, C., Williams, J., Mellman, T.A., Gross, C., Peskind, E.R., Raskind, M.A., 2008. Prazosin effects on objective sleep measures and clinical symptoms in civilian trauma posttraumatic stress disorder: a placebo-controlled study. *Biol. Psychiatry* 63, 629–632. <http://dx.doi.org/10.1016/j.biopsych.2007.07.001>.
- Theeler, B.J., Mercer, R., Erickson, J.C., 2008. Prevalence and impact of migraine among US army soldiers deployed in support of

- Operation Iraqi Freedom. *Headache: J. Head Face Pain* 48, 876–882. <http://dx.doi.org/10.1111/j.1526-4610.2008.01159.x>.
- Theeler, B.J., Flynn, F.G., Erickson, J.C., 2012. Chronic daily headache in US soldiers after concussion. *Headache: J. Head Face Pain* 52, 732–738. <http://dx.doi.org/10.1111/j.1526-4610.2012.02112.x>.
- Upledger, J.E., Vredevoogd, J.D., 1996. The spinal dura matter and sacrococcygeal complex. In: *Craniosacral Therapy*. Eastland Press, Seattle, WA, pp. 131–151.
- Vickers, A.J., Rees, R.W., Zollman, C.E., McCarney, R., Smith, C.M., Ellis, N., Fisher, P., 2004. Acupuncture for chronic headache in primary care: large, pragmatic, randomised trial. *BMJ* 328, 744 doi: <http://dx.doi.org/10.1136/bmj.38029.421863.EB>.
- Walker, W.C., Seel, R.T., Curtiss, G., Warden, D.L., 2005. Headache after moderate and severe traumatic brain injury: a longitudinal analysis. *Arch. Phys. Med. Rehabil.* 86, 1793–1800.
- Weathers, F.W., Litz, B.T., Herman, D.S., Huska, J.A., Keane, T.M., 1993. The PTSD Checklist (PCL): Reliability, Validity, and Diagnostic Utility. Paper presented at the Annual Convention of the International Society for Traumatic Stress Studies, San Antonio, TX, October 1993.
- Zwart, J.-A., Dyb, G., Hagen, K., Svebak, S., Holmen, J., 2003. Analgesic use: a predictor of chronic pain and medication overuse headache: the Head–HUNT Study. *Neurology* 61, 160–164. <http://dx.doi.org/10.1212/01.WNL.0000069924.69078.8D>.