A COMPARISON OF THE INITIAL AND SHORT TERM EFFECTS OF CERVICAL SPINE ADJUSTMENTS AND ACETYLSALICYLIC ACID IN THE TREATMENT OF MILD TO MODERATE EPISODIC TENSION-TYPE HEADACHE AND ITS RECURRENCE

A dissertation submitted to the Faculty of Health, Technikon Natal, in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic.

By

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I, Mark Andrew Rex Kidson, do hereby declare that this dissertation is representative of my own work, both in concept and execution, exept where otherwise indicated in the text.

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Abstract

Episodic tension-type headache is more prevalent than chronic tension-type headache (Schwartz, et al. 1998). The exact causes of episodic tension-type headaches are not known (Headache Classification Committee, 1988:30-31). Episodic tension-type headache and chronic tension-type headache have different characteristics. Thus the mechanism of episodic tension-type headache is still unclear, and should be studied separately from chronic tension-type headache (Kim, et al. 1995). Presently, studies conflict with regard to spinal manipulation and its efficacy in the treatment of episodic tension-type headache. Therefore, the purpose of this study was to investigate the relative effectiveness of 500mg of acetylsalicylic acid as opposed to cervical spine manipulation for the treatment of episodic tension-type headache.

It was hypothesized that manipulation would provide a significantly greater immediate and short-term benefit in comparison to acetylsalicylic acid. This study was conducted as a clinical trial at the Technikon Natal Chiropractic Day Clinic. Sixty patients presenting with episodic tension-type headaches were selected and randomly allocated into two equal groups.

Patient's were provided with one of the two treatments at the initial consultation, and again upon a second consultation after a minimum "washout period" of forty-eight hours, but within two weeks. Patient's in Group 1 received cervical spine manipulation, whereas patients in Group 2 received 500mg of acetylsalicylic acid.

The subjective responses of each patient were recorded by means of the Short-form McGill Pain Questionnaire, the Numerical Pain Rating Scale, the CMCC Neck

Disability Index and Headache Diaries. The first three questionnaires were completed at both consultations under the supervision of the researcher. The Headache Diaries were taken home by the patients and completed at 15, 30, 45, 60, 90, 120 and 150 minutes and then returned to the clinic. The objective data collected was the pressure pain thresholds of the upper and middle portions of the SCM muscles and trapezius insertion bilaterally. The objective measurements were taken at both consultations by the researcher. The subjective and objective data was analysed using two-tailed parametric tests due to the large sample size (n = 60) with the degree of significance set at the 95% confidence level.

Comparison of Group 1 and Group 2 for 15 and 30 minutes post-treatment of the initial consultation revealed a statistically significant difference, in favour of group 1 in terms of pain intensity. Comparison of the groups for 15, 30, 45 and 60 minutes post-treatment of the follow up consultation revealed a statistically significant difference, in favour of group 1 in terms of pain intensity. The other comparisons between group 1 and 2 revealed no other statistical differences. This data indicates that manipulation brings about earlier benefit (in terms of pain relief), when compared to Acetylsalicylic Acid.

The pain-pressure threshold measurements comparing the results of the of the pre- and post-treatment results for Group 1 demonstrated that manipulation increases the pain threshold readings for the trapezius insertion bilaterally, the left middle SCM and the right upper SCM muscles.

The results obtained from the study indicated that cervical spine manipulation provides more rapid relief in the treatment of episodic tension-type headache as compared to acetylsalicylic acid. Consequently the results of this study indicate that cervical spine manipulation is recommended for the treatment of episodic tension-type headache.

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CHAPTER 1

1.0.INTRODUCTION

1.1 The Problem and its Setting

Episodic tension-type headache is more prevalent than chronic tension-type headache, and it has a greater societal impact, an overall prevalence of 38,3% in Baltimore country, Maryland and an overall sex prevalence ratio of 1:1,16 in the same area (Schwartz et al. 1998). Episodic tension-type headache of moderate intensity was found in 68% of those effected (Gobel, Petersen-Braun and Soyka, 1994). Patients with episodic tension-type headache also report 43,6% reduced-effectiveness days, with average 5,0 reduced-effectiveness days per person per year (Schwartz, et al. 1998).

The exact causes of Episodic Tension-type Headaches are not known (Headache Classification Committee, 1988:30-31). Episodic Tension-type Headache and Chronic Tension-type Headache have different characteristics; consequently there may be differences from a pathophysiological point of view. Consequently the mechanism of Episodic Tension-type Headache is still unclear, and should be studied separately in its chronic and episodic forms (Kim, et al. 1995). Kim, et al. (1995) concluded their findings support the hypothesis that nociception is primarily myofascial in origin, specifically sternocleidomastoid and trapezius insertion and that this may be the primary characteristic of episodic tension-type headache. However, supraspinal facilities may play a larger role in tension-type headache.

Gatterman (1995) is of the opinion that cervical spine dysfunction makes a significant contribution to the cause of a number of different headache types. In a study Muller (1999) found a significant incidence of cervical dysfunction in the 40 subjects suffering tension-type headache, as compared to the 40 assymptomatic controls.

The present studies conflict with regard to spinal manipulation and its efficacy in the treatment of episodic tension-type headache. Despite this, Vernon and McDermaid (1998) found in a survey of Chiropractors that cervical spine manipulation (especially of the upper cervical spine) is more commonly used, than any other form of therapy in the treatment of episodic tension-type headache.

Our present knowledge of medication habits in headache sufferers is poor and mainly based on the headache prone populations (Rassmussen, 1995).

The most commonly used analgesic was acetylsalicylic acid preparations (Rassmussen, 1995). There are many contra-indications for, and side effects from the use of acetylsalicylic acid (Snyman, 1999:1155-1156).

There have been no studies to determine the effectiveness of cervical spine manipulation's immediate and short-term effects in the treatment of episodic tension-type headache. There is, further more, a paucity of studies comparing cervical spine manipulation with acetylsalicylic acid in the treatment of episodic tension-type headache.

As acetylsalicylic acid is the most commonly used form of analgesic, one could argue that any therapy considered should be at least as effective.

1.2. Statement of Research Objective

To conduct a comparative clinical trial investigating the initial and short term effects of manipulation of the cervical spine compared to acetylsalicylic acid in the treatment of mild to moderate episodic tension-type headache and its recurrence, in terms of subjective and objective clinical findings.

1.2.1. OBJECTIVE ONE

The first objective is to determine the relative effectiveness of manipulation of the cervical spine compared to acetylsalicylic acid, in terms of subjective clinical findings.

1.2.2. OBJECTIVE TWO

The second objective is to determine the relative effectiveness of manipulation of the cervical spine compared to acetylsalicylic acid, in terms of objective clinical findings.

1.3. Hypotheses

1.3.1. HYPOTHESIS ONE

The first hypothesis was that manipulation of the cervical spine would be significantly more effective than 500mg acetylsalicylic acid in the subjective clinical findings on analysis of the data.

1.3.2. HYPOTHESIS TWO

The second hypothesis was that manipulation of the cervical spine would be significantly more effective than 500mg acetylsalicylic acid in the objective clinical findings on analysis of the data.

CHAPTER 2

2.0 REVIEW OF THE RELATED LITERATURE

2.1. CLASSIFICATION OF EPISODIC TENSION-TYPE HEADACHE

A significant problem in the study of primary headache has been lack of standardisation in the definition of headache disease entities, because no laboratory correlates or other objective markers exist. The Headache Classification Committee of the International Headache Society in 1988, gave explicit diagnostic criteria for all headache disorders, where previous classifications lacked precision, included ambiguous expressions, and were non-operational, which resulted in vague criteria (Rasmussen and Olesen, 1994). The classification of headaches according to the Headache Classification Committee of the International Headache Society is closer to clinical reality with respect to the past attempts of headache classification (Biondi and Portuesi, 1994). However, as the diagnostic criteria, which were developed by the Headache Classification Committee of the International Headache Society, are based mainly on clinical experience, they are not on the basis of scientific evidence (Jensen, et al. 1998). One could therefore argue that any scientific investigation which contributes to a greater understanding of headaches should be considered.

Leone, et al. (1995) assessed the reliability of the diagnostic criteria developed by the Headache Classification Committee of the International Headache Society. The clinical records for 100 consecutive outpatients were evaluated. The results revealed that the criteria developed by the Headache Classification Committee of the International

Headache Society are satisfactorily applicable to high quality medical records, with inter-observer concordance of kappa = 0,81 for episodic tension-type headache.

The Headache Classification Committee of the International Headache Society has divided the classification of tension-type headache into episodic and chronic tension-type headache (Headache Classification Committee, 1988:29):

- Episodic tension-type headache requires a minimum of 10 previous episodes with less than 15 days per month frequency (i.e. less than 180 headache days per year). Each episode may last from 30 minutes to 7 days. This condition may or may not be associated with disorders of the pericranial muscles as determined by manual palpation, pressure algometer elevated electromyograph level of pericranial muscles at rest or during physiological tests (Headache Classification Committee, 1988:30-32).
- Chronic tension-type headache has an average headache frequency of at least 15 days per month (i.e. at least 180 days per year), for a minimum of at least 6 months. As with episodic tension-type headache, a disorder of the pericranial muscles may or may not be associated with chronic tension-type headache (Headache Classification Committee, 1988:31-32).
- Tension-type headache not fulfilling the operational diagnostic criteria for either episodic or chronic tension-type headache by one criterion, is temporarily defined as a tension-type headache till such time as it fulfills all the diagnostic criteria for either diagnosis (Headache Classification Committee, 1988:32-33).

2.2. EPIDEMOLOGY

Episodic tension-type headache is more prevalent than chronic tension-type headache, and despite chronic tension-type headache's greater individual impact, it has a smaller societal impact than episodic tension-type headache (Schwartz, et al. 1998).

2.2.1. Prevalence

A literature search failed to reveal any information on the prevalence of this disorder in South Africa.

The overall prevalence of episodic tension-type headache for Baltimore country, Maryland was 38,3% (Schwartz, et al. 1998). In a Malaysian study, a prevalence of 27,2% was found for tension-type headache, with episodic tension-type headache accounting for 94,4% of the total tension-type headache-afflicted population and 39,3% of the total headache population. Consequently, episodic tension-type had a prevalence of 25,7% in the Malaysian study population (Alders, et al. 1996). In a study of the epidemology of headaches in Germany 38,3% met the criteria for tension-type headaches, this suggests some 29 million people are effected by episodic tension-type headache in Germany (Gobel, et al. 1994). Wong, et al. (1995) found that in Hongkong 25,7%of headache sufferers met the criteria for episodic tension-type headache.

2.2.2. Age

Gobel, et al. (1994) found that episodic tension-type headache does not exhibit any differences in prevalence by age. However, prevalence was found to peak at 30- to 39-year-old age group in both sexes, and declined thereafter, in the study conducted in

Maryland (Schwartz, et al. 1998). The literature review failed to find any hypotheses pertaining to age and this condition.

2.2.3. Gender

Women had higher prevalence than men did at all ages (Rasmussen, 1995) (Schwartz, et al. 1998) (Gobel, et al. 1994) (Rasmussen, et al. 1992). Schwartz, et al. (1998) found the overall sex prevalence ratio was 1:1,16 in Maryland. In clinical populations women also outnumber men in the occurrence of episodic tension-type headache, but this may be unproportional as women are more likely to seek care for their headaches than men (Bove and Nilsson, 1998) (Rasmussen, 1995). According to Rasmussen (1995) this female preponderance of tension-type headache has never been definitively explained, although female hormones have been suggested. The results are inconclusive for migraine, and are unsubstatiated by Rasmussen, (1995) for tension-type headache.

2.2.4. Education

In the study conducted in Baltimore Country, Maryland a strong association between prevalence of episodic tension-type headache and education was found, with increasing education an increase in prevalence of episodic tension-type headache was found peaking with graduate school education, in both sexes and all ages (Schwartz, et al. 1998). The literature review failed to find any hypotheses in regard to education levels and episodic tension-type headache.

2.2.5. Severity

Episodic tension-type headache of moderate intensity was found in 68% of those effected, while those of weak intensity constitute 10% and severe intensity constitute 22% of all episodic tension-type headache sufferers respectively (Gobel, et al. 1994). The method to determine the distribution of the headache pain intensity was not discussed in the above study.

2.2.6. Assessment of Disability

A total of 8,3% of patients with episodic tension-type headache reported lost workdays due to their headaches, with an average of 8,9 lost workdays being reported per person per year. Patients with episodic tension-type headache also report 43,6% reduced-effectiveness days, with average 5,0 reduced-effectiveness days per person per year. Two summary measures of disability were derived based on responses to 5 questions. Lost workdays in the past year were estimated as the number of headaches reported per year that caused the subject to miss part or all of a workday. While reduced effectiveness days were estimated from the product of headache frequency and duration, and the proportion of headaches that cause a decreased effectiveness level and the average proportion reduction in effectiveness at work, home, or school (Schwartz, et al. 1998).

2.2.7. Provoking Factors and Precipitants

The most common provoking factors for tension-type headache was stress and mental tension. Precipitants (also called trigger factors and promoters) are factors which alone or in combination with other exogenous or endogenous exposures induce attacks in

susceptible individuals. Precipitants especially noted in tension-type headaches were smoking and weather changes (Rasmussen,1995). Alders et al. (1996) found the following precipitating factors for tension-type headache in a community-based prevalence study in Malaysia: sun exposure (55,7%), lack of sleep (53,4%), stress (46,0%), menstruation (18,2%), missing a meal (9,8%), fever (6,1%), oversleeping (3,1%), amongst other isolated causes. The literature review did not reveal any information on specifically episodic tension-type headache.

2.3. CLINICAL SIGNS AND SYMPTOMS

The diagnostic criteria for episodic tension-type headache are:

A. At least 10 previous headache episodes fulfilling the criteria B-D listed below. The number of days with such a headache must be less than 15 days per month.

B. The headache must last from 30 Minutes to 7 days.

C. The headache must have at least 2 of the following pain characteristics:

- Pressing or tightening quality (non-pulsating)
- Mild or moderate intensity (may inhibit, but does not prohibit the patient's activities)
- Bilateral location
- No aggravation by routine activity

D. The headache must have both of the following qualities:

- No nausea or vomiting (although anorexia may occur)
- Photophobia or phonophobia are absent, or one but not the other is present

E. The headache must have at least one of the following:

- The history, physical or neurological examinations do not suggest one of the

following disorders: migraine headache, cluster headache, increased intracranial pressure-type headache, decreased intracranial pressure-type headache, local lesion-type headache, vasodilator-type headache and headache with stabbing head pains.

- The history and/or physical and/or neurological examinations do suggest such a disorder, however, it is ruled out by appropriate examinations.
- If such a disorder is present, the headache does not occur for the first time in close temporal relation to the disorder (Headache Classification Committee, 1988:29-30).

2.4. PATHOGENESIS OF ETTH

As stated previously the exact causes of Episodic Tension-type Headaches are not known, however, involuntary tightening in muscle induced mentally or physically is postulated as a possible mechanism. Psychological etiologies are also suspected (Headache Classification Committee, 1988:30-31). Episodic Tension-type Headache and Chronic Tension-type Headache have different characteristics; consequently there may be differences from a pathophysiological point of view. Consequently the mechanism of Episodic Tension-type Headache is still unclear, and should be studied separately in its chronic and episodic forms (Kim, et al. 1995).

2.4.1. Vascular Hypothesis

Bogduk as cited by Vernon, et al. (1992) noted that mechanical irritation of the vertebral artery, vertebral nerve and ascending sympathetic chain can initiate an "autonomic barrage" sufficient to cause cerebral vasospasm, and accepted the hypothesis that subluxation of the cervical apophyseal joints might compromise these structures. The

mechanical derangement of the cervical apophyseal, craniocervical synovial joints produces the headache, and is characterized by a "chronic hypomobility."

Vernon, et al. (1992) found no positive findings of vertebrobasilar insufficiency while assessing cervical spine dysfunction in tension-type and migraine headache subjects. The role of vertebrobasilar insufficiency, due to cervical spine dysfunction, resulting in tension-type headache, has not been found to have a high prevalence in the tension-type population. However, the Underberger test that was used to determine if there was vertebrobasilar insufficiency has not been demonstrated to be reliable (Ladermann, 1990). Consequently, tension-type headaches may be associated with vertebrobasilar insufficiency but currently there are no tests that are sensitive enough to demonstrate the insufficiency. There was no specific information regarding episodic tension-type headache and this particular hypothesis.

2.4.2. The Continuum Hypothesis

The continuum hypothesis discusses the possibility that tension-type headaches and migraine headaches do not exist as distinct physiological entities but form a continuum. The evidence proposed that tension-type headaches and migraines are different expressions of a common disorder:

- Pathophysiological similarities. There is autonomic instability evident in both headache types, and the central pain-modulating system is important to the pathophysiology of both tension-type headache and migraine.

- Epidemiological studies. There are similarities in the tension-type headache and migraine populations. Women outnumber the men by approximately 2:1, and the age distribution is similar with a peak in the 25-45 age group, in both headache populations.
- Psychological similarities. Both tension-type headache and migraine patients show similar psychological trends, with increased incidence of affective disorders (e.g. depression), and personality traits (e.g. hysteria and hypochondriasis).
- Symptomatic similarities. Patients diagnosed with either tension-type headache or migraine consistently manifest symptoms that are associated with the other type of headache.
- Diagnostic overlap. Applying the diagnostic criteria of the Headache Classification Committee of the International Headache Society, many patients fulfil the criteria for both tension-type headache and migraine.
- Therapeutic overlap. A variety of therapeutic approaches with very different modes of action have been shown to be effective in the treatment of both tension-type headache and migraine, including antidepressants, serotonin agonists, anti-inflammatory agents and spinal manipulation (Nelson, 1994).

However this model is designed for chronic headaches, and does not explain episodic tension-type headache to a satisfactory degree.

2.4.3. Psychological Hypotheses

It is unknown whether headache is primary or secondary to psychopathology (Bondi and Portuesi, 1994). Of all those suffering headache as a primary complaint receiving

psychological assessment, 95,5% suffered from chronic tension-type headache (Sebit, 1996). Chronic tension-type headache has also been attributed to a failure to mourn (Kaiser and Primavera, 1992) and inadequate coping mechanisms (Sebit, 1996). Anxiety, insomnia and depression are also associated with chronic tension-type headache (Bondi and Portuesi, 1994). A number of studies have made use of amitriptyline, a tricyclic anti-depressant for the treatment of chronic tension-type headaches (Mitsikostas et al.1997) (Boline et al. 1995).

There are 3 hypothesis pertaining to the psychopathological features in tension-type headache:

- The headache is primary, and the psychological changes that are noted in tension-type headache patients are a secondary reaction.
- The tension-type headache is secondary to the primary psychological disorders.
- The initial distress and gradual model, suggests the patient's distress peaks within the first three years of illness, and gradually subsides as the patient adapts and develops coping mechanisms (these coping mechanisms are not specified). The headache is not removed by these strategies, but there is diminished psychopathology (Bondi and Portuesi, 1994).

The literature review failed to find reference to psychological studies discussing episodic tension-type headache.

2.4.4. ETTH with Pericranial Muscle Dysfunction

Jensen (1995) studied the pericranial tenderness of tension-type headache sufferers and found increased tenderness of these muscles in the subjects compared to normal controls. It was also found that the pericranial tenderness increased during headache, but there was no change in the electro-myographic readings (a 4 channel electromyograph recorded the temporal and trapezius signals bilaterally). As pressure pain thresholds were unaffected by the headache state while thermal pain detection and tolerance thresholds decreased selectively in the temporal region, indicating the actual headache episode may be associated with a segmental central sensitization and/or a decrease antinociception. A generally defective central pain modulation, is less likely because pressure pain thresholds and tolerances in the hands were completely normal. Consequently, a transient and reversible segmental disturbance at the spinal or trigeminal level is possible, as pain tolerances were normal outside of a headache.

The decreased pain tolerance found during headache in the study performed by Jensen (1995) suggests a central hyperalgesia. The central changes are probably reversible while the headache is in its episodic form, as the pain tolerances were normal outside of headache.

Jensen, et al. (1998) favored subjects suffering muscle disorders of the pericranial muscles. Subjects with episodic tension-type headache were found to have no significant differences in the pressure pain thresholds and tolerances, thermal pain thresholds, and no

relation between tenderness and pain thresholds could be detected in either those patients with a muscular disorder of the pericranial muscles or those without (Jensen, et al. 1998).

Jensen and Olesen (1996) induced tension-type headaches in a group of volunteers by several hours of tooth clenching. Pericranial myofascial tenderness was found to precede headache by several hours. Possible mechanisms for this tenderness include:

- Sensitization of the peripheral myofascial nociceptors.
- Sensitization of the second order neurons at the spinal/trigeminal level.
- Impaired central modulation of the nociceptive activity.

Most of these subjects have normal thermal pain and tolerance thresholds, which suggests that the pain mediated by the C fibers is registered and modulated normally. Jensen, et al. (1998) found increased tenderness, but normal thermal thresholds at cephalic and extracephalic locations in chronic tension-type headache patients associated with muscular disorders of the pericranial muscles indicates a central sensitization may be mediated by low threshold mechanosensative afferent neurons projecting to the dorsal horn neurons. However, the mechanisms of pain in tension-type headache without associated pericranial muscle dysfunction cannot be explained by simple allodynia or hyperalgesia as both mechanical and thermal pain thresholds from these patients were elevated, indicating an increased pain tolerance as compared to controls. Consequently, other mechanisms, possibly the central modulation of pain, must be considered.

Episodic tension-type headache unlike chronic tension-type headache was found to have no difference in the nociceptive mechanical thresholds between those subjects with

pericranial muscular disorders, and those without. However, there was increased pericranial muscle tenderness. The hypothesis that Jensen, et al. (1998) create attempts to explain the pathophysiological evolution of tension-type headache. In subjects with episodic tension-type headache with disorder of the pericranial muscles, the most probable mechanism is a slightly increased input from myofascial nociceptors projecting to a predominantly normal central pain perception system. It is suggested that prolonged painful input from the periphery may sensitize the central nervous system and the pain associated with muscle disorders, may be as a result of, central misinterpretation of the incoming signals at the dorsal horn or trigeminal level. Muscular disorders may, consequently, be responsible for the conversion of episodic into chronic tension-type headache. Central supraspinal involvement is also probably involved, as the precipitating factors leading to tension-type headache are stress, mental tension, and fatigue (Rasmussen, 1993). It is also possible that pericranial muscular disorders are the result of episodic tension-type headache as opposed to the cause.

2.4.5. ETTH Without Pericranial Muscle Dysfunction

Episodic Tension-type Headache without associated pericranial muscle tenderness does occur, however it is not known how frequently such cases exist (Kim, et al. 1995). The mechanisms of such a headache are not known, but psychogenic etiologies are suspected (Headache Classification Committee, 1988:31). However, the results of Kim, et al. (1995) indicate that the pain-pressure thresholds of the head and more particularly the neck region should be considered in the pathogenic mechanism in episodic tension-type

headache. This suggests the pathophysiological process may involve localized pericranial disruption of muscle nociception.

There remains considerable controversy surrounding the pathogenic mechanism in tension-headache. Contraction of the pericranial muscles and possibly increased pain sensitivity are thought to play a role in the pathogenesis of tension-type headache. Sustained muscle contraction is mentioned as a main feature, however there are no criteria for the verification of sustained muscular contraction in an individual. Some studies have found increased tenderness of the pericranial muscles, but failed to find elevated electro-myographic levels (both during headache episodes, and during headache-free periods). Hence the credibility of marked tonic muscle contraction as the direct cause of tension-type headaches is now questioned and a hypothesis that nociception is myofascial in origin is favoured (Kim, et al. 1995).

Abnormal muscle tenderness has been found of the pericranial muscles in studies of tension-type headache using manual palpation and pressure algometers (Jensen, et al. 1998)(Jensen, 1995). However, Kim, et al. (1995) found that the pain pressure thresholds of only the upper and middle sternocleidomastoid and trapezius insertion were lowered in a study specifically on episodic tension-type headache. The pericranial muscles and other cervical muscles examined revealed no statistically significant differences between the controls pain-pressure thresholds and those of the headache subjects. The difference is attributed to different diagnostic criteria (i.e. only patients diagnosed with episodic tension-type headache were used as opposed to just a diagnosis of tension-type headache)

and different methodological differences. Due to the specificity of tenderness, the results of Kim et al. (1995) do not support the hypothesis of a diffuse disruption of the central pain modulating system. As a consequence, a presence of more localized pericranial disruption of muscular nociception is supported.

Kim, et al. (1995) support the hypothesis that nociception is primarily myofascial in origin, specifically sternocleidomastoid and trapezius insertion and that this may be the primary characteristic of episodic tension-type headache. However, supraspinal facilities may play a larger role in tension-type headache.

2.4.6. Myofascial Considerations

Vernon, et al. (1992) found 85% of all tension-type headache subjects have at least one myofascial trigger point of the posterior cervical muscles. A myofascial trigger point as defined by Travell and Simons, (1983:12) is a hyperirritable locus within a taut band of skeletal muscle, located in the muscular tissue and/or its associated fascia. The spot is painful on compression and can evoke characteristic referred pain and autonomic phenomena. Myofascial trigger points are defined as either active or latent. An active myofascial trigger point causes the patient pain. A latent myofascial trigger point is clinically silent with regard to pain, however, may cause restriction of movement and weakness of the affected muscle. The sternocleidomastoid muscles are frequently the basis for diagnoses of tension-type headache (Travell and Simons, 1983: 202).

Apart from causing local and referred pain, myofascial trigger points in hypertonic muscles are also considered to be responsible for causing joint fixation. This is due to ligamentous shortening and articular adhesions that occur with muscle hypertonicity. The concept of restricted segmental movement due to muscle hypertonicity is popular with a number of authors (Gatterman, 1990: 42-43).

2.4.7. Cervical Spine Dysfunction and ETTH

Vernon, et al. (1992) define cervical spine dysfunction as impaired or altered function of related components of the cervical spine, including skeletal, arthrodial and myofascial structures, resulting in the following aspects of cervicogenic dysfunction:

- Inter-segmental Hypomobility
- Tender points in the soft tissue
- Reduced regional ranges of motion
- Radiographic findings of : static misalignment, and dynamic intersegmental abnormality.

The neck has received scant attention in the orthodox paradigms of cephalgia, despite the results arising from researchers such as Edmeads and Bogduk and his colleagues (Vernon, et al. 1992). Gatterman (1995) argues the hypothesis that cervical spine dysfunction makes a significant contribution to the cause of a number of benign forms of headache. In a study Muller (1999) found a significant incidence of cervical dysfunction in those suffering tension-type headache, as compared to the asymptomatic controls. Bogduk (1992) defines cervicogenic headache as pain perceived as arising from the head,

but whose actual source lies not in the head but in the cervical spine. Vernon, et al. (1992) discuss the cervicogenic headache model, and consider that the cervical spine may play a much larger role than previously recognized in tension-type headache.

According to Edmeads (1988) for neck disorders to cause head pain, they must have:

- Pain sensitive structures in the neck.
- Identifiable pathological processes or physiological dysfunction's within the neck, providing an adequate stimulus to the nociceptors in the cervical structures.
- Identifiable neurological pathways and mechanisms through which the pain originating in the cervical segments may refer to the head.

The possible sources of a headache of cervical origin are any of the structures innervated by the by the first three cervical nerves (bar the skin), as listed below:

- C1-C3 rami: Atlantooccipital joint; lateral atlantoaxial joint; longus capitis; longus cervicus; rectus capitis anterior; rectus capitis lateralis; trapezius; sternocleidomastoid; dura mata of posterior fossa; vertebral artery.
- C1-C3 Sinuvertebral nerves: Median atlantoaxial joint; transverse ligaments; alar ligaments; dura mater of spinal cord; dura mata of clivus; C2-C3 intervertebral disc.
- C1-C3 dorsal rami: C2-C3, C3-C4 zygopophysial joints; suboccipital muscles; semispinalis capitis; semispinalis cervicis; multifidus; longissimus capitis; splenius capitis (Bogduk, 1992).

The trigeminal nerve is the principle general sensory nerve to the head, especially the face, but is also the motor nerve to the muscles of mastication (Moore, 1992: 822).

Bogduk (1992) defined the trigeminocervical nucleus as those cells in the upper three cervical segments that receive both trigeminal and cervical peripheral input. Hence, all noxious stimuli from the structures of this region, regardless of innervation, will be mediated by the trigeminocervical nucleus. As a result nociceptive neurons of the trigeminocervical nucleus have extensive receptive fields that encompass both the field of the trigeminal nerve and the fields of the first three cervical nerves. These nociceptive neurons have central connections that are poorly organized somatotopically. Consequently, information relayed by them is interpreted from anywhere within their peripheral receptive field.

If there is disinhibition, the antinociception system fails to function, trivial somatic disturbance may produce headaches (Nelson, 1994). This can cause excitation and hyperfacilitation to arise in the trigeminocervical nucleus, and may explain the formation of the headache and of deep tissue pain and hyperalgesia of the surrounding cutaneous areas. Hence, the hyperalgesia and deep tissue pain can be explained in terms by hypersensitivity of the dorsal horns of the cervical nerves. This can also explain the poor localization and the pain referral because of the general convergence of sensory input into the trigeminocervical nucleus. Hence, all these phenomena are components of myofascial dysfunction and pain referral likely to be operative in tension-type headache (Vernon, 1995). If the subject has an optimally functioning antinociception system, mild, moderate or even severe cervical spine dysfunction may not give rise to a headache (Nelson, 1994).

In the majority of tension-type subjects there is a significant loss of the normal lordosis of the cervical spine. There is palpable hypomobility of the upper cervical spine, confirmed by computer-aided dynamic X-ray analysis in flexion/extension (most frequently involving C0-C1), with a tendency for hypomobility in the lower cervical spine (Vernon, et al. 1992).

Gatterman (1995) states the neurophysiological basis of headache referral from the neck, particularly from inflammatory pain arising from the posterior suboccipital muscles and joints, can be explained by the phenomenon of "central sensitization" and neuroplastic changes that these second order neurons undergo in prolonged peripheral deep somatic pain. These are the mechanisms thought for many years by chiropractors to arise from a dysfunction state of the vertebral motion segment.

Vernon (1988) proposed the vertebrogenic model of headache, which has 4 categories:

- Extrasegmental, referring to the long regional myofascial structures, the ligamentum nuchae, and the interface between the occiputofrontalis muscle and the regional cervicothoracic structures.
- Intersegmental, referring to the three joint complexes of C2-C4 and the articulations of C0-C2, with there associated ligaments and deep intersegmental muscles.
- Infrasegmental, referring to the nerve structures within and surrounding the intervertebral foramina.
- Intrasegmental, referring to the spinal cord and medullary dorsal horn with the trigeminocervical nucleus.

The arthrokinetic reflex is initiated by irritation to the intra-articular nociceptors, by either mechanical or chemical stimulus produced by joint pain. The reflex initiates arthrogenic muscle spasm with referred pain due to the activation of convergent neurons. Joint fixation or hypermobility may also initiate the arthrokinetic reflex (Gatterman, 1990:252).

The chiropractic subluxation is composed of five parts: neural, kinesiopathological, muscular, cellular and biomechanical (Dishman, 1988). The mechanism of pain due to subluxation, develops as follows:

- A mild to moderate bony disrelationship will cause stretching of the tendons and ligaments which activates nervous stimuli in the dorsal roots of a specific nerve (Faucet et al. 1980).
- The stimuli then travel to the dorsal columns via the posterior funiculus, and from there to the nucleus ventralis posterolateralis of the thalamus. This registers crude pain and from here the stimulus is transmitted to somethetic cortex (Tan and Wong, 1990:208).
- A subluxation also induces nervous stimuli, via the dorsal roots of the spinal nerves at the effected level transmit impulses through the posterior horns through association neurons, and then up the spinoreticular tracts to the reticular activating system (Faucet et al. 1980).

- The impulse can from this point effect several different structures (e.g. a stimulus to the limbic lobe may cause mental and behavioral changes leading to anxiety and headache (Faucet et al. 1980).
- Any conduction to the cerebral cortex will then run through the corticoreticular spinal tracts down the medial and lateral reticulospinal tracts, which then synapse with the anterior horns and lower motor neurons to cause alteration of muscle tone leading to increased muscle tone and eventually pain (Faucet et al. 1980).

2.5. TREATMENT

No specific figures were found in the literature review for the incidence of treatment for episodic tension-type headache by medical or non-medical personnel exist. One could presume from the frequency and natural history of the condition that the treatment would be predominantly symptomatic in nature.

2.5.1. Allopathic Treatment

Our present knowledge of medication habits in headache sufferers is poor and mainly based on the headache prone populations. It is suspected that as little as only 16%of all tension-type headache sufferers have attended the rooms of a general practitioner, while 4% of all tension-type headache sufferers have attended the rooms of a specialist. However, only 13% of all tension-type headache sufferers managed without medication. The most commonly used analgesics were acetylsalicylic acid preparations and paracetamol (Rassmussen, 1995).

2.5.1.1 TREATMENT UTILIZING ACETYLSALICYLIC ACID

In a study in 1987 Campbell (as cited by Kim, et al. 1995) found that more than 30 million pounds of aspirin – of which at least a major part is taken for the relief of headaches – is consumed annually worldwide. Neal (1992:66-67) states acetylsalicylic acid is the longest standing non-steroidal anti-inflammatory drug and is an effective analgesic.

In a double blind, threefold crossover double-dummy trial of 65 patients 500mg of acetylsalicylic acid was found to be equivalent to 200mg of ibuprofen and both were significantly superior to placebo (α=5%). The main response criterion, was a minimum 50% decrease of headache intensity on a visual analogue scale (VAS) at one hour after treatment (Nebe, et al. 1995).

2.5.1.1.1. PHARMACOLOGY AND CONTRA-INDICATIONS OF ACETYLSALICYLIC ACID

Acetylsalicylic acid has two main therapeutic effects, the production of analgesia and antipyresis. For the interests of this study only the analgesic effect is of interest as the antipyretic effect has no bearing on episodic tension-type headache(Craig and Stitzel, 1994:433). Acetylsalicylic acid has duration of action of approximately 4 hours, with peak plasma concentrations 1-2 hours after oral admission. Acetylsalicylic acid is distributed across membranes primarily by passive diffusion and can be detected in most body tissues and fluids. The analgesic dose of acetylsalicylic acid has a half-life of 2-3 hours, while the plasma half-life of acetylsalicylic acid is of 15 minutes, and the salicylic

acid is bound to plasma proteins in 50-80% of the total blood concentration (Neal, 1992:66-67)(Craig and Stitzel, 1994:433)(Dewey, 1991:406).

As a weak acid (p*K*a = 3,5), the acid pH of the stomach keeps most of the acetylsalicylic acid non-ionised and therefore promotes absorption in the stomach, although most acetylsalicylic acid is absorbed via the large surface of the small intestine. The absorbed acetylsalicylic acid is hydrolysed by esterases in the blood and tissues to salicylate (which is active) and acetic acid. The analgesic effect is produced through both central and peripheral mechanisms. The salicate interferes with the pain perception centrally by action within the hypothalamus, and since the cortex is not affected, analgesic doses do not cause mental disturbances or drowsiness. The salicylate alter pain reception peripherally by interfering with the input into peripheral nerve endings by inhibiting cyclooxygenase, the enzyme that converts arachidonic acid to prostalandins E and F, which are thought to sensitize nerve endings to pain. Most of the salicylate is converted in the liver to water-soluble conjugates that are excreted by the kidney. Alkalisation of the urine ionises the salicylate, which reduces tubular reabsorbtion; hence excretion is increased (Neal, 1992:66-67)(Craig and Stitzel,1994:433).

The contra-indications for use of acetylsalicylic acid include: peptic-ulceration, haemophilia, renal impairment, oral anticoagulants, 1st and 3rd trimester during pregnancy, and lactation; and the side effects include: dizziness, gastro-intestinal irritation, skin eruptions, paroxysm, bronchospasm and dyspnea. Special precautions are warranted should the patient: take other gastro-intestinal irritants, a week before surgery

(due to a possibly increased bleeding time), suffers asthma, have impaired renal function, dyspepsia, anaemia, or dehydrated. Reye's Syndrome has been implicated in children and teenagers (Snyman, 1999:1155-1156).

Consequently, it would make sense to search for an alternative form of treatment. In the light of the postulated aetiologies of this disorder, the involuntary tightening of the musculature and cervical spine dysfunction amongst others, cervical spine manipulation could therefore provide relief.

2.5.2. Chiropractic Treatment

There are few articles that discuss specifically with episodic tension-type headache in chiropractic literature. A synopsis of these follows:

In a randomised controlled trial where 75 patients suffering episodic tension-type headaches received 8 treatments over a 4-week period, one group received soft tissue therapy and cervical spine manipulation, while the other group received soft tissue therapy and placebo laser treatment. There was no significant difference between the two groups in mean daily headache hours and mean number of analgesics per day. The headache pain intensity was unchanged for the duration of the trial, consequently concluding cervical spine manipulation as an isolated intervention does not have a significant effect (Bove and Nilsson, 1998).

The above findings are in conflict with those of a study performed on 11 male patients, between 18-40 years of age, at the Palmer College of Chiropractic-West Outpatient Clinic. The patients received 16 treatments over an 8-week period, with a 2-week baseline period prior to the commencement of treatment. The patients were treated with primarily cervical manipulation, but secondarily with ischaemic compression, as well as thoracic and lumbar adjustments if indicated. There was a statistically significant decrease in headache frequency and headache duration, however, no statistical decrease was found in headache intensity. The small sample size and the non-specific treatment protocol limit these headache findings (Mootz, et al. 1994). Vernon and McDermaid (1998) found in a survey of Chiropractors conducted in Canada, that most clinical specialists used upper cervical spine manipulation more commonly than any other form of therapy in the treatment of episodic tension-type headache.

2.5.2.1. THE KORR MODEL

The Korr model suggests that the intrafusal fibres and golgi tendon organ receptors provide the mechanism whereby hypertonicity of the muscle producing joint fixation is relieved by manipulation. The intrafusal fibres and golgi tendon organ receptors act as breaks and limit excessive joint movement by initiating a reflex inhibition of motor activity in muscles operating over the joint. It is feasible that a high velocity thrust performed at the extreme of the restricted joints range of motion activates the golgi tendon organ receptors inhibiting muscle activity, thereby reducing hypertonicity (Butler, 1994:98-99).

2.5.2.2. MOTION PALPATION

Motion palpation is a diagnostic tool used to determine where to manipulate and may be defined as palpatory diagnosis of passive and active segmental joint range of motion (Bergmann, et al. 1993: 762). Motion palpation assesses joint movement, slowly and smoothly with the minimum force necessary moving through the entire range of motion, with the start and end at neutral. The single assessment of endfeel is an exception to returning to neutral. When evaluating segmental movement test 1 movement, at one joint, around one axis, in one plane on one side of neutral whenever possible. One compares the contralateral side and adjacent segments for their mobility, prior to determining where to manipulate (Bergmann, et al. 1993: 96-97). Motion palpation has been found to have good intra-examiner reliability, however, inter-examiner reliability results have been inconclusive (Bergmann, et al. 1993: 738-739).

2.5.2.3. INDICATIONS AND CONTRA-INDICATIONS TO SPINAL MANIPULATIVE THERAPY

The term adjustment is considered unique as a term to describe chiropractic manipulation, in that it entails the use of short-lever, specific, high velocity, controlled forceful thrusts by hand aimed at individual articulations (Gatterman, 1995:12).

Schafer and Faye (1990: 40) cited the following indications for manipulation:

- Increasing spinal mobility.

- Freeing entrapped or stretched nerves.
- Returning intervertebral discs and foramina to their normal boundaries.
- Extend shortened tendons and ligaments.
- Break adhesions.

Serious injuries as a result of spinal manipulation are uncommon, and are less frequently associated with iatrogenic complications than many other health-care procedures. Even so contra-indications to spinal manipulation do exist:

- Vertebrobasilar insufficiency
- Aneurysm
- Disc prolapse with neurological deficit
- Fracture
- Dislocation
- Bone tumors
- Bone infection (Bergmann, et al. 1993:133).

2.5.3. Theoretical considerations regarding Treatment

Kim, et al. (1995) support the hypothesis that nociception is myofascial in nature in episodic tension-type headache, specifically at the sternocleidomastoid and trapezius insertion. Myofascial trigger points in hypertonic muscles are also considered to be responsible for causing joint fixation (Gatterman, 1990: 42-43). The Korr model suggests that a high velocity thrust performed at the extreme of the restricted joints range of motion activates the golgi tendon organ receptors inhibiting muscle activity, thereby

reducing hypertonicity (Butler, 1994:98-99). One of acetylsalicylic acid two main therapeutic effects, is the production of analgesia (Craig and Stitzel, 1994:433). However, acetylsalicylic acid unlike spinal manipulation has no direct effect on the pathophysiology of episodic tension-type headache.

2.6 CONCLUSION

Episodic tension-type headache seems to be more prevalent than chronic tension-type headache, and has a greater societal impact (Schwartz, et al. 1998). The mechanism of Episodic Tension-type Headache is still unclear (Kim, et al. 1995). Kim, et al. (1995) concluded their findings support the hypothesis of the presence of more localized pericranial disruption of muscular nociception, and is primarily myofascial in origin, specifically sternocleidomastoid and trapezius insertion and that this may be the primary characteristic of episodic tension-type headache. The possible sources of a headache of cervical origin are any of the structures innervated by the by the first three cervical nerves (Bogduk, 1992). Gatterman (1995) argues the hypothesis that cervical spine dysfunction makes a significant contribution to the cause of a number of benign forms of headache.

One of the most commonly used analgesics is acetylsalicylic acid preparations (Rassmussen, 1995), Neal (1992:66-67) states acetylsalicylic acid is an effective analgesic. Nebe, et al. (1995) found 500mg of acetylsalicylic acid to be equivalent to 200mg of ibuprofen and both are significantly superior to placebo.

Vernon and McDermaid (1998) found in a survey of Chiropractors conducted in Canada, that most clinical specialists used upper cervical spine manipulation in the treatment of episodic tension-type headache. This however, is in direct contrast to a study by Bove and Nilsson (1998) who found that spinal manipulation is as effective as soft tissue therapy.

However, Bove and Nilsson (1998) patients received 8 treatments over a 4-week period. No short-term symptomatic trials have been conducted on subjects with episodic tension-type headache, which are typical of drug trials. Consequently, a comparative clinical trial of cervical spine manipulation compared to acetylsalicylic acid in the treatment of episodic tension-type headache investigating the initial and short term effects will help to determine the effectiveness of cervical spine manipulation in the treatment of this condition.

CHAPTER 3

3.1. INTRODUCTION

This chapter will concern itself with the specific method followed in the experimental procedure.

3.2. MEASUREMENTS AND OBSERVATIONS

3.2.1. The Data

The data required for this study consists of both primary and secondary data.

3.2.1.1. The Primary Data

The primary data was obtained by way of a standardized case history, physical and cervical regional examination according to the Technikon Natal Chiropractic Day Clinic forms (Appendix A, B, and C). As well as subjective questionnaires, pressure pain thresholds (using an algometer), and intersegmental mobility (using motion palpation).

3.2.1.2. The Secondary Data

The secondary data required to document and explain the primary data by means of statistical analysis was obtained from books, journal articles and periodicals.

3.3 STUDY DESIGN AND PROTOCOL

3.3.1. The Sample and Allocation of Subjects

Candidates were recruited by means of advertisements placed on various suitable notice boards and in newspapers in circulation in the greater Durban area. Therefore the sampling procedure was of a non-probability, purposive nature. In this kind of sampling procedure, there is a deliberate subjective choice in drawing a 'representative' sample, and can eliminate anticipated sources of distortion, however, there remains the risk of unrecognised sources of distortion and subjective bias (Barnett, 1991).

Given the relatively high frequency of the condition (Schwartz, et al. 1998), a larger sample size would statistically increase the power of the study, however, due to the difficulty in acquiring an adequate sample, the sample size was set at 60. Simple random allocation was used to divide the subjects into either group by using a hat, wherein 60 pieces of paper were placed as described by Scott-Dawkins (1995). Thirty pieces of paper for the group of subjects receiving acetylsalicylic acid, and 30 pieces of paper for the group of subjects receiving cervical spine manipulation. Each subject upon being accepted drew a piece of paper; consequently all subjects had an equal chance of falling into either group. The patients were told that they had either joined the medication group or the cervical spine manipulation group. The next new patient joining the study then replaced the position of any patient that dropped out of the study.

3.3.2. Inclusion and Exclusion Criteria of Subjects

Only those candidates who fulfilled the following inclusion criteria were considered for examination:

- Fulfilled the criteria for the diagnosis of episodic tension-type headache (or failed by one criterion) as stipulated by the Headache Classification Committee of the International Headache Society (1988:31-32).
- 18-70 years of age (Nebe, Heier and Diener, 1995).
- Must have suffered from 2-6 mild-moderate headache episodes per month for at least 6 months duration (Nebe, Heier and Diener, 1995).
- The subject recorded the initial headache severity on a visual analogue scale, and only those subjects with a rating of 3-7 on a 10cm visual analogue scale were included in the study. This was to ensure greater homogeneity in the sample, as clinical impression would not narrow this parameter down (Nebe, Heier and Diener, 1995).

Candidates were excluded from the study if they present with:

- Any contraindications to spinal manipulative therapy as outlined by Bergmann et al. (1993:133).
- Any contraindications to acetylsalicylic acid as outlined by Nebe, Heier and Diener (1995) and Snyman (1999:1188-1189).
- Patients must not have received any other manual treatment or Schedule 3 medication (or above) for their headache in the month prior to entering this study.

The subjects which were considered for the study were informed as to the nature and reasons for the study and read the covering letter (Appendix D), where after they completed and signed an informed consent form (Appendix E) which explains the terms and conditions of the study. Those subjects meeting the stated criteria were then assigned to either the spinal manipulative therapy or medication groups by the method previously

described. Each subject then underwent a thorough case history, physical examination, and cervical spine examination. Those patients who were diagnosed with episodic tension-type headache and met the above criteria had their cases reviewed by a clinician who signed permission to treat the patient, having reviewed the case and finding the patient suitable.

3.3.3. Interventions

Those patients selected for the spinal manipulative therapy group was motion palpated and the relevant manipulation was performed according to the findings, as outlined by Bergmann, Peterson and Lawrence (1993:241-292). While those patients having been selected for the medication group were supplied with a tablet containing 500mg of acetylsalicylic acid, which the subject ingested under the supervision of the researcher (Nebe, Heier and Diener, 1995).

All the subjects in both groups were treated twice. The first treatment upon the completion of all the necessary diagnostic procedures, and the second treatment upon the next consecutive headache within two weeks of the initial consultation, but not within 48 hours of the first treatment (Nebe, Heier and Diener, 1995). Those patients who did not have a headache in the stipulated time period leave the study.

3.3.4. Method of Measurement

The subjects were assessed for both subjective and objective findings prior to both treatments, and the headache diary noted the patient's symptoms for the next 150

minutes. An additional objective assessment was performed directly after the second treatment in the manipulation group.

3.3.4.1. SUBJECTIVE MEASURES

The subjective assessment was obtained (on each consultation) through the short-form McGill pain questionnaire (Appendix F) (Melzack, 1987), the 101 point numerical rating scale (Appendix G) (Jenson, Karoly and Braver, 1986), the CMCC neck disability index (Appendix H) (Vernon and Mior, 1991) and the headache diary (Appendix I) (Nebe, Heier, and Diener, 1995).

The numerical rating scale - 101 (NRS - 101), was completed to evaluate the short-term and relative long-term benefits of each treatment. This system operates by having the patient write down their subjective level of pain with 0 being no pain at all and 100 being as bad as the pain could possibly be. This system is considered statistically sensitive and practical (Jenson, Karoly and Braver, 1986).

The short-form McGill pain questionnaire consists of 15 descriptors which are rated on an intensity scale: 0 = none, 1 = mild, 2 = moderate and 3 = severe. This system of questionnaire has been shown to be sufficiently sensitive to demonstrate differences to treatment at statistical levels (Melzack 1987).

The CMCC neck disability index assesses the patient's ability to manage the activities of daily living. It consists of 10 questions with a total of 50 points, which are converted to a

percentage. This questionnaire has a high degree of internal consistency and reliability according to Vernon and Mior (1991).

The subjects were provided with a diary for each treated headache episode. The diary had a visual analogue scale for the initial headache, and the severity of the headache was noted on a visual analogue scale at 15, 30, 45, 60, 90, 120 and 150 minutes. Consequently, short-term effects are defined as the changes in the patient's symptoms from 15 minutes to 150 minutes for the interests of this study. The diaries were also used for the classification of single headache events, including questions about the initial headache characteristics, localisation and accompanying symptoms in questionnaire form. There was additional space for remarks concerning any symptoms or adverse effects (Nebe, Heier and Diener, 1995).

3.3.4.2. OBJECTIVE MEASURES:

The objective assessment was obtained with an algometer. The algometer permits the pressure-pain thresholds to be objectively determined. In a controlled study patients with episodic tension-type headaches were found to have increased pain sensitivity of the superior sterno-cleido-mastoid, middle sterno-cleido-mastoid and trapezius insertion muscles (Kim et al. 1995).

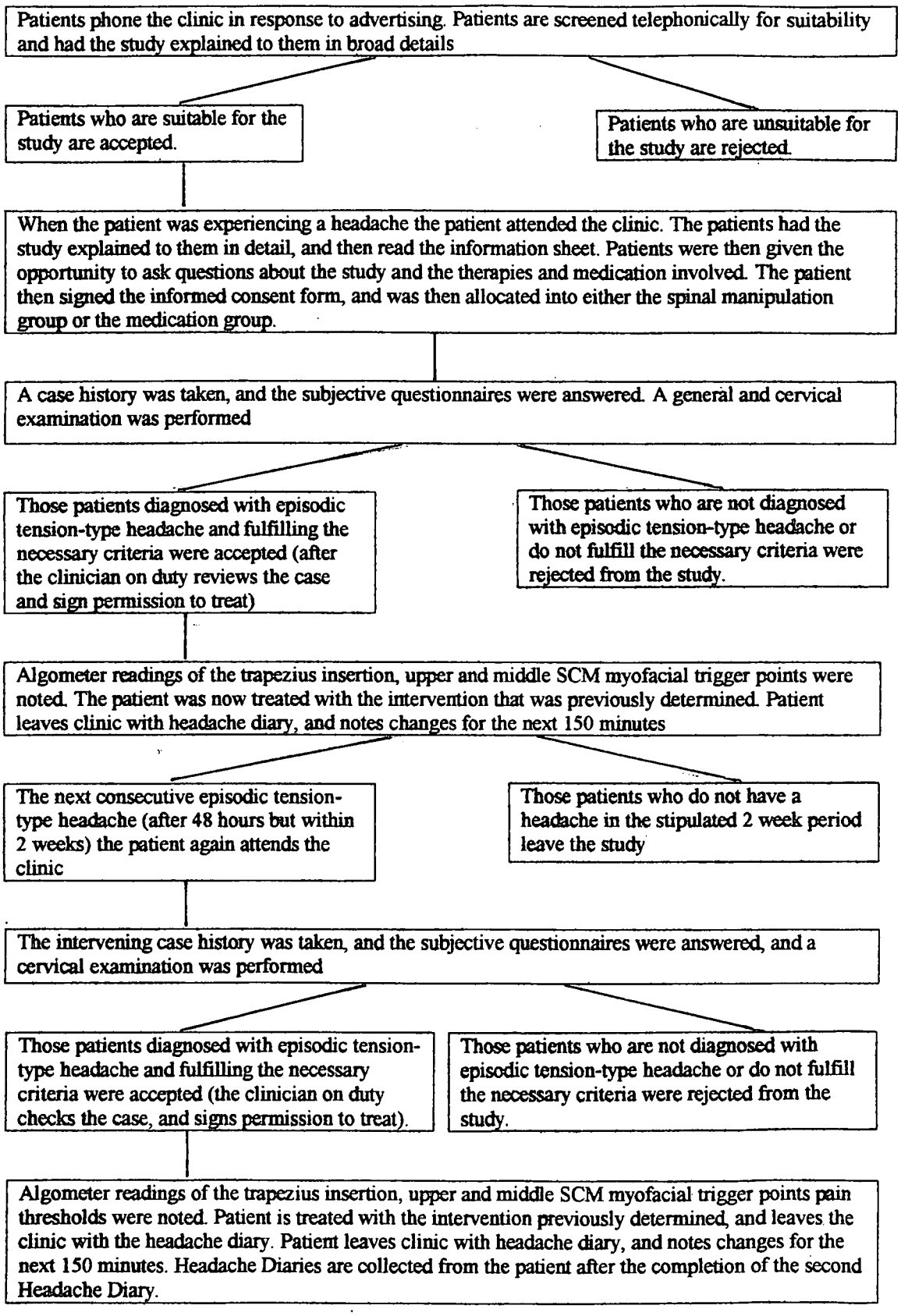
3.3.5. Admissibility of the Data

The whole initial assessment for each subject was completed on the same day. Only the results of those subjects that met the criteria of the study were utilized.

3.3.6. Ethical Considerations

Ethical criteria were instituted as per the recommendation of the Technikon Natal Ethical Committee for patient orientated research.

3.3.6. A Flow Diagram of the Study Design and Protocol



3.4. STATISTICAL ANALYSIS

Statistical analysis utilised parametric studies, specifically the use of two sample t-tests with power analysis for the continuous variables. Intra-group comparison was analysed using the two sample paired t-test, while inter-group comparison was analysed with the t-test. Visual analysis was made using bar charts and graphs.

3.4.1. The Decision Rule and the Null Hypothesis

The null hypothesis (Ho) stated that there was no significant difference between the acetylsalicylic acid group and the cervical spine manipulation group. The alternative hypothesis (H1) stated that there would be a significant difference between the acetylsalicylic acid group and the cervical spine manipulation group.

Ho: there was no significant difference

H1: there was a significant difference

$\alpha = 0.05$ =the level of significance

For a two-tailed test,

Reject Ho if $P < \alpha/2 = 0.025$

Accept Ho if $P > \alpha/2 = 0.025$

P was the observed significance level.

3.4.2. Treatment of the Data

3.4.2.1. SUBJECTIVE DATA

The subjective data was treated as follows:

- Questionnaires and headache diaries that the patients completed were screened to ensure they had been completed correctly.
- Raw data from the 101 point numerical rating scale (Jenson, Karoly and Braver, 1986), the CMCC neck disability index (Vernon and Mior, 1991) and the headache diary (Nebe, Heier, and Diener, 1995), was converted into percentages and recorded separately for each group.
- Raw data from the short-form McGill pain questionnaire (Melzack, 1987) was recorded separately for each group.
- The data was analyzed using a 95% confidence level (5% level of significance).

3.4.2.2. OBJECTIVE DATA

The objective data was treated as follows:

- The algometer readings were recorded separately for each group.
- The data was statistically analyzed using a 95% level of confidence (5% level of significance).

3.4.3. Statistical Analysis of the Data

An external statistician was consulted for advice on how to statistically analyze the data obtained from this research study. Due to the sample size (n1 = 30 and n2 =30) only

parametric tests were used to analyze the data. Data was transferred to a spreadsheet and statistical analysis was conducted at a 95% confidence level.

3.4.3.1. PARAMETRIC TESTING

Parametric testing was used to analyse the continuous variables and the variances (Fisher, 1993). The continuous variables include results from:

- Short-form McGill pain questionnaire
- The 101 point numerical rating scale
- The CMCC neck disability index
- The Headache Diary
- The algometer measurements

Means, ranges and standard deviations were used for analysis.

3.4.3.1.1. Two Sample t-test

Subjective and objective data, from the results of the continuous variables, were analyzed using the Two Sample t-test for inter-group comparison. This was in order to determine whether any significant difference existed between the mean values within the spinal manipulation group and the medication group at both consultations. Levene's test was used to determine the equality of variances.

Confidence levels were conducted at a 95% confidence interval (Alpha = 0.05).

3.4.3.1.2. Two Sample Paired t-test

Subjective and objective data from the continuous variables was analyzed using the Two sample paired t-test for intra-group comparison. This was in order to determine whether any significant difference existed between the mean values within each group at both consultations.

Confidence levels were conducted at a 95% confidence interval (Alpha = 0.05).

3.4.4. Hypothesis Testing

The null hypothesis (Ho) for subproblem one stated that the relative effectiveness of manipulation of the cervical spine compared to acetylsalicylic acid that there was no significant difference in the patient's condition in terms of subjective clinical findings.

The alternative hypothesis (H1) for subproblem one stated that the relative effectiveness of manipulation of the cervical spine compared to acetylsalicylic acid that there was a significant difference in the patient's condition in terms of subjective clinical findings.

The null hypothesis (Ho) for subproblem two stated that the relative effectiveness of manipulation of the cervical spine compared to acetylsalicylic acid that there was no significant difference in the patient's condition in terms of objective clinical findings.

The alternative hypothesis (H2) for subproblem two stated that the relative effectiveness of manipulation of the cervical spine compared to acetylsalicylic acid that there was a significant difference in the patient's condition in terms of objective clinical findings.

3.4.5. Inferential Statistics

If the parametric tests determined by way of calculation that there was a significant difference between the two groups in terms of subjective or objective clinical findings, the mean was used to identify the superior treatment group. The standard deviation could then be used to measure the reliability of the mean by measuring the spread of data around the mean.

CHAPTER 4

4.0 RESULTS

4.1. INTRODUCTION

In this chapter, the criteria governing the admissibility of the data will be outlined and the collected data from the study will be presented in tabulated form. Demographic data from the study will be presented, followed by the intra-group data and then the inter-group data. Each table of the intra-group data will contain the mean, standard deviation and the standard error of the paired t-test. The p-value and correlation from the paired samples is also displayed, as well as the confidence interval and p-value of the paired t-test. Each table of the inter-group data will contain the mean, standard deviation and standard error of the group statistics as well as the p-value for Levene's test for equality of variance. The p-value and confidence intervals for the equality of means concludes the presentation of the independent sample tests. The discussion of this data will be covered in chapter 5.

4.2. CRITERIA GOVERNING THE ADMISSABILITY OF THE DATA

The information obtained from the case history, physical and regional examinations, questionnaires and algometer readings was used as the data for this study. The McGill Pain Questionnaire, NRS 101 and CMCC neck disability Index was completed under the supervision of the researcher. The Headache Diaries were completed independently by each patient and returned to the researcher. The researcher took all the algometer measurements.

For the following data, the level of significance (Alpha) was set at 0.05, thus the null hypothesis was rejected when $p < 0.05$ and the null hypothesis was accepted when $p \geq 0.05$.

ABBREVIATIONS USED IN TABLES

1. C.I. - 95% confidence interval
2. CMCC - CCMC Neck Disability Index
3. Corr - Correlation
4. McGill - McGill Pain Questionnaire
5. n - Number
6. NRS 101 - Numerical Pain Rating Scale
7. S.D. - Standard deviation
8. S.E. - Standard error
9. SCM - Sterno-cleido-mastoid
10. Trap Insert - Trapezius Insertion
11. tx - Treatment
12. VAS - Visual Analogue Scale

4.3. DEMOGRAPHIC DATA TABLE

	GROUP 1	GROUP 2
Size:	n = 30	n = 30
Age Range:	18 – 56 years	19 – 54 years
Mean Age:	33,2 years	29,4 years
Male : Female:	12 : 18	8 : 22
Also suffers Migraines:	09	04
Previous episodes over:	08,6 years	07,0 years
Mean Frequency per Month:	11,0	10,5
Precipitating Factors:		
○ Stress:	20	19
○ Light:	06	10
○ Heat:	04	06
○ Computers:	06	03
○ Sound:	04	02
○ Sun:	03	02
○ Eyestrain:	02	01
○ Fatigue:	01	02
○ Menstruation	00	02
○ Other:	03	01

Headache location:	**Treatment 1**	**Treatment 2**	**Treatment1**	**Treatment 2**
○ Frontal:	16	19	19	22
○ Occipital:	15	15	16	12
○ Temporal:	12	08	12	12
○ Vertex:	04	03	02	00
○ Parietal:	00	00	01	00
Headache duration:	05,2 hours	08 hours	05,5 hours	05,8 hours
Pain description:				
○ Dull ache	16	19	19	22
○ Oppressive	03	03	05	02
○ Band-like	04	01	03	04
○ Throbbing	04	03	01	01
○ Gnawing	02	02	01	01
○ Cramping	02	02	01	00

Level of Fixation:

◦ C0	13	09	13	13
◦ C1	11	13	17	16
◦ C2	07	06	04	05
◦ C3	10	12	07	08
◦ C4	05	02	02	06
◦ C5	06	05	06	05
◦ C6	05	07	11	09
◦ C7	24	20	20	20

4.4. INTRA-GROUP DATA

4.4.1. Subjective Data

Table 1: Statistical results of the subjective findings comparing the Initial Consultation and the Follow up Consultation in Group 1.

	Consultation 1			Follow up 1			P-value (α=5%)	Corr	P-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
McGill (0-45)	4.77	2.57	0.47	4.40	2.97	0.54	0.080	0.325	0.539
CMCC (%)	19.47	7.26	1.33	15.50	8.06	1.47	0.047	0.365	0.018
NRS 101 (worst)	54.33	14.84	2.71	46.00	13.98	2.55	0.962	-0.009	0.034
NRS 101 (best)	30.50	16.10	2.94	32.90	15.49	2.83	0.293	0.199	0.516

Table 2: Statistical results of the subjective findings comparing the Initial Consultation and the Follow up in Group 2.

	Consultation 1			Follow up 1			P-value (α=5%)	Corr	P-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
McGill (0-45)	4.97	2.30	0.42	4.47	1.83	0.33	0.54	0.356	0.258
CMCC (%)	17.20	5.32	0.97	14.87	4.75	0.87	0.36	0.383	0.30
NRS 101 (worst)	50.93	10.87	1.99	46.83	14.53	2.65	0.406	-0.157	0.258
NRS 101 (best)	28.00	14.77	2.70	31.33	17.52	3.20	0.107	0.300	0.350

Table 3: Statistical results of the VAS comparing the Patient's usual Headache and the Headache presenting at the Initial Consultation in Group 1.

	Patient's usual headache			At Consultation			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	50.77	13.98	2.55	46.23	16.76	3.06	0.210	0.236	0.204

Table 4: Statistical results of the VAS comparing the Patient's usual Headache and the Headache presenting at the Initial Consultation in Group 2.

	Patient's usual Headache			At Consultation			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	52.13	11.48	2.10	47.17	12.62	2.30	0.112	0.296	0.068

Table 5: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 15 minutes post-treatment from the Initial Consultation in Group 1.

	At Consultation			15 minutes post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	10.23	16.18	2.95	0.003	0.526	0.000

Table 6: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 15 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			15 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	37.63	16.72	3.05	0.010	0.462	0.002

Table 7: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 30 minutes post-treatment from the Initial Consultation in Group 1.

	At Consultation			30 minutes post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	6.97	12.94	2.36	0.008	0.473	0.000

Table 8: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 30 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	29.40	18.35	3.35	0.422	0.152	0.000

Table 9: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 45 minutes post-treatment from the Initial Consultation in Group 1.

	At consultation			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	6.33	12.59	2.30	0.011	0.456	0.000

Table 10: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 45 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	17.83	17.14	3.13	0.193	0.244	0.000

Table 11: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 1.

	At consultation			60 minutes post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	6.40	12.05	2.20	0.009	0.470	0.000

Table 12: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	12.37	15.24	2.78	0.268	0.209	0.000

Table 13: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 1.

	At consultation			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	7.27	13.53	2.47	0.015	0.438	0.000

Table 14: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	8.53	13.73	2.51	0.723	0.068	0.000

Table 15: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 1.

	At consultation			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	5.47	9.29	1.70	0.014	0.444	0.000

Table 16: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	6.10	11.38	2.08	0.894	0.025	0.000

Table 17: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	At consultation			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	5.17	8.71	1.59	0.015	0.441	0.000

Table 18: Statistical results of the VAS comparing the Headache presenting at the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	At Consultation			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	4.63	10.56	1.93	0.652	0.86	0.000

Table 19: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 30 minutes post-treatment from the Initial Consultation in Group 1.

	15 minutes Post-treatment			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	6.97	12.94	2.36	0.000	0.850	0.45

Table 20: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 30 minutes post-treatment from the Initial Consultation in Group 2.

	15 minutes Post-treatment			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	29.40	18.35	3.35	0.000	0.731	0.002

Table 21: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 45 minutes post-treatment from the Initial Consultation in Group 1.

	15 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	6.33	12.59	2.30	0.000	0.796	0.038

Table 22: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 45 minutes post-treatment from the Initial Consultation in Group 2.

	15 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	17.83	17.14	3.13	0.000	0.613	0.000

Table 23: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 1.

	15 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	6.40	12.05	2.20	0.000	0.789	0.044

Table 24: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 2.

	15 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	12.37	15.24	2.78	0.011	0.458	0.000

Table 25: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 1.

	15 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	7.27	13.53	2.47	0.000	0.749	0.144

Table 26: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 2.

	15 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	8.53	13.73	2.51	0.181	0.251	0.000

Table 27: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 1.

	15 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	5.47	9.29	1.70	0.000	0.823	0.038

Table 28: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 2.

	15 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	6.10	11.38	2.08	0.247	0.218	0.000

Table 29: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	15 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	5.17	8.71	1.59	0.000	0.761	0.018

Table 30: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	15 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	4.63	10.56	1.93	0.177	0.253	0.000

Table 31: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 45 minutes post-treatment from the Initial Consultation in Group 1.

	30 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.97	12.94	2.36	6.33	12.59	2.30	0.000	0.985	0.129

Table 32: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 45 minutes post-treatment from the Initial Consultation in Group 2.

	30 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	29.40	18.35	3.35	17.83	17.14	3.13	0.000	0.823	0.000

Table 33: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 1.

	30 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.97	12.94	2.36	6.40	12.05	2.20	0.000	0.982	0.227

Table 34: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 2.

	30 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	29.40	18.35	3.35	12.37	15.24	2.78	0.000	0.673	0.000

Table 35: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 1.

	30 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.97	12.94	2.36	7.27	13.53	2.47	0.000	0.715	0.871

Table 36: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 2.

	30 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	29.40	18.35	3.35	8.53	13.73	2.51	0.008	0.472	0.000

Table 37: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 1.

	30 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.97	12.94	2.36	5.47	9.29	1.70	0.000	0.655	0.409

Table 38: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 2.

	30 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	29.40	18.35	3.35	6.10	11.38	2.08	0.032	0.392	0.000

Table 39: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	30 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.97	12.94	2.36	5.17	8.71	1.59	0.000	0.639	0.330

Table 40: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	30 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	29.40	18.35	3.35	4.63	10.56	1.93	0.051	0.360	0.000

Table 41: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 1.

	45 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.33	12.59	2.30	6.40	12.05	2.20	0.000	0.995	0.787

Table 42: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Initial Consultation in Group 2.

	45 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	17.83	17.14	3.13	12.37	15.24	2.78	0.000	0.930	0.000

Table 43: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 1.

	45 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.33	12.59	2.30	7.27	13.53	2.47	0.000	0.746	0.588

Table 44: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 2.

	45 minutes Post-treatment after Consultation			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	17.83	17.14	3.13	8.53	13.73	2.51	0.000	0.630	0.001

Table 45: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 1.

	45 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.33	12.59	2.30	5.47	9.29	1.70	0.000	0.650	0.626

Table 46: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 2.

	45 minutes Post-treatment after Consultation			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	17.83	17.14	3.13	6.10	11.38	2.08	0.003	0.528	0.000

Table 47: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	45 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.33	12.59	2.30	5.17	8.71	1.59	0.000	0.649	0.510

Table 48: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	45 minutes Post-treatment after Consultation			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	17.83	17.14	3.13	4.63	10.56	1.93	0.004	0.510	0.000

Table 49: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 1.

	60 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.40	12.05	2.20	7.27	13.53	2.47	0.000	0.738	0.616

Table 50: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Initial Consultation in Group 2.

	60 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	12.37	15.24	2.78	8.53	13.73	2.51	0.000	0.801	0.031

Table 51: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 1.

	60 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.40	12.05	2.20	5.47	9.29	1.70	0.000	0.645	0.588

Table 52: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 2.

	60 minutes Post-treatment after Consultation			120 minutes Post-treatment after Consultation			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	12.37	15.24	2.78	6.10	11.38	2.08	0.000	0.700	0.004

Table 53: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	60 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.40	12.05	2.20	5.17	8.71	1.59	0.000	0.645	0.471

Table 54: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	60 minutes Post-treatment after Consultation			150 minutes Post-treatment after Consultation			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	12.37	15.24	2.78	4.63	10.56	1.93	0.000	0.673	0.001

Table 55: Statistical results of the VAS comparing 90 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 1.

	90 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	7.27	13.53	2.47	5.47	9.29	1.70	0.000	0.924	0.116

Table 56: Statistical results of the VAS comparing 90 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Initial Consultation in Group 2.

	90 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	8.53	13.73	2.51	6.10	11.38	2.08	0.000	0.902	0.035

Table 57: Statistical results of the VAS comparing 90 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	90 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	7.27	13.53	2.47	5.17	8.71	1.59	0.000	0.845	0.148

Table 58: Statistical results of the VAS comparing 90 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	90 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	8.53	13.73	2.51	4.63	10.56	1.93	0.000	0.771	0.021

Table 59: Statistical results of the VAS comparing 120 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 1.

	120 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.47	9.29	1.70	5.17	8.71	1.59	0.000	0.865	0.073

Table 60: Statistical results of the VAS comparing 120 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Initial Consultation in Group 2.

	120 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.10	11.38	2.08	4.63	10.56	1.93	0.000	0.939	0.50

Table 61: Statistical results of the VAS comparing the Patient's usual Headache and the Headache presenting at the Follow up Consultation in Group 1.

	Patient's usual Headache			At Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	50.77	13.98	2.55	44.33	10.27	1.87	0.642	0.089	0.042

Table 62: Statistical results of the VAS comparing the Patient's usual Headache and the Headache presenting at the Follow up Consultation in Group 2.

	Patient's usual headache			At Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	52.13	11.48	2.10	46.47	11.79	2.15	0.190	0.246	0.038

Table 63: Statistical results of the VAS comparing the Follow up Consultation and 15 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			15 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	44.33	10.27	1.87	0.001	0.555	0.000

Table 64: Statistical results of the VAS comparing the Follow up Consultation and 15 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			15 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	41.20	17.25	3.15	0.000	0.773	0.014

Table 65: Statistical results of the VAS comparing the Follow up Consultation and 30 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	5.17	13.47	2.46	0.000	0.625	0.000

Table 66: Statistical results of the VAS comparing the Follow up Consultation and 30 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	31.90	18.67	3.41	0.000	0.617	0.000

Table 67: Statistical results of the VAS comparing the Follow up Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	5.23	13.99	2.56	0.000	0.675	0.000

Table 68: Statistical results of the VAS comparing the Follow up Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	22.83	18.98	3.46	0.007	0.483	0.000

Table 69: Statistical results of the VAS comparing the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	5.67	14.48	2.64	0.000	0.633	0.000

Table 70: Statistical results of the VAS comparing the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	19.63	18.35	3.35	0.003	0.524	0.000

Table 71: Statistical results of the VAS comparing the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	5.33	15.53	2.84	0.000	0.645	0.000

Table 72: Statistical results of the VAS comparing the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	15.33	18.89	3.45	0.000	0.618	0.000

Table 73: Statistical results of the VAS comparing the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	5.63	16.22	2.96	0.000	0.645	0.000

Table 74: Statistical results of the VAS comparing the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	13.60	16.50	3.01	0.001	0.585	0.000

Table 75: Statistical results of the VAS comparing the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	At Follow up			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	44.33	10.27	1.87	6.23	17.61	3.22	0.000	0.630	0.000

Table 76: Statistical results of the VAS comparing the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	At Follow up			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.47	11.79	2.15	12.10	14.55	2.66	0.003	0.525	0.000

Table 77: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 30 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.87	14.30	2.61	5.17	13.47	2.46	0.000	0.972	0.268

Table 78: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 30 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment			30 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	41.20	17.25	3.15	31.90	18.67	3.41	0.000	0.828	0.000

Table 79: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.86	14.30	2.61	5.23	13.99	2.56	0.000	0.912	0.563

Table 80: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment after Follow up			45 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	41.20	17.25	3.15	22.83	18.98	3.46	0.000	0.613	0.000

Table 81: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.86	14.30	2.61	5.67	14.48	2.64	0.000	0.873	0.881

Table 82: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment after Follow up			60 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	41.20	17.25	3.15	19.63	18.35	3.35	0.001	0.576	0.000

Table 83: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.86	14.30	2.61	5.33	15.53	2.84	0.000	0.822	0.747

Table 84: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment after Follow up			90 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	41.20	17.25	3.15	15.33	18.89	3.45	0.004	0.515	0.000

Table 85: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.86	14.30	2.61	5.63	16.22	2.96	0.000	0.844	0.884

Table 86: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment after Follow up			120 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	41.20	17.25	3.15	13.60	16.50	3.01	0.008	0.476	0.000

Table 87: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.86	14.30	2.61	6.23	17.61	3.22	0.000	0.862	0.824

Table 88: Statistical results of the VAS comparing 15 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment after Follow up			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	41.20	17.25	3.15	12.10	14.55	2.66	0.016	0.437	0.000

Table 89: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 1.

	30 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.17	13.47	2.46	5.23	13.99	2.56	0.000	0.981	0.895

Table 90: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 2.

	30 minutes Post-treatment			45 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	31.90	18.67	3.41	22.83	18.98	3.46	0.000	0.891	0.000

Table 91: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 1.

	30 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.17	13.47	2.46	5.67	14.48	2.64	0.000	0.937	0.593

Table 92: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 2.

	30 minutes Post-treatment after Follow up			60 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	31.90	18.67	3.41	19.63	18.35	3.35	0.000	0.857	0.000

Table 93: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 1.

	30 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.17	13.47	2.46	5.33	15.53	2.84	0.000	0.913	0.887

Table 94: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 2.

	30 minutes Post-treatment after Follow up			90 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	31.90	18.67	3.41	15.33	18.89	3.45	0.000	0.745	0.000

Table 95: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	30 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.17	13.47	2.46	5.63	16.22	2.96	0.000	0.922	0.694

Table 96: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	30 minutes Post-treatment after Follow up			120 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	31.90	18.67	3.41	13.60	16.50	3.01	0.000	0.707	0.000

Table 97: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	30 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.17	13.47	2.46	6.23	17.61	3.22	0.000	0.919	0.440

Table 98: Statistical results of the VAS comparing 30 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	30 minutes Post-treatment after Follow up			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	31.90	18.67	3.41	12.10	14.55	2.66	0.000	0.661	0.000

Table 99: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 1.

	45 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.23	13.99	2.56	5.67	14.48	2.64	0.000	0.954	0.590

Table 100: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 2.

	45 minutes Post-treatment			60 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	22.83	18.98	3.46	19.63	18.35	3.35	0.000	0.913	0.033

Table 101: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 1.

	45 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.23	13.99	2.56	5.33	15.53	2.84	0.000	0.944	0.916

Table 102: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 2.

	45 minutes Post-treatment after Follow up			90 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	22.83	18.98	3.46	15.33	18.89	3.45	0.000	0.799	0.002

Table 103: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	45 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.23	13.99	2.56	5.63	16.22	2.96	0.000	0.943	0.696

Table 104: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	45 minutes Post-treatment after Follow up			120 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	22.83	18.98	3.46	13.60	16.50	3.01	0.000	0.767	0.000

Table 105: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	45 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.23	13.99	2.56	6.23	17.61	3.22	0.000	0.927	0.440

Table 106: Statistical results of the VAS comparing 45 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	45 minutes Post-treatment after Follow up			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	22.83	18.98	3.46	12.10	14.55	2.66	0.000	0.720	0.000

Table 107: Statistical results of the VAS comparing 60 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 1.

	60 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.67	14.48	2.64	5.33	15.53	2.84	0.000	0.987	0.499

Table 108: Statistical results of the VAS comparing 60 minutes post-treatment from the Follow up Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 2.

	60 minutes Post-treatment			90 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	19.63	18.35	3.35	15.33	18.89	3.45	0.000	0.911	0.006

Table 109: Statistical results of the VAS comparing 60 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	60 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.67	14.48	2.64	5.63	16.22	2.96	0.000	0.987	0.952

Table 110: Statistical results of the VAS comparing 60 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	60 minutes Post-treatment after Follow up			120 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	19.63	18.35	3.35	13.60	16.50	3.01	0.000	0.889	0.000

Table 111: Statistical results of the VAS comparing 60 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	60 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.67	14.48	2.64	6.23	17.61	3.22	0.000	0.988	0.446

Table 112: Statistical results of the VAS comparing 60 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	60 minutes Post-treatment after Follow up			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	19.63	18.35	3.35	12.10	14.55	2.66	0.000	0.851	0.000

Table 113: Statistical results of the VAS comparing 90 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	90 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.33	15.53	2.84	5.63	16.22	2.96	0.000	0.997	0.279

Table 114: Statistical results of the VAS comparing 90 minutes post-treatment from the Follow up Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	90 minutes Post-treatment			120 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	15.33	18.89	3.45	13.60	16.50	3.01	0.000	0.984	0.024

Table 115: Statistical results of the VAS comparing 90 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	90 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.33	15.53	2.84	6.23	17.61	3.22	0.000	0.985	0.174

Table 116: Statistical results of the VAS comparing 90 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	90 minutes Post-treatment after Follow up			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	15.33	18.89	3.45	12.10	14.55	2.66	0.000	0.920	0.033

Table 117: Statistical results of the VAS comparing 120 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	120 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.63	16.22	2.96	6.23	17.61	3.22	0.000	0.991	0.229

Table 118: Statistical results of the VAS comparing 120 minutes post-treatment from the Follow up Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	120 minutes Post-treatment			150 minutes Post-treatment			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	13.60	16.50	3.01	12.10	14.55	2.66	0.000	0.948	0.135

Table 119: Statistical results of the VAS comparing the Initial Consultation and the Follow up Consultation in Group 1.

	At consultation			At Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	46.23	16.76	3.06	44.33	10.27	1.87	0.936	-0.015	0.603

Table 120: Statistical results of the VAS comparing the Initial Consultation and the Follow up Consultation in Group 2.

	At Consultation			At Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	47.17	12.62	2.30	46.47	11.79	2.15	0.480	0.134	0.813

Table 121: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 15 minutes post-treatment from the Follow up Consultation in Group 1.

	15 minutes Post-treatment after Consultation			15 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	10.23	16.18	2.95	5.87	14.30	2.61	0.006	0.491	0.133

Table 122: Statistical results of the VAS comparing 15 minutes post-treatment from the Initial Consultation and 15 minutes post-treatment from the Follow up Consultation in Group 2.

	15 minutes Post-treatment after Consultation			15 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	37.63	16.72	3.05	41.20	17.25	3.15	0.093	0.312	0.335

Table 123: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 30 minutes post-treatment from the Follow up Consultation in Group 1.

	30 minutes Post-treatment after Consultation			30 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.97	12.94	2.36	5.17	13.47	2.46	0.002	0.535	0.445

Table 124: Statistical results of the VAS comparing 30 minutes post-treatment from the Initial Consultation and 30 minutes post-treatment from the Follow up Consultation in Group 2.

	30 minutes Post-treatment after Consultation			30 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	29.40	18.35	3.35	31.90	18.67	3.41	0.077	0.328	0.528

Table 125: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 1.

	45 minutes Post-treatment after Consultation			45 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.33	12.59	2.30	5.23	13.99	2.56	0.008	0.473	0.663

Table 126: Statistical results of the VAS comparing 45 minutes post-treatment from the Initial Consultation and 45 minutes post-treatment from the Follow up Consultation in Group 2.

	45 minutes Post-treatment after Consultation			45 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	17.83	17.14	3.13	22.83	18.98	3.46	0.039	0.379	0.185

Table 127: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 1.

	60 minutes Post-treatment after Consultation			60 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.40	12.05	2.20	5.67	14.48	2.64	0.000	0.630	0.732

Table 128: Statistical results of the VAS comparing 60 minutes post-treatment from the Initial Consultation and 60 minutes post-treatment from the Follow up Consultation in Group 2.

	60 minutes Post-treatment after Consultation			60 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	12.37	15.24	2.78	19.63	18.35	3.35	0.078	0.326	0.052

Table 129: Statistical results of the VAS comparing 90 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 1.

	90 minutes Post-treatment after Consultation			90 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	7.27	13.53	2.47	5.33	15.53	2.84	0.21	0.421	0.506

Table 130: Statistical results of the VAS comparing 90 minutes post-treatment from the Initial Consultation and 90 minutes post-treatment from the Follow up Consultation in Group 2.

	90 minutes Post-treatment after Consultation			90 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	8.53	13.73	2.51	15.33	18.89	3.45	0.009	0.467	0.041

Table 131: Statistical results of the VAS comparing 120 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 1.

	120 minutes Post-treatment after Consultation			120 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.47	9.29	1.70	5.63	16.22	2.96	0.022	0.416	0.952

Table 132: Statistical results of the VAS comparing 120 minutes post-treatment from the Initial Consultation and 120 minutes post-treatment from the Follow up Consultation in Group 2.

	120 minutes Post-treatment after Consultation			120 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	6.10	11.38	2.08	13.60	16.50	3.01	0.013	0.450	0.012

Table 133: Statistical results of the VAS comparing 150 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 1.

	150 minutes Post-treatment after Consultation			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	5.17	8.71	1.59	6.23	17.61	3.22	0.007	0.478	0.708

Table 134: Statistical results of the VAS comparing 150 minutes post-treatment from the Initial Consultation and 150 minutes post-treatment from the Follow up Consultation in Group 2.

	150 minutes Post-treatment after Consultation			150 minutes Post-treatment after Follow up			p-value (α=5%)	Corr	p-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
VAS	4.63	10.56	1.93	12.10	14.55	2.66	0.014	0.444	0.006

4.4.2. Objective Data

Table 135: Statistical results of the objective findings comparing the Initial Consultation and the Follow up Consultation in Group 1.

	Consultation 1			Follow up 1			P-value (α=5%)	Corr	P-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
Left Upper SCM	1.29	0.28	0.005	1.41	0.37	0.007	0.000	0.694	0.019
Right Upper SCM	1.25	0.38	0.007	1.27	0.33	0.006	0.000	0.672	0.710
Left Middle SCM	1.19	0.36	0.007	1.27	0.32	0.006	0.000	0.687	0.117
Right Middle SCM	1.12	0.31	0.006	1.21	0.29	0.005	0.000	0.677	0.050
Left Trap Insert	2.06	0.70	0.13	2.10	0.54	0.01	0.000	0.613	0.677
Right Trap Insert	1.87	0.45	0.008	2.04	0.56	0.10	0.043	0.371	0.121

Table 136: Statistical results of the objective findings comparing the Follow up Consultation Pre-treatment findings and the Follow up Consultation Post-treatment findings in Group 1.

	Follow up Pre-treatment			Follow up Post-treatment			P-value (α=5%)	Corr	P-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
Left Upper SCM	1.41	0.37	0.007	1.48	0.35	0.006	0.000	0.886	0.034
Right Upper SCM	1.27	0.33	0.006	1.47	0.37	0.007	0.000	0.852	0.000
Left Middle SCM	1.27	0.32	0.006	1.36	0.30	0.005	0.000	0.818	0.017
Right Middle SCM	1.21	0.29	0.005	1.30	0.36	0.007	0.000	0.81	0.025
Left Trap Insert	2.10	0.54	0.01	2.35	0.61	0.11	0.000	0.77	0.002
Right Trap Insert	2.04	0.56	0.10	2.34	0.65	0.12	0.000	0.799	0.000

Table 137: Statistical results of the objective findings comparing the Initial Consultation and the Follow up Consultation in Group 2.

	Consultation 1			Follow up 1			P-value (α=5%)	Corr	P-value (α/2)
	Mean	S.D.	S.E.	Mean	S.D.	S.E.			
Left Upper SCM	1.37	0.26	0.005	1.37	0.26	0.005	0.001	0.570	0.881
Right Upper SCM	1.25	0.23	0.004	1.26	0.24	0.004	0.000	0.615	0.794
Left Middle SCM	1.29	0.33	0.006	1.21	0.27	0.005	0.010	0.463	0.214
Right Middle SCM	1.24	0.30	0.005	1.20	0.29	0.005	0.000	0.704	0.339
Left Trap Insert	1.86	0.39	0.007	1.88	0.45	0.008	0.002	0.532	0.824
Right Trap Insert	1.86	0.29	0.005	1.90	0.45	0.008	0.000	0.695	0.473

4.5. INTER-GROUP DATA

4.5.1. Subjective Data

Table 138: Statistical results of the subjective findings comparing the Initial Consultation of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of Means
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	p-value (α=5%)	p-value (α/2)
McGill (0-45)	4.77	2.57	0.47	4.97	2.30	0.42	0.899	0.752
CMCC (%)	19.47	7.26	1.33	17.20	5.32	0.97	0.095	0.173
NRS 101 (worst)	54.33	14.84	2.71	50.93	10.87	1.98	0.050	0.316
NRS 101 (best)	30.50	16.10	2.94	28.00	14.77	2.70	0.885	0.533

Table 139: Statistical results of the subjective findings comparing the Follow up Consultation of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of Means
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	p-value (α=5%)	p-value (α/2)
McGill (0-45)	4.40	2.97	0.54	4.47	1.83	0.33	0.018	0.917
CMCC (%)	15.50	8.06	1.47	14.87	4.75	0.87	0.019	0.713
NRS 101 (worst)	46.00	13.98	2.55	46.83	14.53	2.65	0.660	0.822
NRS 101 (best)	32.90	15.49	2.83	31.33	17.52	3.20	0.486	0.715

Table 140: Statistical results of the subjective VAS findings comparing the Initial Consultation of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of Means
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	p-value (α=5%)	p-value (α/2)
Patient 's usual H/A	50.77	13.98	2.55	52.13	11.48	2.10	0.543	0.680
At Consul tation	46.23	16.76	3.06	47.17	12.62	2.30	0.084	0.808
15 min Post-tx	10.23	16.18	2.95	37.63	16.72	3.05	0.690	0.000
30 min Post-tx	6.97	12.94	2.36	29.40	18.35	3.35	0.067	0.000
45 min Post-tx	6.33	12.59	2.30	17.83	17.14	3.13	0.012	0.005
60 min Post-tx	6.40	12.05	2.20	12.37	15.24	2.78	0.092	0.098
90 min Post-tx	7.27	13.53	2.47	8.53	13.73	2.51	0.523	0.720
120 min Post-tx	5.47	9.29	1.70	6.10	11.38	2.08	0.601	0.814
150 min Post-tx	5.17	8.71	1.59	4.63	10.56	1.93	0.940	0.832

Table 141: Statistical results of the subjective VAS findings comparing the Follow up Consultation of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of Means
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	p-value (α=5%)	p-value (α/2)
At Follow up	44.33	10.27	1.87	46.47	11.79	2.15	0.164	0.458
15 min Post-tx	10.23	16.18	2.95	37.63	16.72	3.05	0.057	0.000
30 min Post-tx	6.97	12.94	2.36	29.40	18.35	3.35	0.010	0.000
45 min Post-tx	5.23	13.99	2.56	22.83	18.98	3.46	0.002	0.000
60 min Post-tx	5.67	14.48	2.64	19.63	18.35	3.35	0.006	0.002
90 min Post-tx	5.33	15.53	2.84	15.33	18.89	3.45	0.010	0.029
120 min Post-tx	5.63	16.22	2.96	13.60	16.50	3.01	0.052	0.064
150 min Post-tx	6.23	17.61	3.22	12.10	14.55	2.66	0.346	0.165

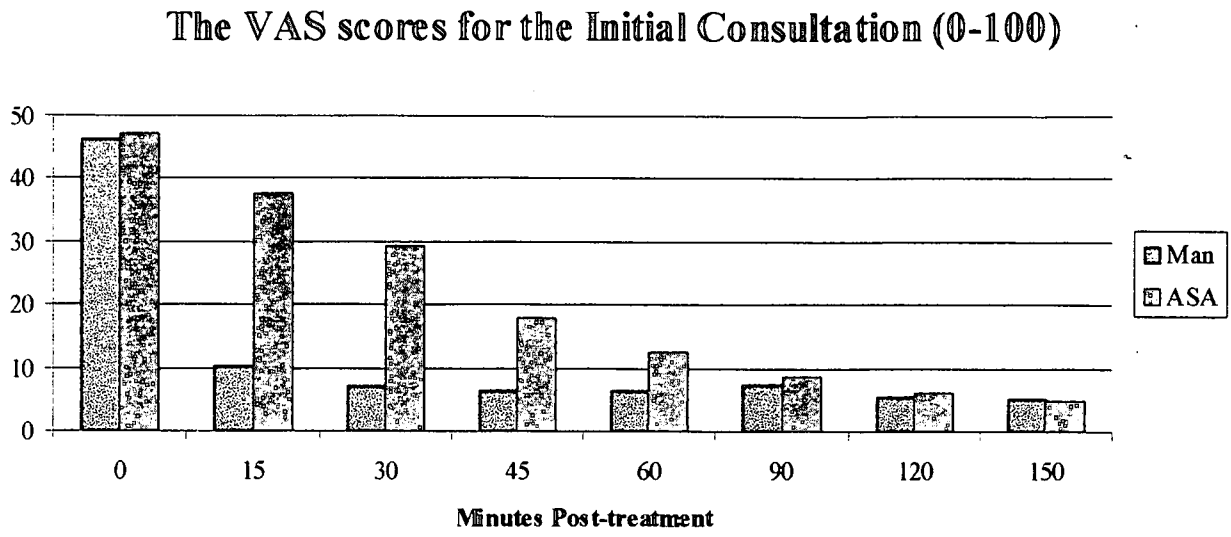
4.5.2. Objective Data

Table 142: Statistical Results of the Objective findings comparing the Initial Consultation of both Group 1 and Group 2.

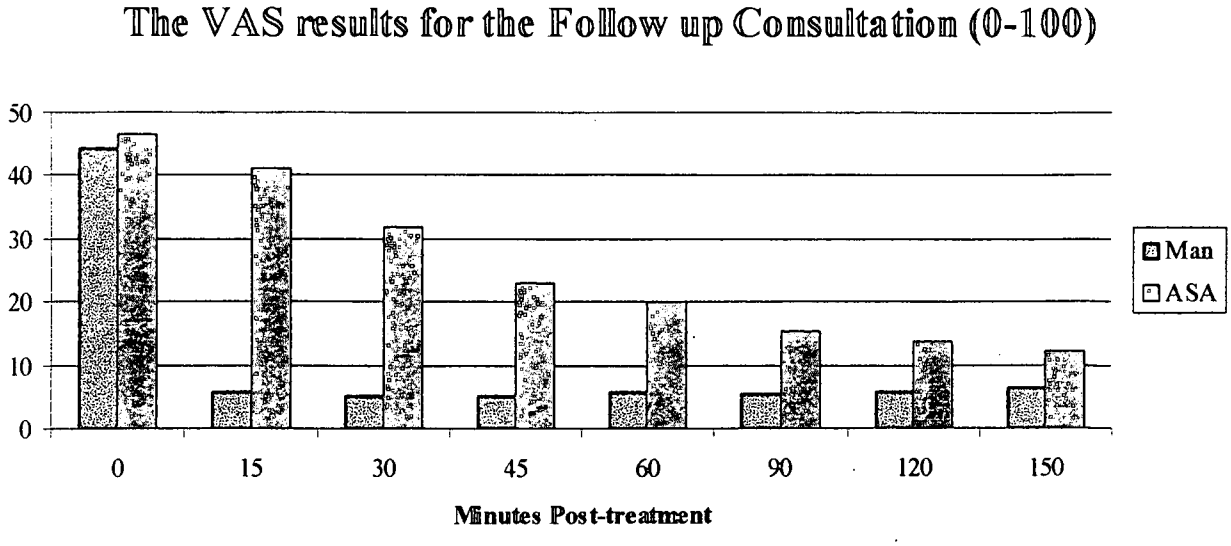
	Group 1			Group 2			Levenes Test	Equality of Means
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	p-value (α=5%)	p-value (α/2)
Left Upper SCM	1.29	0.28	0.005	1.37	0.26	0.005	0.971	0.255
Right Upper SCM	1.25	0.38	0.007	1.25	0.23	0.004	0.190	0.934
Left Middle SCM	1.19	0.36	.0007	1.29	0.33	0.006	0.843	0.302
Right Middle SCM	1.12	0.31	0.006	1.24	0.30	0.005	0.718	0.113
Left Trap Insert	2.06	0.70	0.13	1.86	0.39	0.007	0.054	0.183
Right Trap Insert	1.87	0.45	0.008	1.86	0.29	0.005	0.195	0.892

Table 143: Statistical Results of the Objective findings comparing the Follow up Consultation of both Group 1 and Group 2.

	Group 1			Group 2			Levenes Test	Equality of Means
	Mean	S.D.	S.E.	Mean	S.D.	S.E.	p-value (α=5%)	p-value (α/2)
Left Upper SCM	1.41	0.37	0.007	1.37	0.26	0.005	0.477	0.574
Right Upper SCM	1.27	0.33	0.006	1.26	0.24	0.004	0.380	0.965
Left Middle SCM	1.27	0.32	0.006	1.21	0.27	0.005	0.874	0.433
Right Middle SCM	1.21	0.29	0.005	1.20	0.29	0.005	0.523	0.964
Left Trap Insert	2.10	0.54	0.009	1.88	0.45	0.008	0.913	0.087
Right Trap Insert	2.04	0.56	0.10	1.90	0.45	0.008	0.404	0.302

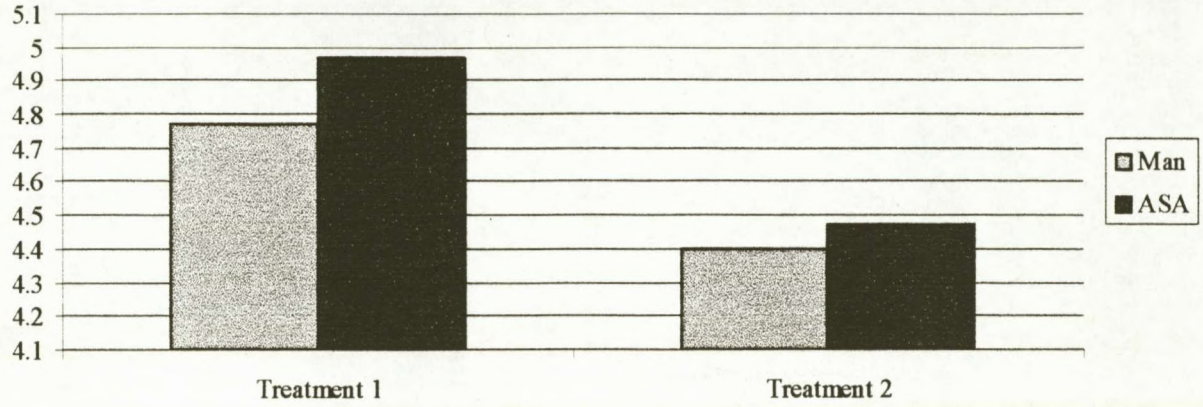


GRAPH 1



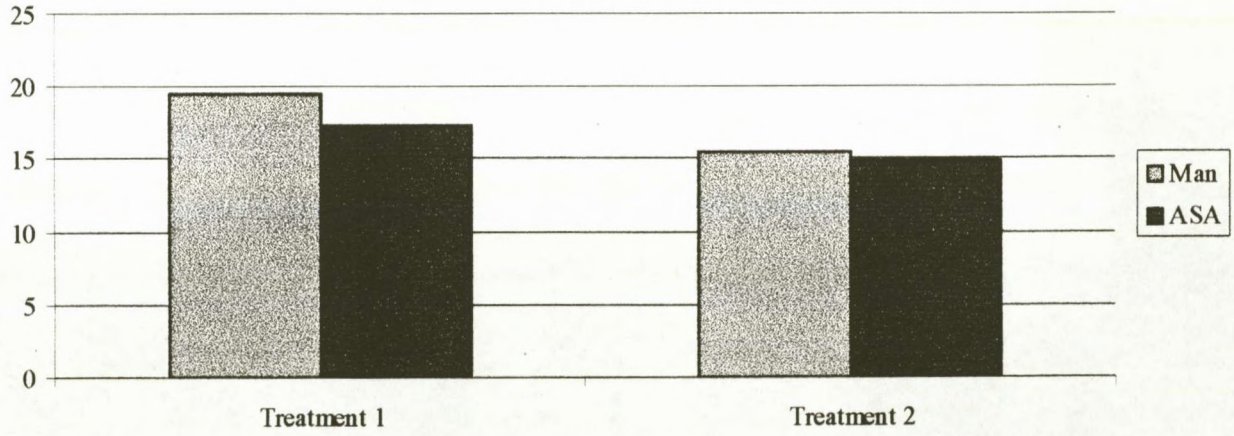
GRAPH 2

McGill Pain Questionnaire (0-45 points)

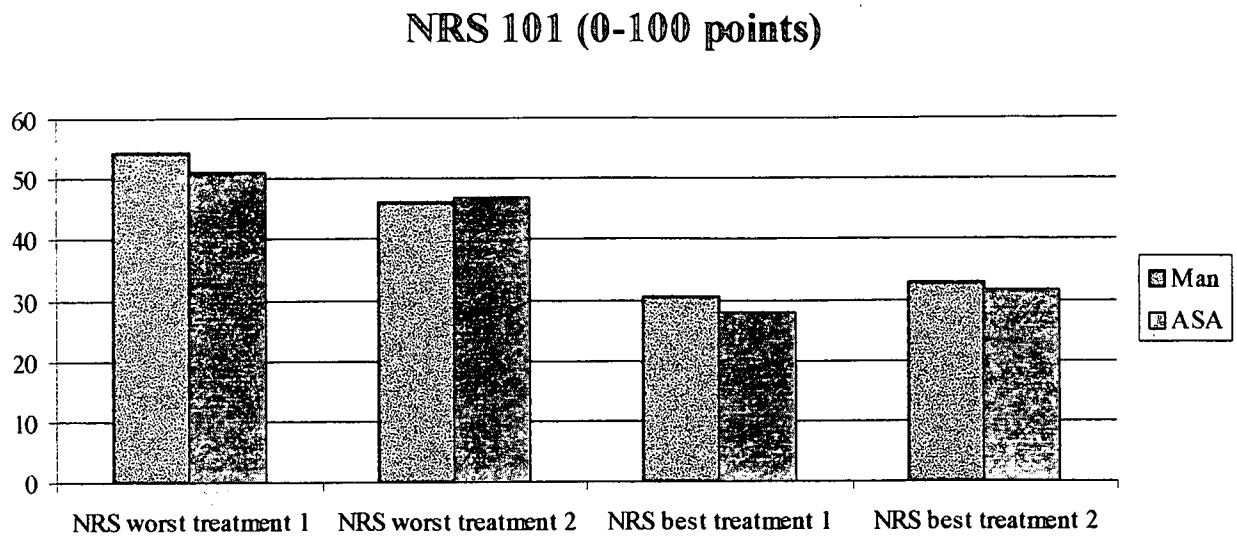


GRAPH 3

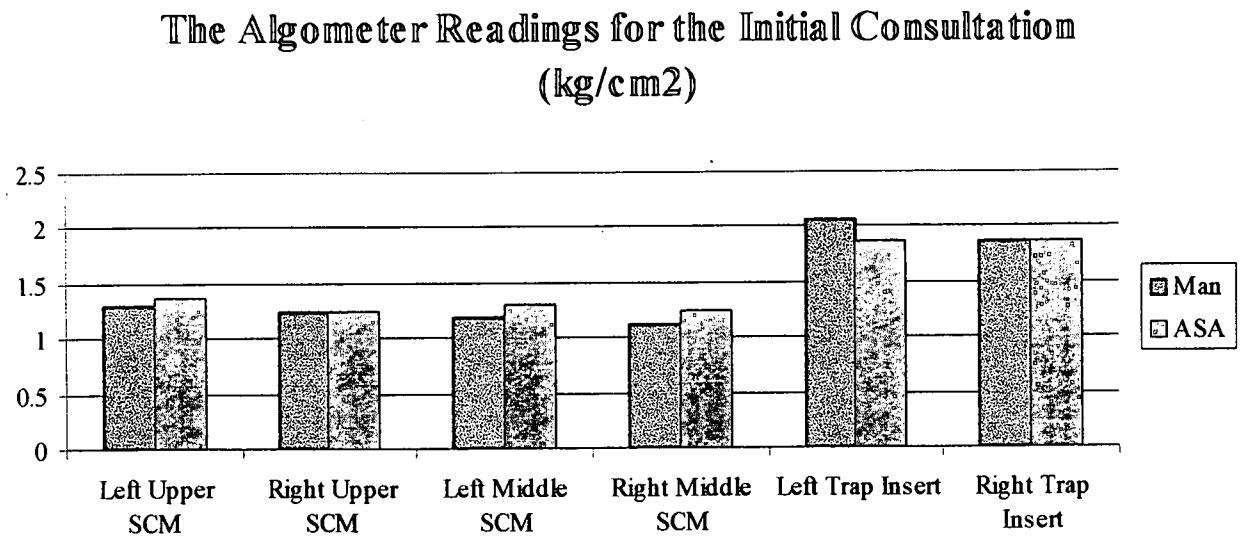
CMCC Neck Disability Index (0-100 points)



GRAPH 4

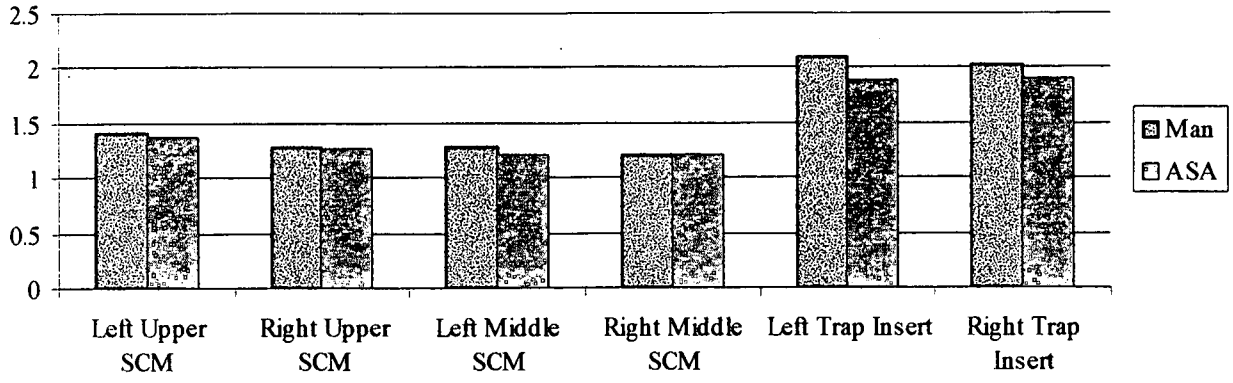


GRAPH 5



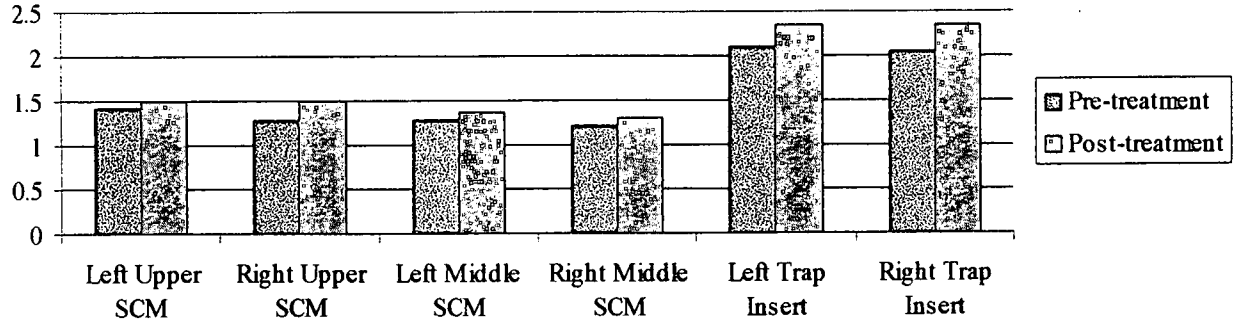
GRAPH 6

The Algometer Readings for the Follow up Consultation (kg/cm2)



GRAPH 7

The Algometer Readings Pre-treatment and Post-treatment on the Follow up Consultation in the Manipulation Group (kg/cm2)



GRAPH 8

4.6. CONCLUSION

The data included in this chapter was collected during the course of the study and represents the subjective and objective measurements for both intra-group and inter-group comparisons. The data has been statistically analyzed by parametric methods using SPSS.

CHAPTER 5

5.0 DICUSSION

5.1. INTRODUCTION

This chapter focuses on 3 main areas of analyses, namely: demographic data analysis, subjective data analysis, and objective data analysis. Analysis of both the subjective and the objective data includes intra-group and inter-group comparisons. The results of this study are then compared to published research in this area to determine if this study compares favorably with previously documented trends in episodic tension-type headache research.

5.2. DEMOGRAPHIC DATA

One hundred and forty two people of those who applied to be part of the study were provisionally accepted, having past the telephonic interview. Candidate's were excluded for the following reasons: 74 candidates failed to make an appointment when they had a headache, 5 candidates failed to make an a second appointment within the stipulated 14 days after the initial consultation, 2 candidates failed to return their headache diaries and 1 of the medication group subjects had abdominal discomfort after ingesting the Acetylsalicylic Acid and was excluded from the study. Both group 1 and group 2 were allocated 30 subjects.

The age range of group 1 was 18-56 years with a mean age of 33,2 years, while the age range for group 2 was 19-54 years with a mean age of 29,4 years. The groups are not similar with regards to age, and this weakens the statistical results obtained for the study.

The male to female ratio revealed that 60% of group 1 was female, whereas 73,3% of group 2 was female. The small male: female ratio in group 1 as compared to group 2 may effect the inter-group analysis to some degree. Both of these ratios however, support the hypothesis that episodic tension-type headache is more prevalent in females.

Migraine headaches were suffered as separate and distinct entities by 9 of the subjects in group 1 and 4 of the subjects in group 2. Consequently, 21,67% of all the subjects in this study also suffered migraine headaches in addition the episodic tension-type headaches. The presence of subjects who suffer migraine headaches with those subjects who don't may effect the inter-group analysis.

Subjects had suffered previous episodes of a range of 6 months to 30 years in group 1 with a mean duration of episodes of 8,6 years. In group 2 however, subjects had suffered previous episodes of a range of 6 months to 25 years with a mean duration of episodes of 7,0 years. The groups are not similar with regards to the duration of headache episodes and this may effect the inter-group analysis.

The mean frequency of the headaches per month in group 1 was 11,0, while in group 2 the headaches mean frequency per month was 10,5. The groups were considered to be similar and comparable with regard to the frequency of headache episodes, and this strengthens the statistical results of the study.

The most common headache pain description in both groups was that of a "dull ache." In group 1 the next most common headache pain description (in descending order) was "oppressive" and then "band-like." In group 2 the next most common headache pain description was equally was "oppressive" and "band-like."

The headache duration in group 1 ranged from 1,5 hours to 72 hours, with mean headache duration of 5,2 hours for the initial consultation, and a mean headache duration of 8,0 hours for the follow up consultation. The headache duration in group 2 ranged from 30 minutes to 48 hours, with a mean headache duration of 5,5 hours for the initial consultation, and a mean headache duration of 5,8 hours for the follow up consultation. Once again group 1 is not similar to group 2 and this weakens the study and may effect the inter-group results.

Headache location in both groups was similar with the majority of subjects complaining of a frontal location, followed by occipital and temporal headache locations. Most of these locations were in combination, with the subject stating that they had pain both over the frontal and occipital regions.

The most common level of fixation in both groups was C7. The following levels in descending order were the subsequently, the most frequently found: C1, C0, C3, C6, C2, C5, and C4. The above fixations were both ligamentous fixations and muscular fixations (Bergmann, et al. 1993: 58). In group 1 there was a reduction in the number of fixations

between initial consultation and the follow up consultation. In group 2 however, there was a slight increase in the number of levels found fixated.

The precipitating factors of episodic tension-type headache have not been examined in previous studies. Stress was found to be a precipitating factor in 65% of the subjects; while other precipitating factors were: light (by 26,67% of subjects); heat (by 16,67% of subjects); computers (by 15% of subjects) and sound (by 10% of subjects).

5.3. INTRA-GROUP DATA ANALYSIS

5.3.1. Subjective Data

5.3.1.1. Group 1 (Manipulation Group)

CMCC, McGill and NRS 101 Questionnaires in group 1.

Comparison of the initial consultation and the follow up consultation (table 1) indicated no statistically significant difference for the McGill and NRS 101 Questionnaires' scores ($p > \alpha/2$); thus Ho was accepted. However, a statistical improvement of 3,97% was noted for the CMCC ($p < \alpha/2$): thus Ho was rejected and H1 was accepted. The initial consultation was thus able to reduce neck disability, but had no effect on the next consecutive headache's symptoms or pain perception. A significant correlation was found for the CMCC Questionnaire's results ($p < \alpha$), while there was no correlation for the McGill and NRS 101 Questionnaires ($p > \alpha$).

The Headache Diary

The headache diary had a visual analogue scale for the initial headache, and the severity of the headache was noted on a visual analogue scale at 15, 30, 45, 60, 90, 120 and 150 minutes (Nebe, Heier and Diener, 1995).

Comparison of the VAS scores of the initial consultation in group 1.

No statistically significant difference was found for the patient's normal headache and the headache presenting at the initial consultation (table 3) ($p > \alpha/2$); thus was Ho accepted.

Comparison of the VAS of the headache presenting at the initial consultation and the VAS of the 15 minutes post-treatment scores (table 5) revealed a statistically significant improvement from 46.23% to 10.23% ($p < \alpha/2$); thus Ho was rejected and H1was accepted. Comparison of the headache presenting at the initial consultation and the subsequent VAS scores all revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The initial consultation VAS score and 30 minutes post-treatment (table 7) revealed a statistically significant improvement from 46.23 to 6.97.
- The initial consultation VAS score and 45 minutes post-treatment (table 9) revealed a statistically significant improvement from 46.23 to 6.33.
- The initial consultation VAS score and 60 minutes post-treatment (table 11) revealed a statistically significant improvement from 46.23 to 6.40.
- The initial consultation VAS score and 90 minutes post-treatment (table 13) revealed a statistically significant improvement from 46.23 to 7.27.

- The initial consultation VAS score and 120 minutes post-treatment (table 15) revealed a statistically significant improvement from 46.23 to 5.47.
- The initial consultation VAS score and 150 minutes post-treatment (table 17) revealed a statistically significant improvement from 46.23 to 5.17.

Thus Ho was rejected and H1 accepted. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 15 minutes post-treatment scores of the initial consultation and the VAS of the 30 minutes post-treatment scores of the initial consultation (table 19) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted.

Comparison of the VAS of the 15-minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed no statistically significant difference for the following:

- The 15 minutes post-treatment VAS scores of the initial consultation and the VAS of the 45 minutes post-treatment scores of the initial consultation (table 21) revealed no statistically significant difference ($p > \alpha/2$).
- The 15 minutes post-treatment VAS scores of the initial consultation and the VAS of the 60 minutes post-treatment scores of the initial consultation (table 23) revealed no statistically significant difference ($p > \alpha/2$).
- The 15 minutes post-treatment VAS scores of the initial consultation and the VAS of the 90 minutes post-treatment scores of the initial consultation (table 25) revealed no statistically significant difference ($p > \alpha/2$).

Thus Ho was accepted, for the above. However, comparison of the VAS of the 15 minutes post-treatment scores of the initial consultation and the VAS of the 120 and 150-minutes post-treatment scores (table 27 and 29) of the initial consultation revealed a statistically significant reduction in pain intensity from 10.23 to 5.47 and 5.17 respectively ($p < \alpha/2$). Thus Ho was rejected and H1 accepted. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 30-minutes post-treatment scores of the initial consultation and the VAS of the 45-minutes post-treatment scores of the initial consultation (table 31) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted. Comparison of the VAS of the 30-minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed no statistically significant difference for the following:

- The 30 minutes post-treatment VAS scores of the initial consultation and the VAS of the 60 minutes post-treatment scores of the initial consultation (table 33) revealed no statistically significant difference ($p > \alpha/2$).
- The 30 minutes post-treatment VAS scores of the initial consultation and the VAS of the 90 minutes post-treatment scores of the initial consultation (table 35) revealed no statistically significant difference ($p > \alpha/2$).
- The 30 minutes post-treatment VAS scores of the initial consultation and the VAS of the 120 minutes post-treatment scores of the initial consultation (table 37) revealed no statistically significant difference ($p > \alpha/2$).

- The 30 minutes post-treatment VAS scores of the initial consultation and the VAS of the 150 minutes post-treatment scores of the initial consultation (table 39) revealed no statistically significant difference ($p > \alpha/2$).

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 45-minutes post-treatment scores of the initial consultation and the VAS of the 60-minutes post-treatment scores of the initial consultation (table 41) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted. Comparison of the VAS of the 45-minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed no statistically significant difference for the following:

- The 45 minutes post-treatment VAS scores of the initial consultation and the VAS of the 90 minutes post-treatment scores of the initial consultation (table 43) revealed no statistically significant difference ($p > \alpha/2$).
- The 45 minutes post-treatment VAS scores of the initial consultation and the VAS of the 120 minutes post-treatment scores of the initial consultation (table 45) revealed no statistically significant difference ($p > \alpha/2$).
- The 45 minutes post-treatment VAS scores of the initial consultation and the VAS of the 150 minutes post-treatment scores of the initial consultation (table 47) revealed no statistically significant difference ($p > \alpha/2$).

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 60-minutes post-treatment scores of the initial consultation and the VAS of the 90-minutes post-treatment scores of the initial consultation (table 49) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted. Comparison of the VAS of the 60-minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed no statistically significant difference for the following:

- The 60 minutes post-treatment VAS scores of the initial consultation and the VAS of the 120 minutes post-treatment scores of the initial consultation (table 51) revealed no statistically significant difference ($p > \alpha/2$).
- The 60 minutes post-treatment VAS scores of the initial consultation and the VAS of the 150 minutes post-treatment scores of the initial consultation (table 53) revealed no statistically significant difference ($p > \alpha/2$).

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 90-minutes post-treatment scores of the initial consultation and the VAS of the 120-minutes post-treatment scores of the initial consultation (table 55) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted. Comparison of the VAS of the 90-minutes post-treatment scores of the initial consultation and the VAS of the 150 minutes post-treatment scores of the initial consultation (table 57) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. For both the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 120-minutes post-treatment scores of the initial consultation and the VAS of the 150-minutes post-treatment scores of the initial consultation (table 59) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted. Comparison of the VAS of the 120-minutes post-treatment scores of the initial consultation and the VAS of the 150-minutes post-treatment scores of the initial consultation demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS scores of the follow up consultation in group 1.

No statistically significant difference was found for the patient's normal headache and the headache presenting at the follow up consultation (table 61) ($p > \alpha/2$); thus was Ho accepted.

Comparison of the VAS of the headache presenting at the follow up consultation and the VAS of the 15 minutes post-treatment scores (table 63) revealed a statistically significant improvement from 44.33% to 5.86% ($p < \alpha/2$); thus Ho was rejected and H1 accepted. Comparison of the headache presenting at the follow up consultation and the subsequent VAS scores all revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The follow up consultation VAS score and 30 minutes post-treatment revealed (table 65) a statistically significant improvement from 44.33 to 5.17.
- The follow up consultation VAS score and 45 minutes post-treatment (table 67) revealed a statistically significant improvement from 44.33 to 5.23.

- The follow up consultation VAS score and 60 minutes post-treatment (table 69) revealed a statistically significant improvement from 44.33 to 5.67.
- The follow up consultation VAS score and 90 minutes post-treatment (table 71) revealed a statistically significant improvement from 44.33 to 5.33.
- The follow up consultation VAS score and 120 minutes post-treatment (table 73) revealed a statistically significant improvement from 44.33 to 5.63.
- The follow up consultation VAS score and 150 minutes post-treatment (table 75) revealed a statistically significant improvement from 44.33 to 6.23.

Thus Ho was rejected and H1 accepted for all the above. For all the above scores a significant correlation ($p < \alpha$).

Comparison of the VAS of the 15 minutes post-treatment scores of the follow up consultation and the VAS of the 30 minutes post-treatment scores (table 77) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the 15 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores all demonstrated statistically significant difference ($p > \alpha/2$):

- The 15 minutes post-treatment follow up consultation VAS score and 45 minutes post-treatment follow up consultation VAS score (table 79) revealed no statistically significant difference.
- The 15 minutes post-treatment follow up consultation VAS score and 60 minutes post-treatment follow up consultation VAS score (table 81) revealed no statistically significant difference.

- The 15 minutes post-treatment follow up consultation VAS score and 90 minutes post-treatment follow up consultation VAS score (table 83) revealed no statistically significant difference.
- The 15 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment follow up consultation VAS score (table 85) revealed no statistically significant difference.
- The 15 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment follow up consultation VAS score (table 87) revealed no statistically significant difference.

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 30 minutes post-treatment scores of the follow up consultation and the VAS of the 45 minutes post-treatment scores (table 89) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the 30 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores all demonstrated statistically significant difference ($p > \alpha/2$):

- The 30 minutes post-treatment follow up consultation VAS score and 60 minutes post-treatment follow up consultation VAS score (table 91) revealed no statistically significant difference.
- The 30 minutes post-treatment follow up consultation VAS score and 90 minutes post-treatment follow up consultation VAS score (table 93) revealed no statistically significant difference.

- The 30 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment follow up consultation VAS score (table 95) revealed no statistically significant difference.
- The 30 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment follow up consultation VAS score (table 97) revealed no statistically significant difference.

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 45 minutes post-treatment scores of the follow up consultation and the VAS of the 60 minutes post-treatment scores (table 99) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the 45 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores all demonstrated statistically significant difference ($p > \alpha/2$):

- The 45 minutes post-treatment follow up consultation VAS score and 90 minutes post-treatment follow up consultation VAS score (table 101) revealed no statistically significant difference.
- The 45 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment follow up consultation VAS score (table 103) revealed no statistically significant difference.
- The 45 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment follow up consultation VAS score (table 105) revealed no statistically significant difference.

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 60 minutes post-treatment scores of the follow up consultation and the VAS of the 90 minutes post-treatment scores (table 107) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the 60 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores all demonstrated statistically significant difference ($p > \alpha/2$):

- The 60 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment follow up consultation VAS score (table 109) revealed no statistically significant difference.
- The 60 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment follow up consultation VAS score (table 111) revealed no statistically significant difference.

Thus Ho was accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 90 minutes post-treatment scores of the follow up consultation and the VAS of the 120 minutes post-treatment scores (table 113) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the 90 minutes post-treatment scores of the follow up consultation and 150 minutes post-treatment follow up consultation VAS score (table 115) revealed no statistically

significant difference; thus Ho was accepted. For both the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 120 minutes post-treatment scores of the follow up consultation and the VAS of the 150 minutes post-treatment scores (table 117) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the VAS of the 120 minutes post-treatment scores of the follow up consultation and the VAS of the 150 minutes post-treatment scores found a significant correlation ($p < \alpha$).

Comparison of the VAS scores for both the initial and the follow up consultation in group 1.

Comparison of the VAS of the initial consultation and the VAS of the follow up consultation scores (table 119) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 15 minutes post-treatment scores for both the initial and the follow up consultation (table 121) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 30 minutes post-treatment scores for both the initial and the follow up consultation (table 123) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 45 minutes post-treatment scores for both the initial and the follow up consultation (table 125) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 60 minutes post-treatment scores for both the initial and the follow up consultation (table 127) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 90 minutes post-treatment scores for both the initial and the follow up consultation (table 129) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 120 minutes post-treatment scores for both the initial and the follow up consultation (table 131) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

The VAS of the 150 minutes post-treatment scores for both the initial and the follow up consultation (table 133) were compared, and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted.

Apart from the comparison of the VAS of the initial consultation and the VAS of the follow up consultation all the above scores demonstrate a significant correlation ($p < \alpha$).

Summary of the Subjective Data for group 1

The initial treatment in the manipulation group was consequently able to significantly reduce neck disability (reduced CMCC Neck Disability Index scores) that had a lasting effect. However, had no significantly lasting effect on the next consecutive headache's symptoms or pain perception (no significant difference in the Short-Form McGill Questionnaire or Numerical Rating Scale 101 respectively).

The patient's normal headache and the headache presenting at the initial consultation were found to be similar in terms of mean pain perception in the manipulation group. The VAS of the headache presenting at the initial consultation and the VAS of the 15 minutes post-treatment scores in the manipulation group revealed a statistically significant improvement of 36%. There were no more significant differences in consecutive readings; however, the 15 minutes post-treatment scores of the initial consultation and the VAS of the 120 and 150-minute post-treatment scores of the initial consultation in the manipulation group revealed a statistically significant reduction in pain intensity. Thus demonstrating that the mean pain intensity continued to diminish, though at a slower rate requiring more time to become statistically significant.

The patient's normal headache and the headache presenting at the follow up consultation were found to be similar in terms of mean pain perception in the manipulation group. The VAS of the headache presenting at the follow up consultation and the VAS of the 15 minutes post-treatment scores in the manipulation group revealed a statistically

significant improvement of 38.46%. However, there were no further statistically significant differences from after this initial improvement.

Comparison of the initial versus follow up consultation results demonstrated that the results were similar with no statistically significant differences. Thus the manipulation has consistent results.

5.3.1.2. Group 2 (Acetylsalicylic Acid Group)

CMCC, McGill, and NRS 101 Questionnaires in group 2

Comparison of the initial consultation and the follow up consultation (table 2) indicated no statistically significant difference for the CMCC, McGill and NRS 101 Questionnaires' scores ($p > \alpha/2$); thus Ho was accepted. A significant correlation was found for the CMCC Questionnaire's results ($p < \alpha$), while there was no significant correlation for the McGill and NRS 101 Questionnaires ($p > \alpha$).

The Headache Diary

The headache diary had a visual analogue scale for the initial headache, and the severity of the headache was noted on a visual analogue scale at 15, 30, 45, 60, 90, 120 and 150 minutes (Nebe, Heier and Diener, 1995).

Comparison of the VAS scores of the initial consultation in group 2.

No statistically significant difference was found for the patient's normal headache and the headache presenting at the initial consultation (table 4) ($p > \alpha/2$); thus was Ho accepted.

The patient's normal headache and the headache presenting at the initial consultation, failed to demonstrate a statistically significant correlation ($p > \alpha$).

Comparison of the VAS of the headache presenting at the initial consultation and the VAS of the 15 minute post-treatment scores (table 6) revealed a statistically significant improvement from 47.17% to 37.63% ($p < \alpha/2$); thus Ho was rejected and H1 accepted. Comparison of the headache presenting at the initial consultation and the subsequent VAS scores all revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The initial consultation VAS score and 30 minutes post-treatment (table 8) revealed a statistically significant improvement from 47.17 to 29.40.
- The initial consultation VAS score and 45 minutes post-treatment (table 10) revealed a statistically significant improvement from 47.17 to 17.83.
- The initial consultation VAS score and 60 minutes post-treatment (table 12) revealed a statistically significant improvement from 47.17 to 12.37.
- The initial consultation VAS score and 90 minutes post-treatment (table 14) revealed a statistically significant improvement from 47.17 to 8.53.
- The initial consultation VAS score and 120 minutes post-treatment (table 16) revealed a statistically significant improvement from 47.17 to 6.10.
- The initial consultation VAS score and 150 minutes post-treatment (table 18) revealed a statistically significant improvement from 47.17 to 4.63.

Thus Ho was rejected and H1 accepted for all the above. None of the above scores have a significant correlation ($p > \alpha$).

Comparison of the VAS of the 15 minute post-treatment scores of the initial consultation and the VAS of the 30 minute post-treatment scores of the initial consultation (table 20) revealed a statistically significant improvement in pain intensity from 37.63 to 29.40 ($p < \alpha/2$); thus is Ho was rejected and H1 is accepted. Comparison of the VAS of the 15-minute post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 15 minutes post-treatment initial consultation VAS score and 45 minutes post-treatment VAS score (table 22) revealed a statistically significant improvement from 37.63 to 17.83.
- The 15 minutes post-treatment initial consultation VAS score and 60 minutes post-treatment VAS score (table 24) revealed a statistically significant improvement from 37.63 to 12.37.
- The 15 minutes post-treatment initial consultation VAS score and 90 minutes post-treatment VAS score (table 26) revealed a statistically significant improvement from 37.63 to 8.53.
- The 15 minutes post-treatment initial consultation VAS score and 120 minutes post-treatment VAS score (table 28) revealed a statistically significant improvement from 37.63 to 6.10.
- The 15 minutes post-treatment initial consultation VAS score and 150 minutes post-treatment VAS score (table 30) revealed a statistically significant improvement from 37.63 to 4.63.

Thus Ho was rejected and H1accepted, for all the above. The 15 minutes post-treatment initial consultation VAS score compared to 30 minutes post-treatment VAS score, the 15 minutes post-treatment initial consultation VAS score compared to 45 minutes post-treatment VAS score and the 15 minutes post-treatment initial consultation VAS score compared to 60 minutes post-treatment VAS score all demonstrated a significant correlation ($p < \alpha$). However, the 15 minutes post-treatment initial consultation VAS score compared to 90 minutes post-treatment VAS score, the 15 minutes post-treatment initial consultation VAS score compared to 120 minutes post-treatment VAS score and the 15 minutes post-treatment initial consultation VAS score compared to 150 minutes post-treatment VAS score failed to show any significant correlation ($p > \alpha$).

Comparison of the VAS of the 30 minutes post-treatment scores of the initial consultation and the VAS of the 45 minutes post-treatment scores of the initial consultation (table 32) revealed a statistically significant improvement in pain intensity from 29.40 to 17.83 ($p < \alpha/2$); thus was Ho is rejected and H1 is accepted. Comparison of the VAS of the 30 minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 30 minutes post-treatment initial consultation VAS score and 60 minutes post-treatment VAS score (table 34) revealed a statistically significant improvement from 29.40 to 12.37.

- The 30 minutes post-treatment initial consultation VAS score and 90 minutes post-treatment VAS score (table 36) revealed a statistically significant improvement from 29.40 to 8.53.
- The 30 minutes post-treatment initial consultation VAS score and 120 minutes post-treatment VAS score (table 38) revealed a statistically significant improvement from 29.40 to 6.10.
- The 30 minutes post-treatment initial consultation VAS score and 150 minutes post-treatment VAS score (table 40) revealed a statistically significant improvement from 29.40 to 4.63.

Thus Ho was rejected and H1accepted, for all the above. Only the 30 minutes post-treatment initial consultation VAS score compared to the 150 minutes post-treatment VAS score of the above results does not have a significant correlation ($p > \alpha$). All the other above results demonstrate a significant correlation ($p < \alpha$).

Comparison of the VAS of the 45 minutes post-treatment scores of the initial consultation and the VAS of the 60 minutes post-treatment scores of the initial consultation (table 42) revealed a statistically significant improvement in pain intensity from 17.83 to 12.37 ($p < \alpha/2$); thus was Ho is rejected and H1 was accepted. Comparison of the VAS of the 45 minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 45 minutes post-treatment initial consultation VAS score and 90 minutes post-treatment VAS score (table 44) revealed a statistically significant improvement from 17.83 to 8.53.
- The 45 minutes post-treatment initial consultation VAS score and 120 minutes post-treatment VAS score (table 46) revealed a statistically significant improvement from 17.83 to 6.10.
- The 45 minutes post-treatment initial consultation VAS score and 150 minutes post-treatment VAS score (table 48) revealed a statistically significant improvement from 17.83 to 4.63.

Thus Ho was rejected and H1accepted, for all the above. All the above results demonstrate a significant correlation ($p < \alpha$).

Comparison of the VAS of the 60 minutes post-treatment scores of the initial consultation and the VAS of the 90 minutes post-treatment scores of the initial consultation (table 50) revealed no statistically significant difference ($p > \alpha/2$); thus is Ho was accepted.

Comparison of the VAS of the 60 minutes post-treatment scores of the initial consultation and the subsequent VAS scores of the initial consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 60 minutes post-treatment initial consultation VAS score and 120 minutes post-treatment VAS score (table 52) revealed a statistically significant improvement from 12.37 to 6.10.

- The 60 minutes post-treatment initial consultation VAS score and 150 minutes post-treatment VAS score (table 54) revealed a statistically significant improvement from 12.37 to 4.63.

Thus Ho was rejected and H1accepted. The VAS of the 60 minutes post-treatment scores of the initial consultation compared to the VAS of the 90 minutes post-treatment scores failed to show a significant correlation ($p > \alpha$), the remainder of the above results however, revealed a significant correlation ($p < \alpha$).

Comparison of the VAS of the 90 minutes post-treatment scores of the initial consultation and the VAS of the 120 minutes post-treatment scores of the initial consultation (table 56) revealed no statistically significant difference ($p > \alpha/2$); thus is Ho is accepted. Comparison of the VAS of the 90 minutes post-treatment scores of the initial consultation and the 150 minutes post-treatment VAS score (table 58) revealed a statistically significant improvement from 8.53 to 4.63 ($p < \alpha/2$); thus Ho was rejected and H1accepted. Both of the above results revealed a significant correlation ($p < \alpha$).

Comparison of the VAS of the 120-minute post-treatment scores of the initial consultation and the VAS of the 150-minute post-treatment scores of the initial consultation (table 60) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho accepted. Comparison of the VAS of the 120-minute post-treatment scores of the initial consultation and the VAS of the 150-minute post-treatment scores of the initial consultation demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS scores of the follow up consultation in group 2.

No statistically significant difference was found for the patient's normal headache and the headache presenting at the follow up consultation (table 62) ($p > \alpha/2$); thus was Ho accepted. The patient's normal headache and the headache presenting at the follow up consultation and failed to demonstrate a statistically significant correlation ($p > \alpha$).

Comparison of the VAS of the headache presenting at the follow up consultation and the VAS of the 15 minute post-treatment scores (table 64) revealed a statistically significant improvement from 46.47% to 41.20% ($p < \alpha/2$); thus Ho was rejected and H1 accepted. Comparison of the headache presenting at the follow up consultation and the subsequent VAS scores all revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The follow up consultation VAS score and 30 minutes post-treatment (table 66) revealed a statistically significant improvement from 46.47 to 31.90.
- The follow up consultation VAS score and 45 minutes post-treatment (table 68) revealed a statistically significant improvement from 46.47 to 22.83.
- The follow up consultation VAS score and 60 minutes post-treatment (table 70) revealed a statistically significant improvement from 46.47 to 19.63.
- The follow up consultation VAS score and 90 minutes post-treatment (table 72) revealed a statistically significant improvement from 46.47 to 15.33.
- The follow up consultation VAS score and 120 minutes post-treatment (table 74) revealed a statistically significant improvement from 46.47 to 13.60.
- The follow up consultation VAS score and 150 minutes post-treatment (table 76) revealed a statistically significant improvement from 46.47 to 12.10.

Thus Ho was rejected and H1 accepted for all the above. For all the above scores a significant correlation was found ($p < \alpha$).

Comparison of the VAS of the 15 minute post-treatment scores of the follow up consultation and the VAS of the 30 minute post-treatment scores of the follow up consultation (table 78) revealed a statistically significant improvement in pain intensity from 41.20 to 31.90 ($p < \alpha/2$); thus was Ho is rejected and H1 is accepted. Comparison of the VAS of the 15-minute post-treatment scores of the follow up consultation and the subsequent VAS scores of the follow up consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 15 minutes post-treatment follow up consultation VAS score and 45 minutes post-treatment VAS score (table 80) revealed a statistically significant improvement from 41.20 to 22.83.
- The 15 minutes post-treatment follow up consultation VAS score and 60 minutes post-treatment VAS score (table 82) revealed a statistically significant improvement from 41.20 to 19.63
- The 15 minutes post-treatment follow up consultation VAS score and 90 minutes post-treatment VAS score (table 84) revealed a statistically significant improvement from 41.20 to 15.33.
- The 15 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment VAS score (table 86) revealed a statistically significant improvement from 41.20 to 13.60.

- The 15 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment VAS score (table 88) revealed a statistically significant improvement from 41.20 to 12.10.

Thus Ho was rejected and H1accepted, for all the above. All the above demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS of the 30 minutes post-treatment scores of the follow up consultation and the VAS of the 45 minutes post-treatment scores of the follow up consultation (table 90) revealed a statistically significant improvement in pain intensity from 31.90 to 22.83 ($p < \alpha/2$); thus was Ho is rejected and H1 is accepted. Comparison of the VAS of the 30 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores of the follow up consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 30 minutes post-treatment follow up consultation VAS score and 60 minutes post-treatment VAS score (table 92) revealed a statistically significant improvement from 31.90 to 19.63
- The 30 minutes post-treatment follow up consultation VAS score and 90 minutes post-treatment VAS score (table 94) revealed a statistically significant improvement from 31.90 to 15.33.
- The 30 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment VAS score (table 96) revealed a statistically significant improvement from 31.90 to 13.60.

- The 30 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment VAS score (table 98) revealed a statistically significant improvement from 31.90 to 12.10.

Thus Ho was rejected and H1accepted, for all the above. All the above demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS of the 45 minutes post-treatment scores of the follow up consultation and the VAS of the 60 minutes post-treatment scores of the follow up consultation (table 100) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. Comparison of the VAS of the 45 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores of the follow up consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 45 minutes post-treatment follow up consultation VAS score and 90 minutes post-treatment VAS score (table 102) revealed a statistically significant improvement from 22.83 to 15.33.
- The 45 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment VAS score (table 104) revealed a statistically significant improvement from 22.83 to 13.60.
- The 45 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment VAS score (table 106) revealed a statistically significant improvement from 22.83 to 12.10.

Thus Ho was rejected and H1accepted, for all the above. All the above demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS of the 60 minutes post-treatment scores of the follow up consultation and the VAS of the 90 minutes post-treatment scores of the follow up consultation (table 108) revealed a statistically significant improvement in pain intensity from 19.63 to 15.33 ($p < \alpha/2$); thus is Ho was rejected and H1 is accepted. Comparison of the VAS of the 60 minutes post-treatment scores of the follow up consultation and the subsequent VAS scores of the follow up consultation revealed statistically significant reduction in pain intensity ($p < \alpha/2$):

- The 60 minutes post-treatment follow up consultation VAS score and 120 minutes post-treatment VAS score (table 110) revealed a statistically significant improvement from 19.63 to 13.60.
- The 60 minutes post-treatment follow up consultation VAS score and 150 minutes post-treatment VAS score (table 112) revealed a statistically significant improvement from 19.63 to 12.10.

Thus Ho was rejected and H1accepted, for all the above. All the above demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS of the 90 minutes post-treatment scores of the follow up consultation and the VAS of the 120 minutes post-treatment scores of the follow up consultation (table 114) revealed a statistically significant improvement in pain intensity from 15.33 to 13.60 ($p < \alpha/2$); thus was Ho is rejected and H1 is accepted. Comparison of the VAS of the 90 minutes post-treatment scores of the follow up consultation and the 150 minutes post-treatment VAS scores of the follow up consultation (table 116) revealed

statistically significant reduction in pain intensity from 15.33 to 12.10 ($p < \alpha/2$); thus Ho was rejected and H1accepted. Both of the above demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS of the 120 minutes post-treatment scores of the follow up consultation and the VAS of the 150 minutes post-treatment scores of the follow up consultation (table 118) revealed no statistically significant difference ($p > \alpha/2$); thus was Ho is accepted. The VAS of the 120 minutes post-treatment scores of the follow up consultation and the VAS of the 150 minutes post-treatment scores of the follow up consultation demonstrated a significant correlation ($p < \alpha$).

Comparison of the VAS scores for both the initial and the follow up consultation in group 2.

Comparison of the VAS of the initial consultation and the VAS of the follow up consultation scores (table 120) revealed no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. The VAS of the initial consultation and the VAS of the follow up consultation scores failed to demonstrate a statistically significant correlation ($p > \alpha$).

The VAS of the 15 minutes post-treatment scores for both the initial and the follow up consultation were compared (table 122), and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. The VAS of the 15 minutes post-treatment scores for both the initial and the follow up consultation were compared, and failed to demonstrate a statistically significant correlation ($p > \alpha$).

The VAS of the 30 minutes post-treatment scores for both the initial and the follow up consultation were compared (table 124), and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. The VAS of the 30 minutes post-treatment scores for both the initial and the follow up consultation were compared, and failed to demonstrate a statistically significant correlation ($p > \alpha$).

The VAS of the 45 minutes post-treatment scores for both the initial and the follow up consultation were compared (table 126), and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. The VAS of the 45 minutes post-treatment scores for both the initial and the follow up consultation were compared, and demonstrated a statistically significant correlation ($p < \alpha$).

The VAS of the 60 minutes post-treatment scores for both the initial and the follow up consultation were compared (table 128), and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. The VAS of the 60 minutes post-treatment scores for both the initial and the follow up consultation were compared, and failed to demonstrate a statistically significant correlation ($p > \alpha$).

The VAS of the 90 minutes post-treatment scores for both the initial and the follow up consultation were compared (table 130), and it was found that there was no statistically significant difference ($p > \alpha/2$); thus Ho was accepted. The VAS of the 90 minutes post-

treatment scores for both the initial and the follow up consultation were compared, and demonstrated a statistically significant correlation ($p < \alpha$).

The VAS of the 120 minutes post-treatment scores for both the initial and the follow up consultation was compared (table 132), and it was found that there was a statistically significant difference in the mean pain perception of the subjects ($p < \alpha/2$); thus Ho was rejected and H1 accepted. The VAS of the 120 minutes post-treatment score of the initial consultation was found as 6.10%, while the VAS of the 120 minutes post-treatment score of the follow up consultation was found as 13.60%. The VAS of the 120 minutes post-treatment scores for both the initial and the follow up consultation was compared, and demonstrated a statistically significant correlation ($p < \alpha$).

The VAS of the 150 minutes post-treatment scores for both the initial and the follow up consultation were compared (table 134), and it was found that there was a statistically significant difference in the mean pain perception of the subjects ($p < \alpha/2$); thus Ho was rejected and H1 accepted. The VAS of the 150 minutes post-treatment score of the initial consultation was found as 4.63%, while the VAS of the 150 minutes post-treatment score of the follow up consultation was found as 12.10%. The VAS of the 150 minutes post-treatment scores for both the initial and the follow up consultation were compared, and demonstrated a statistically significant correlation ($p < \alpha$).

Summary of the Subjective Data for group 2

The CMCC, McGill and NRS 101 Questionnaires' scores failed to demonstrate any statistically significant differences when the initial consultation and the follow up consultation were compared in the Acetylsalicylic Acid group.

No statistically significant difference was found for the patient's normal headache and the headache presenting at the initial consultation. The VAS of the headache presenting at the initial consultation and the VAS of the 15 minutes post-treatment scores revealed a statistically significant improvement of 9.54%. The VAS of the 15 minutes post-treatment scores of the initial consultation and the VAS of the 30 minutes post-treatment scores of the initial consultation revealed a statistically significant improvement in pain intensity of 8.23%. The VAS of the 30 minutes post-treatment scores of the initial consultation and the VAS of the 45 minutes post-treatment scores of the initial consultation revealed a statistically significant improvement in pain intensity of 11.57%. The VAS of the 45 minutes post-treatment scores of the initial consultation and the VAS of the 60 minutes post-treatment scores of the initial consultation revealed a statistically significant improvement in pain intensity of 5.46%. There were no more significant differences in consecutive readings; however, the 60 minutes post-treatment scores of the initial consultation and the VAS of the 120 and 150-minutes post-treatment scores of the initial consultation in the Acetylsalicylic Acid group revealed a statistically significant reduction in pain intensity of 6.27% and 7.74% respectively. The 90 minutes post-treatment scores of the initial consultation and the VAS of the 150-minutes post-treatment scores of the initial consultation in the Acetylsalicylic Acid group revealed a

statistically significant reduction in pain intensity of 3.9%. Thus demonstrating that the mean pain intensity continued to diminish although at a slower rate, requiring more time to become statistically significant.

No statistically significant difference was found for the patient's normal headache and the headache presenting at the follow up consultation. The VAS of the headache presenting at the follow up consultation and the VAS of the 15 minutes post-treatment scores revealed a statistically significant improvement from 6.27%. The VAS of the 15 minutes post-treatment scores of the follow up consultation and the VAS of the 30 minutes post-treatment scores revealed a statistically significant improvement in pain intensity 9.3%. The VAS of the 30 minutes post-treatment scores of the follow up consultation and the VAS of the 45 minutes post-treatment scores of the follow up consultation revealed a statistically significant improvement in pain intensity 9.07%. The VAS of the 45 minutes post-treatment scores of the follow up consultation and the VAS of the 60 minutes post-treatment scores revealed no statistically significant difference. The VAS of the 60 minutes post-treatment scores of the follow up consultation and the VAS of the 90 minutes post-treatment scores revealed a statistically significant improvement in pain intensity of 4.3%. The VAS of the 90 minutes post-treatment scores of the follow up consultation and the VAS of the 120 and 150 minutes post-treatment scores revealed a statistically significant improvement in pain intensity of 1.73% and 3.23% respectively.

Comparison of the initial versus follow up consultation results demonstrated that the results were similar with no statistically significant differences, until 120 minutes post-

treatment was compared for the initial and the follow up consultation, where the initial consultation was found to be 7.5% lower than the follow up consultation. Similarly 150 minutes post-treatment was compared for the initial and the follow up consultation, where the initial consultation was found to be 7.47% lower than the follow up consultation. The difference in the results could be due to the number drop outs the Acetylsalicylic Acid group had after the initial treatment, thus lowering the initial consultations result, whereas the follow up consultation had no such drop outs.

5.3.2. Objective Data

5.3.2.1. Group 1 (Manipulation Group)

The algometer measurements comparing the results of the initial and follow up consultations (table 135) showed no statistically significant difference ($p > \alpha/2$): for the trapezius insertion bilaterally, the middle SCM bilaterally and the right upper SCM muscles; thus Ho was accepted. However, the algometer measurements comparing the results of the initial and follow up consultations showed a statistically significant increase in pain threshold readings ($p < \alpha/2$) of (0,12kg.); thus was Ho rejected and H1 was accepted. All the algometer measurements of the initial and follow up consultations demonstrate a significant correlation ($p < \alpha$).

The algometer measurements comparing the results of the of the pre- and post-treatment measurements for the follow up consultation (table 136) revealed statistically significant increase in pain threshold readings ($p < \alpha/2$): for the left trapezius insertion (0,24kg.), right trapezius insertion (0,31kg.), left middle SCM (0,01kg.), right upper SCM (0,21kg.)

muscles; thus was Ho rejected and H1 was accepted. The algometer measurements comparing the results of the of the pre- and post-treatment measurements for the follow up consultation failed to demonstrate a statistically significant difference ($p > \alpha/2$) for the left upper SCM and the right middle SCM muscles ($p > \alpha/2$); thus Ho is accepted. All the algometer measurements for the of the pre- and post-treatment measurements for the follow up consultation demonstrate a significant correlation ($p < \alpha$).

Summary of the Objective Data in group 1

The objective findings for the initial and follow up consultations in the manipulation group found no lasting improvement between the initial and the follow up consultations for the algometer pain threshold readings for the trapezius insertion bilaterally, the middle SCM bilaterally and the right upper SCM muscles. However, a lasting improvement between the initial and the follow up consultations was found for the algometer pain threshold readings for the left upper SCM muscles. The algometer measurements comparing the results of the of the pre- and post-treatment measurements for the follow up consultation demonstrate that manipulation increases the pain threshold readings for the trapezius insertion bilaterally, the left middle SCM and the right upper SCM. However, the algometer measurements comparing the results of the of the pre- and post-treatment measurements for the follow up consultation for the left upper SCM and the right middle SCM muscles revealed no statistically significant difference in the pre- and post-treatment results.

5.3.2.2. Group 2 (Acetylsalicylic Acid Group)

The algometer measurements comparing the results of the initial and follow up consultations (table 137) showed no statistically significant difference ($p > \alpha/2$): for the trapezius insertion bilaterally, the middle SCM bilaterally and the upper SCM muscles bilaterally; thus Ho was accepted. All the algometer measurements of the initial and follow up consultations demonstrate a significant correlation ($p < \alpha$).

Summary of the Objective Data for group 2

The algometer measurements comparing the results in the Acetylsalicylic Acid group of the initial and follow up consultations showed no statistically significant difference.

5.4. INTER-GROUP ANALYSIS

5.4.1. Subjective Data

Comparison of the CMCC, McGill and NRS 101 Questionnaires in group 1 and group 2.

Comparison of group 1 and group 2 for the initial consultation (table 138) indicated no statistically significant difference for the CMCC, McGill and NRS 101 Questionnaires ($p > \alpha/2$), consequently Ho was accepted. Levene's test demonstrated that the groups are comparable in terms of variance ($p < \alpha$).

In the follow up consultation comparison of the groups (table 139) failed to demonstrate any statistically significant difference for the CMCC, McGill and NRS 101 Questionnaires ($p > \alpha/2$), consequently Ho was accepted. Levene's test demonstrated that the groups are comparable in terms of variance for the NRS 101 Questionnaire ($p < \alpha$),

however revealed that the CMCC and McGill Questionnaires were not comparable in terms of variance ($p > \alpha$).

Thus, comparison of the groups failed to demonstrate a statistically significant difference for the CMCC, McGill and NRS 101 Questionnaires for either the initial or the follow up consultation.

The Headache Diary

The headache diary had a visual analogue scale for the initial headache, and the severity of the headache was noted on a visual analogue scale at 15, 30, 45, 60, 90, 120 and 150 minutes (Nebe, Heier and Diener, 1995).

Comparison of the Initial Treatment's VAS scores of group 1 and group 2.

The groups comparison for the patient's usual headache VAS results (table 140) showed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test demonstrated that the groups were not comparable in terms of variance ($p > \alpha$).

Comparison of the groups for the patient's headache presenting at the initial consultation VAS (table 140) results revealed no statistically significant difference ($p > \alpha/2$), thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 15 minutes post-treatment of the initial consultation (table 140) revealed a statistically significant difference ($p < \alpha/2$), in favor of group 1in terms of pain intensity; thus Ho was rejected and H1 was accepted. Group 1 had a mean of 10.23%, and group 2 had a mean of 37.63%, thus group 1 demonstrated a mean pain intensity of 27.4% lower than group 2. This data indicates that manipulation brings about greater benefit earlier (in terms of pain relief), when compared to Acetylsalicylic Acid. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 30 minutes post-treatment of the initial consultation (table 140) revealed a statistically significant difference ($p < \alpha/2$), in favor of group 1in terms of pain intensity; thus Ho was rejected and H1 was accepted. Group 1 demonstrated a decreased pain intensity of 22.43% when compared to group 2. This data indicates that manipulation brings about greater benefit earlier (in terms of pain relief), when compared to Acetylsalicylic Acid. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 45 minutes post-treatment of the initial consultation (table 140) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test demonstrated that the groups were not comparable in terms of variance ($p > \alpha$).

Comparison of the groups for 60 minutes post-treatment of the initial consultation (table 140) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 90 minutes post-treatment of the initial consultation (table 140) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 120 minutes post-treatment of the initial consultation (table 140) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 150 minutes post-treatment of the initial consultation (table 140) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Summary of the Initial Treatment's comparison of the VAS scores of group 1 and group 2.

Comparison of the groups for 15 and 30 minutes post-treatment of the initial consultation revealed a statistically significant difference, in favor of group 1in terms of pain intensity. None of the other comparisons between group 1 and 2 revealed any statistical differences in the initial consultation. This data indicates that manipulation brings about earlier benefit (in terms of pain relief), when compared to Acetylsalicylic Acid.

Comparison of the Follow up Treatment's VAS scores of group 1 and group 2.

Comparison of the groups for the patient's headache presenting at the follow up consultation VAS results (table 141) revealed no statistically significant difference ($p > \alpha/2$), thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 15 minutes post-treatment of the follow up consultation (table 141) revealed a statistically significant difference ($p < \alpha/2$), in favor of group 1in terms of pain intensity; thus Ho was rejected and H1 is accepted. Group 1 had a mean of 5.87%, and group 2 had a mean of 41.2%, thus group 1 demonstrated a mean pain intensity of 35.3% lower than group 2. This data indicates that manipulation brings about earlier benefit (in terms of pain relief), when compared to Acetylsalicylic Acid. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 30 minutes post-treatment of the follow up consultation (table 141) revealed a statistically significant difference ($p < \alpha/2$), in favor of group 1in terms of pain intensity; thus Ho was rejected and H1 is accepted. Group 1 had a mean of 5.17%, and group 2 had a mean of 31.9%, thus group 1 demonstrated a mean pain intensity of 26.73% lower than group 2. This data indicates that manipulation brings about earlier benefit (in terms of pain relief), when compared to Acetylsalicylic Acid. Levene's test for variance found that the groups are not comparable in variance ($p > \alpha$).

Comparison of the groups for 45 minutes post-treatment of the follow up consultation (table 141) revealed a statistically significant difference ($p < \alpha/2$), in favor of group 1in terms of pain intensity; thus Ho was rejected and H1 is accepted. Group 1 had a mean of 5.23%, and group 2 had a mean of 22.83%, thus group 1 demonstrated a mean pain intensity of 17.6% lower than group 2. This data indicates that manipulation had greater benefit (in terms of pain relief), when compared to Acetylsalicylic Acid. Levene's test for variance found that the groups are not comparable in variance ($p > \alpha$).

Comparison of the groups for 60 minutes post-treatment of the follow up consultation (table 141) revealed a statistically significant difference ($p < \alpha/2$), in favor of group 1in terms of pain intensity; thus Ho was rejected and H1 is accepted. Group 1 had a mean of 5.67%, and group 2 had a mean of 19.63 %, thus group 1 demonstrated a mean pain intensity of 13.96% lower than group 2. This data indicates that manipulation brings about earlier benefit (in terms of pain relief), when compared to Acetylsalicylic Acid. Levene's test for variance found that the groups are not comparable in variance ($p > \alpha$).

Comparison of the groups for 90 minutes post-treatment of the follow up consultation (table 141) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are not comparable in variance ($p > \alpha$).

Comparison of the groups for 120 minutes post-treatment of the follow up consultation (table 141) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Comparison of the groups for 150 minutes post-treatment of the follow up consultation (table 141) revealed no statistically significant difference ($p > \alpha/2$), in respect to the pain intensity indicated, thus Ho was accepted. Levene's test for variance found that the groups are comparable in variance ($p < \alpha$).

Summary of the comparison of the Follow up Treatment's VAS scores of group 1 and group 2.

Comparison of the groups for 15, 30, 45 and 60 minutes post-treatment of the follow up consultation revealed a statistically significant difference, in favor of group 1in terms of pain intensity. The other comparisons between group 1 and 2 revealed no other statistical differences in the follow up consultation. This data indicates that manipulation brings about earlier benefit (in terms of pain relief), when compared to Acetylsalicylic Acid.

5.4.2. Objective Results

Comparison of the algometer scores of group 1 and group 2.

The objective results of the groups for both the initial (table 142) and the follow up consultations (table 143) when compared revealed no statistically significant difference ($p > \alpha/2$), in respect to algometer readings for the upper and middle SCM muscle bilaterally and the trapezius insertion bilaterally, thus Ho was accepted. Levene's test for variance found that the groups were not comparable ($p > \alpha$).

5.5. PROBLEMS ENCOUNTERED WITH THE SUBJECTIVE AND THE OBJECTIVE DATA

The greatest difficulty in this study was to get the subjects to attend the clinic when the subjects had a headache. Another problem encountered was the subjects in the medication group would frequently request manipulation, which had to be refused. Those subjects' requesting manipulation were recommended that they could attend the clinic as a normal patient when the study had been completed, however most of the 5 subjects who failed to make an a second appointment within the stipulated 14 days after the initial consultation were in the acetylsalicylic Acid group. Another difficulty was that the headache diaries were frequently not returned to the clinic, thus necessitating the researcher to collect them; however, this was not always possible and subject's results were thereby excluded from the data. One of the medication group subjects had abdominal discomfort after ingesting the Acetylsalicylic Acid and was excluded from

continuing the study. The manipulation group had no noted side effects noted by any of the subjects.

5.6. COMPARISON OF RESULTS OF THIS STUDY WITH PAST RESEARCH

The mean age of group 1 was 33,2 years. Schwartz, et al. (1998) found the prevalence of episodic tension-type headache peaked at the 30- to 39- year age group. However, the mean age for group 2 was 29,4 years and group 1 and 2 were not comparable in terms of age. Gobel, et al. (1994) found that episodic tension-type headache does not demonstrate any differences in prevalence by age. But the mean age for the study population was 31.3 years, which would support the findings of Schwartz et al. (1998).

The male to female ratio revealed that 60% of group 1 was female, whereas 73,3% of group 2 was female. In previous studies of episodic tension-type headache, women had higher prevalence than men did at all ages (Rasmussen, 1995) (Schwartz, et al. 1998) (Gobel, et al. 1994) (Rasmussen, et al. 1992). Thus the findings of this study support the hypothesis that episodic tension-type headache is more prevalent in females.

No research has previously examined episodic tension-type headache's relationship to migraine headaches, which 21,67% of the study population suffered as separate and distinct entities.

No research has previously examined the mean duration of previous episodes, of specifically episodic tension-type headache. Gobel, et al. (1994) found that tension-type

headaches had a mean duration of 10,3 years. The mean duration of previous episodes in group 1 was 8,6 years, and in group 2 mean duration of episodes of 7,0 years. This could support the hypothesis that Jensen, et al. (1998) creates attempting to explain how episodic tension-type headache converts into chronic tension-type headache.

Headache location in both groups was similar with the majority of subjects complaining of a frontal, occipital and temporal pain, usually in a combination of locations. Vernon et al. (1992) found that tension-type headache sufferers demonstrated high occurrences of occipital and neck pain during headaches. The findings of this study support that this is also true of episodic tension-type headache.

The precipitating factors of specifically episodic tension-type headache have not been previously examined. The most common provoking factors for tension-type headache was stress and mental tension (Rasmussen, 1995). Alders et al. (1996) found the following precipitating factors for tension-type headache in a community-based prevalence study in Malaysia: sun exposure, lack of sleep, stress, menstruation, missing a meal, fever, oversleeping, amongst other isolated causes. In this study, stress was found to be a precipitating factor of episodic tension-type headache in 65% of the subjects; while other precipitating factors for episodic tension-type headache were: light, heat, computers, sound, sun, eyestrain, fatigue, menstruation and other isolated causes.

No research has previously made use of the CMCC Neck Disability Index for episodic tension-type headache. The CMCC Neck Disability Index demonstrated that

manipulation unlike Acetylsalicylic Acid was able to reduce neck disability on an intra-group level, which was carried over to the follow up consultation. Thomson (2000) found that manipulation was able to reduce neck disability also using the CMCC Neck Disability Index. In this study, there was no improvement in the Short-form McGill Pain Questionnaire results. This data is similar to the results of a study previously examining episodic tension-type headache. The Short-form McGill Pain Questionnaire did not appear to provide any useful information in assessing change (Mootz, et al. 1994). Mootz, et al. (1994) conducted a small case series analysis of chiropractic treatment that failed to demonstrate a reduction in self reported pain intensity. This study utilized the NRS 101 Questionnaire that also failed to reduce pain intensity of the headache episodes.

The literature review failed to find any studies that discussed the treatment of episodic tension-type headache and the initial effects post-manipulation.

Mootz et al. (1994) found significant reductions in frequency and duration of headache episodes. Unfortunately, this study did not consider frequency or duration of headache episodes.

Bove and Nilsson, (1998) found that there was no significant difference between a group receiving manipulation and one receiving massage and placebo laser therapy. The two groups in mean daily headache hours, mean number of analgesics per day and the headache pain intensity was unchanged for the duration of the trial, consequently concluding cervical spine manipulation as an isolated intervention does not have a

significant effect. This study did not consider: mean daily headache hours, mean number of analgesics per day and the headache pain intensity; and is consequently unable to comment on the above factors. However, this study made use of cervical spine manipulation as an isolated intervention and demonstrated that when compared to acetylsalicylic acid that it does have a significant effect in terms of pain relief.

Nebe, et al. (1995) used a minimum of a 50% decrease of headache intensity on a VAS for the episodic tension-type headache as a response criterion, and found that acetylsalicylic acid was significantly superior to placebo. Thus, using this response criterion the results of this study would find both groups to have significant results. Comparison of the groups for 60 minutes post-treatment of the follow up consultation revealed a statistically significant difference, in favor of group 1in terms of pain intensity. One could speculate that this would suggest that manipulation is significantly superior to placebo in the treatment of episodic tension-type headache.

Kim, et al. (1995) found that the pain-pressure thresholds of the upper and middle sternocleidomastoid muscles and trapezius insertion were lower in a study specifically on episodic tension-type headache. The findings of this study are similar with the pre- and post-manipulation results demonstrated a significant improvement in the pain-pressure thresholds for the trapezius insertion bilaterally, the left middle SCM and the right upper SCM. However, the algometer measurements comparing the results of the of the pre- and post-treatment measurements for the follow up consultation for the left upper SCM and the right middle SCM muscles revealed no statistically significant difference.

CHAPTER 6

6.1. CONCLUSIONS

6.1.1. Subjective Data

Analysis of the subjective results reflects that the cervical spine manipulation group (Group 1), subjectively benefited in terms of reduced neck disability and marked decreased pain intensity directly after treatment which then slowly progressed over the 150 minute duration of the headache diary. The subjective results of acetylsalicylic acid group (Group 2) when analyzed demonstrated only reduced pain intensity that progressed over the 150 minutes duration of the headache diary.

Upon comparison, the cervical spine manipulation group had significantly greater relief than the acetylsalicylic acid group for the first 30 minutes in the initial consultation, and the first hour on the follow up consultation.

6.1.2. Objective Data

The objective results upon the analysis of the cervical spine manipulation group for the initial and follow up consultation only demonstrated a significant improvement of the upper portion of the left SCM muscle. Analysis of the objective results for the acetylsalicylic acid group failed to reveal any significant difference between the initial and the follow up consultation.

The objective results of the pre- and post-treatment measurements for the follow up consultation revealed significant improvement of the trapezius insertion bilaterally, the

middle portion of the SCM muscles bilaterally and the upper portion of the right SCM muscle. No significant difference was found for the upper portion of the left SCM muscle.

6.1.3. Final Conclusions

Cervical spine manipulation gives faster relief of symptoms when compared to acetylsalicylic acid, and is as a consequence the recommended treatment choice in the short-term management of episodic tension-type headache.

6.2. RECOMMENDATIONS

The diagnostic criteria for episodic tension-type headache are clear, concise and easy to apply, and is recommended for future studies involving episodic tension-type headache.

The Numerical Rating Scale 101was easy to administer and is recommended for future studies involving episodic tension-type headache. The treatment of episodic tension-type headache it is suggested that the Short-form McGill Pain Questionnaire is excluded as both this study and a previous study have failed it has failed to provide any useful information (Mootz, et al. 1994). The CMCC Neck Disability Index should only be considered for studies investigating episodic tension-type headache, which are going to provide a course of treatments. The headache diaries are easy to administer and use; however it is suggested that a directly post-treatment visual analogue scale be provided.

The algometer apparatus was easy to use and the subjects reported no excess discomfort.

A pre-treatment evaluation for a minimum of 4 weeks using headache diaries is recommended to record base line levels, to plot the natural course of the headache, and to provide data on the subjects' self medication habits. Similarly post-treatment evaluation is recommended to determine differences in the condition post-treatment.

The focus of this study was the first 150 minutes, and to determine the effect of acetylsalicylic acid compared to cervical spine manipulation. However in a future study this could be extended for 24 hours as acetylsalicylic acid duration of action of approximately 4 hours, with peak plasma concentrations 1-2 hours after oral admission (Neal, 1992:66-67)(Craig and Stitzel, 1994:433)(Dewey, 1991:406).

Further, future studies could examine other drugs and modalities and compare them to manipulation.

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APPENDIX A

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:_____ Date: _____
file #:_____ X-Ray#:_____
Age:_____ Sex:_____ Occupation:_____
Intern:_____ Signature:_____

FOR CLINICIAN'S USE ONLY
Initial visit clinician:_____Signature:_____

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. lab:
Previous: Current:

Case Status:

PTT: Conditional: Signed Off: Final Sign out:

Recommendations:

Intern's Case History

1. Source of History:

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

3. Present Illness:

- Location
- Onset
- Duration
- Frequency
- Pain (Character)
- Progression
- Aggravating Factors
- Relieving Factors
- Associated S & S
- Previous Occurrences
- Past Treatment and 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
- Environmental Hazards (Home, School, Work)
- Safety Measures (seat belts, condoms)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
- 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 B

TECHNIKON NATAL

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:_____ File#: _____ Date:_____
Clinician:_____ Signature:_____
Intern:_____ Signature:_____

1. VITALS

Pulse rate:
Respiratory rate:
Blood pressure: R L
Temperature:
Height:
Weight:

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in Cardiac Failure ?
2) Does this patient have signs of Infective Endocarditis ?
3) Does this patient have Rheumatic Heart Disease ?

Inspection - Scars
- Chest deformity:
- Precordial bulge:
- Neck -JVP:

Palpation: - Apex Beat (character + location):
- Right or left ventricular heave:
- Epigastric Pulsations:
- Palpable P2:
- Palpable A2:

Pulses:
- General Impression:
- Radio-femoral delay:
- Carotid:
- Radial:
- Dorsalis pedis:
- Posterior tibial:
- Popliteal:
- Femoral:

Percussion: - borders of heart

Auscultation:
- heart valves (mitral, aortic, tricuspid, pulmonary)
- Murmurs (timing,systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

1) Is this patient in Respiratory Distress ?

Inspection
- Barrel chest:
- Pectus carinatum/cavinatum:
- Left precordial bulge:
- Symmetry of movement:
- Scars:

Palpation
- Tracheal symmetry:
- Tracheal tug:
- Thyroid Gland:
- Symmetry of movement (ant + post)
- Tactile fremitus:

Percussion
- Percussion note:
- Cardiac dullness:
- Liver dullness:

Auscultation
- Normal breath sounds bilat.:
- Adventitious sounds (crackles, wheezes, crepitations)
- Pleural frictional rub:
- Vocal resonance
  - Whispering pectoriloquy:
  - Bronchophony:
  - Egophony:

5. ABDOMINAL EXAMINATION

1) Is this patient in Liver Failure ?

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

Auscultation - Bowel sounds:
- Arteries (aortic, renal, iliac, femoral, hepatic)

Rectal Examination
- Perianal skin:
- Sphincter tone & S4 Dermatome:
- Obvious masses:
- Prostate:
- Appendix:

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

Gait and Posture
- Abnormalities in gait:
- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Rombergs test (Pronator Drift):

Higher Mental Function
- Information and Vocabulary:
- Calculating ability:
- Abstract Thinking:

G.C.S.:
- Eyes:
- Motor:
- Verbal:

Evidence of head trauma:

Evidence of Meningism:
- Neck mobility and Brudzinski's sign:
- Kernigs sign:

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

II External examination of eye:
- Visual Acuity:
- Visual fields by confrontation:

- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:

b. Motor - Masseter:
- Jaw lateral movement:

c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

VII a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance:
- Show teeth:
- Blow out cheeks:

b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function - Nystagmus:
- Rombergs:
- Wallenbergs:
Otoscope examination:

IX & X Gag reflex:
Uvula deviation:
Speech quality:

XI Shoulder lift:
S.C.M. strength:

XII Inspection of tongue (deviation):

Motor System:

a. Power
- Shoulder = Abduction & Adduction:
  = Flexion & Extension:
- Elbow = Flexion & Extension:
- Wrist = Flexion & Extension:

- Forearm = Supination & Pronation:
- Fingers = Extension (Interphalangeals & M.C.P's):
- Thumb = Opposition:
- Hip = Flexion & Extension:
= Adduction & Abduction:
- Knee = Flexion & Extension:
- Foot = Dorsiflexion & Plantar flexion:
= Inversion & Eversion:
= Toe (Plantarflexion & Dorsiflexion):

b. Tone
- Shoulder:
- Elbow:
- Wrist:
- Lower limb - Int. & Ext. rotation:
- Knee clonus:
- ankle clonus:

c. Reflexes
- Biceps:
- Triceps:
- Supinator:
- Knee:
- Ankle:
- Abdominal:
- Plantar:

Sensory System:

a. Dermatomes
- Light touch:
- Crude touch:
- Pain:
- Temperature:
- Two point discrimination:

b. Joint position sense
- Finger:
- Toe:

c. Vibration:
- Big toe:
- Tibial tuberosity:
- ASIS:
- Interphalangeal Joint:
- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:
= Intention Tremor:
= Nystagmus:
= Truncal Ataxia:

Finger-nose test (Dysmetria):
Rapid alternating movements (Dysdiadochokinesia):
Heel-shin test:
Heel-toe gait:
Reflexes:
Signs of Parkinsons:

8. SPINAL EXAMINATION:(See Regional examination)

Obvious Abnormalities:
Spinous Percussion:
R.O.M:
Other:

9. BREAST EXAMINATION:

Summon female chaperon.

Inspection - Hands rested in lap:
- Hands pressed on hips:
- Arms above head:
- Leaning forward:

Palpation - masses:
- tenderness:
- axillary tail:
- nipple:
- regional lymph nodes:

APPENDIX C

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
REGIONAL EXAMINATION - *CERVICAL SPINE*

Patient: _____ File: _____

Date: _____ Intern/Resident: _____

Clinician: _____ Sign: _____

OBSERVATION:

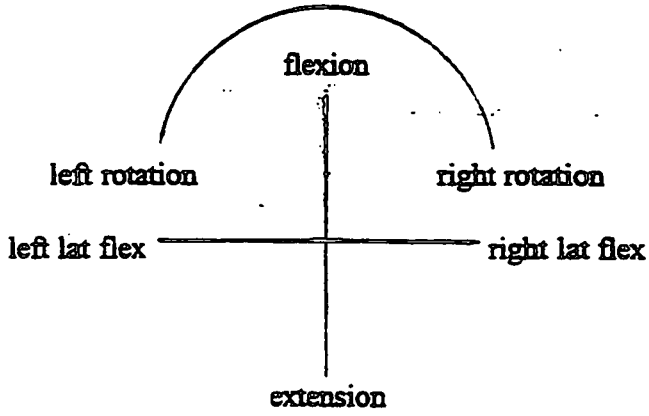
Posture
Swellings
Scars
Discolouration
Hair Line
Bony & Soft Tissue Contours

Shoulder position:
Left:
Right:
Muscle spasm
Facial expression

RANGE OF MOTION:

Flexion (45°):
L/R Rotation (70°):

Extension (70°):
L/R Lat Flex (45°):



PALPATION:

Lymph Nodes
Thyroid Gland
Trachea

ORTHOPAEDIC EXAMINATION:

Tenderness
Trigger Points: SCM, Scalenii, Post Cervicals, Trapezius, Lev Scap

Doorbell sign
Kemp's test
Cervical distraction
Halstead's test
Hyperabduction test
Shoulder abduction test

Cervical compression
Lateral compression
Adson's test
Costoclavicular test
Eden's test
Shoulder depression test

Dizziness rotation test
Brachial plexus tension

Lhermitte's sign

NEUROLOGICAL EXAMINATION:

Dermatomes	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					

VASCULAR:

	Left	Right
Blood Pressure		
Carotid arts.		
Subclavian 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:
Observ/Palpation:

Upper T horacics:
Motion Palpation:
Joint Play:

Basic Exam: Thoracic Spine:
Case History:

ROM: Motion Palp:
Active:
Passive:
Orthopaedic/Neuro/
Vascular:
Observ/Palpation:

APPENDIX D

Dear Participant

The aim of this study is to compare the relative effectiveness of two treatment therapies in the management of Episodic Tension-type Headache.

120 people will be required to complete the study. These participants will be randomly divided into 2 treatment groups of 60 patients each. Patient's in both groups will receive treatment.

The first group of patient's will receive manipulative treatment of the cervical spine. Manipulation of the cervical spine has been suggested as an effective treatment for Episodic Tension-type Headache.

The second group of patient's will receive a 500mg tablet of Acetylsalicyclic Acid. Acetylsalicyclic Acid is a non-steriodal anti-inflammatory drug, which reduces inflammation, and has been proven to relieve Episodic Tension-type Headache. This drug may, however, produce side-effects in some patient's (e.g. gastric irritation and bleeding). Consequently patient's with a history of analgesic abuse, peptic ulcer disease, bleeding disorders or known allergy to non-steriodal anti-inflammatory drugs as well as pregnant or lactating women will be excluded.

Patient's will be required to return after the initial consultation for a second treatment on the next consecutive headache. Should your second headache start when the clinic is closed, provided the same headache is still present when the clinic reopens, please make an appointment to attend.

All treatments will be performed under the supervision of a qualified chiropractor and will be free of charge.

Thank you.

Yours faithfully

Mark Kidson
(Chiropractic Research Student)

APPENDIX E

INFORMED CONSENT FORM

(To be completed in duplicate by patient /subject)

Date :_____

Title of research project :_____

_____

_____

Name of supervisor :_____

Name of research student :_____

_____

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.	Who have you spoken to? _____		
7.	Do you understand the implications of your involvement in this study?	Yes	No
8.	Do you understand that you are free to withdraw from this study?	Yes	No
	a) at any time		
	b) without having to give any a reason for withdrawing, and		
	c) without affecting your future health care.		
9.	Do you agree to voluntarily participate in this study	Yes	No

If you have answered no to any of the above, please obtain the information before signing

Please Print in block letters:

Patient /Subject Name:_____ Signature:_____

Parent /Guardian Name:_____ Signature:_____

Witness Name:_____ Signature:_____

Research Student Name:_____ Signature:_____

APPENDIX F

Short-form McGill Pain Questionnaire (SF-MPQ)

Ronald Melzack (1984)

Date:_____ File no.:_____ Visit no:____

Patient name:_____

	NONE 0	MILD 1	MODERATE 2	SEVERE 3
THROBBING				
SHOOTING				
STABBING				
SHARP				
CRAMPING				
GNAWING				
HOT-BURNING				
ACHING				
HEAVY				
TENDER				
SPLITTING				
TIRING-EXHAUSTING				
SICKENING				
FEARFUL				
PUNISHING-CRUEL				

APPENDIX G

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.

_____

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.

_____

CMCC NECK DISABILITY INDEX

APPENDIX H

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

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

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

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

Section 3 - Lifting

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

Section 4 - Reading

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

Section 5 - Headaches

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

Section 6 - Concentration

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

Section 7 - Work

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

Section 8 - Driving

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

Section 9 - Sleeping

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

Section 10 - Recreation

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

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

APPENDIX I

HEADACHE DIARY

Name : .....

Gender : .....

Age : .....

Body weight (kg): .....

Usual headache duration (hours): .....

Usual headache intensity (VAS):

Usual character of the pain: Dull, Oppressive, Pulsating, Throbbing, Stabbing

Localization of the pain: Unilateral, Bilateral

Accompanying symptoms: Nausea, Vomiting, Photophobia, Phonophobia

Additional remarks: .....

.....

At consultation:

Current headache duration (hours): .....

Current headache intensity (VAS):

Current character of the pain: Dull, Oppressive, Pulsating, Throbbing, Stabbing

Localization of the pain: Unilateral, Bilateral

Accompanying symptoms: Nausea, Vomiting, Photophobia, Phonophobia

Post treatment side effects: .....

Additional remarks: .....

.....

HEADACHE DIARY

15 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

30 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

45 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

60 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

90 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

120 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

150 minutes after-treatment:
Headache intensity (VAS):

Post treatment side effects: .....

Additional remarks: .....

.....