

TWO EFFICACY STUDIES FOR ACUTE TMJ RELATED HEADACHES  
AND CHRONIC HEADACHES

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## DEDICATION

To my supportive family,  
and dedicated thesis committee: Dr. Robert Gatchel Ph.D., ABPP, Robbie  
Haggard MS, CRC, LPC, and Dr. Chung-Yi Chiu Ph.D., CRC.

TWO EFFICACY STUDIES FOR ACUTE TMJ RELATED HEADACHES  
AND CHRONIC HEADACHES

by

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## ABSTRACT

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This project focused on two efficacy studies. The aim of the first study conducted by Dr. Robert Gatchel at University of Texas at Arlington was to evaluate the efficacy of the Biobehavioral, Self-care, and Non-Intervention treatment groups on the presence and distress of the headache symptom related to acute temporomandibular joint disorder. The study consists of a cohort of 283 patients with acute TMD. Participants are being referred to UT Southwestern Medical Center in Dallas, Texas through the community dental clinics in the Dallas/Ft. Worth area. Questionnaires were administered to patients before and after treatment. At the time of data collection 283 participants were enrolled in the

study. 238 participants (84%) of 283 met eligibility requirements and were placed in one of the three treatment groups. 91 participants endorsed having regular headaches that are either new or different from headaches you had prior to the onset of your illness. A Pearson Chi-Square ( $\chi^2$ ) found a significant difference in the presence of headaches before treatment ( $\chi^2 = 11.082, p = .004$ ). No significant difference was found in the presence of headaches after treatment ( $\chi^2 = .335, p = .846$ ). Non-Parametric analysis found a significant difference of improvement (.021) in the Biobehavioral group post-treatment. A significant difference of improvement (.023) was also found in the Self-care group post-treatment. Non-Parametric analysis found a significant improvement of distress of headache in each treatment group. This study shows a significant prevalence of 38% headaches related to TMD. It also shows that Biobehavioral and Self-care treatments significantly reduce headache presence. The study also finds a psychological effect of “attending the project” in decreasing levels of distress relating to headaches.

The second study aimed to measure the effectiveness of a dental technique pioneered by Dr. Neeley DDS. Patients were referred through his private dental clinic in Dallas, TX. Qualitative analysis was used through a case study of 6 patients of an original 12. The data from the second study indicated that this treatment is very efficacious. All 6 participants showed a reduction in headache symptoms and all reported satisfaction with their treatment over a year later.

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## LIST OF DEFINITIONS

Primary Headache – a disorder on its own caused by changes in brain chemistry or recognized brain diseases.

Secondary Headache – headaches caused by other widely varying medical conditions such as immune diseases, infections, metabolic conditions, neurologic conditions, and head trauma.

Temporomandibular Joint Disorder – a heterogeneous collection of disorders involving the muscles of mastication and the hard and soft tissues of the temporomandibular joint.

Temporomandibular Joint – a complex joint that connects the lower jaw, or mandible, to the temporal bone at the side of the head.

Biopsychosocial Model – a model focuses on the complex interaction of the biological, psychological and social factors that affect disease and illness.

## **CHAPTER ONE**

### **Introduction**

Temporomandibular disorder (TMD) is both a common and costly disorder. The American Academy of Orofacial Pain estimates that 75% of the U.S. population experiences symptoms of TMD during their lifetime. Although prevalence rates vary among studies of TMD, research indicates in any given year 10% of women and 6% of men have TMD pain which translates to 20 million adults (Drangshold and LeResche 1999). Drangshold and LeResche (1999) also estimate that more than 5.3 million U.S. residents will seek treatment at a conservative estimate of \$2.3 billion of direct costs for treatment alone. Von Korff, Ormel, Keefe, and Dworkin (1992) found that 28% of TMD patients report disability and limitations, including unemployment. With this in mind, the researcher's projected costs, indirect and direct, of TMD are estimated to be over \$4 billion a year. Patients with TMD experience a variety of symptoms, including headaches. Research suggests that headache patients and TMD patients overlap considerably in diagnosis and parafunctional behaviors (Damrin and Kes 2010, Shankland 2002). DeRossi, Stoopler & Sollecito (2005) state that head pain is one of the ten most common presenting symptoms in general medical practices. Recurring headaches occur in 76% of women and 57% of men. The incidence of headache is 39% at age 6 and increases to 70% by 15 years of age (DeRossi, Stoopler & Sollecito 2005). According to DeRossi, Stoopler & Sollecito, it is

estimated that headache is responsible for up to one million days of school and one hundred and fifty million days of work missed per year. According to DeRossi, Stoopler & Sollecito (2005), headaches afflict a large portion of the population and, with their varying severity, headaches can result in discomfort, disruption of daily activity, and occasionally debilitating pain. The goal of the initial pilot study is to document and quantify the validity of current methods employed within a private dental practice for the evaluation and treatment of chronic frontal headaches related to dental abnormalities. The evaluation and treatment techniques involve the identification, through a dental examination involving palpation of portions of orofacial regions which appear to be physiologically linked to one or more dental abnormalities. Various remedies for these abnormalities that are routinely prescribed in dental practices include: equilibration, developing an individualized splint, and treatment with transcutaneous electrical stimulation (TENS). The goal of the large study of acute TMD at University of Texas at Arlington, investigated by Dr. Robert Gatchel, is to evaluate and compare the efficacy of several treatment methods for acute TMD on the symptom of the headache. The three groups for comparison are: the Biobehavioral Group, the Self-care Group, and the Non-Intervention Group.

## **CHAPTER TWO**

### **Review of the Literature**

#### **Headaches**

Since 1988 the classification of the International Headache Society (IHS), along with the second edition in 2004, is the accepted standard for diagnosis, instituting uniform terminology, and consistent operational diagnostic criteria for the full range of headache disorders according to Lipton, Bigal, Steiner, Silberstein, and Olesen (2004). Lipton et al. (2004) separates headaches into two main categories: primary and secondary headaches. A primary headache is a disorder on its own caused by changes in brain chemistry or recognized brain diseases (Tepper 2004). Secondary headaches are caused by other widely varying medical conditions such as immune diseases, infections, metabolic conditions, neurologic conditions, and head trauma (Tepper 2004). Lipton et al. further separates primary headaches into 3 main subtypes: migraine, cluster headaches, and tension-type headaches (Lipton et al. 2004).

#### **Migraine.**

Goadsby, Lipton, and Ferrari (2002) define the migraine as a common, chronic, incapacitating neurovascular disorder, characterized by incidents of severe headache, autonomic nervous system dysfunction, and in some patients, an aura involving neurologic symptoms. Lipton et al. (2004) created a list of symptoms that can be used to diagnose a migraine. The criteria state that the

migraine must last for 4 to 72 hours and the patient should experience at least 5 headaches to be considered a migraine. The headache must have two of the following: one-sided location, pulsing or throbbing quality, moderate or severe intensity, inhibiting or prohibiting daily activities, and/or headache is worsened by routine physical activity, such as bending over or climbing stairs. The headache must also be accompanied by at least 1 of the following: nausea and/or vomiting or dislike of light (photophobia), and dislike of noise (phonophobia). The American Migraine Study II was completed in 1999 and aimed to describe the prevalence, sociodemographic profile, and the burden of migraine in the United States (Lipton, Stewart, Diamond, Diamond, and Reed (2001). Lipton et al. (2001) find that the median frequency of attacks is 1.5 per month, and the median duration of an attack is 24 hours; at least 10% of patients have weekly attacks, and 20% have attacks lasting two to three days. The study (Lipton et al. 2001) found that 27.9 million people in the United States reported having migraines. A number of studies (Stewart, Lipton, Celentano, and Reed (1992), Rasmussen and Oleson (1992) and Steiner, Stewart, Kolodner, Liberman, and Lipton (1999)) estimate the prevalence of migraines to be 6% in men and 15% to 18% in women. Lipton et al. (2001) approximate that 23% of households contain at least one member who suffer from migraine headaches; however the prevalence of headaches may be under-diagnosed. As cited in Dahlof and Solomon (1998), Lipton and Stewart (1992) find that factors such as low income, youth, and being male are associated

with a decreased probability of being diagnosed with a migraine by a physician. Goadsby et al. (2002) cite that Lipton, Stewart and von Korff (1997) find that in the United States, most patients with migraine have not seen a physician for headache during the previous year, have never received a medical diagnosis of migraine, and use over-the-counter medications to the exclusion of prescription drugs. Tepper (2004) cite a population based survey done in Maryland in 1999 where 52% of the participants in this survey who met IHS criteria had not received the diagnosis of migraine. According to Lipton (2001), not only are migraine headaches under-diagnosed and under-treated but also associated with substantial disability. More than half (53%) of migraineurs reported severe impairment in activity or the requirement for bed rest with severe headaches. Work or school productivity was reduced by at least 50% among half (51%) of migraineurs (Lipton 2001). A survey by the World Health Organization (WHO) rates severe migraine, along with quadriplegia, psychosis, and dementia, as one of the most disabling chronic disorders (Menken, Munsat, and Toole (2000) which is found in Goadsby, Lipton, and Ferrari (2002). Pryse-Phillips, Findlay, Tugwell, Edmeads, Murray, and Nelson (1992) found that in a population of Canadian adults 19% of migraine sufferers had taken time off work during their last attack and 50% had to discontinue normal activities because of their headaches (Found in Dahlof and Solomon 1998). Lipton (2001) found similar results where approximately 31% missed at least one day of work or school in the previous

three months because of migraines as well as 51% reported that work or school productivity was reduced by at least 50%.

### **Cluster headaches.**

The International Association for the Study of Pain (IASP) defines cluster headache as unilateral, excruciatingly severe attacks of pain principally in the ocular, frontal and temporal areas recurring in separate bouts with daily or almost daily attacks for weeks to months usually with ipsilateral lacrimation (normal or excessive shedding of tears), conjunctival injection (swollen red eyes), photophobia and nasal stuffiness and/or rhinorrhoea (discharge of thin nasal mucus). The IHS classification requires at least five attacks of severe, unilateral, orbital, supraorbital or temporal pain (or both) that last 15–180 min if untreated. Zakrzewska (2001) report that the major division is between episodic and chronic cluster headaches. The definition of episodic is that of cluster periods of 7 days to 1 year with periods of remission of more than 14 days but which may last for months or years. In chronic cluster headaches, there are no remissions for 1 year or, if remissions do occur, they last less than 14 days. Zakrzewska (2001) also note that some patients experience facial flushing, stinging or itching sensations of scalp hairs, tenderness of the carotid artery on that side, and bradycardia. Fischera, Marziniak, Gralow, and Evers (2008) state that several population-based studies on its prevalence and incidence have been performed, but with different methodology resulting in different figures. . Fischera, Marziniak,



Gralow, and Evers (2008) ran a meta-analysis on all available population-based epidemiological studies on cluster headache and compared the data. Fischera, Marziniak, Gralow, and Evers (2008) found that lifetime prevalence of 124 per 100,000 and a one-year prevalence of 53 per 100,000. The overall sex ratio, according to Fischera, Marziniak, Gralow, and Evers (2008), was 4 to 3 (male to female). The analysis of Fischera, Marziniak, Gralow, and Evers (2008) revealed a relatively stable lifetime prevalence, which approximates about 1 in 1000 people suffer from cluster headache, the prevalence being independent of the region of the population study. In 2007, Jensen, Lyngberg and Jensen published a study analyzing the socioeconomic burden of cluster headaches in patients from a headache center in Denmark. Jensen, Lyngberg and Jensen (2007) found that 78% reported restrictions in daily living and 25% reported a major decrease in their ability to participate in social activities, family life and housework. The absence rate among patients was 30%, which was significantly higher than 12% among the general population (Jensen, Lyngberg and Jensen 2007).

### **Tension-type headaches.**

To be diagnosed with a tension-type headache, Lipton et al. (2004) state that you must have at least two of the following pain characteristics: pressing or tightening (nonpulsating) quality, mild to moderate intensity (nonprohibitive), bilateral location, and/or no aggravation from walking stairs or similar routine activities. Lipton et al. (2004) also requires that there must be at least 10 previous

headache episodes, and frequency must be less than 180 per year or 15 per month and duration of headaches can be from 30 minutes to seven days. Tension type headaches are also separated into the subgroups of episodic and chronic by Lipton et al. (2004). Lipton et al. (2004) further subdivided the episodic type tension headache into infrequent and frequent subtype. The prevalence of tension-type headaches vary widely depending on the way the study is designed and many studies estimate the range to be anywhere from, 29% to 78% (Millea and Broadie 2002, Schwartz, Stewart, Simon, and Lipton 1998, Lipton et al. 2004, and Wober-Bingol, Wober, Karwautz, Schnider, Vesely, Wagner-Ennsgraber, Zebenholzer, and Wessely 1996). According Lipton et al. (2004), this makes tension-type headaches the most common type of primary headache, but it is the least studied of the primary headaches. Schwartz, Stewart, Simon, and Lipton (1998) found that of participants with episodic tension headaches, 8.3% reported lost workdays because of their headaches, while 43.6% reported decreased effectiveness at work, home, or school. In the same study, subjects with chronic type tension headaches lost even more work days, with a mean of 27.4 days versus 8.9 days from episodic type tension headaches. Chronic type tension headache participants had a mean of 20.4 days of less reduced effectiveness (Schwartz, Stewart, Simon, and Lipton 1998).

## **Etiology of TMD**

TMD is a heterogeneous collection of disorders involving the muscles of mastication and the hard and soft tissues of the temporomandibular joint (TMJ). The TMJ is a complex joint that connects the lower jaw, or mandible, to the temporal bone at the side of the head. According to the National Institute of Dental and Craniofacial Research (NIDCR), “When we open our mouths, the rounded ends of the lower jaw, called condyles, glide along the joint socket of the temporal bone. The condyles slide back to their original position when we close our mouths. To keep this motion smooth, a soft disc lies between the condyle and the temporal bone. This disc absorbs shocks to the jaw joint from chewing and other movements.” Disorders of the TMJ vary based on type of onset and the component of the TMJ affected. The NIDCR separates the condition into three main categories: myofascial pain, internal derangement, and arthritis. “Myofascial pain, the most common temporomandibular disorder, involves discomfort or pain in the muscles that control jaw function. Internal derangement of the joint involves a displaced disc, dislocated jaw, or injury to the condyle. Arthritis refers to a group of degenerative/inflammatory joint disorders that can affect the temporomandibular joint” (NIDCR). These disorders are not mutually exclusive and an individual may have one or more of these at the same time. According to Glaros and Lausten (2003), the primary symptoms of TMD are as follows: Pain in the muscles of mastication in the preauricular area (immediately in front of the

ear) or in the TMJ, clicking, popping, or grating sounds in the joint, difficulty in opening the mouth wide, patient's perception that their occlusion or bite is off, and jaw locking in the open or closed position. When looking at TMD it is important to distinguish between acute and chronic. As Gatchel, Garofalo, Ellis, and Holt (1996) note, that treating acute and chronic patients as a homogeneous group may diminish the efficacy of treatment. Glaros and Lausten (2003) also note that patients with TMD may also report a wide variety of other conditions, such as headache, other facial pains, earache, dizziness, tinnitus, tooth pain, as well as neck, shoulder and upper and lower back pain.

### **Headache and TMD**

The focus of this study is on one particular symptom of TMD, the headache. Mittrirattanakul & Merrill (2006) point out that self-reported headache is one of the most common symptoms in patients with TMD. They also report that studies have demonstrated that treating various symptoms can significantly decrease headache, which indicates a close relationship between the two. They found the prevalence of secondary a secondary diagnosis of primary headaches related to musculoskeletal disorders to be 63 of 199 which is 31.6%. Their study concluded that patients with chronic orofacial pain had a higher prevalence of headache with greater disability than the control group (Mittrirattanakul & Merrill 2006). The most recent study by Troeltzsch et al. (2011) found that the prevalence of TMD in their headache study to be 58.7% out of 696 participants with TMD.

Within the group with orofacial pain, the most prevalence was from those with musculoskeletal disorder like that of a TMD. Glaros, Urban, and Locke (2007) found that the headache symptoms described by TMD patients are similar to those reported by patients diagnosed as having tension-type or migraine headaches as defined by the International Headache Society. They also report an emerging line of evidence that parafunctional activities (activities with increased teeth contact such as grinding) can increase the myofacial pain of TMD. Headache patients also reported significantly more frequent and more intense tooth contact, more masticatory muscle tension, more stress and more pain in the face/head and other parts of the body than non-headache controls. These results are similar to those reported for TMD patients and suggest that headache patients and TMD patients overlap considerably in diagnosis and parafunctional behaviors (Glaros, Urban, & Locke 2007). Ciancaglinia and Radaelli (2001) conducted a personal interview survey in 1995 on 483 adult subjects from the metropolitan community of Segrate, northern Italy, with the objective of describing the relationship between headache and symptoms of TMD in a general population, and to assess whether there are specific symptoms associated with headache. Ciancaglinia and Radaelli (2001) found after adjustment for confounding variables, a multiple logistic regression confirmed a significant relationship of headache with temporomandibular pain.

### **Theories of Pain**

Traditionally, the dominant models approached disease and pain from a biomedical approach. Engel (1977) states the biomedical model assumes that all aspects of disease can only be measured by biological variables. Therefore, according to Engel (1977), the biomedical model embraces both reductionism, a view that says complex processes originate from a singular process, and mind-body dualism, a principle that separates mental from physical. Rene Descartes is often viewed as the historical figure that popularized the mind-body dualism. A Cartesian view of how pain worked was that there was a similar relationship between pain and tissue injury (Gatchel, Peng, Peters, Fuchs, and Turk 2007). A more formal model was proposed by von Frey in 1894 called the specificity theory of pain. Gatchel et al. (2007) shows the specificity theory as stating, that there were unique receptor mechanisms and pathways that transduced and transmitted specific painful information from the periphery to the spinal cord and then to the brain. According to Gatchel et al. (2007), von Frey's work suggested that specialized nerve endings are involved in the transmission of pain information. An alternate sensory theory is known as the pattern response theory. Gatchel et al. (2007) explains that according to this theoretical perspective, nociceptive information was not primarily due to activation of specific receptors and pathways but rather was due to the pattern of responses in afferent systems. It was the stimulus intensity and the processing of the pattern of responses that determined the perceptual response to the nociceptive input, namely, pain. The

next major advancement in the field of pain research was the gate control theory of pain. According to Melzack and Wall (1965), this model suggests that psychological factors influence pain response by acting on a gate control system and that control of pain may be achieved by selectively influencing the large, rapidly conducting fibers. The gate may be closed by decreasing the small-fiber input and also by enhancing the large-fiber input (Melzack and Wall 1965). This model introduced the importance of the central nervous system and psychosocial factors in the perception of pain. Melzack further extended the gate control theory of pain and integrated it with stress creating a new neuromatrix model of pain. According to Melzack (2004), the neuromatrix theory characterizes pain as a multidimensional experience produced by patterns of nerve impulses generated by a wide neural network referred to as the “body-self neuromatrix” which is in the brain. This theory provides a new framework to explore the relationship between chronic psychological or physical stress and chronic pain and its syndromes (Melzack 2004).

### **Biopsychosocial Model of Pain**

In 1977 George Engel felt there was a need to move past the traditional biomedical model and use a model that includes other factors. According to Engel (1977), it leaves no room within its framework for the social, psychological, behavioral dimensions of illness. The biopsychosocial model focuses on the complex interaction of the biological, psychological and social factors that affect

disease and illness, according to Gatchel et al. (2007). Therefore, it is important to take into consideration emotional effects of chronic pain. International Association for the Study of Pain defines pain as a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience (Merskey and Bogduk 1994). Gatchel et al. (2007) note the three most common psychological effects of chronic pain being anxiety, depression and anger. According to Gatchel et al. (2007), levels of anxiety have been shown to influence not only pain severity but also complications following surgery and number of days of hospitalization. Also, there is a reduction in pain-related anxiety, it predicts improvements on functioning, affective distress, pain, interference with activity (Gatchel et al. 2007). They also mentioned that 40%-50% of chronic pain patients suffered from depressive disorders. The patient with chronic pain's perception of how effective they are at controlling their pain, as well as, the pain itself, play big parts in the severity of the depression, says Gatchel et al. (2007). As this article shows, illness does not only affect patients physically, it can be detrimental psychologically and socially. It is important to take the biopsychosocial model of chronic pain into consideration when considering treatments for TMD.

### **Psychopathology and TMD**

Psychopathology is a significant comorbid factor in patients with TMD. In a study conducted by Gatchel, Ellis, Garofalo, and Holt (1996), 51 patients



with acute TMD and 50 patients with chronic TMD found a significant amount of patients with psychopathology. 80% of patients with acute TMD had at least one Axis I disorder before the onset of their TMD symptoms. Likewise, 86% of patients with chronic TMD had at least one Axis I disorder before the onset of their TMD symptoms. Over half of the acute TMD patients were diagnosed with Anxiety followed by affective disorder and substance abuse. In chronic TMD, the highest disorder diagnosed was affective disorder followed by somatoform and substance abuse. Gatchel et al. (1996) also found a significantly high amount of Axis II diagnoses as well. The most frequently diagnosed Axis II disorder for the acute group was paranoid personality disorder (15.7%), followed by histrionic personality disorder (7.8%). For the chronic group, paranoid personality disorder was also the most frequently diagnosed Axis II disorder (18%), followed by obsessive compulsive and borderline personality disorders (both 10%) (Gatchel et al. 1996). These data show that psychological disorders are a major attendant factor of chronic TMD. They also found that the rates of psychological disorders in patients with chronic TMD far exceeded the base rates found in epidemiologic studies for the general population (Gatchel et al. 1996). In another study, Dworkin et al. (2002) reported the finding that many of these TMD patients meet the criteria for the diagnosis major depressive disorder and or somatoform disorder. They also note that many patients exhibit many indicators of these disorders but do not meet full DSM criteria. Both of these disorders are risk

factors for poor treatment outcomes and should be considered in a multidisciplinary treatment for TMD (Dworkin et al. 2002). Dworkin et al. (2002) also note that many patients with TMD show, in addition to psychological disturbance, interference with activities of daily living. Such activities include usual functions at work, home or school. This highlights the importance of not focusing solely on biological treatment.

### **Treatment**

When treating TMD related headaches, one may wonder whether you begin by treating the symptom of the headache or do you treat the TMD and see if the headache will subside. The two studies being compared use a wide variety of treatments for TMD and headaches.

#### **Equilibration.**

Equilibration, also known as occlusal adjustment, is a procedure that involves removing a small or large part of enamel from the tooth, and its purpose is to have simultaneous bilateral and positions of stable contacts upon closing the jaw and at favorable location of contacts during jaw movements (Kappinen, Eklund, Suoninen, Eskelin, and Kirveskari (1999). According to Kappinen et al. (1999), when a large amount of enamel is removed, restorative material can be used to reshape the surface of the tooth which will prevent excessive grinding. Kappinen et al. (1999) found that when comparing occlusal adjustment and mock occlusal adjustment, in the short term, both groups responded well in terms of

reducing cervicobrachial pain and headache. However in the long term, the group that received actual occlusal adjustment responded significantly better. For example, headache was reported by fourteen patients in the occlusal adjustment group. At twelve months, only one of them still reported headaches, and at sixty months only three patients reported headaches (Kappinen et al. 1999). Forssell, Kirveskari, and Kangasniemi (1985) analyzed the effect of occlusal adjustment on 91 patients with varying types of headaches (35 patients with migraine, 20 patients with combination headache and 36 patients with muscle contraction headache). This clinical double-blind trial showed that for patients suffering from muscle contraction headache or combination headache and who received successful occlusal adjustment, the frequency of headache was reduced by 79% and the intensity by 53% for these patients. In a study conducted by Wenneberg, Nystrom, and Carlsson (1988), 30 patients with craniomandibular disorders and headache were randomly divided into 2 groups. One received occlusal equilibration (O group) and the other (S group) routine stomatognathic treatment, including an occlusal splint. In both groups, the patients reported reduction of symptoms, but the clinical dysfunction score used was significantly diminished only in the S group (Wenneberg, Nystrom, and Carlsson 1988). Vallon, Ekberg, Nilner, and Koop (1995) aimed to evaluate the therapeutic effect of occlusal adjustment on symptoms and signs of craniomandibular disorders (CMD), including headaches, after 3 and 6 months. They found that there was significant

improvement in overall subjective symptoms within the treatment group at the 3- and 6-month follow-up visits, but a statistically significant difference between groups was found at the 3-month follow-up only (Vallon, Ekberg, Nilner, and Koop 1995).

### **Individualized splint therapy.**

According to the TMJ & Facial Pain Institute, splint therapy uses a removable appliance that fits over the upper or lower teeth and provides a surface for the dentist to control how the teeth opposite the splint will hit. By using splint therapy, a dentist can control the positioning of the jaw and reduce forces to the affected temporomandibular joints, relax muscles, and prevent further wear on natural teeth from grinding forces (TMJ & Facial Pain Institute). This type of treatment has been shown to be effective on headaches in the past. Quayle, Gray, Metcalfe, Guthrie, and Wastell (1990) found that a statistically significant number of patients presenting with migraine or tension vascular headache experienced marked improvement or complete relief of headache symptoms using soft occlusal splint therapy. However, it was found that patients with tension headaches failed to benefit from splint therapy (Quayle, Gray, Metcalfe, Guthrie, and Wastell 1990). Quayle, Gray, Metcalfe, Guthrie, and Wastell (1990) also found that patients with craniomandibular symptoms experienced a reduction in these symptoms as well. Kemper and Okeson (1983) also studied the effectiveness of occlusal splint therapy on patients with headache pain. It was

found that out of 33 patients with headache pain, twenty-one patients (63.6%) showed a decrease in the frequency of their headaches and ten patients (30.3%) showed complete remission of headaches (Kemper and Okeson 1983). According to Kemper and Okeson (1983), no patient showed an increase in the frequency of headaches and the group the average number of headaches per week before treatment was 5.06; after occlusal splint therapy. the average number of headaches per week was 2.15. Wassell, Adams, and Kelly (2004) found that using stabilizing splints produced mean improvements at six weeks for all outcome criteria, including headaches. The study was followed up by Wassell, Adams, and Kelly one year later. Wassell, Adams, and Kelly (2006) found that improvements after initial treatment were maintained at one year for all outcomes, except for TMJ clicking, which returned to pretreatment levels.

#### **Transcutaneous electrical stimulation.**

According to Johnson and Jones (2009), transcutaneous electrical nerve stimulation (TENS) is a non-invasive analgesic technique that is used to relieve nociceptive, neuropathic, and musculoskeletal pain. During TENS, pulsed electrical currents are generated by a portable pulse generator and delivered across the intact surface of the skin via the self-adhering conducting pads called electrodes (Johnson and Jones 2009). Solomon and Guglielmo (1985) found that TENS has been used extensively for many types of pain but only rarely for headache. Following treatment with TENS for patients with headache Solomon

and Guglielmo (1985) found that 55% of patients noted improvement as compared to 18% after application of placebo, which is a significant difference. Allais, De Lorenzo, Quirico, Lupi, Airola, Mana and Benedetto (2003) found that a significant decrease in headache days was already reached after 1 month of therapy and maintained at 2 and 3 months. Farina, Granella, Malferrari, and Manzoni (1986) found that out of 35 patients with muscle contraction or mixed headaches, improvement of greater than 60% in 70–80% of cases, were obtained.

### **Cognitive behavioral therapy.**

According to the National Alliance on Mental Health (NAMI) (2003), Cognitive Behavioral Therapy (CBT) is an empirically supported treatment that focuses on patterns of thinking that are maladaptive and the beliefs that underlie such thinking. CBT has shown to be helpful in treating TMD in the past. In a study of the efficacy of brief CBT with TMD pain by Turner, Mancl, and Aaron (2006), as compared with the control group, the group that received CBT showed significantly greater improvement across the follow-ups on outcome, belief, and catastrophizing measures. Also the scores that measured ability to complete daily activities were almost three times higher (35%) than in the control. Dworkin, Turner, Mancl, Wilson, Massoth, Huggins, Leresche, and Truelove (2002) used CBT for patients with TMD who showed poor psychosocial adaptation to their illness. Dworkin et al. (2002) showed that 4 months after the baseline evaluations, the comprehensive care group which included CBT, when compared to the usual

treatment group, showed significantly lower levels of characteristic pain intensity, significantly higher self-reported ability to control their TMD pain, and a strong trend toward lower pain-related interference in daily activities. Morishige, Ishigaki, Yatani, and Hirokawa (2006) aimed to evaluate the clinical effectiveness of CBT for TMD and found that out of 134 TMD outpatients with no history of treatment for TMD, symptoms had disappeared and improved in 112 patients within 2 months. Gatchel, Stowell, Wildenstein, Riggs, and Ellis (2006) concluded that an early intervention for TMD patients using cognitive behavioral skills training and biofeedback reduced pain levels, improved coping abilities and reduced emotional distress, even at one year. CBT has also been shown to be efficacious when treating headaches. Tsakona, Skapinakis, Damigos, and Mavreas (2009) examined information about the effectiveness of CBT on TTH, migraine and TMD. The findings from their review suggest that the combination of CBT techniques (for instance, relaxation therapy plus stress management and biofeedback) results in a significant reduction on levels of pain when compared to placebo or usual therapy (Tsakona, Skapinakis, Damigos, and Mavreas 2009). Martin, Forsyth, and Reece (2007) compared CBT with temporal pulse amplitude (TPA) biofeedback training for patients with recurring headaches. CBT was highly effective, with an average reduction in headaches from pre- to post-treatment of 68%, compared with 56% for biofeedback, and 20% for the control condition. Headaches continued to decrease to 12 month follow-up for CBT.

Thorn, Pence, Ward, Kilgo, Clements, Cross, Davis, and Tsui (2007) aimed to reduce catastrophizing in chronic headache sufferers using CBT. Not only did they find significant reductions in catastrophizing and anxiety and increased self-efficacy compared with wait-list control subjects, but they also found that approximately 50% of treated participants showed clinically meaningful reductions in headache indicators as well.

### **Biofeedback.**

According to the Association for Applied Psychophysiology and Biofeedback (2008) (AAPB), biofeedback is a process that enables an individual to learn how to change physiological activity for the purposes of improving health and performance. Biofeedback uses precise instruments that measure physiological activity such as brainwaves, heart function, breathing, muscle activity, and skin temperature (AAPB 2008). In 1999, Crider and Glaros published a literature search which located 13 studies of EMG biofeedback treatment for TMD, including 6 controlled, 4 comparative treatment, and 3 uncontrolled trials. Crider and Glaros (1999) found that five of the six controlled trials found EMG biofeedback treatments to be superior to no treatment or psychologic placebo controls. Additionally, they found that 69% of patients who received EMG biofeedback treatments were rated as symptom-free or significantly improved, compared with 35% of patients treated with a variety of placebo interventions. The studies reviewed by Crider and Glaros (1999) showed



a maintenance of gains or continued improvement for follow-up periods lasting up to two years. Dohrmann and Laskin (1976) treated 24 patients: 16 were placed in an auditory EMG biofeedback situation and 8 received placebo treatment. 75% of the successfully treated patients required no further therapy during one year of observation (Dohrmann and Laskin 1976). Carlsson and Gale (1977) studied eleven patients with long-term pain related to TMD. They found that at a follow-up examination 4-15 months after the termination of treatment, 8 of the 11 patients were totally symptom-free or significantly better. Gatchel, Mishra, and Gardea (2000) found that when comparing biofeedback, CBT, combined biofeedback and CBT, and a non-intervention group for patients with TMD, the results suggested that biofeedback is the most effective of the three treatment conditions in pain reduction. The results also showed that the three groups showed an increase in pain reduction in comparison with the non-intervention group. Biofeedback therapy has also been shown to be efficacious in treating patients with headaches. In an evaluative review of biofeedback therapy for headache and other pain, Jessup, Neufeld, and Merskey (1979) found that taken together, the 5 studies comparing EMG biofeedback to a control group tended to support the effectiveness of biofeedback for alleviating headache symptoms, over and above non-specific effects. The strongest support was supplied by Kondo and Canter (1978), who reported an 81% decrease in headache frequency during treatment with correct EMG feed-back, compared to a 30%

decrease under false feedback (Jessup, Neufeld, and Merskey 1979). According to Jessup, Neufeld, and Merskey (1979), comparisons between correct EMG feedback and no treatment or self-relaxation groups offered fairly clear support for the effectiveness of biofeedback.

### **Self-care.**

According to Dworkin et al. (2002), structured, manual based brief educational interventions have been shown efficacious for self-management and self-care of the most common chronic pain conditions. Self care for TMD can include education about TMD, learning to monitor symptoms, logging daily levels of pain, learning about better oral habits, such as recognizing foods to stay away from and correct jaw posture, jaw exercises, and home treatments such as ice or hot packs and OTC medications. Riley et al. (2007) wanted to document the frequency of self-care in a clinical sample of patients with TMD pain, report the perceived relief and control of pain for each of the self-care behaviors, and to test for associations between the frequency and efficacy of each self-care behavior. The results showed that the passive self-care behaviors, such as resting when experiencing pain and relaxation techniques, were the most commonly used (Riley et al. 2007). Patients reported that hot or cold packs and massage provided the greatest relief from pain, whereas resting, relaxation, and massage resulted in the greatest ability to control pain (Riley et al. 2007). A previous study from Dworkin et al. (2002) shows self-care treatment when compared with usual dental

treatment showed significant decrease in TMD pain, pain-related interference with daily activity, reduced masticatory muscle pain, and fewer visits for TMD treatment. McGrath, Humphreys, Keene, Goodman, Lascelles, Cunningham and Firestone (1992) conducted a study where eighty seven adolescents (63 females and 24 males) ranging in age from 11 to 18 years who suffered headaches were randomly assigned to receive a self-administered treatment, the same treatment delivered by a therapist or a control treatment. McGrath et al. (1992) found self-administered treatment and clinic treatment were equally effective and superior to the control treatment and both active treatments were durable at 1-year follow-up.

### **Purpose of the Studies**

The literature review suggests the treatments used in both studies are efficacious in treating TMD and headaches. The first study, conducted by UTA, aims to provide evidence regarding which treatment group is the most effective in reducing headache symptoms and distress of headache in patients with TMD. The second study through Dr. Neeley proposes to provide evidence for the efficacy of reducing chronic headache symptoms of patients with dental abnormalities using Dr. Neeley's dental techniques.

### **Hypotheses**

#### ***UTA study.***

No significant differences (.05) will be found with demographic variables in patients endorsing headaches across Biobehavioral Treatment Group, Self-Care

Treatment Group, and Non-Intervention Treatment Group. Demographic variables include gender, ethnicity, education, and income. Also, compare study participants across three study groups: Biobehavioral Group, Self-Care Group, and Non-Intervention Group, and they will evidence significant differences (.05) across outcome scores over time. Primary outcome variables include measures of presence and levels of distress from the RDC (Research Diagnostic Criteria) History Questionnaire and the Symptom Checklist.

***Dental study.***

Study participants undergoing dental treatment in the initial pilot study, will report improvement after treatment. Primary outcome variables include intensity, treatment satisfaction, and need for medication for headache symptoms from the Headache Report Card and Headache Exam Form.

## **CHAPTER THREE**

### **Methodology**

#### **Subjects**

The UTA study consists of a cohort of 283 patients with acute TMD. Participants are being referred to UT Southwestern Medical Center in Dallas, Texas through the community dental clinics of Drs. Riggs, Curtis, and Neely, which are located in the Dallas/Ft. Worth area. In addition to those sites, the Baylor College of Dentistry of the Texas A&M University System Health Science Center and Texas Women's University Dental Hygiene Clinic are also participating sites in the ongoing study of TMD. Advertisements are also placed in local newspapers and flyers. The dental study is run through the dental offices of Dr. Michael Neeley. The cohort currently consists of 11 patients with chronic frontal headaches. Patients are referred through Dr. Neeley's dental practice and flyers are being created to be placed in the community. Both studies were approved by the Institutional Review Board at University of Texas at Arlington.

#### **Procedures**

The study conducted through UTA, researchers will begin by explaining the purpose and procedure of the study, and provide the participant with a packet including the consent form, HIPAA form, patient information form, and a payment voucher for \$20. Participants will then fill out a general information form and the history form before scheduling a series of pre-intervention

biopsychosocial evaluations. The pre-intervention biopsychosocial evaluations will be completed within one week, and they include many measures including the RDC History Questionnaire and the Symptom Checklist. To qualify for the study, the patient must be over 18 years old, have no significant comorbid physical conditions that may exacerbate the participant's pain symptoms, and must have had jaw pain symptoms for less than six months. Participants will then be assigned to a treatment group based on the results of their initial pre-intervention evaluations and screening. The groups are classified as: biobehavioral treatment, self-care treatment, or non-intervention. Dentists and clinicians working on this study will be kept blind to the group assignments. Those participants assigned to the biobehavioral group will be provided six intervention sessions, which will consist of individual meetings with a trained clinician who will adhere to a standardized treatment protocol. The sessions will consist of biofeedback, relaxation techniques, and cognitive behavioral coping skills training. The self-care group will also be assigned six intervention sessions, but these participants will not receive any training on coping techniques like progressive muscle relaxation or cognitive interventions. The participants in this group will receive readings over the course of their treatment that are geared toward educating the patient on TMD, self-care activities, medications, nutrition, treatment options, and patient-physician communication. Clinicians will then review the major points of the readings in each session and request feedback on

the participant's reactions. Participants will also be required to fill out a daily log recording their pain, stress, and tension. The Non-Intervention group will be offered care that they would normally receive through outside medical appointments. They will be required to document all visits to outside medical providers. The patients will be followed up every three months through 24 months. Months 3, 6, 9, 15, 18, and 21 will be followed up by phone. Immediately following their assigned treatment sessions and months 12 and 24, the patients will be required to participate in a biopsychosocial evaluation that is identical to the one conducted at the beginning of the study or the pre-intervention BPS evaluation. The forms used in this study to collect headache data (the RDC History Questionnaire and the Symptoms Checklist) are given a total of four times. They are given pre-intervention, post-intervention, 12 month and 24 month evaluations. The study ran through the office of Dr. Neeley will begin by Dr. Neeley or his staff explaining the purpose and procedure of the study, and provide the participant with a packet including the consent form, HIPAA form, patient information form. Patients will undergo a dental examination. The examination will determine where the areas of pressure in the patient's bite are the greatest. Patients will also verbally and physically report where on their heads their headache is most painful. Using a technique he pioneered, Dr. Neeley will be able to identify the dental technique to use by the location the patient identifies that their headache is located. Dr. Neeley will then use a dental treatment which may

include equilibration, individualized splint, or a TENS unit. Currently, Dr. Neeley mainly uses the technique of equilibration. Patients are then followed-up by Dr. Neeley as needed. Patients are given the Headache Report Card to measure improvement.

## **Measures**

### **Informed consent.**

This form is given at the very beginning of each study. It allows the patient to be fully informed of the scope and risks of the study and to agree to participate. See Appendix A for full form.

### **Patient information form.**

The Patient Information Form gathered data such as demographics, education, contact information, employment status, history of jaw pain (including onset, date of treatment, type of treatment, etc), and chronic health conditions. This is given once at the beginning of the research process. See Appendix B for full form.

### **Headache exam form.**

The headache exam form is filled out during the initial dental examination in Dr. Neeley's office by the examiner. The form gathers information on the history, symptoms, and signs of the headache as well as the wear facets of the structure of the patient's occlusion and the treatment plan. See Appendix C for full form.



**Headache report card.**

This form is filled out by the patient or the researcher over the phone during the follow-up. This form measures the improvement of the symptoms of the headache. It asks questions regarding the need for medication for their symptoms, their satisfaction with their treatment, and the intensity and frequency of their headaches. This measure is given in the initial pilot with Dr. Neeley. It is proposed to be given initially and approximately a year after treatment to follow up with the symptom reduction of the patient. See Appendix D for full form.

**RDC history questionnaire.**

The Research diagnostic History Questionnaire is filled out by the clinician and the patient in the TMD study at UTA. It asks demographic questions, questions regarding facial pain, and the impact the pain has had on daily functioning. The specific question used for this study is (20a) “In the last month, how much have you been distressed by... Headaches Not at all, A Little Bit, Moderately, Quite a bit, Extremely”. This measure is given 4 times at pre-intervention, immediate post treatment, 12 month, and 24 month follow-up. See Appendix E for full form.

**Symptom checklist.**

The patient is responsible for completing this form. It asks questions regarding many physical symptoms a patient might be having. It covers groups of symptoms including low back pain, bladder habits, and symptoms after a head

injury. The specific question used for this study is “Since you’ve been sick, have you had the following: (34) Regular headaches that are either new or different from headaches you had prior to the onset of your illness. Yes or No This measure is given 4 times at pre-intervention, immediate post treatment, 12 month, and 24 month follow-up. See Appendix F for full form.

### **Statistical Analysis**

#### **UTA study.**

Analyses will be carried out to detect any significant differences in demographic variables across treatment groups. Pearson Chi-Square analyses will be used for categorical variables including gender, ethnicity, education, and income. A one way ANOVA will be conducted on headache pain-related symptoms for Biobehavioral, Self-Care and Non-Intervention groups. According to the G Power Analysis (see Appendix G), with an Effect size of .25 and a power of .8 a total sample size of 120 is needed. That would calculate to at least 40 participants per treatment group. Type of intervention will be the between-groups factor and time interval will be the repeated measure. Other analyses include Non-Parametric McNemar and covariate analysis.

#### **Dental study.**

The analysis to measure improvement in participants’ symptoms for the pilot study will be shown through a case study. According to G Power Analysis (see Appendix G), with an Effect size of .15, power of .8, the number of tested

predictors is 1, and the total number of predictors is approximately 5, a sample size of 55 is needed.

## CHAPTER FOUR

### Results

#### UTA Study

##### **Descriptive analysis.**

##### ***Demographic background.***

The participants that endorsed headaches that were new or different since the onset of their illness were comprised of 72 females (80%) and 18 males (20%) (N=91). There was 1 participant (1.1%) with missing gender data. There were 60 participants (68.9%) that identified themselves as White, 13 Black (14.9%), 28 Latinos (9.9%), 2 Asian or Pacific Islander (2.2%), and 3 participants classified themselves as Aleut, Eskimo, American Indian (4.2%) (N=87). There are 4 participants (4.3%) missing ethnicity data. In a separate question 31.8% identified themselves as having Hispanic origin (N=91). Seventeen participants (18.7%) endorsed a household income of \$0-\$14,999, 7 (7.7%) endorsed having a household income of \$15,000-\$24,999, 11 (12.1%) endorsed having a household income of \$25,000-\$34,999, 5 (5.5%) endorsed having a household income of \$35,000-\$49,999, and 49 (53.8%) endorsed having a household income of \$50,000 or more annually. Twenty-Two participants (24.4%) completed 16 years of education, 21 (21.3%) completed 18 years of education, 17 (18.7%) completed 14 years of education, and 10 (11%) completed 12 years of education. The complete report of participants' years of education is shown in Table 1.

**Comparison of demographic variables.**

The hypothesis stated no significant differences will be found with demographic variables in patients endorsing headaches across Biobehavioral Treatment Group, Self-Care Treatment Group, and Non-Intervention Treatment Group. No significant differences were found among all demographic variables including gender, ethnicity, education, and income in treatment groups with participants that endorsed headache symptoms.

**Headache Presence Inquiry.**

At the time of data collection 283 participants were enrolled in the study. There were 238 participants (84%) of 283 met eligibility requirements and were placed in one of the three treatment groups. The question used to define the participants that endorsed headache symptoms was “Since you’ve been sick, have you had the following: Regular headaches that are either new or different from headaches you had prior to the onset of your illness”. Participants would respond yes or no. This question was chosen to attempt to target participants that had secondary headaches related to TMD. The descriptive analysis showed 91 participants (38.2%) of 238 endorsed headaches and 147 participants (61.7%) of 238 did not endorse headaches. The same question is then given again immediately after treatment. In this stage 152 participants had completed their treatment and completed the evaluation. The descriptive analysis showed 41

participants (26.9%) of 152 reported having headache symptoms and 111 (73%) of 152 did not report having headache symptoms.

### **Comparison of headache presence.**

The second hypothesis aimed to see if there was a significant difference in people with and without headaches in pre and post-treatment stages. A Pearson Chi-Square ( $\chi^2$ ) found a significant difference in the presence of headaches before treatment ( $\chi^2 = 11.082, p = .004$ ). Specifically, 43.4% endorsed headaches in the Biobehavioral treatment group, 50.7% in the Self-Care treatment group, and 26.2% in the Non-Intervention treatment group. No significant difference was found in the presence of headaches after treatment ( $\chi^2 = .335, p = .846$ ). Specifically, 28.9% in the Biobehavioral treatment group, 41.2% in the Self-Care treatment group, and 21.1% in the Non-Intervention treatment group. Upon further examination Non-Parametric analysis was used due to the data being preliminary and the sample size is smaller than it will be on completion of study. A Related-Samples McNemar test was used on individual treatment groups to test for significance of improvement in headache presence in each treatment group. It found a significant difference of .021 in the Biobehavioral group post-treatment. A significant difference of .023 was also found in the Self-care group post-treatment. A non significant difference was found of .1 in the Non-Intervention group post-treatment. When comparing treatment groups with each other a Pearson Chi-Square ( $\chi^2$ ) analysis was used. It is important to note that effect size goes down when using a  $\chi^2$  analysis. When

comparing Biobehavioral group versus Self-care group for headache presence a  $\chi^2$  analysis found ( $\chi^2 = .247, p = .619$ ) which is not significant. When comparing Self-care versus Non-Intervention a  $\chi^2$  analysis found ( $\chi^2 = 1.092, p = .296$ ) which is not significant. When comparing Biobehavioral and Self-care versus Non-Intervention a  $\chi^2$  analysis found ( $\chi^2 = .857, p = .355$ ) which is also not significant. When you compared Biobehavioral treatment with Non-Intervention for headache presence a  $\chi^2$  analysis found ( $\chi^2 = .274, p = .600$ ) which is not significant.

### **Headache distress inquiry.**

The headache distress was measured by the question “In the last month, how much have you been distressed by headaches” The participants would respond on a 5 point Likert scale (not at all=0, a little bit=1, moderately=2, quite a bit=3, or extremely=4). The distress level was measured only among patients that endorsed having new or regular headaches since the onset of their illness (N=91). At the initial evaluation 16 participants (17.6%) reported being extremely distressed by their headaches, 39 (42.9%) reported being quite a bit distressed by their headaches, 27 (29.7%) reported being moderately distressed by their headaches, and 8 participants (8.8%) reported being a little bit distressed by their headaches. During the immediate post treatment stage a total of 49 participants completed their treatment and completed the evaluation. Six participants (12.2%) reported being extremely distressed by their headaches, 10 (11%) reported being quite a bit distressed by their headaches, 15 (20.4%) reported being moderately

distressed by their headaches, and 8 participants (16.3%) reported being a little bit distressed by their headaches (N=49). Forty-two participants (46.2%) of 91 from the pre-treatment stage that endorsed new or different headaches since the onset of their illness did not move on to the post treatment stage because they were still undergoing treatment or did not continue on with the study. To measure improvement in distress the change in distress score was operationalized by the difference between pre-treatment to post-treatment. One participant (1.1%) had a reduction in distress by 4 points, 4 (4.4%) had a reduction in distress by 3 points, 8 (8.8%) had a reduction in distress by 2 points, 10 (11%) had a reduction in distress by 1 point. Eighteen participants (19.8%) had no change in their level of distress. Seven participants (7.7%) had an increase in distress by 1 point and 1 (1.1%) had an increase in distress by 3 points.

### **Comparison of headache distress.**

The hypothesis also posited that there would be a significant difference in the change in distress score from pre to post treatment when comparing the Biobehavioral treatment group and the Non-Intervention treatment group. A one way ANOVA analysis found that there was no significant difference comparing the change in distress in the Biobehavioral and Non-Intervention treatment group ( $F=.096$ ,  $p=.983$ ). Results are summarized in Table 2. A covariate analysis was also used to measure for a significant difference as well and control for the pre-treatment distress level. The initial distress score was used as the covariate and the



post treatment distress score was used as the dependent variable. No significant difference was found between treatment groups. Upon further examination Non-Parametric analysis was used because the data are preliminary and the sample size is smaller than it will be on completion of study. A Related-Samples McNemar test was used on individual treatment groups to test for significance of improvement of headache distress in each treatment group. It found a significance of 1 when looking at the distributions of different values of distress scores post-treatment in the Biobehavioral group. This is not a significant finding. The Related-Samples McNemar test also found a significance of 1 when looking at the distributions of different values of distress scores post-treatment in the Self-care group, which is not significant. The same analysis found a non-significant finding of .845 in the Non-Intervention group.

#### **Comparison of change in headache distress.**

However, when looking at the change in distress scores after treatment it produced more significant results. A Related-Samples McNemar test found a significant amount (.000) people were likely to improve at least one distress level or stay the same in the Biobehavioral group. The test also found a significant amount (.000) people were likely to improve at least one distress level or stay the same in the Self-care group. It also found that a significant amount (.000) of people were likely to improve at least one distress level or stay the same in the Non-Intervention group. When comparing treatment groups a Pearson Chi-Square

( $\chi^2$ ) analysis was used. It is important to note that effect size goes down when using a  $\chi^2$  analysis. When comparing Biobehavioral group versus Self-care group for a change in distress score a  $\chi^2$  analysis found ( $\chi^2 = 1.302, p = .254$ ) which is not significant. When comparing Biobehavioral group versus Non-Intervention group for a change in distress score a  $\chi^2$  analysis found ( $\chi^2 = 1.723, p = .189$ ) which is not significant. It is important to note that some studies find a value under .1 to be significant and this value is close to .1. When comparing Self-care versus Non-Intervention a  $\chi^2$  analysis found ( $\chi^2 = .024, p = .876$ ) which is also not significant. When comparing Biobehavioral and Self-care versus Non-Intervention a  $\chi^2$  analysis found ( $\chi^2 = .724, p = .395$ ) which is not significant.

#### **Headache presence and distress inquiry.**

Further analysis was completed to evaluate the headache presence outcome of participants who endorsed having headaches and had a high level of distress (either quite a bit or extremely distressed). This analysis was completed with the reasoning that the high level of distress of the participant may be another possible contributing factor to their headache. A descriptive analysis showed that 55 participants (60.4%) endorsed headache and a high level of distress pre-treatment. After treatment it was found that only 27 participants (49.1%) reported no headache, which is approximately half.

#### **Comparison of headache presence and distress.**

Upon further examination Non-Parametric analysis was run because the data are preliminary and the sample size is smaller than it will be on completion of study. A Related-Samples McNemar test was used on individual treatment groups to test for significance of improvement in headache presence and high distress in each treatment group. It found an almost significant difference of .077 in the Biobehavioral group post-treatment. It is important to note that some studies find a value under .1 to be significant. A significant difference of .039 was found in the Self-care group post-treatment. A significant difference was found of .013 in the Non-Intervention group post-treatment. When comparing treatment groups with each other a Pearson Chi-Square ( $\chi^2$ ) analysis was used. It is important to note that effect size goes down when using a  $\chi^2$  analysis. When comparing Biobehavioral group versus Self-care group for headache presence score improvement a  $\chi^2$  analysis found ( $\chi^2 = .952, p = .329$ ) which is not significant. When comparing Biobehavioral group versus Non-Intervention group for a improvement in headache presence a  $\chi^2$  analysis found ( $\chi^2 = .014, p = .906$ ) which is not significant. When comparing Self-care versus Non-Intervention a  $\chi^2$  analysis found ( $\chi^2 = 1.036, p = .309$ ) which is also not significant. When comparing Biobehavioral and Self-care versus Non-Intervention a  $\chi^2$  analysis found ( $\chi^2 = .386, p = .535$ ) which is not significant.

## **Dental Study**

### **Case study analysis.**

The second study had a total of 12 participants that participated in the chronic headache treatment program designed by Dr. Michael Neeley. Participants were referred to his office through friends and of patients in his dental practice or were patients receiving other dental treatment. Participants went through an initial evaluation that assessed history, symptoms of headaches, and the exact location of the headache pain in the patient's head. The amount of pressure associated with occlusion is then measured. A palpitation technique pioneered by Dr. Neeley that hasn't been studied in previous studies is then used to trace the location of the pain of the headache in the patient's head to the occlusal area with the most pressure. The participant's occlusion is then adjusted through equilibration by Dr. Neeley to equalize the pressure of their occlusion. When done in the correct area this will relieve associated headache pressure. With participants a year past treatment evaluation it was a challenge to contact participants and collect follow-up data. All 12 participants were attempted to be contacted through phone and email by a research assistant approved by the IRB. Data could not be collected from 6 participants because they were unable to be reached for follow-up. Data were collected from 6 participants through a combination of phone and email (n=6).

**Case one.**

***Evaluation and outcome.***

Case One (C1) is a 41 year-old female. C1 underwent pre-treatment initial evaluation on March 5<sup>th</sup> 2010. She reported an onset of headaches at age 23 and has a family history of headaches with her mother. She reported headache triggers as heat, light, sound, stress, wine, and sometimes no trigger at all. C1 reported that her headaches usually occur in the day time, over 4 times a month, and last for over 4 hours. She reported an intensity of 8 on a Likert scale from 0 to 10 and rates her headaches as severe. She reported the location of her headaches to be in the right front area of her head. She reported experiencing aura and sensitivity to light. She has taken efforts to control headaches in the past including acupuncture, herbs, Immitrex, and Advil. C1 completed her post-treatment Headache Report Card follow-up on March 12<sup>th</sup> 2011. After a year she reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 5 on a Likert scale from 0 to 10. She indicated that the location of her pain was in the right temple and forehead. She expressed feeling that she is getting better. She reported feeling very satisfied with the progress of her treatment. She indicated that she has been able to decrease the need of medications to control her headaches.

**Case two.**

***Evaluation and outcome.***

Case Two (C2) is a 32 year-old female. C2 underwent pre-treatment evaluation on October 16<sup>th</sup> 2009. She reported an onset of headaches at age 29

and has no family history of headaches. She reported headache triggers as reading and computer work. C2 reported that her headaches usually occur in the evening, 4-6 times a month, and last for 1-6 hours. She reported an intensity of 7 on a Likert scale from 0 to 10 and rates her headaches as moderate. She reported the location of her headaches to be in her forehead and in both sides of her temporomandibular joint. She did not report experiencing aura and sensitivity to light. She has taken efforts to control headaches in the past including Excedrin. C2 completed her post-treatment Headache Report Card follow-up on May 4<sup>th</sup> 2010. After 19 months she reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 5 on a Likert scale from 0 to 10. She indicated that the location of her pain was in her forehead. She expressed feeling that she is getting better. She reported feeling very satisfied with the progress of her treatment. She indicated that she has been able to decrease the need of medications to control her headaches.

### **Case three.**

#### ***Evaluation and outcome.***

Case Three (C3) is a 29 year-old female. C3 underwent pre-treatment evaluation on November 23<sup>rd</sup> 2009. She reported an onset of headaches at under the age of 21 and has an unspecified family history of headaches. She reported headache triggers as stress, sugar, alcohol, dark chocolate, gum, and processed

foods. She reported that her headaches are associated with blurred thoughts and memory. C3 reported that her headaches usually occur in the day and night, 15-20 times a month, and last anywhere from 30 minutes to 3 days. She reported an intensity of 10 on a Likert scale from 0 to 10 and rates her headaches as mild to extreme. She reported the location of her headaches to be in the right front area of her head. She reported occasionally experiencing aura at onset. She has taken efforts to control headaches in the past including massage and Zomig. C3 completed her post-treatment Headache Report Card follow-up on May 24<sup>th</sup> 2011. After 18 months she reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 5 on a Likert scale from 0 to 10. She indicated that the location of her pain was in her lower neck on the right side. She expressed feeling that she is getting better. She reported feeling happy and satisfied with the progress of her treatment. She indicated that she has been able to decrease the need of medications to control her headaches.

#### **Case four.**

##### ***Evaluation and Outcome.***

Case Four (C4) is a 48 year-old female. C4 underwent pre-treatment initial evaluation on November 5<sup>th</sup> 2009. She reported an onset of headaches at age 45 and has a family history of headaches with her father. She reported headache triggers as caffeine withdrawal and red wine. C4 reported that her headaches

usually occur in the morning, 3-4 times a month, and last for 1 hour with medication. She reported an intensity of 5 on a Likert scale from 0 to 10 and rates her headaches as mild to moderate. She reported the location of her headaches to be in her left and right temples. She did not report experiencing aura or sensitivity to light. She has taken efforts to control headaches in the past including Aleve. C4 completed her first post-treatment Headache Report Card follow-up on April 21<sup>st</sup> 2010. After 17 months she reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 7 on a Likert scale from 0 to 10. She indicated that the location of her pain was in her forehead. She expressed feeling that she is getting better. She reported feeling very satisfied with the progress of her treatment. She indicated that she has been somewhat able to decrease the need of medications to control her headaches. C4 completed a second post-treatment Headache Report Card follow-up on February 15<sup>th</sup> 2011. She reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 3 on a Likert scale from 0 to 10. She indicated that the location of her pain was in both upper temples. She expressed feeling that she is getting better. She reported feeling very satisfied with the progress of her treatment. She indicated that she has been able to decrease the need of medications to control her headaches.

**Case five.**



***Evaluation and outcome.***

Case Five (C5) is a 63 year-old female. C5 underwent pre-treatment initial evaluation on October 21<sup>st</sup> 2009. She reported an onset of headaches in her 60's and has no family history of headaches. She reported the end of the day as a headache trigger. C5 reported that her headaches usually occur in the morning and evening, 10 times a month, and last for 15 minutes. She reported an intensity of 8 on a Likert scale from 0 to 10 and rates her headaches as mild. She reported the location of her headaches to be in her forehead. She reported experiencing aura with her headaches. She has taken efforts to control headaches in the past including BC Powder. C5 completed her post-treatment Headache Report Card follow-up on February 15<sup>th</sup> 2011. After 16 months she reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 4 on a Likert scale from 0 to 10. She indicated that the location of her pain was across her eyes on both sides of her head. She expressed feeling that she is getting better. She reported feeling very satisfied with the progress of her treatment. She indicated that she has been unable to decrease the need of medications to control her headaches.

**Case six.*****Evaluation and outcome.***

Case Six (C6) is a 37 year-old female. C6 underwent pre-treatment initial evaluation on February 8<sup>th</sup> 2010. She reported an onset of headaches at age 16 and has a family history of headaches with her mother. She did not report any headache triggers. C6 reported that her headaches usually occur in the morning, 20 times a month, and last for 4 hours. She reported an average intensity of 5 on a Likert scale from 0 to 10 and rates her headaches as moderate to severe. She reported the location of her headaches to be in the front of her face. She did not report experiencing aura or sensitivity to light. She has taken efforts to control headaches in the past including Ibuprofen and Phrenelin Forte. C6 completed her post-treatment Headache Report Card follow-up on March 9<sup>th</sup> 2011. After 13 months she reported fewer headaches since her last visit to the dentist office. She reported that the intensity of her headache is less. She indicated that the level of her pain is a 3 on a Likert scale from 0 to 10. She indicated that the location of her pain was right between her eyes and in the center of her forehead. She expressed feeling that she is getting better. She reported feeling exceptionally satisfied with the progress of her treatment. She indicated that she has been able to decrease the need of medications to control her headaches.

### **Case Study Outcome Summary**

All 6 participants (100%) endorsed having fewer amount headaches and less intense headaches after their treatment. 100% of participants saw a decrease in their level of headache pain. 100% of participants felt that they were getting

better. 100% of participants were very or exceptionally satisfied with the progress of their treatment. 83.3% of participants were able to decrease their need for medication to control their headache and 16.7% were unable to decrease the need for medication. A summary of results is shown in Table 3.

## **CHAPTER FIVE**

### **Discussion**

#### **Demographic Background**

In the first study through UTA, no significant differences were found between treatment groups among all demographic variables including gender, ethnicity, education, and income in treatment groups with participants that endorsed headache symptoms. These results indicate that no demographic is statistically significantly more likely to endorse headaches. It also shows that no demographic variable endorsing headaches is more likely to be high-risk or low-risk. This distinction is made in the early phases of the study when the patients determined to meet eligibility criteria and are entered in to the study. In the beginning participants are first broken up in to two groups either high-risk or low-risk. High-risk participants are thought to be more likely to progress from acute jaw pain to chronic jaw pain. Low-risk participants are thought to be less likely to progress to chronic jaw pain. This determination is made using an “at risk” algorithm which is comprised of questions from various measurements including the RDC History Questionnaire, the Characteristic Pain Intensity (CPI), and the assessment of oral facial pain from muscle palpation during the Oral Facial exam. The patients classified as high-risk are then randomized in to 1 of 2 treatment groups, biobehavioral or self-care. The low-risk patients are placed in to the non-intervention group.

## **Headache Presence**

As mentioned earlier, this present study shows an overall statistically significant amount of people endorsed having headaches since they began experiencing TMD symptoms. The prevalence of secondary headaches was 38% which is similar to the prevalence estimate by Mitirattanakul and Merrill's (2006) 31.6% of patients that had a secondary diagnosis of primary headaches. However, it was less than Troeltsch et al.'s (2011) study that found that 58.7% of their headache cohort had TMD. A possible reason of the difference from the study by Troeltsch et al. (2011) may be that the UTA study targeted a specific type of headache. The UTA study was specifically looking at headaches that were new or different than the onset of their illness which would be secondary headaches related to TMD. For example, Troeltsch et al.'s (2011) study included a variety of headaches including migraine, tension-type headaches, and other headaches. Troeltsch et al. (2011) also did not designate whether the participants in their study had acute or chronic TMD. Mitirattanakul and Merrill's (2006) found a secondary diagnosis of headaches, but still included primary headaches. They also did not make the designation between acute or chronic TMD. It is a positive reflection on this study's results to have 91 patients that reported headache with such a strict and specific headache definition. The statistical analysis clearly demonstrates the importance headaches play in the diagnosis and treatment of TMD. However, a statistically significant difference was not found after

treatment. This suggests that the treatment may be effective in reducing headache symptoms. The biobehavioral treatment group showed the most improvement in the reduction of headache presence of 14.5%. A significant difference was also found when looking at the distributions of different values of headache presence post-treatment. This indicates that the biobehavioral treatment is effective in reducing headaches related to TMD. The Self-Care treatment group showed the second most reduction of headache presence by 9.5%. A significant difference was also found when looking at the distributions of different values of headache presence post-treatment. This indicates that Self-care is similarly effective as the Biobehavioral group. As expected the Non-Intervention group showed the least amount of reduction of headache presence at 5.1%.

### **Headache Distress**

A significant difference was found among all three treatment groups when looking at the change in distress scores after treatment. This may mean that just by participating in the study that the participants found themselves a little less distressed. 83.7% saw an improvement or stayed the same in their levels of distress after treatment. This further backs up that there were “attending the project” psychological factors involved. When comparing groups in distress improvement, Biobehavioral versus Non-Intervention was the most significant at .189 which suggests that it is the most useful treatment for decreasing headache distress. Another attendant factor is the outside distress in the patients’ life may

have contributed their perceived level of stress of the headache. Distress is such a subjective measure that even though the presence or amount of headaches went down, the distress over the headache could be the same. Secondly, the results indicated that only 16 participants (17.6%) indicated their distress as severe. The more decrease in distress level would produce a greater chance of obtaining more significant scores. With the majority of participants with quite a bit and moderate pain levels it is less likely to produce such a significant distress reduction. With a larger sample the study may have been able to increase the effect size and be able to more accurately get a better look at the change for participants severely distressed by their headache. This finding may also mean that treatment for TMD may need to have a larger focus on coping with their headache pain and not just their myofacial pain.

### **Headache Presence and Distress**

A significant finding was found among the Self-care and Non-Intervention group and an almost significant finding in the Biobehavioral group. This again shows that there is a psychological effect of “attending the project” when participants with high distress levels are evaluated. The lack of significant findings when compared between groups may indicate that high levels of distress may have a large impact on the ability of the headache symptoms to go down. This finding may suggest a positive correlation between distress level from headache and presence of headaches.

## **Case Study**

The data from the second study indicated that this treatment is very effective in reducing headache symptoms because all 6 participants showed a reduction. It also showed that all 6 participants were satisfied with the treatment they received. This was shown to be even more effective than the study conducted by Forssell, Kirveskari, and Kangasniemi (1985). The previous study by Forssell, Kirveskari, and Kangasniemi (1985) found the frequency of headache was reduced by 79% and the intensity by 53% for their patients. The study used equilibration but did not use the technique used by Dr. Neeley. They also conducted their follow-up at 4 and 8 months. The key difference in the success of the treatment using the technique by Dr. Neeley may be that it is most important to know where to properly apply the equilibration technique. This study collected data further out from treatment than the study conducted by Forssell, Kirveskari, and Kangasniemi (1985). These results may indicate that the treatment is effective for the long term because most patients were contacted over a year since their treatment and the patients were still satisfied with their treatment and showed positive results.

## **Limitations**

### ***TMD study.***

While there were significant differences found there may have been factors may have contributed to fewer significant findings. The question used to



define the presence of headaches could have been misinterpreted by participants causing less people to endorse this specific type of headache. The question asked if you have had new or different headaches since the onset of your illness. A more specific question would be if you have had new of different headaches since the onset of myofacial pain. Secondly, more participants that endorsed headache symptoms would increase the power of the findings. The power analysis found that 40 participants per treatment group that endorsed headache symptoms to have a power of .8. In this study there were 33 participants in the biobehavioral treatment group, 32 in the self-care group, and 26 in the non-intervention group. This gave the current study a power of .68. The effect size was also lowered when changing from Non-Parametric analysis to a  $\chi^2$ . A larger sample would more likely present more significant findings. Finally, the demographics in the TMD study trended towards a largely female, higher socioeconomic status, and White. To get a more true representative picture of the population, a more even number of sex, socioeconomic status, and an increase in diverse ethnicities could be collected.

### ***Initial pilot study.***

Some promising results were found regarding the treatment. However, a sample size of six participants is not a significant amount. The power analysis found that a sample size of 55 participants would be needed to have a power of .8. The demographics of the dental study were 100% female. To get a true representative of the population more males would need to be included. Finally, a

far amount of time passed between treatment and follow-up. More information could have been gained if more frequent follow-ups were given.

### **Further Research**

Future research would benefit from a long term follow up on headache participants in the TMD study. At least a 2-year follow would be beneficial to incorporate in to further studies. In addition, it would be valuable to gather more data from the ongoing TMD to increase the power of the current findings. More information can be gathered from different demographic groups such as more male, lower socioeconomic status, and more diverse ethnicities. The initial pilot study shows promising results for further research using this dental technique pioneered by Dr. Neeley. Further research would be beneficial with more patients to gain power for analysis. Further research could also be conducted to assess the cost effectiveness of this treatment compared with the use of medication to treat headaches. It may also be beneficial to add psychosocial and educational components in addition to biological equilibration to increase ability to cope with headaches post-treatment.

## TABLES

Table 1

*Highest Grade Completed in Headache Population*

Highest Grade Completed	Frequency	Percent
11	1	1.1%
12	10	11%
13	7	7.8%
14	17	18.9%
15	9	10%
16	22	24.4%
17	3	3.3%
18+	21	23.3%
Total	90	100%
Missing	1	
Total	91	

Table 2

*Comparison of Distress*

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.369	2	.184	.096	.909
Within Groups	88.733	46	1.929		
Total	89.102	48			
Tukey HSD					
(I) Patient Group Assignment	(J) Patient Group Assignment	Mean Difference (I-J)	Std. Error	Sig.	
Biobehavioral	Self-Care	-.21667	.49916	.902	
Biobehavioral	Non-Intervention	-.08333	.47721	.983	
Self-Care	Biobehavioral	.21667	.49916	.902	
Self-Care	Non-Intervention	.13333	.48556	.959	
Non-Intervention	Biobehavioral	.08333	.47721	.983	
Non-Intervention	Self-Care	-.13333	.48556	.959	

Table 3

*Summary of Case Study Outcomes*

Cases (C)	Headache Amount	Headache Intensity	Headache Pain Level	Feel I am Getting	Treatment Satisfaction	Need for Medicine
C1	Fewer	Less	5	Better	Very satisfied	Decrease
C2	Fewer	Less	5	Better	Very satisfied	Decrease
C3	Fewer	Less	5	Better	Happy and satisfied	Decrease
C4	Fewer	Less	7	Better	Very satisfied	Somewhat able to Decrease
C5	Fewer	Less	4	Better	Very satisfied	Unable to Decrease
C6	Fewer	Less	3	Better	Exceptionally satisfied	Decrease

## APPENDIX A

### FORMS

#### Informed Consent

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#### INFORMED CONSENT

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**PRINCIPAL INVESTIGATOR NAME:**

Robert J. Gatchel, Ph.D., ABPP, and Michael J. Neeley, D.D.S. (co-investigators)

**TITLE OF PROJECT:**

Chronic Headache and Dental Treatment

**INTRODUCTION**

*You are being asked to participate in a research study. Your participation is voluntary. Please ask questions if there is anything you do not understand.*

---

**PURPOSE:**

The purpose of this study is to document and quantify the validity of current methods employed in the private practice of Michael Neeley, D.D.S. for the evaluation and treatment of chronic frontal headaches related to dental abnormalities.

**DURATION:**

It is expected that once you have been evaluated by Dr. Neeley and begin treatment, that you will likely be considered a participant in this treatment protocol for the duration of 12 months from the date of your initial evaluation.

**PROCEDURES:**

The evaluation and treatment techniques involve the identification, through a dental examination involving palpation, of portions of orofacial regions which appear to be physiologically linked to one or more dental abnormalities. Various remedies for these abnormalities that are routinely prescribed in dental practice, including: equilibration, developing an individualized splint, and treatment with transcutaneous electrical stimulation (TENS).

All interested individuals who experience headaches will be examined by Mike Neeley, D.D.S. as to the duration and location of their symptoms before enrollment and inclusion into the treatment phase of this program. Due to the prospective nature of this investigation, no randomization or comparison groups will be utilized. Therefore, all participants who are accepted into this program will receive the same standard treatment.

**POSSIBLE BENEFITS:**

To you/the participant: Your headache discomfort may get better or go away; however, it is not possible to guarantee that it will. In the future, other people with your type of headache symptoms may benefit from the findings of this current evaluation. Information gained from this program may lead to improved treatment at a reduced cost and within a shorter period of time than is traditional. However, it is not possible to determine whether there are benefits to other people with your range of symptoms until all of the information obtained from this program has been collected and analyzed.

To others: The results of this program may help other people in the future. New information may lead to improvements in medical care for people suffering from chronic headaches.

**COMPENSATION:**

NA

**POSSIBLE RISKS/DISCOMFORTS:**

Unforeseen risks: A previously unknown problem could possibly result from your participation in this program, although this is quite unlikely. However, it is not possible to estimate the chances of any such problems. Consequently we ask that you inform us of any problems that arise. You may discontinue any and all aspects of the treatment program at any time. Telephone numbers where you may reach the study personnel are listed on the front page of this consent form.

What to do if you have problems: If you have a problem during this treatment program, the investigators and your dentist (Dr. Neeley) can recommend alternative treatments. Please report the problem to us promptly. Call any one of the telephone numbers listed on the first page of this consent form.

**RECORDS OF YOUR PARTICIPATION IN THIS RESEARCH:** You have the right to privacy. Any information about you that is collected for this research will remain confidential as required by law. In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information for Research Purposes," which will contain more specific information about who is authorized to review, use, and/or receive your protected health information for the purposes of this study.

**ALTERNATIVE PROCEDURES/TREATMENTS:**

If you choose not to participate in this program at this time, your care under Dr. Neeley will remain unaffected. Further, if desired, at your request, a list of alternate treatments and treatment providers will be made available.

**WITHDRAWAL FROM THE STUDY:**

You have the right to agree or refuse to participate in this treatment program. Your continuing care within Dr. Neeley's practice will remain unaffected by this decisions. If you decide to participate and later change your mind, you are free to discontinue participation in the treatment program at any time without consequences.

**NUMBER OF PARTICIPANTS:** We expect 300 of participants to enroll in this study.

**CONFIDENTIALITY:**

If in the unlikely event it becomes necessary for the Institutional Review Board to review your research records, then The University of Texas at Arlington will protect the confidentiality of those records to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate you with it, or with your participation in any study. If the results of this

research are published or presented at scientific meetings, your identity will not be disclosed.

**CONTACT FOR QUESTIONS:**

Questions about this research or your rights as a research subject may be directed to Robbie Haggard, M.S. at (214) 645-8749. You may contact Michael Neeley, D.D.S. at (214) 524-3148 in the event of a research-related injury to the subject.

**CONSENT:**

**Signatures:**

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

\_\_\_\_\_  
Signature and printed name of principal investigator or person obtaining consent

\_\_\_\_\_  
Date

By signing below, you confirm that you have read or had this document read to you. You have been informed about this program's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time

You voluntarily agree to participate in this examination and treatment protocol. By signing this form, you are not waiving any of your legal rights. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

\_\_\_\_\_  
SIGNATURE OF VOLUNTEER

\_\_\_\_\_  
DATE



## APPENDIX B

### Patient Information Form

Patient ID Number <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <i>For Study Use Only</i>
---

#### PATIENT INFORMATION FORM

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

Address:

Street	Apt. #	City	State	Zip Code
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Home Phone Number: \_\_\_\_\_

Number of Children (under 18) Living in Your Home: \_\_\_\_\_

Ethnicity (circle one): White   Latino/a   African/American   Asian   Other \_\_\_\_\_

Are You Employed:      Yes \_\_\_\_\_      No \_\_\_\_\_      Date of Birth: \_\_\_\_\_

Full-time?      Yes \_\_\_\_\_      No \_\_\_\_\_      SSN: \_\_\_\_ -- \_\_\_\_ -- \_\_\_\_

Place of Employment: \_\_\_\_\_

Work Phone Number: \_\_\_\_\_

Occupation: \_\_\_\_\_

Highest Grade Completed: \_\_\_\_\_

Age: \_\_\_\_ Sex: \_\_\_\_ Marital Status (circle): Single   Married   Divorced/Separated   Widowed

Names and Phone Numbers of Three Individuals Who Would Know Where You Live Six Months from Now:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

Who referred you/How did you find out about this program? \_\_\_\_\_

Workers' Compensation Claim (circle one): NO CLAIM   ACTIVE CLAIM   POSSIBLE CLAIM

Personal Injury Suit (circle one): NO CLAIM   ACTIVE CLAIM   POSSIBLE CLAIM

#### **PHYSICAL HEALTH**

Date of Onset of Pain/Headache Symptoms: \_\_\_\_\_ (mm/dd/yyyy)

Please also describe what may have produced (or led to) your headaches (use back of this page if you need more space):

---



---



---



---

Have you had prior treatments for your headaches? Yes \_\_\_\_\_ No \_\_\_\_\_

**PATIENT INFORMATION FORM**

If YES, please give approximate dates of previous treatment received:

---

---

Describe any other chronic health problems:

---

---

---

## APPENDIX C

### Headache Exam Form

PID # \_\_\_\_\_

#### Headache Exam Form

Name \_\_\_\_\_ Date \_\_\_\_\_ Age \_\_\_\_\_ Gender \_\_\_\_\_

Physician \_\_\_\_\_

#### History

Age of onset \_\_\_\_\_ Family history \_\_\_\_\_ Triggers \_\_\_\_\_

History of Ortho \_\_\_\_\_ Efforts to control headache \_\_\_\_\_

Associate headache with \_\_\_\_\_

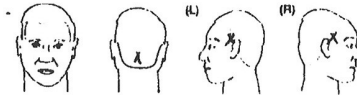
Occur in A.M. /P.M. # Headaches / month \_\_\_\_\_

#### Symptoms

Duration \_\_\_\_\_ Intensity \_\_\_\_\_ Epicenter \_\_\_\_\_

Frequency \_\_\_\_\_ Cervical \_\_\_\_\_ Aura/Nausea \_\_\_\_\_

Location of headache



#### Signs

ROM \_\_\_\_\_ Verticle \_\_\_\_\_ Left \_\_\_\_\_ Right \_\_\_\_\_ Protrusive \_\_\_\_\_

Deflection \_\_\_\_\_ Velocity \_\_\_\_\_ Deviation \_\_\_\_\_

Dominant chewing side \_\_\_\_\_ Overbite \_\_\_\_\_

Joint Noise \_\_\_\_\_ Temperature \_\_\_\_\_ Fremitus \_\_\_\_\_

Arch Constriction \_\_\_\_\_ Ortho Class \_\_\_\_\_ Coronoid process \_\_\_\_\_

Masseter \_\_\_\_\_ Pre Auricular \_\_\_\_\_ Lat Pteryg \_\_\_\_\_

Abfraction \_\_\_\_\_ Cold sens \_\_\_\_\_ Shimbashi \_\_\_\_\_

#### Wear facets



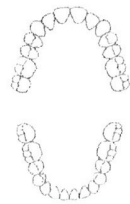
Fremitus (head ) \_\_\_\_\_

Diagnosis \_\_\_\_\_

#### Treatment Plan

Equilibrate \_\_\_\_ Splint \_\_\_\_ H/S TENS \_\_\_\_ Aqualizer \_\_\_\_\_

Radiographs \_\_\_\_\_ Build up of teeth \_\_\_\_\_



Notes

## APPENDIX D

### Headache Patient Report Card

PID# \_\_\_\_\_

#### Headache patient report card

Name \_\_\_\_\_ Today's date \_\_\_\_\_

Date of last visit \_\_\_\_\_

Since your last visit are the number of headache that you have had:

FEWER                  MORE                  ABOUT THE SAME

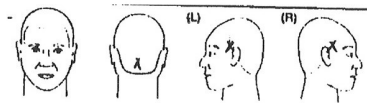
Since your last visit was the intensity of the headache:

MORE                  LESS

Draw a line that indicates the level of pain with 10 being as bad as it gets of your last headache

0 \_\_\_\_\_ 5 \_\_\_\_\_ 10

Indicate the location of pain



Do you feel that you are getting:

BETTER                  WORSE                  ABOUT THE SAME

How satisfied are you with the progress of your treatment?

\_\_\_\_\_

Have you been able to decrease the need for medications to control your headache?

YES                  SOMEWHAT                  NO

## APPENDIX E

### RDC History Questionnaire

Page 1

#### RDC HISTORY QUESTIONNAIRE

ID# \_\_\_\_\_

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Please read each question and respond accordingly. For each of the questions below circle only one response.

1. Would you say your health in general is excellent, very good, good, fair or poor?

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Would you say your oral health in general is excellent, very good, good, fair or poor?

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

3. Have you had pain in the face, jaw, temple, in front of the ear or in the ear in the past month?

No	0
Yes	1

**[If no pain in the past month, SKIP to question 14]**

**If Yes,**

- 4.a. How many years ago did your facial pain begin for the first time?

\_\_\_\_\_ years

**[If one year ago or more SKIP to question 5]**

**[If less than one year ago, code 00]**

- 4.b. How many months ago did your facial pain begin for the first time?

\_\_\_\_\_ months

5. Is your facial pain persistent, recurrent or was it only a one-time problem?

Persistent	1
Recurrent	2
One-Time	3

6. Have you ever gone to a physician, dentist, chiropractor or other health professional for facial ache or pain?

No	1
Yes, in the last six months	2
Yes, more than six months ago	3

## Research Diagnostic Criteria

Page 2

7. How would you rate your facial pain on a 0 to 10 scale at the present time, that is right now, where 0 is "no pain" and 10 is "pain as bad as could be"?
- No pain** **Pain as bad as could be**
- 0 1 2 3 4 5 6 7 8 9 10
8. In the past six months, how intense was your worst pain rated on a 0 to 10 scale where 0 is "no pain" and 10 is "pain as bad as could be"?
- No pain** **Pain as bad as could be**
- 0 1 2 3 4 5 6 7 8 9 10
9. In the past six months, on the average, how intense was your pain rated on a 0 to 10 scale where 0 is "no pain" and 10 is "pain as bad as could be"? [That is, your usual pain at times you were experiencing pain].
- No pain** **Pain as bad as could be**
- 0 1 2 3 4 5 6 7 8 9 10
10. About how many days in the last six months have you been kept from your usual activities (work, school or housework) because of facial pain?
- \_\_\_\_\_
- DAYS
11. In the past six months, how much has facial pain interfered with your daily activities rated on a 0 to 10 scale where 0 is "no interference" and 10 is "unable to carry on any activities"?
- No** **Unable To**
- Interference** **Carry On Any**
- 0 1 2 3 4 5 6 7 8 9 10 **Activities**
12. In the past six months, how much has facial pain changed your ability to take part in recreational, social and family activities where 0 is "no change" and 10 is "extreme change"?
- No** **Unable To**
- Change** **Carry On Any**
- 0 1 2 3 4 5 6 7 8 9 10 **Activities**
13. In the past six months, how much has facial pain changed your ability to work including housework) where 0 is "no change" and 10 is "extreme change"?
- No** **Unable To**
- Change** **Carry On Any**
- 0 1 2 3 4 5 6 7 8 9 10 **Activities**

## Research Diagnostic Criteria

Page 3

- |       |   |     |   |
|-------|---|-----|---|
| 14.a. | Have you ever had your jaw lock or catch so that it won't open all the way? | No  | 0 |
|       |   | Yes | 1 |

**[If no problem opening all the way, SKIP to question 15]**

**If Yes,**

- |       |   |     |   |
|-------|---|-----|---|
| 14.b. | Was this limitation in jaw opening severe enough to interfere with your ability to eat? | No  | 0 |
|       |   | Yes | 1 |

- |     |  |     |   |  |     |   |
|-----|--|-----|---|--|-----|---|
| 15. | a. Does your jaw click or pop when you open or close your mouth or when chewing? | No  | 0 | d. During the day, do you grind your teeth or clench your jaw? | No  | 0 |
|     |  | Yes | 1 |  | Yes | 1 |

- |  |   |     |   |  |     |   |
|--|---|-----|---|--|-----|---|
|  | b. Does your jaw make a grating or grinding noise when it opens and closes or when chewing? | No  | 0 | e. Does your jaw ache or feel stiff when you wake up in the morning? | No  | 0 |
|  |   | Yes | 1 |  | Yes | 1 |

- |  |   |     |   |  |     |   |
|--|---|-----|---|--|-----|---|
|  | c. Have you been told, or do you notice that you grind your teeth or clench your jaw while sleeping at night? | No  | 0 | f. Do you have noises or ringing in your ears?   | No  | 0 |
|  |   | Yes | 1 |  | Yes | 1 |
|  |   |     |   | g. Does your bite feel uncomfortable or unusual? | No  | 0 |
|  |   |     |   |  | Yes | 1 |

- |       |   |     |   |
|-------|---|-----|---|
| 16.a. | Do you have rheumatoid arthritis, lupus, or other systemic arthritic disease? | No  | 0 |
|       |   | Yes | 1 |

- |       |   |     |   |
|-------|---|-----|---|
| 16.b. | Do you know of anyone in your family who has had any of these diseases? | No  | 0 |
|       |   | Yes | 1 |

- |       |   |     |   |
|-------|---|-----|---|
| 16.c. | Have you had or do you have any swollen or painful joint(s) other than the joints close to your ears (TMJ)? | No  | 0 |
|       |   | Yes | 1 |

**[If no swollen or painful joints, SKIP to question 17.a.]**

**If Yes,**

- |       |   |     |   |
|-------|---|-----|---|
| 16.d. | Is this a persistent pain which you have had for at least one year? | No  | 0 |
|       |   | Yes | 1 |

- |       |   |     |   |
|-------|---|-----|---|
| 17.a. | Have you had a recent injury to your face or jaw? | No  | 0 |
|       |   | Yes | 1 |

**[If no recent injuries, SKIP to question 18]**

**If Yes,**

- |       |  |     |   |
|-------|--|-----|---|
| 17.b. | Did you have jaw pain before the injury? | No  | 0 |
|       |  | Yes | 1 |

- |     |  |     |   |
|-----|--|-----|---|
| 18. | During the last six months have you had a problem with headaches or migraines? | No  | 0 |
|     |  | Yes | 1 |



## Research Diagnostic Criteria

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19. What activities does your present jaw problem prevent or limit you from doing?

a. Chewing	No	0	g. Sexual activity	No	0
	Yes	1		Yes	1
b. Drinking	No	0	h. Cleaning teeth or face	No	0
	Yes	1		Yes	1
c. Exercising	No	0	i. Yawning	No	0
	Yes	1		Yes	1
d. Eating hard foods	No	0	j. Swallowing	No	0
	Yes	1		Yes	1
e. Eating soft foods	No	0	k. Talking	No	0
	Yes	1		Yes	1
f. Smiling/laughing	No	0	l. Having your usual facial appearance	No	0
	Yes	1		Yes	1

20. In the last month, how much have you been distressed by . . .

	Not At All	A Little Bit	Moder- ately	Quite A Bit	Ex- tremely
a. Headaches	0	1	2	3	4
b. Loss of sexual interest or pleasure	0	1	2	3	4
c. Faintness or dizziness	0	1	2	3	4
d. Pains in the heart or chest	0	1	2	3	4
e. Feeling low in energy or slowed down	0	1	2	3	4
f. Thoughts of death or dying	0	1	2	3	4
g. Poor appetite	0	1	2	3	4
h. Crying easily	0	1	2	3	4
i. Blaming yourself for things	0	1	2	3	4
j. Pains in the lower back	0	1	2	3	4
k. Feeling lonely	0	1	2	3	4
l. Feeling blue	0	1	2	3	4
m. Worrying too much about things	0	1	2	3	4
n. Feeling no interest in things	0	1	2	3	4
o. Nausea or upset stomach	0	1	2	3	4
p. Soreness of your muscles	0	1	2	3	4
q. Trouble falling asleep	0	1	2	3	4
r. Trouble getting your breath	0	1	2	3	4
s. Hot or cold spells	0	1	2	3	4
t. Numbness or tingling in parts of your body	0	1	2	3	4
u. A lump in your throat	0	1	2	3	4
v. Feeling hopeless about the future	0	1	2	3	4
w. Feeling weak in parts of your body	0	1	2	3	4
x. Heavy feelings in your arms or legs	0	1	2	3	4
y. Thoughts of ending your life	0	1	2	3	4
z. Overeating	0	1	2	3	4
aa. Awakening in the early morning	0	1	2	3	4

## Research Diagnostic Criteria

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- |     |                                     | Not At<br>All | A Little<br>Bit | Moder-<br>ately | Quite<br>A Bit | Ex-<br>tremely |
|-----|-------------------------------------|---------------|-----------------|-----------------|----------------|----------------|
| bb. | Sleep that is restless or disturbed | 0             | 1               | 2               | 3              | 4              |
| cc. | Feeling everything is an effort     | 0             | 1               | 2               | 3              | 4              |
| dd. | Feelings of worthlessness           | 0             | 1               | 2               | 3              | 4              |
| ee. | Feeling of being caught or trapped  | 0             | 1               | 2               | 3              | 4              |
| ff. | Feelings of guilt                   | 0             | 1               | 2               | 3              | 4              |
21. How good a job do you feel you are doing in taking care of your health overall?
- |           |   |
|-----------|---|
| Excellent | 1 |
| Very good | 2 |
| Good      | 3 |
| Fair      | 4 |
| Poor      | 5 |
22. How good a job do you feel you are doing in taking care of your oral health?
- |           |   |
|-----------|---|
| Excellent | 1 |
| Very good | 2 |
| Good      | 3 |
| Fair      | 4 |
| Poor      | 5 |
23. When were you born?      Month \_\_\_\_      Day \_\_\_\_      Year \_\_\_\_
24. Are you male or female?
- |        |   |
|--------|---|
| Male   | 1 |
| Female | 2 |
25. Which of the following groups best represent your race?
- |                                  |   |
|----------------------------------|---|
| Aleut, Eskimo or American Indian | 1 |
| Asian or Pacific Islander        | 2 |
| Black                            | 3 |
| White                            | 4 |
| Other                            | 5 |
| (please specify) _____           |   |
26. Are any of these groups your national origin or ancestry?
- |                  |   |                      |   |
|------------------|---|----------------------|---|
| Puerto Rican     | 1 | Chicano              | 5 |
| Cuban            | 2 | Other Latin American | 6 |
| Mexican/Mexicano | 3 | Other Spanish        | 7 |
| Mexican American | 4 | None of the above    | 8 |
27. What is the highest grade or year of regular school that you have completed?
- |                                 |    |    |    |    |    |     |   |   |
|---------------------------------|----|----|----|----|----|-----|---|---|
| Never attended or Kindergarten: | 00 |    |    |    |    |     |   |   |
| Elementary School:              | 1  | 2  | 3  | 4  | 5  | 6   | 7 | 8 |
| High School:                    | 9  | 10 | 11 | 12 |    |     |   |   |
| College:                        | 13 | 14 | 15 | 16 | 17 | 18+ |   |   |

## Research Diagnostic Criteria

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28. a. During the past 2 weeks, did you work at a job or business not counting work around the house (include unpaid work in the family farm/business)?

Yes	1
No	2

(If Yes, **SKIP** to question 29)

- b. If no, even though you did not work during the past 2 weeks, did you have a job or business?

Yes	1
No	2

(If Yes, **SKIP** to question 29)

- c. If no, were you looking for work on layoff from a job during those 2 weeks?

Yes, looking for work	1
Yes, layoff	2
Yes, both on layoff and looking for work	3
No	4

29. Are you married, widowed, divorced, separated or never been married?

Married-spouse in household	1
Married-spouse not in household	2
Widowed	3
Divorced	4
Separated	5
Never Married	6

30. Which of the following best represents your total combined household income during the past 12 months?

___ \$0-\$14,999	___ \$25,000-\$34,999	___ \$50,000 or more
___ \$15,000-\$24,999	___ \$35,000-\$49,999	

31. What is your USA 5 digit zip code or your national postal code?    \_ \_ \_ \_ \_

## APPENDIX F

### Symptom Checklist

#### SYMPTOM CHECKLIST

PID#: \_\_\_\_\_

Please provide the following information about yourself and your illness:

1. Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_
2. Your date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_
3. Sex: Female Male
4. Number of years of education: \_\_\_\_\_ (for example, high school = 12)
5. Marital status: Single      Divorced/Separated/Widowed      Married
6. Name of this clinic: \_\_\_\_\_
7. Name of your doctor: \_\_\_\_\_
8. Date you first got sick with this illness \_\_\_\_/\_\_\_\_/\_\_\_\_
9. Diagnosis given to you by THIS clinic: \_\_\_\_\_
10. Other diagnoses that you have received since you've been sick:
  - a. \_\_\_\_\_
  - b. \_\_\_\_\_
  - c. \_\_\_\_\_
  - d. \_\_\_\_\_
  - e. \_\_\_\_\_
  - f. \_\_\_\_\_

Have you ever been told by a health care provider that you have:

- |         |    |  |
|---------|----|--|
| 11. YES | NO | Chronic fatigue syndrome   |
| 12. YES | NO | Chronic tension headaches  |
| 13. YES | NO | Irritable or spastic bowel syndrome                                |
| 14. YES | NO | Interstitial cystitis or irritable bladder                         |
| 15. YES | NO | Post-concussion syndrome   |
| 16. YES | NO | Multiple chemical sensitivities                                    |
| 17. YES | NO | Chronic pelvic pain or chronic nonbacterial prostatitis            |
| 18. YES | NO | Chronic low back pain  |
| 19. YES | NO | Temporomandibular joint (TMJ) arthritis                            |
| 20. YES | NO | Fibromyalgia or fibrositis   |
| 21. YES | NO | Depression, anxiety, or other mental health or psychiatric problem |

22. During the last year, how many medical care visits have you made to a doctor, osteopath, chiropractor, physician assistant, or nurse practitioner? Number: \_\_\_\_\_

23. During the last year, which of the following types of health care providers have you seen? (check ALL that apply).

- ☐ Environmental physician or clinical ecology physician  
☐ Allergist or immunologist  
☐ Other medical doctor  
☐ Chiropractor  
☐ Naturopathic or homeopathic physician  
☐ Psychiatrist, psychologist, or other counselor  
☐ Other (please list): \_\_\_\_\_

24. Do you think your health condition is: (check ALL that apply)

- ☐ Mostly physical  
☐ Mostly psychological  
☐ Both physical and psychological  
☐ Caused by a virus or an improperly functioning immune system  
☐ Caused by something else: (describe) \_\_\_\_\_

#### SECTION 1

**In this next section, a variety of symptoms are listed. Please circle ONE answer for each of the questions below.**

25. YES      NO      Have you been fatigued for at least 6 months?
26. YES      NO      Have you been so fatigued that you have had to reduce your average activity level below half of what your normal level was before you became ill?
- Since you've been sick, have you had any of the following:?
27. YES      NO      Mild fever (oral temperature between 99.4 and 101.4) or chills
28. YES      NO      Sore throat
29. YES      NO      Painful lymph nodes in your neck or under your arms
30. YES      NO      Unexplained muscle weakness of most of your muscles
31. YES      NO      Muscle pain, aching, or discomfort
32. YES      NO      Burning, shooting, or throbbing muscle pain
33. YES      NO      Increased fatigue (with or without an increase in other symptoms) after exercise that lasts at least 24 hours
34. YES      NO      Regular headaches that are either new or different from headaches you had prior to the onset of your illness
35. YES      NO      Joint aches that move around with no redness or swelling of the painful joints

36. YES NO Difficulty concentrating or thinking, forgetfulness, depression or irritability, temporary blind spots or problems with bright lights bothering your eyes
37. YES NO Problems falling asleep, staying asleep or sleeping too much
38. YES NO Did your fatigue and other symptoms start suddenly over a few hours or days?
39. YES NO Do you wake up in the morning feeling tired, unrested, or unrefreshed even after a full night's rest?
40. YES NO Do your fingers swell up?
41. YES NO Do your symptoms change with the weather?
42. YES NO Have you ever had a change in the color of your fingers from blue to white to red with exposure to cold?
43. YES NO Do you have tingling or numbness of your extremities?

## SECTION 2

**This section asks about headaches. Please answer question 44, then follow the instructions below.**

44. YES NO Have you had a headache at least 15 days per month for the last 6 months?

**If your answer to question 44 is "NO", please skip to Section 3. If your answer to question number 44 is "YES", please indicate if your typical headaches are:**

45. YES NO Associated with vomiting
46. YES NO Accompanied by nausea
47. YES NO Accompanied by sensitivity to lights
48. YES NO Accompanied by sensitivity to loud noises
49. YES NO Feel like a pressing or tightening feeling
50. YES NO Such that they decrease your normal activity level, but not prevent it entirely
51. YES NO On both sides of your head
52. YES NO Not made worse by activity or exercise

## SECTION 3

**The questions below are concerned with low back pain. Please answer question 53, then follow the instructions below.**

53. YES NO Do you have constant low back pain?

**If your answer to question 53 is "NO", please skip to Section 4. If your answer to question number 53 is "YES", please answer the questions about your low back pain on the top of the next page:**

- 54. YES      NO      Made worse by an increase in activity or exercise
- 55. YES      NO      Made worse by emotional stress
- 56. YES      NO      Made worse by sitting, standing, or even lying down for too long
- 57. YES      NO      Made better by inactivity or rest
- 58. YES      NO      Made better by opioid (narcotic) medications
- 59. YES      NO      Made better by sedative medications
- 60. YES      NO      Made better by heat or massage
- 61. YES      NO      Do you believe that your pain is being caused by something that is wrong with your body, such as damaged bones, damaged nerves, or scar tissue?
- 62. YES      NO      If your low back pain was originally caused by some injury, do you believe that the original injury is now healed?
- 63. YES      NO      Does your pain interfere with your ability to do the things you want to do?
- 64. YES      NO      Is your low back pain problem getting worse or not getting better over time?

## SECTION 4

**The following section asks about gastrointestinal symptoms. Do you have any of the following symptoms either on a CONTINUOUS or RECURRENT basis?**

- 65. YES      NO      Abdominal pain relieved by having a bowel movement
- 66. YES      NO      Abdominal pain associated with a change in the frequency or consistency of stool
- 67. YES      NO      Changes in stool frequency
- 68. YES      NO      Hard or loose or watery stools
- 69. YES      NO      Straining or a feeling of urgency or incomplete evacuation with passing of stool
- 70. YES      NO      Mucus on or with bowel movements
- 71. YES      NO      Bloating or feeling of abdominal distention

## SECTION 5

**This section deals with symptoms of pain in your face and jaw muscles. Do you have:**

- 72. YES      NO      Pain in your jaw, face, or temples?
- 73. YES      NO      Muscle pain in at least 2 areas on your jaw, face, or temples when pressure is applied to the area?
- 74. YES      NO      If you have such pain with pressure, on a scale of 0 to 3 (0 = no pain), is this pain at least a "2" in at least one area?
- 75. YES      NO      Are you unable to fully open your mouth?

76. YES NO Do you have a "click" that is associated with opening or moving your jaw?

#### SECTION 6

**This section contains questions about a variety of symptoms. Please answer question 77, then follow the instructions below.**

77. YES NO Did your current health problems begin after an environmental or chemical exposure?

**If "NO", SKIP to Section 7**

**If "YES", please indicate if you have problems with:**

- 78. YES NO Loss of memory or forgetfulness
- 79. YES NO Confusion or clouded thinking
- 80. YES NO Hoarseness or trouble speaking
- 81. YES NO Burning or irritation of your nose or mouth
- 82. YES NO Burning or watery eyes
- 83. YES NO Blurred vision or blind spots
- 84. YES NO Excessive coughing
- 85. YES NO Trouble getting your breath
- 86. YES NO Eyes sensitive to light
- 87. YES NO Faintness or dizziness
- 88. YES NO Itching or irritation of your skin
- 89. YES NO Nausea or upset stomach

**Does exposure to any of the following substances reliably cause the symptoms listed above?**

- 90. YES NO Air pollution or exhaust
- 91. YES NO Vitamin pills or supplements
- 92. YES NO Food additives or preservatives
- 93. YES NO Cigarette smoke
- 94. YES NO Drinking alcohol
- 95. YES NO Gasoline, paint or solvent fumes
- 96. YES NO Perfumes or fragrances
- 97. YES NO Tension or stress

#### SECTION 7

**The questions on the following page are about your bladder habits.**



98. YES NO Do you routinely wake up more than one time at night to pass your urine?
99. YES NO Do you routinely pass your urine more often than every 2 hours during the day?
100. YES NO When you feel the need to empty your bladder (urinate) do you worry that you may not be able to get to the bathroom in time and start to wet your clothing?
101. YES NO When you feel the need to empty your bladder (urinate) do you have pain, discomfort, or another bothersome sensation (for example, burning, prickling, or spasm) that is not simply a strong desire or urge to urinate?
102. YES NO Do you experience difficulty starting the flow of urine?
103. YES NO Do you experience painful or burning sensation during urination?
104. YES NO Do you experience pain or cramping after urination?
105. YES NO Do you routinely have pain or discomfort during or after sexual activity?

## SECTION 8

**The questions below are concerned with head injuries. Please answer question 106, then follow the instructions that follow.**

106. YES NO Have you ever had an accident injury that resulted in a loss of consciousness or a period of confusion?

**If your answer to question 106 is "NO", please skip to Section 9. If your answer to question number 106 is "YES", please indicate complete the following items.**

107. What was the date of the accident or injury \_\_\_/\_\_\_/\_\_\_

108. YES NO Did you lose consciousness?

109. If YES, for how long did you approximately lose consciousness? (that is, how long did it take before you opened your eyes after the accident or injury?)

\_\_\_\_\_ minutes \_\_\_\_\_ hours \_\_\_\_\_ days

110. For how long after the accident or injury were you disoriented or had trouble remembering things on a moment-to-moment basis?

\_\_\_\_\_ minutes \_\_\_\_\_ hours \_\_\_\_\_ days \_\_\_\_\_ weeks

111. YES NO Do you remember the events that led up to the accident or injury?

**Please indicate below if you experienced any of the following symptoms IMMEDIATELY AFTER the accident or injury.**

112. YES NO Headaches
113. YES NO Dizziness
114. YES NO Trouble concentrating
115. YES NO Fatigue

116. YES NO Memory difficulty

Please indicate below if you CURRENTLY experience any of these symptoms and circle your response. Also circle only ONE answer to indicate how the severity NOW compares to your symptoms immediately after the accident or injury.

	Symptoms Now		Compared to Time of Injury		
117. Headaches	YES	NO	Improved	Worse	Same
118. Dizziness	YES	NO	Improved	Worse	Same
119. Trouble concentrating	YES	NO	Improved	Worse	Same
120. Fatigue	YES	NO	Improved	Worse	Same
121. Memory difficulty	YES	NO	Improved	Worse	Same

#### SECTION 9

Answer the questions about abdominal and pelvic problems in the following section only if you are FEMALE. If you are MALE, skip to SECTION 10.

122. YES NO Did you have especially severe menstrual pain when you were a teenager?
123. YES NO Do you have occasional pelvic or abdominal pain?
124. YES NO Have you decreased the frequency of sexual intercourse because of your pain?
125. YES NO Is sexual intercourse the only activity that your pain interferes with?
126. YES NO When you engage in intercourse, do you find it unpleasant, whether or not it is painful for you?

#### SECTION 10

Answer the questions about genital pain in the following section only if you are MALE. If you are FEMALE, you have completed this questionnaire.

127. YES NO Do you occasionally have pain or other unpleasant sensations in your genital area?  
If "YES", please answer the following questions:
128. YES NO Have the pain or unpleasant sensations interfered with your frequency of intercourse?
129. YES NO Are the pain or unpleasant sensations affected by ejaculation?
130. YES NO Have the pain or unpleasant sensations affected your exercise patterns, especially activities like bicycling?
131. YES NO Have the pain or unpleasant sensations kept you from establishing new relationships?
132. YES NO Are very few, if any, people you know socially or through work aware of your problem?

## APPENDIX G

### G\*Power Analysis

#### Large TMD Study- UTA

**F tests** - ANOVA: Repeated measures, between factors

**Analysis:** A priori: Compute required sample size

<b>Input:</b>	Effect size $f$	= 0.25
	$\alpha$ err prob	= 0.05
	Power (1- $\beta$ err prob)	= 0.8
	Number of groups	= 3
	Number of measurements	= 2
	Corr among rep measures	= 0.5
<b>Output:</b>	Noncentrality parameter $\lambda$	= 10.0000000
	Critical F	= 3.0737629
	Numerator df	= 2.0000000
	Denominator df	= 117
	Total sample size	= 120
	Actual power	= 0.8048112

#### Intial Pilot Study- Dr. Neeley

**F tests** - Linear multiple regression: Fixed model,  $R^2$  increase

**Analysis:** A priori: Compute required sample size

<b>Input:</b>	Effect size $f^2$	= 0.15
	$\alpha$ err prob	= 0.05
	Power (1- $\beta$ err prob)	= 0.80
	Number of tested predictors	=1
	Total number of predictors	=5
<b>Output:</b>	Noncentrality parameter $\lambda$	= 8.2500000
	Critical F	= 4.0383926
	Numerator df	= 1
	Denominator df	= 49
	Total sample size	= 55
	Actual power	= 0.8038932

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