EFFECTS OF MASSAGE THERAPY ON TENSION-TYPE HEADACHE: A PLACEBO CONTROLLED TRIAL

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EFFECTS OF MASSAGE THERAPY ON TENSION-TYPE HEADACHE: A PLACEBO CONTROLLED TRIAL (109 pp.)

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The current study investigated the effects of massage therapy on headache activity of individuals with tension-type headache using a placebo controlled design. Participants received either six sessions of medium pressure ("true") massage or light pressure (placebo) massage or no treatment (headache-recording control). Results indicated massage was associated with a moderate decrease in headache activity regardless of whether the massage involved the manual manipulation of soft tissues.

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Table of Contents

	Page
Abstract	3
Acknowledgements	4
List of Tables	8
List of Figures	9
List of Appendices	10
Introduction	11
Tension-type Headache	13
Pathophysiology of Tension Headache	13
Psychological Distress, Headaches, and Headache Related Disability	16
Definition of Massage Therapy	17
Massage and Headaches	18
Massage Therapy and Pain in other Medical Disorders	22
Mechanism of Massage-Induced Reduction of Pain	28
Purpose of Present Study	30
Method	31
Participants	31
Screening Measures	
Headache Screening Questionnaire	32
Structured Diagnostic Interview for Headache, Brief Version	
Outcome Measures	34
Daily Headache Records	

Sleep	
Psychophysiological Assessments	
Pericranial Muscle Tenderness (PMT)	
Pressure Pain Thresholds (PPT)	
Psychological Assessments	
Beck Depression Inventory II (BDI-II)	
Beck Anxiety Inventory (BAI)	
Credibility Assessment	
Perceived Treatment Credibility	
Ancillary Measures	
Medication	
Headache Disability Index (HDI)	
Headache Self-Efficacy Scale (HSES)	
The Headache-Specific Locus of Control Scale (HSLC)	
Procedure	
Massage Therapist	
Massage Procedures	
Headache Recording Control	
Analysis	
Initial analysis	
Predictions	
Results	
Attrition	

Credibility Assessment	
Outcome Measures	
Headache Activity Hypothesis	
Physiological Functioning Hypothesis	
Pericranial Muscle Tenderness	
Pressure Pain Thresholds	
Psychological Functioning Hypothesis	
Sleep Functioning Hypothesis	
Discussion	
Headache Activity Hypothesis	
Physiological Functioning Hypothesis	
Psychological Functioning Hypothesis	
Sleep Functioning Hypothesis	
Limitations	
Future Directions	
Conclusions	
References	

List of Tables

Page

Table 1.	Diagnostic Criteria for Frequent Episodic Tension-Type Headaches	78
Table 2.	Diagnostic Criteria for Chronic Tension-Type Headaches	79
Table 3.	Possible Mechanism for Tenderness in Tension-Type Headache	80
Table 4.	Inclusion Criteria for this study	81
Table 5.	Demographics and Baseline Headache Data	82
Table 6.	Daily Headache Diary: Daily Averages of Headache Activity for	
	Massage, Placebo Massage, and Headache-Recording Group	83
Table 7.	Median PMT Values and Percentiles around the Median	84
Table 8.	Median Finger and Temporalis PPT Values and Percentiles around the	85
	Median	
Table 9	Depression and Anxiety Scores: Mean Scores for Massage, Placebo	
	Massage and Headache-Recording Groups	87

List of Figures

Figure 1.	Diagram of Study Protocol	88
F :	Headache Activity for Massage, Placebo Massage and Headache-	89
Figure 2.	Recording Control	89

Page

List of Appendices

Appendix A.	Headache Screening Questionnaire	_ 9
Appendix B.	Consent Form	_ 9
Appendix C.	Headache Assessment Interview	_ 9
Appendix D.	Daily Headache and Sleep Record	_ 9
Appendix E.	PMT/PPT Assessment Form	_ 9
Appendix F.	Beck Depression Inventory, Form II	_ 9
Appendix G.	Beck Anxiety Inventory Questionnaire	_ 1
Appendix H.	Measure of Perceived Treatment Validity	_ 1
Appendix I.	Headache Disability Inventory Questionnaire	_ 1
Appendix J.	Headache Self-Efficacy Questionnaire	1
Appendix K.	Headache-Specific Locus of Control Questionnaire	_ 1
Appendix L.	Analysis of Ancillary Measures	_ 1

Introduction

Tension-type headaches present a significant health problem for many individuals. In the United States, there is a one-year prevalence rate of about 38% for episodic tension-type headache and about 2-3% for chronic tension-type headache (Schwartz, Stewart, Simon, & Lipton, 1998). Infrequent tension-type headache often has little impact on quality of life and may be effectively managed with over-the-counter medication. When frequent, however, tension-type headache may impair an individual's mood, energy level and quality of life (Holroyd, 2002). Sleep-related problems are also common in individuals with chronic headache (Passchier et al, 1996; Holroyd, et al, 2000; Spierings, Ranke, & Honkoop, 2001). In the population-based study conducted by Schwartz et al (1998), 8% of individuals with episodic tension-type headache and 12% of individuals with chronic tension-type headache lost workdays because of their headaches and 44% experienced impairment of their effectiveness at home, school or at work. Of the chronic tension-type headache sufferers in their study, 40% lost 40 or more workdays in the last year. The level of impairment experienced by individuals with chronic tensiontype headache may be similar to or greater than that experienced by those afflicted with arthritis or back pain (Holroyd et al, 2000).

To treat their headache, individuals often turn to over-the-counter and prescription analgesics that, if used frequently (i.e., more than three days per week), may aggravate a headache problem as well as lead to other health problems. As a result, individuals who experience chronic tension-type headache are at risk for analgesic abuse and thus rebound headache (Holroyd, 2002).

A growing number of people are turning to complementary health care services such as massage therapy to treat or prevent their headache. Eisenberg et al (1998) conducted two nationally representative surveys of the United States population on the use of complementary medicine. Responses to the survey were weighted based on geographic location and socio-demographic variables in order to have the sample population match US census data. The study reported that complementary medicine was used by 33.8% of the US population in 1990 and 42.1% of the US population in 1994, with visits to chiropractors and massage therapists accounting for nearly half of all visits to complimentary health care practitioners in the nation. In both the 1990 and 1994 surveys, complementary therapists were primarily treating chronic conditions such as headaches, back pain, depression and anxiety. In 1997, Americans made an estimated 114 billion visits to complimentary health care practitioners and spent an estimated \$21.2 billion (Eisenberg et al, 1998). Considering that an estimated 114 thousand visits were made to massage therapists in 1997 (Eisenberg et al, 1998) and the average massage costs typically range from \$45 to \$90 an hour (AMTA, 2001), Americans spend between four and nine million dollars annually on massage therapy.

The American Massage Therapy Association (2001) commissioned a randomly sampled telephone survey of one thousand Americans in 2000. Twenty-seven percent of American adults reported having received at least one massage in the last 5 years. Thirtyfive percent of those who received at least one massage in the last 5 years received one or more massages for medical reasons. Of those who got a massage for medical reasons, 10% did so as a means to manage or reduce their pain. Despite the widespread use of massage as a treatment for chronic pain disorders, there is a paucity of well-controlled studies evaluating the effectiveness of massage therapy. Without such studies, health care professionals do not know if massage should be recommended and the potential exists for health care resources to be misallocated. The present study has addressed these problems by examining the effectiveness of massage therapy in reducing the frequency and intensity of tension-type headache and in altering psychophysiological abnormalities associated with tension-type headache using a placebo-controlled design. A secondary purpose of this present study was to assess the impact of massage on psychological symptoms of depression and anxiety.

Tension-Type Headache

A prototypical tension-type headache is characterized by bilateral, constant pressing pain that is not accompanied by nausea and/or photo- or phonophobia. The pain is usually of mild to moderate intensity. This tension-type headache differs from a migraine in that the pain is neither pulsating nor aggravated by routine physical activity. In addition, tension-type headaches, unlike some migraines, are not accompanied by neurological deficits, i.e., termed an aura. Table 1 and 2 provides the diagnostic criteria of tension-type headache (International Headache Society, 2002).

Pathophysiology of Tension Headache

The etiology of tension-type headache is currently unknown. An early theory postulated that tension headaches are the result of abnormal and sustained pericranial muscle tension (Ad Hoc Committee on Classification of Headache, 1962). However, this hypothesis has not been supported by research. Many studies have found electromyographic (EMG) activity in pericranial muscles (i.e., temporalis, massiter,

suboccipital, frontalis and middle trapezius muscles) only trivially or not increased at all (Gobel, Weigle, Kropp, & Soyka, 1992; Pikoff, 1984; Jensen & Rasmussen, 1996).

A second possibility is that tension headaches result from a central nervous system dysfunction. Bendtsen, Jensen and Olesen (1996) have argued that tension-type headache reflects central sensitization that is initiated, in part, by prolonged nociceptive inputs from pericranial myofascial tissues. The central nervous system may be sensitized at the supraspinal level, at the segmental level of the spinal dorsal horn/trigeminal nucleus and at the peripheral myofacial nociceptors (Bendtsen, 2000). Central sensitization may result in lower pain thresholds and elevated pericranial muscle tenderness (Holroyd, 2002). Elevated level of pericranial muscle tenderness therefore may be an indication that nociceptive processing is qualitatively altered in those with chronic myofascial pain (Bendtsen, Jensen, & Olesen, 1996). Table 3 outlines the possible mechanisms for tenderness in Bendtsen's model of tension-type headache.

Elevated levels of pericranial muscle tenderness, as measured by sensitivity to blunt pressure in pericranial muscles, has been the most consistent observation in tensiontype headache, particularly in individuals with chronic tension-type headache (Holroyd, 2002; Jensen et al 1993, 1996, 1998; Jensen, 1994, Lipchik et al, 1996, 1997; Langmark & Olesen, 1987; Neufield, Holroyd, & Lipchik, 2000). The trapezius is the most likely to be tender (Lipchik et al, 1996) and has been reported to have significantly more muscle activity (EMG) in tension-type headache sufferers as compared to controls (Jensen & Olesen, 1996). In addition, pressure pain detection thresholds have been found to be significantly decreased both in the pericranial muscles and peripherally in individuals with tension-type headache as compared to healthy controls (Bendtsen, Jensen, & Olesen, 1996). Lowered pressure pain thresholds may indicate the presence of "allodynia, i.e. pain elicited by stimuli which are normally not perceived as painful, and hyperalgesia, i.e. increased sensitivity to painful stimuli" (Bendtsen, 2000) in those with tension-type headache. Although the exact source of pericranial muscle tenderness tension-type headache is not yet understood (Lipchik, Holroyd, Tolbot, & Greer, 1997), the presence of increased pain sensitivity in both pericranial muscles and in peripheral muscles of the fingers indicates that pain sensitivity may be increased via central nervous system mechanisms as opposed to peripherial mechanisms (Bendtsen, Jensen, & Olesen, 1996).

Furthermore, individuals with chronic tension-type headache, have been reported to have increased muscle hardness, which is positively correlated with muscle tenderness (Ashina, Bendtsen, Jensen, Sakai, & Olesen, 1999; Sakai, Ebihara, Akiyama, & Horikawa, 1995). Muscle hardness is assessed by a hardness meter or by manual palpation. Manual palpation involves palpation of the muscles and a measurement of the amount of pressure felt (Sakai et al, 1995). The hardness meter is a pressure/displacement transducer; pressure is applied to the muscle and the displacement of the tissues is monitored with a laser (Sakai et al, 1995). The mechanisms leading to increased muscle hardness are not known (Bendtsen, 2000). However, increased muscle hardness and increased muscle activity may be the result of neuroplastic changes in the central nervous system that increase motor neuron activity at both the supraspinal and segmental level (Bendtsen, 2000).

In conclusion, the hypothesis that central sensitization underlies frequent tensiontype headache is supported by evidence of increased peripheral muscle tenderness and muscle hardness in individuals with tension-type headaches. Whereas, the proposition that increased muscle tension is the cause of tension headaches has not been supported by research. However, it is unclear if muscle hardness and/or tenderness are merely an indication of nociceptive sensitivity (which may be a result of central sensitization) or if the increase in muscle hardness and/or tenderness influences the initiating or maintaining sensitization.

Psychological Depression and Anxiety, Headaches and Headache-Related Disability

Disability and symptoms of anxiety and depression are major dimensions of headache impact (Holroyd, Malinoski, Davis, & Lipchik, 1999). Disability is described as impairment in work, social, and in other activities caused by headache (Holroyd et al, 1999). Affective distress, which includes symptoms of anxiety and depression, is correlated with headache-related disability (Passchier et al, 1996; Holroyd et al, 1999 Rasmussen, 1993; Rokicki & Holroyd, 1994; Sexton-Radek, 1994; Ficek & Wittrock, 1995; Ho, Ong, & Lee, 1997; Asmundson, Norton & Veloso, 1999). Life is frequently described as more distressing by headache sufferers than by headache-free individuals (Holm, Holroyd, Hursey & Penzien, 1986).

Similarly, fatigue and impairment of sleep is frequently noted as an impact of headache by headache sufferers (Holroyd et al, 2000; Ulrich, Russell, Jensen, & Olesen, 1996; Rasmussen, 1993). Research using self-report measures has indicated that individuals with chronic tension-type headache may take significantly longer to fall asleep than headache-free individuals (Spierings & van Hoof, 1997) and have more sleep-related problems (Rasmussen, 1993). One study that examined the prevalence of sleep disorders in children who suffer from headache reported that 25% of healthy children and 60% of those suffering from headache had sleep disorders (Crenca et al, 1999).

The experience of frequent or chronic tension-type headache has been related to significant increases in distress and headache-related disability. Although sleep related difficulties are common in headache sufferers, it is still unclear what role sleep may play in the maintenance or severity of headache-related disability. Research has found that massage therapy is associated with significant decreases in distress, disability and sleep-related problems for individuals with other pain disorders (Field et al, 1997, 1998; Sunshine et al, 1996). The current study has examined the use of massage therapy to decrease headache activity, distress, headache-related disability and sleep impairment in individuals with frequent or chronic tension-type headache.

Definition of Massage Therapy

As one of the most common forms of complimentary medicine used to treat pain (Eisenberg et al, 1998), massage is defined as the "manual soft tissue manipulation, including holding, movement, and/or applying pressure to the body" (American Massage Therapy Association, 1999). Massage has a wide variety of forms and techniques which all involve the use of touch to manipulate soft tissues (Moyer, Rounds, & Hannum, 2004). Swedish massage is the basic technique most frequently practiced in the United States (AMTA, 1999). This method is based on Western concepts of anatomy and physiology and it involves long strokes (effleurage), kneading (petrassage) and friction. The motions of the strokes are towards the heart with the goal of increasing circulation and bringing fresh blood to help heal areas of the body (Beck, 1999). Swedish massage is the primary technique utilized in research which examines the effects of massage therapy (Field et al. 1997; Sunshine et al, 1996; Hernandez-Reif et al, 1998, 2001; Puustjarvi et al, 1990).

Other massage therapies have occasionally been the subject of research studies; the following is a brief description of these techniques. Myofascial release is a form of bodywork that utilizes long stretching strokes in an effort to release tension in the fascia (AMTA, 1999). The term fascia refers to a sheet or band of fibrous connective tissues below the skin or surrounding muscles and other organs (Tortora & Gradowski, 1996). Trigger point therapy (also called Myotherapy or Neuromuscular therapy) applies concentrated finger pressure to "trigger points" in muscles to break cycles of spasms and pain (AMTA, 2002). Connective tissue massage is often used in disorders of the circulatory system and muscular tension. For this technique, the therapist applies slow subdermal traction (deep stroking).

Overall, Swedish massage is the most widely practiced technique, but there is disagreement concerning the specific massage procedure that is preferred for different ailments. To my knowledge, there are no studies comparing different massage modalities to treat an ailment. The current study used Swedish massage techniques in order to allow for direct comparisons to previous research in this area.

Massage and Headache

Although the use of massage is prevalent, there has been a limited amount of research to support its effectiveness; thus, the usefulness of massage remains controversial. The few studies that have examined the effects of massage therapy on headaches have all reported significant improvements; however, none of these studies has controlled for pressure. Controlling for this variable allows for the evaluation of the expected therapeutic effects of therapist attention and physical contact.

Puustjarvi, Airakstinen and Pontinen (1990) determined that individuals with chronic tension headaches experienced decreases in pain intensity and the number of days of neck pain following massage therapy. In this study, 21 females with chronic tensiontype headache received 10 one-hour sessions of massage to their upper body over a period of two and a half weeks. The massage was a combination of two techniques: deep tissue (Swedish style) massage and trigger point work to their upper body.

Following the completion of massage, a statistically significant increase in cervical range of motion and decreases in pain (as assessed by a visual analogue scale) and depression (as assessed by the Beck depression inventory) were observed. (Range of motion, which is a factor of muscle tightness, was assessed because it is a common finding in individuals with tension-type headache.) Puustjarvi et al (1990) reported that at the end of the 2-week and the 3- and 6-month follow-up periods there remained a significant decrease in intensity (measured on a visual analogue scale) and number of days (assessed by self-report) with neck pain as compared to the pretreatment levels. Depression symptoms significantly decreased immediately following the 10 massages (measured by BDI), then slowly increased at the 3- and 6-month follow-up.

This study's limitations include: the absence of a control group, daily diary assessments of headaches, and insufficient headache diagnostic history. Additionally, the use of a massage treatment that incorporates a combination of massage modalities lends to difficulty in determining which technique may be beneficial. Nonetheless, the results indicate that massage therapy may benefit headache sufferers by leading to decreases in neck pain and depression.

The only other prior study examining the effects of massage on individuals with IHS-diagnosed chronic-tension type headache was a four person case series (Quinn, Chandler and Moraska, 2002). Participants received a massage technique that consisted of a combination of two techniques: trigger point therapy on points on the upper back and neck region as well as some Swedish-style strokes and stretching. The treatment sessions lasted 30 minutes and took place twice a week for a total of 8 sessions. Headache frequency, as assessed with a daily headache diary, significantly decreased during the treatment period as compared to the baseline period. Headache duration and intensity did not significantly decrease. The sample size (4) and lack of a control group render this a case series with limited generalizability. Furthermore, the fact that improvements were observed on only 1 of 3 headache measures also may suggest massage is of limited benefit for tension-type headache.

Lastly, Hernandez-Reif, Dieter, Field, Swerdlow and Diego (1998) studied the effects of massage therapy on individuals with migraine headaches. The 26 participants were randomized into either a massage therapy or a wait-list control group. Swedish-style massage was administered to the neck, face and head twice weekly for 30 minutes over the course of 5 weeks. Throughout the study, a daily headache diary was used to assess headache frequency and intensity. Based on the headache diary, the massage group experienced significantly fewer mild migraines, but not fewer moderate or severe migraines or significantly more headache-free days than did the wait-listed control group.

Moreover, a significant decrease in the intensity of headache pain (as assessed with a visual analogue scale) was noted following the first and last massage when compared to an assessment taken immediately prior to the massages. The massage group reported fewer somatic symptoms, a decrease in anxiety, and significant increase in the number of hours slept and decreases in night awakenings. The authors noted a significant increase in serotonin (assessed via urine) from the first to the last day of massage. Limitations of this study include: the lack of baseline measures of headache frequency and intensity; follow-up data; the absence of a group that controls for attention and touch, and deficiency of analysis directly comparing the treatment and control groups. Results of this study note that the effects of massage therapy on headache may be limited to the reduction of mild migraine headache pain which resulted in an increase in headache-free days. Tension-type headache tends to be less severe than migraine headache and thus massage may be more beneficial for tension-type headache.

In summary, these few available studies into the effects of massage therapy have all reported decreases in the frequency of headaches. One study reported treatment effects that were maintained for six months (Puustjarvi et al, 1990). Other improvements have included reductions in psychological distress, headache related disability, and sleeping difficulties. Hernandez-Reif et al (1998) reported significant decreases in headache severity as well as frequency, but these results were not replicated by the study of Quinn et al (2002). Puustjarvi et al (1990) noted significant decreases in neck pain, which frequently accompany tension-type headache.

Unfortunately, these studies have significant methodological limitations. No study has employed a placebo group to control to examine the effects of interpersonal attention and physical contact and most studies completely lacked any control group (Puustjarvi et al, 1990; Quinn et al, 2002). Sample sizes have been unacceptably small (Quinn et al, 2002) and no baseline headache diary measures (Hernandez-Reif et al, 1998) or followup data (Quinn et al, 2002; Hernandez-Reif et al, 1998) have been obtained. Thus these studies cannot indicate whether observed improvements were due to massage rather than the passage of time or simple attention and physical contact.

Massage Therapy and Pain in Other Medical Disorders

Massage therapy has frequently been used to treat chronic pain (Eisenberg et al, 1998) and research with other chronic pain disorders provides additional information about the effectiveness of massage therapy. Cherkin et al (2001) examined the effects of massage versus both acupuncture and self-care in treating back pain. Participants were randomized to groups receiving acupuncture (n = 94), massage (n = 78) or self-care (n = 94)90). Participants received up to 10 sessions of either acupuncture or massage therapy over a 10-week period or were given a self-care regimen. The treatments were not standardized but individualized to the participant. For example, the massage therapy protocol focused on manipulation of soft tissues and permitted the use of Swedish massage, deep tissue, neuromuscular, hydrotherapy, and/or trigger and pressure point techniques, but proscribed other therapies, such as energy techniques and acupressure. The self-care education group received educational material designed for people with chronic back pain, including a book and two videos. Participants in the massage group reported significantly less disability (self-report of reduction in activity) than individuals in either the self-care education group or acupuncture group at the completion of the study. The Roland Disability Scale was used to assess changes in symptoms. At the 52week follow-up, individuals in the massage group reported significantly fewer symptoms (back or leg pain, numbress or tingling, and limitations in daily activity due to back pain) than individuals in the acupuncture group, but did not differ from the self-care group.

Additionally, Cherkin et al (2001) reported outpatient costs of back care during the year following participants' entry into the study. The amounts were based on the fee schedule used by major insurance companies in Washington State who cover massage and acupuncture. The estimated cost of these interventions was \$48 per massage visit and \$60 for the initial acupuncture visit and \$45 per follow-up visit. The massage group's outpatient care costs over this year were 30-45% lower than the other two treatment groups (\$139 versus acupuncture at \$252 and self-care at \$200). Results indicated that not only was massage therapy associated with decreases in lower back pain symptoms, but massage was associated with lower health care costs. Massage was less expensive than acupuncture or self-care. Follow-up reports indicated that massage may have long lasting effects in reducing pain. The lack of standardized treatment for the acupuncture and massage groups was both a limitation and a strength. As a limitation, the individualization of the treatments is difficult to replicate because no algorithm was provided to replicate the treatments. A noteworthy strength of this study was the customizing of the therapy that approximated actual practice and rendered results more generalizeable to the clinical environment.

Field, Hernandez-Reif, Seligman, Krasnegor and Sunshine (1997a) studied the effects of massage on individuals with juvenile rheumatoid arthritis. Daily massage was compared with parent-administered progressive muscle relaxation therapy on 20 children (between the ages of 5-15 years) with mild to moderate juvenile rheumatoid arthritis.

Parents, trained in massage, gave their child a 15-minute full-body massage daily for 30 days. The massages consisted of Swedish-type strokes and kneading to the stomach, face, legs, feet arms, shoulders and back. The relaxation group received a half hour of daily progressive muscle relaxation, with instructions read by the parents. Over time, a significant decrease in pain (as assessed by the Varni/Thompson Pediatric Pain Questionnaire-Child Form) and pain-related disability (assessed by Varni/Thompson Pediatric Pain Questionnaire-Parent Form) was found in the massage group but not in the progressive muscle relaxation group. The massage group also reported significant reduction in anxiety (STAI) and had significant decreases in cortisol levels (assessed in saliva) 30 days after the initial treatment. Limitations of this study include: the failure to directly compare improvements produced by the two treatments; lack of follow-up data; and failure to control for physical contact. Having the treatments delivered by parents may have posed an additional problem with reliability of treatments. Results indicate that massage is beneficial in reducing pain and pain-related disability when compared to progressive muscle relaxation.

Sunshine et al (1996) examined the effects of massage therapy on fibromyalgia. Thirty females received 10 thirty-minute sessions of either massage therapy, TENS (transcutaneous electrical stimulation), or Sham TENS. The massage therapy sessions consisted of Swedish massage to the head, neck, shoulders, back, arms, hands, legs and feet. TENS sessions involved a pen-sized steel roller that transmits a weak electrical current across the body. The Sham TENS sessions used the same roller minus the current. In both TENS groups, the participants had the roller moved over the same parts of the body that was massaged in the massage therapy group. Those in the massage therapy group and the TENS group had significantly decreases in anxiety (STAI), depression (POMS), and cortisol (assessed via saliva). Only those in the massage group had significant decreases in overall pain (assessed by self-report), pressure pain threshold levels (measured by using a dolorimeter on 18 tender points), stiffness, fatigue and difficulty sleeping. A weak point in the study is the absence of analysis comparing the improvements in the two treatment groups. The comparison of massage to TENS and Sham TENS allowed for observation of the effects of massage, controlling for physical contact. However, the credibility of these two treatments was not assessed, so it is not known whether the participants felt that either of the comparison groups (TENS and Sham TENS) were viable treatments.

Field et al (1997b) examined the effects of 10 sessions of massage therapy or Sham TENS (interpersonal-attention control) on 20 individuals with chronic fatigue syndrome. The Swedish-style massage was performed on the arms, torso, legs and head. Individuals in the massage therapy group, but not the interpersonal-attention control group, had significant decreases in self-reported levels of overall pain (assessed using a visual analogue scale) and depression (assessed with the Profile of Mood States) and in salivary cortisol levels immediately following treatment. On the last day of treatment, only the massage therapy group had significant decreases in self-reported levels of pain, depression, sleep problems and salivary cortisol levels. Both groups had decreases in anxiety but the massage therapy group's change was significantly greater. This study supports the use of massage to decrease pain and includes a control group that also incorporates physical contact but no measure of treatment credibility was reported concerning participants' belief in the validity of the control treatment. Hernandez-Reif, Field, Krasnegor and Theakston (2001) compared the effects of massage therapy to relaxation therapy in 24 adults with lower back pain. Participants received half hour sessions of massage two times a week for five weeks. The massage sessions consisted of Swedish-style techniques on the neck, back, hip and legs. Sham TENS involved rolling a small ball over the same body parts. Both groups had significant decreases in self-reported levels of anxiety and pain. The massage therapy group reported significantly fewer sleeping disturbances (Sleep Scale) and depressive symptoms (POMS-D) and showed a significant increase in serotonin (5-HIAA) and dopamine (as assessed in urine) as compared to the changes in relaxation control group's pre and post scores. Dopamine and serotonin levels were measured because these may be depleted with chronic pain. This study, which also included a physical contact control group (Sham TENS), indicated that massage is associated with decreases in pain. No measure of treatment credibility was reported.

Hernandez-Reif, Martinez et al (2000) noted that women with premenstrual syndrome reported significant decreases in pain, anxiety and depression following the first and last (10th) massage therapy session. Twenty-four women received either 30 minutes of massage therapy or self -administered progressive muscle relaxation therapy twice a week for five weeks. The Swedish massage sessions consisted of massage to the neck, head, arm, shoulder, stomach, feet, leg and back. For relaxation therapy, participants were asked to tense and relaxed large muscle groups throughout their bodies, starting with their feet. Participants in the relaxation therapy group were telephoned weekly to monitor their compliance. Two participants were dropped due to noncompliance. On the last day of treatment, only individuals in the massage group

reported significant decreases in anxiety (State-Trait Anxiety Inventory: STAI), depression (Profile of Mood States: POMS) and pain (Visual Analog Scale: POMS). In this study, massage was associated with decreases in pain. However, it appears likely that the two treatments differed in credibility and consistency within treatments; the massage was always professionally administered and the relaxation therapy was only professionally administered for the first and last sessions. Otherwise, it was selfadministered.

In conclusion, massage therapy has consistently yielded improvements in pain and, in a few studies; improvements were maintained in follow-ups as long as six months (Cherkin et al, 2001; Puustjarvi et al, 1990). Cherkin et al (2001) reported that not only was massage more effective than acupuncture and self care, but treatment costs for the year following initial treatment were lower. Other significant results include improvements in sleep problems (Sunshine et al, 1996; Hernandez-Reif et al, 1998,2001), affective distress (Hernandez-Reif et al, 1998; Field et al, 1997a; Sunshine et al, 1996) and disability (Cherkin et al, 2001), as well as increases in serotonin-5-HIAA (Hernandez-Reif et al, 1998) and decreases in cortisol (Field et al, 1997a,b; Sunshine et al, 1996). Unfortunately, these studies also suffer from some methodological problems. Many have no measure of the longevity of treatment effects (Hernandez-Reif et al, 1998, 2001; Field et al, 1997a, 1997b, Sunshine et al, 1996; Quinn et al 2002) and lack a control group (Puustjarvi et al, 1990; Quinn et al, 2002). Additional studies are needed, particularly studies that: allow for the examination of the potential effects of attention and physical contact, have an adequate sample size, and include long term follow up evaluations that allow the maintenance of treatment effects to be evaluated. Welldesigned studies would allow for a further exploration of massage therapies' potential benefits and would lend credibility to the findings of reduction in headache pain. *Mechanism of Massage-Induced Reduction of Pain*

Massage has been associated with decreases in pain (Puustjarvi et al, 1990), distress (Hernandez-Reif, Dieter et al, 1998) and stress hormones (cortisol & catecholamines) (Sunshine et al, 1996). (The levels of stress hormones were compared to a control group.) However, the specific mechanism by which massage may affect tension headaches is not known. Field (1996) postulated that the manual manipulation of soft tissues results in a decrease in pain by increasing parasympathetic activity. Pressure (e.g., manual manipulation of soft tissues) associated with touch may increase vagal activity, thus reducing stress hormones (particularly cortisol), the associated sensations of anxiety or depression, and muscle tension. This hypothesis is consistent with findings showing that massage therapy for pain in a variety of medical disorders is correlated with decreases in cortisol levels (Sunshine et al, 1996; Field et al, 1997b; Field, Peck et al, 1998), anxiety (Field, Peck et al, 1998; Hernandez-Reif, Martinez et al, 2000), depression (Puustjarvi et al, 1990; Field et al, 1997b; Hernandez-Reif, Field, & Theakston, 2001; Hernandez-Reif, Martinez et al, 2000) and muscle tension (Puustjarvi et al, 1990).

Despite the supportive findings, only one study has compared massage to a pseudo-massage procedure that removes the pressure from massage to determine if the two procedures produce similar changes. Diego, Field, Sanders, & Hernandez-Reif (2004) reported the effects of a 10 minute medium pressure massage, a light pressure massage or a vibratory massage on self-reported anxiety and stress and relaxation response (i.e., changes in EEG and heart rate). They noted significant reductions in self-

reported anxiety and stress among individuals in both the medium and light pressure massage and evidence for a relaxation response (increased slow wave EEG activity and decreased heart rate) in individuals who obtained the medium pressure massage. Assessments were taken a few minutes after the treatment and only provide information on an immediate response. The findings suggest that while massage therapy, regardless of the pressure applied, may have therapeutic effects on emotional well-being. Furthermore although no direct comparisons were made between treatment groups, the deep pressure applied during the massage appears to have more of a physiological effect associated with a relaxation response.

The gate control theory has also frequently been used to explain massage effects. Gate control theory presents a hypothetical model of central nervous system pain facilitation and modulation. Melzack and Wall (1994) postulated that pain may in part be modulated by sensory input from the skin as well as from psychological factors and cognitive events. According to this theory, pain may be alleviated by pressure because the pain fibers are thin and less myelinated than the thick myelinated fibers that transmit innocuous sensation like pressure and mechanical stimuli (Bendtsen, 2000). Then the pressure stimuli may be received by the central pain control systems prior to the pain stimuli, effectively closing the "gate" and therefore decreasing pain or preventing noiceptive input pain from being processed (Field, 2000). The central control trigger in the dorsal column is theorized to activate brain processes that can exert control over sensory input (Melzack & Wall, 1983). The "gate" in this theory is proposed to be a neural mechanism in the spinal cord that acts like a gate in that it may facilitate or inhibit neural impulses from the peripheral to central nervous system (Larbig, 1991). Melzack and Wall (1983) hypothesized that the gate was located in the substantia gelatinosa. The gate control theory may explain the efficacy of massage therapy by suggesting that the physical pressure of a massage, which is transmitted to the central pain control systems via faster myelinated fibers, may close the gate to noxious pain signals of tender muscles, whose signals are transmitted via slower less myelinated fibers. This theory is limited to immediate effects (Moyer, Rounds, & Hannum, 2004).

In conclusion, Field hypothesized that massage alleviates pain by systematically applying pressure to soft tissues, which increases parasympathetic activity, while Melzack and Wall's gate control theory postulates that pressure blocks noiceptive information more locally. These are not mutually exclusive hypotheses and both may be true. Field (1996) has thus suggested that a pseudo-massage or placebo massage might be created by removing the pressure from the massage procedure while maintaining other elements constant. This would control for attention and for physical contact to specified areas of the body surface. It appears that such a placebo would allow for a better examination of attention and physical contact than Sham TENS (Sunshine et al, 1996; Field et al, 1997b) or alternative treatments such as acupuncture (Cherkin et al, 2001), progressive muscle relaxation (Hernandez-Reif et al, 2001, 2000; Field et al, 1997a) or self care (Cherkin et al, 2001).

Purpose of Present Study

The primary purpose of the present study was to examine the effectiveness of massage therapy for reducing frequent or chronic tension-type headache. This study was the first treatment study of massage to incorporate both placebo and headache-recordingonly control groups. A second purpose was to assess the impact of massage on physiological (pericranial muscle tenderness and pressure pain thresholds) and psychological (depression and anxiety) variables that might mediate the effects of massage therapy. Lastly, it was hypothesized that "true" massage therapy would lead to a greater decrease in headache activity than either placebo massage or the headacherecording control group. The placebo massage group was hypothesized to experience a greater decrease in headache activity than the headache-recording control group.

Method

Participants

Approximately, one thousand five hundred undergraduate students were screened for tension-type headaches through a mass screening of introductory psychology classes. Individuals, who reported experiencing frequent or chronic tension-type headaches, were invited to a diagnostic interview. Frequent or chronic tension headaches were defined as a tension-type headache occurring at least two times a week for at least the past three months. Following the interview, individuals who met the International Headache Society diagnostic criteria for episodic or chronic tension-type headache and confirm they experience at least two tension-type headaches per week were invited to participate in this study. A daily headache diary was used to determine if diagnostic criteria was met. Fifty-three undergraduate females at Ohio University participated in this study. (See table 1 and 2 for diagnostic criteria of tension-type headaches.)

The average age of participants was 18.7(SD=.54) years and a one-way ANOVA indicated there were no significant differences between the groups in terms of age (F(2,52)=.143, n.s.). The ethic/racial makeup of the participants was as follows: 94.3 %

European American, 1.9% Hispanic, 1.9 % African American, 1.9% other. A one-way ANOVA indicated there were no significant differences in terms of ethnic make-up between the groups (F(2,52)=1.20, *n.s.*).

Furthermore, participants did not differ in terms of history of experiencing headaches, average length of headache, and average headache intensity; as described below. Participants reported an average 3.91 (SD=2.29) year history of experiencing tension-type headaches. A one-way ANOVA indicated there was no significant difference between the groups in terms of chronicity of tension-type headaches (F(2,52)=.437, n.s.). Participants reported the average length of time their typical untreated tension-type headache to be 4.9(SD=7.7) hours. A one-way ANOVA indicated there is no significant difference between the groups in terms of average length of headache (F(2,52)=.411, n.s.). Participants noted an average of 2.01 (SD=1.26) days per week with a headache intensity greater than 5 (on a scale from 1 to 10 with 10 being the most intense head pain). The average baseline headache index was 1.7 (SD=.88). A oneway ANOVA indicated there is no significant difference between the groups in terms of headache index (F(2,52)=..576, n.s.). The majority of the participants meet the diagnostic criteria for frequent tension-type headaches (5 out of 53 participants experienced chronic tension-type headaches, 1 individual in the "true" massage group, 2 individuals in the placebo massage group, and 3 individuals in the headache recording control group). See table 5 for more information.

Screening Measures

Headache Screening Questionnaire. A modified version of the Headache Screening Questionnaire (Holm, 1983) was used to ascertain the frequency and type of headaches experienced. This instrument includes a total of 22 questions about chronicity, duration, intensity, frequency, familial history and quality of headaches as well as previous medication use and presence of concurrent pain disorders.

Structured Diagnostic Interview for Headache, Brief Version. Individuals who report experiencing two or more headaches a week and appear to have meet criteria for tension-type headache on the Headache Screening Questionnaire were interviewed by a graduate student using the Structured Diagnostic Interview for Headache, Brief Version (Penzien & Holroyd, 1990). It included questions regarding: pain quality, headache location, onset, chronicity, frequency, duration, intensity, previous treatments used, headache history, and associated symptoms, family history, and general medical/medication history. This measure included 25 questions. The inclusion criteria (described on table 4) is based on diagnostic criteria for frequent tension-type headaches proposed by the Headache Classification Committee of the International Headache Society (2002). (See table 1 and 2 for an outline of the diagnostic criteria for tension-type headaches.)

Exclusion criteria were as follows: more than two migraine headaches per month, cluster headache, headaches aggravated by analgesic use (rebound headaches), sinus headaches or other headache disorders. Individuals who report experiencing another pain disorder (e.g., fibromyalgia) or have an acute pain problem (e.g., back injury) have also been excluded. Also, individuals taking preventive medication for their headaches were excluded, for example the use of tricyclic antidepressants would exclude an individual from participating in the study because the medication itself may reduce their headache activity.

Outcome Measures

Daily Headache Records: Headache activity was recorded on headache recording charts (Holroyd, 2001). Participants were instructed on how to numerically rate their headache activity. Headache intensity ratings range from (0) "no headache" to (10) "extremely painful - I cannot do anything when I have this headache". Headache intensity was rated at four times during the day: breakfast, lunch, dinner, and at bedtime. From the daily recordings the headache index, peak intensity and number of headache free days was obtained. The headache index is a mean of all diary ratings (including zeros) and provides a measure of overall headache activity. The scores may range from 0 to 10. Peak intensity represents the most intense pain experienced and may range from 0 to 10. Headache free days represent the percentage of days in which no headaches were experienced; this ranges from 0 to 100%.

Sleep. Quality of sleep is often negatively affected in individuals with headaches (Passchier, de Boo, Quaak, & Brienen, 1996; Rasmussen, 1993; Spierings & van Hoof, 1997). Increase in restorative sleep may result in lower levels of substance P (an inflammatory peptide) and then perhaps, less pain (Sunshine et al, 1996). A few studies have considered the role massage may play with sleep and little is known about the role sleep difficulties may play in headaches. Because pain disorders and specifically headache disorders are associated with sleep problems this study examined the effects massage has on sleep. As a part of the daily headache recordings, participants were asked to record the number of hours they slept that night as well as the frequency of night awakenings (0 = sleep soundly, 10 = very often). They were asked to record this information upon awakening.

For the following measures, the assessor was blind to the group assignment of the subject. To prevent the blind from being broken the participant was instructed not to discuss their group assignment with the assessor.

Pericranial Muscle Tenderness (PMT): A manual palpation technique that is a modified version of Langemark and Olesen's (1987) procedure includes the use of a fingertip palpometer (Dolorimenter Systems Inc, Victoria BC). Five bilateral pairs of pericranial muscles (suboccipital, posterior cervical, middle trapezius, masseter, and temporalis) were palpated using fingertip pressure of 500g/cm as measured by the palpometer (Neufield, Holroyd, & Lipchik, 2000; Langemark & Olesen, 1987; Janke & Holroyd, 2002). The participant were asked to report the tenderness of each palpation site on an ordinal scale from 0 to 10; 0- no pain and 10 – the most excruciating pain (Hatch et al, 1992; Langemark & Olesen, 1987). The standardization of manual palpation by use of a palpometer has increased the reliability and utility of manual palpation as a research tool in myofascial pain disorders (Bendtsen, Jensen, Jensen, & Olesen, 1995).

Pressure Pain Thresholds (PPT): Using a hand-held pain threshold meter, (Pain Diagnostics and Thermography, Great Neck, NY) PPT was measured at two points, the left anterior temporalis and the left middle. The device consists of a spring-loaded dial that registers pressure applied to the 1 cm rubber tip of the instruments it is pressed into the tissue and it is commonly used in muscle pain assessments (Fischer, 1993). The body of the anterior temporalis is located by palpation, and then pressure will be applied and increased at a constant rate of about 0.5 kg/s (Langemark, Jensen, Jensen, & Olesen, 1989). The participant was asked to indicate when the pressure first becomes painful and

then the pressure will be immediately released. The maximum force to be applied was read from the dial. The final PPT score consisted of the average of three readings taken at about 5-10 seconds apart.

Psychological Assessments

Beck Depression Inventory II (BDI-II): Depressed mood was measured using the Beck Depression Inventory - II (Beck, Steer, & Brown, 1996). This is a 21-item self-report questionnaire that assesses current depressive sympomatology, including cognitive, affective, behavioral, and somatic symptoms of depression. Each item consists of four statements that assess the severity and presence of a particular symptom. The minimum score is 0 and the maximum score is 63. The coefficient alpha for college students is .93 (r = .93); the correlation between BDI-IA and BDI-II was .92.

Beck Anxiety Inventory (BAI): This self-report assessment was used to measure the severity of anxiety. The Beck Anxiety Inventory consists of 21 descriptive statements of anxiety symptoms, such as "Heart pounding or racing" or "Shaky". Items are rated on a 4-point scale, from "Not at all" (0 points); "Mildly; it did not bother me much" (1); "Moderately; it was very unpleasant, but I could stand it" (2); and "Severely, I could barely stand it" (3) (Beck & Steer, 1990). The minimum score is 0 and the maximum score is 63. The test-retest reliability coefficient is .75. The alpha reliability coefficient is .92.

Credibility Assessment

The following measure was used as a manipulation check to verify that the placebo and massage treatments are equally credible.

Perceived Treatment Credibility: Following the initial treatment, participants in either the deep pressure massage or light touch massage were asked to indicate their perceived validity and effectiveness in the treatment they have received. Participants were (a) asked how effective they rate the treatment being received, (b) if they would recommend the treatment to another individual, and (c) if they would be willing to pay for the treatment. All questions are on a scale from 1 to 10 with 10 being a very positive response and 1 being negative. The responses of the two treatment groups were compared to indicate any possible discrepancy in perceived credibility.

Ancillary Measures

The following measures are not the primary focus of this study but they are included for exploratory analyses.

Medication. Individuals who use analgesic medication were asked to record their use in the daily headache record. A tally of their medication use was obtained from the daily headache recordings and each pill was weighted by its analgesic potency (Coyne, Sergent, Sergerson, & Obourn, 1979), for example, analgesics containing codeine were weighted more than over-the-counter aspirin.

Headache Disability Index (HDI): This measure was created to assess the distress and disability that are experienced as a result of chronic headaches (Jacobson, Ramadan, Aggarwal, & Newman, 1994). This 2- item questionnaire inquires about the impact of headaches on emotional functioning (e.g. My headaches make me angry) and daily activities (e.g. I restrict my recreational activities because of my headaches). The stability over one week is r = 0.93-0.95 and over longer term (2 months) it is r = 0.76-0.83. *Headache Self-Efficacy Scale (HSES):* This scale was designed to measure selfefficacy expectations of an individual's ability to prevent the occurrence of headache pain and to control the amount of pain experienced (French, et al., 2000). It is a 17-item; self report scale in which each item is rated on a scale of 1 (strongly disagree) to 7 (strongly disagree). Internal consistency is measured at .88.

The Headache-Specific Locus of Control Scale (HSLC): This is a measure of the expectancy an individual has regarding their own feelings of control over their headaches. The 33 items reflect respondent's belief about what determines their headaches (Martin, Holroyd, & Penzien, 1990). Internal locus of control reflects the individual's own responsibility for health-related behaviors. The other locus refers to the respondent's reliance on physicians and other healthcare professionals (r = .78, alpha =.88). The chance locus measures the amount an individual attributes their condition to luck, fate or an accidental occurrence (r = .72, alpha =.84). For the internal locus measures, respondents will indicate their level of agreement to the items that reflect either primarily internal (e.g. If I take care of myself, I can avoid headaches) or primarily external (e.g., No matter what I do, I'm likely to get headaches) variables that influence their headache activity (r = .75, alpha =.86). The Headache Locus of Control (HLOC) total score was used as a measure of the individual's perceived external control over factors that control their headaches.

Procedure

The entire experiment was conducted in four three-week phases (see figure 1). To begin with, female undergraduate students who indicate that they suffer from frequent or chronic tension headaches on the Headache Screening Questionnaire were asked to participate in an assessment interview to further determine their eligibility. A clinical psychology graduate student conducted the assessment. The structured diagnostic interview included an assessment of the individuals' headache characteristics and history as well as a brief explanation of the nature of the study. Individuals who qualify for the study were administered the physiological measures during this first session. This was done to allow the participant to experience the potentially painful assessment procedures because the first assessment may elicit greater reaction than later assessments. A detailed description of the study was given to each patient before informed consent is signed. Finally, eligible participants were taught how to complete daily headache and sleep recordings that they begin recording the following day.

For the next three weeks, participants keep daily headache and sleep recordings in order to confirm that they experienced at least two headache days per week and to provide a baseline measure of their headache activity. Completed daily headache recordings were dropped off weekly.

At the conclusion of the pretreatment phase (end of week 3), participants were randomized into one of three groups: "true" massage, placebo massage, and a headacherecording control group. The participants were stratified on level of headache activity (headache index) and then randomized. Immediately following the first treatment participants in the "true" massage and placebo massage groups were asked to complete the assessment of treatment credibility. In the middle of this phase, immediately before session four and following the sixth treatment, all participants were asked to complete the psychological and physiological assessments. At the end of week 3, the participants completed all the self-report psychological measures (depression, anxiety, headache self-efficacy, headache disability, and locus of control) and a baseline assessment of the two physiological measures (pressure pain thresholds and pericranial muscle tension). Participants were asked to continue completing their daily headache and sleep recordings during the treatment phase.

During weeks 7 through 9, participants were asked to continue to complete their daily headache recordings; at the end of week 9, the participants returned to the clinic and the psychological and physiological measures were reassessed. Three months later, all participants were asked to fill out their daily headache recordings. At the end of the final follow-up three-week recording phase (weeks 10-12), participants completed a final follow-up psychological and physiological measures were re-administered. Participants were asked what if any treatments they have used in the previous three months.

Massage therapist. Student massage therapists from a local school and the Principle Investigator (RM) provided massages for the two treatment groups. Massage therapists have undergone standardization training to ensure the same procedure is employed by each therapist. All massage therapists in this study practiced the massage procedure prior to the study. To standardize the amount of pressure used in the two massage therapy groups, a bathroom-type scale was used. (To my knowledge no validated system to control for pressure has been constructed.) The scale was placed on a massage table to be at the correct massage height. For the "true" massage, the massage therapists pushed on the scale with their fingertips until it reads 25 pounds, which is approximately .04 pounds (18.14 grams) per square cm. They then practice on a volunteer graduate student and the principle investigator, checking pressure against on the scale. The placebo massage utilized a light pressure that involved gently placing the hands on the body without added pressure, which was no more than .008 pounds (3.63 grams) per square centimeter.

Massage Procedures: The massage technique used in this study is based on the massage used in Hernandez-Reif, Dieter et al's (1998) migraine treatment study with some alteration. In their study, participants were supine while their neck and head was massaged. For this study, the head, neck, and trapezius were massaged using Swedish massage techniques. The trapezius was added due to sensitivity of this muscle commonly reported by individuals with tension-type headache (Lipchik et al, 1996). Each 30-minute session was divided into 2 equal time segments. In the initial 15-minute segment, the participant is lying prone, feet bolstered, as the therapist applies gliding strokes to the back and shoulders, followed by kneading of the upper trapezius and neck muscles and circular friction of the suboccipital muscles. In segment two, the participant was supine as the therapist applies sweeping strokes along the shoulders and up the posterior neck followed by circular friction and kneading to the posterior neck, and digital kneading along the inferior nuchal line. The therapist then mobilized the cervical spine while applying thumb pressure to suboccipital muscles followed by a gliding stroke along the cervical lamina groove. Next, the initial shoulder and neck stroke was repeated followed by digital pressure along the inferior nuchal line. The entire supine sequence was then repeated to complete the session. The number of treatment sessions and the massage technique was identical in the "true" and placebo massage groups.

It has been hypothesized that pressure is the critical "active" component of massage that is required to achieve the therapeutic effects of massage (Field, 1996). Thus,

there were two massage therapy groups, a "true" (medium pressure) and a placebo (light pressure) massage group. The use of a light pressure placebo massage group allows for a more appropriate examination of massage, controlling for the role pressure. This allowed for an examination of the influence of touch and interpersonal attention. To my knowledge, no previous study has utilized a placebo massage therapy group.

All massage therapists were trained in using the identical technique and practiced on a volunteer graduate student. The massage therapist practiced the technique until the volunteer graduate student (who was receiving the massage) could not distinguish between therapists.

Both massage groups employed the identical massage procedure described above. The same pattern of strokes was used for both massage treatment groups. In placebo (light touch) massage the maximum pressure involved gently placing the hands on the body were as the "true" (medium pressure) massage involved a more substantial pressure on the part of the therapist. The only difference between the two massage conditions will be the difference in the pressure.

Headache Recording Control. The participants in this group continued with the daily headache recordings but did not receive treatment. At the completion of the follow-up phase, participants who continue to meet inclusion and exclusion criteria and wish to continue to participate in this study were randomized again into either the deep or light touch massage group. (Only two participants requested to be re-randomized into one of the treatment groups, due to the small number, their data is not included in this study.)

Analysis

Initial analysis. During analysis, the three groups ("true" massage therapy, placebo massage, and headache recording control) were compared with respect to all variables of interest. Factorial ANOVAs were performed on the primary measures of headache activity. Time served as the within subjects factor and treatment group as the between subjects factor. Kruskal-Wallis One-Way Analysis of Variance by Ranks was completed on the physiological measures of muscle tenderness and pressure thresholds. Kruskal-Wallis analyses were completed due to non-normal distribution of the pressure pain thresholds. All groups were compared with respect to demographic variables (ethnicity and age), headache activity, physiological variables, and psychological variables.

Predictions. It was hypothesized that differences between "true" massage and the control group (headache-recording) would be similar to the results reported in the research literature (Hernandez-Reif, et al, 1998, Quinn et al, 2002), in that the "true" massage group was expected to experience a significantly greater decrease in headache activity than the control group. Based on predictions of the importance of pressure in the effectiveness of massage therapy (Field, 2000), individuals in the "true" massage group were expected to experience a greater decrease in headache activity than individuals in the placebo massage group. These differences were predicted to be evident at the three-week and the three-month follow-up phases of the headache activity recordings.

Results

Attrition

For this study, attrition was defined as follows: refusing to participate further, not attending all of the treatment sessions, or failing to complete the questionnaires and headache diary up until the three-month follow-up. The overall attrition rate at the threeweek follow-up was 4%, with 2 participants of the placebo massage group (10%) dropping out due to health problems (i.e., the two participants who dropped out were suffering from influenza). At the three-month follow-up, overall attrition was 45%, with 5 (33%) participants dropping out of the "true" massage therapy group, 10 (44%) of participants dropping out of the placebo massage group and 7 (39%) of participants dropping out of the headache-recording control. A chi-square analysis did not indicate any significant difference in the proportion of drop outs among the groups, $\gamma^2 = 2.91$, *n.s.* Of the participants who failed to complete their three-month follow-up, 3 cited lack of interest (2 from the placebo massage group and 1 from the headache-recording control), and we were unable to contact 20 at follow-up (5 of those in the "true" massage group, 8 from the placebo massage group, and 6 from the headache recording control group). The three-month follow-up data were provided by all other participants. Analyses were completed to examine potential differences in attrition among the three groups at the three-month follow-up. Several one-way ANOVAs and a Chi square analysis revealed no significant differences across groups in terms of age (F(2,52)=.143, n.s.), ethnic makeup $(\chi^2(6,53)=7.17, n.s.)$, baseline headache index (F(2,23)=.544, n.s.), pericranial muscle tenderness (F(2,23)=2.418, n.s.), distress (F(2,23)=.916, n.s.) or sleep functioning (F(2,23)=.494, n.s.). In order to allow for the analysis of all participant's at the threemonth follow-up, missing data were replaced with the participant's last score carried forward (LOCF) (Tabachnick & Fidell, 2001). In this case data from the three-week assessment was carried forward to the three-month follow-up.

Credibility assessment

The perceived credibility of the massage and placebo-massage treatments was assessed via three items. The items were summed to create a single credibility score. A Cronbach's alpha was .67. To analyze the perceived differences in credibility between the massage group and the placebo-massage group an ANOVA was conducted. Results of the analysis indicated there were no significant difference in perceived credibility between the treatment groups, F(1,28) = .35, *n.s.* The mean score for the "true" massage group was 28.00 (SD = 2.80) and 27.47 (SD = 2.03) for the placebo-massage group. The analysis suggests that participants rated both treatments as highly credible.

Outcome measures

Headache Activity Hypothesis. Two factorial ANOVAs were conducted to examine differences among the treatment groups in the changes in headache activity over time. Headache activity was first compared between the baseline, treatment, and threeweek follow-up. The second analysis examined changes in headache activity between the three-week, and three-month follow-up period. Table 7 displays these comparisons.

A 3 x 3 factorial ANOVA with one within-subjects factor (time) and one between-subjects factor (treatment) was conducted. The between-subjects factor had three levels ("true" massage therapy, placebo massage, and headache-recording control). The within subjects factor, time, included headache recordings between the baseline, treatment, and three-week follow-up assessments. There were no outliers and the results of the evaluation of assumptions of homogeneity of variance-covariance matrices were satisfactory. The analysis indicated there was a significant interaction between treatment groups by time on headache index, F(4,100) = 2.66, p < .05, reflecting a difference in improvement over time between the three treatment groups.

Pairwise post hoc comparisons were completed to examine differences in improvement between particular groups. Results indicated a significantly greater decrease in headache activity for the "true" massage group as compared to the headache recording control group, F(2,62) = 4.52, p < .05. There were no significant differences between "true" massage and placebo massage (F(2,66)=.867, *n.s.*) or between placebo massage and headache recording control groups (F(2,72)=2.45, *n.s.*). The difference in the effect size between the "true" massage and placebo massage was small (.03); it would require 250 participants per group to detect this difference.

To assess the longevity of changes in headache index, a 2 x 3 factorial ANOVA with one within-subjects factor (time) and one between-subjects factor (treatment) was completed. Headache activity was considered through the last two time periods, from baseline up to the three month follow-up assessments. The between-subjects factor was treatment group ("true" massage, placebo massage, and headache-recording control). Results indicated no significant difference between the groups, (F(2,50)=1.47, *n.s.*). This analysis was limited by the amount of missing data; missing data from the three month follow-up assessment was replaced via the last data point carried forward. An analysis without the replacement of missing data and results indicated no significant difference in between the 3-week and 3-month follow-up periods (F(2,26)=1.47, *n.s.*).

Some participants were lost to the three-month follow-up. Originally, a total of 29 individuals completed the three-month follow-up phase of the headache severity and intensity measure (67% of those in the "true" massage group, 40% of placebo massage and 61% of the headache recording control group). Missing data were replaced with the participants' last score carried forward (LOCF), in this case their data from the three-week follow-up was carried forward to the three-month follow-up phase. (The two participants who did not complete the three-week follow-up were not included in this analysis.) (Without the replacement of missing data in the to analysis headache activity, a 4x3 factorial ANOVA with one within-subjects factor (time and one between-subjects factor (treatment) was conducted. Results indicated a no significant difference between the groups, *F* (6,78) = 1.91, *n.s.*.)

To further examine the effect of massage therapy on tension-type headaches chisquare analysis was completed comparing the number of participants per group who experienced a 50% or greater reduction in headache index by the three-week follow-up assessment. Results indicated a significant difference between the groups (χ^2 (2,53)= 8.32, p < .05). Forty-seven percent (7 out of 15) of individuals in the "true" massage therapy group and 35% of individuals in the placebo massage group (7 out of 20) experienced a fifty percent reduction in headache activity by the three-week follow-up phase; in contrast, only 16.7% of individuals in the headache recording control group (3 out of 18) experienced at least a fifty percent decrease in headache activity.

Psychological Functioning Hypothesis.

Pericranial muscle tenderness (PMT). Group differences in muscle tenderness at the five assessment times were analyzed via the Kruskal-Wallis One-Way Analysis of

Variance by Ranks (alpha = .05). When group differences were significant, pairwise comparisons were performed using the same test. The Kruskal-Wallis analysis was chosen for this analysis due to the skewed distribution of the pericranial muscle tenderness scores. Analysis of the baseline PMT assessment indicated no significant differences between the groups (H[2]=1.97, *n.s.*). During the treatment phase, there was a marginally significant difference between the groups' PMT values H(2)=5.70, p = .058). Immediately following the treatment phase (the end of treatment assessment) there was an overall significant difference between the groups (H[2]=10.80, p < .01). Pairwise analysis further revealed that the "true" massage (p < .01) and the placebo massage (p < .01) groups had significantly lower PMT values than individuals in the headache-recording control group at the end of treatment assessment. No significant differences between "true" massage therapy and placebo massage group. The differences between the three group's PMT values at the three-week follow-up assessment only approached significance (H[2]=5.36, p = .07).

The analysis of the PMT assessment taken at the three-month follow-up phase involved the replacement of missing data. The method utilized was the last observation carried forward (LOCF) method. This allowed for all individuals to be considered in the analysis, not only participants who were compliant with the study. At the three-month follow-up assessment, 13 participants in the placebo massage group, 12 in the headache recording control group and 4 in the "true" massage group were missing data. Following the replacement of missing data, a Kruskal-Wallis One-Way Analysis of Variance by Ranks (alpha=.05) was conducted to examine differences between the groups at the threemonth follow-up assessment. Results indicated an overall significant difference between the groups (H[2] = 9.03, p < .05). Pairwise comparisons indicated that both the "true" massage and the placebo massage groups had significantly lower PMT values than individuals in the headache-recording control group at the three-month follow-up assessment (p's < .01). No difference was noted between "true" massage and the placebo massage groups. Due to the significant loss of data at the three-month follow-up, these analysis need to be considered cautiously. (An analysis of PMT data excluding replaced values indicated a near significant difference between the three groups at the three-month follow-up assessment [H(2) = 5.07, p = .07]).

Although the previous analyses revealed a significant difference between PMT values during the treatment phase, immediately following the treatment phase and at the three-month follow-up assessment; the baseline PMT values appear to vary greatly. The median PMT values for the three groups was 5.00 ("true" massage and placebo massage groups) and 13.50 (headache recording control group). Although this difference was non-significant, change scores were analyzed due to the apparent discrepancy between the groups. Change scores were calculated by subtracting the baseline PMT value from each subsequent PMT value (for example, baseline PMT values were subtracted from the assessment taken during the treatment phase in order to analyze change between these two time periods). Change scores for PMT were analyzed with a Kruskal-Wallis One-Way Analysis of Variance by Ranks (alpha = .05). Results indicated a near significant difference at the three-week follow-up assessment (H [2]= 1.71, *n.s.*) and no significant difference at the three-month follow-up assessment (H [2]= 1.04, p =*n.s.*).

Median PMT values and percentile around the median for each group at each assessment are reported in Table 8.

Pressure pain thresholds. To examine group differences in PPT values at each of the five assessment times, a Kruskal-Wallis One-Way Analysis of Variance by Ranks (alpha = .05) was conducted. A Kruskal-Wallis analysis was completed due to nonnormal distribution of the pressure pain thresholds. Results of the analysis of baseline PPT scores revealed a significant difference between the groups for both temporalis pressure thresholds (H [2]= 6.849, p < .05) and finger pressure thresholds (H [2]= 8.27, p < .05). The placebo massage group's baseline PPT levels were higher than either the massage (p < .05) or the headache-recording control group (p < .05). Separately, a loglinear transformation and a square root transformation were completed to reduce the skewed distribution. Following the transformations, several one-way ANOVAs were completed to analysis baseline differences among the three groups. Results indicated that, following both the square root transformation and the loglinear transformation, the baseline temporalis pressure thresholds were no longer significant, (F (2,52)=2.21, n.s.; F (2,52)=2.58, *n.s.*, respectively) where as the baseline finger pressure threshold remained significant, (F(2.52)=4.42, p=.02; F(2.52)=4.66, p=.01, respectively).

Following the square root transformation, a 4x3 and a 2x3 factorial ANOVAs were conducted to analysis change over time in temporalis pressure thresholds. Both analyses had one between-subjects factor with three levels ("true" massage, placebo massage, and headache-recording control). Both analyses included a within-subjects factor, time. The first analysis was conducted to examine change in temporalis pressure thresholds from baseline, mid treatment, post treatment, and three-week follow-up assessments. The second analysis examined the maintenance of changes over time between three-week follow-up assessments and three-month follow-up assessment. Results of both analysis indicated no significant change in temporalis pressure thresholds over time, F (6,150)=1.12, p=n.s.; F (2,50)=.03, p=n.s, respectively.

The change scores between treatment times was then examined due to the significant difference between the groups baseline finger pressure threshold levels. To compute the change scores, the baseline PPT assessment score was subtracted from each subsequent time, for example, baseline was subtracted from the post treatment assessment to allow for the examination of change over that time period. Change scores for PPT were analyzed with a Kruskal-Wallis One-Way Analysis of Variance by Ranks (alpha = .05). Results indicated no significant difference between groups at the post treatment assessment for either the temporalis (H [2]= .57, *n.s.*) or the finger pressure thresholds (H [2]= 1.09, *n.s.*), the three-week follow-up assessment for either the temporalis (H [2]= .58, *n.s.*), or the finger pressure thresholds (H [2]= .58, *n.s.*), or the finger pressure thresholds (H [2]= .10, *n.s.*). Median finger and temporalis PPT values and percentiles around the median are displayed in Table 9.

Psychological Functioning Hypothesis.

Depression and Anxiety. A 3 x 4 factorial ANOVA with one within-subjects factor (time) and one between-subjects factor (treatment) was performed to assess changes in distress (summed depression and anxiety assessment) between the baseline, the mid-treatment, the end of treatment, and the three-week follow-up assessments. The analysis indicated no significant interaction between time and group (F(6,150)=1.66,

n.s.). A 4 x 3 factorial ANOVA with one within-subjects factor (time) and betweensubjects factor (treatment) was conducted to assess changes in distress from baseline through the three-month follow-up. This analysis used LOCF for missing data points. The analysis indicated no significant interaction between time and group (F(6,150)=2.00, p=.07). (Analysis conducted without LOCF indicated no significant effect over time between the group [F(6,78)=1.91, *n.s*

The lack of significant change in depression and anxiety score may be a result of low baseline scores or because participants suffered primarily from frequent tension-type headaches rather than a more severe headache disorder such as chronic tension-type headache or migraine. The baseline means for the composite score of depression and anxiety were 19.5 for both the massage and placebo massage groups and 18.3 for the headache-recording control group. The range for this assessment was 0-126. See table 10 for mean data on depression and anxiety.

Sleep Functioning Hypothesis

Sleep. A 3 x 3 factorial ANOVA with one within-subjects factor (time) and one between-subjects factor (treatment) was conducted to compare sleep disturbances over the baseline, treatment, and 3-week follow-up periods for all three groups ("true" massage therapy, placebo massage, and headache recording control). Results indicated no significant differences between the groups (F(4,98)=1.58, *n.s.*). A 4 x 3 factorial ANOVA with one within-subjects factor (time) and one between-subjects factor (treatment) was conducted to compare sleep disturbances over all four time phases for all three groups (massage therapy, placebo massage, and headache recording control). Sleep disturbances missing at time 4 [three-month follow-up phase] were replaced with values from time 3 [LOCF]. Results indicated no significant differences between the groups (F(6,147)=1.09, *n.s.*). (Analysis of number of sleep disturbances without replacement of missing values indicated no significance between the groups [F(6,72)=.83, *n.s.*].) However, the average number of hours of sleep reported at baseline suggested sleep may not have been impaired. The average number of baseline hours of sleep per group were 7.0 hours (massage group), 7.2 hours (placebo massage), and 7.1 hours (headache-recording control group).

Analyses of ancillary measures are reported in Appendix L.

Discussion

The goal of the present study was to determine the effects of massage therapy, placebo massage (light touch massage) and headache-recording control (no treatment) on headache activity, pericranial muscle tenderness, anxiety and depressive symptoms, and sleep duration in individuals with episodic or chronic tension-type headaches. This study adds to a small but growing amount of research that shows significant decreases in headache frequency, headache severity and neck pain symptoms associated with massage therapy (Hernandez-Reif et al, 1998; Quinn, Chandler, & Moraska, 2002; Puustjarvi, Airakstinen, & Pontinen, 1990). While earlier studies employed an alternate treatment comparison group, the current study is the first study that we know of, to incorporate a placebo massage group. This study design enabled us to examine the potential effects of interpersonal factors that might contribute to the beneficial effects of massage therapy (Moyer, Rounds, & Hannum, 2004). Specifically, the inclusion of a placebo massage group enabled the examination of other factors such as interpersonal attention and

physical contact, which allowed for a better understand of the effects that may be attributed to massage therapy and not to a placebo effect.

Headache Activity Hypothesis

The primary hypothesis of this study predicted that participants receiving "true" massage therapy would report significant reductions in headache activity relative to individuals in either the headache recording control group or the placebo massage group. Headache activity was measured by recording headache intensity levels four times a day for the duration of the study. Consistent with our hypothesis, participants in the "true" massage group recorded significant reductions in headache activity compared to individuals who received no form of massage therapy in the study (headache recording control).

It was also hypothesized that participants in the "true" massage group would experience significantly greater improvements in headache activity than the placebo massage group. Findings indicated that participants' headache activity in the "true" massage group did not significantly differ from those in the placebo massage group. Improvements in headache activity were comparable, with 47% of individuals in the "true" massage group and 35% of individuals in the placebo massage group recording a fifty percent or greater decrease in the amount of headache activity at the three-week follow-up assessment. This finding was surprising given that the pressure applied during the "true" massage group was dramatically different from that of the placebo massage group. In fact, the pressure applied during the "true" massage therapy was almost six times greater than the pressure applied during the placebo massage (i.e., 18.14 grams/cm verses 3.63 grams/cm respectively). Pressure is hypothesized to be a key component of the massage techniques (Field, 2000) and significantly less pressure was employed in the placebo massage group to ensure the effects of "true" massage could be separated from effects of physical contact. Thus, contrary to our hypothesis, reductions in headache activity were not affected by the differences in pressure applied during the two forms of massage therapy, suggesting that pressure may not be necessary for salubrious effects of massage.

Furthermore, findings indicated that individuals who received either "true" or placebo massage therapy maintained their decrease in headache activity at the threemonth follow-up phase. Specifically 71% of participants in the "true" massage group (5 out of 7) and 85% in the placebo massage group (6 out of 7) maintained the significant decrease by the three-month follow-up phase as compared to 33% of individuals in the headache-recording control group (1 out of 3). However, it is important to note that the rates of attrition were high at the three month assessment. Of the participants that maintained at least a 50% decrease in headache activity at the three-month follow-up assessment, 20% of participants in the "true" massage (1 out of 5), 67% of participants the placebo massage group (4 out of 6), and none of the participants in the headache-recording control group did not complete the three-month assessment.

Although no significant differences were found between participants who did and did not complete this study, the high rate of attrition warrants caution in the interpretation of these findings.

While the current study did not find significant differences between the two types of massage, one previous study did report a significant correlation between the pressure applied during massage and a relaxation response. Diego, Field, Sanders, & HernandezReif (2004) reported the effects of a 10 minute medium pressure massage, a light pressure massage or a vibratory massage on self-reported anxiety and stress and relaxation response (i.e., changes in EEG and heart rate). They noted significant reductions in self-reported anxiety and stress among individuals in both the medium and light pressure massage and evidence for a relaxation response (increased slow wave EEG activity and decreased heart rate) in individuals who obtained the medium pressure massage. Assessments were taken a few minutes after the treatment and only provide information on an immediate response. The findings suggest that while massage therapy, regardless of the pressure applied, may have therapeutic effects on emotional well-being. Furthermore although no direct comparisons were made between treatment groups, the deep pressure applied during the massage appears to have more of a physiological effect associated with a relaxation response.

Diego et al (2004) and the current study both reported some evidence that massage may be equally effective regardless of the use of pressure, thus suggesting components other than pressure may be more important to the effectiveness of massage. Differences between the two massages did begin to appear with a physiological assessment of relaxation response, in which the medium pressure massage was associated with a significantly greater relaxation response (Diego et al, 2004). The current study did not include a similar assessment. A clear conclusion to the role of pressure may not be reached due to differences between the studies in terms of the population studied (i.e., tension-type headache suffers verses healthy adults), the length of treatment (i.e., 6 halfhour massages verses 1 ten minute massage), when the assessments were taken (i.e., immediately following treatment verses longer term follow-up assessment) and the assessments utilized. More research is needed to examine the influence of manual manipulation to the effectiveness of massage therapy. Such research needs to include physiological assessments such as EEG, heart rate changes, measures of stress hormones, or changes in muscle tenderness.

A possible explanation for the similarities this study found between "true" and placebo massage is that massage effects may be an outcome of interpersonal attention, touch and/or another nonspecific aspect of the massage rather than the technique itself. The effectiveness of massage therapy may be a result of factors shared by all forms of massage rather than a specific ingredient (Moyer, Rounds, & Hannum, 2004). A recent meta-analysis of massage effects suggest that the common factors model of psychotherapy may provide a more accurate explanation (Moyer, Rounds, & Hannum, 2004) than the hypothesized importance of manual manipulation (Field, 2000). This model proposes that common aspects of a treatment may be of greater importance to outcome than adherence to a specific modality (Wampold, 2001). For example, the benefits arising from massage may be a result of factors such as an individual's attitude towards massage, the therapist's personal characteristics and expectations, interpersonal attention, conversation, and touch that takes place during treatment as opposed to the specific form or technique used in the massage (Moyer, Rounds, & Hannum, 2004; Fraser & Kerr, 1993). Future research is needed to examine the effectiveness of massage therapy while controlling for nonspecific elements of massage such as interpersonal attention or physical contact. Such research will need to consider the potential that nonspecific aspects of massage therapy may have a more central role than previously theorized.

Physiological Functioning Hypothesis

Participants in the "true" massage group were hypothesized to exhibit significant decreases in both pressure pain thresholds and pericranial muscle tenderness (PMT) relative to the placebo massage and the headache recording control groups. Contrary to our hypothesis, findings indicate no significant change in temporalis PPT among the three groups. Also, findings of the PMT analysis suggest that "true" massage did not result in greater decreases than placebo massage. However, both massage groups reported significantly greater reductions in PMT relative to individuals who did not undergo massage treatments (headache recording control). Overall, analyses indicate that although massage was associated with a decrease in pericranial muscle tenderness its effectiveness was not influenced by the manual manipulation of soft tissues. The results of this study were supportive of the only previous research examining changes in muscle tenderness following massage.

One study measured changes in muscle tenderness of individuals with fibromyalgia (Sunshine et al, 1996). Researchers found significant reductions in muscle tenderness following 10 sessions of massage verses TENS (involves a pen-sized steel roller that transmits a weak electrical current across the body) or Sham TENS (sessions used the same roller without the electrical current), although the three treatments were not directly compared. Findings from both studies indicated that massage may be effective in reducing muscle tenderness. Dissimilarities between the studies (i.e., the treatment comparison groups utilized [TENS and Sham TENS verses placebo massage and headache recording control group], how muscle tenderness was assessed [16 points thought the body verses 5 bilateral pairs of pericranial muscles] and the individuals studied [fibromyalgia verses tension-type headache suffers]) indicates further research is needed to better understand how massage may affect muscle tenderness.

The current study proposed that individuals who received massage, regardless of the use of pressure, experienced a significant decrease over time in PMT as compared to individuals who did not receive massage treatments. A closer examination of the baseline PMT levels indicated that these findings may be an artifact of the data. While baseline PMT levels among the three groups were not significant, the ranges were wide with individuals in the "true" massage and placebo massage group reporting median PMT levels of 5.00 versus individuals in the headache recording control group reporting a median PMT level of 13.50. It is unclear why baseline PMT levels were dissimilar as the groups were randomized. To address the disparate levels, an analysis of change scores was conducted between baseline PMT and post treatment PMT. Results indicated no significant changes in PMT among the three groups.

A possible explanation for the lack of change in PMT and PPT between the groups may be a floor effect. Although previous studies have consistently noted elevated muscle tenderness in individuals with tension-type headache (Bendtsen et al, 1996; Holroyd 2002; Jensen et al 1993, 1996, 1998) the current study's participants (in the "true" and placebo massage groups) reported a modestly increased muscle tenderness compared to the average college student (5.00 vs. 6.41) (Janke, 2004). (See table 6 for more on baseline headache characteristics.) Future research is needed to further the examination of the effects of massage therapy on PMT and PPT in individuals with tension-type headache.

Psychological Functioning Hypothesis

It was hypothesized that individuals would report decreases in depression and anxiety symptoms following "true" massage therapy as compared to both placebo massage and headache recording control groups. Results of this study were expected to support the findings of previous research denoting significant decreases in depression and anxiety following massage (Hernandez-Reif et al, 1998, 2001; Field et al, 1992). Contrary to our hypothesis, findings of this study indicated no significant changes among the three groups. A possible explanation for the lack of change is the relatively low levels of baseline anxiety and depression. In fact, the average baseline anxiety scores were 11 (massage therapy), 8.15 (placebo massage therapy) and 9.65 (headache recording control). The anxiety assessment was on a scale from 0 to 63 with a score between 0-7 defined as minimal anxiety, 8-15 defined as mild anxiety, 16-25 defined as moderate anxiety and 26-63 defined as severe anxiety (Beck, Steer, & Brown, 1996). The analysis of participant's self-report anxiety levels indicated a mild level of anxiety, which did not allow for much improvement. Likewise the average baseline depression scores were 9.43 (massage therapy), 10.40 (placebo massage therapy) and 8.50 (headache recording control). The depression assessment was on a scale from 0 to 63 with depression defined as a score of 13 or greater (Beck & Steer, 1990). On average, participants' baseline depression levels did not meet the BDI-II requirements for depression, which also did not allow for much improvement.

The results of this study may have been influenced by floor effect. Although anxiety and depression are commonly reported by individuals with tension-type headache (Rassmussen, 1993; Rokicki & Holroyd, 1994; Sexton-Radek, 1994; Ficek & Wittrock, 1995), the current study's participants reported a relatively few symptoms of anxiety and depression. Future research is needed to continue to examine the effects of massage therapy on headache suffers with more severe headache diagnosis.

Sleep Functioning Hypothesis.

For the current study, it was hypothesized that sleep duration would be significantly improved for individuals in the "true" massage group compared to the placebo massage and headache recording control groups. The findings were expected to support previous research that noted significant increases in the amount of sleep following massage therapy (Field et al, 1997, 1998; Sunshine et al, 1996). Sleep duration was assessed using a sleep diary in which participants kept a daily record of the number of hours slept in a 24 hour period. Contrary to our hypothesis and previous findings (Field et al, 1997, 1998; Sunshine et al, 1996), the current study found no increases in sleep duration following massage therapy. This may be due to either: the lack of sleep deficiencies initially reported by participants (i.e., a mean of 7.0 hours for the "true" massage group, 7.2 hours for the placebo massage group and 7.1 hours for the headache recording control group), or as aspect of the assessment method utilized to measure changes in sleep functioning. In addition, lack of sleep deficiencies found in this study may be explained by the primary headache diagnosis of frequent tension-type headache. Previous research has noted that sleep is often disturbed in individuals with chronic tension-type headache (Ulrich, Russell, Jensen, & Olesen, 1996; Rasmussen, 1993). To continue to examine the correlation between massage therapy and sleep functioning, future research should measure changes in sleep quality following massage (e.g., how

rested the participant feels upon waking) as well as, assess changes in sleep functioning for individuals with a more debilitating headache diagnosis.

Limitations

A possible major limitation of the study was the small sample size. The current study obtained a sample size that was comparable to the sample sizes employed in previous research which examined the effects of massage therapy as a treatment for headache (Hernandez-Reif et al, 1998; Puustjarvi et al, 1990). Analyses indicated this study had a small effect size (.03). (This effect size is based on the mean difference in headache activity between the "true" and placebo massage groups.). While the current study's effect size was .03, to detect statistical significance with the number of participants in this study (n=53) the effect size would have needed to be moderate (.4). This suggests that the current study may not have had sufficient power to detect a statistically significant difference between the "true" massage and placebo massage group. However, the similar levels of improvement reported by individuals in both the "true" and placebo massage groups (i.e., 47% and 35%, respectively, recorded at least a fifty percent reduction in headache activity) suggests that observed differences between "true" and placebo massage would not be clinically meaningful. This provides further evidence that manual manipulation of soft tissues may not be an essential ingredient of massage.

Another possible limitation involves the participant's primary diagnosis of frequent tension-type headache (average of 2 headaches a week), which is a milder headache disorder and not associated with as severe disability as chronic tension-type headache (Holroyd et al, 1999, 2000). (Forty-eight of the 53 participants meet the

diagnostic criteria for frequent tension-type headache, whereas only 5 meet the criteria for chronic tension-type headaches.) The current study attempted, unsuccessfully, to recruit an equal number of participants who suffered from either frequent or chronic tension type headache. This limitation may have an effect on the generalizability of the findings.

Next, the massage therapists' level of expertise and experience may have been a possible limitation. Three of the four therapists were in the final stages of massage training and one had approximately six years of experience. The differences were evident during the training of the massage protocol for this study. For example, the massage therapists with less experience had some difficulty learning the massage procedures. However by the end of standardization of the massage protocol, these differences were eliminated, indicating that it is not likely that the level of experience had an effect of the results of the study. Also, a recent meta-analysis of massage effects found no significant association between outcome and massage therapist's level of training (Moyer, Rounds, & Hannum, 2004).

An additional limitation concerned the number of massages participants received from each massage therapist. While each participant in a massage group received a massage from at least two therapists; they did not receive an equal number of massages from each therapist. The variability in therapists was due to logistical issues related to scheduling conflicts on the part of either the participant or the therapist. This could have affected the results of the study if the techniques of the therapist varied, however, due to standardization of the massage treatment it is not likely that not receiving an equal number of massage from each therapist had an effect on the results of this study. Lastly, there was a significantly high rate of participant attrition at the three month follow-up phase. This limitation may be due to the relatively transient nature of the student population. Most of follow-up assessments were conducted during the summer break at which time the majority of students were no longer on or near campus. Due the limited data available, discussion of the three-month follow-up assessments need to be considered with the caveat that this data is limited by a significant loss of subjects and should be treated as only a potential trend. Analysis of differences between participants who did not complete the three-month follow-up assessment and those who did revealed no significant differences in terms of age, ethnic background, headache activity, PMT, anxiety and depression or sleep functioning. (See page 42 for more on the attrition seen in this study.) Despite the limitations of this study, the results appear to be an accurate representation of the effectiveness of massage therapy to treat tension-type headaches. The following section examines implications for future research that are based on the findings of the current study.

Future Directions.

The current study examined the hypothesis that manual manipulation of soft tissues is a necessary component to the effectiveness of massage therapy (Field, 2000) and was unable to find evidence to support this hypothesis. Alternatively findings suggest a nonspecific factor, such as interpersonal attention, may be essential to the outcome. Despite the reliance of massage on interpersonal attention, no research has attempted to manipulate, or even measure, the kind of psychological interactions that take place between the therapist and recipient of massage (Moyer, Rounds, & Hannum, 2004). Future research is needed in which nonspecific aspects of massage, such as touch and interpersonal contact, are evaluated. For example, to further assess the effect of interpersonal attention, traditional Swedish massage (which involves interpersonal attention and manipulation of soft tissues) may be compared to either self-massage or self-vibratory massage (both which involve the manipulation of soft tissues without interpersonal attention or physical contact by the massage therapist).

A recent meta-analysis of massage effects proposed that massage therapy may benefit from being analyzed using the common factors model (Moyer, Rounds, & Hannum, 2004). Future examination of massage effectiveness using the common factors model would allow for a greater understanding of the applicability of this model which may provide a useful and predictive means of conceptualizing and predicting outcome. Such studies would allow for a greater understanding of not only how massage may be effective but it may aid in determining what the best practices of massage are. Future research may also assist in ensuring health care resources are properly applied and health care providers are able to be aware of the efficacy of massage.

Conclusions

Although no previous studies have investigated the effectiveness of massage therapy as a treatment for tension-type headaches using a placebo-controlled design, the results of the current study suggest massage may be a moderately effective treatment for alleviating headache activity, with a decrease in headache activity noted up to three weeks after treatment. An improvement in headache activity was noted regardless of whether or not the massage included the manual manipulation of soft muscle tissues. Pericranial muscle tenderness appeared to have possibly decreased following both "true" massage therapy and placebo (light pressure) massage. No significant changes in headache activity or muscle tenderness were noted in the headache-recording control group. In addition, no overall significant changes in temporalis pressure tenderness thresholds, distress or sleeprelated problems were found.

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Diagnostic Criteria for Frequent Episodic Tension-Type Headaches

- A. At least 10 episodes occurring on ≥ 1 but <15 days per month for at least 3 months
- B. Headache lasting from 30 minutes to 7 days
- C. Headache has at least two of the following characteristics:
 - a. bilateral location
 - b. pressing/tightening (non-pulsating) quality
 - c. mild or moderate intensity
 - d. not aggravated by routine physical activity such as walking or climbing stairs
- D. Both of the following:
 - a. no nausea or vomiting (anorexia may occur)
 - b. no more than one of photophobia or phonophobia
- E. Not attributed to another disorder

From Headache Classification Subcommittee of the International Headache Society (2004). The international classification of headache disorders. *Cephalalgia*, 24 (1), 37-43.

Diagnostic Criteria for Chronic Tension-Type Headaches

- F. Headache occurring on ≥ 15 days per month on an average for >3 months
- G. Headache lasts hours or may be continuous
- H. Headache has at last two of the following:
 - a. Bilateral location
 - b. Pressing/tightening (non-pulsating) quality
 - c. Mild or moderate intensity
 - d. Not aggravated by routine physical activity such as walking or climbing stairs
- I. Both of the following:
 - a. Not more than one of photophobia, phonophobia, or mild nausea
 - b. Neither moderate or severe nausea nor vomiting
- J. Not attributed to another disorder

From Headache Classification Subcommittee of the International Headache Society (2004). The international classification of headache disorders. *Cephalalgia*, 24 (1), 37-43.

Possible Mechanisms for Tenderness in Tension-Type Headache:

- A. Sensitization of peripheral myofascial nociceptorsB. Sensitization of second order neurons at the spinal and/or trigeminal nucleus
- C. Decreased antiociceptive activity from supraspinal neurons
- D. Increased sensitivity of supraspinal pain perception

Bendtsen, 2000

Inclusion Criteria for this study:

- A. Two or more tension-type headaches a week for the past three months
- B. Bilateral headache pain that is usually located in the frontal, occipital, or suboccipital regions of the head
- C. Headache described as a continuing "dull ache" or "pressing/tightening"

Headache Recording Variable Massage Placebo Massage 18.67 (.54) 18.67 (.49) Age 18.76 (.55) Headache Index 1.88 (.90) 1.57 (.99) 1.79 (.75) (baseline) History of TTH 4.3(2.32) 3.57(2.58) 3.95(1.97) (months) Headache Days per 5.68 (1.44) 5.63 (1.14) 4.87 (1.57) Week (>1) Headache Days per 1.94 (1.05) 2.15 (1.36) 2.14 (1.49) Week (>5) Average Headache 5.77 (.98) 6.30 (1.18) 5.90 (1.33) Severity 6.18 (11.06) Avg. length of 4.30 (5.67) 4.08 (3.90) untreated headache (in hours) Avg. Peak Intensity 5.77 (.98) 6.23 (1.17) 5.87 (1.37)

Daily Headache Diary: Daily Averages of Headache Activity for Massage, Placebo Massage and Headache-Recording Group

	Treatment Gro	oups	
Outcome Measure	Massage Therapy	Placebo- Massage Therapy	Headache Recording Control
Headache Index			
N	15	20	18
Pretreatment (weeks 1-3)			
M (SD)	1.88 (.90)	1.57 (.99)	1.79(.75)
Treatment (weeks 4-6)			
M (SD)	1.44 (.97)	1.36 (1.09)	1.78(.87)
Post-Treatment (weeks 7-9)*			
M (SD)	1.12 (.94)	1.05 (.83)	1.69(.99)
Follow-up (three months later)			
Ν	10	8	11
M (SD)	1.18 (.99)	.68 (.40)	1.30(.72)

Note. *p < .05 significant difference between groups over time

Table 7:

Median PMT Values and Percentiles around the Median Quartiles

	Treatment Gr		
Outcome Measure	Massage Therapy	Placebo- Massage Therapy	Headache Recording Control
Total Tenderness			
Pretreatment			
Ν	15	20	18
25%	1.00	.25	2.25
50%	5.00	5.00	13.50
75%	19.00	10.50	22.00
During Treatment*			
N	15	18	18
25%	1.00	1.00	4.50
50%	3.00	4.50	13.00
75%	13.00	15.00	19.75
Immediately Post**			
N	15	20	18
25%	.00	.00	5.00
50%	4.00	2.50	12.50
75%	7.00	8.75	21.75
3-Week Follow-up			
N	15	17	18
25%	.00	.00	1.75
50%	5.00	2.00	10.50
75%	7.00	7.00	16.75
3-Month Follow-up			
N	11	7	6
25%	.00	.00	2.25
50%	2.00	.00	7.50
75%	4.00	2.00	15.25

*overall marginally significant difference, p = .058, **p<.01 (massage and placebo massage significantly

lower than the headache recording control group)

	Treatment Groups		
	Massage Therapy	Placebo- Massage Therapy	Headache Recording Control
Outcome Measure			
Average Finger			
Pretreatment			
N	15	20	18
25%	3.08	4.18	3.01
50%	4.38	5.54	3.88
75%	5.29	9.32	5.41
During Treatment	··->		
N N	15	18	18
25%	3.63	3.96	3.77
50%	5.33	5.29	4.90
75%	7.08	8.68	6.72
Immediately Post	1.00	0.00	0.72
N	15	20	18
25%	3.92	4.47	3.53
50%	5.17	6.90	4.33
75%	8.21	9.64	5.85
3-Week Follow-up	0.21		0.00
N	15	17	18
25%	4.13	4.39	3.80
50%	5.88	6.35	4.69
75%	6.63	9.51	6.01
3-Month Follow-up	0.05	9.01	0.01
N	11	7	6
25%	5.92	4.54	6.06
50%	8.38	8.00	8.21
75%	9.92	9.96	9.63
Temporalis			
Pretreatment			
N	15	20	18
IN 25%	2.29	20 2.76	2.36
23% 50%	4.38	3.08	2.30
50% 75%	4.38 3.21		3.06
75% During Treatment	3.21	3.74	5.00
N	15	18	18
25%	2.63	2.84	2.53
23% 50%	5.33	2.84 3.38	3.08

Median Finger and Temporalis PPT Values and Percentiles around the Median

				86
75%	3.46	4.11	3.50	
Immediately Post				
N	15	20	18	
25%	2.75	2.71	2.52	
50%	5.17	3.40	2.96	
75%	4.00	4.66	3.88	
3-Week Follow-up				
N	15	17	18	
25%	2.88	2.79	2.60	
50%	5.88	3.36	2.96	
75%	4.13	5.00	3.88	
3-Month Follow-up				
N	11	7	6	
25%	3.17	2.79	3.76	
50%	8.38	4.00	4.60	
75%	6.33	4.58	5.65	

Table 9:

	Treatment Gr	oups	
Outcome Measure	Massage Therapy	Placebo- Massage Therapy	Headache Recording Control
Depression			
Baseline	9.43(6.84)	10.40(5.44)	8.50(5.11)
Mid Tx	10.21(9.69)	8.50(5.03)	8.89(5.09)
Post Tx	9.64(10.02)	6.85(5.57)	6.89(5.20)
3-wk Post	8.79(8.36)	5.60(4.65)	6.83(6.65)
Anxiety			
Baseline	11.00(7.58)	8.15(6.33)	9.65(6.46)
Mid Tx	8.64(7.41)	7.45(4.29)	8.82(4.99)
Post Tx	9.29(8.47)	5.45(3.49)	6.35(5.24)
3-wk Post	9.00(8.39)	5.10(4.12)	7.47(6.45)

Depression and Anxiety Scores: Mean Scores for Massage, Placebo Massage and Headache-Recording Group

Depression scores range from 0 to 63. Depression defined as score of 13 or greater.

Anxiety scores range from 0 to 63. Anxiety is defined as a score between 0-7(minimum) 8-15(mild) 16-25(moderate) 26-63 (severe).



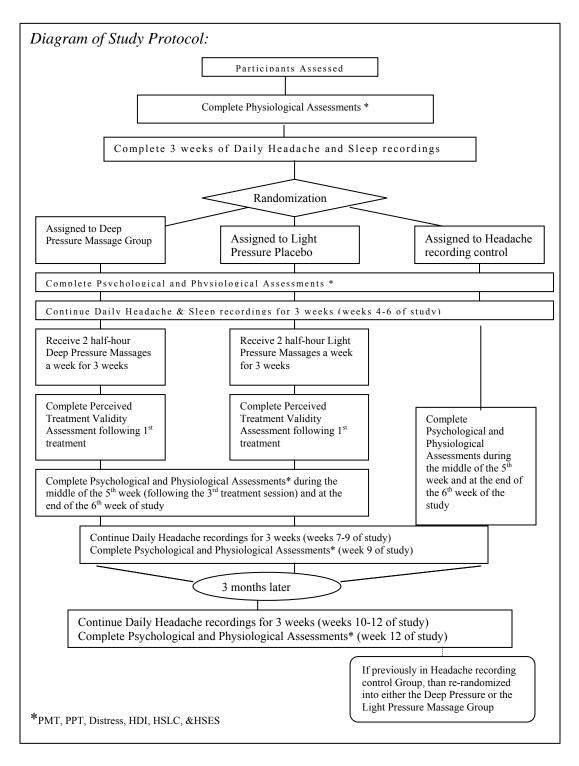
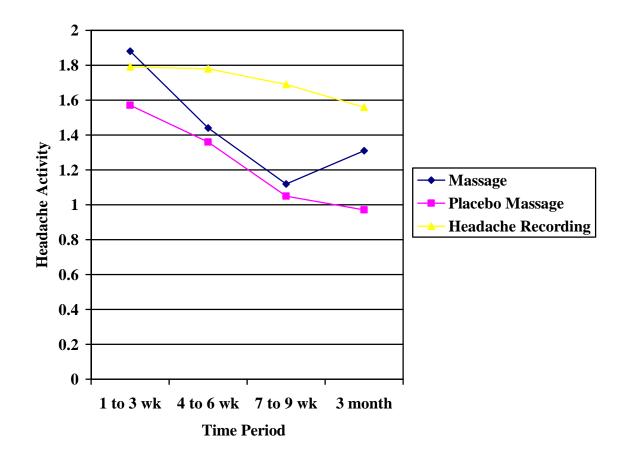


Figure 2:

Headache Activity for Massage, Placebo Massage and Headache-Recording Groups



Appendix A: Headache Screening Questionnaire

HEADACHE SCREENING QUESTIONNAIRE (Revised 7/02)

This information will be used later this quarter about people with headaches.

Name:	SEX: M F	AGE:
LOCAL PHONE #:	QUARTER: Fall	Winter Spring

YEAR: Freshman Sophomore Junior Senior RACE:

<u>Instructions</u>: Please read each question below and mark one answer per question that best describes your headache experience. DO NOT include headaches due to substance abuse or withdrawal (i.e., hangovers, caffeine, medications, etc.). **PLEASE COMPLETE BOTH SIDES**

How often do you get headaches, i.e., how many times per week, month, or year do you experience a headache?

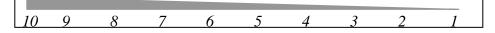
Where on your head or neck do you most often experience your headaches (forehead, neck, back of your head, top of your head, etc.)?

Do you experience your most typical headache on one or both sides of your head? ___One side ____Both sides

Please circle the one that best describes your most typical headache:

① pressing/ tightening ②dull ache ③pulsating/sharp

On a scale of 0 to 10, with 0 being no pain and 10 being the most intense pain you can imagine, how would you rate the pain of your most typical headache?



Are your headaches frequent and/or severe enough to interfere with your daily activities?

On the average, how long does your most typical headache last if you **<u>DO NOT</u>** take pain medication?

Does routine physical activity, such as walking a flight of stairs, worsen your headache? _____ Yes _____ No

ald noise make your headache worse? Yes No you experience any visual disturbances of Yes No you often feel nauseous during your type Yes Yes No you often experience vomiting during your type you often experience vomiting during your type you often experience vomiting during you you experience any other symptoms that	oical headache?	lache?	
you experience any visual disturbances of Yes No you often feel nauseous during your typi Yes No you often experience vomiting during yo Yes No	oical headache?	lache?	
YesNo you often feel nauseous during your typi YesNo you often experience vomiting during yo YesNo	oical headache?	lache?	
YesNo you often experience vomiting during yo _YesNo	our typical head		
Yes No			
you experience any other symptoms that	t have not been	discussed here?	
e you ever been to a heath care provider apist) because of your headaches? _YesNo	r (i.e., medical o	doctor, psycholog	gist, massa
If so what kind of provider did you s	see?		
When was the last time you saw this	s provider regar	ding your headac	ches?
you currently taking any antidepressant Yes No		Dose:	_
	Diana	D050	
you have any medical problems? _YesNo	Explain:		
			, etc.) that

On the average, how many hours of sleep do you get every night? _____ hours

Do you frequently experience difficulty falling as leep -i.e., does it often take you more than 10-20 minutes to fall as leep?

____Yes ____No

Do you frequently have difficulty remaining asleep – i.e., do you wake up several times during the night? _____Yes _____No

 WOMEN: Are you currently taking birth control pills?

 ____Yes
 ____No
 Brand: _____Dose: _____

Appendex B: Consent Form

Consent Form

Federal and university regulations require us to obtain signed consent for participation in research involving human subjects. After reading the statements below, please indicate your consent by signing this form.

Explanation of the Study:

Research has indicated that massage may be beneficial in relieving pain. The purpose of this project is to study the effects of massage therapy on headaches. Daily monitoring of headaches, as well as questionnaires and a couple of physiological assessments will be used to obtain information about headaches.

Procedure:

If you choose to participate, you will be asked to monitor your headaches daily during the entire course of the study. Participants in this study will be monitoring their headaches for three weeks at the beginning of the study. Depending on which group you are in you will begin receiving treatment after three weeks. Three weeks after receiving treatment participants will continue to monitor their headaches. Three months later, participants will monitor their headaches for another three weeks.

At the beginning and ending of each three-week period, participants will complete several assessments. Assessments will also be completed one time following the third massage. At each of these assessment periods, participants will be given the opportunity to receive course credit points (1) per assessment with a total of 6 possible points.

Participants will be expected to complete daily headache monitoring for at least 12 weeks and complete several assessments a total of six times. The muscular assessments involve palpation of muscles in the head and face region. All responses will remain in a locked cabinet and will be confidential to the extent allowed by law.

If you are assigned to a headache recording control group than you will began receiving massage immediately following the follow-up period.

Risks and Discomforts:

The primary risk associated with this study is a slight discomfort during muscle tension assessments of muscles in the head and face region. These assessments involve pressure applied to muscles using a finger and a small handheld device. You may also experience some muscle soreness following massage. While completing some of the questionnaires, you may experience some distress. Another assessment will require a sample of saliva be given. However, you participation is voluntary, and you may withdraw from the study at any time without penalty or negative consequences.

Benefits:

As a participant in this study, you may experience a decrease in the amount of headaches, as well as decreases in anxiety and depression following massage therapy.

Compensation

For your commitment, you will receive up to 6 credit hours. The credit hours will be given to complete assessments that will take approximately an hour. Monetary compensation will be given at the completion of the first 9 (\$5) weeks of the study and then again at the completion of the follow-up period (\$10) or earlier if you decide not to complete this study.

Confidentiality of Record:

All records will remain confidential and in a locked cabinet.

Contact Information:

If you have any questions or concerns, please feel free to contact Roen Montalva; 44N Porter Hall, (740) 593-6363; roen_montalva@ohio.edu or Dr. Ken Holroyd; 225 Porter Hall, 740-593-1085; holroyd@ohio.edu. If you have any questions regarding your rights as a research participant, please contact Jo Ellen Sherow, Director of Research Compliance, Ohio University, (740) 593-0664.

I certify that I have read and understand this consent form and agree to participate as a subject in the research described. I agree that known risks to me have been explained to my satisfaction and I understand that no compensation is available from Ohio University and its employees for any injury resulting from my participation in this research. I certify that I am 18 years of age or older. My participation in this research is given voluntarily. I understand that I may discontinue participation at any time without penalty or loss of any benefits to which I may otherwise be entitled. I certify that I have been given a copy of this consent form to take with me.

Signature_____I

Date	

Printed Name_____

Appendix C. Headache Assessment Interview

Headache Assessment Interview (7/02)

Interv	viewer _		Date	
Subject #			Subject Nar	ne
DX _				
Μ	F	Age	Race	_ Grade

These questions refer to your typical headache:

1. Please describe your typical headache (Be explicit in your recording of information):

2. Pain Quality

Pressing/tightening	dull ache	pulsating/sharp
3. Location of headache (where	e does headache begi	n? Does it spread?):
4. Does your headache occur		
Bilaterally (both sides)	Unilaterally (o	ne side)
5. Chronicity:		
6. Frequency:		

7. Duration:

8. Intensity (0-10):

Photophobia (If you had one of your typical headaches right now, would this room light increase your head pain?)

Phonophobia (If you had one of your typical headaches right now, would this conversation with me increase your head pain?)

Physical Activity (If you have one of your typical headaches right now, would walking upstairs increase your head pain?)

During a typical headache do you experience...

Nausea:

Vomiting:

Visual Disturbances:

Family History (mother, sister, etc.):

What do you think causes your headaches?

Have you ever sought care from any health professional for your headaches? (i.e., doctor, massage therapist, etc. – include traditional and nontraditional care)

If so, what kind of professional(s) did you see? What was their diagnosis and prescription for treatment?

How often do/did you see this professional? (i.e., 3x a month)

How long did you see this professional?

Do you have any other medical problems? If so, what are they?

What medication/supplements are you currently taking? Please include all doctor prescribed medication, herbal/vitamin supplements, etc.

Appendix D. Daily Headache and Sleep Record

Daily Headache and Sleep Record

Step 1: INDICATE HEADACHE INTENSITY

Four times each day, please update the pain graph using the following scale:

O – No pain

2 – Slightly painful: I only notice my pain when I focus on it

4 – Midly painful: *I can ignore my pain most of the time*

5 –

1 –

3 –

6 – Painful: It is painful but I can continue what I am doing.

7 –

8 - Very painful: My pain makes concentration difficult but I can perform undemanding tasks.

9 –

10 - Extremely painful: I can't do anything when I am in such pain

Step 2: MAKE COMMENTS This section is for making notes.

Step 3: RECORD MEDICATION

Each time you take medication for pain, please indicate the type and amount of medication, ex. 2 Tylenol (500mg).

Step 4: RECORD THE AMOUNT YOU SLEPT

Record the amount of sleep you had for the previous night (i.e., if you are recording for your headaches for Tuesday, reported the amount of sleep you had for Monday night).

Name: <u>-</u> <u>Sa Su</u>		Date:	Day: <u>M Tu W Th F</u>
Time	Intensity (0 1 2 3 4 5 6 7 8 9 10)	Comments	Medication
(10am)	· · · · · · · · · · · · · · · · · · ·		
(2pm)	: /		
(6pm)	: /		
(10am)	: /		Total hours slept hrs
Record ac	ctual time: Record intensity of current head-pain		Frequency of night awakenings
	•		(1 – none) (10 – very often)

Appendix E: PMT/PPT Assessment Form

PMT/PPT

Subject #: _____

Quarter:_____ Date:____

Session #:_____

PERICRANIAL MUSCLE TENDERNESS

<u>To the subject:</u> Describe device and procedure. "*I am going to touch various areas of your head and neck with this device. This device only measure how hard I am pressing.* When I am finished, please rate how my touch felt to you on a sclare of 0 to 10 with 0 being no pain and 10 being the most excruciating pain you can imagine."

Remind subejcts of 0 to 10 scale as you conduct the assessment.

Left	Temporalis	Right
Left	Masseter	Right
Left	Suboccipital	Right
Left	Posterior Cervical	Right
Left	Trapesius	Right

PRESSURE PAIN THRESHOLDS

<u>To the subject</u>: Describe device and procedure. "*I am going to press on your finger and the muscle in your head with this device three times. This device only measure how hard I am pressing. Each time, please tell me when you first experience pain from this pressure and I will release the device."*

 The Beck Depression Inventory II measure cannot be reprinted due to copyright concerns. Please see: Beck AT, Steer RA, Brown GK: Manual for Beck Depression Inventory II (BDI-II). San Antonio, TX, Psychology Corporation, 1996 for a copy of this measure.

Appendix G: Beck Anxiety Inventory

The Beck Anxiety Inventory measure cannot be reprinted due to copyright concerns. Please see Beck, A.T., & Steer, R.A. (1993). Beck Anxiety Inventory Manual. San Antonio, TX: Psychological Corporation for a copy of this measure.

Appendix H: Measure of Perceived Treatment Validity

ID#	Date//
-----	--------

How effective would you rate the treatment you just received? (10 being very and 1 being not at all)



Would you recommend this treatment to someone else? (10 being definitely yes and 1

being never)

10	9	8	7	6	5	4	3	2	1

Would you be willing to pay for this type of treatment? (10 being definitely yes and 1 being never)

10	9	8	7	6	5	4	3	2	1

Appendix I. Headache Disability Inventory

TSM HDI						
ID#			Date	//	_	
Session #:Pre	Tx1	Tx3	Tx4	Post	F-U	

The purpose of this scale is to identify difficulties that you may be experiencing because of your headaches. Please circle "NO, "SOMETIMES", or "YES" to each item. Answer each question as it pertains to your headaches only.

Because of my headaches I feel handicapped.	NO	SOMETIMES	YES
Because of my headaches I feel restricted in performing my routine daily activities.	NO	SOMETIMES	YES
No one understands the effect my headaches have on my life.	NO	SOMETIMES	YES
I restrict my recreational activities (eg., sports, hobbies) because of my headaches.	NO	SOMETIMES	YES
My headaches make me angry.	NO	SOMETIMES	YES
Sometimes I feel that I am going to lose control because of my headaches.	NO	SOMETIMES	YES
Because of my headaches I am less likely to socialize.	NO	SOMETIMES	YES
My spouse (significant other), or family and friends have no idea what I am going through because of my headaches.	NO	SOMETIMES	YES
My headaches are so bad that I feel that I am going to go insane.	NO	SOMETIMES	YES
My outlook on the world is affected by my headaches.	NO	SOMETIMES	YES
I am afraid to go outside when I feel that a headache is starting.	NO	SOMETIMES	YES
I feel desperate because of my headaches.	NO	SOMETIMES	YES
I am concerned that I am paying penalties at work or at home because of my headaches.	NO	SOMETIMES	YES
My headaches place stress on my relationships with family or friends.	NO	SOMETIMES	YES
	 Because of my headaches I feel restricted in performing my routine daily activities. No one understands the effect my headaches have on my life. I restrict my recreational activities (eg., sports, hobbies) because of my headaches. My headaches make me angry. Sometimes I feel that I am going to lose control because of my headaches. Because of my headaches I am less likely to socialize. My spouse (significant other), or family and friends have no idea what I am going through because of my headaches. My headaches are so bad that I feel that I am going to go insane. My outlook on the world is affected by my headaches. I am afraid to go outside when I feel that a headache is starting. I feel desperate because of my headaches. I am concerned that I am paying penalties at work or at home because of my headaches. 	Because of my headaches I feel restricted in performing my routine daily activities.NONo one understands the effect my headaches have on my life.NOI restrict my recreational activities (eg., sports, hobbies) because of my headaches.NOMy headaches make me angry.NOSometimes I feel that I am going to lose control because of my headaches.NOBecause of my headaches.NOMy spouse (significant other), or family and friends have no idea what I am going through because of my headaches.NOMy headaches are so bad that I feel that I am going to go insane.NOMy outlook on the world is affected by my headaches.NOI am afraid to go outside when I feel that a headache is starting.NOI feel desperate because of my headaches.NOI am concerned that I am paying penalties at work or at home because of my headaches.NOMy headaches place stress on my relationshipsNO	Because of my headaches I feel restricted in performing my routine daily activities.NOSOMETIMESNo one understands the effect my headaches have on my life.NOSOMETIMESI restrict my recreational activities (eg., sports, hobbies) because of my headaches.NOSOMETIMESMy headaches make me angry.NOSOMETIMESSometimes I feel that I am going to lose control because of my headaches.NOSOMETIMESBecause of my headaches.NOSOMETIMESMy spouse (significant other), or family and friends have no idea what I am going through because of my headaches.NOSOMETIMESMy outlook on the world is affected by my headaches.NOSOMETIMESI am afraid to go outside when I feel that a headache is starting.NOSOMETIMESI feel desperate because of my headaches.NOSOMETIMESI am concerned that I am paying penalties at work or at home because of my headaches.NOSOMETIMESMy headaches place stress on my relationshipsNOSOMETIMES

15	I avoid being around people when I have a headache.	NO	SOMETIMES	103 YES
16	I believe my headaches are making it difficult for me to achieve my goals in life.	NO	SOMETIMES	YES
17	I am unable to think clearly because of my headaches.	NO	SOMETIMES	YES
18	I get tense (eg, muscle tension) because of my headaches.	NO	SOMETIMES	YES
19	I do not enjoy social gatherings because of my headaches.	NO	SOMETIMES	YES
20	I feel irritable because of my headaches.	NO	SOMETIMES	YES
21	I avoid traveling because of my headaches.	NO	SOMETIMES	YES
22	My headaches make me feel confused.	NO	SOMETIMES	YES
23	My headaches make me feel frustrated.	NO	SOMETIMES	YES
24	I find it difficult to read because of my headaches.	NO	SOMETIMES	YES
25	I find it difficult to focus my attention away from my headaches and on other things.	NO	SOMETIMES	YES

Appendix J: Headache Self-Efficacy Questionnaire

		TSM HSE			
ID#			Date	_//	
Session #:Pre	Tx1	Tx3	Tx4	Post	F-
U					

Instructions: You will find below a number of statements related to headaches. Please read each statement carefully and indicate how much you agree or disagree with the statement by circling a number next to it. Use the following scale as a guide.

Strongly	Moderately	Slightly	Neither Agree	Slightly	Moderately	Strongly
Disagree	Disagree	Disagree	or Disagree	Agree	Agree	Agree
1	2	3	4	5	6	

1.	I can keep even a <i>bad</i> headache from disrupting my day by changing the way I respond to the pain.	1	2	3	4	5	6	7
2.	When I'm in some situations, nothing I do will prevent headache	s. 1	2	3	4	5	6	7
3.	I can reduce the intensity of a headache by relaxing.	1	2	3	4	5	6	7
4.	There are things I can do to reduce headache pain.	1	2	3	4	5	6	7
5.	I can prevent headaches by recognizing headache triggers.	1	2	3	4	5	6	7
6.	Once I have a headache there is nothing I can do to control it.	1	2	3	4	5	6	7
7.	When I'm tense, I can prevent headaches by controlling the tension	on.1	12	3	4	5	6	7
8.	Nothing I do reduces the pain of a headache.	1	2	3	4	5	6	7
9.	If I do certain things every day, I can reduce the number of headaches I will have.	1	2	3	4	5	6	7
10.	If I can catch a headache before it begins, I often can stop it.	1	2	3	4	5	6	7
11.	Nothing I do will keep a mild headache from turning into a bad headache.	1	2	3	4	5	6	7
12.	I can prevent headaches by changing how I respond to stress.	1	2	3	4	5	6	7

Strongly	Moderately	Slightly	Neither Agree	Slightly	Moderately	Strongly
Disagree	Disagree	Disagree	or Disagree	Agree	Agree	Agree
1	2	3	4	5	6	

13.	I can do things to control how much my headaches interfere with my life.	1	2	3	4	5	6	7
14.	I cannot control the tension that causes my headaches.	1	2	3	4	5	6	7
15.	I can do things that will control how long a headache lasts.	1	2	3	4	5	6	7
16.	Nothing I do will keep a bad headache from disrupting my day.	1	2	3	4	5	6	7
17.	When I'm not under a lot of stress, I can prevent many headaches	s. 1	2	3	4	5	6	7
18.	When I sense a headache is coming, there is nothing I can do to stop it.	1	2	3	4	5	6	7
19.	I can keep a <i>mild</i> headache from disrupting my day by changing the way I respond to the pain.	1	2	3	4	5	6	7
20.	If I am under a lot of stress, there is nothing I can do to prevent headaches.	1	2	3	4	5	6	7
21.	I can do things that make a headache seem not so bad.	1	2	3	4	5	6	7
22.	There are things I can do to prevent headaches.	1	2	3	4	5	6	7
23.	If I am upset, there is nothing I can do to control the pain of a headache.	1	2	3	4	5	6	7
24.	I can control the intensity of headache pain.	1	2	3	4	5	6	7
25.	I can do things to cope with my headaches.	1	2	3	4	5	6	7

Annendix	K [·] Hea	dache-Sp	ecific I	ocus of	Control	Questionnaire
ripponan	11. 1100	aucile op			control	Zuestionnune

TSM HSLC						
ID#			Da	ate//		
Pre	Tx1	Tx3	Tx4	Post	F-U	

Instructions: This is a questionnaire designed to determine the way in which people view certain important headache-related issues. Each item is a belief statement with which you may agree or disagree. Beside each statement are numbers that correspond to a scale on which you may rate the extent to which you agree or disagree with each item. The values range from "Strongly Disagree" = 1 to "Strongly Agree" = 5. Circle the number that represents the extent to which you disagree or agree with the statement. Please make sure that you <u>answer every item</u> and that you circle <u>only one</u> number per item. This is a measure of your personal beliefs; there are no right or wrong answers.

1 = Strongly Disagree 2 = Moderately Disagree 3 = Neutral 4 = Moderately Agree 5 = Strongly Agree

1.	When I have a headache, there is nothing I can do to affect its course	1	2	3	4	5
2.	I can prevent some of my headaches by avoiding certain stressful situations	1	2	3	4	5
3.	I am completely at the mercy of my headaches	1	2	3	4	5
4.	I can prevent some of my headaches by not getting emotionally upset		2	3	4	5
5.	If I remember to relax I can avoid some of my headaches	1	2	3	4	5
6.	Only my doctor can give me ways to prevent my headaches	. 1	2	3	4	5
7.	My headaches are sometimes worse because I am overactive	. 1	2	3	4	5
8.	My headaches can be less severe if medical professionals (doctors, nurses, etc.) take proper care of me	. 1	2	3	4	5
9.	My headaches are beyond all control	. 1	2	3	4	5
10.	My doctor's treatment can help my headaches	1	2	3	4	5

		1
11.	When I worry or ruminate about things I am more likely to have headaches12345	5
12.	Just seeing my doctor helps my headaches 1 2 3 4 5	,
13.	No matter what I do, if I am going to get a headache, I will get a headache 1 2 3 4 5	
14.	Having regular contact with my physician is the best way for me to control my headaches 1 2 3 4 5	5
15.	When I have headaches, I should consult a medically trainedprofessional12345	
16.	Following the doctor's medication regimen is the best way for me not to be laid-up with a headache 1 2 3 4 5	5
17.	When I drive myself too hard I get headaches 1 2 3 4 5	
18.	Luck plays a big part in determining how soon I will recoverfrom a headache12345	
19.	By not becoming agitated or overactive I can prevent many headaches 1 2 3 4 5	
20.	My not getting headaches is largely a matter of good fortune 1 2 3 4 5	
21.	My actions influence whether I have headaches 1 2 3 4 5	
22.	I usually recover from a headache when I get proper medical help 1 2 3 4 5	5
23.	I'm likely to get headaches no matter what I do 1 2 3 4 5	
24.	If I don't have the right medication, my headaches will be a problem 1 2 3 4 5	
25.	Often I feel that no matter what I do, I will still have headaches 1 2 3 4 5	5
26.	I am directly responsible for getting some of my headaches 1 2 3 4 5	
27.	When my doctor makes a mistake I am the one to suffer with headaches	
28.	My headaches are worse when I'm coping with stress 1 2 3 4 5	

29.	When I get headaches I just have to let nature run its course	1	2	3	4	5
30.	Health professionals keep me from getting headaches	1	2	3	4	5
31.	I'm just plain lucky for a month when I don't get headaches	1	2	3	4	5
32.	When I have not been taking proper care of myself, I am likely to experience headaches	1	2	3	4	5
33.	It's a matter of fate whether I have a headache	1	2	3	4	5

Appendix L: Analysis of Ancillary Measures

Analysis of Ancillary Measures

Several measures were administered to participants repeatedly over the course of the study. These measures were not the primary focus of interest for this study and these analyses should be regarded as exploratory in nature. For all of the following analysis, the between subjects factor had three levels ("true" massage therapy, placebo massage, and headache-recording control) and unless otherwise indicated the within-subjects factor, time, had four levels (baseline, mid treatment, post treatment, 3-week follow-up and 3-month follow-up assessment).

Headache Disability Index. A 4x3 factorial ANOVA was completed to examine changes in headache related disability over time. Analysis results indicated a significant difference between the groups over time (F[6,126]=1.12, p=n.s.).

Headache Self-Efficacy Score. A 4x3 factorial ANOVA was completed to examine changes in headache self-efficacy over time. Analysis results indicated no significant differences between the groups over time (F[6, 102]=1.09, p=n.s.).

<u>Locus of Control.</u> Change scores from Headache Locus of Control (external locus of control) were analyzed via a 4x3 factorial ANOVA to examine any change in headache related external locus of control over time. Results of the analysis indicated no significant change over time between the groups (F[6,135]=1.31, p=n.s.)

Medication Use. Average weights of medication use per phase of the study was analyzed via a 3x3 factorial ANOVA to examine change in medication use over time. The within-subjects factor, time, had three levels (baseline, treatment, and 3-week follow-up assessment). Analysis indicated no significant change over time between the groups (F[4,88]=.73, p=n.s.). Although, the massage therapy group did appear to report a more immediate decrease in medication use relative to both baseline and to participants in the other two groups.

Night Restlessness. A 3 x 3 factorial ANOVA with one within-subjects factor (time) and between subjects factor (treatment) was conducted to compare night restlessness over time. The within-subjects factor, time, had three levels (baseline, treatment, and 3-week follow-up assessment). Results indicated no significant differences between groups (F[4,92]=1.54, p=n.s.). Although results of the between subjects analysis indicated no significance between the groups, the massage and placebo-massage group did appear to experience decrease in night restlessness over time.