The relative effectiveness of non-steroidal anti-inflammatory drugs (Ibuprofen®) and a taping method (Kinesio Taping® Method) in the treatment of Episodic Tension-Type Headaches

by

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A dissertation submitted in partial compliance with the requirements for a Master's Degree in Technology in the Department of Chiropractic and Somatology at Durban University of Technology.

I, Justin Michael Henry do declare this work to be my own, both in conception and execution, except where otherwise indicated in the text**.**

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DEDICATION

I dedicate this dissertation to Jesus Christ, my all.

ACKNOWLEDGEMENTS

I would firstly like to honour and thank Jesus Christ for being my rock during my Chiropractic studies, as well as for giving me endurance through the process of this research dissertation.

I would like to thank Michael and Jean Henry for their love, encouragement and support during this dissertation and the duration of my studies.

I would like to thank Michael and Jean Henry, as well as my grandfather for their financial support.

I would like to thank Dr. Charmaine Korporaal for her unending patience, encouragement and help through this dissertation and also my Chiropractic studies.

I would like thank Mrs. Ireland for her patience, encouragement and help through the course of this dissertation.

I would like to thank Pat and Linda for their service from behind the reception desk.

I would like to thank Dr. Charlton Butt for his assistance and friendship.

I would like to thank Tonya Esterhuizen, my research statistician for her assistance.

I would like to thank all the patients who participated in this study.

I would like to thank the DUTs library staff for their help.

I would like to thank Bronwyn Jones for proof reading my research dissertation.

I would like to thank all those who played a part in my dissertation and also throughout my Chiropractic studies.

To all of you, this dissertation and my Chiropractic qualifying was made possible because of your help.

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ABSTRACT

Background: Headaches are one of the most common clinical conditions in medicine, and 80% of these are tension-type headaches (TTH). TTH has a greater socioeconomic impact than any other type of headache due to its prevalence. Within the TTH category, episodic TTH are more prevalent than chronic TTH. The mainstay in the treatment of TTH are simple analgesics and NSAIDs. Unless contraindicated, NSAIDs are often the most effective treatment for ETTH. However patients suffering with TTH tend to relate their headaches to increased muscle stiffness in the neck and shoulders and thus the non-pharmacological treatment of ETTH could be directed at the associated musculoskeletal components of ETTH. It is therefore proposed that the Kinesio Taping® Method may have an effect in the treatment of the muscular component of ETTH.

Method: This study was a prospective randomised clinical trial with two intervention groups (n=16) aimed at determining the relative effectiveness of a NSAID and the Kinesio Taping® Method in the treatment of ETTHs. The patients were treated at 5 consultations over a 3 week period. Feedback was obtained using the: NRS – 101, the CMCC Neck Disability Index and a Headache Diary.

Results: The Headache Diary showed a reduction in the presence and number, mean duration and pain intensity of ETTH in both groups. These treatment effects were sustained after the cessation of treatment with the exception of mean pain intensity in the Kinesio Taping® Method group. The mean NRS score decreased in both groups but at a slightly faster rate in the Kinesio Taping® Method group. The CMCC showed an improvement in the functional ability of the patients in both groups.

Conclusion: There seems to be no significant difference in the relative effectiveness of the treatment modalities. We can thus state that the overall short-term reduction in symptomatology supports the use of NSAIDs or Kinesio Taping® Method in the treatment of ETTH.

Key words: Clinical trial, tension-type headache, taping, anti-inflammatory agents, non steroidal.

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DEFINITION OF TERMS

Analgesics:

This is an agent that relieves pain without causing a loss of consciousness (Dorland's, 1988; Farlex, 2009).

A priori:

Philosophically: "Logic relating to or involving deductive reasoning from a general principle to the expected facts or effects" (Farlex, 2009).

Mathematically: "The probability assigned to a parameter or to an event in advance of any empirical evidence often subjectively, or on the assumption of the principle of indifference" (Farlex, 2009).

Cervical:

Pertaining to this study, cervical will refer to the neck or (Dorland's, 1988) part of the body joining the head to the shoulders (Farlex, 2009).

Chiropractic:

This health care profession is concerned with the neuromusculoskeletal system, and the diagnosis, treatment and prevention of disorders and their effects, on general health. Manual therapeutic techniques including joint adjustment and/or manipulation with a particular focus on the subluxation as the emphasis of treatment" (World Health Organisation, 2004). According to Gatterman (1990) This is "a discipline of the scientific healing arts concerned with the pathogenesis, diagnosis, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes and neurophysiological effects related to the statics and dynamics of the locomotor system, especially of the spine and pelvis." In this context, it is a health-care discipline which emphasizes the inherent recuperative powers of the body to heal itself without the use of drugs or surgery" (Redwood and Cleveland, 2003) achieved by a therapeutic

procedure (an adjustment) (Gatterman, 1995). This procedure is defined as “a controlled force, with leverage, direction, amplitude, and velocity directed at specific joints or anatomic regions” (Gatterman, 1995).

CMCC: Abbreviates Canadian Memorial Chiropractic College (Vernon and Mior, 1991) and represents the “CMCC Neck Disability Index” within the text of this study.

Episodic Tension-Type headache (ETTH):

The International Headache Society (IHS) (1991) defines ETTH as recurrent episodes of headache lasting from minutes to days where the pain is typically pressing or tightening in quality, of a mild or moderate intensity, bilateral in location and does not worsen with routine physical activity; with nausea being absent, and photophobia or phonophobia occasionally being present (International Headache Society, 1991).

Hypersensitive/Hypersensitivity:

This is a state of abnormally increased sensitivity, or having the specific or general ability to react with characteristic signs and symptoms to the application or contact with certain substances (allergens) in amounts innocuous (ineffective) to normal (non-sensitised) individuals (Dorland’s, 1988).

Hyposensitive/Hyposensitivity:

This is a state of abnormally decreased sensitivity. It can be induced by repeated, gradual increased doses of the offending substance (allergen), resulting in state of reduced reactivity (Dorland’s, 1988).

Incidence:

Pertaining to this study, incidence refers to the number of new cases of tension-type headache within a specified time period (Dorland's, 1988; Farlex, 2009).

Joint Dysfunction:

The loss of one or more movements (due to a number of reasons) within the normal range of motion and the associated pain (Schafer and Faye, 1990).

Kinesio Taping® Method:

Kinesio Taping® Method is the "definitive" rehabilitative taping method within the international medical community (Authentic Kinesio® About us, 2009) used in the application of Kinesio® Tex Tape.

Kinesio® Tex Tape:

A latex free, gentle cotton fibre strip with a 100% medical grade acrylic adhesive and a 3-5 day wearing time which has become the standard for therapeutic and rehabilitative taping. (Authentic Kinesio® About us, 2009). The term "Kinesio® Tex Tape" will be used within the text.

Myofascial Trigger Point picture:

A hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is painful on compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction, and autonomic phenomena (Simons, Travell and Simons, 1999).

NSAID (e.g. Ibuprofen®-used in this study, ketoprofen and naproxen sodium)**:**

This is a non-steroidal anti-inflammatory and analgesic agent. Its effects are similar to aspirin without as many adverse effects-particularly those of the gastrointestinal system (Diamond, 1983). The general abbreviation "NSAID" or more specific Ibuprofen® will be used within the text.

Pathogenesis:

Pertaining to this study, it is the cellular events, reactions and other pathologic mechanisms that occur during the development of a disease process (Dorland's, 1988).

Pericranial:

Pertaining to this study, pericranial will refer to the pericranium (Dorland's, 1988).

Pericranium:

Pertaining to this study, pericranium will refer to a structure around or next to the skull (Farlex, 2009).

Photophobia:

This is "the abnormal intolerance of light" (Dorland's, 1988).

Phonophobia:

This is "the abnormal intolerance of sound" (Dorland's, 1988).

Prevalence:

Pertaining to this study, it indicates the number of cases of tension-type headaches that are present in a population at any given time point (Dorland's, 1988; Farlex, 2009) or the total number of diseased individuals divided by the total population (Farlex, 2009).

Rhomboid Muscle:

This broad, thin muscle forms parallel bands that pass inferolaterally from the thoracic vertebrate to the scapula (medial border) as it runs deep to the trapezius muscle. Their muscular action is to retract and rotate the scapula (Moore and Dalley, 1999).

Trapezius Muscle:

This is a large triangular muscle that provides a direct connection to the trunk (skull and vertebral column) to the pectoral girdle (shoulder). It is divided into three parts of which we are only interested in two in this research study. The upper fibres elevate (raise) the scapula and the middle fibres retract (pull it posteriorly) the scapula (Moore and Dalley, 1999).

Vascular: Pertaining to this study, vascular means a tube-like structure (Farlex, 2009) transporting the blood throughout the body.

CHAPTER ONE: Introduction

1.1 Introduction

Headaches are one of the most common clinical conditions in medicine (Edwards and Bouchier, 1991), and of these, TTHs have been found to be the most common (Rasmussen, Jensen, Schroll and Olesen, 1991; Schwartz, Stewart, Simon and Lipton, 1998; Davies, 2000; Boon, Colledge and Walker, 2006). Eighty percent of headache patients who consult a doctor are diagnosed as suffering from TTH (Dalessio, 1987, and of these, episodic TTH is the most prevalent form (Schwartz, Stewart and Lipton, 1997).

In 1988 the International Headache Society (IHS) introduced new diagnostic criteria for headaches and craniofacial pain. TTH was the term designated to describe what was previously called “tension headache”, “muscle contraction headache”, “psychomyogenic headache”, and/or “stress headache”. The condition was clearly delineated and defined by the IHS classification and a distinction between an ETTH (which occurs less than 50% of all days) and a chronic TTH (which occurs 50% or more, and in most cases daily), was made.

It is therefore assumed that the aetiology (cause) and pathogenesis (development/evolution) of TTH would be researched and well understood, but this is not the case. In fact, scientific interest can be described as being sparse (Bendtsen, 2000). The aetiology of TTH remains unknown, and the pathogenesis of TTH is believed to be multi-factorial and includes muscular (Langemark and Olesen, 1987; Schoenen, Gerard, De Pasqua and Sianard-Gainko, 1991; Jensen et al., 1993; Jensen, 1999; Bendtsen, 2000), vascular and psychological (stress, anxiety and depression) factors as well as cervical spine dysfunction (IHS, 1991). As a result, the basic processes of TTH are poorly understood, and so, the treatment protocols have not been sufficiently developed to deliver satisfactory clinical outcomes.

Thus, the treatment of TTH is generally defined by the type of management, and includes pharmacologic (medication) or non-pharmacologic (drug free) interventions (Ashkenazi and Silberstein, 2004). In this study, as a result of simple analgesics and NSAIDs being the mainstay in the treatment of TTH (Jensen and Olesen, 2000), and that research (Diamond, 1983; Schachtel, Furey and Thoden, 1996; Diamond, 1999; Ashina and Ashina, 2003; Ashkenazi and Silberstein, 2004) indicates that NSAIDs are the most effective treatment for ETTH, Ibuprofen® was chosen as the drug of choice for this study, unless contraindicated (Sandoz, 1997; Diamond, 1999).

With respect to the non-pharmacological treatment of ETTHs, Langemark and Olesen, (1987); Lebbink, Spierings and Messinger, (1991); Jensen and Rasmussen, (1996); Fernandez-de-las-Penas, Ge, Arendt-Nielson, Cuadrado and Pareja, (2007) and the IHS definition (1991), note that soft tissues (e.g. muscles) are a cause of ETTH. Thus, it is recommended that the treatment of the associated soft tissue component is indicated (Vernon, 1995). Based on this recommendation, it is proposed that the Kinesio Taping® Method (Friedman, 2007b) may be an effective treatment of the muscular component of ETTH.. This effect is based on the four major functions and effects of Kinesio ® Tex Tape, identified as: normalizing muscle function, improving lymphatic and blood flow (thus helping to break the muscular spasm associated with the ETTH), reducing and managing pain and lastly correcting posture (Friedman, 2007a). Therefore the proposed philosophy behind the Kinesio Taping® Method is that it allows free range of motion allowing the body's muscular system to heal itself biomechanically (Friedman, 2007a).

Since the Kinesio Taping® Method is considered an easy-to-use modality which allows the patient to receive the therapeutic benefits for 24 hours per day for several days, and that it has fewer side-effects and contra-indications than NSAIDs, the Kinesio Taping® Method was the modality used in the treatment of the ETTH in this study with the aim to determine the relative effectiveness of NSAIDs and a Kinesio Taping® Method in the treatment of ETTHs.

1.2 Aim/Purpose of study

The aim was to determine the relative effectiveness of NSAIDs (Ibuprofen®) and the Kinesio Taping® Method in the treatment of ETTH, in terms of subjective findings and associated symptoms.

1.3 Objectives of the study:

- **Objective One**

  The first objective was to determine the relative effectiveness of Ibuprofen® and the Kinesio Taping® Method treatment in terms of subjective clinical measures: pain intensity (NRS-101 and the Headache Diary), duration (Headache Diary), frequency (Headache Diary) and nature (Headache Diary) of the pain.

  Null Hypothesis One

  There would be no difference between the treatment effects of Ibuprofen® and the Kinesio Taping® Method in terms of subjective clinical findings.

- **Objective Two**

  The second objective was to determine the relative effectiveness of Ibuprofen® and the Kinesio Taping® Method of treatment in terms of associated symptoms of the ETTH (Headache Diary) and activities of daily life (CMCC Neck Disability Index).

  Null Hypothesis Two

  There would be no difference between the treatment effects of Ibuprofen® and the Kinesio Taping® Method in terms of associated clinical findings.

- **Objective Three**

The third objective was a comparison between the trends evidenced in the subjective clinical measures and the associated symptoms between the two groups.

Null Hypothesis Three

There would be no trends observed between the subjective clinical findings and associated symptoms.

1.4 Rationale

- To have provided a clinical study regarding the effectiveness of the use of the Kinesio Taping® Method as a treatment modality.

- To test whether the proposed mechanisms of effect and effectiveness were confirmed through response of the patient to the Kinesio® Taping Method.

- Practitioners may be able to include the Kinesio Taping® Method into their treatment method should the Kinesio Taping® Method be shown to be an effective treatment modality.

- Should the Kinesio Taping® Method be shown to be effective, it would provide patients with an opportunity for a drug free and non-invasive treatment option in the treatment of ETTH.

- It will provide a viable alternative to patients with ETTH that exhibit contraindications to standard pharmacological care, or manual therapy care.

1.5 Benefits of the Study

The outcomes of this study were to establish whether a potentially new modality would be shown to be effective in the treatment of ETTH. This could therefore increase the number of effective treatment modalities available to the practitioner in the treatment of ETTH. This is especially important as it would serve to validate a drug free treatment modality which would reduce any side-effects caused by drugs, including drug-induced headaches.

1.6 The Inherent Limitations of the study

The inherent limitations of the study were:

- There was no objective measurement to verify the severity of the headache, the associated symptoms and the effect on the activities of daily living.

- No *a priori* power analysis was done to determine an appropriate sample size for this study, as no literature could be found indicating the minimum improvement ratios required within the subjective measures (used in this study) that would indicate a significant clinical outcome.

- The patient's honesty in their answering their various feedback forms especially as they was subjective.

- There is no confirmation that the Ibuprofen® group adhered to the daily dosage instructions.

1.7 Conclusion

In conclusion, this was an important study in that the results would be important in confirming the effectiveness of the Kinesio Taping® Method in relation to NSAID therapy in the treatment of ETTH. This would therefore increase the number of effective treatment modalities available to the practitioner in the treatment of ETTH.

CHAPTER 2: Literature Review

2.1 Introduction

This chapter discusses the literature surrounding ETTH and the two treatment modalities involved in this study, namely NSAIDs (Ibuprofen®) and the Kinesio Taping® Method.

2.2 A Brief History of Tension-Type Headache

Headaches are one of the most common and difficult clinical conditions in medicine (Edwards and Bouchier, 1991), and of these, TTH has been found to be the most common (Rasmussen et al., 1991; Schwartz et al., 1998; Davies, 2000; Boon, Colledge and Walker, 2006). Eighty percent of headache patients who consult a doctor are diagnosed as suffering from TTH, (Dalessio 1987) with ETTHs being the more prevalent form (Schwartz, Stewart and Lipton, 1997) and thus it stands to reason that much of the literature regarding TTH is with regards to ETTH. Taking this into account, knowledge about the key pathophysiological issues such as the site and nature of this noxious stimulus is surprisingly limited because of prior lack of classification (Jensen and Olesen, 2000).

Mental stress and tension were the most frequently reported precipitants of TTH (Rasmussen, 1993; Ulrich, 1996) and thus according to Jensen and Olesen (2000), many scientists did not try to describe the pathophysiology and mechanisms behind the condition because they equated the stress and tension with the causative factors (e.g. muscular and vascular factors). Also, according to Jensen and Bendtsen (2006), most clinicians and patients in headache clinics tended to focus on the more severe headaches, usually cluster or migraine headaches, and so within clinical settings, TTH is often forgotten. According to Jensen and Bendtsen (2006) recognition of TTH as a specific clinical or pathophysiological entity may be bothersome for the following reasons:

1. It is a “normal” featureless headache not easily classified,
2. Patients generally suffer to a lesser extent when TTHs are compared to other headache types and therefore pay less attention to these “less severe” headaches,
3. Specialists often overlook TTH as they are looking for more sinister pathology,
4. Many scientists overlook TTH as it is not easily classified and therefore researchable,
5. The pharmaceutical industry overlooks TTH as it has no aetiology at which to direct treatment.

In 1988 the International Headache Society (IHS) introduced new diagnostic criteria for the first time for headaches and craniofacial pain. TTH was the term designated to describe what was previously called “tension headache”, “muscle contraction headache”, “psychomyogenic headache”, and “stress headache”. The condition was clearly delineated and defined by the IHS classification and a distinction between an ETTH (which occurs less than 50% of all days) and a CTTH (which occurs 50% or more, and in most cases daily), was made. The condition was therefore defined, and this has now made scientific study possible in order to obtain research results that are useful worldwide (Jenson, 2003a).

2.3 Definition and Characteristics of Tension-Type Headache

According to Jensen (2003a), there is considerable variation in the frequency and duration of TTH from headaches that are rare, short-lasting episodes of discomfort, to frequent, long-lasting or even continuous disabling headaches. Jensen (2003a) states that when it is milder and less frequent, it is considered a nuisance, and is not regarded as a condition by the affected patients or doctors (Jensen, 2003a). However, when it is in its more frequent form, the TTH becomes distressing and socially disruptive, which is similar to other primary headaches like migraine or cluster headache (Jensen, 2003a). TTH can be described as being primarily in the forehead, temples, and back of the neck and head, although other locations may be involved and are usually bilateral (Diamond, 1999).

The International Headache Society (1991) subdivides TTH into ETTH and CTTH. It specifically defines ETTH as recurrent episodes of headache lasting from minutes to days where the pain is typically pressing or tightening in quality, of a mild or moderate intensity, bilateral in location and does not worsen with routine physical activity, with nausea being absent, but photophobia (light-sensitivity) or phonophobia (sound-sensitivity) being present occasionally. ETTH is further described by Bates (1995) as being generalised or localised to the back of the head and upper neck, or to the fronto-temporal area (Bates, 1995; Diamond, 1999).

2.4 Epidemiology of Tension-Type Headache

2.4.1 Incidence and Prevalence

As previously mentioned, TTH has been found to be the most common type of headache (Edwards and Bouchier, 1991; Rasmussen et al., 1991; Schwartz, Stewart and Lipton, 1997; Schwartz et al., 1998), with ETTH being the more prevalent form (Schwartz, Stewart and Lipton, 1997). Jensen (2003a), states that due to its prevalence levels, TTH has a greater socioeconomic impact than any other type of headache. Dalessio (1987) stated that eighty percent of headache patients who consult a doctor are diagnosed as suffering from TTH. Rasmussen et al. (1991) stated that up to 69% of men and as much as 88% of women experience TTH during their lifetime and Mueller (2002) in referencing this statistic, goes on to state that nearly 80% of the population will experience a TTH at some stage during their lifetime.

According to Martin (1993) 66%-83% of the population in developed countries are affected by TTH and according to Lavados (1998), TTH represent 72.3% of all headaches in Chile. In a meta-analysis by Jensen (2003a), the prevalence of TTH is rather uniform in various populations. Results from Pop, Gierveld, Karis and Tiedink (2002) found that in a Dutch manufacturing setting there was a prevalence rate of 34.5%; and in a population of medical students in Brazil, Bigal, Bigal, Betti, Bordini and

Speciali (2001) found that there was a prevalence rate of 32.1%. Furthermore, in a population based study in Denmark the lifetime prevalence of TTH was as high as 78%. However, it is noted that 59% of the patients had TTH one day of the month or less and did not need medical attention, and so cannot be regarded as true headache patients (Rasmussen et al., 1991). Nevertheless, 24% to 27% of the patients had TTH several times each month, 10% of the patients had TTH weekly (Rasmussen et al., 1991; Pryse-Phillips, Findlay, Tugwell, Edmeads, Murray and Nelson, 1992; Goebel, Peterson-Braun and Soyka, 1994; Lavados and Tenhamm, 1998; Schwartz et al., 1998; Castillio, Munoz, Guitera, and Pascual, 1999; Rasmussen, 1999; Cheung, 2000; Wang, Fuh, Lu, Liu, Hsu, Wang, and Liu, 2000).

Goebel, Peterson-Braun and Soyka (1994) reported that in an epidemiological study on headache distribution in Germany, 38.3% (1555) of 4061 Germans suffer from TTH, of which 67% (1042) fall into the ETTH category.

In conclusion, due to the prevalence levels of ETTH within TTH, and the socioeconomic impact of TTH, ETTH is an important topic of study in that more understanding is gained regarding this condition, and therefore measures can be undertaken to develop treatment strategies to limit this condition.

2.4.2 Male/Female Ratio

The TTH ratio between men and women is 4:5 indicating that women (46.9%) are only slightly more affected than men (42.3%) (Rasmussen et al., 1991; Goebel, Peterson-Braun and Soyka, 1994; Rasmussen, 1995; Schwartz et al., 1998). According to Rasmussen (1993, 1995), hormonal factors may possibly be responsible for the higher ratio in women and so menstruation may be the principle precipitant to an attack.

2.4.3 Genetic Predisposition

According to Davies (2000), a family history of TTH may be found in at least one first degree relative in TTH sufferers which may indicate a genetic predisposition.

2.4.4 Duration and Lifetime Consistency

Linet, Stewart, Celentano, Ziegler and Sprecher (1989) carried out an epidemiological study of headaches amongst young adults and adolescents. It was discovered that the average duration of the patient's most recent headache was 5.9 hours for males and 8.2 hours for females. King and Sharpley (1990), recorded that 47% of respondents questioned in a self reported questionnaire, indicated that the average headache (the study referred to TTH and migraine headache as the average headache) lasted less than 1 hour; 35,8% indicated 1-3 hours; 9.3% indicated 3-6 hours; 2.9% indicated 6-9 hours; 2.0% indicated 9-12 hours and 2.8% indicated more than 12 hours. In congruence with Linet et al. (1989), on average, females reported headaches of a greater duration than males (King and Sharpley, 1990).

Rasmussen et al. (1991) stated that up to 69% of men and as much as 88% of women experience TTH during their lifetime and Mueller (2002) in referencing this statistic, goes on to state that nearly 80% of the population will experience a TTH at some stage during their lifetime. In a later epidemiological study done by Rasmussen (1995), it was shown that, of those who suffered from TTH, 24% had TTH for 8-14 days a year, and 41% had TTH for more than 41 days per year.

2.4.5 Site and Quality

According to Raskin (1988), ETTH is bilateral 90% of the time, waxes and wanes with intensity throughout the day with no predilection for any cranial pattern and is usually described as dull, pressing or band-like. The site of the headache varies, with it frequently being reported over the forehead and temples or at the back of the head and

neck (Diamond, 1987). Similarly the IHS Classification committee (1991) also described the pain as a pressure or tightening sensation which is bilateral in location, steady and non-pulsating. More recently Mueller (2002) also described the pain as being a mild to moderate pressure-type pain, also usually bilateral and occurring in the occipital or frontal region or as a band around the head.

According to Kunkel (1991), tenderness and soreness of the scalp is also experienced during a TTH headache episode, and the patient may describe their scalp as feeling too tight, like swelling is occurring and is about to "explode". Furthermore, Kunkel (1991) reports that these patients may concurrently suffer from stiff, tight necks and with tightness in the trapezius, other upper back (e.g. rhomboid major) and suboccipital muscles (Davies, 2000).

2.4.6 Associated Symptoms

Kunkel (1991) stated dizziness, tiredness and fatigue commonly accompany TTH and anxiety may also be evident in persons with recent onset of TTH. Unlike migraine, in TTH there are no vascular disturbances such as any visual disturbances present and/or nausea and/or vomiting (Kunkel, 1991; Rasmussen, 1995).

2.4.7 Age

Diamond (1999) states that TTH can occur at any age, although it is more common in adulthood. Similarly, it was found in cross-sectional epidemiologic studies that the average age of onset is 25-30 years of age (Rasmussen et al., 1991; Goebel, Peterson-Braun and Soyka, 1994; Schwartz et al., 1998). The prevalence seems to peak between 30 and 39 years of age in both genders and then declines with increasing age which supports Dalessio's (1987) findings which also highlighted that TTH correlates to the time that individuals experience a stress increase in life (Dalessio, 1987). Mueller (2002) and Rasmussen (1995) go on to state that stress is undoubtedly the most common precipitating factor and that up to 80% of TTHs are triggered by stress.

2.5 Precipitants and Provoking Factors

According to Rasmussen (1995), precipitants, which are also called promoters or trigger factors, are those factors which on their own, or in combination with other endogenous or exogenous factors, induce headache attacks in susceptible individuals. Mueller (2002) states that the triggers of TTH are not always identifiable and consistent, but that multiple triggers may have the additive effect of lowering the threshold of headache activation.

In an older study by Rasmussen (1993) the results indicated that various precipitating factors such as stress and tension were the main contributing factors, followed by smoking, alcohol, weather changes, menstruation, certain foods and sexual activity. One or more of these were identified as triggers in 88% of the TTH group.

Torelli, Abribnani, Castellini, Lambru and Manzoni (2008), state that avoidance of triggers may lessen the severity and frequency of the attacks.

2.5.1 Stress and Mental Tension in TTH

According to Hatch, Schoenfeld, Boutros, Seleshi, Moore and Cyr-provost (1991), TTH patients are more prone to be mildly anxious and depressed compared to normal control patients and Diamond (1999) states that ETTH is a manifestation of the body's reaction to stress, anxiety, emotional conflicts, repressed hostility, depression or fatigue. Mueller (2002) and Rasmussen (1995) further state that stress is undoubtedly the most common precipitating factor with up to 80% of TTH triggered by stress due to the body being biochemically affected by emotions. Thus, muscle contraction (through the limbic/neuro-emotional system) can be elicited by mental stress alone. Bendtsen (2000) remarks, that it is "obvious" to the clinician that psychological stress is an aggravating factor of TTH and Torelli et al. (2008) indicate that stress, nervous tension, mental fatigue and prolonged attention and concentration are factors that may trigger headaches.

2.5.2 Smoking and alcohol consumption in TTH

In the context of addictive substances, 38% of females and 34% of males indicated that smoking aggravated their headaches, whilst 28% of females and 25% of males found alcohol to be a precipitant to their headaches (Rasmussen, 1993, 1995).

2.5.3 Head Trauma

TTH may be exacerbated or initiated by head trauma, even if it is a mild whiplash injury unassociated with a blow to the head or a loss of consciousness (Mueller, 2002).

2.5.4 Food and TTH

Regarding food, 5% of males and 11% of females were affected by various foods. There was no indication made as to the specific food types in question (Rasmussen, 1993).

2.5.5 Climatic Changes and TTH

Climatic changes affected 28% of females and 26% of males (Rasmussen, 1993, 1995).

2.5.6 Muscle Tension and Magnesium

According to Altura and Altura (2001), pain accompanying severe muscle-tension spasm is mediated by similar mediators as those found in TTH. Magnesium-deficiency promotes a release of these pain mediators and in TTH, approximately 40-50% of TTH sufferers have a magnesium-deficiency and so they are likely to experience pain resulting in a TTH presentation.

2.5.7 Menstruation and Pregnancy in TTH

In a study carried out by Rasmussen (1993), it was found that in women suffering from TTH with onset prior to 51 years of age, 39% reported that menstruation affected their headaches. In relation to the menstrual cycle, 71% stated that their headache prevalence was greater 1-2 days before their cycle, and 29% indicated that it was greater during their cycle. Additionally, 45% of all women said that of their headaches, more than 50% were menstrual related. Regarding women with TTH during pregnancy, 5% stated that their headache worsened, 28% stated that it disappeared or improved, but for 67%, the headaches remained unchanged.

2.5.8 Sexual Activity in TTH

Sexual activity aggravated TTH in 2% of males and 3% of females (Rasmussen, 1993).

2.5.9 Physical Activity in TTH

In the study done by Rasmussen (1993), the level of activity was divided into sedentary; moderate activity, active and heavy work/competitive sport. In this context, 33% of males and 33% of females in the “sedentary” group reported aggravation of their headache by activity, whereas 28% of females and 14% of males in the “moderate activity” and “active” reported that their headaches were made worse by activity. Finally 40% of females and 23% of males in the “heavy work/competitive category” indicated that activity worsened their headache (Rasmussen, 1993). These results are unexpected due to the results contrasting with the IHS (1991) diagnostic criteria which states that ETTH should not be aggravated by exercise.

2.5.10 Temporomandibular Joint

Mueller (2002) points out that disturbances in mastication (chewing), grinding and clenching of teeth or abnormal mouth closure may result in aggravation of TTH (Mueller, 2002).

2.5.11 Sleep Pattern in TTH

In another study done by Rasmussen (1995), irregular sleep patterns were also found to be positively associated with TTH. Among TTH respondents, 41% of females and 24% of males experienced sleeping problems. Among TTH sufferers, the usual onset of attacks occurred in 1% at night, 11% in the morning, 49% during the day, 6% in the evening and 33% varied in onset (Rasmussen, 1995).

2.5.12 Congestion

Mueller (2002) states that sinusitis from allergic or structural turbinate (nasal septum) congestion may initiate, aggravate or perpetuate TTH.

2.6 Pathophysiology

As a result of the varying factors associated with the development of TTH, the pathogenesis is believed, by most, to be multi-factorial and includes muscular, vascular and psychological (stress, anxiety and depression) factors as well as cervical spine dysfunction although the exact aetiology remains unknown (IHS, 1991; Kabe, Tezuka, Nagazumi and Terashi 1991; Kunkel, 1991; Olesen, 1991; Schoenen et al., 1991; Bogduk, 1992, Rasmussen, 1992, Vernon, Steiman, and Hagino, 1992; Bernat and Vincent, 1993; Rasmussen, 1993; Rasmussen, 1995; Ulrich, 1996; Jensen, 1999; Bendtsen, 2000; Jensen and Olesen, 2000).

Research has debated for the last two decades whether TTH pain originates from the myofascial tissues or from the central mechanisms within the brain (Olesen, 1991; Schoenen et al., 1991; Jensen, 1999; Bendtsen, 2000). The pain clinically resembles pain from myofascial tissues but modern pain physiology indicates that both central and peripheral mechanisms may contribute to the production of pain associated with TTHs (Jensen and Olesen, 2000).

2.6.1 Peripheral Mechanisms

2.6.1.1 Vascular Factors

Bare and Lieou, as cited by Vernon, Steiman and Hagino (1992), were the first to implicate a vascular factor as a possible cause of TTH, and they stated that the irritation of the sympathetic system (nervous system) of the cervical region was linked to vascular disturbances, which was primarily a disturbance of the vasomotor (neurovascular) tone in the distribution of the vertebral artery.

Bogduk, as cited by Vernon, Steiman, and Hagino (1992) held a similar belief. He noted that mechanical irritation of the vertebral artery, vertebral nerve and ascending sympathetic chain could cause an “autonomic barrage” (excessive stimulation of the nervous system) that is great enough to cause cerebral (an area within the brain) vasospasm (blood vessel spasm). Additionally, he believed that cervical facet (joint surface) joint dysfunction may compromise these or similar structures and that this mechanical derangement of the cervical facet and craniocervical synovial joints ultimately leads to the headache.

In thermographic studies completed by Kabe et al. (1991) on TTH patients, it was reported that there was a possibility of pathological vasodilatory mechanisms occurring in patients with TTHs of less than 6 months presentation since high temperatures were measured in the painful pericranial areas. Patients who presented with TTH for longer than 6 months, however, had low temperature readings in the same areas and there

appeared to be a change in the sympathetic nerve regulation by some reflex or psychogenic mechanisms to enable this (Kabe et al., 1991).

According to Bernat and Vincent (1993) the result of malfunction, displacement or encroachment of pain-sensitive structures, is that the headache may also originate from various sources within the cranium. These structures are mostly vascular and include the proximal portions of the cerebral arteries, venous sinuses and large veins. In addition, the meninges (coverings of the brain and spinal cord), scalp and neck muscles and the upper cervical nerve roots may also be involved as the cause of TTH.

2.6.1.2 Psychological factors

Research has found that stress and tension are reported to be the most frequent perpetuating factors of TTH among the commonly associated psychological factors (e.g. depression, anxiety and repressed hostility) (Jensen, 1999; Rasmussen, 1995). According to Jensen (2003b) TTH is generally reported to occur in relation to emotional conflict and psychosocial stress. Diamond (1999) states that ETTH is a manifestation of the body's reaction to stress, anxiety, emotional conflicts, repressed hostility, depression or fatigue. It must be noted that according to Rasmussen (1993) and Ulrich, Russell, Jensen and Olesen (1996), mental tension and stress are not only reported in TTH, but they are repeated just as frequently in migraine. Torelli et al. (2008) indicate that stress, nervous tension, mental fatigue and prolonged attention and concentration are factors that may trigger headaches.

Kunkel (1991) believes that depression is quite common in patients with TTH and states that the majority of patients having TTH showed raised depression scores on Minnesota Multiphasic Personality Inventory (MMPI) testing. This concurs with Bernat and Vincent (1993), who indicate that depression may be the cause of the TTH in as much as 85% of patients.

Similarly, in a study done by Hatch et al. (1991), a battery of psychometric tests were done on 47 ETTH patients, and to 47 headache free controls. The tests that were administered included the Cook Medley Hostility scale, MMPI, Anger Expression Scale, State-Trait Personality Inventory, the Depression Adjective Check lists, and the Beck Depression Inventory. Compared to the control patients, the results indicated that ETTH patients showed a greater level of anxiety, depression, anger and hostility. They were also more prone to feelings of mistrust, suspicion, resentment and antagonism in their interpersonal relationships. The ETTH patients also showed greater levels of suppressed anger than the controls. [Hatch et al., 1991]

2.6.1.3 Cervical Joint Dysfunction

According to Bogduk (1992), upper cervical synovial joint dysfunction may play a role in the source of headache. According to Boline (1995), as cited by Redwood and Cleveland (2003), spinal manipulation resulted in improvements of the tension headaches.

2.6.1.4 Muscular Factors

Jensen (1995) reported that within TTH, myofascial pain has been considered as an important source of nociception by some. In this study, it was reported that the pericranial musculature of those suffering from TTH are more tender than healthy patients and for the first time, it was shown that during the headache phase, tenderness of musculature increased. Jensen (1988) did a study in which it was stated that pericranial tenderness was increased in both ETTH sufferers and in CTTH sufferers, and that in ETTH patients with a disorder of the pericranial muscles, the most likely mechanism is a slightly increased input from the myofascial nociceptors (muscle and connective tissue pain receptors).

The traditional link between various cervical musculoskeletal abnormalities has been TTH and cervicogenic headaches (Dawn, Scharff, Mercer and Turk, 1999). Patients

suffering with TTH tend to relate their headaches to increased muscle stiffness in the neck and shoulders (Jensen, 1999).

The most pronounced and consistent finding in TTH is the increased tenderness probably representing the activation of the peripheral nociceptors (Langemark and Olesen, 1987; Schoenen et al., 1991; Jensen, Rasmussen, Pedersen and Olesen, 1993; Jensen, 1999; Bendtsen, 2000). Similarities between TTH and migraine have been discovered and this has led to the study of cervical abnormalities in migraine sufferers as well (Blau and MacGregor, 1994; Pritchard, 1995). The results of studies such as these have suggested that approximately 70% of patients with TTH or migraine reported that they have muscular tenderness and tightness (Langemark and Olesen, 1987; Lebbink, Spierings and Messinger, 1991; Jensen and Rasmussen, 1996). Lipchik, Holroyd, Talbot and Greer (1997) reported that there were significantly higher levels of pericranial tenderness in both TTH and migraine headache sufferers compared to a control group, with no significant differences between the two headache groups. According to Jensen (1999), pericranial muscles show significantly higher levels of tenderness in patients with TTH than in those with migraines and those who are headache free. Furthermore, Jensen (2003b) indicates that with increasing frequency and intensity of TTH, there is an increase in tenderness and this is the crucial factor in the understanding of the pathophysiology of TTH.

The role of pericranial muscle tenderness in TTH is supported by the fact that in patients with TTH or migraine, the frontalis and cervical musculature show increased electromyographic activity (Langemark and Olesen, 1987; Lebbink, Spierings and Messinger, 1991; Lichstein, Fischer, Eakin, Amberson, Bertorini and Hoon, 1991). In a study done by Mercer, Marcus and Nash (1993), over 25% of patients had trigger points located in the levator scapulae, rhomboid and upper trapezius muscle.

Even though Dawn et al. (1999), contradicts this by stating that muscular abnormalities are frequently seen in pain free controls, Jensen and Olesen (2000), propose that what has been presented is that myofascial tenderness can precede the headache and is

therefore very likely to be involved in the underlying mechanism of the headache production.

Oksanen, Poyhonen, Metsahonkala, Anttila, Hiekkanen, Laimi and Salminen (2007), indicated that there is a change in muscle recruitment patterns in patients with ETTH. This is thought to be as a result of neck extensor (muscles causing backward movement of the neck) hypertonicity (increase in muscle tone), resulting in concomitant neck flexor (muscles causing forward movement of the neck) fatigability (tiring out) with resultant postural changes which predisposes to ETTH. These findings expand on the earlier findings of Jensen (1995), and Ashina, Bendtsen, Jensen, Lassen, Sakai, and Olesen, (1999a), where they found that of the mechanical and pain thresholds measured, tenderness only significantly increased between TTH (ETTH and CTTH) and normal age matched controls in the extensor muscles (trapezius muscle in particular (Fernandez-de-las-Penas et al., (2007)) and pericranial muscles.

Mongini, Ciccone, Deregibus, Ferrero and Mongini (2004) indicated that general cervical muscle tenderness and tightness was more highly associated with ETTH and pericranial muscle tenderness and tightness was more highly associated with CTTH. Ashina et al. (1999a) also indicated that the muscles of the ETTH and CTTH patients had permanently altered muscle hardness and tenderness in a blind, crossover designed trial where the effect of a NOS inhibitor on muscle hardness and tenderness was measured. Karst, Rollnik, Fink, Reinhard and Piepenbrock (2000) agreed with the findings of Ashina et al. (1999a) when they compared an active to a placebo intervention with needle acupuncture. Giacomini, Alessandrini, Evangelista, Napolitano, Lanciani and Camaioni (2004), was able to link the muscle tenderness to muscle inefficiency, postural changes and finally long term proprioceptive changes in TTH patients.

According to Moerk, Ashina, Bendtsen, Olesen and Jensen (2001), local experimental pain models have been done in which different algogenic substances were injected into the trapezius muscle, it was shown that patients with a history of ETTH develop

significantly more local pain than healthy controls, but that none of these groups developed headaches. Thus, an effect of either spatial or temporal summation of peripheral stimuli or both in predisposed individuals may therefore be the underlying pain mechanisms for TTH (Jensen, 2003b).

Pericranial, shoulder and masticatory muscle texture is also often altered in TTH, with generalized increased consistency. These findings have only been detected by manual palpation in the past but a hardness meter (a device used to measure muscle hardness), has confirmed this observation (Sakai, Ebihara, Akiyama and Horikawa, 1995; Ashina, Bendtsen, Jensen, Sakai and Olesen, 1998; Ashina et al., 1999a). But according to Jensen (2003b), the pathophysiological significance and background of these findings has not yet been clarified.

In a study done at a university headache clinic by Mercer, Marcus and Nash (1993), the presence of both muscular and joint pathology was assessed in 90 consecutive chronic headache sufferers. Of these, a primary diagnosis of TTH was diagnosed in 11 patients, migraine in 39 patients, and a combination of these two in 9 of these patients. Other headache diagnoses were assigned to 31 patients that included drug rebound, posttraumatic or cluster headache. Active (a trigger point that causes a clinical pain complaint (Simons, Travell and Simons, 1999)) or latent (“a trigger point that is clinically quiescent with respect to spontaneous pain” (Simons, Travell and Simons, 1999) myofascial trigger points were identified in the neck of 77%, shoulder of 51% and in the head of 6.7% of these patients. All patients who had active myofascial trigger points also had latent myofascial trigger points. Active myofascial trigger points were recorded in 9% of those with TTH, 15% of those with migraine, 22% with a combination of those two and 32% of those with the other diagnoses. In more than 25% of the same patients, trigger points were located in the rhomboid, levator scapulae and upper trapezius muscles.

Thus, as discussed where, and according to Langemark and Olesen, (1987) Lebbink, Spierings and Messinger, (1991) Jensen and Rasmussen, (1996) and Fernandez-de-

las-Penas et al. (2007), and from the definition of the IHS (1991:20), it is noted that soft tissues (e.g. muscles) are a cause of ETTH. It thus stands to reason that the treatment of the associated soft tissue component is indicated (Vernon, 1995), as a result of the peripheral mechanisms.

2.6.2 Central Mechanisms

Jensen (1995) states that myofascial pain has been considered an important source of nociception, however, it was also reported that some favour central pain processing alterations. It was stated that these result in a state of hypersensitivity to stimuli arriving from myofascial and other cephalic tissues. To this end, Jensen's (1995) findings revealed an increase in pericranial muscle tenderness indicating central or peripheral sensitization of myofascial nociception. Pain tolerances in the healthy individuals were normal which indicates that central changes are probably reversibly linked to the headache pain in ETTH whereas a more permanent pain condition (CTTH) involving central or peripheral sensitization of myofascial nociception may, however, be induced by more frequent nociceptive activation.

According to Bendtsen (2000), the likelihood of the importance of central mechanisms in TTH is far greater than previously anticipated. According to Schoenen, Jamart, Gerard, Lenarduzzi, and Delwaide (1987), and Wang and Schoenen (1994), brainstem involvement through limbic pathways was previously suggested due to exteroceptive measurements taken. This may help to provide information about the central mechanisms but the applied methodology has been challenged, and negative studies have recently been published (Zwart and Sand, 1995; Bendtsen, Jensen and Olesen, 1996). Changes in central processing of sensory information are also likely contributors and this is supported by the decreased threshold to pain observed during thermal and electric stimulation in CTTH patients (Bendtsen, Jensen and Olesen, 1996).

A defect in the production of neurotransmitters (chemical messengers) or the opioid system (chemical messengers) has also been suspected as the nociceptive flexor reflex

(a spinally organised reflex) is decreased in CTTH (Langemark, Bach, Jensen, and Olesen, 1993). No recent studies have, however, been found to confirm these findings (Jensen and Olesen, 2000). According to Jensen and Olesen (2000), endorphin (chemical messengers) and neuropeptide (chemical messengers) studies in these patients, have been found mainly to be negative (Bach, Langemark, Secher and Olesen, 1992; Ashina et al., 1999) and only one former study (Langemark, Bach, Ekman and Olesen, 1995) had noted increased metenkephalin (chemical messengers) in the cerebrospinal fluid (fluid surrounding brain and spinal cord). The primary eliciting cause and the evolution of pain are still unknown but these various abnormalities may result in or be a function of the disturbed balance between peripheral input and central modulation (Jensen and Olesen, 2000).

Generally emotional conflict and psychosocial stress are reported to occur in relation to TTH but the cause-effect relationship is not clear (Jensen and Olesen, 2000). Stress and mental tension were the precipitating factors most frequently reported but they occurred with similar frequency in TTH and migraine (Rasmussen, 1993; Ulrich et al., 1996). According to Jensen and Olesen (2000) this corresponds with the findings of widely normal personality profile in individuals with ETTH. However, studies of patients with CTTH often reveal a higher frequency of depression and anxiety (Rasmussen, 1992; Holroyd, France, Nash and Hursey, 1993; Mitsikostas and Thomas, 1999).

According to Jensen (2003b), the underlying pain mechanisms in TTH are highly dynamic because TTH represents a wide variety of intensity and frequency not only between the individuals but also within the subject over time. His study highlighted that mental stress, motor (muscular) stress, a local myofascial release of irritants, or a combination of these may all be initiating substances. Furthermore, the supraspinal pain perception structures may become activated secondary to the peripheral stimuli and because of the central modulation of the incoming stimuli, a self-limiting process will be the result in most cases. An effective prevention of the evolution from a peripheral mechanism in ETTH to a central mechanism in CTTH will be of major importance in

future treatment strategies as CTTH usually evolves from the episodic form (Jensen, 2003b).

2.7 Diagnosis

Jensen and Olesen (2000), assert that an accurate diagnosis of TTH is essential as this distinguishes it from migraine or a secondary headache. Most patients with daily headaches may mimic TTH, migraine headache and medication overuse headache (overuse of analgesics and migraine headache-specific drugs) at the same time, and so a precise diagnosis at the initial consultation can be difficult to give (Jensen, 2003a).

The IHS (1988, 1991) Operational Diagnostic criteria for ETTH are as follows:

A. "At least 10 previous headache episodes fulfilling criteria B through to D listed below. Number of days with such a headache less than 180/year (less than 15/month).
B. Headache lasting from 30 minutes to 7 days.
C. At least 2 of the following pain characteristics:
    1. Pressing or tightening quality,
    2. Mild or moderate intensity (may inhibit, but does not prohibit activities),
    3. Bilateral location,
    4. No aggravation by walking stairs or similar routine physical activity,
D. Both of the following:
    1. No nausea or vomiting (anorexia may occur),
    2. Photophobia and phonophobia are absent, or one but not the other is present,
E. At least one of the following:
    1. History, physical and neurological examinations do not suggest one of the Following:
        a. Trauma,
        b. Vascular conditions,
        c. Non-vascular intracranial conditions,

d. Substances or their withdrawal e.g. drug abuse,
e. Non-cephalic infection,
f. Metabolic condition,
g. Conditions of the cranium, neck, eyes, nose, sinuses, teeth, mouth or other facial or cranial structures,

2. History and/or physical and/or neurological examinations do suggest such a condition, but it is ruled out by appropriate investigations.

3. Such a disorder is present, but tension-type headache does not occur for the first time in close temporal relation to the disorder."

Two subtypes of ETTH are proposed by the IHS (1991). "The first is ETTH "associated with disorder of pericranial muscles", and the second subtype is ETTH "unassociated with disorder of pericranial muscles." No specification is given by the IHS (1991) for pericranial muscles.

a) ETTH associated with *a disorder of pericranial muscles.*

This was previously termed "muscle contraction headache" and is defined as ETTH with increased levels of tenderness and/or electro myographic activity (EMG) activity of the pericranial muscles. The diagnostic criteria for this subtype fulfils all of the criteria listed above for ETTH, with the addition of the following two findings:

1. Increased tenderness of pericranial muscles demonstrated by manual palpation or pressure algometer,
2. Increased EMG level of pericranial muscles at rest or during physiological tests,

b) ETTH unassociated with *a disorder of pericranial muscles.*

Previously termed “Idiopathic headache, essential headache and psychogenic headache,” it is defined as ETTH with normal levels of tenderness and/or EMG of pericranial muscles. The diagnostic criteria for this subtype of headache fulfil all of the criteria listed above for ETTH with the addition of the following finding:

1. No increased tenderness of the pericranial muscles. If studied, EMG of pericranial muscles shows normal levels of activity.”

Headaches can only be diagnosed by subjective information received from the patient, and thus it is essential that the criteria for diagnosing the headaches be reproducible and consistent (Leone, D’Amico, Farinotti and Bussone, 1994).”

Leone et al., (1994) assessed the reliability of the first set of diagnostic criteria set aside by the IHS (1988) for the different headache conditions. One hundred consecutive out-patients clinical records were evaluated by two neurologists who transferred data about the headache and associated phenomena to a form reflecting the IHS (1988) criteria. The results indicated that the diagnostic criteria are satisfactorily applicable to high quality medical records with the inter-observer concordance of kappa values = 0.81 for ETTH and thus it is a scientifically acceptable set of diagnostic criteria.

2.8 Treatment

There is no selective, specific treatment as a result of a lack of pathophysiological knowledge (Jensen and Olesen, 2000). The treatment strategy at present is largely empirical and can be divided into prevention, treatment and prophylaxis of the acute episode (Mathew and Bendtsen, 2000; Mathew and Schoenen, 2000).

2.8.1 Prevention

Jensen and Olesen (2000) assert that prevention consists of elimination of possible triggers like dental pathology, sinus disease, unhealthy working conditions, improvement of posture, inadequate sleep and unbalanced meals. They also state that stress management and an analysis of psychological triggers or depressive conditions may also be of value to reducing symptoms (Jensen and Olesen, 2000).

2.8.2 Pharmacological treatment

Jensen and Olesen (2000), propose that pharmacological treatment of an acute episode is effective with the use of over the counter (OTC) analgesics, NSAIDs or muscle relaxants. This supports Diamond's (1999) findings indicating that ETTH often responds to treatment with OTC medications which supports studies (Rasmussen, Jensen and Olesen, 1992; Forward, McGrath, MacKinnon, Brown, Swann and Currie, 1998) highlighting that due to the lack of specific and effective treatment for TTHs, OTC drugs are used more often in the treatment of TTH. This is confirmed by Jensen (2003a), who says that aspirin and paracetamol usually cause symptomatic relief in those suffering from ETTH.

Also, Katsarava et al. (2001) states that the intake of analgesics for more than 10 days each month may actually worsen the headache due to medication overuse. This is supported by Jensen (2003a), who says that patients usually seek the help of many doctors and end up spending large amounts of money on alternative treatments. The headache sufferers however still end up having to live a large portion of their lives with the headache and without effective pain relief.

Diamond (1999), indicates that aspirin is still used to treat ETTH but has mostly been replaced by other NSAIDs that offer increased tolerability and efficacy (e.g. ibuprofen®, ketoprofen and naproxen sodium). In fact, unless contraindicated (e.g. patients with peptic ulcer condition or hypersensitivity to aspirin), NSAIDs are often the most effective

treatment for ETTH (Diamond, 1999). Diamond (1983) did a study which revealed that Ibuprofen® effectively relieved ETTH pain. Ibuprofen® is available generically as an OTC NSAID and when it is used in doses of 400mg to 800mg it is highly effective (note that the 400mg dose is better tolerated) (Diamond, 1983). It must be noted that Jensen and Olesen (2000) however state that the use of NSAIDs has been poorly substantiated.

Although habituation is a risk, Diamond (1999) highlights that several combination products containing butalbital and aspirin or acetaminophen may also be effective in the treatment of TTH but the dosing instructions need to be followed closely to avoid habituation. As the number of individuals who develop CTTH from ETTH is unknown, the risk of potentiating the problem due to drug dependency should be carefully considered when prescribing these combination products as well as narcotic analgesics-like those containing propoxyphene or codeine.

Studies carried out by Diamond (1997) and Diamond (1999), found that combination products like those containing caffeine, aspirin and acetaminophen are often effective in the treatment of ETTH or a combination of caffeine and Ibuprofen® has also been shown to be effective (Diamond et al., 2000). But these findings highlighted that these agents should, however, be avoided in patients who have recurrent headaches with a frequency of greater than twice a week. Also, these findings indicated that beverages containing caffeine (e.g. coffee, caffeine containing fizzy drinks and tea), when used in excess, also often contributed to the TTH by causing rebound headaches when the caffeine is withdrawn.

In this study, as a result of simple analgesics and NSAIDs being the mainstay in the treatment of TTH (Jensen and Olesen, 2000), and NSAIDs often being the most effective treatment for ETTH unless contraindicated (Diamond, 1999), Ibuprofen® was chosen as the drug of choice for this study.

2.9 Kinesio Taping® Method

2.9.1 Introduction to Kinesio® Tex Tape

A Japanese chiropractor, Kase, developed Kinesio® Tex Tape and the method used in it's application, namely the Kinesio Taping® Method (Friedman, 2007a). He searched for a healing technique which helped the body to heal traumatized tissue. Unlike normal athletic tape, he wanted to develop something which was similar to the elasticity of the skin or the muscles. This Kinesio ® Tex Tape received worldwide exposure when it was used at the Seoul Olympics by Japanese athletes. This technique then spread to the United States and then to the 2004 Olympic Games in Athens where it was used extensively to treat the athletes (Friedman, 2007a). Since then, its use has greatly increased notwithstanding limited research into its use.

2.9.2 Kinesio Taping® Method Concepts

Kinesio® Tex Tape has an elasticity of 130-140% of its original length which enables normal muscle stretch with its application. This is important as the proposed philosophy behind the Kinesio Taping® Method is that it allows free range of motion which allows the body's muscular system to heal itself biomechanically (Friedman, 2007a).

Friedman (2007a) states that muscles are contracting and stretching continuously within a normal range, however when a muscle over-extends or over contracts, it leads to trauma of the muscle tissue, and thus an inflammatory response results. This causes an influx of inflammatory fluid and thus a resultant increase in pressure resulting in restriction to the flow of lymphatics in the area. This pressure stimulates the subcutaneous pain receptors resulting in impulses to the brain, and a resultant discomfort. The perceived pain is known as myalgia or muscle pain.

The four major functions and effects of Kinesio ® Tex Tape have been identified as (Friedman, 2007a),

- Normalization of muscle function,
- Improvement of lymphatic and blood flow,
- Pain reduction and management and
- Correction of the posture.

Friedman (2007a) states that the alleviation of pain is thought to be affected by a shortening of the muscle, caused by inflammation in overused muscles. This is thought to decrease the stimulation of the neural and sensory fibres and thus decrease pain (Melzack and Wall, 1965). Muscle function is thought to be normalised through the support offered by this therapeutic method, decreasing the need for muscle hypertonicity and allowing for normalisation of function and posture (Friedman, 2007a).
According to a study done by Yasukawa, Patel and Sisung (2006), the Kinesio Taping® Method resulted in improved functional status of the upper limb in children receiving rehabilitative treatment as measured by the Melbourne Assessment. The alleviation of oedema due to the inflammation is achieved in that the Kinesio ® Tex Tape forms convolutions in the skin which increases the interstitial space facilitating lymphatic flow and oedema resolution.

Dvorak (1985), Gatterman and Goe (1990) and Mense (1991) models as referenced by Leach (2004) are also a possible explanation for the treatment effects of the Kinesio Taping® Method. It was indicated that inflammation is the cause of muscle pain, joint pain, and joint dysfunction (subluxation). Resolution of this will result in alleviation of symptoms. The Kinesio Taping® Method not only helps to facilitate oedema resolution by raising the skin enabling lymphatic drainage (Friedman, 2007a), but also helps to restore muscle function resulting in increased joint movement and muscle movement and thus further resolution of the inflammatory oedema through a mechanical effect. Kinesio® Tex Tape may also help to reduce pain due to its proprioceptive effect through stimulation of the large pressure and touch nerve fibres, thus overriding the small pain nerve fibres (Gate-Control Theory) (Melzack and Wall, 1965).

2.9.3 Principles regarding the Kinesio Taping® Method

When a muscle is weakened, the basic principle regarding the Kinesio Taping® Method is to wrap the Kinesio® Tex Tape around the affected muscle. Start taping from the muscles origin (closest to axial skeleton) to its insertion (closest to appendicular skeleton) whilst stretching the Kinesio® Tex Tape to 25-50% of its available tension) (Kase, Wallis and Kase, 2003). This technique is used typically for supportive purposes, which supports the muscle contraction by pulling and stimulating the skin back to the point of origin (Friedman, 2007a).

The basic principle to prevent over-contraction (muscle over-use) or cramping is that the Kinesio® Tex Tape is applied vice-versa or from insertion to origin whilst stretching the it to 15-25% of its available tension (Kase, Wallis and Kase, 2003). This application is typically used for acute conditions like sprain or strain, muscle spasm, oedema from injury or surgical procedures. As the muscle fibres contract, the Kinesio® Tex Tape will relax the muscle (Friedman, 2007a).

In this regard, the Kinesio Taping® Method is considered an easy-to-use modality which allows the patient to receive the therapeutic benefits for 24 hours per day for several days.

It was proposed that Kinesio® Tex Tape will be used in the treatment of the muscular component namely the upper and middle trapezius (Fernandez-de-las-Penas et al., 2007; Friedman, 2007b) and the rhomboid musculature (Friedman, 2007b; Mercer, Marcus and Nash, 1993).

2.9.4 Properties of Kinesio® Tex Tape

Kinesio® Tex Tape is made up of polymer elastic strands which have 100% cotton fibres wrapped around them. It has been designed to stretch lengthways only and this is 55-60% of its resting length which is similar to the elastic qualities of the human skin.

The elastic qualities of the Kinesio® Tex Tape are effective for 3-5 days as the elastic polymers diminish after this. The cotton is important as it allows for evaporation of body moisture and it allows for quick drying (Kase, Wallis and Kase, 2003; Kinesio Taping® in Canada, 2004).

The Kinesio® Tex Tape thickness is designed in that it's approximately the same as the epidermis (outer layer) of the skin. This limits the body's perception of weight and serves to avoid sensory stimuli when applied correctly. Generally after about 10 minutes, the patient will hardly notice that there is Kinesio® Tex Tape on the skin. The adhesive in the Kinesio® Tex Tape is 100% acrylic and is activated by heat and so becomes more adherent, the longer the tape is worn. The acrylic is applied in a wave-like pattern which is meant to mimic the fingerprints of the skin which causes lifting of the skin as well as areas in the Kinesio® Tex Tape from which moisture can escape. It is important to note that the skin needs to be free of moisture or oils before application and that there is no latex in the Kinesio® Tex Tape (Kase, Wallis and Kase, 2003).

On removal of Kinesio® Tex Tape from the skin, there is no residual glue left, which normally allows for multiple Kinesio Taping® Method applications without skin irritation. If a patient has sensitive skin, a small strip of the Kinesio® Tex Tape should be applied to the skin to determine what the patients' response is, prior to its therapeutic use (Kase, Wallis and Kase, 2003).
Its capability to stretch, its thickness and its adhesion combination, are what gives the Kinesio® Tex Tape its skin like properties. The design of Kinesio® Tex Tape, together with the unique application creates the Kinesio Taping® Method (Kase, Wallis and Kase, 2003).

The Kinesio Taping® Method success is thought to be determined by 2 factors: There needs to be proper evaluation of the condition of the patient to ensure that the Kinesio® Tex Tape is applied over the correct areas, and that the proper application of the Kinesio Taping® Method is performed (Kase, Wallis and Kase, 2003).

Notwithstanding contraindications to the above, there are still contraindications that need to be assessed for, and noted when Kinesio® Tex Tape is utilised. These include, but are not limited to:

- Open wounds, scars recently formed or skin that has been recently irradiated;
- Allergies to certain adhesives – to determine if an allergy exists, test a piece of Kinesio® Tex Tape, by applying it to the skin prior to its therapeutic application;
- Skin irritation (redness, rash, itchiness etc.).

2.9.5 Kinesio Taping® Method Testing

There are a number of tests that are used within the Kinesio Taping® Method to determine the areas of the musculo-skeletal system involved, as well as the method of treatment application. The tests relevant to ETTH are:

- Linder Test 1
- Bulge in an Artery Test
- Muscle Specification Tests : Upper and Middle Trapezius Muscle Strength Test and Rhomboid Major Muscle Strength Test

These are described in Chapter Three within the methodology.

2.10 Prognosis

The prognosis of TTHs has scarcely been analyzed and never with longitudinal epidemiologic research designs (Jensen, 2003a). A clinical 10 year follow up study of 62 patients showed that 75% (those patients with ETTH) continued to have ETTH, but 25 % had evolved to the chronic form of the headache. Out of those who initially had the chronic form, 31% continued with CTTHs, 21% had developed medication overuse and 48% (with or without prophylactic treatment) had reversed to the ETTH (Moerk, 2000). A poor outcome was predicted if the patients had depression, anxiety and if the patients were overusing medication (Jensen, 2003a). A former cross-sectional clinical study revealed that most patients with CTTH had evolved over a period of years from the episodic form (Langemark, Olesen, Poulsen and Bech, 1988). This confirmed numerous

pathophysiologic studies that showed that on the basis of peripheral and central sensitization of the pain system, a patient is at risk for suffering from chronic and treatment resistant forms of TTH if s/he suffers with frequent episodes of headache (Rasmussen, Jensen and Olesen, 1992; Ashina, Bendtsen, Jensen, Lassen, Sakai, and Olesen, 1999b; Bendtsen, 2000; Bendtsen, 2002;).

2.11 Impact of Tension-type Headache

The effect of TTH on an individual, besides physical suffering is a negative emotional effect resulting in a marked loss in quality of life and frequency of social and family activities, as well as a large socioeconomic effect on society greater than any other headache type (Mueller, 2002).

Jensen (2003a), states that TTH has a greater socioeconomic impact than any other type of headache due to its prevalence. Direct costs include social services and medical costs and indirect costs cause a loss of production in the economy as a result of morbidity with the loss of quality of life also being an intangible factor (Jensen, 2003a). The socioeconomic cost of patients with TTHs is great due to reduction in work capability and absenteeism (Jensen, 2003a). The total loss of work days each year due to TTH is 820 days per 1000 employees whereas with migraine headaches it is 270 days per 1000 employees per year (Rasmussen, Jensen and Olesen, 1992). More than 10% of the total population were absent in 1991 as a result of TTH (Rasmussen, Jensen and Olesen, 1992).

Another Danish population based study reported impaired or non-existent working capacities and social activities in 60% of the Danish population suffering from TTH (Rasmussen, Jensen and Olesen, 1992). Rasmussen (1995) states that work absence occurs in 12% of those suffering from TTH with 5-7 days being the most common number of days off work in a year. In a US study, decreased work effectiveness was caused by a large proportion of TTH sufferers (Schwartz, Stewart and Lipton, 1997). Bigal et al. (2001) did a study in Brazil, where a university student population showed a

profound impact of ETTH in productivity (44%), physical capacity (33%) and student performance (44%).

Regarding the financial cost of TTH, the direct costs caused by medical services and medications are scarcely analyzed as these headache patients seek less medical attention than patients suffering with migraine headache - 16% with TTH in comparison to 56% with migraine headache (Rasmussen, Jensen and Olesen, 1992). Similarly, consultation rates for TTH sufferers in Chile were 39% as opposed to 63% in those suffering with migraine headache (Rasmussen, Jensen and Olesen; 1992).

In conclusion, due to its high prevalence levels (Rasmussen et al., 1991; Edwards and Bouchier, 1991; Schwartz et al., 1998) and the wide spectrum of disability and incapacitance (e.g. work and socially related) it causes, Mueller (2002) states that TTH is the most important headache type regarding reduction of work productivity, socioeconomic impact and quality of life.

2.12 Conclusion

In conclusion, due to the fact that ETTH is such a common condition (Rasmussen et al., 1991; Schwartz et al., 1998; Schwartz et al., 1997; Boon,Colledge and Walker, 2006) and that there is no selective, specific treatment as a result of a lack of pathophysiological knowledge (Jensen and Olesen, 2000). A study was designed to evaluate two treatment techniques in order to evaluate their relative effectiveness. Thus NSAIDs and the Kinesio Taping® Method were compared using a prospective randomised clinical trial.

CHAPTER THREE: Methodology

3.1 Introduction

The methodology followed an experimental procedure, which is described within this chapter. This includes the methods used in obtaining the subjective clinical data from the study, as well as the methods used for statistical interpretation and presentation.

3.2 Materials and Method

3.2.1 The Data

The data collected for this study consisted of primary as well as secondary data.

3.2.1.1 The Primary Data

Primary data for inclusion into the study was obtained from a standardized case history (Appendix C), physical examination (Appendix D), cervical regional examination (Appendix E) according to the Durban University of Technology Chiropractic Day Clinic forms, as well as from Kinesio Taping® Method-related tests (Appendix J and K). Data of reported measures were obtained from subjective measures (viz. Headache Diary (Appendix G), NRS -101 Questionnaire (Appendix H), CMCC Neck Disability Index (Appendix I)).

3.2.1.2 The Secondary Data

The secondary data was required to explain and document the primary data by means of statistical analysis which was obtained from books, journals, periodical, lectures and websites.

3.3 Study Design and protocol

3.3.1 The Study Design

A prospective randomised clinical trial with two intervention groups aimed at determining the relative effectiveness of NSAID (Ibuprofen®) and the Kinesio Taping® Method in the treatment of ETTHs.

Based on this study design, this research was approved by the Faculty of Health Sciences Research and Ethics Committee (FHSEC 031/07)(Appendix Q) indicating that the research protocol satisfied the ethical requirements set out by the Faculty of Health Sciences Research and Ethics Committee for such studies. Furthermore, this approval indicates that the research protocol is in line with the Declaration of Helsinki, 1975 (Johnson, 2005).

3.3.2 Sampling and allocation of patients

3.3.2.1 Advertisements (Appendix L1, L2, L3):

This was done through advertisements being placed at the Durban University of Technology Chiropractic Day Clinic (Appendix L1), Durban University of Technology Campus (Appendix L1), and Durban University of Technology intranet (Appendix L2), flyers (Appendix L2), local newspapers (Appendix L3) and through word of mouth.

3.3.2.2 Sampling Technique:

A non-probability sampling technique (Esterhuizen, 2007) was used to attract patients. No bias to ethnicity, religion or socio-economic standing group was shown.
The study was limited to include patients between the age of 18 and 45.

3.3.2.3 Sampling size

The study was limited to 32 patients (16 per group).

3.3.2.4 Interview

All patients who responded to the advertisements were screened by telephonic or personal interview by the researcher. The following questions were asked:

1. Do you know if you have tension-type headaches?
2. Are you between the ages of 18 and 45?
3. Do you have recurrent episodes of headache lasting for minutes or days?
4. Are you receiving current treatment for your headaches?
5. Are you pregnant or, you have peptic ulcer condition. Do you suffer with haemorrhagic conditions, asthma, history of hypersensitivity reactions to aspirin or other anti-inflammatory drugs, hypertension, impaired renal, hepatic or cardiac function?
6. Are you on any medication, and if so what?
7. Are you able to be involved for the full duration of the research (i.e. 5 consultations over 3 weeks)?

3.3.2.5 Sampling allocation / Randomisation:

A group of 16 patients was allocated to each of 2 groups with the allocation of the patients to each group occurring only after their inclusion into the study had been ascertained by assessment of the patient's compliance with the inclusion and exclusion criteria. The allocation of patients to the two groups was completed by means of the patients, drawing a folded piece of paper out of an envelope. These pieces of paper had either NSAID, or KT written on the inside of the folded paper. Group one was only treated by giving them Ibuprofen®. Group two was only treated with the Kinesio Taping® Method over the relevant musculature (viz. the upper and middle trapezius and rhomboid musculature).

3.3.3 Inclusion and Exclusion Criteria of Patients

3.3.3.1 Inclusion Criteria

- According to the International Headache Society (Headache Classification Committee, 1988, 1991), the diagnostic requirements of ETTH are defined as follows:
    A. At least 10 previous headache episodes fulfilling criteria B-D listed below. Number of days with such a headache less than 180 per year (or less than 15 per month).
    B. Headache lasting from 30 minutes to 7 days.
    C. At least 2 of the following pain characteristics:
        - Pressing or tightening (non-pulsatile) quality,
        - Mild or moderate intensity (may inhibit but does not prohibit activities),
        - Bilateral location,
        - No aggravation by walking up or down stairs or similar routine physical activity,
    D. Both of the following:
        - No nausea or vomiting,
        - anorexia may occur,
        - Photophobia and phonophobia are absent, or one but not the other is present,

- All patients who received the Kinesio Taping® Method were required to present with weakness or pain (see 3.3.4.9.1 and 3.3.4.10.1) (Appendix J) in 1 or all of the following muscles: upper trapezius, upper and middle trapezius and rhomboid major (Friedman, 2007b). A positive Linder Test 1 (Appendix K) if the trapezius muscles were affected, and a positive “Bulge in an artery test” (Appendix K) if the rhomboid major muscle were affected (Friedman, 2007a), were required.

- All patients had to be between the ages of 18 to 45. Schwartz et al., (1998), found that the prevalence of ETTH peaked in the 30 to 39-year-old age group in both males (42.3%) and females (46.9%). Dalessio (1987) suggested that TTH is more commonly found in adults, which is about the time that individuals experience a stress increase in life.

- All patients received a letter of information (Appendix A) informing them about the study. They then had to read it and sign that they had understood the parameters of the study as per the Informed Consent Form (Appendix B).

3.3.3.2 Exclusion Criteria

- According to the International Headache Society (Headache Classification Committee, 1988, 1991), exclusion resulted if one of the following were present:
    1. History and physiological or neurological examinations that suggested one of the following:
        - Trauma,
        - Vascular conditions,
        - Non-vascular intracranial conditions,
        - Substances or their withdrawal (e.g. cigarettes),
        - Non-cephalic infection (e.g. malaria),
        - Metabolic conditions (e.g. diabetes mellitus), and
        - Conditions of the cranium, neck, eyes, nose, sinuses, teeth, mouth or other facial or cranial sutures.
    2. History and/or physical and/or neurological examinations that suggested such a condition, and required further appropriate investigation.
    3. If such a condition was present (as in 1), but TTH did not occur for the first time in close temporal relation to the condition.

- Any other treatment received or taken for the neck pain during the duration of the study resulted in the patient's exclusion (Seth, 1999).

- Patients were asked to refrain from taking any headache medication during the course of the study unless it was allocated to them. Those that were on medications for their headache before the course of the trial required a wash-out period of 3-7 days before being allowed to enter the study (Poul, West, Buchanan, Grahame, 1993). Patients who took routine medications, however, were allowed to continue with these, unless they were a contraindication to medication of the Ibuprofen® or would interfere with the results.

- Contraindications to NSAIDs (Ibuprofen®):
  Safety of Ibuprofen® in pregnant woman has not been demonstrated and Ibuprofen ® is contra-indicated during pregnancy and peptic ulceration (Sandoz, 1997) therefore patients that were pregnant or suspected that they were pregnant were excluded.

  Patients were excluded if the following precautions / relative contra-indications to NSAIDs (Ibuprofen ®) applied to them (Sandoz, 1997):

  1. Patients peptic ulceration and/or had a history of such conditions. Ibuprofen ® should be used with caution in patients with infections.
  2. "Patients with haemorrhagic conditions, asthma, a history of hypersensitivity reactions to aspirin or other NSAIDs, hypertension, impaired renal, hepatic or cardiac function" were excluded.
  3. "In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients," therefore these patients were excluded.

  If any of the following scenarios occurred where certain drugs are taken in conjunction with Ibuprofen®, then the patients would have been excluded

from the study due to the negative effects of these drug interactions (Sandoz, 1997):

1. Ibuprofen® may possibly enhance the effects of oral anticoagulants, phenytoin and sulphonylurea antidiabetics as well as cause convulsions due to interactions with quinolones.
2. “The anti-hypertensive effects of some antihypertensive agents including angiotensin-converting enzyme inhibitors, beta-blockers and diuretics may be reduced.”
3. “The risk of nephrotoxicity may be increased if given with angiotensin-converting enzyme inhibitors, cyclosporine or diuretics.”
4. “There may also be an increased risk of hyperkalemia with angiotensin-converting enzyme inhibitors and potassium-sparing diuretics.”
5. “The risk of gastrointestinal bleeding and ulceration is increased when used with corticosteroids.”
6. “Alcohol may increase the risk of gastrointestinal side-effects, including ulceration or haemorrhage.”
7. “The concomitant use of more than one NSAID should be avoided because of the increased risk of adverse effects.”

- Contraindications to Kinesio® Tex Tape include (North Star Therapeutics, n.d.):

1. Open wounds, scars recently formed or skin that has been recently irradiated
2. Allergies to certain adhesives.
3. Skin irritation (redness, rash, itchiness etc.) due to the Kinesio® Tex Tape, [remove it immediately if this occurs and discontinue the course of the treatment]

3.3.4 Clinical procedure

3.3.4.1 Telephonic/Personal Interview:

As potential patients responded to the adverts for this study, they were interviewed telephonically or in person and were asked questions in order to gauge the probability of their acceptance onto the research study. These questions are listed in Appendix M. If the potential participant was likely to fit into the study, the first appointment was scheduled.

3.3.4.2 Consultations

Once the patient had been received at the consultation, the assessment and treatment protocol were clearly explained to them. All patients that were included in the study were required to read through a Letter of Information (Appendix A) and fill in an Informed Consent Form (Appendix B).

A total of thirty two patients were evaluated at their initial consultation during which a case history (Appendix C), a physical examination (Appendix D), a cervical regional examination (Appendix E), trapezius and rhomboid muscle strength tests, a Linder Test and a Bulge in an Artery Test were performed (Appendix J). Screening for suitability of the study was done by applying the inclusion and exclusion criteria as described in 3.3.3.1 and 3.3.3.2. All patients were divided into two groups. In addition, feedback regarding his/her neck pain was obtained using: NRS – 101(Appendix H) for pain intensity, The CMCC Neck Disability Index (Appendix I) for resultant disability and a Headache Diary (Appendix G) for intensity, frequency, associated symptoms, duration and disability which was be completed at home daily.

The second consultation was conducted six or seven days after the initial consultation. The third consultation was conducted either three or four days after the second consultation. The fourth consultation occurred six or seven days after the second

consultation and the fifth consultation occurred seven days after the fourth consultation. The subjective measurements were obtained prior to the treatment. Those being treated using the Kinesio Taping® Method had new Kinesio® Tex Tape applied at the second consultation and third consultations. At the fourth consultation, the Kinesio® Tex Tape was removed from the patient. The fourth consultation was conducted fourteen days after the first appointment and the fifth consultation was conducted twenty one days after the initial consultation. Only feedback was obtained at the fourth and fifth consultations. Those participants in the Ibuprofen® Group started taking the Ibuprofen ® (a daily dose of 400mg) on the day of their second consultation, for seven days

For the purposes of this study, the Kinesio Taping® Method patients received two applications of Kinesio® Tex Tape for a total of seven days. Those receiving Ibuprofen ® medication received a daily dose of 400mg for seven days.

3.3.4.3 Screening Tests for application

Within the Kinesio Taping® Method, a system was developed involving 8 screening tests to examine the patients overall physical condition. Combining these screening tests with muscle tests enables the examiner to accurately determine where the problem is and to select the most appropriate treatment technique (Kase, Wallis and Kase, 2003). The tests significant to the muscles implicated in headache (Friedman, 2007b) are the Linder Test 1 and Bulge in an artery test (Friedman, 2007a).

3.3.4.4 Linder Test 1 (Friedman, 2007a)

This test aims to evaluate muscle and superficial fascia in the region of the upper back – particularly the trapezius.

The examiner lifted the patients head whilst flexing the chin towards the chest with the subject lying in a relaxed, supine position. A positive result was elicited when the subject felt tense or felt pain in the upper back or neck. The reason for this may be as a

result of increased muscle tension in the upper back muscles (especially the middle and upper trapezius muscles). If a positive result was obtained, the system moved to the most appropriate Muscle Specification test. In this study, we already know that the two muscles involved in ETTH are the upper and middle trapezius muscles as well as the rhomboid musculature (Friedman 2007a) and thus the Linder Test was done to determine fulfil the Kinesio Taping® Method protocol.

3.3.4.5 Bulge in an Artery Test (Friedman 2007a)

This test was done in the supine position. A bulge in an artery in the cephalic region (temporalis muscle posterior to lateral part eye) can be caused by muscular or vascular rigidity. People at risk of high blood experience many problems in the upper body. Blood pressure is usually measured by using a baumanometer (blood pressure monitor), but it is also possible to use the fingers to take the pulse. High blood pressure is a possibility if a rigid pulse is felt under the fingers in the temple area. This may indicate rhomboid muscle involvement.

In this study, we already know that the muscles involved in ETTH are the upper and middle trapezius muscles as well as the rhomboid major musculature (Friedman 2007b), and thus the Bulge in an Artery Test was done to fulfil the Kinesio Taping® Method protocol.

3.3.4.6 Skin preparation for application

The skin was cleaned before the application of the Kinesio® Tex Tape to ensure it was free of lotions and oils. Anything limiting the ability of the acrylic to adhere (including hair), would have limited both the length of time of the Kinesio® Tex Tapes adherence, as well as the degree to which the tape would have been effective (Kase, Wallis and Kase, 2003). Therefore it was ensured that the skin was clean and that the tape was applied only up to the hairline.

3.3.4.7 Application

Two factors that determined the success in the use of Kinesio® Tex Tape were the proper evaluation of the patient's condition to ensure that the Kinesio® Tex Tape application was over the correct areas, and the correct application of the Kinesio® Tex Tape using the Kinesio Taping® Method (Kase, Wallis and Kase, 2003).

In the application of the Kinesio® Tex Tape to a muscle, it is important to stretch the skin of the affected area. This is easily achieved by stretching the involved muscles and joints. When the affected area is taken from the stretched position to the normal position, convolutions will form as the skin is lifted off the subcutaneous tissue, due to shortening of the Kinesio® Tex Tape. It is thought that this then enables blood and lymphatic flow to improve. In the treatment of muscle pain, if the skin is not stretched the treatment is ineffective (Friedman, 2007a).

3.3.4.8 The Treatment

Group One was treated with Ibuprofen®. A pharmacist (Appendix R) distributed the Ibuprofen ® which was taken over 7 consecutive days at a dosage of 400mg daily (2x200mg tablets after meals-one in the morning and one in the evening). This was based on the premise that Ibuprofen ® is very effective when used in doses of 400 to 800mg and the lower the dose the better it is tolerated (Diamond, 1999).

Group Two was treated with Kinesio® Tex Tape, using the Kinesio Taping® Method. The Kinesio® Tex Tape has a durable 3-4 day wearing period (www.kinesiotape.ca, 2009) which avoids having to take the Kinesio® Tex Tape off and reapplying it every few hours as with traditional Kinesio® Tex Tape. The upper and lower trapezius and/or the rhomboid musculature had Kinesio® Tex Tape applied depending on the pain/weakness (see 3.3,4.9.1 and 3.3.4.10.1) experienced during the various muscle tests (Friedman, 2007a).

If at any stage, the Kinesio® Tex Tape came off, the patient was required to contact the researcher immediately for a reapplication of the Kinesio® Tex Tape to ensure standardization in the treatment protocol.

3.3.4.8.1 Ibuprofen® Treatment Protocol

Table 3.1 Treatment Protocol – Group 1

DAY OF CONSULTATION	WEEK	TREATMENT	DATA COLLECTION
1-7	Week 1	None	Headache Diary
8	Week 2	Ibuprofen ® medication	NRS-101, CMCC Neck Disabilty Index, Headache Diary
10/11		Ibuprofen ® medication	NRS-101, CMCC Neck Disabilty Index, Headache Diary
13/14		Ibuprofen ® medication	NRS-101, CMCC Neck Disabilty Index, Headache Diary
15-20	Week 3	None	Headache Diary
21		None	NRS-101, CMCC Neck Disabilty Index, Headache Diary

3.3.4.8.2 Kinesio Taping® Method Treatment Protocol

Table 3.2 Treatment Protocol – Group 2

DAY OF CONSULTATION	WEEK	TREATMENT	DATA COLLECTION
1-7	Week 1	None	Headache Diary
8	Week 2	Applied Kinesio® Tex Tape	NRS-101, CMCC Neck Disabilty Index, Headache Diary
10/11		Removed old Kinesio® Tex Tape and reapplied new Kinesio® Tex Tape	NRS-101, CMCC Neck Disabilty Index, Headache Diary
13/14		Removed old Kinesio® Tex Tape	NRS-101, CMCC Neck Disabilty Index, Headache Diary
15-20	Week 3	None	Headache Diary
21		None	NRS-101, CMCC Neck Disabilty Index, Headache Diary

3.3.4.9 Upper and Middle Trapezius Muscle

3.3.4.9.1 Muscle Test (Combined Method) (Friedman 2007a)

Of the tests used to assess the trapezius muscle strength in the study, the clinical test delineated by Friedman (2007a) was the seated trapezius muscle strength test. Whilst seated and performing ipsilateral (to the same side) and posterolateral (backward and to the side) neck extension (backward) with the face turned in the opposite direction, the patient elevated the acromial end of the clavicle (collar bone) and scapula (shoulder blade). This brought the occiput (back of the skull) to the raised shoulder. The only muscle to elevate the acromial end of the clavicle and scapula, and to rotate the scapula as it elevates, is the upper trapezius.

The examiner then applied downward pressure to move the shoulder into depression, as well as applying pressure against the head pushing it toward an anterolateral (forward and to the side) and flexed (forward) position.

3.3.4.9.2 Kinesio® Tex Tape Length (Friedman, 2007a)

The Kinesio® Tex Tape length was from the hairline at the base of the occiput to the acromium process of the patient.

3.3.4.9.3 Kinesio Taping® Method (Friedman, 2007a)

The patient was seated and the base of the Kinesio® Tex Tape was applied to the acromium process. They were then asked to laterally flex their neck and head to the contralateral (opposite) side, whilst looking down and away from the Kinesio® Tex Tape (combined cervical spine flexion and rotation). The base of the Kinesio® Tex Tape was then stabilized and downward pressure was applied to increase tissue tension. The superior “Y” tail was then applied to the hairline at the base of the occiput.

The patient was than asked to return the neck and head to a neutral starting position. The shoulder was placed into horizontal adduction with the patient's ipsilateral (same side) hand resting on the opposite shoulder. The examiner then placed his hand on the acromium process of the scapula and pulled the skin laterally and anteriorly while simultaneously passively internally rotating the glenohumeral (shoulder) joint. This caused tissue stretch to the underlying fascia and skin of the middle trapezius. The inferior "Y" tail was then applied to the spinous process of the 5th thoracic vertebra, along the spine of the scapula.

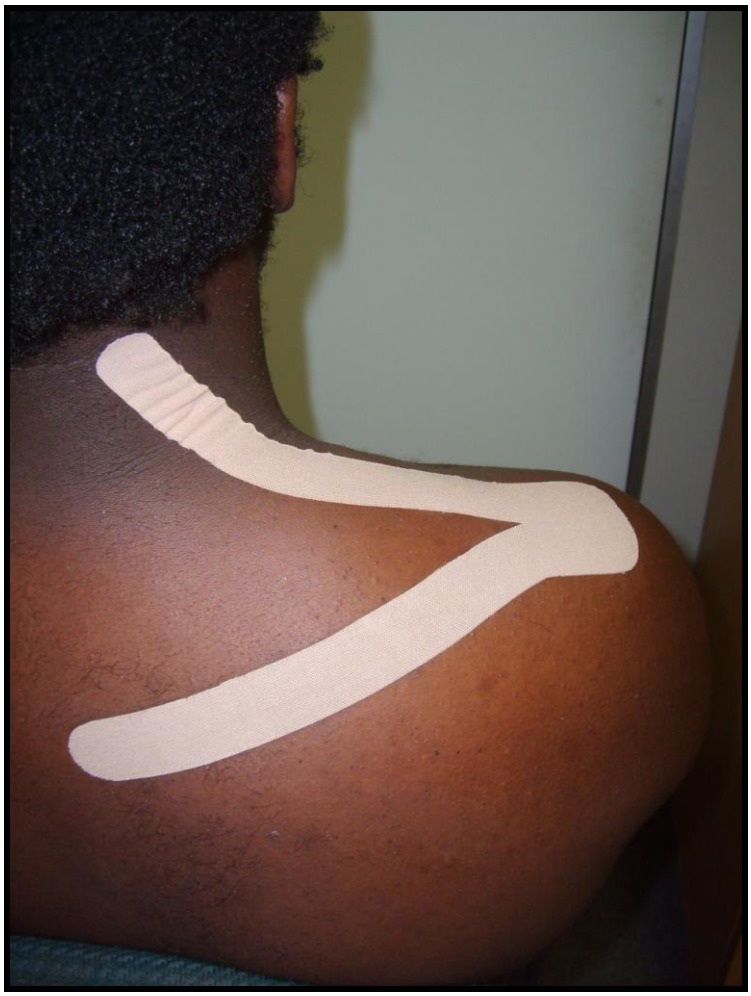


Figure 3.1 Kinesio Tex® Tape Application to the Upper and Middle Trapezius Muscle

3.3.4.10 Rhomboid Major Muscle

3.3.4.10.1 Muscle Testing (Friedman, 2007a)

Of the tests used to asses rhomboid major muscle strength in the study, the clinical test delineated by Friedman (2007a) was the prone rhomboid major muscle strength test. Whilst lying prone, the patients arm (on the unaffected side) was placed on the table, and the mandible was placed on the hand (dorsal surface) of the unaffected side. The shoulder was then adducted and medially rotated on the affected side, and whilst this position was maintained, the examiner depressed the scapula by applying pressure to its inferior angle while the medial border of the scapula was stabilized with the other hand.

3.3.4.10.2 Kinesio® Tex Tape Length:

The length of the Kinesio® Tex Tape is from the midpoint of the spine of the scapula to the spinous process of the second thoracic vertebra. (Friedman, 2007a)

3.3.4.10.3 Kinesio Taping® Method (Friedman, 2007a):

Whilst seated, the middle of the Kinesio® Tex Tape was applied over the middle of the muscle belly following the fibre direction. The muscle was found two fingerbreadths below the spine of the scapula along the medial vertebral border at its midpoint. The Kinesio® Tex Tape tails were then placed temporarily over the skin without rubbing the glue and activating it. The arms were then crossed in front of the body, the elbows were raised, the neck and the head were flexed, and the upper back was rounded to place the tissues over the rhomboid muscle under tension.

The examiner then placed his hand over the centre of the “X” shaped Kinesio® Tex Tape, and the skin was pulled laterally to increase tissue tension as the tails of the Kinesio® Tex Tape were applied. The upper medial tail of the Kinesio® Tex Tape was

then applied to the spinous process of the 2nd thoracic vertebra, with the examiners other hand pulling the skin laterally to increase tissue tension. The lower medial tail of the Kinesio® Tex Tape was then applied to the spinous process of the 5th thoracic vertebra with the examiners other hand pulling the skin laterally to increase tissue tension. The two lateral tails were then applied to the vertebral border of the scapula, following the fibre direction of the rhomboid major, with the skin pulled medially with the examiners other hand.

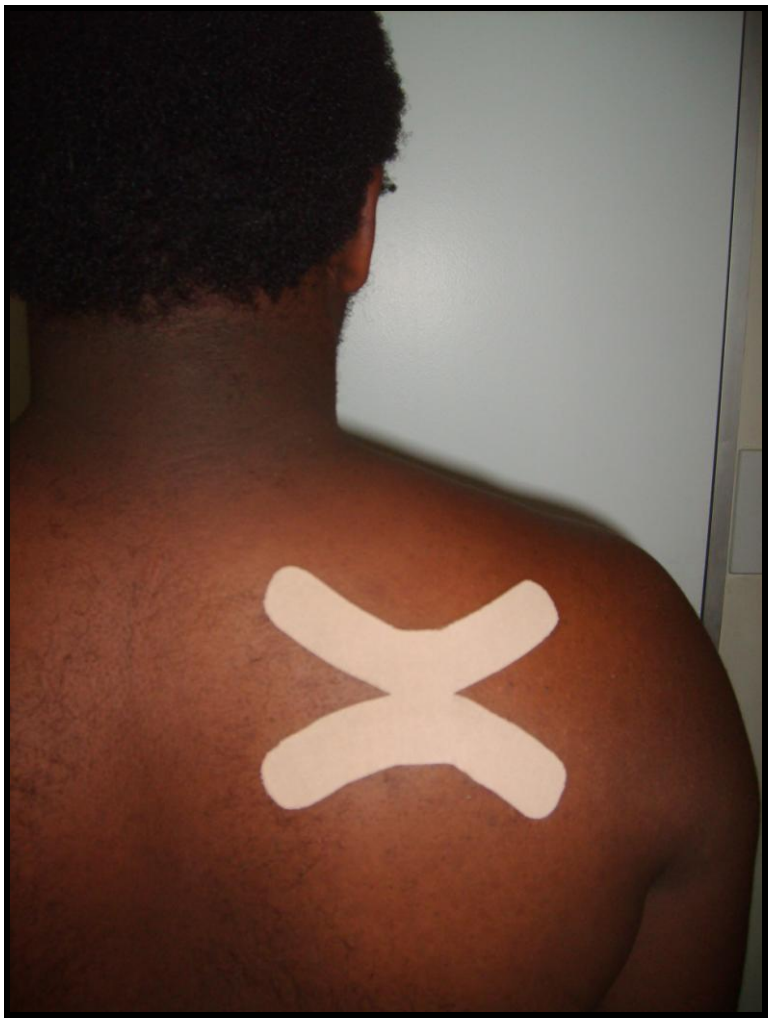


Figure 3.2 Kinesio Tex® Tape application to the Rhomboid Major Muscle

3.4. Methods of Measurement

Subjective data was collected at the initial (prior to treatment), second (prior to treatment), third (prior to treatment), fourth and fifth consultations by the use of:

3.4.1 The Numerical Rating scale (NRS) – 101(Appendix G)

Part of the subjective feedback from the patient is pain measurement. In a study done by Downie, Leatham, Rhind, Wright, Branco and Anderson (1978), it was concluded that the Numerical Rating Scale has a greater accuracy regarding pain ratings than the vertical and horizontal visual analogue scale, as well as the simple descriptive scale. The NRS-101 measures the perceived level of pain intensity the patient experiences (Jensen, Karoly and Braver, 1986). It is made up of 2 linear scales from 0-100 where 0 represents no pain and 100 represents maximum pain. On the one scale the patients are required to record their pain as a numerical value when the pain is at its worst and on the other when it is at its least. Jensen, Karoly and Braver, (1986) states that when compared to 5 other scales, in a group of 75 chronic patients the NRS-101 was found to be the most practical index of measuring clinical pain intensity.

3.4.2 The CMCC Neck Disability Index (Appendix H)

Vernon and Mior (1991) concluded from their study that it has a high degree of internal validity (it measures the construct that it is designed to) and consistency.

3.4.3 Headache Diary (Appendix F)

The Headache Diary was designed by the student and various chiropractic lecturers. The patient was required to fill in the relevant information daily over the 21 day research period (Penter, 1994).

3.5 Statistical Analysis

SPSS version 15.0 (SPSS Inc., Chicago, Illinois) was used to analyze the data. A p value <0.05 was considered as statistically significant. Independent samples t-test was used to compare quantitative normally distributed variables between the two treatment groups. Pearson's chi square test was used to compare categorical variables between the treatment groups. Repeated measures ANOVA testing was used to compare CCMC between treatment groups over time. The generalized estimating equations (GEE) family of generalized linear models were used to assess the Headache Diary variables which were collected over a period of 21 days each.

These models were used because they are able to deal with repeated measures over time conforming to many different statistical distributions, such as the outcomes measured in this study. The binomial distribution with the log link was specified in the case of a binary outcome such as presence of headache. The Poisson distribution with a log link was used to model count data (number of headaches per day), while the normal distribution with identity link was assumed for pain and duration of headaches.

The independent variables used were time, treatment group, age, and the time*treatment group interaction. Age was used as a covariate in all analyses since age was significantly different between the treatment groups and may have acted as a confounder. The time*group interaction effect was used to indicate the differential treatment effect in each analysis. Profile plots were used to assess visual trends of rate of change in each variable over time by treatment group. Symptom data were multiple response variables and each was relatively rarely reported, making GEE analysis of these outcomes unreliable and invalid. Thus the number of times that each symptom was reported over the 21 day period for each participant was summed up and the mean totals between the groups were compared using t-tests. This analysis strategy ignores the time effect, and thus it is a more crude method of analysis than the GEE models.

If the p value for the time*group interaction (intervention effect) was <0.05, a statistically significant treatment effect was declared. Profile plots were generated to examine the rates of change over time in each group and to visually assess trends.
(Esterhuizen, 2007).

CHAPTER 4: Results and Discussion

4.1 Introduction

In the following chapter, the criteria involving the admissibility of the data are discussed. The results collected in the study are presented in tabulated and graphic form and include demographic data, followed by inter-group and intra-group data. Each inter-group Table contains: mean, standard deviation, mean ranks and p-values for the relevant data. Each intra-group table contains: mean, standard deviation, mean ranks and p-values for the relevant data. The discussion of this data is covered in this chapter as well. Although discussion of the results is unconventional in Chapter 4, it was recognized as the best method of presentation for this particular study and its outcomes.

4.2 Criteria Governing the Admissibility of the Data

Information obtained from the following questionnaires were included to formulate the statistics: the NRS – 101(Appendix G) for pain intensity, the CMCC Neck Disability Index (Appendix H) for disability and a Headache Diary (Appendix F) for intensity, frequency, associated symptoms, duration and disability. These were all completed by the patient under the researcher's supervision.

The null hypothesis (Ho) stated that there was no significant difference between the two groups with respect to the variable of interest. The alternative hypothesis (H1) stated that there was a significant difference between the two groups for the following objectives:

4.2.1 Objectives of the study:

- **Objective One**

The first objective was to determine the relative effectiveness of Ibuprofen ® and the Kinesio Taping® Method in terms of subjective clinical measures: pain intensity (NRS-101 and the Headache Diary), duration (Headache Diary), frequency (Headache Diary) and nature (Headache Diary) of the pain.

- **Objective Two**

The second objective was to determine the relative effectiveness of Ibuprofen ® and the Kinesio Taping® Method in terms of associated symptoms of the ETTH being reduced (Headache Diary) and whether the daily life function was improved (CMCC Neck Disability Index).

- **Objective Three**

The third objective was a comparison between a) the trends evidenced in the subjective clinical measures and b) the associated symptoms between the two groups.

The level of significance for all data was set at $p = 0.05$. The null hypothesis was rejected if $p = 0.05$ and failed to be rejected (accepted) if $p \geq 0.05$.

4.3 Data – Primary Data and Secondary Data

4.3.1 The Primary Data

Data was also obtained from subjective measures (viz. Headache Diary (Appendix G), NRS-101 Questionnaire (Appendix H), CMCC Neck Disability Index (Appendix I)).

4.3.2 The Secondary Data

The secondary data was required to explain and document the primary data by means of statistical analysis, which was obtained from books, journals, periodicals, lectures and websites.

4.4 Abbreviations used in the Tables

1. B = Regression co-efficient
2. Df = Degrees of freedom
3. GEE = Generalized Estimating Equations
4. N = Number of patients
5. NSAID = Non-Steroidal Anti-Inflammatory Drug
6. *P* value = Probability that the null hypothesis is true value
7. Std. Deviation = Standard Deviation
8. Std. Error Mean = Standard Error Mean
9. Std. Error = Standard Error

4.5 Results

4.5.1 Demographics

4.5.1.1 Age

Table 4.1: T-test comparison of age between treatment groups

	Treatment	N	Mean	Std. Deviation	Std. Error Mean	*p* value
Age	Kinesio Taping® Method	16	21.19	1.834	0.458	0.011
	NSAIDs	16	27.38	8.461	2.115	

4.5.1.1.1 Discussion of Age

There was a statistically significant difference in mean age between the two treatment groups (p=0.011). The mean age was higher in the NSAIDs group, with the average age of the Kinesio Taping® Method group being younger than the NSAID group (Table 4.1). This affected the overall number of headaches experienced by the two groups, in that the Kinesio Taping® Method group had an overall smaller average number of headaches than the NSAID group (Table 4.1). This is in accordance with Rasmussen et al. (1991); Goebel, Peterson-Braun and Soyka (1994) and Schwartz,. (1998) who found that in a cross-sectional epidemiologic study, that the average age of onset was 25-30 years of age. Dalessio (1987) also previously identified this relationship and suggested that TTH are more commonly found in adults, as it correlates to the time that individuals experience a stress increase in life.

The fact that the overall age and therefore number of headaches varied between the two groups was taken into account, and the statistical analysis was adjusted accordingly to compensate for this difference.

4.5.1.2 Gender

Table 4.2: Chi square test comparison of Gender between treatment groups

			Treatment		Total
			Kinesio Taping® Method	NSAID	
Gender	Male	Count	6	6	12
		% within Treatment	37.5%	37.5%	37.5%
	Female	Count	10	10	20
		% within Treatment	62.5%	62.5%	62.5%
Total		Count	16	16	32
		% within Treatment	100.0%	100.0%	100.0%

p=1.000

4.5.1.2.1 Discussion of Gender

There was absolutely no difference in gender distribution between the two treatment groups (*p*=1.000). The literature however states that the TTH ratio between men and women is 4:5 indicating that women (46.9%) are only slightly more affected than men (42.3%) (Rasmussen et al., 1991; Goebel, Peterson-Braun and Soyka, 1994; Schwartz et al., 1998). The slight discrepancy may be as a result of this research study being of a small scale regarding the number of patients and thus encountering an increased risk of statistical error.

4.5.1.3 Ethnicity

Table 4.3: Chi square test comparison of ethnic group between treatment groups

			Treatment		Total
			Kinesio Taping® Method	NSAID	
Ethnic	Black	Count	9	8	17
		% within Treatment	56.3%	50.0%	53.1%
	White	Count	7	8	15
		% within Treatment	43.8%	50.0%	46.9%
Total		Count	16	16	32
		% within Treatment	100.0%	100.0%	100.0%

p=0.723

4.5.1.3.1 Discussion of Ethnicity

There was no significant difference in ethnic groups between the treatment groups (p=0.723) which is in accordance with the literature reviewed for this study (Langemark, 1988; Linet et al., 1989; Rasmussen et al., 1991; Rasmussen, 1993; Rasmussen, 1995; Schwartz et al., 1998; Castillo et al., 1999; Rasmussen, 1999; Pop et al., 2002; Jensen, 2003a), in which no predisposition to a particular ethnic group was found.

4.5.1.4 Discussion of the Demographics in Totality

Regarding the fact that the average age of the NSAID group being significantly higher(p=0.011) than that of the Kinesio Taping® Method group, it was decided that it should be statistically controlled for as a confounding factor. The statistical procedures negate the statistical effect of age. It could be concluded that the demographics would not affect the statistics regarding the clinical outcomes and the associated symptoms of the ETTH in this study.

4.5.2 Subjective outcomes

4.5.2.1 CMCC Neck Disability Index

Table 4.4: Within- and between- patients effect for CMCC

Effect	Statistic	*p* value
Time	Wilk's lambda=0.837	0.308
Time*group	Wilk's Lambda=0.782	0.156
Group	F=0.065	0.801

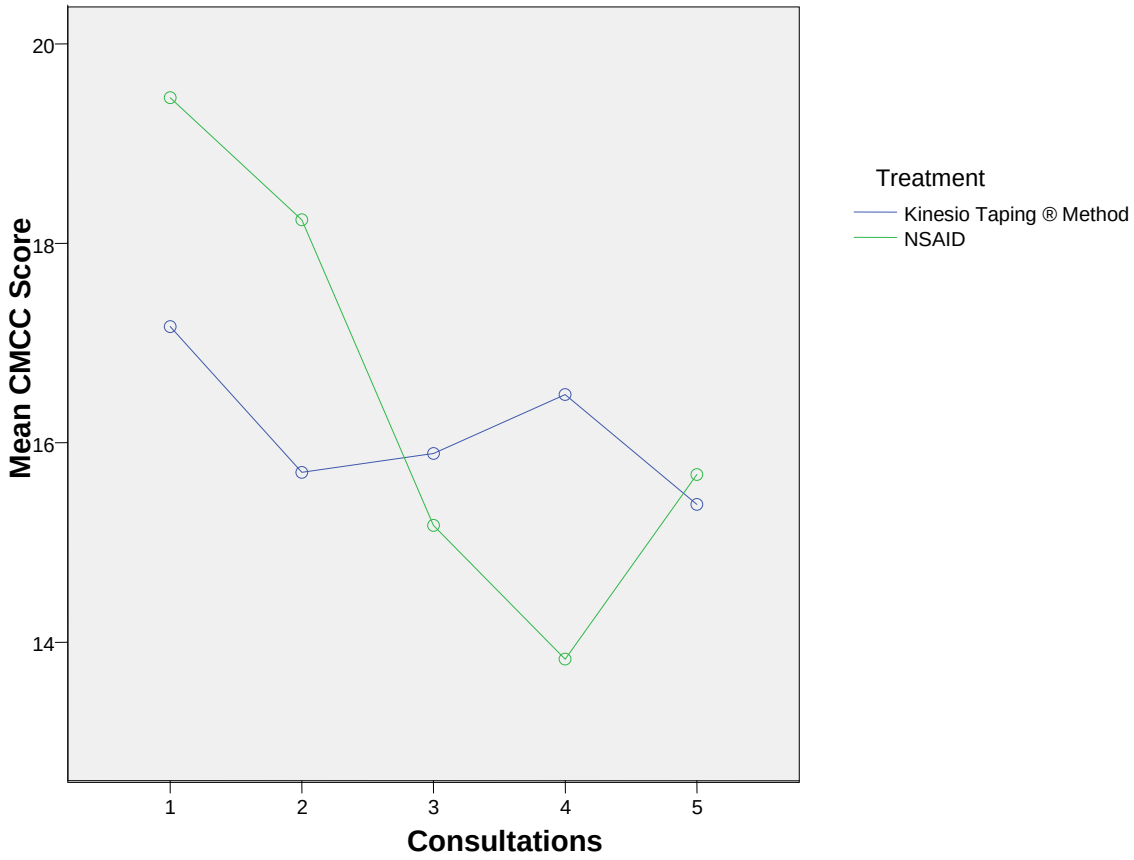


Figure 4.1: Profile plot of mean CCMC scores over the five consultations by group

4.5.2.1.1 Discussion of the CMCC Neck Disability Index

There was a non significant treatment effect for CMCC (p=0.156). The trend shown in Figure 1 was that the CMCC mean value decreased at a faster rate and to a greater extent over time in the NSAIDs group than in the Kinesio Taping® Method group.

It can be seen that there was a steady decline in the slope from the first until the fourth consultation after which the value for the average CMCC score increased again at the fifth consultation. This is in accordance with Jensen and Olesen (2000), who stated that the mainstay in the treatment of TTH is simple analgesics and NSAIDs. Diamond (1999) also stated that unless contraindicated, NSAIDs are often the most effective treatment for ETTH and that when Ibuprofen ® is used in doses of 400mg to 800mg it is highly effective (Diamond, 1983). It was also observed, that according to the CMCC scores, the NSAIDs caused an immediate and sustained effect during the treatment week, yet a short-lived effect once the NSAID was removed. This is congruent with the literature stating that the wash-out period for medication is 3-7 days (Poul et al., 1993), and thus the treatment effect is short-term once the NSAID treatment was stopped.

The Kinesio Taping® Method treatment group also showed an overall decrease in CMCC scores from the first to fifth treatments with an unexpected increase in the average CMCC scores at the third and fourth consultation. This rate of decrease in the Kinesio Taping® Method group appears relatively constant compared to the steep slope of the NSAIDs group. The overall reduction and sustained reduction in CMCC scores indicated a positive treatment effect on ETTH, (i.e. the muscle function is thought to be normalised through the support offered by the Kinesio® Tex Tape, decreasing the need for muscle hypertonicity and allowing for normalisation of function and posture (Yasukawa, Patel and Sisung, 2006; Friedman, 2007a)). Friedman (2007a) also stated that the Kinesio Taping® Method helped in muscle pain reduction and management and that the alleviation of pain is thought to be affected by muscle spasm caused by inflammation in overused muscles. It can be stated that the overall reduction and sustained reduction in CMCC scores provided a strong indication that the prescribed

Kinesio Taping® Method using Kinesio® Tex Tape on the muscular component, namely the upper and middle trapezius (Fernandez-de-las-Penas et al., 2007; Friedman, 2007b) and the rhomboid musculature (Friedman, 2007b), is effective.

The Kinesio Taping® Method treatment group indicated a slow yet significant reduction in CMCC scores not only during treatment but after treatment as well. This seems to indicate a longer lasting treatment effect in the Kinesio Taping® Method group than in the NSAID treatment group.

The difference in the results of the two treatment groups could possibly be described by Dvorak (1985), Gatterman and Goe (1990) and Mense's (1991) inflammatory models as cited by Leach (2004). They state that inflammation can be the cause of muscle pain, joint pain, and joint dysfunction (subluxation). Resolution of this inflammation will result in alleviation of symptoms. NSAIDs temporarily help reduce this inflammation within the joints and muscles, but once the medication is stopped, the symptoms of pain reoccur and the daily functional abilities are limited as the inflammation remains. Unlike NSAIDs however, the Kinesio Taping® Method not only helps to facilitate oedema resolution by raising the skin enabling lymphatic drainage, but also helps to restore muscle function resulting in increased joint movement and muscle movement and thus enabling further resolution of the inflammatory oedema through mechanical means (Friedman, 2007a). Kinesio® Tex Tape also helps reduce pain due to its proprioceptive effect through stimulation of the large pressure and touch nerve fibres thus overriding the small pain nerve fibres (Gate-Control Theory) (Melzack and Wall, 1965). The mentioned reasons may be why the Kinesio Taping® Method group had more sustained effects regarding daily functional abilities than the NSAID group, after treatment had stopped at reading 4.

It can be concluded that over the five consultations, although there was a non significant treatment effect for CMCC (p=0.156), it can be seen that both treatment groups were able to reduce CMCC scores (Figure 1).

4.5.2.2 Headache Diary

4.5.2.2.1 Presence of Headache

Table 4.5: GEE Model for Presence of Headache

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-0.059	0.4130	-0.869	0.750	0.020	1	0.886
[Treatment= the Kinesio Taping® Method	-0.620	0.2280	-1.067	-0.173	7.388	1	0.007
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.019	0.0109	-0.041	0.002	3.117	1	0.077
Age	-0.017	0.0140	-0.044	0.010	1.471	1	0.225
[Treatment=1] * day	0.003	0.0189	-0.034	0.040	0.021	1	0.886
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: Headache or no headache
Model: (Intercept), Treatment, day, age, Treatment * day
a Set to zero because this parameter is redundant.

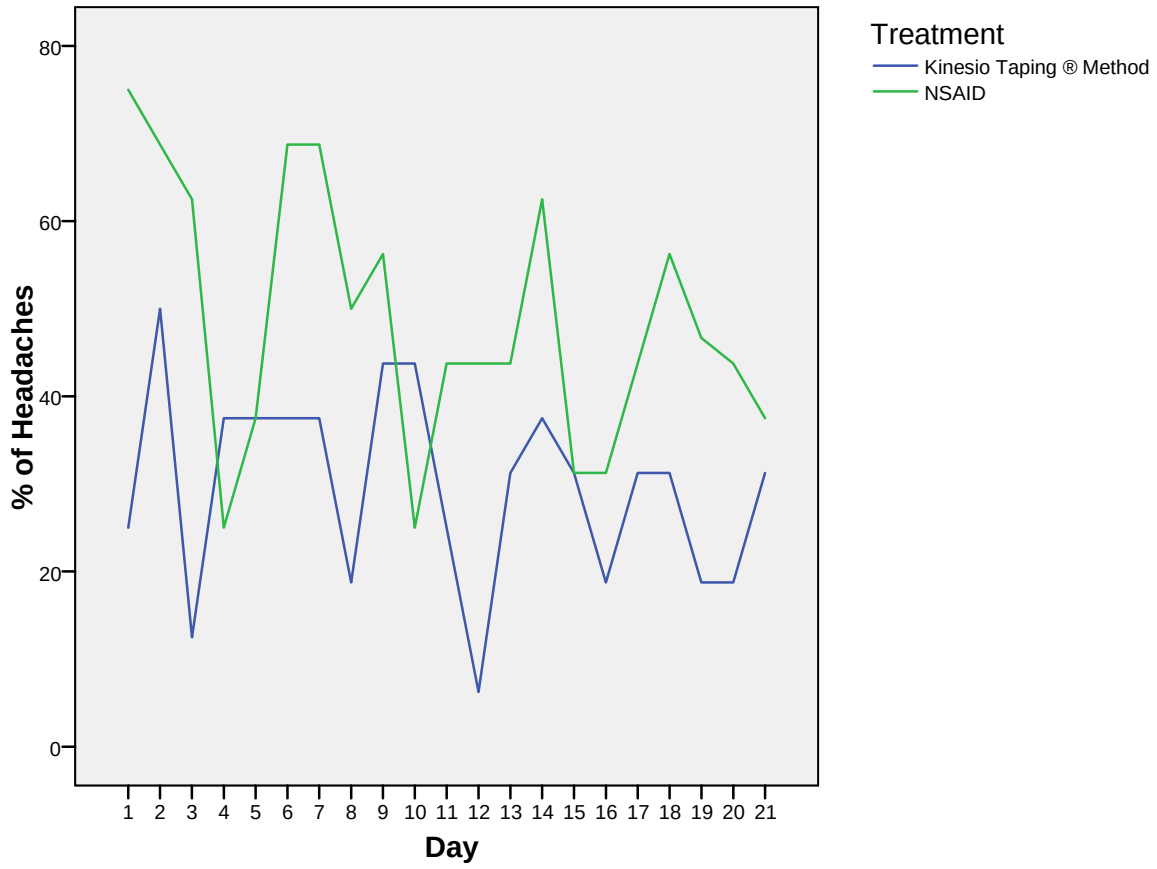
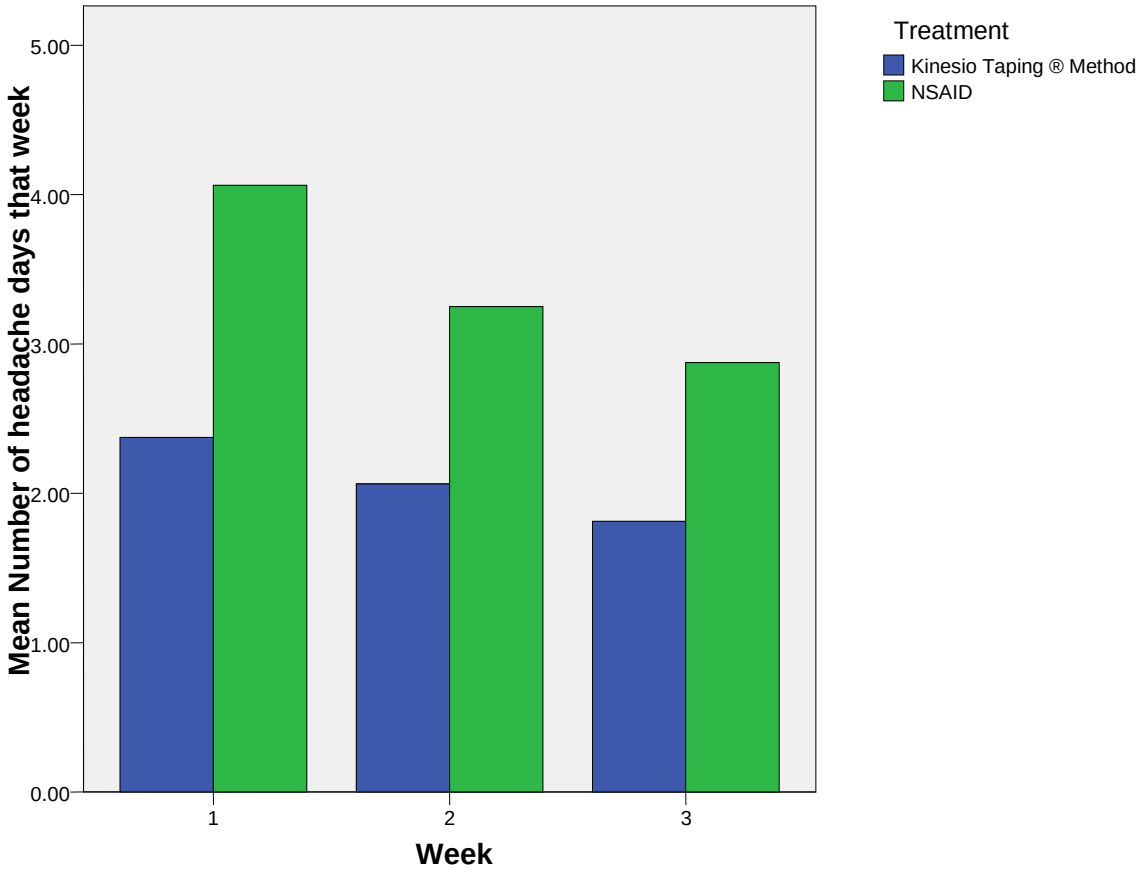


Figure 4.2: Percentage of headaches over time by treatment group



Graph 4.1: Mean number of headache days that week per week over time by treatment group

4.5.2.2.1.1 Discussion of Presence of Headache

The presence or absence of headache on any day over the 21 days of observation using the Headache Diary was a binary variable (0 or 1) and thus modelled using a binomial distribution, with an exchangeable correlation matrix having being specified. The independent variables used in the model were treatment group (the Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect). Table 4.5 shows the results of the analysis, where the interaction between treatment group and time was not significant (p=0.886), thus there was no differential treatment effect between the treatment groups over time, however this may have been affected by the significant difference between the presence of headaches in the two treatment groups (p=0.007)

as this suggested that there were baseline differences between the groups which were not due to the intervention.

Figure 2 shows that at almost all time points, the NSAIDs group had a higher prevalence of headaches, especially on day 1. This may imply that there was a bias from the start in that there were more headaches in the NSAIDs group at day 1. In fact there was a statistically significant difference between the two groups in terms of the presence of headaches at day 1 (p=0.003) with the 76.5% of the NSAIDs group having a headache and 25% of the Kinesio Taping® Method group having headaches. Therefore the repeated measures ANOVA/GEE was used to correct for these baseline differences by measuring the rate of change over time and comparing this between the treatment groups (day*treatment interaction-the interaction between day and treatment group).

The significant difference in the number of headaches between the two groups from the outset may be as a result of the mean age of the NSAID group being higher than the ETTH. This would then predispose them to having more ETTH (Rasmussen et al., 1991; Goebel, Peterson-Braun and Soyka, 1994 and Schwartz et al., 1998).

When comparing the treatment effects, after controlling for the differences, there was no significant differential treatment effect between the two treatment groups over time, but both had a positive effect according to Fig. 2 and Graph 1. This is in accordance with the literature (Dvorak, 1985; Gatterman and Goe, 1990; Mense, 1991; cited by Leach (2004); Diamond, 1983; Diamond, 1999; Jensen and Olesen, 2000; Yasukawa, Patel and Sisung, 2006; Friedman, 2007a) thus indicating that the NSAID and the Kinesio Taping® Method group are both effective in the treatment of ETTH.

4.5.2.2.2 Number of Headaches

Table 4.6: GEE Model for Number of Headache

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	0.053	0.4577	-0.844	0.950	0.014	1	0.907
[Treatment=Kinesio Taping® Method]	-0.521	0.2631	-1.037	-0.006	3.924	1	0.048
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.022	0.0113	-0.044	0.001	3.625	1	0.057
Age	-0.017	0.0153	-0.047	0.013	1.297	1	0.255
[Treatment=1] * day	0.004	0.0205	-0.037	0.044	0.031	1	0.860
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: Headache number for that day
Model: (Intercept), Treatment, day, age, Treatment * day
a Set to zero because this parameter is redundant.

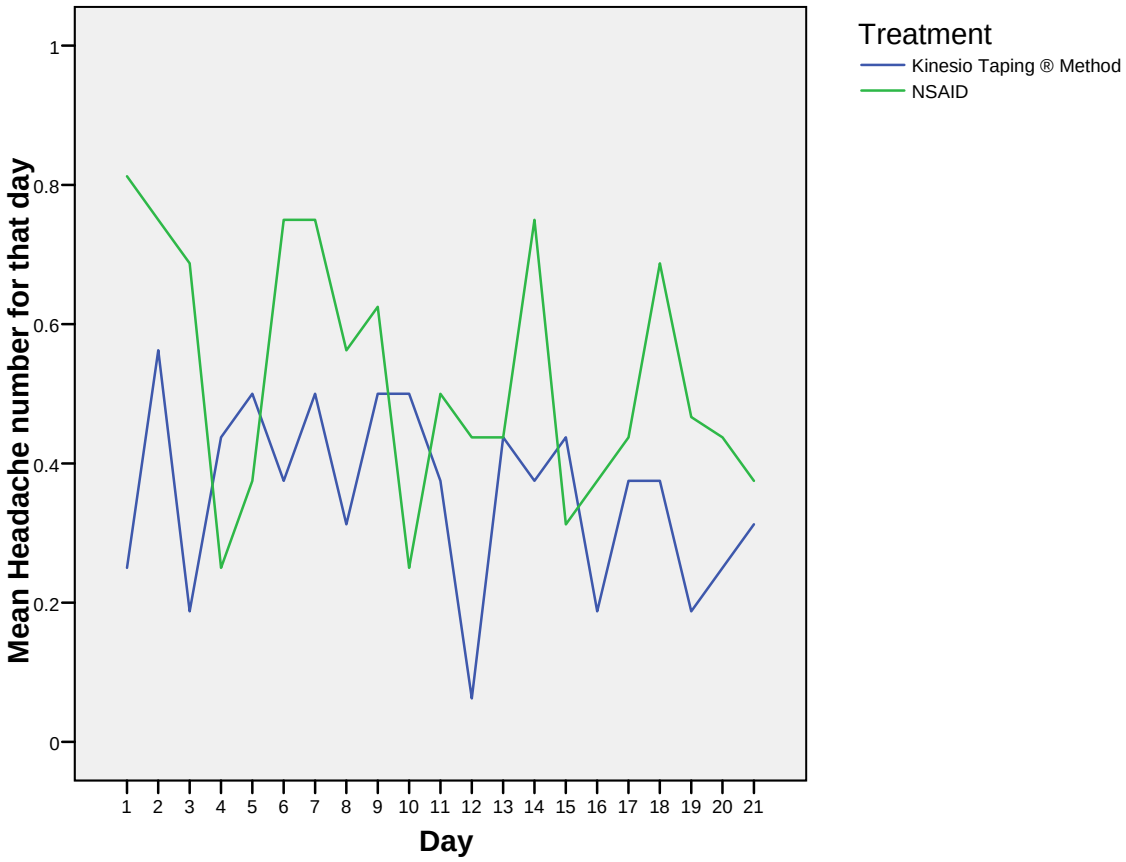
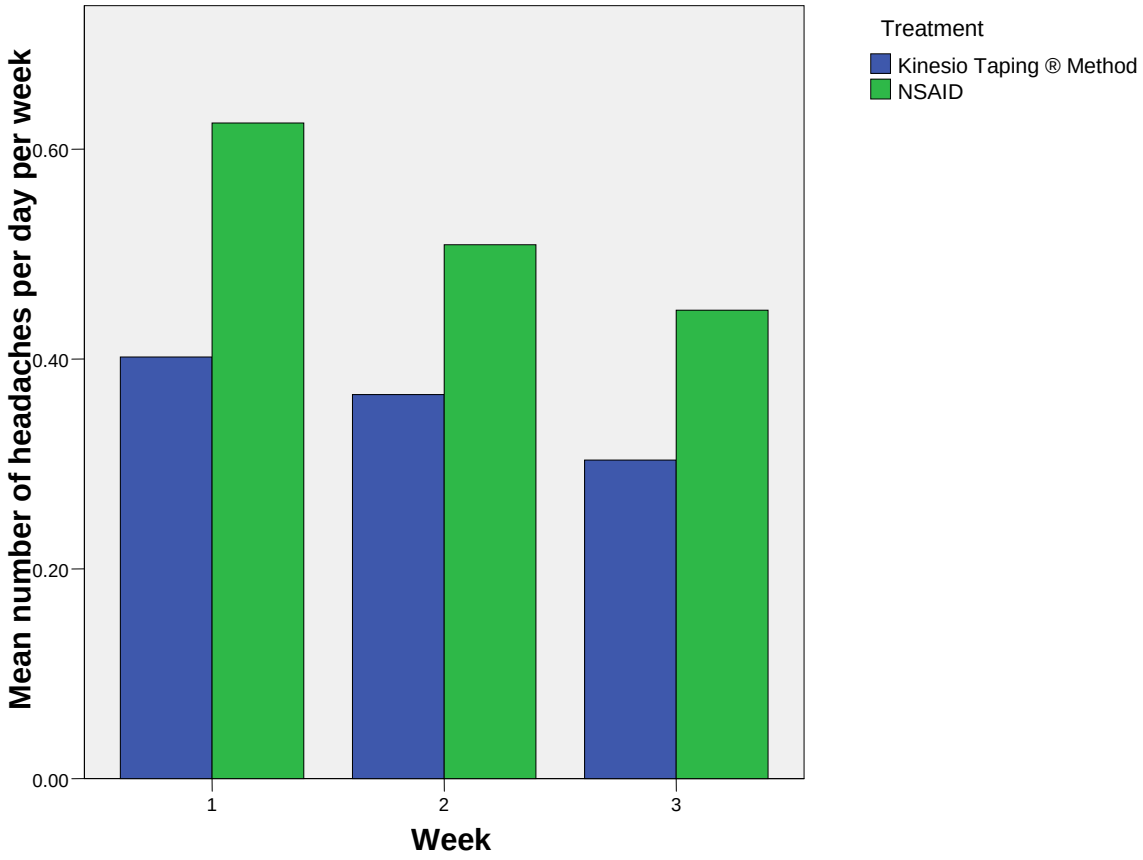


Figure 4.3: Mean headache number for that day over time by treatment group



Graph 4.2: Mean number of headaches per day per week over time by treatment group

4.5.2.2.2.1 Discussion of Number of Headaches

The number of headaches on any day over the 21 days of observation using the Headache Diary was a count variable where values ranged between 0 and 3 per day, and thus modelled using a Poisson distribution (Esterhuizen, 2007). An exchangeable correlation matrix was specified. The independent variables used in the model were treatment group (the Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect). Table 4.6 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.860), thus there was no differential treatment effect between the treatment groups over time. Again the significant difference between the number of headaches in the two treatment groups (p=0.048) suggests that there

were baseline differences (e.g. age) between the groups which were not due to the intervention. Figure 3 shows that at almost all time points the NSAIDs group had a higher number of headaches, especially on day 1.

According to Graph 2, the overall number of headaches per day, and the overall number of days in which a patient experienced a headache decreased with consecutive weeks for both groups. This indicates that each of the treatment modalities had a beneficial and short-term effect on the headache which is in accordance with the literature (Diamond, 1983; Diamond, 1999; Jensen and Olesen, 2000; Yasukawa, Patel and Sisung, 2006; Friedman, 2007a). There was no differential treatment effect regarding number of headaches between the two treatment groups over time (see Table 4.6 and Figure 3) and so the two treatments were similarly effective. The fact that the overall number of headaches per day, and the overall number of days in which a patient experienced a headache decreased with consecutive weeks not only provides relief of pain experienced by the patient, but it also serves to reduce the possibility of the ETTH progressing into CTTH (Jensen, 2003b).

4.5.2.2.3 Pain Intensity

Table 4.7: GEE Model for Pain Intensity

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	3.969	1.0232	1.964	5.975	15.051	1	0.000
[Treatment=the Kinesio Taping® Method]	-1.475	0.6432	-2.735	-0.214	5.256	1	0.022
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.081	0.0284	-0.136	-0.025	8.049	1	0.005
Age	-0.042	0.0273	-0.096	0.011	2.371	1	0.124
[Treatment=1] * day	0.050	0.0360	-0.021	0.120	1.915	1	0.166
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: Pain
Model: (Intercept), Treatment, day, age, Treatment * day
a Set to zero because this parameter is redundant.

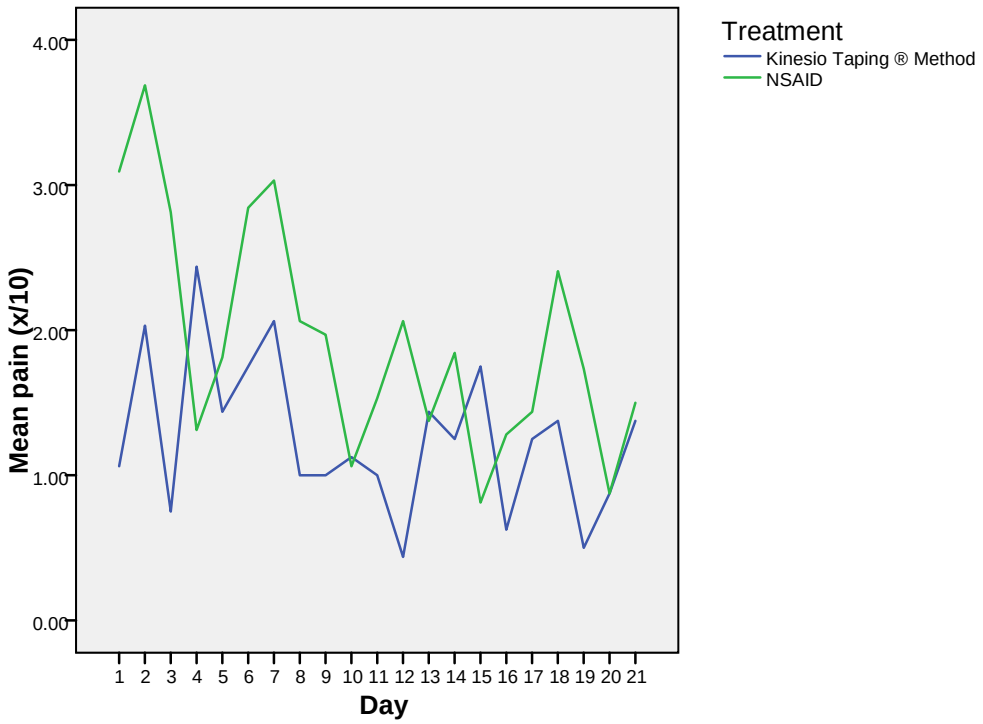
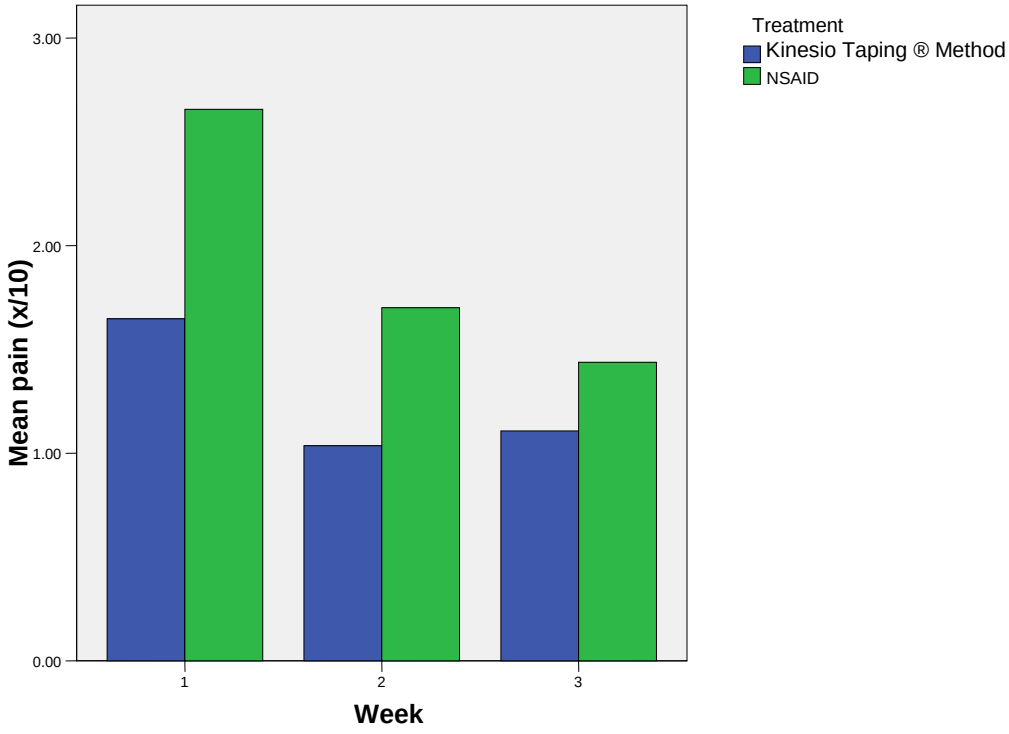


Figure 4.4: Mean pain intensity level over time by treatment group



Graph 4.3: Mean pain per week by treatment group

4.5.2.2.3.1 Discussion of Pain Intensity

The pain level recorded each day over the 21 days of observation using the Headache Diary was a quantitative variable with values ranging between 0 and 9 out of 10 per day. When more than one headache was recorded for a particular day, the headache with the highest pain level was used and thus modelled using a normal distribution (Esterhuizen, 2007). An exchangeable correlation matrix was specified and the independent variables used in the model were treatment group (the Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect).

Table 4.7 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.166), thus there was no differential treatment effect between the treatment groups over time. The significant difference between the pain levels in the two treatment groups (p=0.022) suggested that there were baseline differences between the groups which were not due to the intervention. Figure 4 shows that at almost all time points the NSAIDs group had a higher average pain level, especially on day 1.

It can be seen from Figure 4 that there was an overall reduction in the mean pain values during the period of the treatment for both groups (Figure 4). According to Graph 3, it can be seen that each of the two treatment groups achieved a significant (p=0.022) reduction in mean pain over the week of treatment and that this effect continued over into the third week within the NSAID group.

This indicates that each of the treatment modalities had a beneficial and continued effect on headache - especially the NSAID group; which is in accordance with the literature (Dvorak, 1985; Gatterman and Goe, 1990; Mense, 1991; cited by (Leach) ,2004; Diamond, 1983; 1999; Jensen and Olesen, 2000; Yasukawa, Patel and Sisung, 2006; Friedman, 2007a). This not only provides relief by reducing the overall number of headaches and therefore pain experienced by the patient, but it also serves to reduce

the possibility of the ETTH progressing into the CTTH form (Jensen, 2003b). This does not correlate with the CMCC Neck Disability Index as the CMCC Neck Disability Index is a more functional measurement rather than a pain intensity measurement.

4.5.2.2.4 Duration of Headache

Table 4.8: GEE Model for Duration of Headache

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	3.874	1.2769	1.371	6.376	9.203	1	.002
[Treatment=the Kinesio Taping® Method]	-1.410	.7439	-2.868	.048	3.593	1	.058
[Treatment=NSAIDs]	0(a)	.	.	.	.	.	.
Day	-.073	.0274	-.126	-.019	7.080	1	.008
Age	-.044	.0338	-.110	.022	1.707	1	.191
[Treatment=1] * day	.032	.0375	-.042	.105	.721	1	.396
[Treatment=2] * day	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: duration
Model: (Intercept), Treatment, day, age, Treatment * day
a Set to zero because this parameter is redundant.

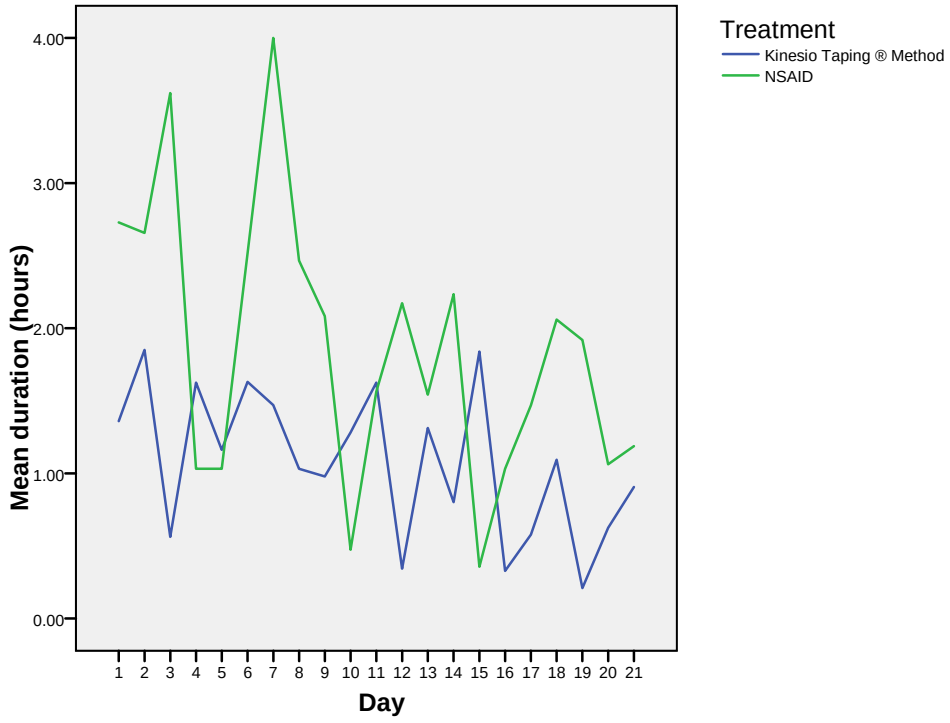
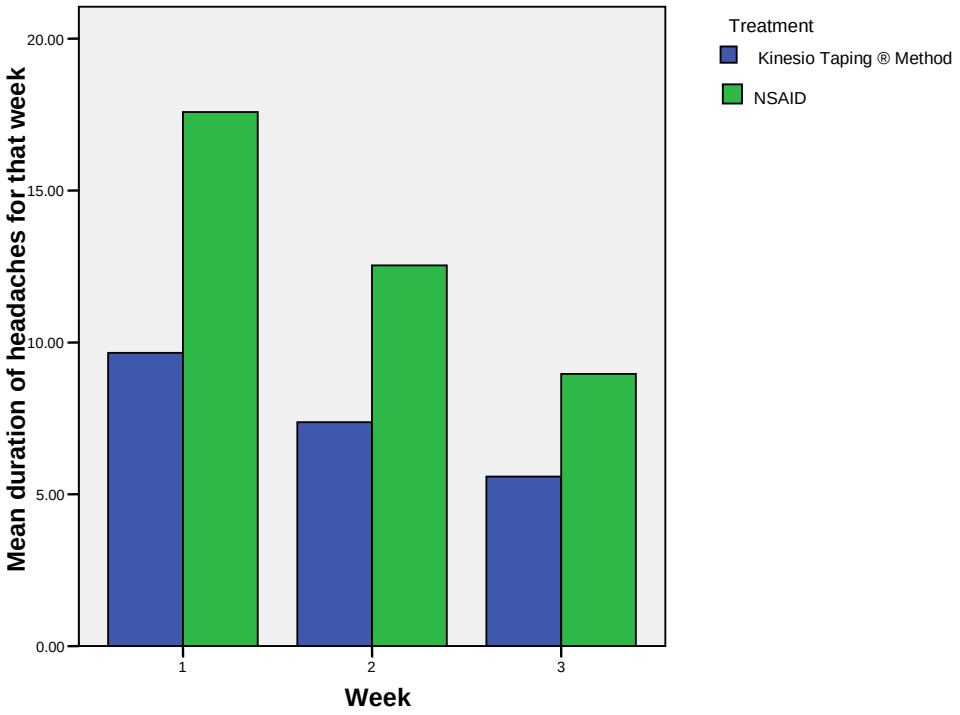


Figure 4.5: Mean headache duration over time by treatment group



Graph 4.4: Mean duration of headaches for that week per week by treatment group

4.5.2.2.4.1 Discussion of Duration of Headache

The headache duration, recorded each day over the 21 days of observation, using the Headache Diary, was a quantitative variable with values ranging between 0 and 24 hours per day). When more than one headache was recorded for a particular day, the duration of each headache was added together and was modelled using a Normal distribution (Esterhuizen, 2007). An exchangeable correlation matrix was specified, with the independent variables used in the model being treatment group (the Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect).

Table 4.8 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.396), thus there was no differential treatment effects between the treatment groups over time. Figure 5 shows that at almost all time points

the NSAIDs group had a higher average duration than the Kinesio Taping® Method group.

According to the trend in Figure 5, it can be seen that each of the two treatment groups had a fairly significant (p=0.058) effect regarding mean headache duration over time which is in conjunction with the literature (Jensen and Olesen, 2000; Diamond, 1983; 1999; Friedman, 2007a). The NSAID group seems to show a greater decrease in mean headache duration than the Kinesio Taping® Method group over the period of the research even though the average headache duration was longer. This indicates that the NSAID group seems to have had a greater treatment effect in terms of headache duration than the Kinesio Taping® Group.

According to Graph 4, the mean weekly headache duration of each group continued to decrease over time which shows that each of the two groups were effective and continued to be effective after the treatment week. Regarding the NSAID group, this continued effect can be explained because the NSAID needs 3-7 days to be fully eliminated from the body (Poul et al., 1993), and so will continue to reduce the headache duration over this period of time. In the collection of literature regarding the Kinesio Taping® Method, no data was found regarding sustained treatment effect after treatment withdrawal (Friedman, 2007a; Kase, Wallis and Kase, 2003). However, with the combined effects of oedema reduction and muscle spasm, it's suggested in the context of Dvorak (1985), Gatterman and Goe (1990), Mense (1991) as cited by Leach (2004), that the Kinesio Taping® Method has a dual effect and should therefore at best equate or be better than the NSAID intervention.

4.5.2.2.5 Photophobia (Sensitivity to Light)

Table 4.9: GEE Model for Photophobia

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-1.257	0.9023	-3.026	0.511	1.941	1	0.164
[Treatment=the Kinesio Taping® Method]	-0.111	0.4623	-1.017	0.795	0.058	1	0.810
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.055	0.0261	-0.106	-0.004	4.460	1	0.035
Age	-0.016	0.0379	-0.090	0.058	0.177	1	0.674
[Treatment=1] * day	0.003	0.0357	-0.067	0.073	0.007	1	0.933
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: sensitivity to light

Model: (Intercept), Treatment, day, age, Treatment * day

a Set to zero because this parameter is redundant.

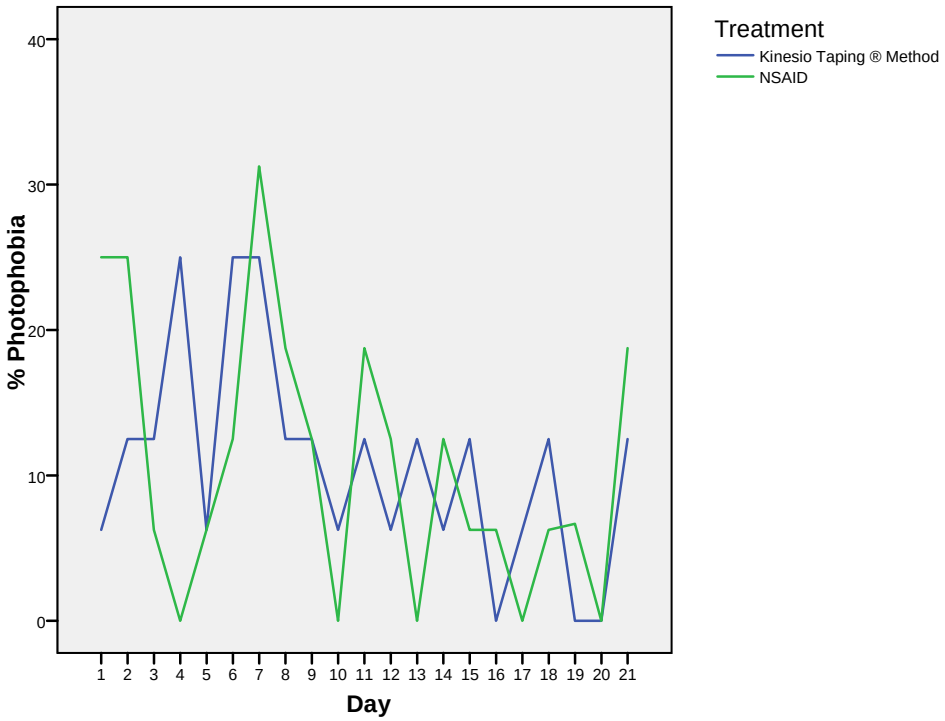
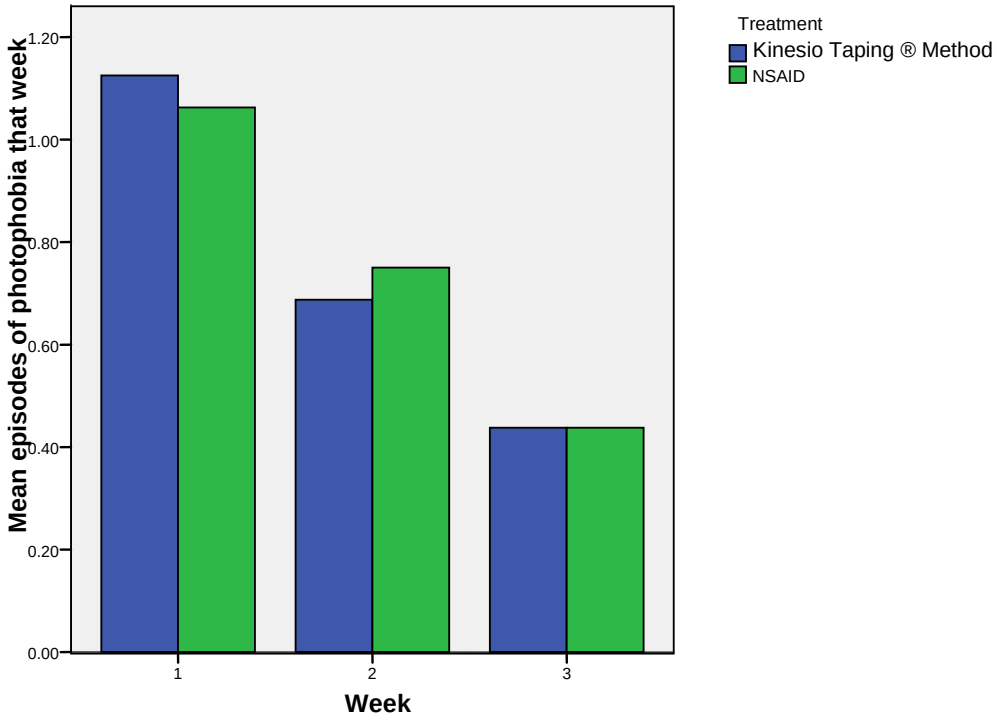


Figure 4.6: Percentage of photophobia over time by treatment group



Graph 4.5: Mean episodes of photophobia that week per week by treatment group

4.5.2.2.5.1 Discussion of Photophobia (Sensitivity to Light)

The presence of sensitivity to light, recorded each day over the 21 days of observation, using the Headache Diary, was a binary variable (0 or 1) and thus modelled using a binomial distribution and a log link function (Esterhuizen, 2007). An exchangeable correlation matrix was specified, the independent variables used in the model being treatment group (Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect).

Table 4.9 shows the results of the analysis, with the interaction between treatment group and time not being significant (p=0.933), resulting in no differential treatment effect between the treatment groups over time. Figure 6 shows that there was much variation in the proportion of each group who had sensitivity to light and the Kinesio Taping® Method group increased and the NSAID group decreased over the 21 days.

From Figure 6 it can be seen that there was a marked reduction in the number of patients who experienced photophobia over the second and third week of the research study. This is in agreement with Table 4.9 in which the interaction between treatment group and time was significant (p=0.035). This tends to suggest that both treatments were effective in achieving sustainable results in the reduction of photophobia. According to Graph 5, photophobia decreased in each of the treatment groups not only in the treatment week but also in the week afterwards which shows that each of the two groups were effective and continued to be effective after the treatment week. This indicates the effectiveness of the Kinesio Taping® Method and NSAIDs in the treatment of ETTH (Jensen and Olesen, 2000; Diamond, 1983; 1999; Yasukawa, Patel and Sisung, 2006; Friedman, 2007a). Furthermore, this outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach (2004) are applied.

4.5.2.2.6 Phonophobia (Sensitivity to Noise)

Table 4.10: GEE Model for Phonophobia

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	2.764	2.6708	-2.471	7.998	1.071	1	.301
[Treatment=the Kinesio Taping® Method]	-.828	1.6867	-4.133	2.478	.241	1	.624
[Treatment=NSAIDs]	0(a)	.	.	.	.	.	.
Day	-.037	.0814	-.197	.122	.209	1	.648
Age	-.272	.0989	-.466	-.079	7.590	1	.006
[Treatment=1] * day	.036	.1146	-.189	.260	.098	1	.754
[Treatment=2] * day	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: sensitivity to noise

Model: (Intercept), Treatment, day, age, Treatment * day

a Set to zero because this parameter is redundant.

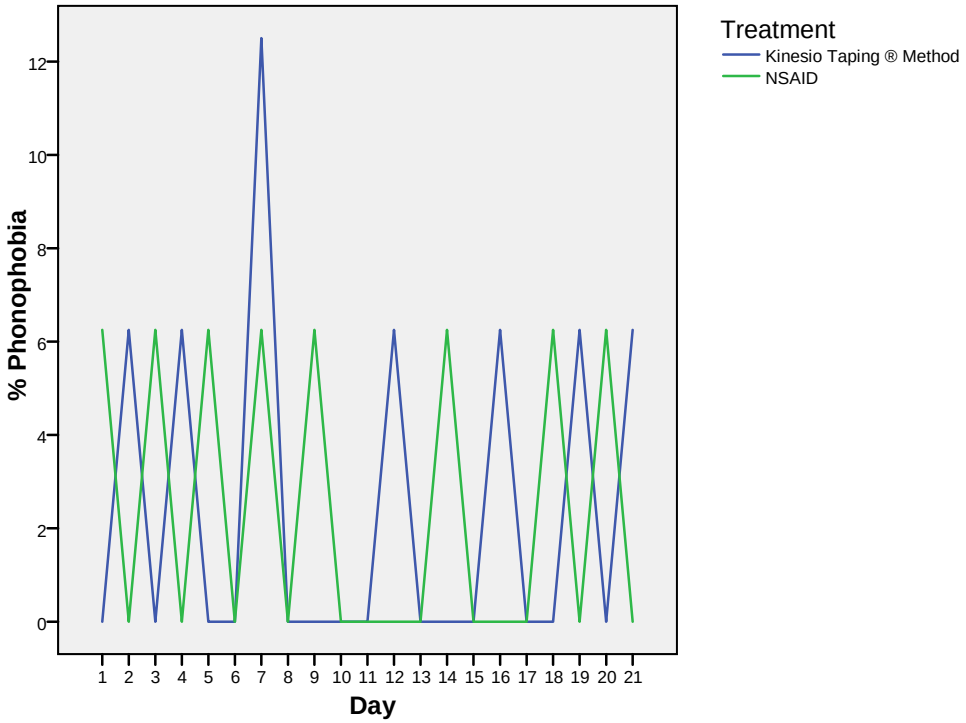
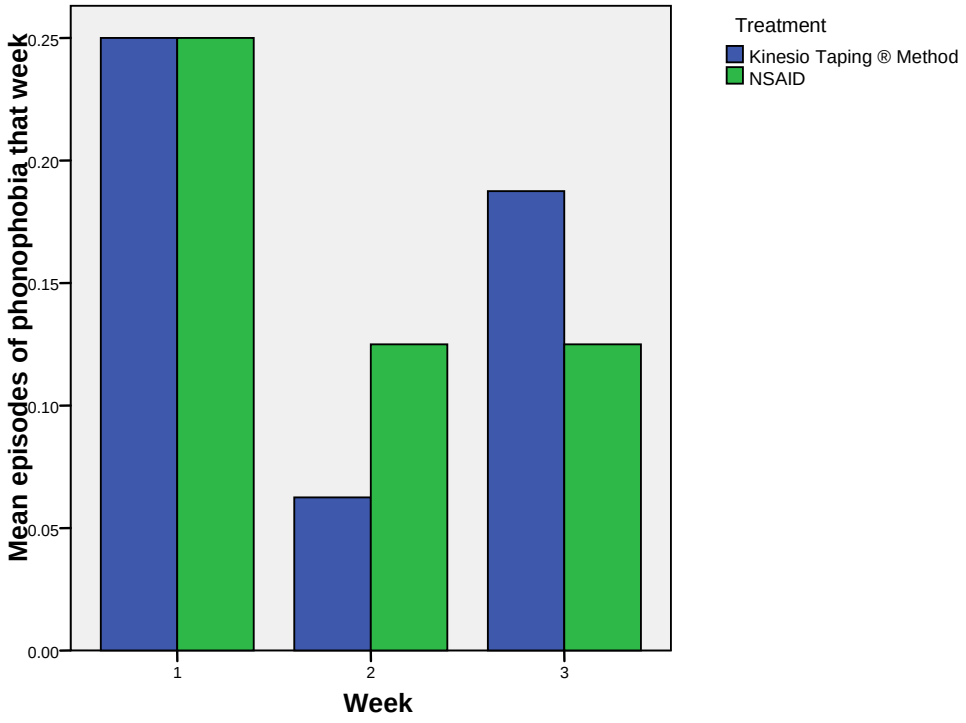


Figure 4.7: Percentage of phonophobia over time by treatment group



Graph 4.6: Mean episodes of phonophobia that week per week by treatment group

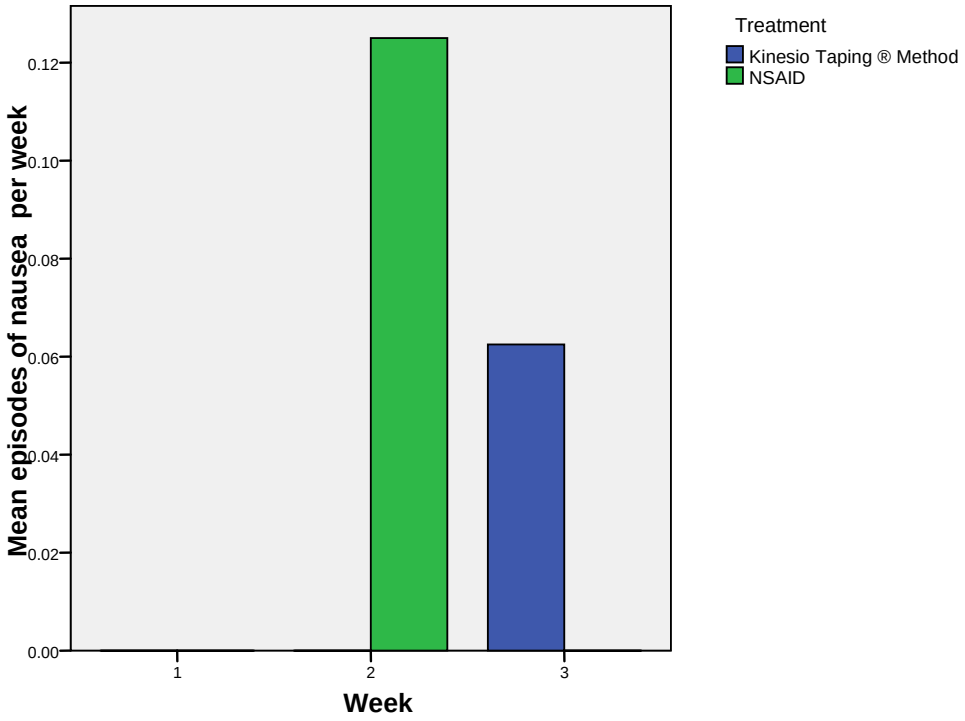
4.5.2.2.6.1 Discussion of Phonophobia (Sensitivity to Noise)

The presence of sensitivity to noise, recorded each day over the 21 days of observation, using the Headache Diary, was a binary variable (0 or 1) and thus modelled using a binomial distribution and a log link function (Esterhuizen, 2007). An exchangeable correlation matrix was specified. The independent variables used in the model were treatment group (Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect).

Table 4.10 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.754), thus there was no differential treatment effect between the treatment groups over time. Figure 7 shows that sensitivity to noise was rarely reported and each group only reported one episode per day (6%) on alternate days except on day 7 when there were two cases in the Kinesio Taping® Method group (12%).

Overall, from Graph 6 we can see that there was a decrease in phonophobia for each of the two treatment groups over the treatment week, and this effect was maintained thereafter in the NSAID group but not in the Kinesio Taping® Method group. This indicates the effectiveness of the Kinesio Taping® Method and NSAIDs in the treatment of ETTH and associated phonophobia (Diamond, 1983; Diamond, 1999; Jensen and Olesen, 2000; Friedman, 2007a).

4.5.2.2.7 Nausea



Graph 4.7: Mean episodes of photophobia per week per week by treatment group

4.5.2.2.7.1 Discussion of Nausea

No GEE model could be computed for the outcome of nausea since only three episodes of nausea were reported over the 21 day period. Two episodes were reported from the NSAIDs group and one from the Kinesio Taping® Method group.

Due to the small number of symptoms experienced by the patient, little can be derived from the reporting of nausea in this study. The fact that episodes of nausea occurred was an unexpected finding as according to the IHS (1991) diagnostic criteria for ETTH, nausea is one of the exclusion criteria for ETTH and so should not occur in ETTH. The nausea in the NSAID group may even be side-effects experienced by the patient as a result of NSAID treatment (See Appendix O).

4.5.2.2.8 Neck Pain or Stiffness

Table 4.11: GEE Model for Neck Pain or Stiffness

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-3.325	0.9245	-5.137	-1.513	12.938	1	0.000
[Treatment= the Kinesio Taping® Method]	-0.163	0.8696	-1.867	1.541	0.035	1	0.851
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.006	0.0564	-0.117	0.104	0.013	1	0.911
Age	0.029	0.0392	-0.047	0.106	0.565	1	0.452
[Treatment=1] * day	-0.050	0.0604	-0.169	0.068	0.694	1	0.405
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: neck p or stiff
Model: (Intercept), Treatment, day, age, Treatment * day
a Set to zero because this parameter is redundant.

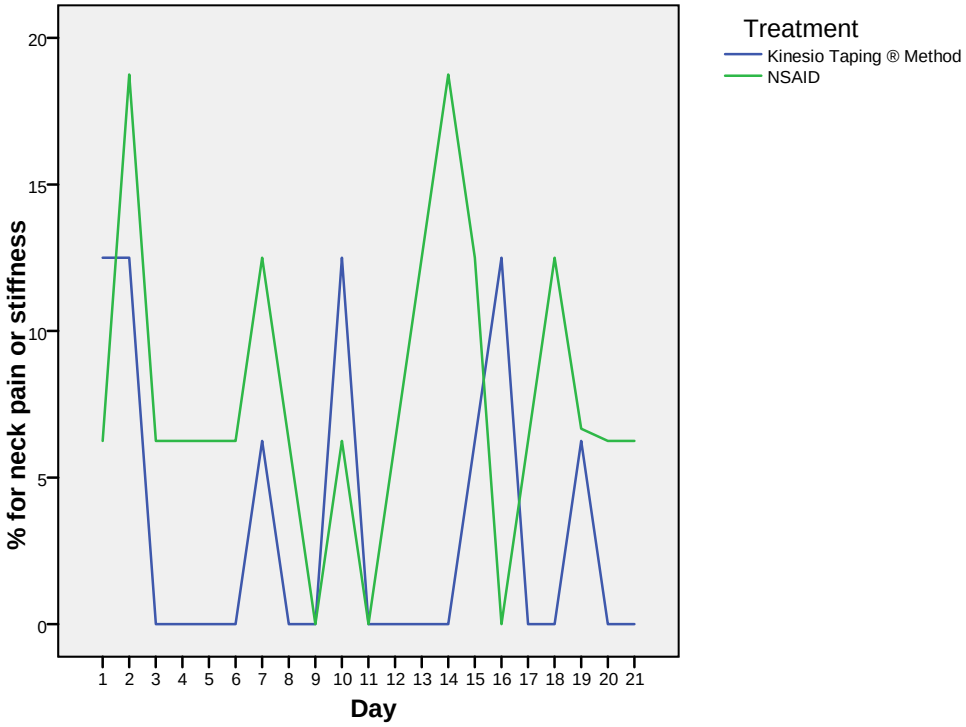
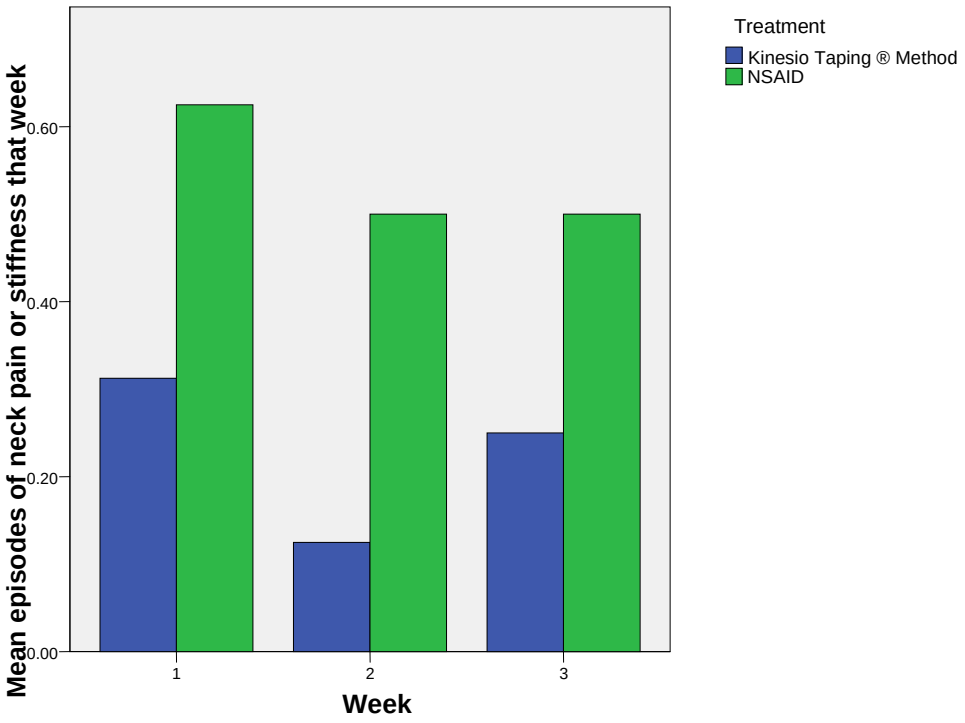


Figure 4.8: Percentage of neck pain or stiffness over time by treatment group



Graph 4.8: Mean episodes of neck pain or stiffness that week per week by treatment group

4.5.2.2.8.1 Discussion of Neck Pain or Stiffness

The presence of neck pain, recorded each day over the 21 days of observation, using the Headache Diary, was a binary variable (0 or 1) and thus modelled using a binomial distribution and a log link function. An exchangeable correlation matrix was specified. The independent variables used in the model were treatment group (Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect). Table 4.11 shows the results of the analysis.

The interaction between treatment group and time was not significant (p=0.405), thus there was no differential treatment effect between the treatment groups over time. Figure 8 shows that neck pain was slightly more frequent in the NSAIDs group but not statistically significantly more (p=0.91).

Graph 8 indicates that there was an overall decrease of neck pain and stiffness for both treatment groups in week 2 and week 3 comparing them to week 1. This benefit was most evident in the Kinesio Taping® Method group during the treatment week. The overall reduction and sustained reduction in neck pain indicates a positive treatment effect on ETTH. Friedman (2007a) suggests that this could be due to the muscle function being normalized, and this is brought about through the support offered by the Kinesio® Tex Tape. This then decreases muscle hypertonicity and allows for normalization of posture and muscle function (Friedman, 2007a). This results in decreased oedema and thus decreased pain and increased movement. Increased movement further reduces the pain as suggested in the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach (2004). Friedman (2007a) also stated that the Kinesio Taping® Method helped in the management and reduction of muscle pain and that the pain alleviation is thought to be affected by a reduction in inflammation in the overused muscles which caused resultant muscle stretch which is supported by the models of Dvorak (1985), Gatterman and Goe (1990) and Mense (1991) as referenced by Leach (2004).

Regarding the relief of neck pain and stiffness provided by the NSAIDs, this is in accordance with the literature stating that unless contraindicated (e.g. patients with peptic ulcer condition or hypersensitivity to aspirin), NSAIDs are often the most effective treatment for ETTH (Diamond, 1999) given that patients suffering with TTH tend to relate their headaches to increased muscle stiffness in the neck and shoulders (Jensen, 1999) and that the most pronounced and consistent finding in TTH is the increased tenderness probably representing the activation of the peripheral nociceptors as a result of inflammation(Langemark and Olesen, 1987; Schoenen et al., 1991; Jensen, 1993b; Jensen, 1999; Bendtsen, 2000). NSAIDs reduce the inflammation and thus reduce the pain. Diamond (1983) also did a study which revealed that Ibuprofen® effectively relieved TTH pain.

4.5.2.2.9 Fatigue

Table 4.12: GEE Model for Fatigue

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-2.710	1.5433	-5.734	0.315	3.083	1	0.079
[Treatment=the Kinesio Taping® Method]	-0.466	1.3652	-3.141	2.210	0.116	1	0.733
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.151	0.0685	-0.285	-0.016	4.841	1	0.028
Age	-0.001	0.0519	-0.103	0.100	0.001	1	0.979
[Treatment=1] * day	-0.041	0.1577	-0.350	0.268	0.067	1	0.795
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: fatigue
Model: (Intercept), Treatment, day, age, Treatment * day
A Set to zero because this parameter is redundant

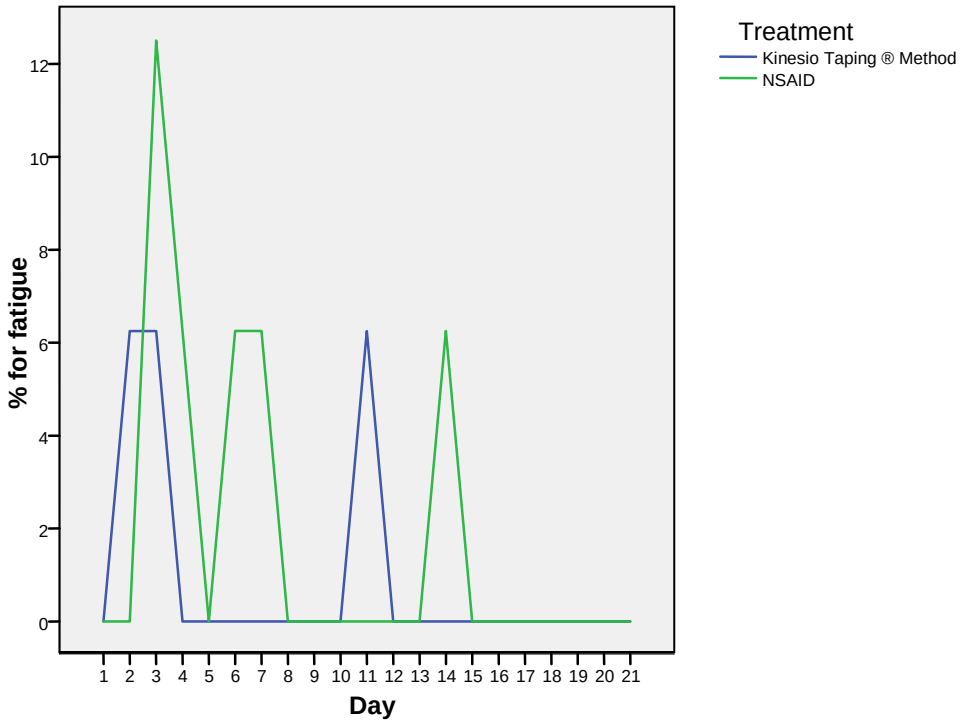
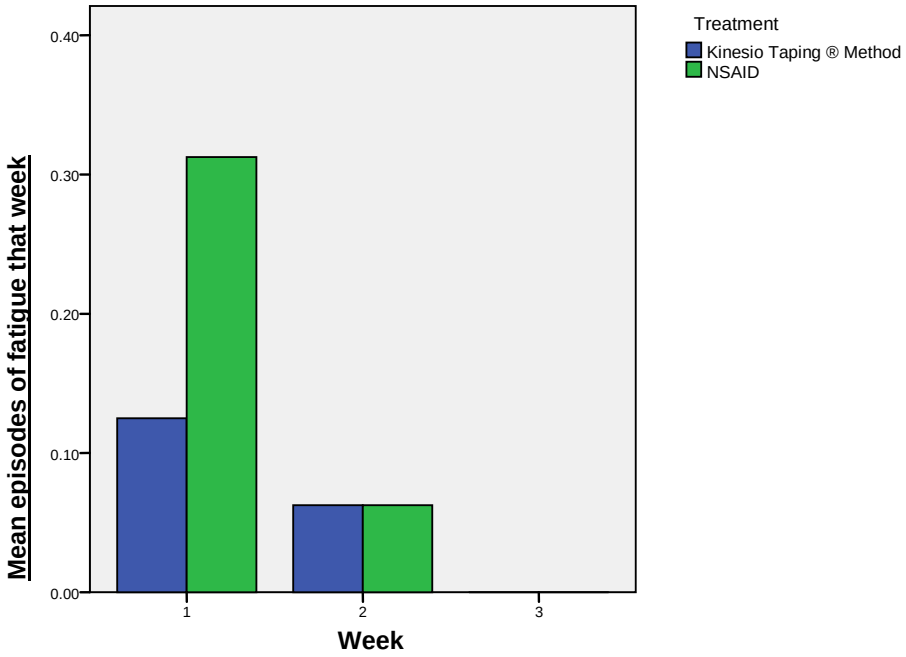


Figure 4.9: Percentage of Fatigue over time by treatment group



Graph 4.9: Mean episodes of fatigue per week per week by treatment group

4.5.2.2.9.1 Discussion of Fatigue

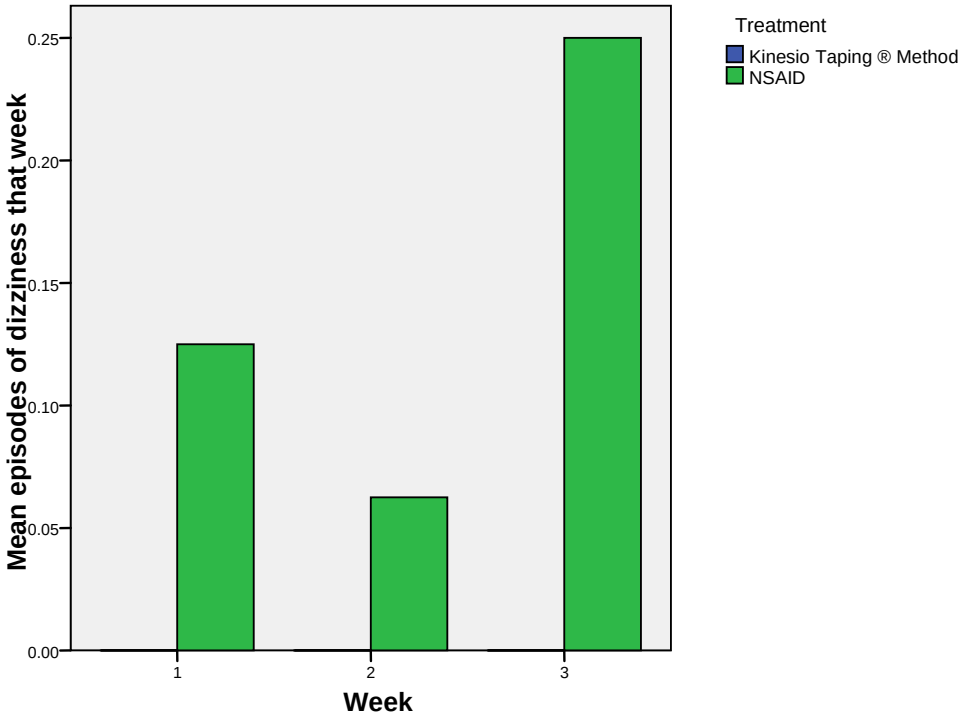
The presence of fatigue, recorded each day over the 21 days of observation, using the Headache Diary, was a binary variable (0 or 1) and thus modelled using a binomial distribution and a log link function. An exchangeable correlation matrix was specified. The independent variables used in the model were treatment group (Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect) (Esterhuizen, 2007).

Table 4.12 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.795), thus there was no differential treatment effect between the treatment groups over time. Figure 9 shows that fatigue was slightly more frequent in the NSAIDs group but not statistically significantly so.

According to Figure 9 and Graph 9, there is a significant and continued reduction in fatigue during the treatment week and continuing on into the week thereafter where no

treatment was given. This indicates the effectiveness and continued effectiveness of both the Kinesio Taping® Method and NSAIDs in the treatment of headaches and the associated symptoms. This is in accordance with the literature regarding the clinical effectiveness of both treatment modalities in ETTH (Jensen and Olesen, 2000; Diamond, 1983; Diamond, 1999; Friedman, 2007a). Furthermore, this outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach (2004) are applied.

4.5.2.2.10 Dizziness



Graph 4.10: Mean episodes of dizziness that week per week by treatment group

4.5.2.2.10.1 Discussion of Dizziness

No GEE model for dizziness could be computed since there were only seven cases of dizziness reported and all cases were from the NSAIDs group.

The fact that dizziness tended to decrease during the treatment week within the NSAID group suggests that Ibuprofen® was effective in the treatment of ETTH and thus the associated dizziness.

No significant comment regarding comparison of the two treatment groups can be made due to insufficient cases of dizziness in the Kinesio Taping® Method group.

4.5.2.2.11 Inability to Study

Table 4.13: GEE Model of Inability to Study

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	Df	*p* value
(Intercept)	-0.454	0.8734	-2.166	1.258	0.270	1	0.603
Day	-0.050	0.0687	-0.185	0.085	0.531	1	0.466
Age	-0.081	0.0361	-0.152	-0.010	5.011	1	0.025
[Treatment=the Kinesio Taping® Method]	-0.665	0.9099	-2.449	1.118	0.534	1	0.465
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
[Treatment=1] * day	0..000	0.0883	-0.173	0.173	0.000	1	0.996
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: could not study
Model: (Intercept), day, age, Treatment, Treatment * day
a Set to zero because this parameter is redundant.

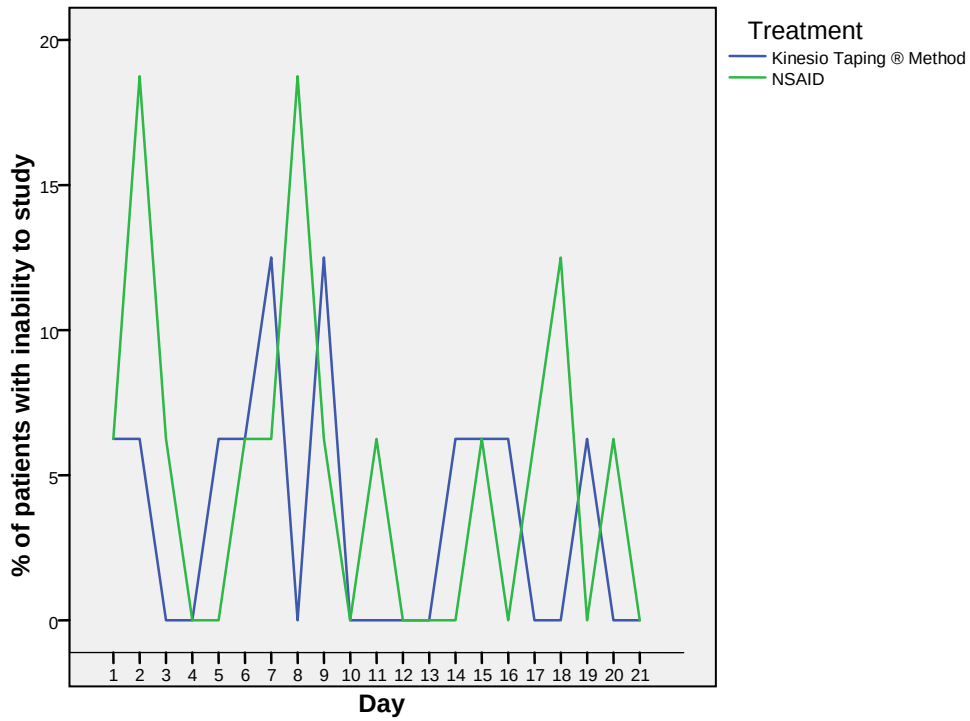
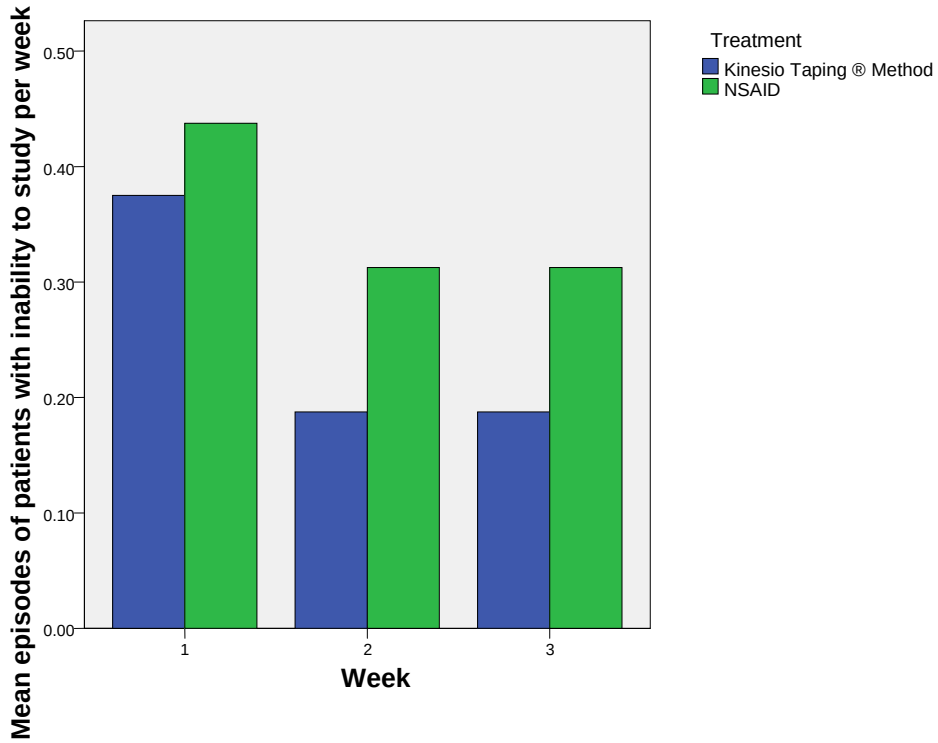


Figure 4.10: Percentage of patients with inability to study over time by treatment group



Graph 4.11: Mean episodes of inability to study that week per week by treatment group

4.5.2.2.11.1 Discussion of Inability to Study

Not being able to study, was recorded each day over the 21 days of observation, using the Headache Diary, was a binary variable (0 or 1) and thus modelled using a binomial distribution and a log link function. An exchangeable correlation matrix was specified. The independent variables used in the model were treatment group (Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect) (Esterhuizen, 2007).

4.13 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.996), thus there was no differential treatment effect between the treatment groups over time. Figure 10 shows that inability to study was slightly more frequent in the NSAIDs group but not statistically significantly so.

According to Figure 10 and Graph 11, the ability of the patients to study improved in the second and third week in both groups. This indicates effective and sustained treatment in both treatment groups which is in accordance with the literature Diamond, 1983; Diamond, 1999; Jensen and Olesen, 2000; Yasukawa, Patel and Sisung, 2006; Friedman, 2007a). Furthermore, this outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach, (2004) are applied. The interaction, however, between treatment group and age was significant (p=0.025) and the older patients were less likely to suffer with an inability to study. This may be as a result of the older patients already being qualified and working and thus studying not being a factor in their lives, or as a result of them being mature students and therefore able to cope better.

Thus a comparison of the patient's inability to study between the two groups is compromised as the mean age of the Kinesio Taping® Method group patients is lower than the NSAID group patients and so a biased response was obtained.

4.5.2.2.12 Inability to Work

Table 4.14: GEE Model for Inability to Work

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	Df	*p* value
(Intercept)	-1.567	1.3442	-4.202	1.067	1.359	1	0.244
[Treatment=the Kinesio Taping® Method]	-0.155	0.6420	-1.414	1.103	0.058	1	0.809
[Treatment=NSAIDs]	0.0(a)	.	.	.	.	.	.
Day	-0.073	0.0333	-0.138	-0.007	4.767	1	0.029
Age	-0.009	0.0464	-0.100	0.082	0.041	1	0.839
[Treatment=1] * day	0.058	0.0375	-0.016	0.131	2.388	1	0.122
[Treatment=2] * day	0.0(a)	.	.	.	.	.	.
(Scale)	1.0						

Dependent Variable: could not work
Model: (Intercept), day, age, Treatment, Treatment * day
a Set to zero because this parameter is redundant.

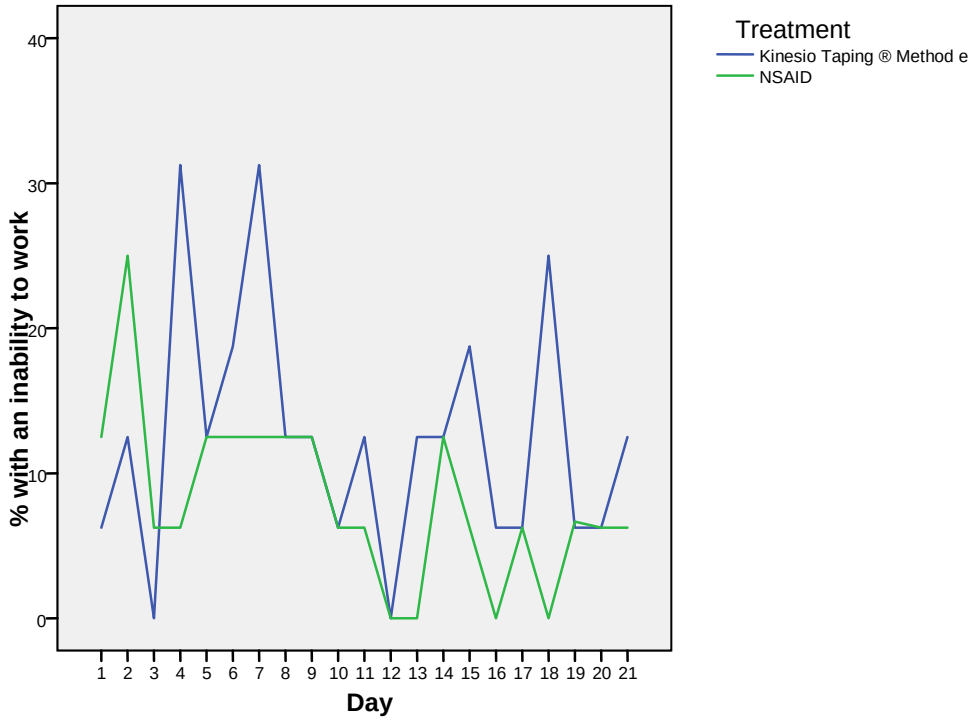
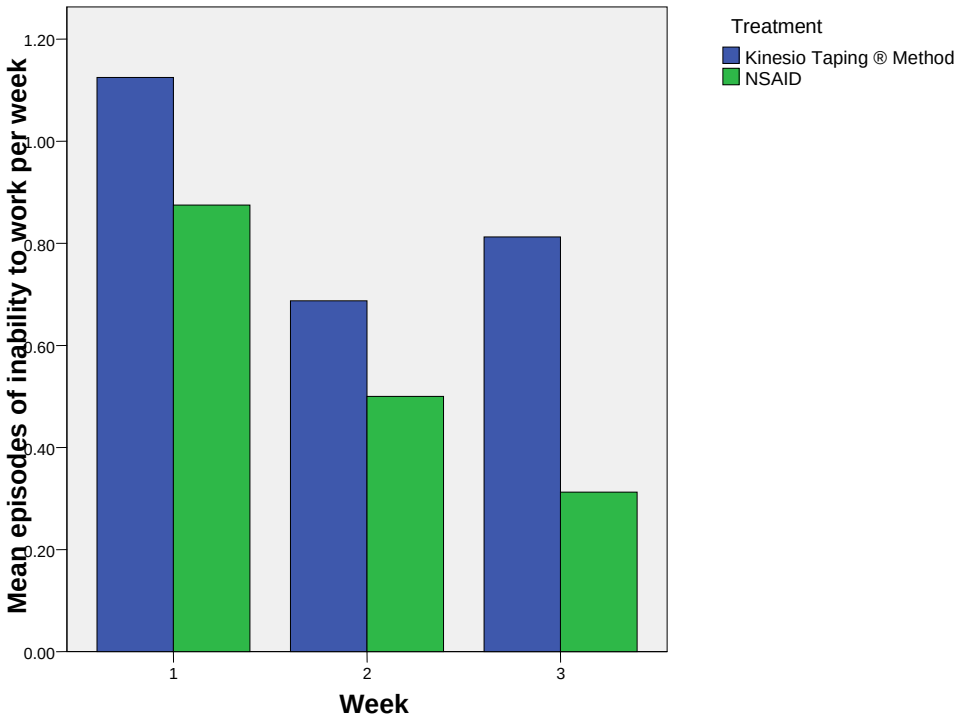


Figure 4.11: Percentage with an inability to work over time by treatment group



Graph 4.12: Mean episodes of inability to work per week per week by treatment group

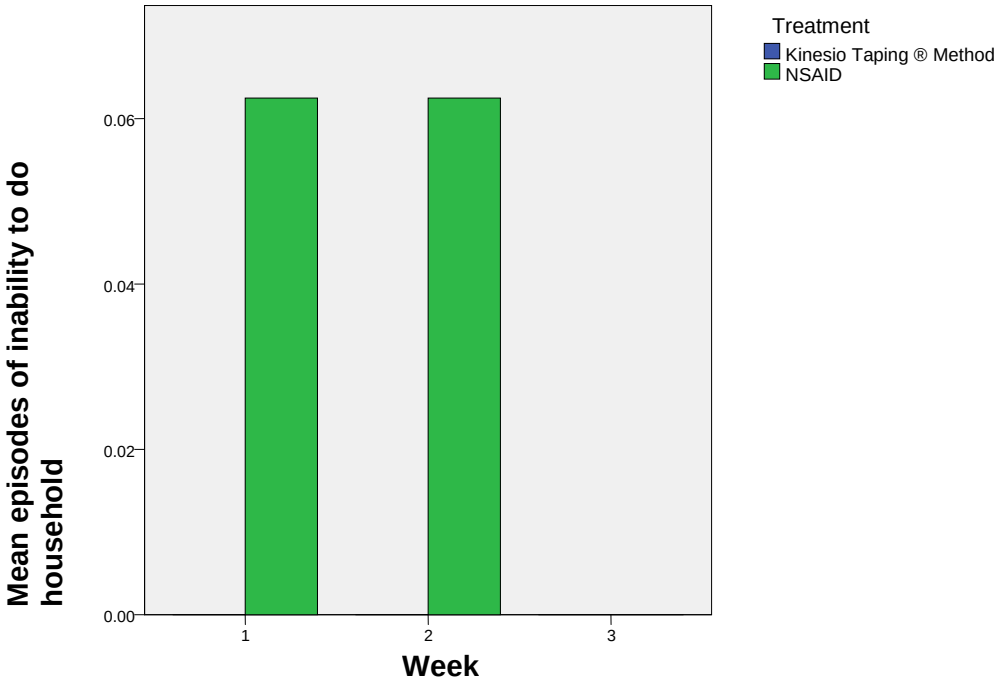
4.5.2.2.12.1 Discussion of Inability to Work

Not being able to work, was recorded each day over the 21 days of observation, using the Headache Diary, was a binary variable (0 or 1) and thus modelled using a binomial distribution and a log link function. An exchangeable correlation matrix was specified. The independent variables used in the model were treatment group (the Kinesio Taping® Method vs. NSAID), day (the 21 days of observation), age, and the interaction between day and treatment group (the treatment effect) (Esterhuizen, 2007).

Table 4.14 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.122), thus there was no differential treatment effect between the treatment groups over time. Figure 11 shows that inability to work was slightly more frequent in the Kinesio Taping® Method group but not statistically significantly so (p=0.809).

According to Figure 11 and Graph 12, in both of the treatment groups the ability of the patients to do work increased during the treatment week. This improvement continued into the third week in the NSAID group as a result of the continued treatment effect due to the half life of the NSAID (Poul et al., 1993), but worsened again within the Kinesio Taping® Method group in the third week due to it being removed and therefore not having a continued treatment effect. This revealed the effectiveness of both treatment groups - which is in accordance with the literature (Diamond, 1983; 1999; Jensen and Olesen, 2000; Friedman, 2007a) - especially the NSAID group where a sustained treatment effect was seen. Furthermore, this outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach, (2004) are applied.

4.5.2.2.13 Inability to Perform Household Chores

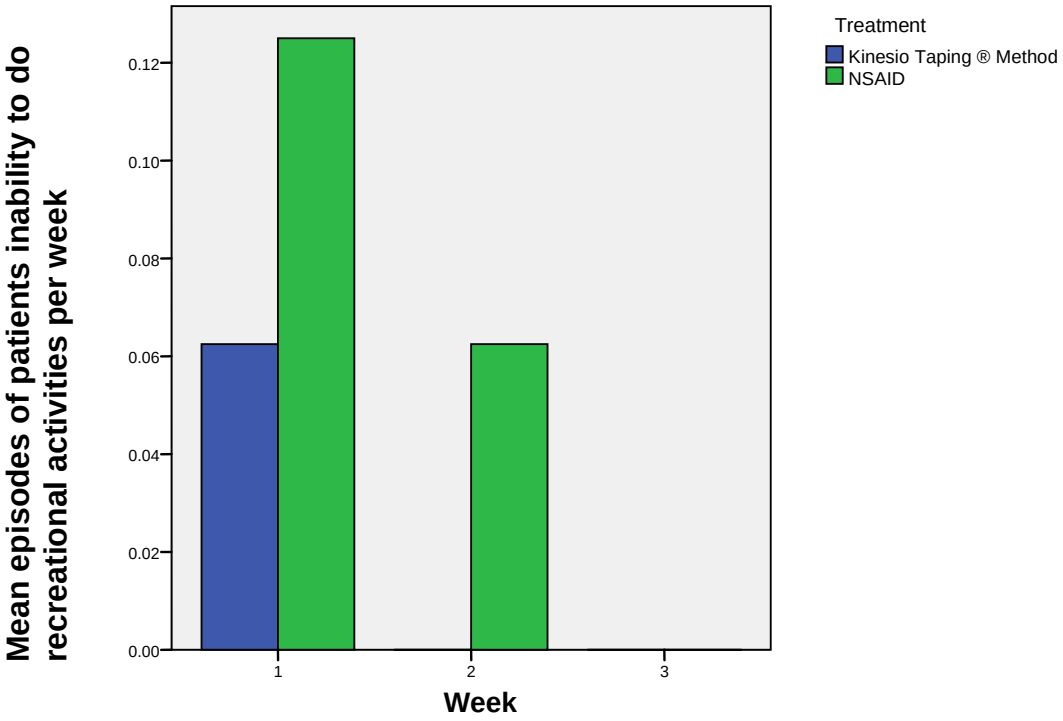


Graph 4.13: Mean episodes of inability to do household chores that week per week by treatment group

4.5.2.2.13.1 Discussion of Inability to Perform Household Chores

No GEE analysis was possible for this outcome since it was only reported on two occasions, both being in the NSAID group and this may be because chores are on the bottom of most peoples' list. Thus there was insufficient information regarding these statistics to make any significant comment regarding either of the treatment groups.

4.5.2.2.14 Inability to do Recreational Activities



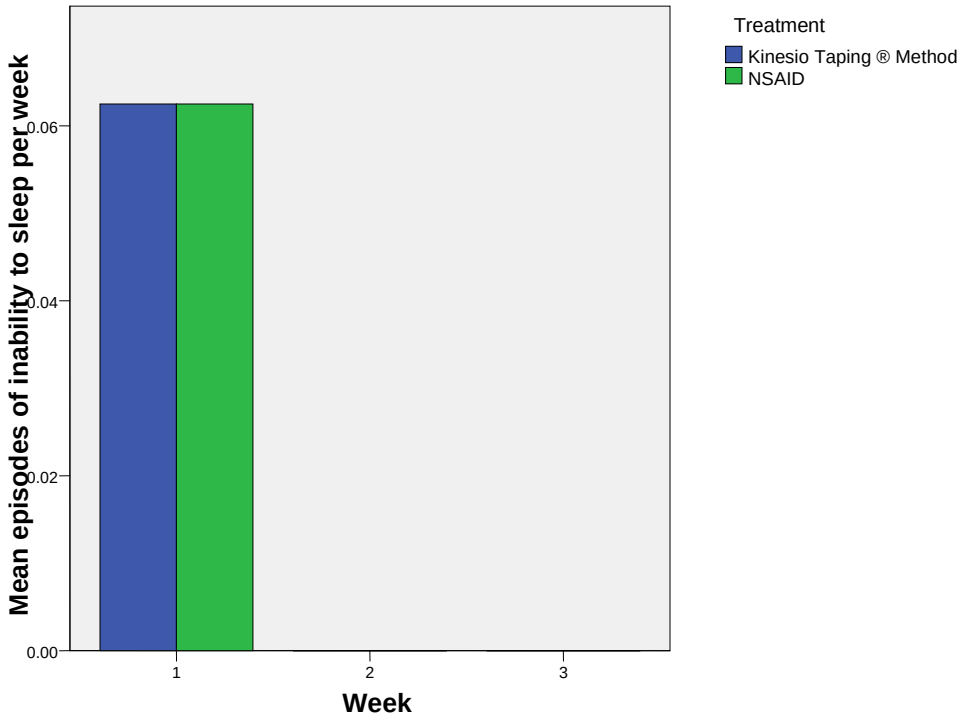
Graph 4.14: Mean episodes of inability to do recreational activities per week per week by treatment group

4.5.2.2.14.1 Discussion of Inability to do Recreational Activities

No GEE analysis was possible for this outcome since only four cases were reported, three from the NSAID group (this may be as a result of the NSAID group being older on average and thus being under more stress resulting in more headaches (Rasmussen et al., 1991; Goebel, Peterson-Braun and Soyka, 1994; Schwartz et al., 1998)). In both of the treatment groups it can be seen that the ability to do recreational activities improved with time and that these were sustained improvements. This is in accordance with the literature which suggests that both treatment modalities may be effective in the treatment of ETTH (Jensen and Olesen, 2000; Diamond, 1983; Diamond, 1999; Friedman, 2007a). It is important to note that the Kinesio Taping® Method group had less “inability to do recreational activity” episodes than the NSAID group. This indicated

the efficacy of the Kinesio Taping® Method group, although the initial number of episodes reported was less than in the NSAID group. This outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach, (2004) are applied.

4.5.2.2.15 Inability to sleep



Graph 4.15: Mean episodes of inability to sleep that week per week by treatment group

4.5.2.2.15.1 Discussion of Inability to sleep

No GEE analysis was possible for this outcome since only two episodes were reported, one from each group. An alternative way to analyze these symptom data where the outcomes were multiple response variables and each was relatively rarely reported, is to sum up all the times that each symptom was reported over the 21 day period for each participant and then compare the mean totals between the groups using t-tests. This analysis strategy ignores the time effect, and thus it is a more crude method of analysis

(Esterhuizen, 2007). Table 4.15 shows that there were no differences in mean total episodes of each symptom between the groups.

According to Graph 14, it indicated improved ability to sleep in week two, and this was maintained into week three in both treatment groups. This indicated the effectiveness of each of the two treatment modalities which is in accordance with the literature which states that both treatment modalities may be effective in the treatment of ETTH (Diamond, 1983; Diamond, 1999; Jensen and Olesen, 2000; Friedman, 2007a). This outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach, (2004) are applied. There were, however, an insufficient number of symptomatic episodes to make significant conclusions from these results.

It must be noted that sleep is a passive activity and so other mechanical and chemical factors may influence these results. Future studies relating to this would be help to clarify this.

4.5.2.2.16 Total number of episodes of each symptom by group

Table 4.15: Mean total number of episodes of each symptom by group

	Treatment				*p* value
	Kinesio Taping® Method		NSAID		
	Mean	Standard Deviation	Mean	Standard Deviation	
Total episodes of sensitivity to light	2.40	2.13	2.25	3.26	0.881
Total episodes of sensitivity to noise	0.53	0.83	0.50	1.51	0.940
Total nausea episodes	0.07	0.26	0.13	0.50	0.689
Total neck stiffness episodes	0.73	1.33	1.63	2.92	0.288
Total fatigue episodes	0.20	0.56	0.38	0.89	0.519
Total dizzy episodes	3.00	11.62	0.44	1.50	0.389
Total episodes of not studying	0.80	1.37	1.06	2.05	0.680
Total episodes of not working	2.80	2.73	1.69	2.91	0.283
Total episodes of not doing household work	0.00	0.00	0.13	0.34	0.167
Total episodes of not doing recreation	0.07	0.26	0.19	0.40	0.332
Total episodes of not sleeping	0.07	0.26	0.06	0.25	0.964

4.5.2.2.16.1 Discussion of total number of episodes of each symptom by group

There was no significant difference between either of the two groups regarding symptoms and thus it can be said that each of the two treatment groups were similarly effective which is in accordance with the literature (Diamond (1983, 1999); Jensen and Olesen (2000); Friedman, 2007(a)).

4.5.2.2.17 Conclusion of the Headache Diary

The fact that Ibuprofen® was effective in the treatment of ETTH is in accordance with the literature (Diamond, 1983; Diamond, 1999; Jensen and Olesen, 2000). This outcome is expected when the models of Dvorak (1985), Gatterman and Goe (1990), and Mense (1991) cited by Leach, (2004) are applied. Jensen and Olesen (2000) stated that the mainstay in the treatment of TTH is simple analgesics and NSAIDs. Diamond (1999) also stated that unless contraindicated, NSAIDs are often the most effective treatment for ETTH and that when Ibuprofen® is used in doses of 400mg to 800mg, it is highly effective (more so the lower the dose as it is more tolerated) (Diamond, 1983).

It is also important to note that the treatment effects regarding many of the symptoms and associated symptoms of ETTH was sustained which may be as a result of the NSAID still functioning within the body during the wash-out period (elimination of the drug from the body) of 3-7 days (Poul et al., 1993). Further follow-up consultations involving data capture would help to determine the intermediate and long term effects of NSAIDs in the treatment of ETTH.

Friedman (2007a) indicated that the Kinesio Taping® Method was effective in the treatment of ETTH because the muscle function is thought to be normalized through the support offered by the Kinesio® Tex Tape, decreasing the need for muscle hypertonicity and allowing for normalisation of function and posture (Friedman, 2007a). Friedman (2007a) also stated that the Kinesio Taping® Method helped in muscle pain reduction

and management and that the alleviation of pain is thought to be affected by a reduction in muscle stretch caused by inflammation in overused muscles.

In viewing the various graphs concerning the associated symptoms, it appears that there is a greater improvement in the functional ability of the patients in the Kinesio Taping® Method group, than in the NSAID group. This is seen in Graphs 11, 13, 14 regarding Inability to Study, Inability to do Recreational Activities, and Inability to do household chores respectively. This may be due to the Kinesio Taping® Method not only facilitating oedema resolution by raising the skin and thus enabling lymphatic drainage, but also by helping to restore muscle function (Yasukawa, Patel and Sisung, 2006; Friedman, 2007a), resulting in increased joint and muscle movement with further resolution of the inflammatory oedema through mechanical means which is supported by the models of Dvorak (1985), Gatterman and Goe (1990), Mense (1991) as cited by Leach (2004), leading to a sustained treatment effect with improved functional ability. The proprioceptive input from the Kinesio® Tex Tape may also serve to reduce pain (Melzack and Wall, 1965).

In looking at the totality of the results, it can be stated that the overall reduction, and often sustained reduction in symptomatology, and associated symptomatology of ETTH supports the prescribed treatment method regarding the Kinesio Taping® Method of the muscular component (viz. the upper and middle trapezius (Friedman, 2007b, Fernandez-de-las-Penas et al., 2007) and the rhomboid musculature (Friedman, 2007b)).

As with the NSAID treatment group, it is also important to note that the treatment effect regarding many of the symptoms and associated symptoms of ETTH were sustained as a result of sustained effects of the Kinesio® Tex Tape. This may be as a result of sustained normalization of muscle function and a sustained reduction in muscle stretch due to resolution of the inflammatory oedema within the affected muscle (Friedman, 2007a).

4.5.2.3 Numerical Rating Scale (NRS)-101

Table 4.16: T-tests to compare mean NRS worst, least and average scores at baseline between the two treatment groups

	Treatment	N	Mean	Std. Deviation	Std. Error Mean	p value
NRS worst score	Kinesio Taping® Method	16	74.50	11.372	2.843	0.335
	NSAID	16	69.06	19.080	4.770	
NRS least score	Kinesio Taping® Method	16	22.25	10.312	2.578	0.004
	NSAID	16	12.00	8.165	2.041	
NRS average score	Kinesio Taping® Method	16	48.3750	7.18911	1.79728	0.029
	NSAID	16	40.5313	11.66972	2.91743	

Table 4.17: Within- and between- patients effect for NRS

Effect	Statistic	P value
Time	Wilk's Lambda=0.919	0.686
Time*group	Wilk's Lambda=0.826	0.272
Group	F=0.229	0.636

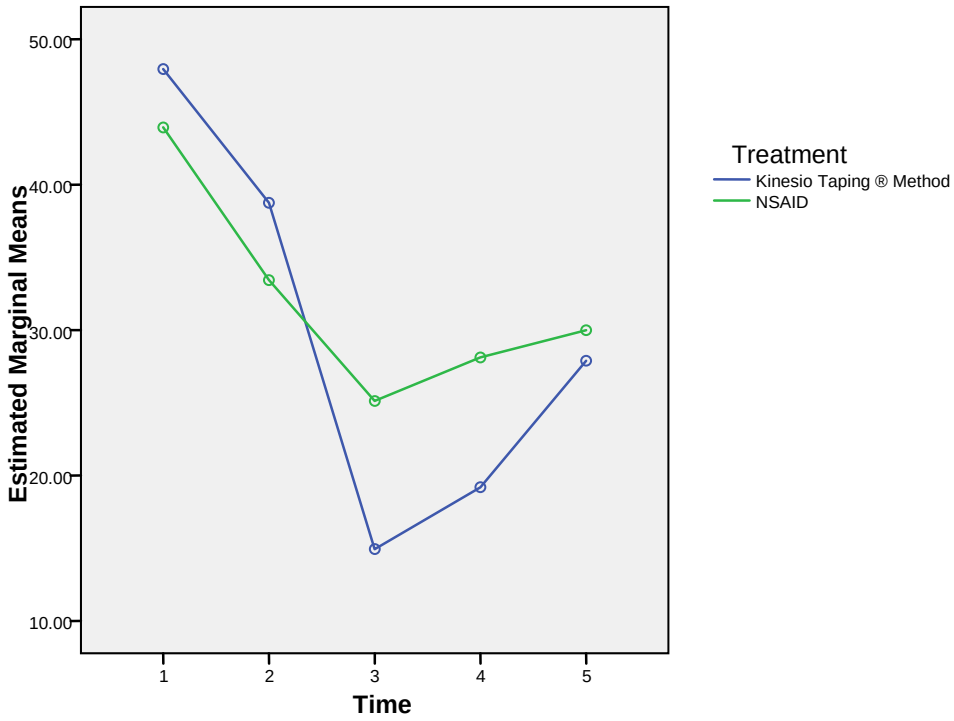


Figure 4.12: Profile plot of mean NRS over time by group

4.5.2.3.1 Discussion of NRS-101

There was a significant difference in NRS least (p=0.004) and average (p=0.029) scores between the two groups at baseline. There was a non-significant treatment effect for NRS (p=0.272). The trend shown in Figure 12 was that the NRS mean value decreased at a slightly faster rate in the Kinesio Taping® Method group than in the NSAID group until time point 3, and especially between time point 2 and 3. After time point 3 both groups showed a mean increase in pain.

This indicates the effectiveness of both treatment groups - especially the Kinesio Taping® Method group. After time point 3 both groups showed a mean increase in pain and yet neither returned to their initial values indicating a sustained treatment effect in both groups even once the treatment had stopped. Regarding the NSAID treatment group, this sustained treatment effect may be due to the NSAID still functioning within the body during the wash-out period (elimination of the drug from the body) of 3-7 days (Poul et al., 1993) however this treatment effect will diminish as seen in the third week of treatment . Regarding the Kinesio Taping® Method this may be as a result of sustained normalization of muscle function and a sustained reduction in muscle stretch as a result of inflammation within the affected muscle being resolved (Friedman, 2007a) as supported by the models of Dvorak (1985), Gatterman and Goe (1990), Mense (1991) as cited by Leach (2004). The possible reason for the pain levels starting to increase once treatment had ceased in both of the groups is that the treatment is symptomatic in each of the groups as opposed to treating the cause.

A further point of consideration is that the treatment results may be due to the placebo effect, and so may not be attributable, or completely attributable to the particular treatment modality used (Mouton, 1996).

4.6 Hypothesis revisited

- **Objective One**

The first objective was to determine the relative effectiveness of Ibuprofen® and the Kinesio Taping® Method treatment in terms of subjective clinical measures: pain intensity (NRS-101 and the Headache Diary), duration (Headache Diary), frequency (Headache Diary) and nature (Headache Diary) of the pain.

Null Hypothesis One

There would be no difference between the treatment effects of Ibuprofen® and the Kinesio Taping® Method in terms of subjective clinical findings.

Null hypothesis one was rejected regarding presence of headache (*p* value = 0.007), number of headache (*p* value = 0.048) and pain intensity (*p* value = 0.022) due to the opposite treatment effect that each of the two treatment groups had on the subjective clinical findings.

Null hypothesis one was accepted due to the positive treatment effect that each of the two treatment groups had on all of the other groups subjective clinical findings (i.e. *p* value > 0.05).

- **Objective Two**

The second objective was to determine the relative effectiveness of Ibuprofen ® and the Kinesio Taping® Method treatment in terms of associated symptoms of the ETTH being reduced (Headache Diary) and whether the daily life function was improved (CMCC Neck Disability Index).

Null Hypothesis Two

There would be no difference between the treatment effects of Ibuprofen® and the Kinesio Taping® Method in terms of associated clinical findings.

Null hypothesis two was accepted due to the positive treatment effect that each of the two treatment groups had on the associated symptoms.

- **Objective Three**

The third objective was a comparison between the trends evidenced in the subjective clinical measures between the two groups.

Null Hypothesis Three

There would be no difference between the treatment effects of Ibuprofen® and the Kinesio Taping® Method in terms of subjective clinical findings and associated clinical findings.

Null hypothesis three was rejected regarding presence of headache (*p* value = 0.007), number of headache (*p* value = 0.048) and pain intensity (*p* value = 0.022) due to the opposite treatment effect that each of the two treatment groups had on the subjective clinical findings.

Null hypothesis three was accepted due to the positive treatment effect that each of the two treatment groups had on all of the other group's subjective clinical findings and associated symptoms (i.e. *p* value > 0.05).

4.7 Conclusion

From the various Graphs, Tables, and Figures, it can be seen that the Kinesio Taping® Method is effective in terms of subjective clinical measures regarding the treatment of ETTH, namely: pain intensity (NRS-101 and the Headache Diary), duration (Headache Diary), frequency (Headache Diary) and nature (Headache Diary) of the pain.

It can be concluded that the Kinesio Taping® Method as well as Ibuprofen® are effective in the treatment of ETTH with sustained treatment results regarding much of the symptomatology and associated symptomatology. There seems to be no significant difference in the efficacy of either of the two treatment modalities and therefore either the Kinesio Taping® Method or NSAID (Ibuprofen®) are acceptable treatment forms in the treatment of ETTH.

CHAPTER 5

5.1 Conclusion

It is important to note that regarding each of the two treatment groups, the treatment effect showed an overall improvement in many of the symptoms and associated symptoms of ETTH, and many of these improvements were sustained.

Within the results regarding the Headache Diary, there was a reduction in the presence and number of ETTH, mean number of days with ETTH, pain intensity and duration of the ETTH in both of the two groups (Figure 4.2, 4.3, 4.4, 4.5 and Graphs 4.1, 4.2, 4.3, 4.4 respectively) and these treatment effects were sustained except in the mean pain intensity in the Kinesio Taping® Method group-Graph 4.3. The mean NRS (Numerical Rating Scale) pain score decreased in both of the treatment groups but at a slightly faster rate in the Kinesio Taping® Method group than in the NSAID group. There was also a sustained treatment effect in both groups even once the treatment had stopped (Figure 4.12).

In viewing the various Graphs concerning the associated symptoms, it appears that there was also an improvement in the functional ability of the patients in both the Kinesio Taping® Method group and the NSAID group. Regarding the Kinesio Taping® Method group, this can be seen in Graphs 11, 13 and 14 regarding 'Inability to Study', 'Inability to do Household chores', and 'Inability to do Recreational Activities' respectively. Regarding the NSAID group, this can be seen in Figure 1-mean CMCC scores where it can be seen that the NSAIDs caused an immediate, significant, yet short-lived effect, whereas the Kinesio Taping® Method group caused a slower, moderate more sustainable effect.

It can be concluded that the Kinesio Taping® Method as well as Ibuprofen ® are effective in the treatment of ETTH with sustained treatment results regarding much of the symptomatology and associated symptomatology in both groups. There seems to

be no significant difference in the efficacy of either of the two treatment modalities and therefore either the Kinesio Taping® Method or NSAID (Ibuprofen®) are acceptable treatment forms in the treatment of ETTH. It can be stated that the overall reduction and often sustained reduction in symptomatology, and associated symptomatology of ETTH supports the prescribed treatment method using NSAIDs, as well as the Kinesio Taping® Method regarding treatment of the muscular component (viz. the upper and middle trapezius).

5.2 Recommendations Regarding the Methodology of the Study

Further follow-up consultations involving data capture would help to determine the intermediate and long term effects of the Kinesio Taping® Method and Ibuprofen® in the treatment of ETTH. Much of the statistical analysis showed a sustained effect of each of the treatment groups and it would thus be beneficial to be able to compare the full length of the continued treatment effect of each of the two groups.

In future studies, perhaps an Algometer reading regarding muscle tenderness would be justified to provide more objective treatment results regarding treatment of the ETTH.

The greater the number of patients in a study, the greater the validity and reliability due to a smaller margin for subjective errors. Thus in the future, the number of patients involved in the study should be increased to improve for this.

In this study, the researcher was able to compare the NSAID group (already shown to be effective in the treatment of ETTH (Jensen and Olesen, 2000; Diamond, 1999)) and the Kinesio Taping® Method group. There was no control group in this study and so the treatment results are not able to be compared to a standard. In future studies, a control group should be introduced to enable this.

There has been little research done into the Kinesio Taping® Method in the past and so simple techniques of taping the muscles associated with ETTH were used. In the future, these techniques along with more complex taping strategies may be researched.

In hindsight, it is recommended that the term “reading” should have been used instead of the term “studying” within the headache questionnaire.

5.3 Clinical applications

It can be concluded, that from the results of this study, that the Kinesio Taping® Method as well as Ibuprofen® are effective in the treatment of ETTH; with sustained treatment results regarding much of the symptomatology and associated symptomatology; and that there seems to be no significant difference in the efficacy of either of the two treatment modalities. It can be concluded that both the Kinesio Taping® Method (application to the upper and middle trapezius and rhomboid musculature) and Ibuprofen® are acceptable treatment forms for ETTH.

The benefit of Kinesio® Tex Tape is that it does not cause the same side-effects as Ibuprofen® or any of the allopathic medications used in the treatment of ETTH. It is a drug free treatment modality which can be applied frequently with sustained treatment effects to those suffering from ETTH.

5.4 Future Research Studies

This is only the beginning in terms of research into the use of the Kinesio Taping® Method in the treatment of various health related conditions. There is a scope for research into this treatment modality which is highlighted in current research.

In terms of research regarding ETTH:

- A similar clinical trial comparing the Kinesio Taping® Method to NSAID treatment with three weeks follow-up would be beneficial to investigate the intermediate- and long-term effects of the two treatments.

- A similar clinical trial comparing the Kinesio Taping® Method to a placebo control group with three weeks follow-up would be beneficial to clinically confirm its treatment effect to a controlled standard.

- A similar clinical trial comparing the Kinesio Taping® Method to an adjustment and a placebo control group with three weeks follow-up would be beneficial to explore the difference in effectiveness between the two treatment modalities.

REFERENCES

Altura, B.M. and Altura, B.T. 2001. Tension headaches and muscle tension: Is there a role for magnesium? *Medical Hypotheses*, 57(6):705-713.

Ashina, S. and Ashina, M. 2003. Current and potential future drug therapies for tension-type headache. *Current Headache Reports*, 2:466–474.

Ashina, M., Bendtsen, L., Jensen, R., Ekman, R. and Olesen, J. 1999a. Plasma levels of substance P, neuropeptide Y and vasoactive intestinal polypeptide in patients with chronic tension-type headache. *Pain*, 83:541-547.

Ashina, M., Bendtsen, L., Jensen, R., Lassen, L.H., Sakai, F. and Olesen, J. 1999b. Possible mechanisms of action of nitric oxide synthase inhibitors in chronic tension-type headache. *Brain*, 122:1629-1635.

Ashkenazi, A. and Silberstein, S.D. 2004. Headache Management for the Pain Specialist. *Regional Anesthesia of Pain Medicine*, 29: 462-473.

Authentic Kinesio®: About us [online]. Available at: http://www.kinesiotaping.com/kinesio-concepts.php [Accessed 19/11/2009].

Bach, F.W., Langemark, M., Secher, N.H. and Olesen, J. 1992. Plasma and cerebrospinal fluid beta-endorphin in chronic tension-type headache. *Pain*, 51:163-168.

Bates, B. 1995. *A guide to Physical Examination and History Taking. 6th edition.* Philadelphia: J.B. Lippincott Company.

Bendtsen, L. 2002. Sensitization: It's role in primary headache. *Current Opinion in Investigational Drugs*, 3:449-453.

Bendtsen, L. 2000. Central sensitization in tension-type headache - possible pathophysiological mechanisms. *Cephalalgia,* 20:486-508.

Bendtsen, L., Jensen, R. and Olesen, J. 1996. Decreased pain detection and tolerance thresholds in chronic tension-type headache. *Archives of Neurology*, 53:373-376.

Bendtsen, L., Jensen, R. and Olesen, J. 1996. Qualitatively altered nociception in chronic myofascial pain. *Pain*, 65: 259-264.

Bernat, J.L. and Vincent, F.M. 1993. *Neurology: Problems in Primary Care.* 2nd ed., USA. PMIC.

Bigal, M.E., Bigal, J.M., Betti, M., Bordini, C.A. and Speciali, J.G. 2001. Evaluation of the impact of migraine and episodic tension-type headache on the quality of life and performance of a university population. *Headache*, 41:710-719.

Blau, J.N. and MacGregor, E.A. 1994. Migraine and the neck. *Headache,* 34:88-90.

Bogduk, N. 1992. The anatomical basis for cervicogenic headache. *Journal of Manipulative and Physiological Therapeutics*, 15 (1): 67-70.

Boon, N.A., Colledge, N.R. and Walker, B.R. 2006. *Davidson's Principles and Practice of Medicine.* 20th ed. India: Churchill Livingstone.

Castillio, J., Munoz, P., Guitera, V. and Pascual, J. 1999. Epidemiology of chronic daily headache in the general population. *Headache*, 39: 190-196.

Cheung, R.T.F. 2000. Prevalence of migraine, tension-type headache, and other headaches in Hong Kong. *Headache*, 40:473-479.

Dalessio, D.J. (ed). 1987. *In Wolff's Headache and other Pain*. 5th ed. New York: Oxford University Press.

Davies, N.J. 2000. *Chiropractic Paediatrics. A Clinical Handbook.* London: Churchill Livingstone.

Dawn, A.M., Scharff, L., Mercer, S. and Turk, D.C. 1999. Musculoskeletal abnormalities in chronic headache: A controlled comparison of headache diagnostic groups. *Headache*, 39:21-27.

Diamond, S., Balm, T.K. and Freitag, F.G. 2000. Ibuprofen ® plus caffeine in the treatment of tension-type headache, *Clinical Pharmacology and Therapeutics*, 68:312-319.

Diamond, S. 1999. Tension-type headache. *Clinical Cornerstone*, 1(6): 33-41.

Diamond, S. 1987. Muscle Contraction Headache. In Dalessio, D.J. (ed.). Wolff's Headache and other Head Pain. 5th ed. Pp. 171-189. New York: Oxford University Press.

Diamond, S. 1983. Ibuprofen® versus aspirin and placebo in the treatment of muscle contraction headache. *Headache*, 23: 206–210.

Dorland's Medical Dictionary. 1988. 27th ed. Philadelphia: W.B. Saunders Company.

Downie, W.W., Leatham, P.A., Rhind, V.M., Wright, V., Branco, J.A. and Anderson, J.A. 1978. Studies with Pain Rating Scales. *Annals of the Rheumatic Diseases*, 37: 378-381.

Dvorak, J. 1985. Neurological and biomechanical aspects of pain. In: Buerger A.A., Greenman, P.E. (eds). Approaches to the validation of spinal manipulation. Springfield: Thomas.

Edwards, C.R.W. and Bouchier, I. A. D (eds). 1991. *Davidson's Principles and Practice of Medicine.* 16th ed. Hong Kong: Churchill Livingstone.

Esterhuizen, T. 2007. Interview by J.Henry. University of Kwazulu-Natal, Durban, 23 July 14.00.

Farlex, Inc. 2009. [online]. Available at: http://www.thefreedictionary.com/neck+and+neck. [Accessed: 5/12/2009].

Fernandez-de-las-Penas, C., Ge, H.Y., Arendt-Nielson, L., Cuadrado, M. L. and Pareja, J.A. 2007. Referred Pain from Trapezius Muscle Trigger Points Shares Similar Characteristics with Chronic Tension Type Headaches. *European Journal of Pain*. 11: 475-482.

Forward, S.P., McGrath, P.J., MacKinnon, D., Brown, T.L., Swann, J. and Currie, E.L. 1998. Medication patterns of recurrent headache sufferers: a community study. *Cephalalgia*, 18:146-151.

Friedman, J. 2007a. Kinesio Taping® level one course notes. Kinesio Taping® Training, Madge Wallace, Johannesburg.

Friedman, J. 2007b. Kinesio Taping® level three advanced course notes. Kinesio Taping® Training, Madge Wallace, Johannesburg.

Gatterman, M.I. 1995. *Foundations of Chiropractic Subluxation*. St. Louis, Missouri: Mosby-Year Book, Inc.

Gatterman, M.I. 1990. *Chiropractic management of spine related disorders.* Baltimore, Maryland: Williams and Wilkins.

Gatterman, M.I. and Goe, D.R. 1990. Muscle and Myofascial pain syndromes. In: Gatterman, M.I. (ed). Chiropractic management of spinal related disorders. Baltimore: Williams and Wilkins.

Giacomini, P.G., Alessandrini, M., Evangelista, M., Napolitano, B., Lanciani, R. and Camaioni, D. 2004. Impaired postural control in patients affected by tension type headache. *European Journal of Pain*, 8: 579-583.

Goebel, H., Peterson-Braun, M. and Soyka, D. 1994. The epidemiology of headaches in Germany: a nationwide survey of a representative sample on the basis of the headache classification of the International Headache Society. *Cephalalgia*, 14(2): 97-106.

Hatch, J.P., Schoenfeld, L.S., Boutros, N.N., Seleshi, E., Moore, P.J. and Cyr-provost, M. 1991. Anger and Hostility in Tension-Type Headache. *Headache*, 31:302-304.

Holroyd, K.A., France, J.L., Nash, J.M. and Hursey, K.G. 1993. Pain state as artifact in the psychological assessment of recurrent headache sufferers. *Pain*, 53:229-235.

International Headache Society. 1991. Classification and Diagnostic criteria for headache disorders, cranial neuralgias and facial pain. *Cephalgia*. 8 (suppl 7).

International Headache Society. 1988. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. *Cephalalgia*, 8 (suppl 7):1-96.

Jensen, R. 2003a. Diagnosis, Epidemiology, and Impact of Tension-type Headache. *Current Headache Reports*, 2:455-459.

Jensen, R. 2003b. Peripheral and central mechanisms in tension-type headache: an update. *Cephalalgia*, 23 (1):49-52.

Jensen, R. 1999. Pathophysiological mechanisms of tension-type headache: a review of epidemiological and experimental studies. *Cephalalgia*, 19: 602-621.

Jensen, R. 1995. Mechanisms of Spontaneous Tension-Type Headaches: an analysis of tenderness, pain thresholds and EMG. *Pain*, 64:251-256.

Jensen, R. and Bendtsen, L. 2006. Tension-type Headache: Why Does this Condition Have to Fight for Its Recognition? *Current Pain and Headache Reports*, 10: 454-458.

Jensen, R., Bendtsen, L. and Olesen, J. 1998. Muscular factors are of importance in tension-type headache. *Headache*, 38:10-17.

Jensen, M.P., Karoly, P. and Braver, S. 1986. The measurement of clinical pain intensity: a comparison of the three methods. *Pain*. 27:117-126.

Jensen, R. and Olesen, J. 2000. Tension-type headache: an update on mechanisms and treatment. *Current Opinion in Neurology*, 13:285-289.

Jensen, R. and Rasmussen, B.K. 1996. Muscular disorders in tension-type headache. *Cephalalgia*, 16: 97-103.

Jensen, R., Rasmussen, B.K., Pedersen, B. and Olesen, J. 1993. Muscle tenderness and pressure pain thresholds in headache. A population study. *Pain*, 52:193-199.

Johnson, C. 2005. On the Subject of Human Subjects. *Journal of Manipulative and Physiological Therapeutics*, 28: 79-80.

Kabe, N., Tezuka, H., Nagazumi, A., and Terashi, A. 1991. Thermographic Investigation of Tension-Type Headache. *Cephalagia*, 11 (11): 63.

Karst, M., Rollnik, J.D., Fink, M., Reinhard, M. and Piepenbrock, S. 2000. Pressure Pain Threshold and Needle Acupuncture in Chronic Tension-Type Headache – A Double-Blind Placebo-controlled Study. *Pain*, 88:199-203.

Kase, K., Wallis, H. and Kase, J. 2003. *Clinical Therapeutic Applications of the Kinesio Taping® Method.* 2nd ed.

Katsarava, Z., Fritsche, G., Muessig, M., Diener, H.C. and Limmroth, V. 2001. Clinical features of withdrawal headache following overuse of triptans and other headache drugs. *Neurology* 57:1694-1698.

Kinesio Taping® in Canada: Teaching certification courses nationwide [online]. Available at: http://www.kinesiotape.ca [Accessed 18/11/2009].

King, N.J. and Sharpley, C.F. 1990. Headache activity in children and adolescents. *Journal of Paediatric Child Health*, 26:50-54.

Kunkel, R.S. 1991. Diagnosis and treatment of muscle contraction (tension-type) headaches. *Medical clinics of North America*. 75 (3): 595-603.

Langemark, M., Bach, F.W., Ekman, R. and Olesen, J. 1995. Increased cerebrospinal fluid met-enkephalin immunoreactivity in patients with chronic tension-type headache. *Pain*, 63:103-107.

Langemark, M., Bach, F.W., Jensen, T.S. and Olesen, J. 1993. Decreased nociceptive flexion reflex threshold in chronic tension-type headache. *Archives of Neurology*, 50:1061-1064.

Langemark, M. and Olesen, J. 1987. Pericranial tenderness in tension headache. A blind, controlled study. *Cephalalgia,* 7:249-255.

Langemark, M., Olesen, J., Poulsen, D.L. and Bech, P. 1988. Clinical characterization of patients with chronic tension-type headache. *Headache,* 28:590-596.

Lavados, P.M. and Tenhamm, E. 1998. Epidemiology of tension-type headache in Santiago, Chile: a prevalence study. *Cephalalgia*, 18:552-558.

Leach, R.A. 2004. *The Chiropractic Theories: A Textbook of Scientific Research*. Baltimore, Maryland: Lippincott Williams and Wilkins.

Lebbink, J., Spierings, E.L.H. and Messinger, H.B. 1991. A questionnaire survey of muscular symptoms in chronic headache: An age- and sex-controlled study. *Clinical Journal of Pain*, 7:95-101.

Leone, M., Filippini, G., D'Amico, D., Farinotti, M. and Bussone, G. 1994. Assessment of International Headache Society diagnostic criteria: A reliability study. *Cephalalgia*. 14:280-284.

Lichstein, K.L., Fischer, S.M., Eakin, T.L., Amberson, J.I., Bertorini, T. and Hoon, P.W. 1991. Psychophysiological parameters of migraine and muscle-contraction headaches. *Headache*, 31:27-34.

Linet, M.S., Stewart, W.F., Celentano, D.D., Ziegler, D. and Sprecher, M. 1989. An epidemiologic study of headache among adolescents and young adults. *Journal of the American Medical Association*. 261 (15): 2211-2216.

Lipchik, G.L., Holroyd, K.A., Talbot, F. and Greer, M. 1997. Pericranial muscle tenderness and exteroceptive suppression of temporalis muscle activity: a blind study of chronic tension-type headache. *Headache,* 37:368-376.

Martin, P. R. 1993. *Psychological Management of Chronic Headaches.* New York: The Guilford Press.

Mathew, N. and Bendtsen, L. 2000. *Prophylactic pharmacotherapy of tension-type headache. In: The headaches*, 2nd ed. Olesen, J., Tfelt-Hansen, P. And Welch, K.M.A. (editors). Philadelphia: Lippincot Williams and Wilkins.

Mathew, N., and Schoenen, J. 2000. *Pharmacotherapy of tension-type headache. In: The headaches*, 2nd ed. Olesen, J., Tfelt-Hansen, P. And Welch, K.M.A. (editors). Philadelphia: Lippincot Williams and Wilkins.

Melzack, R. and Wall, P.D. 1965.Pain mechanisms: a new theory, *Science,* 150 (699): 971-979.

Mense. S., Hoheisel, U. and Reinert, A. 1991. Considerations concerning the neurobiological basis of muscle pain. *Canadian Journal of Physiology and Pharmacology*. 69: 610-616.

Mercer, S., Marcus, D.A. and Nash, J. 1993. Cervical musculoskeletal disorders in migraine and tension-type headache. Paper presented at the 68th Annual Meeting of the American Physical Therapy Association Cincinnati, Ohio.

Mitsikostas, D.D. and Thomas, A.M. 1999. Comorbidity of headache and depressive disorders. *Cephalalgia*, 19:211-217.

Moerk, H. and Jenson, R. 2000. Prognosis of tension-type headache: a 10-year follow-up study of patients with frequent tension-type headache. *Cephalgia*, 20:433-434.

Moerk, H., Ashina, M., Bendtsen, L., Olesen, J. and Jensen, R. 2001. A new experimental human model of myofascial pain. Pain perception in patients with episodic tension-type headache. *Cephalalgia*, 21:486-489.

Mongini, F., Ciccone, G., Deregibus, A., Ferrero, L. and Mongini, T. 2004. Muscle Tenderness in Different Headache Types and its Relationship to Anxiety and Depression. *Pain*. 112: 59-64.

Moore, K.L. and Dalley, A. F. 1999. *Clinically Orientated Anatomy*. 4th ed. Maryland: USA, Lippincott Williams and Wilkins.

Mouton, J. 1996. *Understanding social research*. Pretoria, South Africa, Van Schaik Publishers.

Mueller, L. 2002. Tension-type, the forgotten headache: how to recognise this common but undertreated condition. *Postgraduate medicine*, 111(4):25-50.

North Star Therapeutics: Information Regarding Kinesiotape® [online]. Available at: http://www.northstartherapeutics.com/ns.info.htm [Accessed 19/11/ 2007].

Oksanen, A., Poyhonen, T., Metsahonkala, L., Anttila, P., Hiekkanen, H., Laimi, K. and Salminen, J.J. 2007. Neck Flexor Muscle Fatigue in Adolescents with Headache – An Electromyographic Study. *European Journal of Pain*. 11: 764-772.

Penter, C.S. 1994. *Determining the Role Chiropractic plays in the role of Tension-Type Headache.* Chiropractic Masters Dissertation: Durban University of Technology Library, Durban.

Pop, P.H.M., Gierveld, C.M., Karis, H.A.M. and Tiedink, H.G.M. 2002. Epidemiological aspects of headache in a workplace setting and the impact on the economic loss. *European Journal of Neurolology*, 9:171-174.

Poul, J., West, J., Buchanan, N. and Grahame, R. 1993. Local Action Transcutaneous Flurbiprofen in the Treatment of Soft Tissue Rheumatism. *British Journal of Rheumatology*, 32:1000-1003.

Pritchard, D. 1995. EMG levels in children who suffer with severe headache. *Headache*, 35:554-556.

Pryse-Phillips, W., Findlay, H., Tugwell, P., Edmeads, J., Murray, T.J. and Nelson, R.F. 1992. A Canadian population survey on the clinical, epidemiologic, and societal impact of migraine and tension-type headache. *Canadian Journal of Neurological Sciences*, 19:333-339.

Raskin, N.H. 1988. *Headache*.2nd ed. New York: Churchill Livingstone.

Rasmussen, B.K. 1999. Epidemiology and socio-economic impact of headache. *Cephalalgia*, 19 (25):20-23.

Rasmussen, B.K. 1995. Epidemiology of headache. *Cephalalgia*, 15:45-68.

Rasmussen, B.K.1993. Migraine and tension-type headache in a general population: precipitating factors, female hormones, sleep pattern and relation to lifestyle. *Pain*, 53:65-72.

Rasmussen, B.K. 1992. Migraine and tension-type headache in a general population: psychological factors. *International Journal of Epidemiology*, 21:1138-1143.

Rasmussen, B.K., Jensen, R. and Olesen, J. 1992. Impact of headache on sickness absence and utilisation of medical services: a Danish population study. *Journal of Epidemiology and Community Health,* 46:443-336.

Rasmussen, B.K., Jensen, R., Schroll, M. and Olesen, J. 1991. Epidemiology of Headache in a general population - a prevalence study. *Journal of Clinical Epidemiology*, 44(11):1147-1157.

Redwood, D. and Cleveland III, C.S. 2003. *Fundamentals of Chiropractic.* St Louis, Missouri: Mosby.

Sakai, F., Ebihara, S., Akiyama, M. and Horikawa, M. 1995. Pericranial muscle hardness in tension-type headache. A non-invasive measurement method and its clinical application. *Brain*, 118:523-531.

Sandoz Ibuprofen® Tablet Package Insert. 1997.

Schachtel, B.P., Furey, S.A. and Thoden, W.R. 1996. Non-prescription Ibuprofen ® and acetaminophen in the treatment of tension-type headache. *Journal of Clinical Pharmacology*. 36: 1120 – 1125.

Schafer, R.C. and Faye, L.J. 1990. *Motion Palpation and Chiropractic Technique-Principles of Dynamic Chiropractic.* 2nd ed. California, USA: The Motion Palpation Institute.

Schoenen, J., Gerard, P., De Pasqua, V. and Sianard-Gainko, J. 1991. Multiple clinical and paraclinical analyses of chronic tension-type headache associated or unassociated with disorder of pericranial muscles. *Cephalalgia*, 11:135-139.

Schoenen, J., Jamart, B., Gerard, P., Lenarduzzi, P. and Delwaide, P.J. 1987. Exteroceptive suppression of temporalis muscle activity in chronic headache. *Neurology*, 37:1834-1836.

Schwartz, B.S., Stewart, W.F. and Lipton, R.B. 1997. Lost workdays and decreased work effectiveness associated with headache in the workplace. *Journal of Occupational and Enviromental Medicine*. 39:320-327.

Schwartz, B.S., Stewart, W.F., Simon, D. and Lipton, R.B. 1998. Epidemiology of tension-type headache. *JAMA*, 279(5):381-383.

Seth, S.D. 1999. *Textbook of* Pharmacology. 2nd ed. Churchill Livingstone.

Simons, D.G., Travell, J.G. and Simons, L.S. 1999*. Myofascial Pain and Dysfunction, The Trigger Point Manual: Upper half of body, vol 1.* Maryland, USA: Williams and Wilkins.

Torelli, P., Abrignani, G., Castellini, P., Lambru, G. and Manzoni, G. C. 2008. Human psyche and headache: tension-type headache. *Neurological Science* [online], 29: S93-S95. Available at: http://springerlink.com [Accessed 8 December 2009].

Ulrich, V., Russell, M.B., Jensen, R. and Olesen, J. 1996. A comparison of tension-type headache in migraineurs and in non-migraineurs: a population based study. *Pain*, 67:501-506.

Vernon, H.T. 1995. The Effectiveness of Chiropractic Manipulation in the Treatment of Headache: An exploration in the Literature. *Journal of Manipulative and Physiological Therapeutics*, 18(9): 611-617.

Vernon, H. and Mior, S. 1991. The Neck Disability Index: A study of reliability and Validity. *Journal of Manipulative and Physiological Therapeutics*, Vol. 14(7): 409-415.

Vernon, H.T., Steiman, I. and Hagino, C. 1992 Cervicogenic dysfunction in muscle contraction headache and migraine: A descriptive study. *Journal of Manipulative and Physiologic Therapeutics*, 15 (7): 418-429.

Wang, S.J., Fuh, J.L., Lu, S.R., Liu, C.Y. Hsu, L.C., Wang, P. N. and Liu, H.C. 2000. Chronic daily headaches in Chinese elderly: prevalence, risk factors, and biannual follow-up. *Neurology*, 54:314-319.

Wang, W. and Schoenen, J. 1994. Reduction of temporalis exteroceptive suppression by peripheral electrical stimulation in migraine and tension-type headaches. *Pain*, 59:327-334.

World Health Organization, guidelines on Chiropractic [online]. 2004. Available at: http://www.wfc.org/website/index.php?option=com_content&view=article&id=90&Itemid=110&lang=en [Accessed 9 December 2009].

Yasukawa, A., Patel, P. and Sisung, C. 2006. Pilot study: Investigating the Effects of Kinesio Taping® in an Acute Pediatric Rehabilitation Setting. *American Journal of Occupational Therapy*, 60: 104-110.

Zwart, J.A. and Sand, T. 1995. Exteroceptive suppression of temporalis muscle activity: a blind study of tension-type headache, migraine and cervicogenic headache. *Headache*, 35:338-343.

Appendix A
Letter of information

Dear Participant,

Welcome to my research project. You have been selected to take part in a trial to determine the efficacy of a Taping Method in Episodic Tension-Type headache. In order for you to take part in this study you have to be between the ages of 20 and 45 and not have any contraindications to the treatment

Title of research:
The relative effectiveness of non-steroidal anti-inflammatory drugs (Ibuprofen) and a taping method (Kinesio Taping® Method) in the treatment of Episodic Tension-Type Headaches.

NAME OF RESEARCH STUDENT
Justin Henry Contact number: (031 3732205) / (0845820019)
NAME OF RESEARCH SUPERVISOR
Dr C. Korporaal Contact number: (0313732611)
M. Tech: Chiropractic, CCFC, CCSP, ICSSD

Purpose of the study:
The aim of this study will be to determine the relative effectiveness of NSAIDs and taping in the treatment of Episodic Tension-Type Headaches.

Procedures:
Thirty two people will be required to take part in this study. They will then be divided into two groups of sixteen each. Each group will have a thorough case history taken together with a physical exam. Trapezius and rhomboid muscle strength tests, a Linder test and a bulge in an artery test will be performed. If you are confirmed as qualifying for the research, feedback will be obtained with respect to your ETTH and treatment will then commence.

The second and third appointments will be conducted with no more than 4 days between consultations. The second consultation will occur six or seven days after the initial. The subjective measurements will be obtained prior to the treatment. Those being treated using the taping method will have tape applied. The third appointment will be conducted two or three days after the second appointment where the subjective measurements will be taken and those being treated with the taping method will have new tape applied. The fourth appointment will occur 14 days after the initial appointment and only feedback will be obtained and no further treatment will be given. Those being treated with the taping method will have the tape removed. At the fifth appointment held 7 days after the fourth appointment, only feedback will be obtained. Please contact me immediately if your taping comes off as a new application will be needed.

Risks and benefits:
In order to minimise any risks to you, I will comprehensively be evaluating you in terms of the inclusion and exclusion criteria. Should any problems arise during this

pre-research evaluation, you will be informed. Once you have been given a full understanding of how your health status fits into the research, it will be your choice to continue or voluntarily exclude yourself (i.e. by either signing or not signing the attached informed consent form). Taping may cause an allergic reaction patients will be questioned about previous allergic reactions in response to taping and will be forewarned about the signs and symptoms of an allergic reaction. Should the reaction be of a serious nature, the patient will be removed from the study for appropriate treatment and / or referral as necessary. Further clinical care will be provided to this patient however that is not within the context of this research.

New Information:
The results of the study will be published as a research Dissertation at the Durban University of Technology Library and you may request a copy of the results, which will be provided.

Cost:
The treatments for the duration of the study will be free of charge.

Withdrawals:
You may withdraw from the study at any time. You may be withdrawn without your consent if you are taking any medication or undergoing any other treatments for ETTH during the duration of the study. If the taping is removed before the subsequent follow-up you may also be excluded from the study. No data will be used if you do not complete the full four measurements.

Confidentiality:
All your information will be kept confidential and your relevant file numbers will be used in order for no names to be displayed on the data sheets. Information may be viewed by the researcher as well as the research supervisor for the period of the study and will be kept for 5 years in your respective files before the data is shredded. Please feel free to ask any questions regarding any aspect of this study. If you experience any problems or want to ask any more questions please don't hesitate to contact me or my supervisor at the contact numbers above. Your full co-operation will assist the Chiropractic profession in expanding its knowledge of this condition.

Should you wish, you are also able to contact the Chair of the Faculty of Health Sciences Research and Ethics Committee via its Chairperson Professor T Gwele, at 031 3732704.

Sincerely yours

Justin Henry.
B. Tech (Chiropractic)
(Researcher)

Dr. C. Korporaal
M.Tech: Chiropractic (SA), CCFC (SA), CCSP, ICCSD (USA)
(Supervisor)

APPENDIX B

INFORMED CONSENT FORM

(To be completed by patient /subject)

Date :

Title of research project : The relative effectiveness of non-steroidal anti-inflammatory drugs (Ibuprofen) and a taping method (Kinesio Taping® Method) in the treatment of Episodic Tension-Type Headaches.

Name of supervisor	**:**	**Dr C Korporaal**
Tel	**:**	**031 2042611**
Qualification	**:**	**M.Tech: Chiropractic(SA), CCFC(SA), CCSP, ICCSD) (USA)**
Name of research student	**:**	**Justin Henry**
Tel	**:**	**031 373 2512/2205**

Please circle the appropriate answer	**YES /NO**	
1. Have you read the research information sheet?	Yes	No
2. Have you had an opportunity to ask questions regarding this study?	Yes	No
3. Have you received satisfactory answers to your questions?	Yes	No
4. Have you had an opportunity to discuss this study?	Yes	No
5. Have you received enough information about this study?	Yes	No
6. Do you understand the implications of your involvement in this study?	Yes	No
7. Do you understand that you are free to withdraw from this study?		
At any time	Yes	No
Without having to give any a reason for withdrawing, and	Yes	No
Without affecting your future health care.	Yes	No
8. Do you agree to voluntarily participate in this study	Yes	No
9. Who have you spoken to? _____		
10. Received insert to read	Yes	No

Please ensure that the researcher completes each section with you
If you have answered NO to any of the above, please obtain the necessary information before signing

Please print in block letters:

Patient /Subject Name:_____ Signature: _____

Parent/ Guardian:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name:_____ Signature:_____

Appendix C

DURBAN UNIVERSITY OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: _____ Date: _____
File # : _____ Age: _____
Sex : _____ Occupation: _____
Intern : _____ Signature _____

FOR CLINICIANS USE ONLY:

Initial visit
Clinician: Signature :

Case History:

Examination: Previous:
Current:

X-Ray Studies: Previous:
Current:

Clinical Path. lab: Previous:
Current:

CASE STATUS:

PTT: Signature: Date:

CONDITIONAL:
Reason for Conditional:

Signature: Date:

Conditions met in Visit No: Signed into PTT: Date:

Case Summary signed off: Date:

Intern's Case History:

1. Source of History:

2. Chief Complaint : (patient's own words):

3. Present Illness:

	Complaint 1	**Complaint 2**
< Location < Onset : Initial: Recent: < Cause: < Duration < Frequency < Pain (Character) < Progression < Aggravating Factors < Relieving Factors < Associated S & S < Previous Occurrences < Past Treatment ➢ Outcome:		

4. Other Complaints:

5. Past Medical History:

< General Health Status
< Childhood Illnesses
< Adult Illnesses
< Psychiatric Illnesses
< Accidents/Injuries
< Surgery
< Hospitalizations

6. Current health status and life-style:

< Allergies

< Immunizations

< Screening Tests incl. x-rays

< Environmental Hazards (Home, School, Work)

< Exercise and Leisure

< Sleep Patterns

< Diet

< Current Medication
Analgesics/week:
< Tobacco

< Alcohol

< Social Drugs

7. Immediate Family Medical History:

< Age
< Health
< Cause of Death
< DM
< Heart Disease
< TB
< Stroke
< Kidney Disease
< CA
< Arthritis
< Anaemia
< Headaches
< Thyroid Disease
< Epilepsy
< Mental Illness
< Alcoholism
< Drug Addiction
< Other

8. Psychosocial history:

< Home Situation and daily life
< Important experiences
< Religious Beliefs

9. Review of Systems:

< General

< Skin

< Head

< Eyes

< Ears

< Nose/Sinuses

< Mouth/Throat

< Neck

< Breasts

< Respiratory

< Cardiac

< Gastro-intestinal

< Urinary

< Genital

< Vascular

< Musculoskeletal

< Neurologic

< Haematologic

< Endocrine

< Psychiatric

Appendix D

Durban University of Technology

PHYSICAL EXAMINATION: SENIOR

Patient Name : _____ **File no :**_____ **Date :**_____

Student : **Signature :**

VITALS:					
Pulse rate:				Respiratory rate:	
Blood pressure:	R	L		Medication if hypertensive:	
Temperature:				Height:	
Weight:	Any recent change? Y / N		If Yes: How much gain/loss		Over what period

GENERAL EXAMINATION:		
General Impression		
Skin		
Jaundice		
Pallor		
Clubbing		
Cyanosis (Central/Peripheral)		
Oedema		
Lymph nodes	Head and neck	
	Axillary	
	Epitrochlear	
	Inguinal	
Pulses		
Urinalysis		

SYSTEM SPECIFIC EXAMINATION:
CARDIOVASCULAR EXAMINATION
RESPIRATORY EXAMINATION
ABDOMINAL EXAMINATION
NEUROLOGICAL EXAMINATION
COMMENTS

Clinician: **Signature :**

APPENDIX E DURBAN UNIVERSITY OF TECHNOLOGY

REGIONAL EXAMINATION - CERVICAL SPINE

Patient: ..... File No: .....

Date: ..... Student: .....

Clinician:..... Sign: .....

OBSERVATION:

Posture

Swellings

Scars, discolouration

Hair line

Body and soft tissue contours

Shoulder position

Left :

Right :

Shoulder dominance (hand):

Facial expression:

RANGE OF MOTION:

rotation

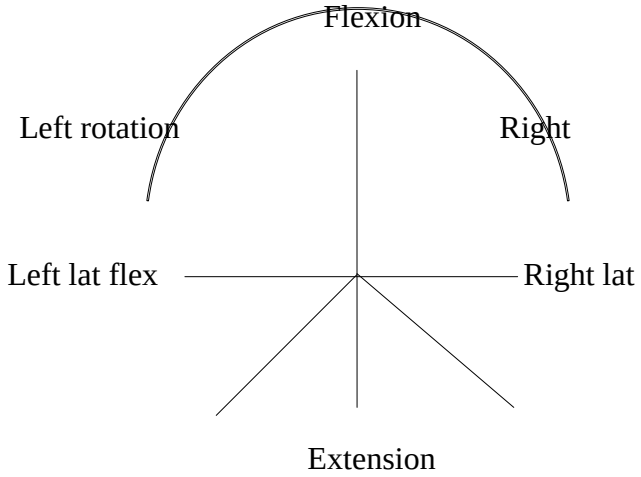
Extension (70º):

L/R Rotation (70º):

L/R Lat flex (45º):

flex

Flexion (45º):



PALPATION:

Lymph nodes

Trachea

Thyroid Gland

ORTHOPAEDIC EXAMINATION:

Tenderness		Right	Left
Trigger Points:	SCM		
	Scalenii		
	Post Cervicals		
	Trapezius		
	Lev scapular		

	Right	Left		Right	Left
Doorbell sign			Cervical compression		
Kemp's test			Lateral compression		
Cervical distraction			Adson's test		
Halstead's test			Costoclavicular test		
Hyper-abduction test			Eden's test		
Shoulder abduction test			Shoulder compression test		
Dizziness rotation test			Lhermitte's sign		
Brachial plexus test					

NEUROLOGICAL EXAMINATION:

Dermatones	**Left**	**Right**	**Myotomes**	**Left**	**Right**	**Reflexes**	**Left**	**Right**

C2			C1			C5		
C3			C2			C6		
C4			C3			C7		
C5			C4					
C6			C5					
C7			C6					
C8			C7					
T1			C8					
			T1					
Cerebellar tests:		Left		Right				
Disdiadochokinesis								

VASCULAR:	**Left**	**Right**		**Left**	**Right**
Blood pressure			Subclavian arts.		
Carotid arts.			Wallenberg's test		

MOTION PALPATION & JOINT PLAY:
Left: Motion Palpation:
Joint Play:
Right: Motion Palpation:
Joint Play:

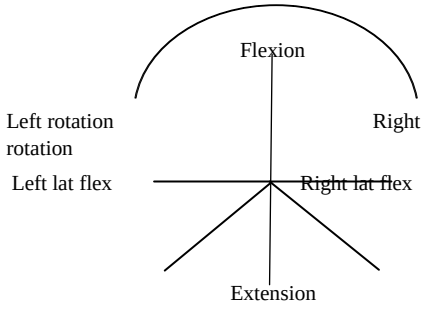
BASIC EXAM: SHOULDER:
Case History:

ROM: Active:
Passive:

RIM:
Orthopaedic:
Neuro:
Vascular:

BASIC EXAM: THORACIC SPINE:
Case History:

ROM:



Motion Palpation:	
Orthopaedic:	
Neuro:	
Vascular:	
Observ/Palpation:	
Joint Play:	

APPENDIX F **DURBAN UNIVERSITY OF TECHNOLOGY**

Patient Name: ***File #:*** ***Page:***

Date: ***Visit:*** ***Intern:***
Attending Clinician: ***Signature:***

S: *Numerical Pain Rating Scale (Patient)* ☐ *Intern Rating* ***A:***
Least ***0 1 2 3 4 5 6 7 8 9 10*** *Worst*

0: ***P:***

E:
Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Intern:***
Attending Clinician: ***Signature:***

S: *Numerical Pain Rating Scale (Patient)* *Intern Rating* ***A:***
Least ***0 1 2 3 4 5 6 7 8 9 10*** *Worst* ☐

O: ***P:***

E:
Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Intern:***
Attending Clinician: ***Signature***

S: *Numerical Pain Rating Scale (Patient)* *Intern Rating* ***A:***
Least ***0 1 2 3 4 5 6 7 8 9 10*** *Worst* ☐

O: ***P:***

E:
Special attention to: ***Next appointment:***

Patient Name: ***File #:*** ***Page:***

Date: ***Visit:*** ***Intern:***
Attending Clinician: ***Signature:***

S: ***Numerical Pain Rating Scale (Patient)*** ***Intern Rating*** ***A:***
Least 0 1 2 3 4 5 6 7 8 9 10 Worst ☐

0: ***P:***

E:
Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Intern:***
Attending Clinician: ***Signature:***

S: ***Numerical Pain Rating Scale (Patient)*** ***Intern Rating*** ***A:***
Least 0 1 2 3 4 5 6 7 8 9 10 Worst ☐

O: ***P:***

E:
Special attention to: ***Next appointment:***

Date: ***Visit:*** ***Intern:***
Attending Clinician: ***Signature***

S: ***Numerical Pain Rating Scale (Patient)*** ***Intern Rating*** ***A:***
Least 0 1 2 3 4 5 6 7 8 9 10 Worst ☐

O: ***P:***

E:
Special attention to: ***Next appointment:***

APPENDIX G

Headache Diary

Day no	**Frequency**	**Pain intensity (x/10) for each headache**	**Duration of each headache**	**Associated Symptoms**	**Disability**	**Nature of Pain**
Example *7*	*Example* *2 headaches*	*Example* *1 (3/10)* *2 (2/10)*	*Example* *1 - 2 hrs* *2 – 5 hrs*	*Example* *1 – sensitivity to light0* *2 - none*	*Example* *1-couldn't work* *2-no effect*	*Example* *1- billateral, pressing* *2- billateral ,pressing*
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						

Appendix H

Numerical Rating Scale - 101 Questionnaire

Date:_____ **File no:**_____ **Visit no:**_____

Patient name: _____

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **when it is at its worst**. A zero (0) would mean "no pain at all", and one hundred (100) would mean "pain as bad as it could be".

Please write only **one** number.

0 _____ 100

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **when it is at its least**. A zero (0) would mean "no pain at all" and one hundred (100) would mean "pain as bad as it could be".

Please write only **one** number.

0 _____ 100

Appendix I

CMCC NECK DISABILITY INDEX

Patient Name:_____File no.:_____Date:_____

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage everyday life. Please answer every section and mark in each section only ONE box as it applies to you. We realize you may consider that two of the statements in any one section could relate to you, but please just mark the box which most closely describes your problem.

Section 1 - Pain Intensity

G I have no pain at the moment.
G The pain is very mild at the moment.
G The pain is moderate at the moment.
G The pain is fairly severe at the moment.
G The pain is very severe at the moment.
G The pain is the worst imaginable at the moment.

Section 2 - Personal Care (Washing, Dressing ...)

G I can look after myself normally without causing extra pain.
G I can look after myself normally but it causes extra pain..
G It is painful to look after myself and I am slow and careful.
G I need some help but manage most of my personal care.
G I need help every day in most aspects of self care.
G I do not get dressed, I wash with difficulty and stay in bed.

Section 3 - Lifting

G I can lift heavy weights without extra pain.
G I can lift heavy weights but it gives extra pain.
G Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table.
G Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned .
G I can lift only very light weights.
G I cannot lift or carry anything at all.

Section 4 - Reading

G I can read as much as I want to without pain in my neck.
G I can read as much as I want to with slight pain in my neck.
G I can read as much as I want with moderate pain in my neck.
G I cannot read as much as I want because of moderate pain in my neck.
G I can hardly read at all because of severe pain in my neck.
G I cannot read at all.

Section 5 - Headaches

G I have no headaches at all.
G I have slight headaches which come infrequently.
G I have moderate headaches which come infrequently.
G I have moderate headaches which come frequently.
G I have severe headaches which come frequently.
G I have headaches almost all the time.

Section 6 - Concentration

G I can concentrate fully when I want to with no difficulty.
G I can concentrate fully when I want to with slight difficulty.
G I have fair degree of difficulty in concentrating when I want to.
G I have a lot of difficulty in concentrating when I want to.
G I have a great deal of difficulty in concentrating when I want to.
G I cannot concentrate at all.

Section 7 - Work

G I can do as much work as I want to .
G I can do only my usual work, but no more.
G I can do most of my usual work, but no more.
G I cannot do my usual work.
G I can hardly do any work at all.
G I cannot do any work at all.

Section 8 - Driving

G I can drive my car without any neck pain.
G I can drive my car as long as I want with slight pain in my neck.
G I can drive my car as long as I like with moderate pain in my neck.
G I cannot drive my car as long as I want because of moderate pain in my neck.
G I can hardly drive at all because of severe pain in my neck..
G I cannot drive at all.

Section 9 - Sleeping

G I have no trouble sleeping.
G My sleep is slightly disturbed (<1 hour sleep loss).
G My sleep is mildly disturbed (1-2 hours sleep loss).
G My sleep is moderately disturbed (2-3 hours sleep loss).
G My sleep is greatly disturbed (3-5 hours sleep loss).
G My sleep is completely disturbed (5-7 hours sleep loss).

Section 10 - Recreation

G I am able to engage in all my recreation activities with no neck pain at all.
G I am able to engage in all my recreation activities, with some pain in my neck.
G I am able to engage in most, but not all of my usual recreation activities because of pain in my neck.
G I am able to engage in a few of my usual recreation activities because of pain in my neck.
G I can hardly do any recreation activities because of pain in my neck.
G I cannot do any recreation activities at all.

Vernon/Hagino, modified from Foubister et al.,Physiotherapy, 1980

APPENDIX J

Muscular Weakness and/or Pain Assessment

	Weakness and Measurement (x/10)	**Pain and Measurement (x/10)**
Upper Trapezius		
Upper and Middle Trapezius		
Rhomboids		

Linder Test 1

Pain

Yes	No

If Yes to Pain, then in which part of the spine?

Upper cervical	Lower Cervical	Upper thoracic	Lower Thoracic

Reduction in Mobility

Yes	No

If Yes to reduction in mobility, then in which part of the spine?

Upper cervical	Lower Cervical	Upper thoracic	Lower Thoracic

Bulge in an Artery Test

No	Yes	Slight	Moderate	Large

APPENDIX K

Linder Test 1 and Bulge in an Artery Test

Linder Test 1

This test aims to evaluate muscle and superficial fascia in the region of the upper back – particularly the trapezius.

The examiner lifted the patients head whilst flexing the chin towards the chest with the subject lying in a relaxed, supine position. A positive result was elicited when the subject felt tense or felt pain in the upper back or neck. The reason for this may be as a result of increased muscle tension in the upper back muscles (especially the middle and upper trapezius muscles). If a positive result was obtained, the system moved to the most appropriate Muscle Specification test. In this study, we already know that according to Kinesio Taping® Method protocol, that the muscles involved in ETTH are the upper and middle trapezius muscles as well as the rhomboid major musculature according to Friedman (2007b), and thus the Linder Test was done to fulfil the Kinesio Taping® Method protocol.

Bulge in an Artery Test

This test was done in the supine position. A bulge in an artery in the cephalic region (temporalis muscle posterior to lateral part eye) can be caused by muscular or vascular rigidity. People at risk of high blood experience many problems in the upper body. Blood pressure is usually measured by using a baumanometer (blood pressure monitor), but it is also possible to use the fingers to take the pulse. High blood pressure is a possibility if a rigid pulse is felt under the fingers in the temple area. This may indicate rhomboid muscle involvement.

In this study, we already know that the muscles involved in ETTH are the upper and middle trapezius muscles as well as the rhomboid major musculature (Friedman 2007b), and thus the Bulge in an Artery Test was done to fulfil the Kinesio Taping® Method protocol.

APPENDIX L1

FREE HEADACHE TREATMENT

Research is being carried out at the
DUT Chiropractic Day Clinic

Come into the DUT library to see if you qualify for this research study

Contact **JUSTIN HENRY** on **0845820019** or **031 3732512**

APPENDIX L2

Hi,

I am a Chiropractic student and am doing **Research** into **Headache** at the Chiropractic Day Clinic. The headache study is specifically tension-type headache. This means that the headache is usually, but not always caused or made worse by stress and is of a tight or pressing sensation over the head and at times the upper neck. There may also be sensitivity to light or sound whilst having the headache, but not to both. The frequency of the headache needs to be between 2-14 days per month. Nausea (the feeling of wanting to vomit) cannot be present for the sake of this study. I am looking for patients between the ages of **18-45** who will qualify for my study.

It is a 3 week study with **Free treatment** being given over a week period. The treatment will depend on which group you are allocated to-either Kinesio Taping® Method (a new and effective tape used by many of the Olympic athletes) or a well known and effective anti-inflammatory known as Ibuprofen®. It is a very worthwhile study and your participation will be greatly appreciated.

If you feel you qualify or are unsure of whether you qualify for this study, and then please contact me and I will confirm it for you.

Many thanks,

Justin Henry

Please contact me on:

Cell: 0845820019

Chiropractic Clinic: 0313732205

E-mail: justintalk2me@yahoo.com

APPENDIX L3

Are you aged between 18-45 and have:

Tension-Type Headaches

Research is currently being carried out

at the Durban University of Technology Chiropractic Day Clinic.

FREE TREATMENT

Is available to those who qualify to take part in this study.

Contact **JUSTIN HENRY** on **0845820019** or **031 3732512** for more information.

APPENDIX M

Questions to be asked at initial or telephonic interview.

All patients who responded to the advertisements were screened by telephonic or personal interview by the researcher. The following questions were asked:

1. Do you know if you have tension-type headaches?
2. Are you between the ages of 18 and 45?
3. Do you have recurrent episodes of headache lasting for minutes or days?
4. Are you receiving current treatment for your headaches?
5. Are you pregnant or do you have peptic ulcer condition. Do you suffer with haemorrhagic conditions, asthma, history of hypersensitivity reactions to aspirin or other anti-inflammatory drugs, hypertension, impaired renal, hepatic or cardiac function?
6. Are you on any medication, and if so what?
7. Are you able to be involved for the full duration of the research (i.e. 5 consultations over 3 weeks)?

APPENDIX N

Dr Vincent Debono's qualification and his function within the research process

Dr Debono will be advising the student with regards to the Kinesio Taping® Method aspect of the research to ensure as much objectivity as possible with regards to treatment techniques.
Dr Debono is qualified with: BSc, DC, Post graduate certification in strength and conditioning

APPENDIX O

Scheduling status: S3

Proprietary names (and dosage forms):

Sandoz Ibuprofen 200 Tablets
Sandoz Ibuprofen 400 Tablets
Sandoz Ibuprofen 600 Tablets

SANDOZ

Composition:
Each Sandoz Ibuprofen 200 tablet contains: Ibuprofen 200 mg.
Each Sandoz Ibuprofen 400 tablet contains: Ibuprofen 400 mg.
Each Sandoz Ibuprofen 600 tablet contains: Ibuprofen 600 mg.

Pharmacological classification:
A 3.1 Antirheumatic (anti-inflammatory agents)

Pharmacological action:
Chemically ibuprofen is described as 2-(4-isobutylphenyl) propionic acid, and is a non-steroidal compound that exhibits anti-inflammatory, analgesic and antipyretic activities. Ibuprofen is well absorbed on oral administration and peak serum levels are reached after 1 to 2 hours. Excretion is rapid, about 60 to 90 % of the administered dose appearing as metabolites or conjugates.

Indications:
Ibuprofen is used for the management of mild to moderate pain and inflammation in conditions such as dysmenorrhoea, migraine, postoperative pain, dental pain, musculoskeletal and joint disorders such as ankylosing spondylitis, osteoarthritis, and rheumatoid arthritis including juvenile rheumatoid arthritis, peri-articular disorders such as bursitis and tenosynovitis, and soft-tissue disorders such as sprains and strains.
Reduction of fever.

Contra-indications:
Safety of ibuprofen in pregnant women has not been demonstrated and ibuprofen is contra-indicated during pregnancy.
Peptic ulceration.

Warnings:
Acute reversible renal failure has been reported. Ibuprofen should be used with care in patients with impaired renal function.

Dosage and directions for use:
If gastrointestinal disturbances occur, ibuprofen should be given with food, antacid or milk.
Adults: The recommended dosage of ibuprofen is 1 200 to 1 800 mg daily in divided doses.
The maintenance dose is 600 to 1 200 mg daily. If necessary, the dose may be increased to 2 400 mg daily.
Children: Ibuprofen is not generally recommended for children under one year of age or in those weighing less than 7 kg.
The dosage is 20 mg/kg daily in divided doses with up to 40 mg/kg being given in juvenile rheumatoid arthritis, if necessary. In children of less than 30 kg the total dose of 400 to 500 mg per day must not be exceeded.

Side-effects and special precautions:
Side-effects:
Gastrointestinal tract: Stomatitis, dyspepsia, nausea and vomiting, gastrointestinal haemorrhage, melaena, diarrhoea, and peptic ulcers and perforation. Colitis and its exacerbation have occured.
Central nervous system: Headache, dizziness, nervousness, tinnitus, depression, drowsiness and insomnia.
Hypersensitivity and skin reactions: Acute allergic reactions have been reported. Because of the possibility of cross-sensitivity due to structural relationships which exist among non-steroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds. Fever, asthma, skin rashes and serious dermatological problems, which include erythema multiforme bullosum, Stevens-Johnson syndrome and toxic epidermal necrolysis. Hepatotoxicity and aseptic meningitis which occur less frequently may also be hypersensitivity reactions.
Visual: Decreased visual acuity and visual-field defects have also occurred. Prolonged treatment will require regular ophthalmological examinations.
Haematological effects: Thrombocytopenia, anaemias, neutropenia, eosinophilia and agranulocytosis. Inhibition of platelet aggregation is reversible.
Kidneys: Oedema, increase in serum creatinine concentrations, acute renal failure and nephrotic syndrome. Cystitis, haematuria, and interstitial nephritis may occur. Acute flank pain and reversible renal dysfunction have been reported.
Electrolytes: Isolated reports in patients with pre-existing renal disease who develop severe hyponatraemia and symptoms of severe water intoxication. All symptoms resolve on discontinuation.
Other: Alterations in hepatic function tests have been noted. Increased values for serum transaminases, serum glutamic pyruvic transaminase, bilirubin and alkaline phosphatase have been reported but have often returned to normal, despite continued treatment.

Precautions:
Because of the gastrointestinal effects, ibuprofen should not be given to patients with peptic ulceration and should be used with caution in patients with a history of such disorders.
Ibuprofen should be used with caution in patients with infections since symptoms such as fever and inflammation may be masked.
Other general precautions to be observed include administration to patients with haemorrhagic disorders, asthma, a history of hypersensitivity reactions to aspirin or other non-steroidal anti-inflammatory medicines (NSAIDs), hypertension, and impaired renal, hepatic or cardiac function.
Patients undergoing therapy with ibuprofen may need to be monitored for the development of blood, kidney, liver or eye disorders.
Ibuprofen should be used with caution in the elderly.
In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Interactions:
Ibuprofen may possibly enhance the effects of oral anticoagulants and increase the plasma concentrations of lithium, methotrexate and cardiac glycosides.
The risk of nephrotoxicity may be increased if given with angiotensin-converting enzyme inhibitors, cyclosporin or diuretics.
There may also be an increased risk of hyperkalaemia with angiotensin-converting enzyme inhibitors and potassium-sparing diuretics.
The antihypertensive effects of some antihypertensive agents including angiotensin-converting enzyme inhibitors, beta-blockers and diuretics may be reduced.
Convulsions may occur due to interaction with quinolones.
Ibuprofen may enhance the effects of phenytoin and sulphonylurea antidiabetics.
The concomitant use of more than one NSAID should be avoided because of the increased risk of adverse effects.
The risk of gastrointestinal bleeding and ulceration is increased when used with corticosteroids.
Alcohol may increase the risk of gastrointestinal side-effects, including ulceration or haemorrhage.

Known symptoms of overdosage and particulars of its treatment:
The most likely symptoms of overdosage are epigastric pain and nausea.
If recently taken, gastric lavage will remove any unabsorbed ibuprofen.
There is no ~~specific antidote to ibuprofen~~.
Treatment is symptomatic and supportive.

Identification:
Sandoz Ibuprofen 200: Round, biconvex, pink sugar-coated tablets.
Sandoz Ibuprofen 400: Round, biconvex, pink sugar-coated tablets.
Sandoz Ibuprofen 600: White, film-coated, oblong tablets with a breakline.

Presentation:
Sandoz Ibuprofen 200: 15, 28, 30 or 84 tablets packed in amber glass containers, securitainers, sealed aluminium bags or blisters. 500 tablets packed in amber glass containers, securitainers or blisters. 1 000 tablets packed into securitainers or blisters.
Sandoz Ibuprofen 400: 30 or 84 tablets packed in securitainers, blisters, sealed aluminium bags or amber glass containers. 500 or 1 000 tablets packed in securitainers or blisters.
Sandoz Ibuprofen 600: 30 or 100 tablets packed in blisters, amber glass containers or securitainers.

Storage instructions:
Store in a dry place below 25 °C and protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

Registration numbers:
Sandoz Ibuprofen 200: Q/3.1/148
Sandoz Ibuprofen 400: Q/3.1/149
Sandoz Ibuprofen 600: U/3.1/136

Name and business address of the holder of the certificate of registration:
Sandoz (Pty) Ltd[1]
a Novartis company[2]
72 Steel Road, Spartan
Kempton Park 1619

Date of publication of this package insert:
20 August 1997

[1]Company Reg No.: 1981/02426/07
[2]Novartis SA (Pty) Ltd Reg No.: 1946/020671/07

60094

APPENDIX P

DURBAN INSTITUTE of TECHNOLOGY

3 October 2007

To
Mr. Kevin Anderson
Kevin@3tiersystems.com and
c/o Anelise Siddle : anelise@kinesiotaping.co.uk

RE: The Kinesio UK and research at the DUT: Contract

It has been agreed that the following be contributed by the various stakeholders per student in terms of finance:

DUT Institutional contribution	R 8650.00
Kinesio UK contribution	R 6960.00

The costs would support

	COST
1. Consumables – photocopying	
• **Informed consent** • **Letter of information** • **Case History** • **Physical Evaluation** • **Cervical Regional Evaluation** • **Short Form McGill Pain Questionnaire** • **Numerical Pain Rating Scale** • **CMCC Neck Disability** • **Data collection sheet**	**R 150.00**
40 patients @ minimally 3 treatments per patient = 120 treatment applications. With a potential 4 treatment per patient should the taping come off = total 160 treatment applications. **With each patient requiring about 180 cm per treatment application = total 28800 cm or 288m** **This equates to 57.6 (58) rolls @ R120.00 per rolls = R 6960 for all the taping**	**Sponsored – see attached contract for R 6960.00**

2.	**Outside Specialist Services**	
3.	**Books/Documents(Kinesio Taping® Method)**	**R 500.00**
4.	**Library Charges**	**R 100.00**
5.	**Small items of equipment**	
6.	**Major items of equipment**	
7.	**Miscellaneous (specify)**	
	• **Telephone**	**R 600.00**
	• **Advertising**	**R 300.00**
	• **Statistical analysis**	**R 2000.00**
	• **Research specific training for the researcher**	**R 4000.00**
	• **Landing costs of the tape in South Africa**	**R1000.00**
	GRAND TOTAL	**R 8650.00**

Thus the student would therefore have access to R 15610.00, for use in the completion of the dissertation.

This would involve the total contribution of R 8650.00 from DUT and R 6960.00 from Kinesio UK for the completion of 1 research project.

The student involved would be Mr. Justin Henry.

Training:

Kinesio UK agreed to provide training in South Africa in order to allow proficiency for the researcher and the supervisor, which the student would budget for in his research budget allocation.

Equipment

It was agreed that Kinesio UK would supply the DUT with Kinesio taping for sole use as part of the proposed research.

The process

The research process as per the DUT research algorithm would be followed, such that the student receives maximal benefit in the learning process (appendix A and appendix B).

Dr Vincent de Bono DC, CSCS, CKTI would be appointed as a co-supervisor for the research student, in terms of his / her proficiency in research and research methods. This appointment would be in addition to a local (DUT) supervisor. To facilitate this process DUT would require an abridged curriculum vita from Dr Vincent de Bono DC, CSCS, CKTI (see below):

Vincent de Bono DC, CSCS, CKTI

* BS, DC, National College of Chiropractic

* Vice President for Academic Services

* Chiropractic Physician

* Certified Strength & Conditioning Specialist

Dr. DeBono has served as a staff clinician at National University of Health Sciences for six years, as well as serving one year as Dean of Clinics. Previously, he was associated with National's Chicago Clinic, Chicago General Service. In addition to chiropractic practice, Dr. DeBono's area of interest includes soft tissue release techniques, Kinesio-taping, and conservative management of sports related injuries. He is certified by the National Strength and Conditioning Association as a strength and conditioning specialist.

The student would be responsible for completing the research process and compiling a dissertation, further to this the student would complete a publishable paper, for publication in a mutually agreed journal.

Intellectual property

The outcomes of this research will be bound by the rules and regulations as stipulated in the Ethical Issues Checklist for Research Approval (Appendix B) and as approved by the DUT Faculty of Health Sciences Research and Ethics Committee.

Time:

The time required for the completion of the study will then be reliant on:

- Patient population required for the completion of the study
- The compilation of the written thesis.

Topic for research that was agreed to in the proposal stages included:

The short term relative effectiveness of Kinesio taping, manipulative and combined therapies in the treatment of mechanical neck pain.

These topics would be refined through the research process and in consultation with ……

Communication would principally be affected by e-mail.

All signatories agree to abide by this contract and are happy with its contents, as well as the completed proposal (Appendix C) to be approved by the DUT Faculty of Health Sciences Research and Ethics Committee.

……
Ms Karin Young
Associate Director

Head: Department of Chiropractic

……
DUT finance

……
Dr Charmaine Korporaal
Senior Lecturer & Research Supervisor
Department of Chiropractic

……..
Mr. Kevin Anderson
Kinesio UK

……
Person appointed by Kinesio UK as research co-supervisor

Appendix A:

RESEARCH PROCEDURE - M. TECH

Idea submitted to the Departmental Research Committee

↓

Idea approved by the Departmental Research Committee

Student develops the proposal (DIT 186) with the supervisor and or co-supervisor.

↓

The student submits the DIT 186 for Departmental Research Committee review.

↓ ↑

DIT 186 passed subject to minor corrections and / or alterations being made by the student	OR	DIT 186 need resubmission to the Departmental Research Committee for second review

↓

The DIT 186 is then submitted to the Faculty Research Committee (The Ethics and Bio safety Committee) for ethical and Institutional budget clearance.

↓ ↑

DIT 186 passed subject to minor corrections and / or alterations being made by the student	OR	DIT 186 need resubmission to the Departmental Research Committee for second review

↓

The student is informed via relevant protocol and procedure of the approval of the proposal, supervisor / co-supervisor and Institutional funds

Appendix B

FACULTY OF HEALTH

G186 – RESEARCH PROPOSAL

NOTE TO STUDENTS

Please complete in font ARIAL – 12
Number all pages

Please check that you have completed all the following before submission

A - Administrative section – Sections A to E "Application for **APPROVAL OF A RESEARCH PROPOSAL** in terms of Rule G40 (1)"

B - Sections F, G and H of the Faculty of Health G186 (research proposal).

Thank you

Faculty of Health
mnp/feb013/research

Application for **APPROVAL OF A RESEARCH PROPOSAL** in terms of Rule G40 (1)

NOTE: Should you wish to use a floppy/hard disk which contains the G186 please consult your Research Co-ordinator.
Please consult your Research Co-ordinator to ensure that you use the latest version of this form.

SECTION A - To be completed by student *[If handwritten, please print]*

Student Number**:** . . . . . .

Surname**:** . . . . . Title**:** . . . . . .

Full First Names**:** . . . . . .

Postal Address**:** . . . . . .

. . . . . .

Telephone No**:** . . . . . (Work) . . . . . .(Home)

Date of Birth**:** . . . . . .

Name of Matriculation (or equivalent) qualification/s attained (attach certified copy/ies)
Post matriculation (or equivalent) qualification/s attained (attach certified copy/ies)
Working experience (attach proof)

Qualification for which topic is to be registered (e.g. Master's Degree in Technology: Fine Art)

Title of MINIDISSERTATION (in respect of Master's Diploma/Degree in Technology) or THESIS (in respect of Doctor's Degree in Technology)

Estimated direct total costs of research to Durban Institute of Technology **R . . . . . .**

ETHICS - Please see section E

AS FAR AS I KNOW AND CAN ASCERTAIN:

(a) no other similar dissertation/thesis exists; AND

(b) all references detailed in the dissertation are complete in terms of all personal communications engaged in and published works consulted.

I HEREBY DECLARE THAT THE ABOVE FACTS ARE CORRECT.
I ACKNOWLEDGE THAT:

(1) I have the responsibility to determine that no similar research at a tertiary institution is being or has been conducted; AND

(2) any approval of my research and any funding of it by Durban Institute of Technology is conditional upon (1).

I will adhere to the Institution's Research Ethics Policy as it relates to my research.

Signed: . . . . . . **. . . . . .**
STUDENT **DATE**

SECTION B – To be completed by Supervisor/Promoter

I, **. . . . . .**
(full names of Supervisor/Promoter)

(a) acknowledge the responsibility to advise the student on how to conduct the necessary literature search in order to ascertain that no other similar research at a tertiary institution is being or has been conducted;

(b) accept the appointment as Supervisor/Promoter and the concomitant responsibilities;

(c) approve of the proposal;

(d)* approve of the Joint Supervisor(s) / Joint Promoter(s) proposed by the Head of Department;

(e)* recommend that the student's project be registered as secret.

Signed: . . . . . . **. . . . . .**
SUPERVISOR/PROMOTER **DATE**

delete and sign alongside if not applicable

SECTION C – To be completed by Head of Department and then forwarded to Faculty HQC/ BOFEX

Department**:** . . . . . .

Proposed: Supervisor (in respect of Master's Diploma/Degree in Technology) or Promoter (in respect of Doctor's Degree in Technology):

Title**:** . . . . . .
Name**:** . . . . . .
Qualifications**:** . . . . . .
Postal Address**:** . . . . . .
Telephone**:** . . . . . (Work) . . . . . (Home)

Proposed Joint Supervisor(s) / Joint Promoter(s):

1. Title**:** . . . . . .
   Name**:** . . . . . .
   Qualifications**:** . . . . . .
   Postal Address**:** . . . . . .
   Telephone**:** . . . . . (Work) . . . . . (Home)

I, ...
(full names of HOD)

(a) am satisfied that the student is in possession of the necessary academic entrance qualifications;
(b) approve of the topic/field of investigation;
(c) propose the Supervisor/Promoter detailed above;
(d)* propose the Joint Supervisor(s) / Joint Promoter(s) detailed above;
(e)* recommend that the student's project be registered as secret.

Signed:. . . . . **. . . . . .**
HEAD OF DEPARTMENT **DATE**
**delete and sign alongside if not applicable*

SECTION D – To be completed by Dean of the relevant Faculty

The Faculty of: . . . . . .
(Complete)

(a) recommends the attached proposal;
(b) proposes the Supervisor/Promoter detailed above;
(c)* proposes the Joint Supervisor(s) / Joint Promoter(s) detailed above;
(d)* recommends that the student's project be registered as secret.

Signed: . . . . . **. . . . . .**
DEAN **DATE**
**delete and sign alongside if not applicable*

SECTION E

APPLICATION FOR ETHICAL APPROVAL OF RESEARCH PROPOSAL

The proposed research is categorised as research:

	Yes	No
on humans and organisations		
on animals		
with environmental implications		

(Head of Department to tick the appropriate box)

It has been reviewed and complies with the Durban Institute of Technology Research Ethics Policy, the general Guidelines and the relevant specific Guidelines for the Ethical Conduct of Research.

CATEGORY	

Comments:………………………………………………………………………………………
……………………………………………………………………………………………………
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……………………………………………………………………………………………………
……………………………………………………………………………………………………
……………………………………………………………………

Signed: . . . .
Head of Department Date

Signed: . . . .
Dean/Faculty Research Committee Chairman Date

Signed: . . . .
Durban Institute of Technology Research Ethics and Bio safety Committee Chairman Date

The completed Ethical Issues Checklist and all documents used to inform potential research participants, including Participant Information Sheets, Consent Forms, research instruments, advertisements and letters must be submitted for ethical approval.

FACULTY OF HEALTH

SECTION F

1. **Title**

2. **Summary** (approximately 250 words)

3. **Aim/Purpose of study**

4. **Rationale for the Study and Research Questions** (give clear reasons why the Research is necessary and indicate potential value of the study in about 4-5 concise statements)

1. 2. 3. 4.

5. **Literature review** (Include any controversies, gaps and / or shortcomings in general knowledge in the literature) maximum of 1000 words

6. **6.1 Research Design** (Research Methods) (You are advised to consider study type, data collection tools and statistical methods)

6.2 Timeframe (flowchart or critical path with dates)

6.3 Confirmation of consultation of statistician

I hereby confirm that I have been consulted by …….(student's name) on the statistical aspects of this proposal. Signed…… Statistician Date:

7. **References** (pertaining to entire document. Should ideally not exceed 10 key references)

SECTION G: Ethics statement (Complete the attached ethics questionnaire)
SECTION H: Budget (complete the accompanying sheet)

SECTION H – BUDGET

SECTION 1 – To be completed by student
REQUEST FOR FUNDING OF THE PROJECT (give details)

		COST
1.	**Consumables**	
	(including questionnaires)	
2.	**Outside Specialist Services**	
	(e.g. testing services, chemical analyses)	
3.	**Books/Documents**	
4.	**Library Charges**	
	(including literature/data bank search, inter-library loans)	
5.	**Small items of equipment**	
6.	**Major items of equipment**	
7.	**Miscellaneous (specify)**	
	GRAND TOTAL	

NB: The following will **not** be supported

(1) any fees;
(2) costs of preparing dissertation/thesis including typing and printing; AND
(3) subsistence to discuss research progress or research ideas or to visit libraries

ALL APPROVED funding is ADMINISTERED by the academic department concerned.

ETHICAL ISSUES CHECKLIST FOR RESEARCH APPROVAL

To be completed by all people wishing to conduct research under the auspices of Durban

Institute of Technology.

1. Use the Durban Institute of Technology Research Ethics Policy and Guidelines to ensure that ethical issues have been identified and addressed in the most appropriate manner, before finalizing and submitting your research proposal.
2. Please indicate [by a X as appropriate] which of the following ethical issues could impact on your research.
3. Please type the motivations/further explanations where required in the cell headed COMMENTS.
4. The highlighted response cells indicate those responses that are of particular interest to the Research Ethics and Biosafety Committee
5. The checklist is divided into sections relevant to all research; research on animals; research on humans; research on human health issues and biotechnology.

ALL RESEARCH

NO.	QUESTION	YES	NO	N/A
	CONFIDENTIALITY			
1.	Does the data collection process involve access to (personal or otherwise) confidential personal data (including access to data for purposes other than this particular research project) without prior consent of subjects? If yes, motivate the necessity.			
	COMMENTS			
2.	Will the data be collected and disseminated in a manner that will ensure confidentiality of the data and the identity of the participants? Explain your answer.			
	COMMENTS			
3.	Will the materials obtained be stored and ultimately disposed of in a manner that will ensure confidentiality of the participants? If no, explain. If yes specify how long the confidential data will be retained after the study and how it will be disposed of.			
	COMMENTS			
4.	Will the research involve access to data banks that are subject to privacy legislation? If yes, specify and explain the necessity.			

	COMMENTS			
	BENEFITS			
5.	Is this research expected to benefit the participants or organisations directly or indirectly? Explain any such benefits.			
	COMMENTS			
6.	Does the researcher expect to obtain any direct or indirect financial or other benefits from conducting the research? If yes, explain.			
	COMMENTS			
NO.	***QUESTION***	**YES**	**NO**	**N/A**
	SPONSORS, INTERESTS AND INDEMNITY			
7.	Will this research be undertaken on the behalf of or at the request of a pharmaceutical company, or other commercial entity or any other sponsor? If yes, identify the entity.			
	COMMENTS			
8.	If yes to 7, will that entity undertake in writing to abide by Durban Institute of Technology Research Ethics Policy and Guidelines? If yes, do not explain further. If no, explain.			
	COMMENTS			
9.	If yes to 8, will that entity undertake in writing to indemnify the institution and the researchers? If yes, do not explain further. If no, explain.			
	COMMENTS			
10.	Does the researcher have indemnity cover relating to research activities? If yes, specify. If no, explain why not.			
	COMMENTS			

11.	Does the researcher have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? If yes, specify.			
	COMMENTS			
12.	Does permission need to be obtained in terms of the location of the study? If yes indicate how permission is to be obtained.			
	COMMENTS			
	DECEPTION/COVERT DATA COLLECTION			
13.	Is deception of any kind to be used? If so provide a motivation for acceptability.			
	COMMENTS			
14.	Does the study involve covert data collection? If yes, explain why this is necessary and what steps have been taken to address the ethical implications of this.			
	COMMENTS			

RESEARCH ON ANIMALS

15.	Does the research involve the use of animals? If yes, describe the nature of this involvement.			
	COMMENTS			
NO.	***QUESTION***	**YES**	**NO**	**N/A**
16.	Is the research being conducted at an approved facility? If no, explain why. If yes, indicate which facility.			
	COMMENTS			

RESEARCH ON HUMANS

	RECRUITMENT			
	Does recruitment involve direct personal approach from the			

17.	researchers to the potential subjects? Explain the recruitment process			
	COMMENTS			
18.	Are participants linked to the researcher in a particular relationship, for example employees, students, family? If yes, specify how.			
	COMMENTS			
19.	If yes to 18, is there any pressure from researchers or others that might influence the potential subjects to enrol? Elaborate.			
	COMMENTS			
20.	Does recruitment involve the circulation/publication of an advertisement, circular, letter etc? If yes, specify and provide copy.			
	COMMENTS			
21.	Will subjects receive any financial or other benefits as a result of participation? If yes, explain the nature of the reward, and safeguards.			
	COMMENTS			
22.	Is the research targeting any particular ethnic or community group? If yes, motivate why it is necessary/acceptable. If you have not consulted a representative of this group, give a reason. In addition explain any consultative processes, identifying participants. Should consultation not take place, give a motivation.			
	COMMENTS			
	INFORMED CONSENT			
23.	Does the research fulfil the criteria for informed consent? [See guidelines]. If yes, no further answer is needed. If no, please specify how and why.			
	COMMENTS			

NO.	*QUESTION*	YES	NO	N/A
24.	Will the research involve the use of no-treatment or placebo control conditions? If yes, explain how subjects' interests will be protected.			
	COMMENTS			
25.	Will a Subject Information Letter be provided and a written consent be obtained? If no, explain. If yes, attach copies to proposal. In the case of subjects who are not familiar with English (e.g. it is a second language), explain what arrangements will be made to ensure comprehension of the Subject Information Letter, Informed Consent Form and other questionnaires/documents.			
	COMMENTS			
26.	Will results of the study be made available to those interested? If no, explain why. If yes, explain how.			
	COMMENTS			
	RISKS TO PARTICIPANTS			
27.	Will participants be asked to perform any acts or make statements that might be expected to cause discomfort, compromise them, diminish self-esteem or cause them to experience embarrassment or regret? If yes, explain.			
	COMMENTS			
28.	Might any aspect of your study reasonably be expected to place the participant at risk of criminal or civil liability? If yes, explain.			
	COMMENTS			
29.	Might any aspect of your study reasonably be expected to place the participant at risk of damage to their financial standing or social standing or employability? If yes, explain.			
	COMMENTS			
30.	Does the research involve any questions, stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, anxiety producing, noxious, aversive or unpleasant during or after the research procedures? If yes, explain.			
	COMMENTS			

RESEARCH ON HUMAN HEALTH ISSUES/ BIOTECHNOLOGY

31.	Does the protocol require any physically invasive, or potentially harmful procedures [e.g. drug administration, needle insertion, rectal probe, pharyngeal foreign body, electrical or electromagnetic stimulation, etc]? If yes, please outline below the procedures and what safety precautions will be used.			
	COMMENTS			
NO.	***QUESTION***	**YES**	**NO**	**N/A**
32.	Will any treatment be used with potentially unpleasant or harmful side effects? If yes, explain the nature of the side effects and how they will be minimized.			
	COMMENTS			
33.	Will any samples of body fluid or body tissues be required specifically for the research that would not be required in the case of ordinary treatment? If yes, explain and list such procedures and techniques.			
	COMMENTS			
34.	Are any drugs/devices to be administered? If yes, list any drugs/devices to be used and their approved status.			
	COMMENTS			
	GENETIC CONSIDERATIONS			
35.	Will participants be fingerprinted or DNA "fingerprinted"? If yes, motivate why necessary and state how such is to be managed and controlled.			
	COMMENTS			
36.	Does the project involve genetic research e.g. somatic cell gene therapy, DNA techniques etc? If yes, list the procedures involved			
	COMMENTS			

The undersigned declare that the above questions have been answered truthfully and accurately

STUDENT NAME:
SIGNATURE:
DATE:

SUPERVISOR NAME:
SIGNATURE:
DATE:

CO-SUPERVISOR NAME:
SIGNATURE:
DATE:

APPENDIX Q

ETHICS CLEARANCE CERTIFICATE

Student Name	Justin Henry	Student No	20100710
Ethics Reference Number	FHSEC 08/05	Date of FRC Approval	30/05/2008
Research Title:	**The relative effectiveness of non-steroidal anti-inflammatory drugs (Ibuprofen) and a taping method (Kinesiotape) in the treatment of Episodic Tension-Type Headaches.**		

In terms of the ethical considerations for the conduct of research in the Faculty of Health Sciences, Durban University of Technology, this proposal meets with institutional requirements and confirms the following ethical obligations:

1. The researcher has read and understood the research ethics policy and procedures as endorsed by the Durban University of Technology, has sufficiently answered all questions pertaining to ethics in the DUT 186 and agrees to comply with them.
2. The researcher will report any serious adverse events pertaining to the research to the Faculty of Health Sciences Research Ethics Committee.
3. The researcher will submit any major additions or changes to the research proposal after approval has been granted to the Faculty of Health Sciences Research Committee for consideration.
4. The researcher, with the supervisor and co-researchers will take full responsibility in ensuring that the protocol is adhered to.
5. ***The following section must be completed if the research involves human participants:***

	YES	NO	N/A
❖ Provision has been made to obtain informed consent of the participants	√		
❖ Potential psychological and physical risks have been considered and minimised	√		
❖ Provision has been made to avoid undue intrusion with regard to participants and community	√		
❖ Rights of participants will be safe-guarded in relation to:	√		
- Measures for the protection of anonymity and the maintenance of Confidentiality			
- Access to research information and findings.	√		
- Termination of involvement without compromise	√		
- Misleading promises regarding benefits of the research	√		

SIGNATURE OF STUDENT/RESEARCHER — 18/08/2008 DATE

SIGNATURE OF SUPERVISOR/S — 18/8/8 DATE

SIGNATURE OF HEAD OF DEPARTMENT — 18/8/8 DATE

SIGNATURE: CHAIRPERSON OF RESEARCH ETHICS COMMITTEE — 18/08/08 19/08/08 DATE

APPENDIX R

KAPLANS
C H E M I S T

233 MUSGRAVE CENTRE • MUSGRAVE ROAD • DURBAN 4001 • TEL: (031) 2015187 FAX: (031) 2014258

29 February 2008

To Whom it May Concern

I have agreed to assist [illegible] Henry and Kgositsile, Lekgoete, in their research, and to supply Sandoz Ibuprofen on their behalf, to their patients on the understanding that they will provide counselling with respect to dosage, side-effects, and contra-indications.

Marilyn Smith
(Dip Pharm M.P.S.)

Kaplans Chemist
(MARILYN SMITH MPS)
233 MUSGRAVE CENTRE
☎ 201 5187