The relative effectiveness of cervical spine manipulation and a Nonsteroidal Anti-inflammatory drug (Ibuprofen) in the treatment of Episodic Tension-Type Headaches

By

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I, Kgosietsile Legoete, do hereby declare that this dissertation is representative of my own work in both conception and execution (except where acknowledgements indicate to the contrary)

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Dedication

To my parents for their unconditional love and incredible support,
I can never thank you enough for the sacrifices you have made.

To my Lord and saviour Jesus Christ, you are my rock.

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Abstract

Purpose: The 1 year overall prevalence of Episodic Tension-Type Headache (ETTH) is 38.3%; with lifetime prevalence at 46% for TTH. Little literature exists to support the effectiveness of spinal manipulation in the treatment of ETTH. Therefore aim of this study was to determine the relative effectiveness of cervical spine manipulation and a Nonsteroidal Anti-inflammatory drug (NSAID) (Ibuprofen®) in the treatment of ETTH.

Method: This study was a prospective randomised clinical trial with two intervention groups (N=32, n_1=16 and n_2=16). The allocation of participants to the two groups was completed by means of simple randomization. Group one were treated using cervical spine manipulation. Group two were treated using Ibuprofen. Subjective measurements included the Numerical Rating Scale 101 Questionnaire (NRS-101), Short Form McGill Pain Questionnaire (SF-MPQ), CMCC Neck Disability Index (CMCC) and Headache Diary. A *p* value <0.05 was considered as statistically significant.

Results: The subjective measurements of the NRS-101, SF-MPQ and CMCC showed a significant time effect in both treatment groups. Several of the subjective Headaches Diary outcomes followed this trend with significant time effect in both groups. There was a significant treatment effect for the NRS-101. Several subject outcomes from the Headache Diary showed a significant treatment effect in favour of manipulation, namely frequency and duration of headaches.

Conclusion: The findings in this study have shown that cervical spine manipulation is more effective than Ibuprofen® for the treatment of ETTH in terms of several subjective outcomes namely: pain intensity (NRS-101), and the frequency and the duration of headache per day.

Key Indexing terms: Chiropractic; NSAIDs; Tension-type headache; Ibuprofen®

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Key

CTTH -Chronic tension-type headache

ETTH -Episodic tension-type headache

TTH -Tension-type headache

IHS -International Headache Society

ICHD -The International Classification of Headache Disorders

MPS -Myofacial Pain Syndromes

NSAIDs - Nonsteroidal anti-inflammatory drug

SF-MPQ - The Short Form McGill Pain Questionnaire

NRS – 101 - Numerical Rating scale 101

CMCC - CMCC Neck Disability Index

Definitions

Ibuprofen	Is a Nonsteroidal Anti-inflammatory drug (NSAID) and analgesic Agent. Its effects are similar to aspirin without as many adverse effects, particularly side effects related to those of the gastrointestinal system (Diamond, 1983).
Chiropractic	Is a discipline of the scientific healing arts that deals with the pathogenesis, diagnosis, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes and neurophysiological effects related to the statics and dynamics of the locomotor system, especially of the spine and pelvis. There is an emphasis on manual treatments such as manipulation of the spine and other joint of the boby and soft-tissue manipulation (Bergmann, Petersen and Lawrence, 1993; World Federation of Chiropractic (WFC), 2009; Chiropractic Association of South Africa (CASA), 2009).
Adjustment	A specific type of direct articular manipulation which uses either long or short leverage techniques with specific contacts and is characterized by a dynamic thrust of controlled velocity, amplitude and direction. (Bergmann, Petersen and Lawrence, 1993;Gatterman, 1990; Haldeman, 2005; Redwood and Cleveland, 2003)

Fixation — A state in which a joint has become temporarily immobilized in a position that it may usually occupy during any phase of physiological movement. The immobilization of a vertebral joint or other joints in a position of movement while the joint is at rest, or in a position of rest while the joint is in motion (Gatterman, 1990; Bergmann, Petersen and Lawrence, 1993; Leach, 2004; Haldeman, 2005).

Facet joint dysfunction — A motion segment in which alignment, movement, and / or physiologic function are changed, but contact between the joint surfaces remains partially intact. This results in pain or dysfunction, but these changes are relatively minor and often reversible (Kirkaldy-Willis and Burton,1992; Gatterman, 1995)

Manipulation — A passive maneuver whereby specifically directed manual forces are applied to vertebra or extravertebra articulations of the body with the object of restoring mobility to restricted areas (Gatterman, 1990).

Motion palpation — The palpatory diagnosis of passive and active segmental joint range of motion to ascertain areas of hypomobility or hypermoility (Gatterman, 1990; Redwood and Cleveland, 2003).

Subjective findings — In this study subjective findings include those measurements that were obtained from the NRS-101 Questionnaire, SF-MPQ and the CMCC.

Tension – type headache (TTH)

Is described by the second of the International Classification of Headache Disorders (ICHD-2) as a headache lasting from 30 minutes to 7 days and should have two of the following four pain features: pressing/tightening (nonpulsating) quality; mild or moderate intensity; bilateral location; no aggravation by walking up or down stairs or similar routine physical activity. In addition, the following are required: an absence of nausea or vomiting, and photophobia and phonophobia. However one of these symptoms, photophobia or phonophobia, may be present but not together at the same time (The second edition of the International Classification of Headache Disorders, 2004).

TTH is classified as follows:

- Episodic tension – type headache (ETTH) which is divided into:
    - Frequent TTH (1-14 attacks per month).
    - Infrequent TTH (≤1 attack per month).
- Chronic tension – type headache (CTTH) : (≥15 attacks per month)

CHAPTER 1: Introduction

1.1 Introduction

Tension-type Headache (TTH) is one of the most common primary headaches, with life time prevalence in the general population that ranges in different studies from 30% to 78% (Jensen, 2003 and Ninan and Mathew, 2006). This means that TTH has a high socioeconomic burden due to its high prevalence (Ninan and Mathew, 2006).

According to the second edition of the International Classification of Headache Disorders (ICHD-2) three forms of TTH can be distinguished: infrequent Episodic Tension-type Headache (ETTH) (<1 attack per month), frequent ETTH (1-14 attacks per month), and Chronic Tension-type Headache (CTTH) (≥15 attacks per month). Each of these types can be further classified into forms associated or not associated with pericranial tenderness (ICHD-2, 2004). In this context TTH is described as a headache lasting from 30 minutes to 7 days, with at least two of the following four pain features: pressing/tightening (nonpulsating) quality; mild or moderate intensity; bilateral location; no aggravation by walking up or down stairs or similar routine physical activity. In addition, the following is required: an absence of nausea or vomiting. Photophobia or phonophobia may be present but not together at the same time (ICHD-2, 2004).

With particular reference to ETTH, a study by Schwartz, Stewart, Simon and Lipton, (1998) indicated that a one year overall prevalence of ETTH was 38.3%. ETTH was more prevalent in females than in males and the peak age was between 30 to 39 in males and females. A total of 8.3% of patients with ETTH reported lost workdays, with an average of 8.9 lost workdays reported per person per year (Schwartz et al., 1998).

The exact aetiology of ETTH is still unknown and the pathophysiology has not been completely clarified (Ashina, Brendtsen and Ashina, 2005). Many agree that its pathogenesis is multifactorial, and includes muscular, vascular, psychological (stress, anxiety and depression) factors as well as cervical spine dysfunction

(International Headache Society (IHS), 1991; Spierings, Ranke and Honkoop, 2001; Rasmussen 1993; Ashina, Brendtsen and Ashina, 2005). However Ashina, Brendtsen and Ashina, (2005) point out that sustained contraction of pericranial muscles has long been thought to play a role in the pathogenesis of TTH.

Ashina and Ashina, (2003) state that simple analgesics (aspirin and paracetamol) and nonsteroidal anti-inflammatory drugs (NSAIDs) (Ibuprofen ®) are the most widely used drugs in the treatment of TTH, which includes ETTH. A comparative randomized, controlled trial study done by Schachtel (1996) indicated that Ibuprofen ® had the best and quicker pain relief than analgesics and placebo.

In addition to the above, Vernon, Steinman and Hagino (1992) suggest that the cervical spine components (skeleton, arthrokinetic and myofascial components) may play a part in TTH and therefore ETTH. According to Boline, Kassak, Bronfort, Nelson and Anderson (1995) and Vernon (1995) manipulation has been demonstrated to be beneficial for TTH. Vernon, (1982) in his study, reported statistically significant reductions in headache activity as measured by frequency, duration and intensity.

1.2 Aim/Purpose of the Study

The aim was to determine the relative effectiveness of cervical spine manipulation and a nonsteroidal anti-inflammatory drug (Ibuprofen ®) in the treatment of ETTH.

1.3 Objectives of the Study

Objectives were to determine

Objective 1

- The effectiveness of Ibuprofen ® in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in lifestyle.

Alternate hypothesis one:

Ibuprofen ® will be effective in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in lifestyle.

Objective 2

- The effectiveness of a spinal manipulation in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in lifestyle.

Alternate hypothesis two:

Spinal manipulation will be effective in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in lifestyle.

Objective 3

- A relative effectiveness in subjective clinical measures in cervical spine manipulation versus Ibuprofen ® groups in the treatment of ETTH.

Alternate hypothesis three:

Spinal manipulation would be better at treating ETTH than Ibuprofen ® in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated symptoms and changes in lifestyle.

1.4 The Alternate and Null Hypotheses

The Null hypothesis (Ho) stated that there was no significant difference in the participant's condition between the two groups in terms of subjective clinical findings, at α=0.05 level of significance and *p* was the observed significant level. The alternative hypothesis (H1) stated that there was a significant difference in participant's condition between the two groups in terms of subjective clinical findings. Decision rule: If the *p*-value was less than α=0.05 level of significance, the null hypothesis was rejected. Otherwise the null hypothesis was accepted at the same level.

1.5 Rationale

- To provide an evidence-based study in South Africa for all health professionals as to the relative effectiveness of cervical spine manipulation versus NSAIDs in the treatment of ETTH.
- To provide a study with which future studies can be compared to with regard to the treatment of ETTH, in order to develop better treatment protocols for ETTH .
- In the event that NSAIDs are contraindicated (see exclusion criteria) in patients, this study may assist in determining if spinal manipulation could be used as an alternative therapy, in achieving reduced intensity, frequency, duration of ETTH and improvement of lifestyle.

1.6 Benefits of the study

The outcomes of this study may allow for the development of a non invasive alternative treatment protocol for ETTH.

1.7 Limitations of the study

No *a prior* analysis of power was done; therefore there is a possibility that the sample size may have decreased the ability for the study results to reach significant findings.

In this study only subjective data was collected. A combination of subjective and objective would yield more accurate results and is recommended for future studies. Additionally since all subjective data would have been supplied by the participants, it was expected that the participants completed the required questionnaires open and honestly reflecting their particular circumstances at that time as realistically as possible.

Participant selection was primarily by means of participant self selection in response to the advertising (Mouton, 1996) employed in this study and thereafter simple randomisation sampling (Mouton, 1996) was employed as the participants met the inclusion and exclusion criteria. Therefore, it is inevitable that, in this sampling process, no matter how carefully carried out, it would potentially result in a sample that is not necessarily representative of the ETTH population (Dyer, 1997).

1.8 Conclusion

There is considerable evidence for the effectiveness of NSAIDs in the treatment of TTH, but only a few studies that investigate the effectiveness of Spinal Manipulation. Therefore this study set out to investigate the trends in subjective clinical outcome measures with regard to cervical spine manipulation and Ibuprofen® in the treatment of ETTH.

CHAPTER 2: Literature Review

2.1 Introduction

This chapter covers the epidemiology and the pathophysiology of ETTH. It will also discuss the differential diagnosis and the treatment of ETTH, as well as review the available literature covering these subjects.

2.2 Definition and Classification of Episodic Tension-Type Headache

Headaches are among the most common clinical conditions in medicine (Edwards, Bouchier, Haslett and Chilvers, 1995). According to Haldeman (2005), the third most common reason a patient will seek Chiropractic care is headaches. Tension type headache (TTH) is the most common type of headache with eighty percent of headache patients who consult a doctor been diagnosed as suffering from TTH (Dalessio, 1987).

Many disorders present with headache and a systematic approach to headache classification and diagnosis are necessary for good clinical management and research. According to the second edition of the International Classification of Headache Disorders (ICHD-2) three forms of TTH can be distinguished: infrequent episodic (<1 attack per month), frequent episodic (1-14 attacks per month), and chronic (≥15 attacks per month). Each of these types can be further classified into forms associated or not associated with pericranial tenderness (ICHD-2, 2004). According to Bates (2003) and ICHD (2004) the location of ETTH is usually bilateral, but may be generalised or localised to the back of the head and upper neck, or to the frontotemporal area. Vernon et al. (1992) found the most commonly affected headache locations in his study were occipital, frontal, orbital and temporal. Kidson (2001) found that majority of the subjects in his study complained of a frontal pain followed by occipital and temporal pain in terms of location. This concurs with the later findings of Prithipal (2003).

2.3 Epidemiology

2.3.1 Prevalence

In a Danish population study conducted in 1979, the lifetime prevalence of TTH was 82%, and the one year prevalence was 79% (Lyngberg, Rasmussen, Jorgensen and Jensen, 2005). The same study was conducted 12 years later, and it was found that the lifetime prevalence increased to 89% and the one year prevalence increased to 87%. Frequent ETTH had increased the most from 29% in 1979 to 37% in 2001 (Lyngberg et al., 2005). According to Stovner et al., (2007) the overall current global prevalence of headache is 47% and of TTH is 38%. He continues to say that the lifetime prevalences are higher at 66% for headache and 46% for TTH. A telephonic interview conducted by Schwartz et al. (1998) in the United States revealed that the 1 year overall prevalence of ETTH was 38.3%.

2.3.2 Age and Gender

ETTH is more prevalent in females than in males (Rasmussen, Jensen, Schroll and Olesen 1991; Schwartz et al, 1998). Rasmussen et al., (1991) found that the male:female ratio was 4:5 in TTH suffers, whereas Schwartz et al. (1998) found that the male:female prevalence ratio was 1:1.16, revealing that women are only slightly more affected by ETTH. The prevalence peaked between the ages of 30 and 39 years in men and women and decreased thereafter for both genders. He also found that Whites had a higher prevalence compared to African American men and women.

2.3.3 Cost and Disability

Schwartz et al. (1998) found that a total of 8.3% of patients with ETTH reported lost workdays, with an average of 8.9 lost workdays reported per person per year. The patients who had ETTH also reported 43.5% reduced effectiveness when at work, with an average of 5 reduced effectiveness days per person per year. He concludes that TTH has a high burden on society due to its high prevalence.

2.3.4 Risk Factors

Diamond (1987) found that TTH can be precipitated by stress, depression, anxiety, emotional conflict, fatigue, repressed hostility or creating a situation or environment that is too great for the patient to handle. The most common provoking factors for TTH were stress and mental tension (Rasmussen, 1993; Spierings, Ranke, Honkoop, 2001) to which changes in weather, smoking and alcohol can be triggers for TTH were added (Rasmussen, 1995). According to Kunkel (1991) ETTH can be provoked by excessive glare, flexion-extension injury to the neck, or neck strain from working in the same position for a long time, bruxism and teeth clenching.

2.4 Mechanism and Pathophysiology of Tension-Type Headache

In the past there has been a poor understanding of the pathophysiology of TTH (Vandeheede and Schoenen, 2002). Understanding of the pathophysiology of TTH may be important in the management of this headache (Ashina and Ashina, 2003). Even though the exact aetiology of tension-type headaches is still unknown, many agree that its pathogenesis is multi-factorial, and includes muscular, vascular, psychological (stress, anxiety and depression) factors as well as cervical spine dysfunction (IHS, 1991).

2.4.1 Psychological factors

According to Friedman (1979), psychological factors may play a role in the development of “physiologic dysfunction” in TTH, which results in sustained pericranial muscle contraction. He continues to say that the muscle contraction may cause relative ischemia and results in TTH.

This is supported by experimental studies done by Gannon, Haynes, Cuevas and Chavez, (1987) revealed that psychological stress can induce TTH. Stress and mental tension have been shown to be common precipitating factors of TTH (Spierings, Ranke and Honkoop, 2001; Rasmussen 1993). It has been suggested that emotional factors could be implicated as precipitating factors to the development of TTH (Schoenen, 2004). Furthermore, behavioural and psychological therapies have demonstrated to be effective in treating TTH (Holroyd, 2002). A laboratory

stress test study showed that vulnerability to TTH was increased by depression during and after the laboratory stress test (Janke, Holroyd and Romanek, 2004).

2.4.2 Muscular factors and Cervicogenic involvement

Sustained contraction of pericranial muscles has long been thought to play a role in the pathogenesis of TTH (Ashina, Brendtsen and Ashina, 2005). A study revealed that sustained tooth clenching with 10% of the maximal electromyographic signal resulted in patients with TTH having more TTH than the control subjects (Jensen and Olesen, 1996). In addition, it has been shown that in patients with TTH, development of shoulder and neck pain in response to static exercise is more likely than in healthy control subjects (Christensen, Bendtsen, Ashina and Jensen, 2005).

In this context, Jensen, Rasmussen, Pedersen and Olesen (1993) found that pericranial tenderness is positively linked with the frequency and intensity of TTH. The study continues to say that pericranial muscle tenderness is a common clinical finding in patients with ETTH. This is supported by Jensen and Rasmussen (1995), who indicated that 66% of ETTH have an associated muscular component, defined as increased tenderness recorded by either manual palpation, pressure algometry and / or increased electromyography (EMG) levels.

This supports Vernon, Steinman and Hagino (1992), who suggested that the cervical spine components (skeleton, arthrokinetic and myofascial) may play a part in TTH. Penter (1994) found that over 90% of ETTH subjects in his experiment and control groups had cervical spine fixations, most frequently at C2 – C3 levels. Additionally, Jansen (1998) found that 93.9% of the experiment group and 94.1% of the control group in her study had fixated cervical spine segments, indicating that cervical spine fixations are very prevalent in TTH subjects. This was later supported by Muller (1999) who found that 97.5% of subjects with TTH in his study had at least one cervical spine fixation.

2.4.3 Central Nervous System Involvement

Based on the presentation of TTH, Olesen (1991) suggested that the central nervous system may play a part in the aetiology of TTH. He proposes that the primary nociceptor is probably myofascial as a result of supraspinal facilitation. The likely mechanism in an ETTH patient with pericranial tenderness is increased input from the myofascial nociceptors projecting to a central pain perception system (Olesen, 1991). It is suggested that ETTH develops into CTTH when there is prolonged painful input from the periphery resulting in the sensitization of the central nervous system (Elliott and Schulman, 2001), which supports the theoretical construct of a "neurological scar" as proposed by Patterson and Steinmetz in Leach, (2004) . A study by Ashina et al., (2005) supported these results and stated that patients with CTTH generally have increased pain sensitivity in the central nervous system, whereas the central pain processing seemed unaffected in patients with ETTH.

2.5 Clinical Features and Differential Diagnosis

The pain of TTH is described as a dull, aching, tight or pressing sensation which may be described as a sensation of a constricting band around the head. The pain is often bilateral but can be localized to the occipital or frontal areas of the head. The headache typically moderate in severity and can last from 30 minutes to 7 days. Patients can usually perform their normal routine activities without any difficulty. In addition nausea and vomiting are not usually present; and the patient may experience photophobia (ICHD-2, 2004; Haldeman, 2005).

Merck manual (1997) cites the following as some of the differential diagnosis of TTH:

Table 2.1 Headache differentials

Organic diseases:	Raised intracranial pressure	Brain abscess Brain tumor Subdural haematoma
	Meningeal irritation	Meningitis Subarachnoid hemorrhage
	Cranial changes	Padget's disease
	Involved sensory nerves of the scalp	
	Vascular disturbances	Migraine Toxic states Hypertension Cluster headache
	Extra-cranial	Lesions of the eye Lesions of the middle ear Lesions of the nasal sinuses Lesions of the oral cavity
Psychogenic:		Anxiety states Conversion hysteria Muscle tension
Post traumatic		

The following (migraine headache, cervicogenic headache, myofacial pain syndrome, brain tumours) will be discussed in connection with TTH.

2.5.1 Migraine

According to the International Classification of Headache Disorders (ICHD1) (1988) migraine headache without aura is described as a unilateral, pulsating headache, which is made worse by physical activity and may be moderate of severe in intensity. It is commonly associated with photophobia, phonophobia and nausea. The attacks may last from four hours to three days. It may be confusing when attempting to separate migraine and ETTH because both are similar and may sometimes coexist (Rasmussen, 1995). The pathognomonic features that separate the headaches include; nausea or vomiting, photophobia and phonophobia occurring at the same time, not aggravated by routine physical activity (Haldeman, 2005).

2.5.2 Cervicogenic Headache

Cervicogenic headache is an infrequent headache which usually involves the same side of the neck and head and trigger points in the neck (Antonica, Fredriksen and Sjaastad, 2001). According to Sjaastad (1987) the headache is felt in the suboccipital area initially and then spread to the vertex and the eye region. He continues stating that the onset of the headache is commonly in the third decade and that the sufferers can often reproduce the headache by placing the head and neck in a certain position. TTH sufferers often report tender points in the scalp, temporal region and the muscles of the head and neck. They often report defuse tenderness in the neck and wrongly diagnosed as cervicogenic headache sufferers (Sjaastad and Fredriksen, 2002). The pathognomonic features that separate this headache from ETTH would be the reproducibility of the headache with neck movement and / or pressure and that the headache is usually on the ipsilateral side to the neck pain (Haldeman, 2005).

2.5.3 Myofascial Pain Syndrome

A typical TTH picture is produced when the referral pattern of the upper Trapezius muscle MPS overlaps with referral patterns of other muscles like Sternocleidomastiod and suboccipital muscles (Travell et al., 1999). It is therefore important to asses for the presence of myofascial trigger points and to differentiate them from the muscle tenderness reported in TTH sufferers (Ashina, Brendtsen and Ashina, 2005). Pain caused by myofascial trigger points is rarely located at the site of the trigger point but is instead projected to a distant reference zone and active trigger points also produce autonomic phenomena in their pain reference zones (Travell et al., 1999). These features help distinguish myofascial trigger points from the muscle tenderness reported in TTH sufferers (Ashina, Brendtsen and Ashina, 2005).

2.5.4 Brain tumours (Raised Intracranial Pressure)

Brain tumours or any other space occupying lesion, typically produce a headache that gradually gets worse and it usually affects a single area on the same side of the head. The headache is often intermittent in the beginning and eventually becomes constant. It might awaken the patient from sound sleep and is often associated with neurological deficit. A new headache in elderly patients should raise suspicion of intracranial tumours or other causes of space occupying lesions (Haldeman, 2005).

2.6 Therapeutic intervention

2.6.1 Manipulation

There are only a few reliable studies that discuss the effectiveness of cervical spine manipulation in treatment of TTH. Nevertheless, according to Vernon (1995) spinal manipulation has been demonstrated to be beneficial for TTH. He conducted a prospective study of spinal manipulation treatment for TTH on 18 patients (20-47 years of age) who received an average of 9 treatments consisting of cervical spine manipulation. He reported statistically significant reductions in headache activity as measured by frequency (from 12 to 2 headaches per month), duration (from 13 to 3 hours) and intensity (from 3.5 to 1.5 out of 5) (Vernon, 1982).

In a similar study conducted by Boline, Kassak, Bronfort, Nelson and Anderson (1995), which consisted of a 2 weeks baseline period, a 6 weeks treatment period and a 4weeks post treatment, follow-up period. The one group received 6 weeks of spinal manipulation provided by chiropractors and the other 6 weeks of amitriptyline treatment managed by a medical physician. During the treatment period, both groups improved at very similar rates. At the end of the 6-week treatment period, there were no clinically significant or statistically significant differences between the two treatment groups. However the amitriptyline group showed more improvement in headache intensity. In relation to baseline values at 4 weeks after cessation of treatment, the spinal manipulation group showed a reduction of 32% in headache intensity, 42% in headache frequency, 30% in over-the-counter medication usage and an improvement of 16% in functional health status. According to the authors the reason for this improvement could be that spinal manipulation corrects abnormal cervical spine function which in turn would eliminate the source of the pain. Due to the fact that the source of pain was removed it would be expected that the effects of this would last beyond the treatment period. This study revealed that by comparison to spinal manipulation group, the amitriptyline therapy group showed little or no improvement in the same four major outcome measures. Therefore the authors concluded that spinal manipulation is an effective treatment for TTH (Boline et al., 1995).

In contrast, a randomised clinical trial of 75 patients suffering with ETTH revealed a significant reduction in mean daily headache hours (Bove and Nilsson, 1998). This study compared soft tissue treatment of the Trapezius muscle and the muscles deep to it together with cervical spinal manipulation to soft tissue treatment combined with placebo laser. Bove and Nilsson, (1998) found that the results obtained were maintained throughout the observation period although headache pain intensity was unchanged for the duration of the trial. This study seemed to imply that as an isolated intervention, spinal manipulation does not seem to have a positive effect on ETTH (Bove and Nilsson, 1998). However according to Bronfort, Assendelft, Evans, Haas and Bouter (2001) the Bove and Nilsson (1998) trial did not assess the isolated effect of spinal manipulation, but that it looked at the combined effect of spinal manipulation with soft tissue massage. Bronfort et al. (2001) continued to state that it is unknown whether there is an interaction that results from combining spinal manipulation with soft tissue massage and that a more appropriate conclusion would have been that spinal manipulation, when combined with soft tissue massage, is no better than soft tissue therapy alone for ETTH. Therefore, this conclusion neither supports nor refutes the efficacy of spinal manipulation as a separate therapy (Bronfort et al., 2001).

2.6.1.1 Indications for Spinal Manipulation

Schafer and Faye (1990), Peterson and Bergman (2002) cite the following as indications for spinal manipulative therapy:

- increasing spinal mobility,
- freeing entrapped or stretched nerves,
- returning intervertebral discs and intervertebral foramina to their normal boundaries,
- to extend shortened tendons and ligaments and
- to break adhesions.

2.6.1.2 Contra-indications to Spinal Manipulative

Peterson and Bergmann (2002) and Gatterman (1990) cite the following as contra-indications to Spinal Manipulative Therapy:

- tumours,
- aneurysm,
- vertebrobasilar artery insufficiency (VBAI's),
- atherosclerosis of the major blood vessels,
- bone infections (tuberculosis, osteomyelitis),
- traumatic injuries (fractures, severe sprains or strains, instability or hypermobility,
  unstable spondylolisthesis),
- arthritis (Rheumatoid, ankylosing spondylitis, psoriatic arthritis, severe osteoporosis, uncoarthritis),
- metabolic disorders (osteoporosis, osteomalacia, clotting disorders) and
- neurologic complications (disc lesions with advancing neurological deficits, space
  occupying lesions).

2.6.1.3 Mechanical and Physiological Effects of Spinal Manipulative

Gatterman (1995) describes a spinal manipulation as a short lever, specific, high velocity, controlled, forceful thrust by hand aimed at individual articulations. According to Curl (1994) spinal joint manipulation is an assisted passive motion applied to a spinal facet joint and that specific effects of these spinal manipulation, can be narrowed down to the following mechanical and reflex mechanisms:

The reflex mechanisms are:

- Inhibition of pain,
- Inhibition of muscle spasm and
- Stimulation of the autonomic nervous system.

The mechanical mechanisms are:

- Mechano-receptor stimulation,
- Stretching of muscle spindles and
- Increase in active and passive joint motion.

According to Gatterman (1995), Peterson and Bergmann (2002), and Haldeman (2005), spinal manipulation has a twofold effect. It restores the motion to the dysfunctional cervical facet joint and secondly as a result of the restored motion, there is a possibility for the reduction in the inflammation, muscle spasm and oedema which is as a result of the spinal dysfunction (Dvorak, 1985; Gatterman and Goe, 1990; Mense, 1991). Spinal manipulation also increases stimulation of the Type I, II and III Wyke receptors (Wyke, Leach 2004), which result in increase Alpha fibre stimulation and the concomitant closure of the C-fibre pain pathways according to Gate Control theory ascribed to Melzack and Wall (1965). Therefore the spinal manipulation addresses the muscular and cervicogenic factors thought to play a role in the pathophysiology of ETTH.

2.6.2 Allopathic treatment

Rasmussen (1995) suspected that only 16% of all TTH sufferers have attended the rooms of a general practitioner, while even less (4%) have attended the rooms of a specialist. He continues to say that 13% of all TTH sufferers managed without medications. This suggests that a large population of TTH sufferers may be using over the counter medications to treat the headache. Several controlled studies of simple analgesics and NSAIDs for treating TTH have suggested that NSAIDs are the first-line drugs of choice (Fumal and Schoenen, 2008).

2.6.2.1 Ibuprofen ®

Simple analgesics and nonsteroidal anti-inflammatory drugs (NSAID's) are the most widely used drugs in the treatment of TTH (Ashina and Ashina, 2003) and according Schachtel (1996) Ibuprofen is one of the most commonly used over-the-counter analgesics in the USA. In a comparative randomized, controlled trial study conducted by Schachtel (1996), one group received 400mg of Ibuprofen ®, the other group

paracetamol and the last group placebo. This showed that those receiving Ibuprofen ® had the best and quicker pain relief than those receiving paracetamol. Furthermore, a double-blind, threefold, crossover, placebo-controlled study by Nebe, Heier and Diener, (1995) studied the effects of 200 mg of Ibuprofen ® and 500 mg of aspirin in 65 patients with ETTH and found that Ibuprofen ® was significantly superior to aspirin and placebo in decreasing headache intensity on a visual analog scale by a minimum of 50%, 1 hour after treatment. In this regard, Packman, Packman, Doyle, Cooper, Ashraf, Koronkiewicz and Jayawardena (2000) found that a new solubilized formulation of 400 mg of Ibuprofen ® was more effective than 1000 mg of paracetamol and placebo in the treatment of ETTH. The authors reported pain relief 39 minutes after administration of the solubilized formulation of Ibuprofen ®, which was significantly faster than with acetaminophen (47minutes) and placebo (113 minutes).

Ashkenazi and Silberstein (2004), agreed with Packman et al., (2000) study, noting that paracetamol (1000mg) and aspirin (500-1000mg) were effective in the treatment of mild to moderate episodes of ETTH only. They added that NSAIDs (i.e. Ibuprofen ®) were effective in the treatment of pain of mild to moderate ETTH and were also recommended for relief of moderate to severe pain (e.g. Ibuprofen ® 200-400mg).
Therefore Ibuprofen was the drug of choice in this study because it is one of the most widely used, readily available (over-the-counter) and better tolerated by participants (Diamond, 1999).

2.6.2.2 Contra-indications of Ibuprofen ®

In a study done by Diamond (1983) where Ibuprofen ® was compared with aspirin or placebo, it was revealed that side-effects were encountered less frequently among patients on Ibuprofen ® than those taking aspirin or placebo. Diamond (1999) stated that in cases where NSAIDs were not contraindicated, NSAIDs were often the most successful treatment for acute ETTH than simple analgesics. This is supported by the premise that Ibuprofen ® is very effective when used in doses of 400 to 800mg (lower doses are generally better tolerated). But, despite this Diamond (1999) highlighted that aspirin is still used in the treatment of ETTH but NSAIDs are replacing aspirin due to their greater tolerability and efficacy.

Contra-indications to Ibuprofen ® include: pregnancy, especially close to term, hypersensitivity and intolerance to aspirin or NSAIDs and gastrointestinal ulceration. Precautions are warranted should the patient be: suffering with hypertension, impaired renal, hepatic or cardiac function; taking ACE inhibitors or corticosteroids which may increase the severity or frequency of gastrointestinal ulceration, when used by an elderly person (Brunton, Lazo and Parker 2006).

Brunton, Lazo and Parker (2006) outline the following as the common adverse and shared effects of NSAIDs medications:

Table 2.2 Adverse effects - NSAIDS

Gastrointestinal	abdominal pain, nausea, gastric ulcers, anemia, GI bleeding, perforation, diarrhea.
Renal	salt and water retention, edema, decrease effectiveness of hypertensive and diuretic medications, decreased urate excretion, hyperkalemia.
Central Nervous System	headache, vertigo, dizziness, confusion, depression, lowering of seizure threshold, hyperventilation.
Platelets	inhibited platelet activation, propensity for bruising, increased risk of hemorrhage.
Uterus	prolongation of gestation and inhibit labor.
Hypersensitivity	vasomotor rhinitis, angioneurutic edema, asthma, urticaria, flushing, hypotension, shock.
Vascular	closure of ductus arteriosus.

2.6.2.3 Pharmacological Effects of Ibuprofen ®

Ibuprofen ® has three main therapeutic effects, anti-inflammatory, analgesic and antipyretic effect. Ibuprofen ® is a reversible inhibitor of cyclooxygenases. Therefore it inhibits the synthesis of prostoglandins but not that of leukotrienes (Mycek, Harvey and Champe, 2000). On oral administration Ibuprofen ® is rapidly absorbed from the gastrointestinal tract, with peak plasma concentration occurring within 15 to 30

minutes (Brunton, Lazo and Parker, 2006). Ibuprofen ® is almost totally bound to serum albumin in the body and is metabolized by the liver and then excreted (Mycek, Harvey and Champe, 2000).

2.7 CONCLUSION

From this literature review, it is clearly evident that ETTH is a prevalent disorder among the population. It is also evident that cervical spine dysfunction makes a significant contribution to a number of benign forms of headache (Gatterman, 1995). Ibuprofen® has been shown to be effective in the treatment of ETTH. Therefore, the aim of this study is to determine the relative effectiveness of cervical spine manipulation and a nonsteroidal anti-inflammatory drug (Ibuprofen ®) in the treatment of ETTH.

CHAPTER 3: Methodology

3.1 Introduction

The aim of this study was to determine the relative effectiveness of cervical spine manipulation versus NSAIDs (Ibuprofen ®) in the treatment of ETTH.

This chapter covers the specific methods followed in the experimental procedure.
It also provides a description of the design, data, the subjects and the intervention.

3.2 Study Design and Protocol

This study was designed as a prospective randomised clinical trial with two intervention groups. Based on this structure and design, the research was approved by the Faculty of Health Sciences Research and Ethics Committee at the Durban University of Technology, indicating that the research complies with the principles enshrined in the Belmont Report (1979), Declaration of Helsinki (1964) and Nuremberg Code (1949) (Johnson, 2005).

3.2.1 Advertising

Potential participants who suffered with ETTH were recruited by advertisements (Appendix K) which were placed at the Durban University of Technology Chiropractic Day Clinic, Durban University of Technology Campus, local sports clubs, gyms and businesses. The advertisement stated that free treatment for ETTH sufferers was available to people who were willing to participate and then also qualified to take part in this study.

3.2.2 Telephonic interview

Potential participants who responded to the advertisement for this study, had their calls returned and were asked the following questions to gauge the probability of their acceptance onto the research study (Appendix L):

- Do you suffer with headaches that feel like a ‘pressure’ or a tight band around the head?
- Are you between the ages of 18 and 45 years?
- Do you have recurrent episodes of headache lasting for minutes or days?
- Are you receiving current treatment for your ETTH?
- Do you have any previously diagnosed neck, bone, joint or circulatory conditions
  which may have been diagnosed by a qualified doctor?
- Are you able to be involved for the full duration of the research (i.e. 4 appointments in which there are 3 treatments over 2 weeks)?

If the potential participant was likely to fit into the study, the first appointment was scheduled.

3.2.3 Sampling

3.2.3.1 Sampling size

Thirty two participants were randomly divided into two groups of sixteen. Group one were treated using cervical spine manipulation. Group two were treated with Ibuprofen ® taken in the morning (200mg) and evening (200mg), daily for a week.

3.2.3.2 Sampling allocation / method

The allocation of participants to the two groups was completed by means of simple randomization (Mouton, 1996). Thirty two pieces of paper were placed in a hat, 16 pieces of paper for the group receiving cervical spine manipulation and 16 pieces of paper for the group receiving Ibuprofen. Each participant that qualified drew a piece of paper and was told that they had either joined the cervical spine manipulation group or the ibuprofen group. The piece of paper was then discarded.

3.2.4 Inclusion and Exclusion Criteria

3.2.4.1 Inclusion Criteria

Only those participants who met the following inclusion criteria were included in this study.

1. The International Classification of Headache Disorders state:
    - At least 10 previous headache episodes fulfilling criteria listed below.
    - Number of days with such a headache fewer than 180 per year (fewer than 15 per month).
    - Headache lasting from 30 minutes to 7 days.
    - At least 2 of the following pain characteristics:
        a) Pressing or tightening (non-pulsatile) quality.
        b) Mild or moderate intensity (may inhibit but does not prohibit activities).
        c) Bilateral location.
        d) No aggravation by walking up or down stairs or similar routine physical activity.
    - Both of the following:
        a) No nausea or vomiting (anorexia may occur).
        b) Photophobia and phonophobia are absent, or one but not the other is present.
2. All participants needed to be between the ages of 18 to 45 years.
3. All participants (whether male or female) were required to present with a facet dysfunction of the cervical spine.
4. All participants received a letter of Information informing them about the study (Appendix A). They then had to read it and sign that they had understood the parameters of the study as per the Informed Consent Form (Appendix B), if they agreed to voluntarily participate in the study.

3.2.4.2 Exclusion Criterion

Participants were excluded from the study for the following:

1. If the participant presented the following as stipulated by the International Headache Society (ICHD1, 1988):

   History, physical or neurological examinations that suggest one of the following:

   a) Trauma.
   b) Vascular disorders.
   c) Non-vascular intracranial disorders.
   d) Substances abuse or the presence of withdrawal from substance abuse.
   e) Non-cephalic infection.
   f) Metabolic disorders.
   g) Disorders of the cranium, neck, eyes, nose, sinuses, teeth, mouth or other facial or cranial sutures.

2. If any contra-indications to spinal manipulation therapy (Peterson and Bergman, 2002; Bergman *et al.* 1993; Edmund, 1993; Gatterman, 1990), including but not limited to :

   a) Marked osteoporosis that was previously diagnosed.
   b) Ankylosing Spondylitis and related systemic arthritides.
   c) The presence of fever, tumours, tuberculosis or any infectious disease.
   d) Local inflammation, thrombosis, metal implants or a hip prosthesis.
   e) Spinal fusion or spinal surgery.
   f) Acute disc herniation / prolapse.
   g) Vascular aneurysms and vertebrobasilar insufficiencies.
   h) Spondylolistheses.
   i) Severe scoliosis,
   j) Hypertension,

3. If radiographic examination of the cervical spine was required to rule out contra-indications to spinal manipulation, then the potential participant was excluded from the study.

4. If the participant received any form of manual treatment or medication for the headache or the neck pain during the course of the study (Poul, West, Buchanan, and Grahame, 1993; Seth, 1999).

5. Participants with contraindications to NSAIDs including but not limited to the following:

    a) Contraindications to NSAIDs (Ibuprofen ®):

    Safety of Ibuprofen ® in pregnant woman has not been demonstrated and therefore is contra-indicated during pregnancy (Sandoz, 1997). In addition peptic / gastric / duodenal ulceration are known contraindications to the use of Ibuprofen ®.

    b. Precautions / relative contra-indications to NSAIDs (Ibuprofen ®) (Sandoz, 1997):

        a) Ibuprofen ® should not be given to participants thought to have peptic ulceration and should be used with caution in a participant with a history of indicating the possibility of previous gastric irritation with such medication. Ibuprofen ® should also be used with restraint in participants who have known infections.

        b) Other relative contraindications include participants with haemorrhagic conditions, asthma, a history of hypersensitivity reactions to aspirin or other NSAIDs, hypertension, impaired cardiac, hepatic and / or renal function.

        c) The development of blood, kidney, and liver or eye conditions whilst on the Ibuprofen ®, excluded the participant.

        d) With Ibuprofen ® having the potential to cause fluid retention, heart failure may be precipitated in some

compromised participants and therefore participants that had signs of compromise or developed signs of compromise were excluded.

c. Drug interactions (Sandoz, 1997):

a) Ibuprofen® may enhance effects associated with oral anticoagulants, increasing the plasma concentrations of lithium, methotrexate and cardiac glycosides. Therefore these participants were closely monitored and excluded if signs of problems arose.

b) The risk of nephrotoxicity may be increased if given with angiotensin-converting enzyme inhibitors, cyclosporine or diuretics. Additionally an increased risk of hyperkalemia with angiotensin-converting enzyme inhibitors and potassium-sparing diuretics is possible. Therefore any potential participant on medication with these characteristics was excluded.

c) The effects of antihypertensive agents including, but not limited to angiotensin-converting enzyme inhibitors, beta-blockers and diuretics may be reduced. Therefore any potential participants on these medications were excluded.

d) Potential participants on quinolones were excluded to prevent the possibility of convulsions due to medication interaction.

e) Ibuprofen ® may enhance the effects of phenytoin and sulphonylurea antidiabetic medication and therefore potential participants taking these medications were excluded.

f) Any potential participant that was on corticosteroids and could not go through a wash-out period was excluded from the study.

g) Alcohol in conjunction with NSAIDs (Ibuprofen ®), may increase the likelihood of participants having had gastric upset. Therefore participants were requested to avoid alcohol consumption for the duration of the study. If however

gastric upset arose the participants were excluded from further participation.

3.2.5 Procedure

Once the potential participant had been received at the first visit, the assessment and treatment protocol were clearly explained to them. All participants that were included in the study were required to read through a letter of information (Appendix A) and fill in an informed consent form (Appendix B).

All the potential participants were evaluated at the initial consultation during which a case history (Appendix C), physical (Appendix D) and cervical spine regional (Appendix E) examination were performed; in order to screen for suitability for the study by means of the inclusion and exclusion criteria. In addition cervical facet joints with dysfunction were identified in the cervical spine by means of motion palpation (Schafer and Faye, 1998).

3.2.5.1 Intervention methods

Group 1 (Spinal manipulation group)

The spinal manipulation group had their cervical spine motion palpated as outlined by Schafer and Faye (1998) and all the dysfunctions were identified and recorded at each consultation by the researcher. There was no treatment given at the first consultation. For the first week the participant was required to complete a headache diary (Rasmussen, Jensen, Schroll and Olesen 1992).The treatment commenced in the second week.

The participant received the relevant spinal manipulation to the dysfunctional cervical spine segment according to the motion palpation findings which was administered by the researcher. The dysfunctions were manipulated using methods outlined by Bergmann, Peterson, and Lawrence 1993) and Szaraz, (1990). If the participant had more than one dysfunction then all the dysfunctions were manipulated.

In week three the participants again completed the headache diary (Rasmussen, Jensen, Schroll and Olesen 1992), before their involvement in the study was complete.

Group 2 (medication group - Ibuprofen ®**)**

The treatment also commenced in the second week for the medication group, with the participants having to complete a head diary (Rasmussen, Jensen, Schroll and Olesen 1992) in the first week. The participant then, received their full prescription of Ibuprofen for the 7 day period from a qualified pharmacist (Appendix M). The participant was told to take one pill (200mg) in the morning after a meal and to take another pill (200mg) in the evening after a meal daily for the 7 days of the second week. According to Diamond (1999), 400mg of ibuprofen is more effective and better tolerated than higher doses.

In week three the participants again completed the headache diary (Rasmussen, Jensen, Schroll and Olesen 1992), before their involvement in the study was complete.

3.2.5.2 Intervention frequency

Table 3.1 Intervention frequency

Appointment	TREATMENT	Week	DAY OF TREATMENT	Data collection [1]
1st	Screening for suitability of the study was done. Participants received the headache dairy.	1	Week before treatment.	1. NRS -101 Questionnaire. 2. Short-Form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
2nd	Group one was treated using cervical spine manipulation. Group two received the Ibuprofen which was taken daily for 7 days. Participants took 200mg in the morning after a meal and 200mg in the evening with after a meal daily.	2	DAY1	1. NRS -101 Questionnaire. 2. Short-Form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
3rd	Group one: subjective measurements were obtained prior to the cervical spine manipulation. Group two: subjective measurements were obtained.		DAY4	1. NRS -101 Questionnaire. 2. Short-form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
4th	Group one: subjective measurements were obtained prior to the cervical spine manipulation. Group two: subjective measurements were obtained.		DAY7	1. NRS -101 Questionnaire. 2. Short-form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
5th	There was no treatment and subjective measurements were obtained for both groups.	3	Week after treatment.	1. NRS -101 Questionnaire. 2. Short-form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.

[1] Note that the participants were expected to complete a headache diary (Rasmussen, Jensen, Schroll and Olesen 1992) for a week before the intervention was commenced, during the period of intervention (second week) and for a week after the completion of the intervention (third week).

Participants received three treatment of spinal manipulation over a period of one week. This was in keeping with recommendations by a consensus conference for the Chiropractic profession which stated that for acute uncomplicated cases, three to five treatment sessions per week for one to two weeks were acceptable (Haldeman, Chapman-Smith and Petersen, 1993). The course of ibuprofen was given only over a period of a week to decrease the chance of developing adverse reaction and side effects.

3.2.6 Measurements and Observations

The data consisted of:

- The Short-Form McGill Pain Questionnaire (SF-MPQ) (Appendix I) (Melzack, 1987).
- Disability as determined by the CMCC Neck Disability Index (Appendix J) (Vernon and Mior, 1991).
- Pain perception as determined by the Numerical Rating Scale 101 Questionnaire (NRS – 101) (Jensen, Karoly and Braver, 1986) (Appendix H).
- Characteristics of headache and effects of treatment as determined by the Headache Diary (Appendix G) (Rasmussen, Jensen, Schroll and Olesen 1992).

3.2.6.1 Short-Form McGill Questionnaire (Melzack, 1987)

The Short-Form McGill questionnaire was used to acquire subjective information on the character, the intensity and how the pain affected the participant. According to Melzack (1987) it has a high correlation with other recognized questionnaires, is sensitive for traditional therapies and easy to understand. The first 11 questions deal with the sensory perception (character) of pain and the last 4 questions deal with how the pain affects the participant. A zero score indicates no pain while a score of three indicates the most severe pain for each question. The participant had to answer all the questions and the scores were added together and a percentage was calculated.

3.2.6.2 CMCC Neck Disability Index (Vernon and Mior, 1991)

The CMCC Neck Disability Index was used to assess how the pain affected the participant's ability to manage everyday life. It assesses disability experienced by the participant in relation to the pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. The participant was asked to mark in each section the one block which described their disability the most. A zero score indicated no disability while a score of five indicated the maximum disability. A total was added from all the sections and a percentage disability was calculated. The CMCC Neck Disability Index has been shown to have a high degree of test-reset reliability and internal consistency, and acceptable level of validity and sensitivity to severity variation (Vernon and Mior, 1991).

3.2.6.3 Numerical Rating Scale 101 Questionnaire (Jensen, Karoly and Braver 1986)

The Numerical Rating Scale 101 was used to assess the intensity of the pain the participant experienced during the study. It has two lines which depict pain intensity. Each line indicated a scale of 0 to 100. On the top line, the participant was asked to indicate a number between 0 and 100 that best described the pain they experienced when it was at its worst. Zero meant the participant did not experience pain at all and hundred meant pain as bad as it could get. On the bottom line the participant was asked to indicate a number between zero and hundred that best described the pain they experienced when it was at its least. The values representing the participant's worst and least pain intensity were added together and divided by two to get an average. According to Jensen, Karoly and Braver (1986), the NRS-101 is considered to be statistically sensitive and most practical in measuring clinical pain.

3.2.6.4 Headache Diary

At the initial consultation the participant was given a headache diary which they were requested to take home, and fill in for the duration of the study (7 days prior to treatment, during the treatment week, 7 days after treatment). The researcher explained to the participant how to complete the diary. The diary included details of

headache intensity, duration, associated symptoms, nature of pain and frequency. Each row of blocks represented a 24 hour day in which the participant recorded the events of that day (i.e. how many headaches they had, intensity and so forth). The participant was required to bring the diary at each consultation so that the researcher could make sure that it was filled in correctly. The Headache Diary was collected at the fifth consultation, 21 days after initial consultation.

Rasmussen et al., (1992) found the headache diary more precise at giving qualitative and quantitative diagnosis. The Headache Diary used in this study was adapted from the headache diary used by de Busser (2001) and Penter (1994). The Headache Dairy was used effectively in both these studies.

3.2.7 Measurement and Observation Frequency

The data was collected by the researcher from the participants at the DUT Chiropractic Day Clinic. All the data was recorded in each of the participant's files at the time of the visit.

At each consultation the participant was required to complete a SF-MPQ (Melzack, 1987), a NRS-101 (Jensen, Karoly and Braver 1986) and the CMCC Neck Disability Index (Vernon and Mior, 1991).

The participant received a Headache Diary (Rasmussen et al., 1992) which they took home and were required to fill in during the three week duration of the study.

Table 3.2: Measurement Frequency

Appointment	TREATMENT	Week	DAY OF TREATMENT	Data collection [2]
1st	Screening for suitability of the study was done. Participants received the headache dairy.	1	Week before treatment.	1. NRS -101 Questionnaire. 2. Short-Form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
2nd	Group one was treated using cervical spine manipulation. Group two received the Ibuprofen which was taken daily for 7 days. Participants took 200mg in the morning after a meal and 200mg in the evening with after a meal daily.	2	DAY 1	1. NRS -101 Questionnaire. 2. Short-Form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
3rd	Group one: subjective measurements were obtained prior to the cervical spine manipulation. Group two: subjective measurements were obtained.		DAY 4	1. NRS -101 Questionnaire. 2. Short-form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
4th	Group one: subjective measurements were obtained prior to the cervical spine manipulation. Group two: subjective measurements were obtained.		DAY 7	1. NRS -101 Questionnaire. 2. Short-form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.
5th	There was no treatment and subjective measurements were obtained for both groups.	3	Week after treatment.	1. NRS -101 Questionnaire. 2. Short-form McGill Pain Questionnaire. 3. CMCC Neck Disability Index.

[2] Note that the participants were expected to complete a headache diary (Rasmussen, Jensen, Schroll and Olesen 1992) for a week before the intervention was commenced, during the period of intervention (second week) and for a week after the completion of the intervention (third week).

3.3 STATISTICAL METHODS AND ANALYSIS

3.3.1 The Objectives

- The effectiveness of Ibuprofen treatment in terms of subjective clinical measures which included the intensity, duration, frequency of the headache, associated symptoms and changes in lifestyle.
- The effectiveness of a spinal manipulation in terms of subjective clinical measures which included the intensity of the headache, duration, frequency, associated symptoms and changes in lifestyle.A relative effectiveness in subjective clinical measures in cervical spine manipulation versus Ibuprofen ® groups in the treatment of ETTH.

3.3.2 The Data required to address the objectives

The data needed for testing the hypothesis was the responses of the patients to the NRS – 101 (Jensen, Karoly and Braver 1986) (Appendix H), the SF-MPQ (Melzack, 1987) (Appendix I), the CMCC Neck Disability Index (Vernon and Mior, 1991) (Appendix J) and Headache Dairy (Appendix G) (Rasmussen et al., 1992).

3.3.3 Treatment of the Data

Subjective Data

The subjective data was treated in the following manner:

- All questionnaires and Headache Diaries that were completed by each participant were screened to ensure that they had been completed correctly. Raw data from the headache diaries was recorded separately for each group.
- Raw data from the NRS-101 (Jensen, Karoly and Braver, 1986) and the CMCC Neck Disability Index (Vernon and Mior, 1991) (Appendix J) was converted into a percentage and recorded separately for each group.
- Raw data from the SF-MPQ (Melzack, 1987) (Appendix I) was recorded only for the spinal manipulation group, as the Ibuprofen ® group was not able to comment.

- The data was analysed using a 95% confidence interval (5% level of significance).

3.3.4 The Decision Rule and the Null Hypothesis

The Null hypothesis (Ho) stated that there was no significant difference in the participant's condition between the two groups in terms of subjective clinical findings, at α =0.05 level of significance. The alternative hypothesis (H_1) stated that there was a significant difference in participant's condition between the two groups in terms of subjective clinical findings.

Decision rule: If the *p*-value was less than α =0.05 level of significance, the null hypothesis was rejected. Otherwise the null hypothesis was accepted at the same level. *p* was the observed significant level.

3.3.5 Statistical Analysis of the Data

An external statistician was consulted on how to statistically analyse the data obtained from this research study. Data was transferred to a spreadsheet and statistical analysis was conducted at a 5% level of significance.

SPSS version 15.0 (SPSS Inc., Chicago, Illinois) was used to analyse the data. A *p* value <0.05 was considered as statistically significant. Independent samples t-test was used to compare quantitative normally distributed variables between the two treatment groups. Pearson's chi square test was used to compare categorical variables between the treatment groups.

Repeated measures ANOVA testing was used to compare NRS-101 and CCMC Neck Disability Index between treatment groups over time. Repeated measures ANOVA was also used to examine the intra-group time trends in the manipulation group in terms of the SF-MPQ. The generalized estimating equations (GEE) family of generalized linear models were used to assess the headache diary variables which were collected over a period of 21 days each. Profile plots were used to assess visual trends of rate of change in each variable over time by treatment group.

Symptom data were multiple response variables and each was relatively rarely reported, making GEE analysis of these outcomes unreliable and invalid. Thus the number of times that each symptom was reported each week for each participant was summed up and the GEE analysis was conducted on the weekly level of measurement rather than the daily level.

3.3.6 Definitions of tests used

- SPSS version 15.0 (SPSS Inc., Chicago, Illinois): Statistical Package for the Social Science is a computer package for analysis of statistical data (Graziano and Raulin, 2004:428).

- Independent samples t-test: a statistical technique designed to analyze mean differences between two independent groups Graziano and Raulin, 2004:429).

- Analysis of variance (ANOVA): a statistical technique that is used for analysing mean differences between two or more groups, by comparing the variability between the groups with the variability within groups Graziano and Raulin, 2004:410).

- The generalized estimating equations (GEE): The generalized estimating equations, an extension of the quasi-likelihood, is a method that is often used to analyze inter-correlated and longitudinal data, particularly if responses are binary (Hanley, Negassa, Edwardes, and Forrester, 2002).

- Pearson's chi square test: is one of the best known chi square tests. It is a statistical distribution that forms the foundation for inferential statistics used with nominal data. This method tests whether two or more variables are independent or homogeneous (Graziano and Raulin, 2004:412).

CHAPTER 4: Results and Discussion

4.1 Introduction

This chapter presents the results and discussion of the statistical analysis of the primary data. Demographic data and inter-group data collected from the study are presented in tabular form and graphs. The following measurements were reported on: Numerical Rating Scale 101 Questionnaire (NRS-101) (Jensen, Karoly and Braver, 1986), the Short-Form McGill Pain Questionnaire (SF-MPQ) (Melzack, 1987), the CMCC Neck Disability Index (Vernon and Mior, 199) and Headache Diary (Rasmussen et al., 1992).

4.2 Criteria Governing the Admissibility of the Data

The questionnaires that were used as data for the study included the NRS-101 (Jensen, Karoly and Braver, 1986), the SF-MPQ (Melzack, 1987) and the CMCC Neck Disability Index (Vernon and Mior, 1991). These were completed under the researcher's supervision. The headache diary was completed by the participant at home for the duration of the study (21 days) and returned to the researcher.

The level of significance was set at $\alpha = 0.05$. The null hypothesis was rejected when $p < 0.05$ and was not rejected (accepted) when $p \geq 0.05$.

4.3 Abbreviations Used In Tables

1. B - Beta coefficient
2. CMCC - CMCC Neck Disability Index
3. df - Degree of freedom
4. F - F statistic
5. n - Number
6. NRS - Numerical Rating scale
7. Std - Standard

4.4 Attendance to the Study

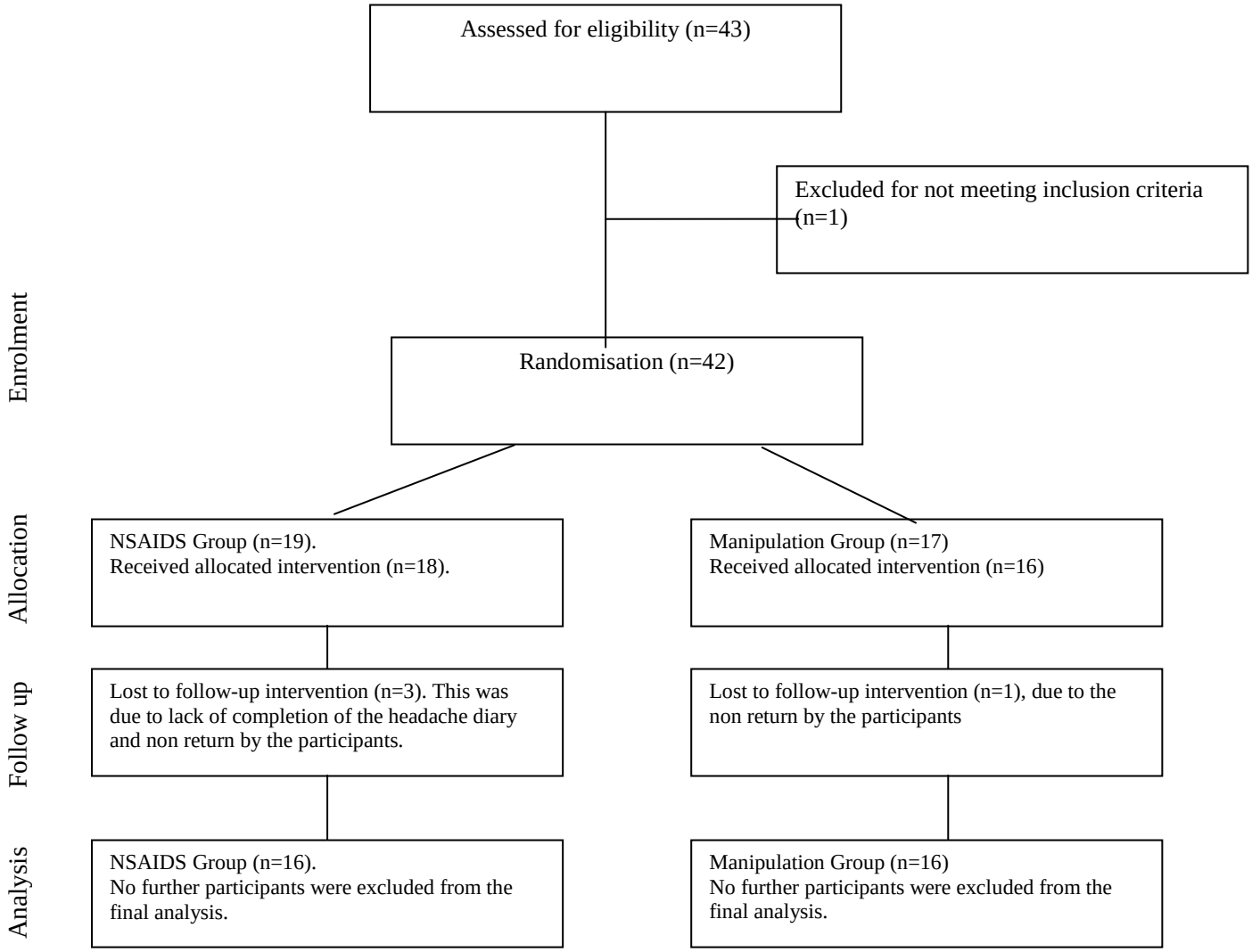

Figure 4.4. Flow diagram of progression through the phases of the randomised controlled trial.

Forty three potential participants were accepted for the first consultation. One was excluded because she did not meet the inclusion criteria for the study. Thereafter 2 dropped out during the first week prior to treatment due to non compliance with the research protocol. A further three from the medication group were excluded because two did not return the headache diary, and the other withdrew without reason. One withdrew without reason from the manipulation group. Therefore thirty two people qualified for and completed the study.

4.5 Demographics

4.5.1 Age

Table 4.5.1: T-test comparison of age between treatment groups

	Treatment	n	Mean	Std. Deviation	Std. Error Mean	*p* value
Age	Manipulation	16	23.06	4.973	1.243	0.091
	Medication	16	27.38	8.461	2.115	

There was a non statistically significant difference in mean age between the two treatment groups (*p*=0.091). The mean age was slightly higher in the medication group.

Both groups had a mean age lower than 30. This is not in accordance with the literature where it was noted that the prevalence of TTH peaks between the ages of 30 and 39 years in men and women and decreases thereafter for both genders (Schwartz et al, 1998). Reasons for this may have been because the Clinic from which the study was conducted, was a Campus based clinic and therefore mostly younger aged students replied to the advertisement, thereby skewing the data results with respect to age in favour of a younger mean average.

4.5.2 Gender

Table 4.5.2: Chi square test comparison of gender between treatment groups.

			Treatment		Total
			Manipulation	Medication	
Gender	Male	Count	6	5	11
		% within gender	54.5%	45.5%	100.0%
	Female	Count	10	11	21
		% within gender	47.6%	52.4%	100.0%
Total		Count	16	16	32
		% within gender	50.0%	50.0%	100.0%

p=1.000

There was statistically no difference in gender distribution between the two treatment groups (*p*=1.000). Even though there was no difference in the distribution in gender between the two groups, the male to female ratio was in accordance to the literature.

The sample consisted of thirty two participants, of whom 11/32 (34%) were male and 21/32 (66%) were female. According to Schwartz et al., (1998) the male:female prevalence ratio was 1:1.16, revealing that women are only slightly more affected by ETTH. This was regardless of their age, ethnicity or educational level. This concurs with the statement that ETTH is more prevalent in females than in males (Rasmussen et al., 1991 and Schwartz et al., 1998).

4.5.3 Ethnicity

Table 4.5.3: Chi square test comparison of ethnic group between treatment groups

			Treatment		Total
			Manipulation	Medication	
Ethnicity	Black	Count	10	9	19
		% within ethnic group	52.6%	47.4%	100.0%
	White	Count	3	7	10
		% within ethnic group	30.0%	70.0%	100.0%
	Indian	Count	3	0	3
		% within ethnic group	100.0%	.0%	100.0%
Total		Count	16	16	32
		% within ethnic group	50.0%	50.0%	100.0%

p=0.098

There was no significant difference in ethnic groups between the treatment groups (p=0.098). In total there were 19 Black participants, 10 White participants and 3 Indian participants who took part in the study. A study by Schwartz et al., (1998) found that Whites had a higher prevalence of ETTH when compared to African American men and women. Majority of students at the campus where the study was conducted are Black people (Kisten, 2009), which could be the reason for the higher number of responses from Black participants. The other reason could simply be due to poor response from the other ethnic group.

4.5.4 Location of pain

Table 4.5.4: Location Frequencies (more than one option was indicated)

		Responses		Percent of Cases
		n	Percent	n
Location(a)	Frontal	17	36.2%	53.1%
	Occipital	14	29.8%	43.8%
	Bilateral temporal	14	29.8%	43.8%
	Parietal	1	2.1%	3.1%
	Unilateral temporal	1	2.1%	3.1%
Total		47	100.0%	146.9%

a Dichotomy group tabulated at value 1.

Some participants reported multiple locations of their headaches. The headaches were mostly located in the frontal region (53.1%) followed by the bilateral temporal and the occipital regions (43.8% each). According to Bates (2003:170) the location of ETTH is usually bilateral, but may be generalised or localised to the back of the head and upper neck, or to the frontotemporal area. Kidson (2001) found that majority of the participants in his study complained of a frontal pain followed by occipital and temporal pain in terms of location. This concurs with the later findings of Prithipal (2003) and seems to concure with the earlier study by Vernon et al. (1992), who found the most commonly affected headache locations were occipital, frontal, orbital and temporal. Therefore the location of the headache in this study correlates with these studies.

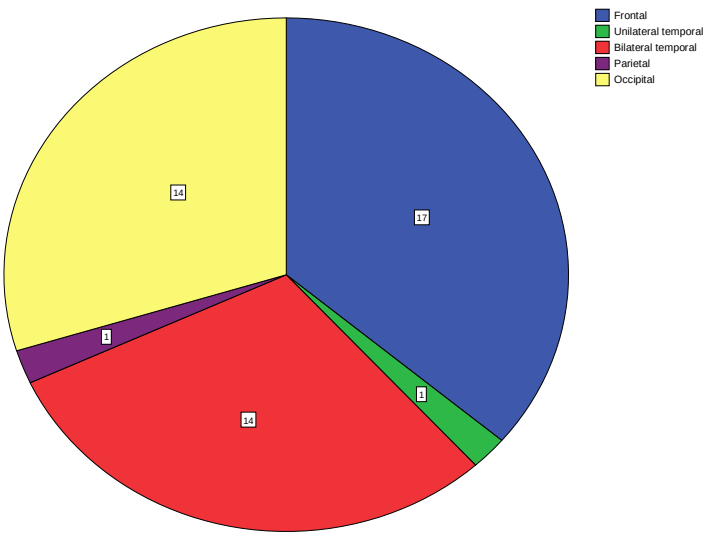

Figure 4.5.4: Pie Chart of the location of headaches in the sample

4.6 Subjective outcomes

4.6.1 CMCC Neck Disability Index

Table 4.6.1: Within- and between-subjects effect for CMCC

Effect	Statistic	*p* value
Time	Wilk's Lambda=0.288	<0.001
Time*group	Wilk's Lambda=0.793	0.167
Group	F=2.754	0.107

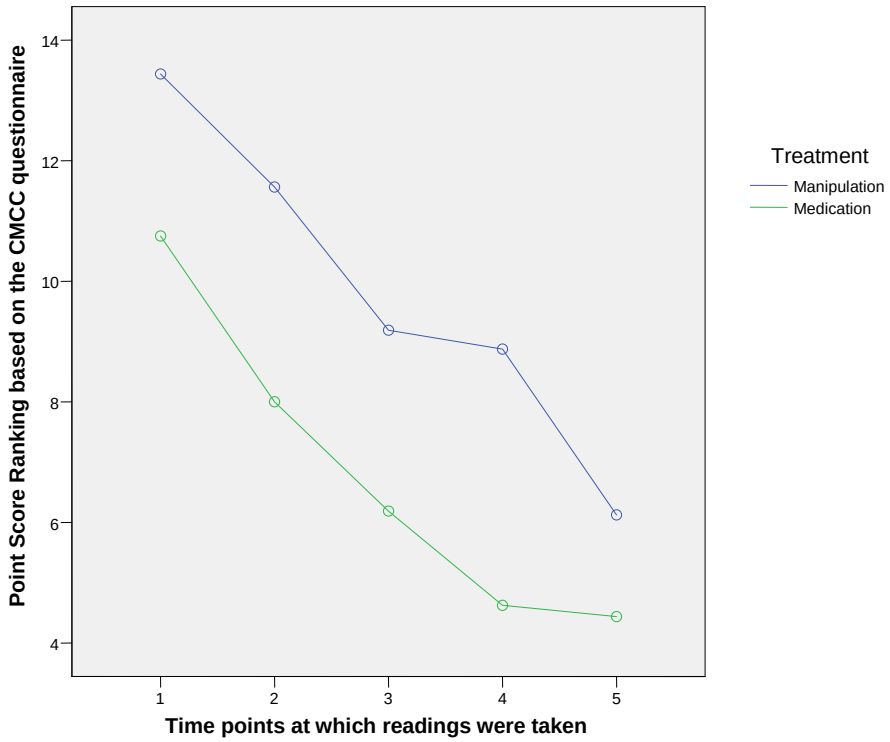

Figure 4.6.1: Profile plot of mean CCMC over time by group

There was a non significant treatment effect for CMCC (p=0.167). Figure 4.6.1 shows that the rate of decrease for both groups was similar. There was a highly significant time effect (p<0.001) which meant that both groups decreased significantly over time.

At the first consultation, none of the participants received any treatment (i.e. both groups), yet in both groups the CMCC scores decreased over the week before the treatment week. This could be due to an influence of the researcher, as the

participants might have improved due to the researcher's influence (commonly known as the Hawthorne effect) (McCarney et al., 2007).

There was a significant decrease in the CMCC scores after the treatment for both groups but a plateau effect was seen between the third and fourth consultation in the manipulation group.

When one considers that a joint dysfunction has both an inflammatory component and a motion restriction component (Gatterman, 1990; Gatterman, 1995; Leach, 2004; Haldeman, 2005). It may be possible to describe the differences in treatment effects between the groups as reflected in the CMCC based on these components.

In the Ibuprofen ® group the relief of symptoms would be related directly to pain mediators and possibly inflammation being decreased (Brunton, Lazo and Parker, 2006) thereby allowing for the participant to perceive a reduction in the symptomatology and a possible increase in activities of daily living. This effect however only lasts for as long as the medication is present in the participant (Brunton, Lazo and Parker, 2006). Therefore it is expected that the week after intervention (where no medication was allowed according to the research protocol), that the participants level of activity starts to plateau.

In contrast, when one looks at the manipulation group, the effect of the manipulation is potentially two fold. Firstly manipulation restores the motion to the dysfunctional cervical facet joint (Gatterman, 1995; Peterson and Bergmann, 2002; Haldeman, 2005) and secondly as a result of the restored motion, there is a possibility for the reduction in the inflammation and oedema (Dvorak,1985; Gatterman and Goe, 1990; Mense, 1991.) as well as increased stimulation of the Type I.II and III Wyke receptors (Wyke, 1981; Leach, 2004) (limited in the NSAIDs group as the restriction of movement is still present), which result in increase Alpha fibre stimulation and the concomitant closure of the C-fibre pain pathways according to Gate Control theory ascribed to Melzack and Wall (1965), However in order to achieve these outcomes there is often a need to break adhesions (Vernon and Mrozek, 2005), which may be responsible for an initial period of pain and discomfort as they of themselves also

result in inflammation and oedema (Leach, 2004; Peterson and Bergmann, 2002; Dvorak et al., 1992). Therefore it is anticipated that the participants may have had mild subjective symptoms, which may have included transient episodes of increased discomfort and headache. These are thought to resolve spontaneously (Leach, 2004; Peterson and Bergmann, 2002:108; Dvorak et al., 1992), as a result of the restored motion in the cervical facet but may have been the reason for limited improvement compared to the medication group.

Additionally due to relatively short period of time between treatment days (3-4 days) participants might have experienced some of these reactions to the manipulations which would have been perceived as a lack of improvement and would explain the plateau effect.

Research needs to be done to determine if this plateau effect was due to the reactions to manipulation or other reasons.

4.6.2 Numerical Rating Scale 101 Questionnaire

Table 4.6.2: Within- and between-subjects effect for NRS

Effect	Statistic	*p* value
Time	Wilk's lambda=0.292	<0.001
Time*group	Wilk's Lambda=0.587	0.005
group	F=1.584	0.218

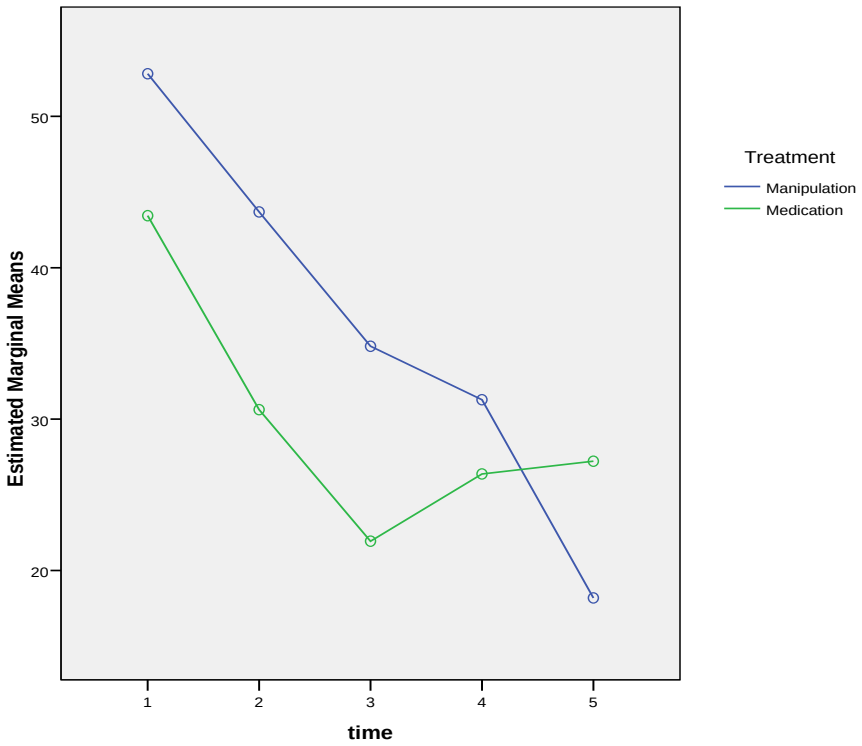

Figure 4.6.2: Profile plot of mean NRS over time by group

There was a significant treatment effect for NRS (p=0.005). The effect shown in Figure 4.6.2 was that the NRS mean value decreased in a linear fashion in the manipulation group while in the medication group this was true up to time point 3 when the pain level started to increase. Thus, overall the manipulation group showed a greater decrease in pain than the medication group.

This is keeping with a study by Vernon (1982), who found a statistically significant reduction in headache activity as measured by frequency, duration and intensity. This was also echoed by Boline et al. (1995) in their study, where a reduction of 32%

in headache intensity in the manipulation group was found. There was a significant decrease in pain intensity after the first treatment for both groups but a slight plateau effect was seen between the third and fourth consultation in the manipulation group. This could be due to reasons discussed above in Section 4.6.1.

There was an increase in pain intensity after the third consultation in the medication group. But, there was still decrease in pain intensity a week after the treatment week in the manipulation group, showing that manipulation has a longer lasting effect on pain intensity than the medication. When one considers that a joint dysfunction has both an inflammatory component and a motion restriction component (Gatterman, 1990; Gatterman, 1995; Leach, 2004; Haldeman, 2005), it may be possible to describe the differences in treatment effects between the groups. The medication group would have relief of symptoms related directly to pain mediators and possibly inflammation (Brunton, Lazo and Parker 2006) thereby allowing for the participant to perceive a reduction in the symptomatology. This effect however only lasts for as long as the medication is present in the participant. Therefore it is expected that the week after intervention (where no medication was allowed according to the research protocol), that the participants pain got worse again as the inflammatory cycle was no longer inhibited. It also supports the possibility that the inflammatory component has an origin that cannot be addressed by the Ibuprofen ® alone.

However in manipulation group, the effect of the manipulation is potentially two fold. Firstly manipulation restores the motion to the dysfunctional cervical facet joint (Gatterman, 1995; Peterson and Bergmann, 2002; Haldeman, 2005). Secondly as a result of the restored motion, there is a possibility for the reduction in the inflammation / oedema (Dvorak, 1985; Gatterman and Goe, 1990; Mense, 1991) as well as increased stimulation of the Type I.II and III Wyke receptors (Wyke, 1981; Leach, 2004) (limited in the NSAIDs group as the restriction of movement is still present), which result in increase Alpha fibre stimulation and the concomitant closure of the C-fibre pain pathways according to Gate Control theory ascribed to Melzack and Wall (1965),

4.6.3 Short-Form McGill Pain Questionnaire

This outcome was only measured in the manipulation group, because the medication group would not have been required to comment on different pain sensations as a result of the medication reducing the pain and therefore pain sensation (headache character). There was a significant change in this outcome over the five time points in the manipulation group (p=0.002).

Table 4.6.3: Within-subjects effect for Short-Form McGill Pain Questionnaire

Effect	Statistic	*p* value
Time	Wilk's lambda=0.261	0.002

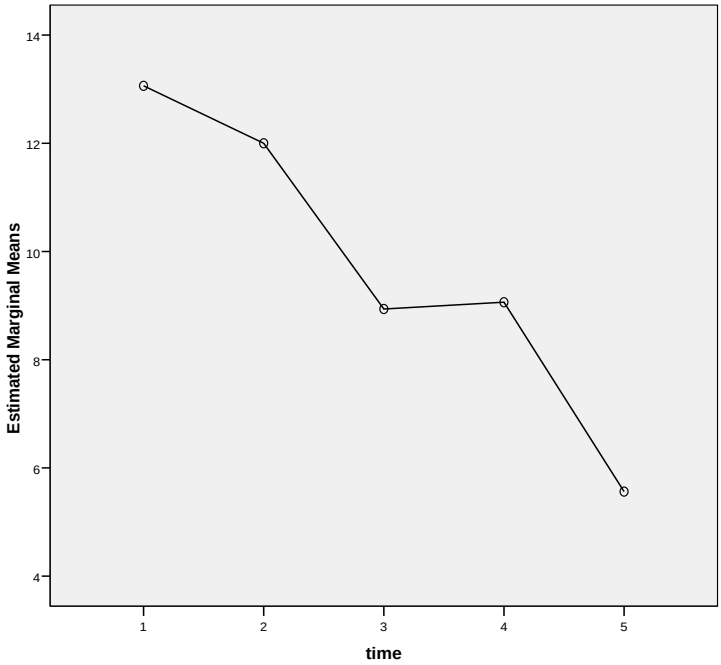

Figure 4.6.3: Profile plot of mean Short-Form McGill Pain Questionnaire score over time by group

Figure 4.6.3 shows that the mean value decreased in an almost linear fashion in the manipulation group. This showed that manipulation can improve the headache character. A plateau effect was seen between the third and fourth consultation in the manipulation group. This is in agreement with discussions in Sections 4.6.1 and 4.6.2, where the CMCC and the NRS respectively had a plateau effect between the third and fourth consultation in the manipulation group.

4.7 Headache Diary

4.7.1 Presence of headaches

The presence or absence of a headache on any day over the 21 days of observation using the headache diary was a binary variable (0 or 1) and thus modelled using a binomial distribution (an exchangeable correlation matrix was specified). The independent variables used in the model were treatment group (manipulation vs. medication), day (the 21 days of observation), and the interaction between day and treatment group (the treatment effect).

Table 4.7.1: GEE model for presence of headaches

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-.517	.1177	-.748	-.286	19.302	1	.000
Day	-.011	.0088	-.028	.006	1.589	1	.207
[Treatment=manipulation]	.438	.1368	.170	.706	10.262	1	.001
[Treatment=medication]	0(a)	.	.	.	.	.	.
[Treatment=manipulation] * day	-.026	.0131	-.052	.000	3.936	1	.047
[Treatment=medication] * day	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: Presence of headache that day

Model: (Intercept), day, treatment, treatment * day

a Set to zero because this parameter is redundant.

Table 4.7.1 shows the results of the analysis. The interaction between treatment group and time was significant (p=0.047), thus there was a significant differential treatment effect between the treatment groups over time.

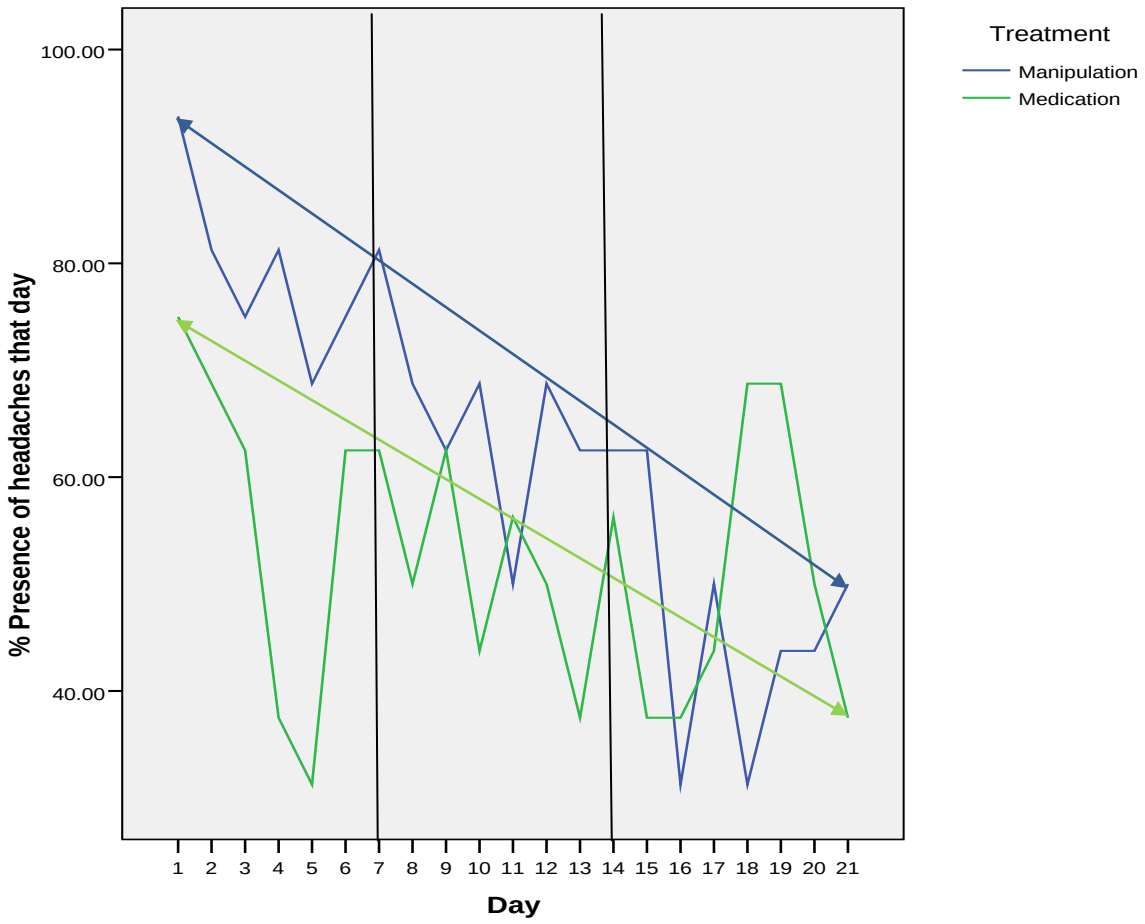

Figure 4.7.1: Percentage of headaches over time by treatment group

Figure 4.7.1 shows that at the start of the research, the spinal manipulation group had a higher prevalence of headaches than the medication group. This is an interesting anomaly, in that the medication group was the “older” of the two groups by mean age (Section 4.5.1); so it stands to reason that the medication group should have been the group reporting an increased number of headaches (Schwartz et al, 1998). The reason for this anomaly cannot be accounted for in this research.

Notwithstanding the above, both groups showed a decrease in the presence of headache in the first week, which agrees with the earlier suggestion of a possible Hawthorne effect (McCarney, Warner, Iliffe, van Haselen, Griffin and Fisher, 2007) (Section4.6.1). Thereafter, the rate of decrease in the presence of headache in the manipulation group dropped over time while the rate in the medication group stayed relatively constant over time. Therefore, the spinal manipulation was effective at reducing the daily presence of headaches. This is in agreement with a study by

Vernon (1982) who reported statistically significant reductions in headache activity as measured by frequency. Additionally this would concur with the findings and discussions of the CMCC and NRS-101 in Section 4.6.1 and 4.6.2 respectively.

4.7.2 Number of headaches

The number of headaches on any day over the 21 days of observation using the headache diary was a count variable (values ranged between 0 and 4 per day) and thus modelled using a Poisson distribution (with an exchangeable correlation matrix specified). The independent variables used in the model were treatment group (manipulation vs. medication), day (the 21 days of observation), and the interaction between day and treatment group (the treatment effect).

Table 4.7.2: GEE model for number of headaches

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-.417	.1611	-.733	-.101	6.701	1	.010
Day	-.009	.0111	-.031	.012	.731	1	.393
[Treatment=manipulation]	.574	.2004	.182	.967	8.215	1	.004
[Treatment=medication]	0(a)	.	.	.	.	.	.
[Treatment=manipulation] * day	-.039	.0167	-.072	-.007	5.595	1	.018
[Treatment=medication] * day	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: Number of headaches per day

Model: (Intercept), day, treatment, treatment * day

a Set to zero because this parameter is redundant.

Table 4.7.2 shows the results of the analysis. The interaction between treatment group and time was statistically significant (p=0.018), thus there was a significant differential treatment effect between the treatment groups over time.

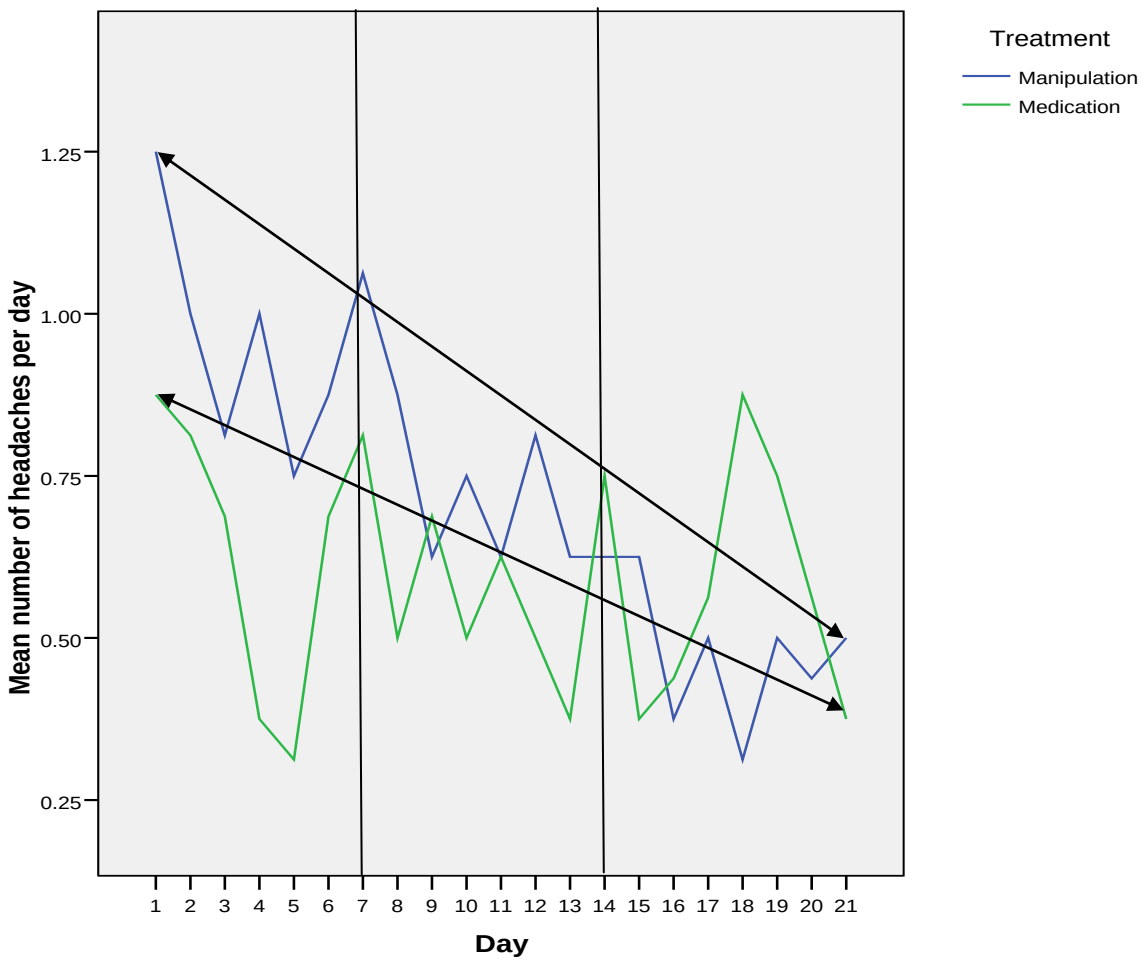

Figure 4.7.2: Mean number of headaches over time by treatment group

Figure 4.7.2 shows that the number of headaches per day decreased over time in the manipulation group while it remained relatively constant in the medication group. Therefore the manipulation was effective for reducing the number of headaches per day. With regards to the manipulative therapy, these results concur with those of Vernon (1982) and Boline et al., (1995). However with the Ibuprofen ® group, there is a return to the baseline values noted between day 16 and 20. This may be as a result of the factors discussed in Sections 4.6.1 and 4.6.2, referring to the outcomes of the CMCC and NRS-101 respectively. This outcome further agrees with Manse's model, where it is stated that oedema and pain are as a result of inciting trauma and therefore without all implications of this being treated, the pain will not go away in the medium to long terms (Leach, 2004:156-157).

There was a significant decrease in the number of headaches in the week before the treatment week in both groups. This could be due to researcher influence on the participant (McCarney et al., 2007).

4.7.3 Pain

The pain level recorded each day over the 21 days of observation using the headache diary was a quantitative variable (values ranged between 0 and 9 per day). When more than one headache was recorded for a particular day, the headache with the highest pain level was used and thus modelled using a Normal distribution, with an exchangeable correlation matrix utilised. The independent variables used in the model were treatment group (manipulation vs. medication), day (the 21 days of observation), and the interaction between day and treatment group (the treatment effect).

Table 4.7.3: GEE model for pain

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	P value
(Intercept)	2.626	.4489	1.746	3.505	34.206	1	<.0001
day	-.056	.0256	-.106	-.006	4.845	1	.028
[treatment=manipulation]	1.211	.5932	.048	2.373	4.166	1	.041
[treatment=medication]	0(a)	.	.	.	.	.	.
[treatment=manipulation] * day	-.070	.0408	-.150	.010	2.927	1	.087
[treatment=medication] * day	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: pain

Model: (Intercept), day, treatment, treatment * day

a Set to zero because this parameter is redundant.

Table 4.7.3 shows the results of the analysis. The interaction between treatment group and time was not significant (p=0.087), thus there was no differential treatment effect between the treatment groups over time. The significant difference between

the pain levels in the two treatment groups (p=0.041) suggested that there were baseline differences between the groups which were not due to the intervention.

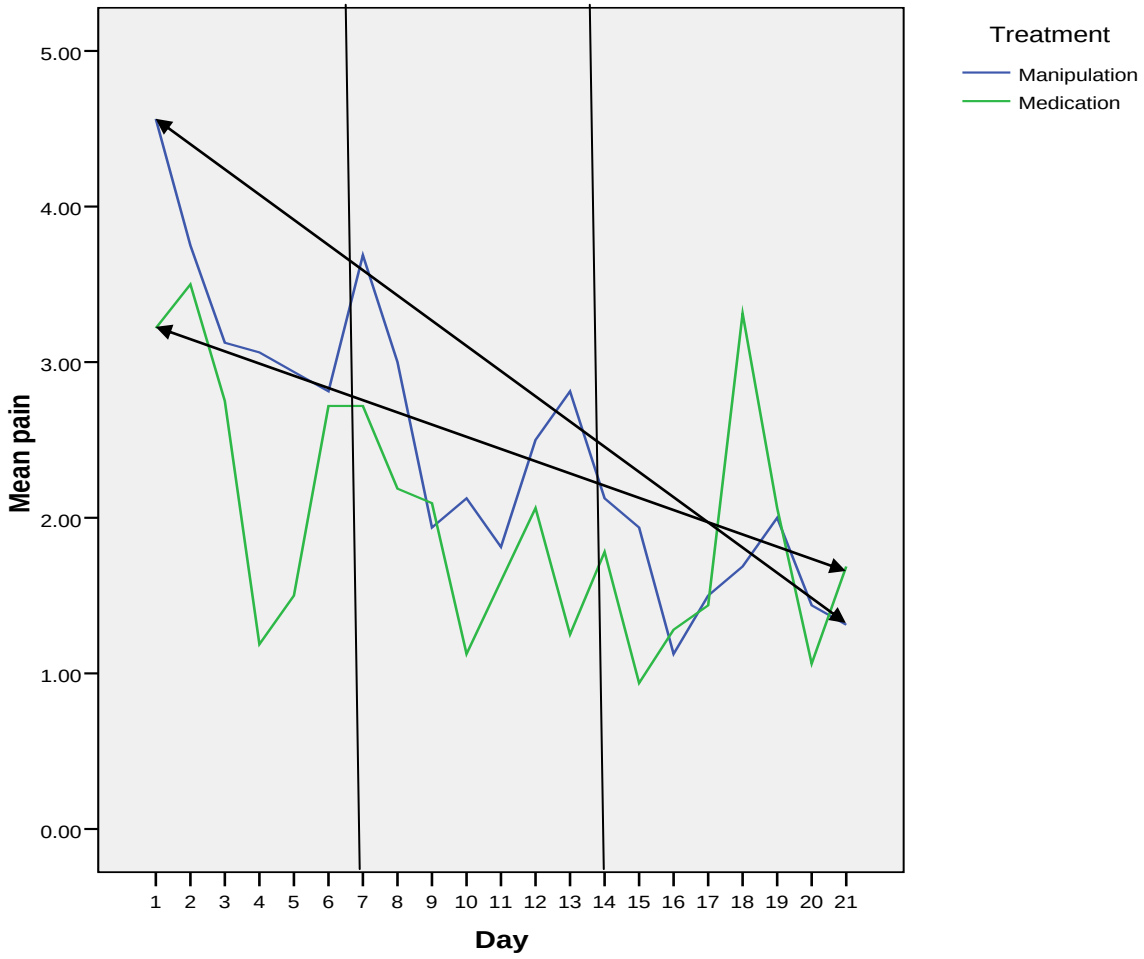

Figure 4.7.3: Mean pain level over time by treatment group

Figure 4.7.3 shows that at almost all time points the manipulation group had a higher average pain level, which concurs with Section 4.6.2, where the NRS-101 was discussed as well as Sections 4.7.1 and 4.7.2. There was also a significant time effect (p=0.028) which meant that regardless of treatment group the average pain decreased significantly over time. Figure 4.7.3 shows that both groups decreased over time. This implies that both treatments have a perceived effect from the participant's perspective. There was however a faster rate of decrease in pain noted in the manipulation group. There was a return to almost baseline values during the last week in the medication group (day 17-20). This could be due to similar reasons

mentioned in Section 4.6.3, where the mean number of headache in the medication group returned to baseline values in the last week.

4.7.4 Duration of headaches

The headache duration recorded each day over the 21 days of observation using the headache diary was a quantitative variable (values ranged between 0 and 24 hours per day). When more than one headache was recorded for a particular day, the durations of each headache were added together and thus modelled using a normal distribution (again an exchangeable correlation matrix was specified). The independent variables used in the model were treatment group (manipulation vs. medication), day (the 21 days of observation), and the interaction between day and treatment group (the treatment effect).

Table 4.7.4: GEE model for duration (hours)

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	2.639	.4726	1.713	3.565	31.178	1	<.0001
[Treatment=1]	1.647	1.0291	-.370	3.664	2.561	1	.110
[Treatment=2]	0(a)	.	.	.	.	.	.
Day	-.049	.0309	-.110	.012	2.517	1	.113
[Treatment=1] * day	-.096	.0480	-.190	-.002	4.019	1	.045
[Treatment=2] * day	0(a)	.	.	.	.	.	.
(Scale)	13.825						

Dependent Variable: duration

Model: (Intercept), treatment, day, treatment * day

a Set to zero because this parameter is redundant.

Table 4.7.4 shows the results of the analysis. The interaction between treatment group and time was statistically significant (p=0.0456), thus there was a differential treatment effect between the treatment groups over time.

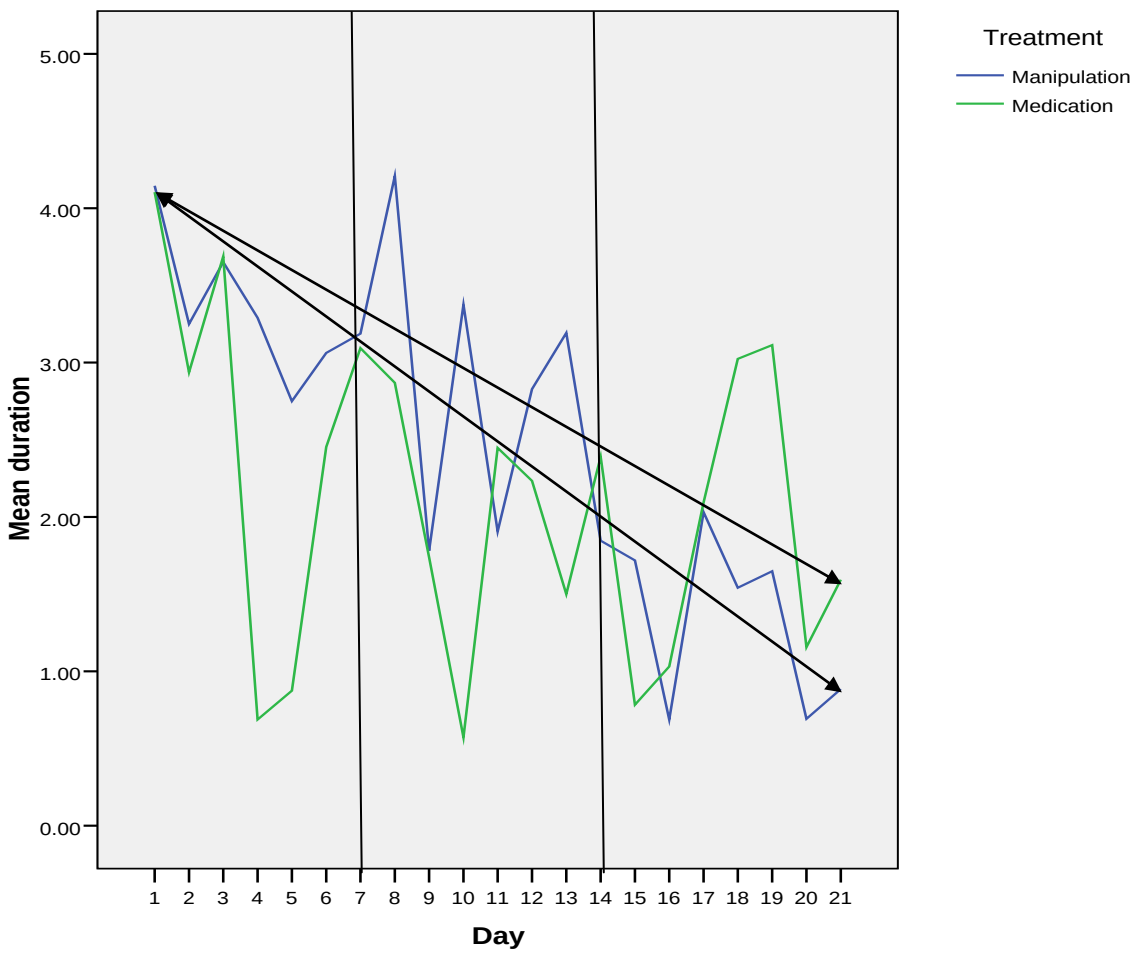

Figure 4.7.4: Mean duration (hours) of headaches over time by treatment group

Figure 4.7.4 shows that at the start of the study the duration of headaches were equivalent in the two groups, but by day 21 the mean duration in the manipulation group was lower than that of the medication group, even though both groups showed an overall mean decrease over the 21 days. Thus the rate of decrease was higher in the manipulation group. A study by Vernon (1982), reported statistically significant reductions in headache activity as measured by duration. An increase in duration of headache slightly above baseline values was noted after the first treatment in the manipulation group (day 7). This could be due to reactions to manipulation as discussed above in Sections 4.6.1 and 4.6.2., where participants may have had increased discomfort after the spinal manipulation treatment, which would explain the increase in the mean duration of the headache after day 7.

A significant increase in duration of headache was noted in the medication group (days 17- 20) was also noted, but this was not to the same extent as that of the manipulation group.

4.8 Disability (lifestyle changes)

For the specific disabilities and associated symptoms which were recorded relatively rarely, the data were further aggregated to the weekly level instead of daily. There were three weeks of data for each participant, and for each week the total number of times each disability or symptom was recorded, it was summed up. This was treated as a count variable and modelled using a Poisson distribution with a log link.

4.8.1 Participants who could not concentrate

Episodes of not being able to concentrate were summed up for each week and modelled using a Poisson distribution (values ranged from 0 to 7 episodes per week) with a log link. There was no treatment effect for this outcome (p=0.977).

Table 4.8.1: GEE model for episodes of participants who could not concentrate

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-.925	1.0099	-2.905	1.054	.840	1	.360
[Treatment=1]	1.540	1.0634	-.544	3.624	2.098	1	.148
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	-.227	.4637	-1.136	.682	.239	1	.625
[Treatment=1] * week	.014	.4984	-.963	.991	.001	1	.977
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: couldn't concentrate

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant.

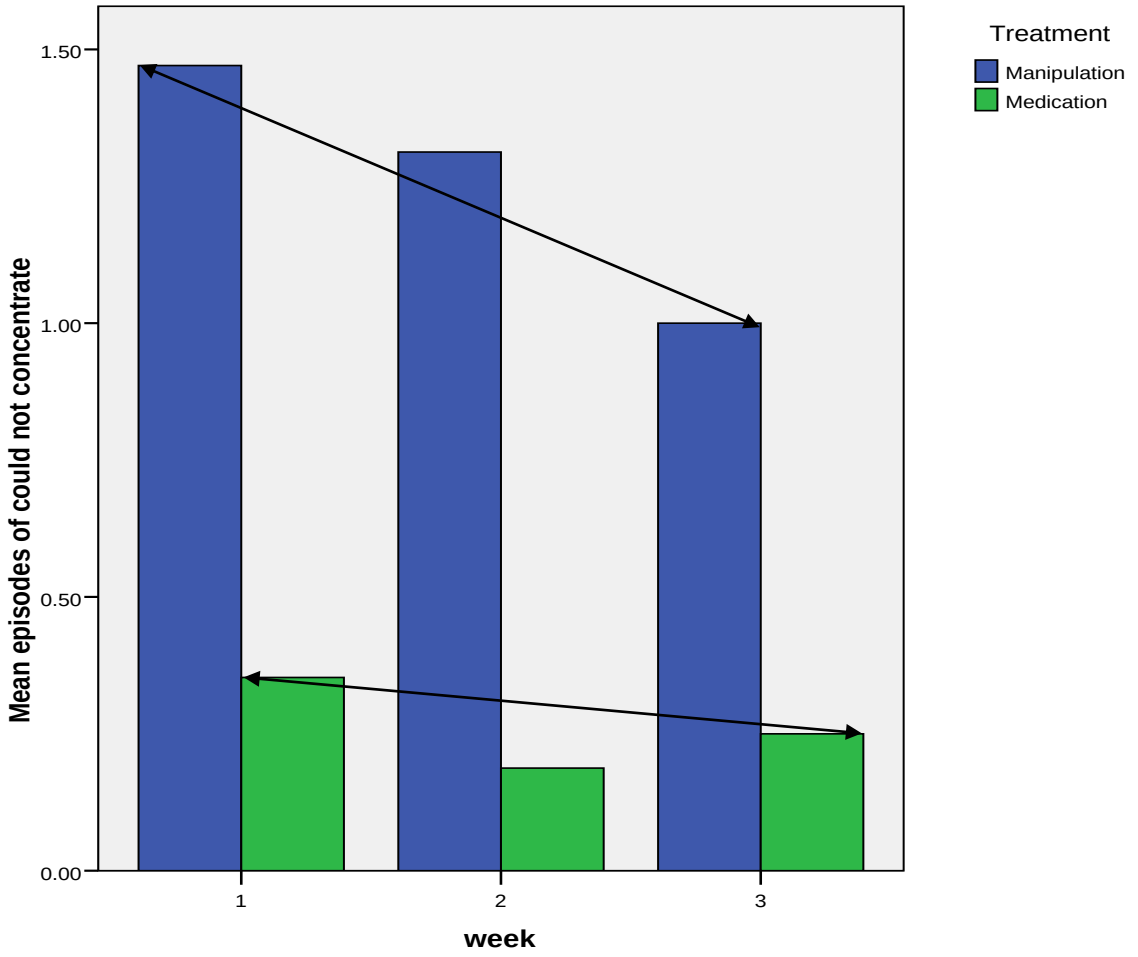

Figure 4.8.1: Clustered bar chart of mean episodes of participants who could not concentrate by week and treatment group.

Figure 4.8.1 shows that the manipulation group had more episodes of 'not being able to concentrate' and that the rate of change over time was not significantly different between the groups. There was a decrease in mean episodes of 'not been able to concentrate' over time in both groups but more so in the manipulation group. The number of episodes was still significantly higher in the manipulation group. This could be due to the fact that the reported headaches (Section 4.7.2) at the outset were greater in the manipulation group and there were more participants who were younger (possibly students) in the manipulation compared to the medication group. Students may have needed to concentrate more in lectures and tests/exams than other participants in the medication group for example domestic worker, chef, youth worker, lecturers and sales person. In addition, many of the students were writing their final exams at the time of the study. Therefore, many of them would had

increased levels stress which would also affect concentration. This, however is speculation and therefore research needs to be conducted to confirm possible reasons for this trend.

4.8.2 Participants who could not work

Episodes of not being able to work were summed up for each week and modelled using a Poisson distribution (values ranged from 0 to 3 episodes per week) with a log link. There was no treatment effect for this outcome (p=0.203).

Table 4.8.2: GEE model for episodes of participants who could not work

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-.471	.9523	-2.337	1.396	.244	1	.621
[Treatment=1]	-1.867	1.3603	-4.533	.799	1.883	1	.170
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	-.701	.3750	-1.436	.034	3.499	1	.061
[Treatment=1] * week	.724	.5692	-.391	1.840	1.619	1	.203
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: couldn't work

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant.

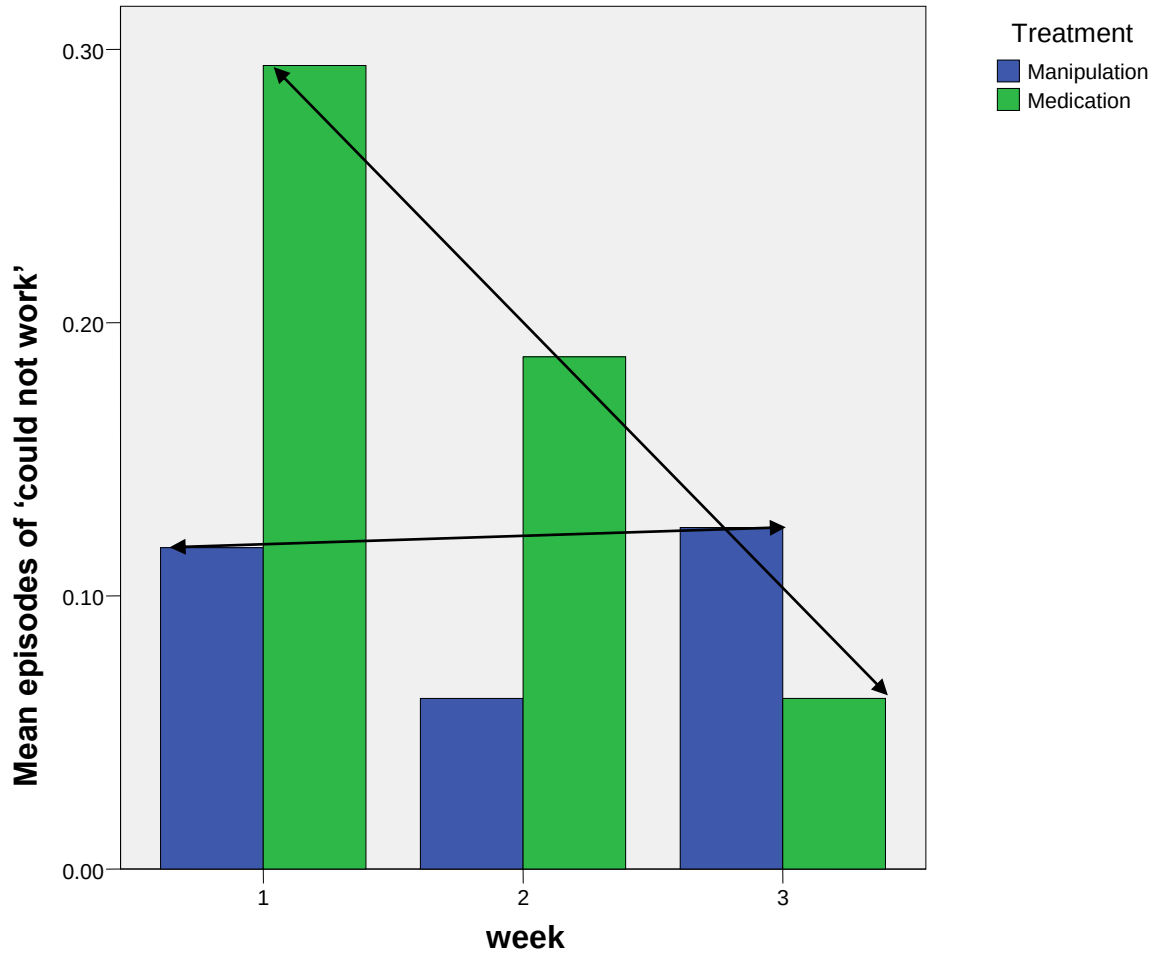

Figure 4.8.2: Clustered bar chart of mean episodes of participants who could not work by week and treatment group.

Figure 4.8.2 shows that the medication group had more episodes of 'not being able to work' in the first week but showed a decrease over time, while the manipulation group showed a very slight increase over time. Statistically there was no significant difference between the two groups as the rates were very low. The larger number of episodes in the medication could be due to the fact that there were more people who perceived themselves as "workers" for example domestic worker, chef, youth worker and lecturers where as the majority of the manipulation group were students who would possibly not consider their studies as work.

The slight overall increase of episodes of not being able to work in the manipulation group could not be explained by the discussions of Sections 4.6.1 and 4.6.2.

4.8.3 Participants who could not study

Episodes of not being able to study were summed up for each week and modelled using a Poisson distribution (values ranged from 0 to 4 episodes per week) with a log link. There was no treatment effect for this outcome (p=0.140). Therefore, the null hypothesis was accepted in this case.

Table 4.8.3: GEE model for episodes of participants who could not study

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-2.004	.9437	-3.854	-.154	4.510	1	.034
[Treatment=1]	1.682	1.1951	-.660	4.025	1.981	1	.159
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	.344	.2556	-.158	.845	1.806	1	.179
[Treatment=1] * week	-.615	.4167	-1.432	.202	2.179	1	.140
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: couldn't study

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant.

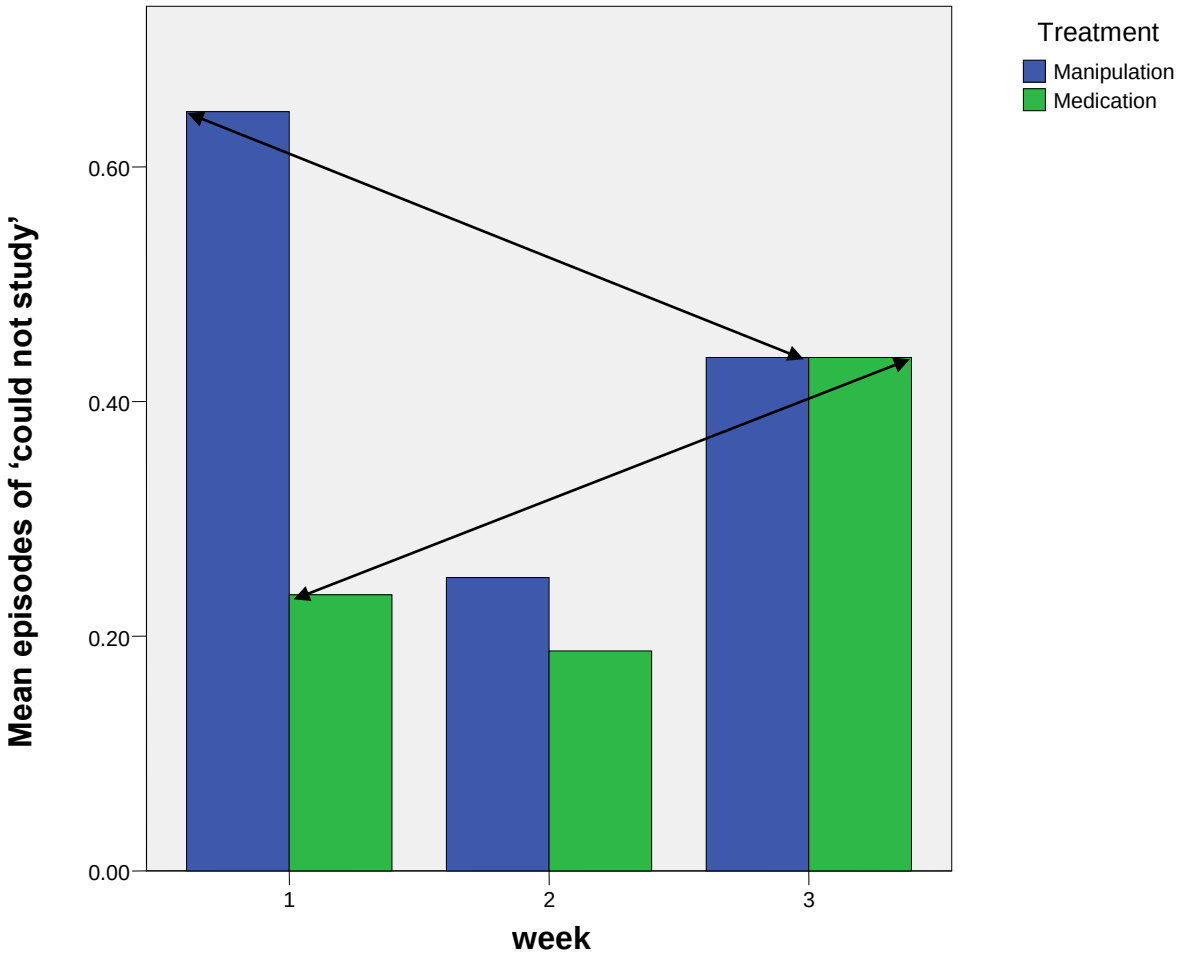

Figure 4.8.3: Clustered bar chart of mean episodes of participants who could not study by week and treatment group.

The manipulation group had more episodes of not being able to study in the first week but showed a decrease over time. Again this could be due to the fact that the majority in this group were students and the fact that many of them were busy with writing their final examinations and then completing these during the course of the research. This would concur with the fact that examinations generally increase stress which in turn would increase vulnerability to headache activity and therefore interfere with the students studying (Janke, Holroyd and Romanek, 2004).

Interestingly there was an increase in the number of episodes in the medication group over time. More research into how different occupations are affected by this headache should be done. The effective difference between Section 4.8.2 and 4.8.3 may be related to the type of activity as well as the need for the activity to have

occurred as these results seem inherently contradictory. Therefore further research into factors affecting these parameters is suggested.

4.8.4 Participants who could not sleep

This outcome could not be modelled since there was only one reported episode in the medication group.

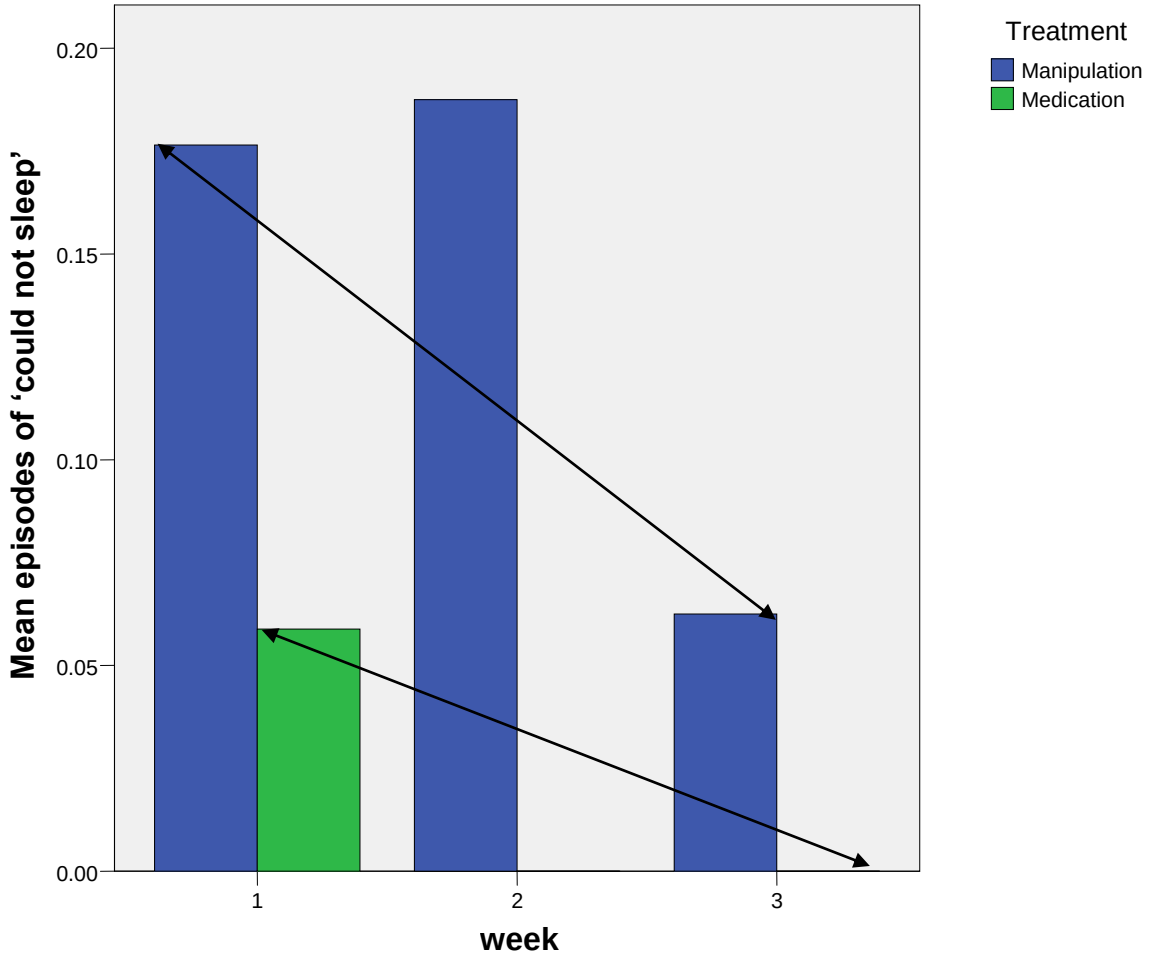

Figure 4.8.4: Clustered bar chart of mean episodes of participants who could not sleep by week and treatment group

Figure 4.8.4 shows the data graphically. There were three episodes reported at week one in the manipulation group, three at week 2 and one at week three. Thus no conclusions about the treatment effect could be gained from this outcome. There was a decrease of the number of episodes over time in both groups.

4.8.5 Participants who could not see properly

This outcome could not be modelled since at week 2 there were no reported episodes in either group.

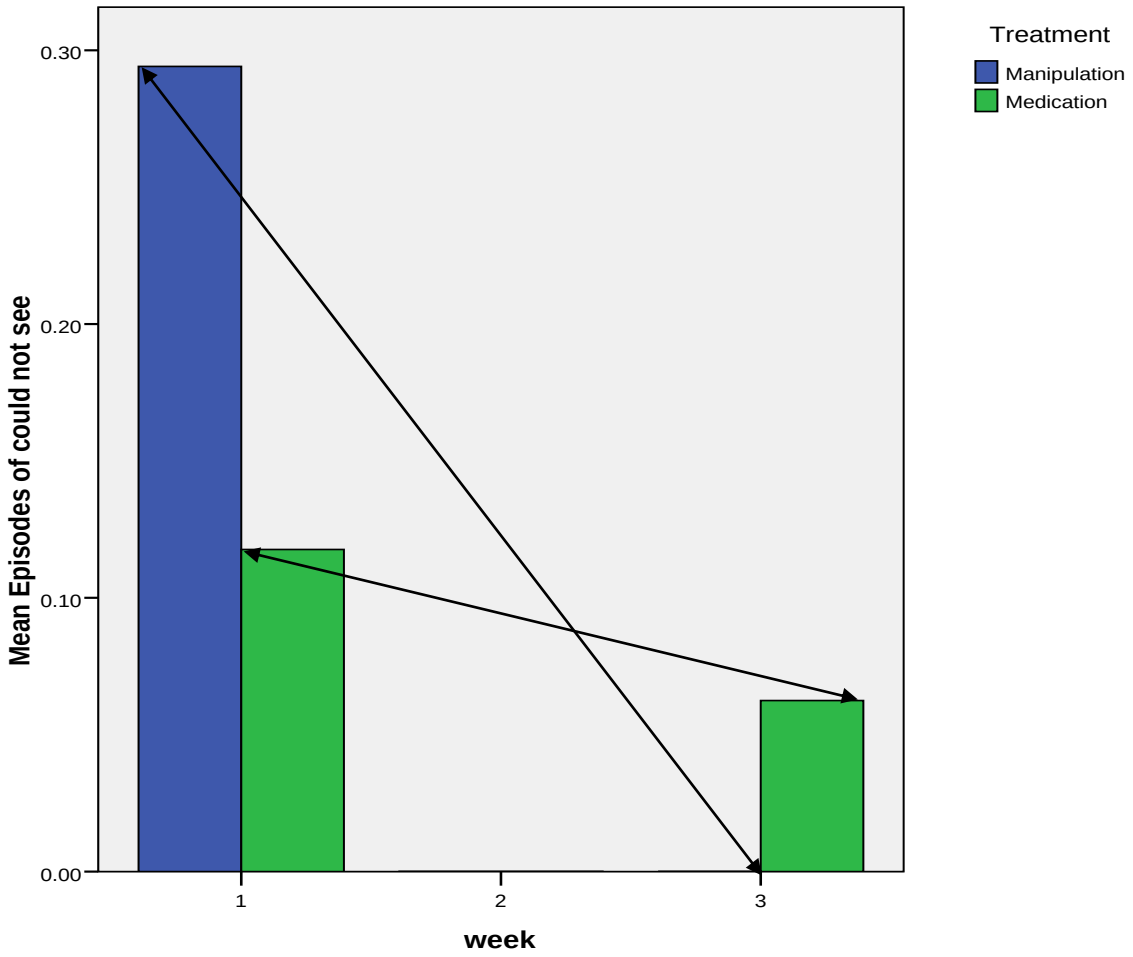

Figure 4.8.5: Clustered bar chart of mean episodes of participants who could not see properly by week and treatment group

Figure 4.8.5 shows the data graphically. There were 5 episodes reported at week one in the manipulation group and two in the medication group. This was reduced to one episode in the medication group at week 3. Thus, no definite conclusions about the treatment effect could be gained from this outcome. It was not clear what the participants meant by “could not see properly”. This could have been due to a range of symptoms that include; photosensitivity, blurred vision, eye fatigue, eye pain.

4.8.6 Participants who could not lift

This outcome could not be modelled since there were no reported episodes in the medication group and only two cases in the manipulation group.

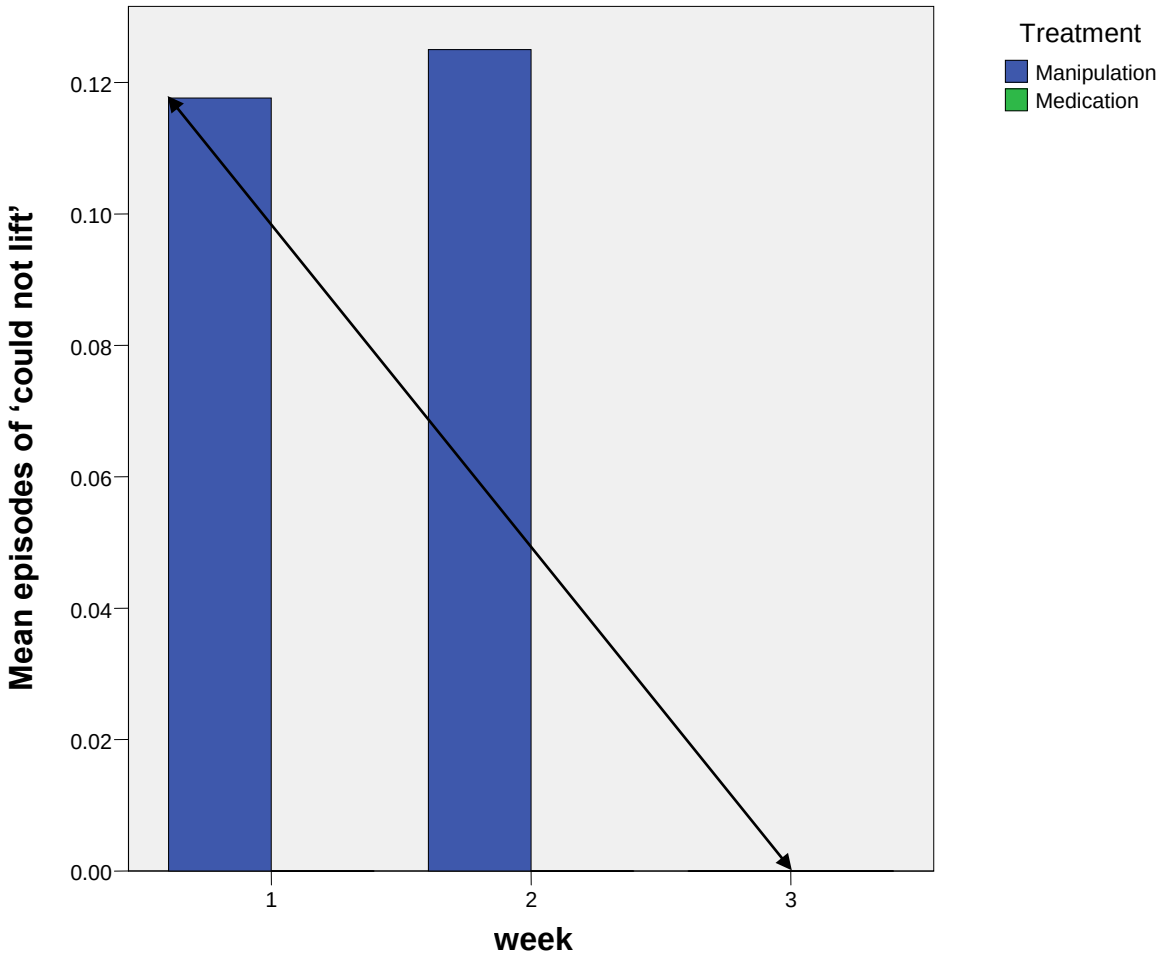

Figure 4.8.6: Clustered bar chart of mean episodes of not being able to lift by week and treatment group

Figure 4.8.6 shows the data graphically. Thus, no definite conclusions about the treatment effect could be gained from this outcome.

4.8.7 Participants who could not exercise and who could not socialize

This outcome could not be modelled since there were no reported “could not exercise” episodes in the manipulation group and only one case in the medication group. Thus no definite conclusions about the treatment effect could be gained from this outcome. With regards to the outcome “could not socialise”, it was noted that this outcome could not be modelled since there was only one reported episode in each group. Thus, no definite conclusions about the treatment effect could be gained from this outcome.

4.9 Associated Symptoms

4.9.1 Photophobia

Total weekly episodes of photophobia were modelled using a Poisson distribution. There was a statistically significant treatment effect (p=0.027) which indicated a benefit in the manipulation group, toward the reduction of the photophobia.

Table 4.9.1: GEE model for episodes of photophobia

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	.325	.5758	-.803	1.454	.319	1	.572
[Treatment=1]	-.500	.8791	-2.223	1.223	.324	1	.569
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	-.476	.2523	-.971	.018	3.564	1	.059
[Treatment=1] * week	-.971	.4403	-1.834	-.108	4.863	1	.027
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: Episodes of photophobia

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant.

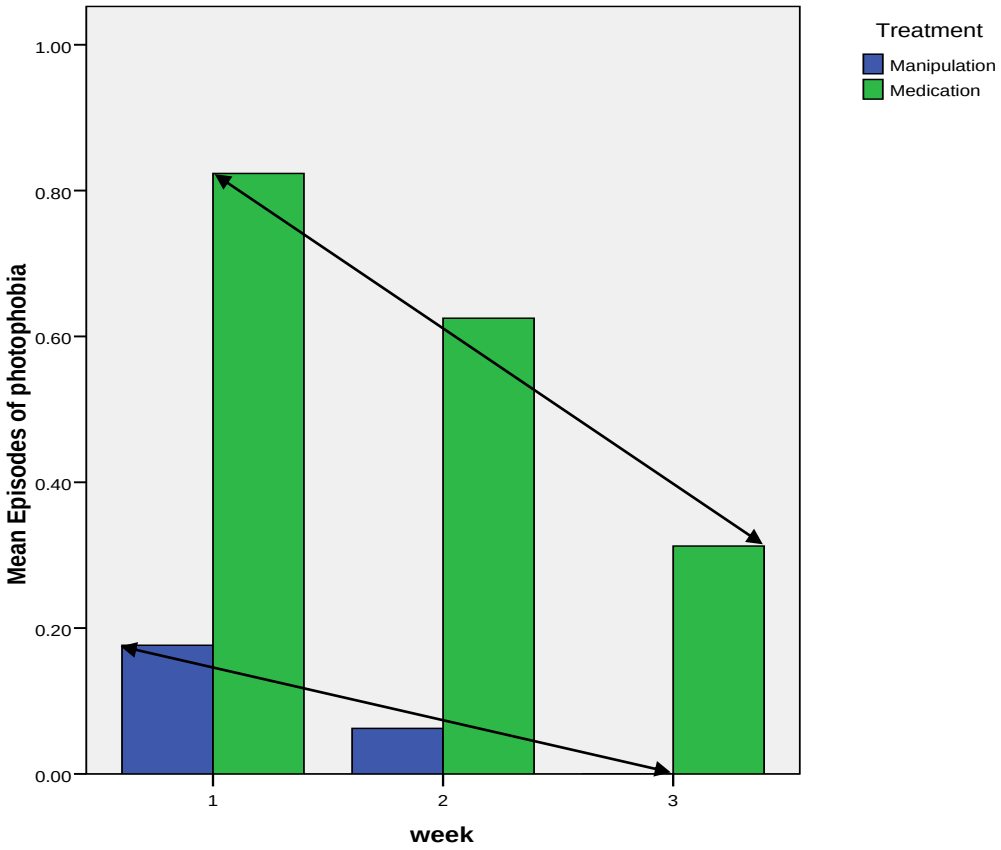

Figure 4.9.1: Clustered bar chart of mean episodes of photophobia by week and treatment group

Figure 4.9.1 shows that the medication group experienced more episodes of photophobia than the manipulation group but that the manipulation group showed a more significant (p=0.027) decrease over time.

According to Doran (2009), patients with migraine headache may have a hyperexcitable occipital lobe, which in turn increases sensitivity to stimulation by light, sound, odours and touch. This might be the case in TTH which will then support the argument that a decrease in headache (intensity, frequency, duration) will result in a decrease in episodes of photophobia. The ICHD-2 (2004) indicates that photophobia may be present but is not a requirement of ETTH.

4.9.2 Neck pain

Total weekly episodes of neck pain were modelled using a Poisson distribution as the weekly number of episodes ranged from 0 to 7 per person. There was no treatment effect (*p*=0.433) for this outcome.

Table 4.9.2: GEE model for episodes of neck pain

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-1.506	1.1701	-3.799	.788	1.656	1	.198
[Treatment=1]	1.547	1.2141	-.832	3.927	1.624	1	.202
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	.349	.4575	-.547	1.246	.583	1	.445
[Treatment=1] * week	-.381	.4866	-1.335	.572	.614	1	.433
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: Episodes of neck pain

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant.

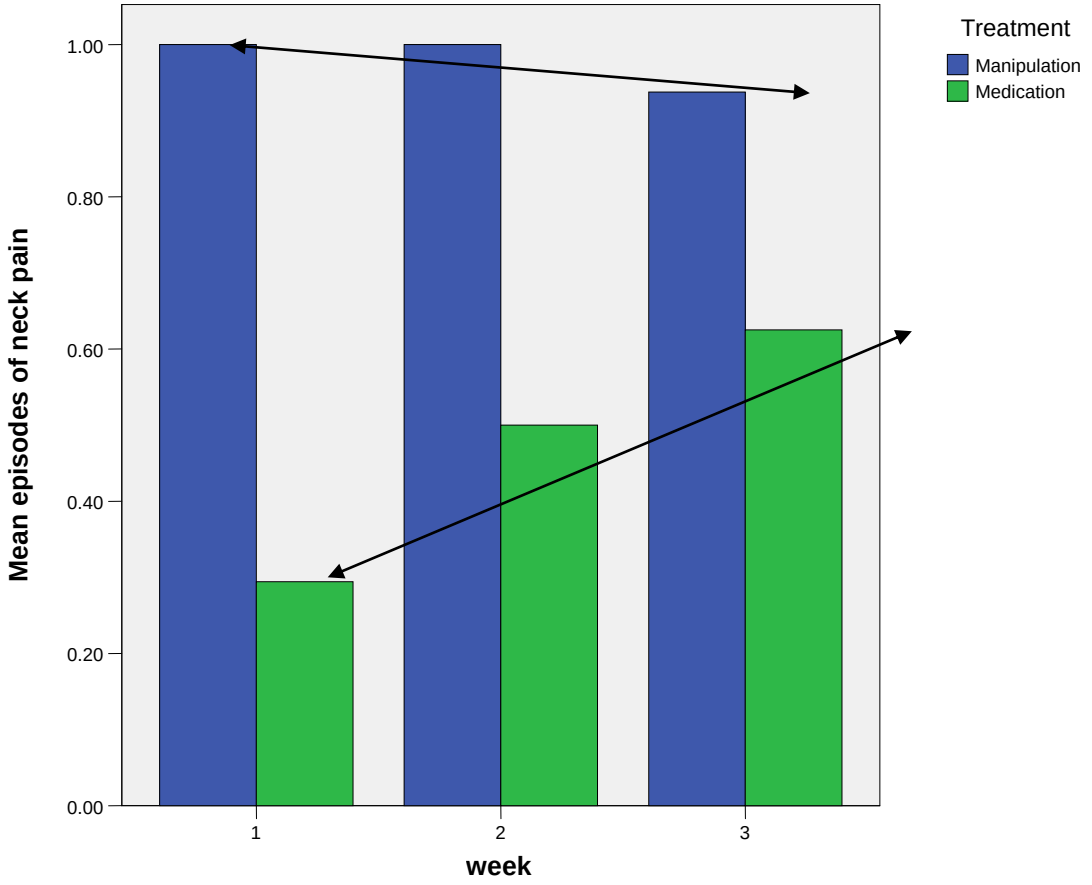

Figure 4.9.2: Clustered bar chart of mean episodes of neck pain by week and treatment group

Figure 4.9.2 shows that the medication group actually increased in frequency of this outcome over the weeks but the numbers of reported cases were small and there was no significant difference between the groups. The number of reported episodes of neck pain in the manipulation group was higher. There was a slight decrease in the number of episodes in this group over time. The medication group showed an increase in neck pain.

4.9.3 Feeling weak

This outcome could not be modelled since there were only two reported episodes in the manipulation group and none from the control group. Thus no definite conclusions about the treatment effect could be gained from this outcome.

4.9.4 Eye pain

Total weekly episodes of eye pain were modelled using a Poisson distribution as the weekly number of episodes ranged from 0 to 7 per person. There was no treatment effect (*p*=0.493) for this outcome.

Table 4.9.4: GEE model for episodes of eye pain

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	p value
(Intercept)	-3.001	1.8724	-6.671	.669	2.568	1	.109
[Treatment=1]	2.812	1.9351	-.981	6.605	2.112	1	.146
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	.323	.7439	-1.135	1.781	.188	1	.664
[Treatment=1] * week	-.531	.7753	-2.051	.988	.470	1	.493
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: Episodes of eye pain

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant.

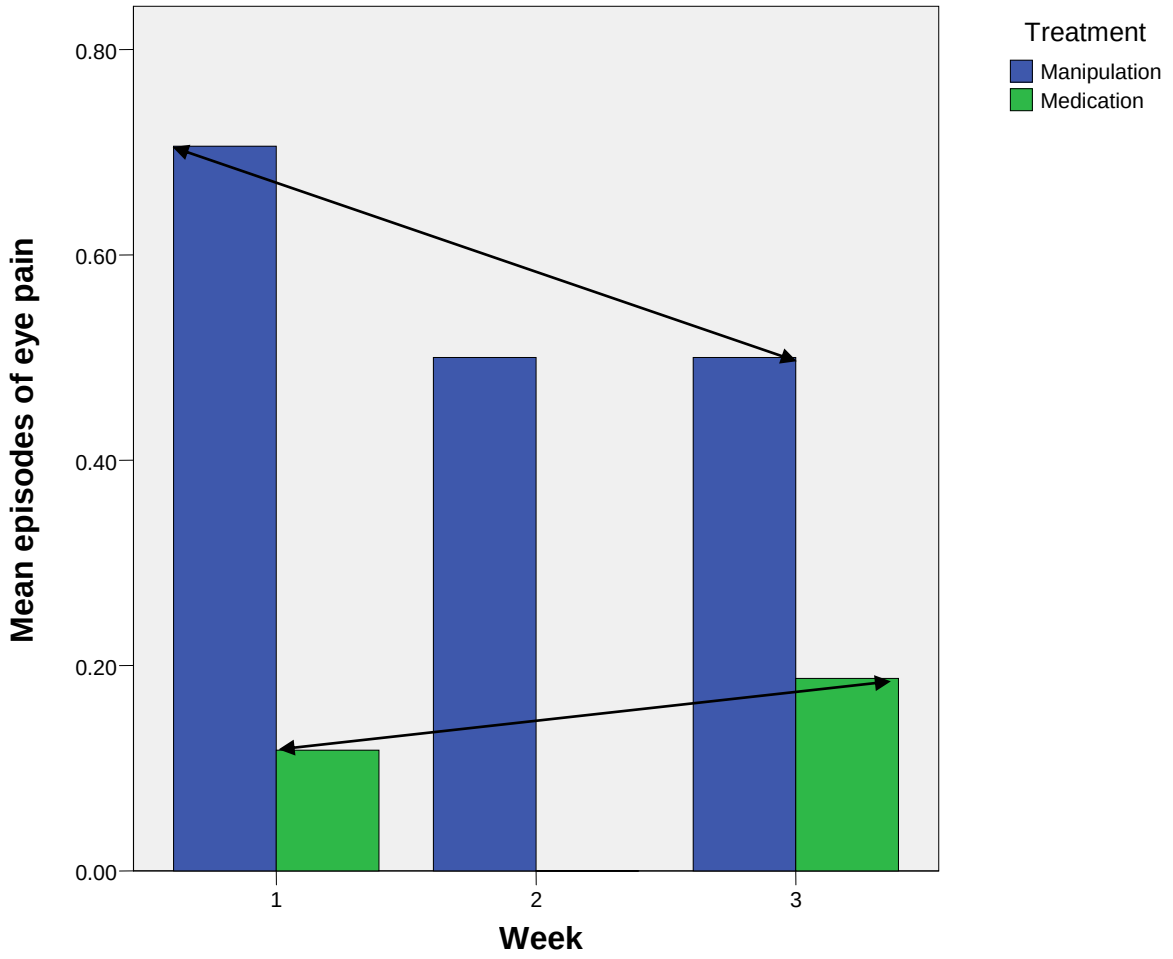

Figure 4.9.4: Clustered bar chart of mean episodes of eye pain by week and treatment group

Figure 4.9.4 shows that the manipulation groups experienced a slight decrease in episodes over time but the medication group did not. Nevertheless, the numbers were small and there was no significant difference between the groups. The higher number of episodes in the manipulation group during the 1st week correlates with the higher number of the episodes during the 1st week of the manipulation group in Figure 4.8.5 (participant could not see properly). The outcomes of this measure would concur with the discussion for Sections 4.9.1

4.9.5 Feeling tired / Blurred vision / Nausea / Back pain

These outcomes could not be modelled since there were limited reported episodes in either the manipulation group or medication group over the three weeks. Thus, no definite conclusions about the treatment effect could be gained from these outcomes.

4.9.6 Dizziness

Total weekly episodes of dizziness were modelled using a Poisson distribution as the weekly number of episodes ranged from 0 to 4 per person. There was no treatment effect (p=0.173) for this outcome.

Table 4.9.6: GEE model for episodes of dizziness

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald chi square	df	*p* value
(Intercept)	-2.974	.8255	-4.592	-1.356	12.978	1	.000
[Treatment=1]	1.791	1.2579	-.674	4.257	2.028	1	.154
[Treatment=2]	0(a)	.	.	.	.	.	.
Week	.464	.4439	-.406	1.334	1.091	1	.296
[Treatment=1] * week	-.982	.7210	-2.395	.432	1.853	1	.173
[Treatment=2] * week	0(a)	.	.	.	.	.	.
(Scale)	1						

Dependent Variable: Episodes of dizziness

Model: (Intercept), treatment, week, treatment * week

a Set to zero because this parameter is redundant

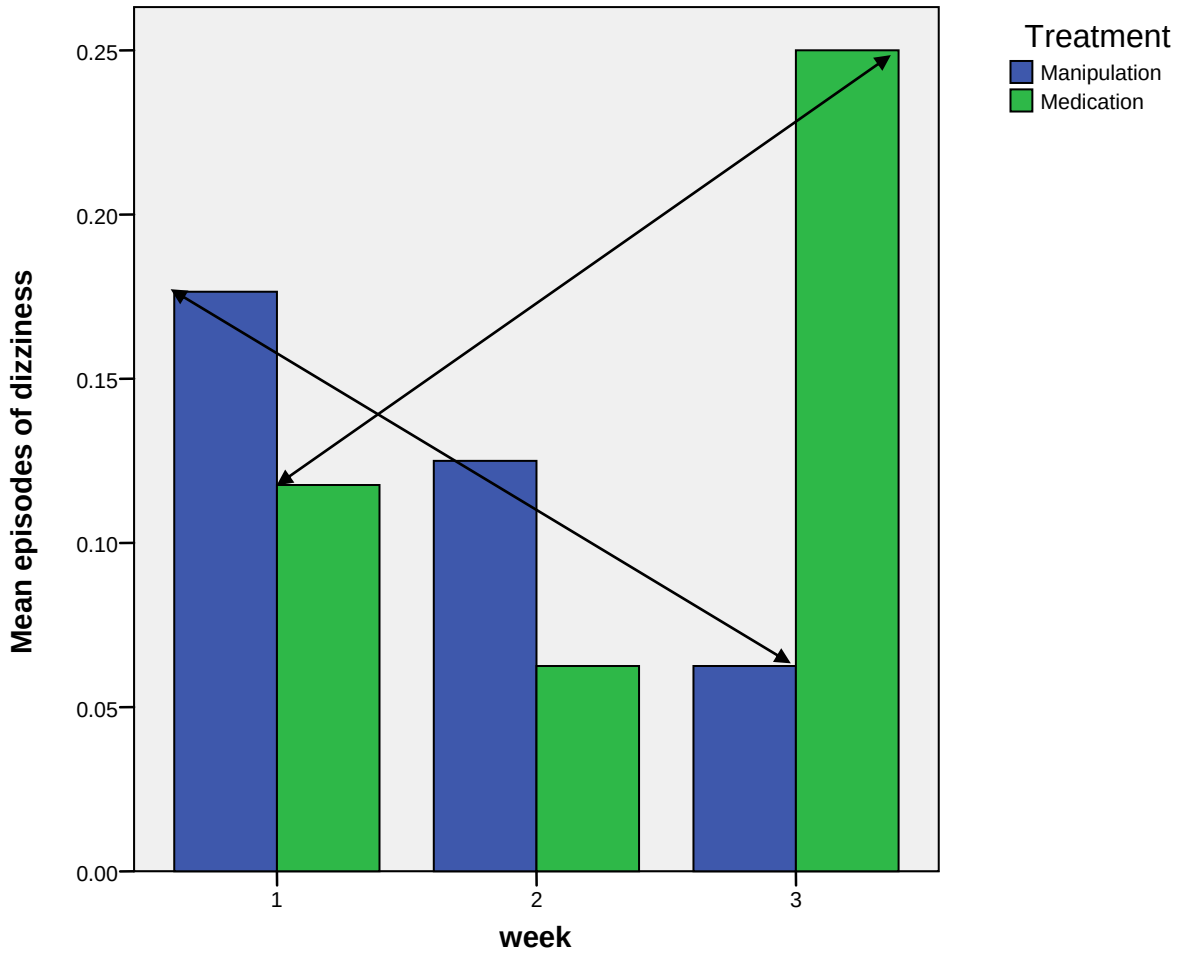

Figure 4.9.6: Clustered bar chart of mean episodes of dizziness by week and treatment group

Figure 4.9.6 shows that the manipulation groups experienced a decrease in episodes over time but the medication group showed an increase. However, the numbers were small and there was no significant difference between the groups. According to Brunton, Lazo and Parker (2006) dizziness is one of the adverse effects of Ibuprofen, which could explain the increase of episodes of dizziness in the medication group over time.

4.9.7 Jaw pain / Itchy eyes / Toothache / Nostril pain / Phonophobia

These outcomes could not be modelled since there was only one reported episode in the manipulation group and none from the control group over the three weeks. Thus no definite conclusions about the treatment effect could be gained from this outcome.

4.10 Qualitative data:

The description of the type of pain experienced at each headache was recorded and each type was summed up over each week and the total number of each type of pain per group per week is shown in Figures 4.10.1 and 4.10.2. The most common headache pain description was a pressing pain, followed by ache, throb, dull and sharp. This was similar to Prithipal (2003) who found that the most common headache pain description was a heaviness of the head, followed by a pressing quality of headache; a tightness of the head; a dull ache; a squeezing sensation; a cramping sensation, and a constricting sensation. Similarly, Thomson (1999) found the most frequently used headache pain descriptions in her study were dull ache, followed by pressure sensation, tight band and throb.

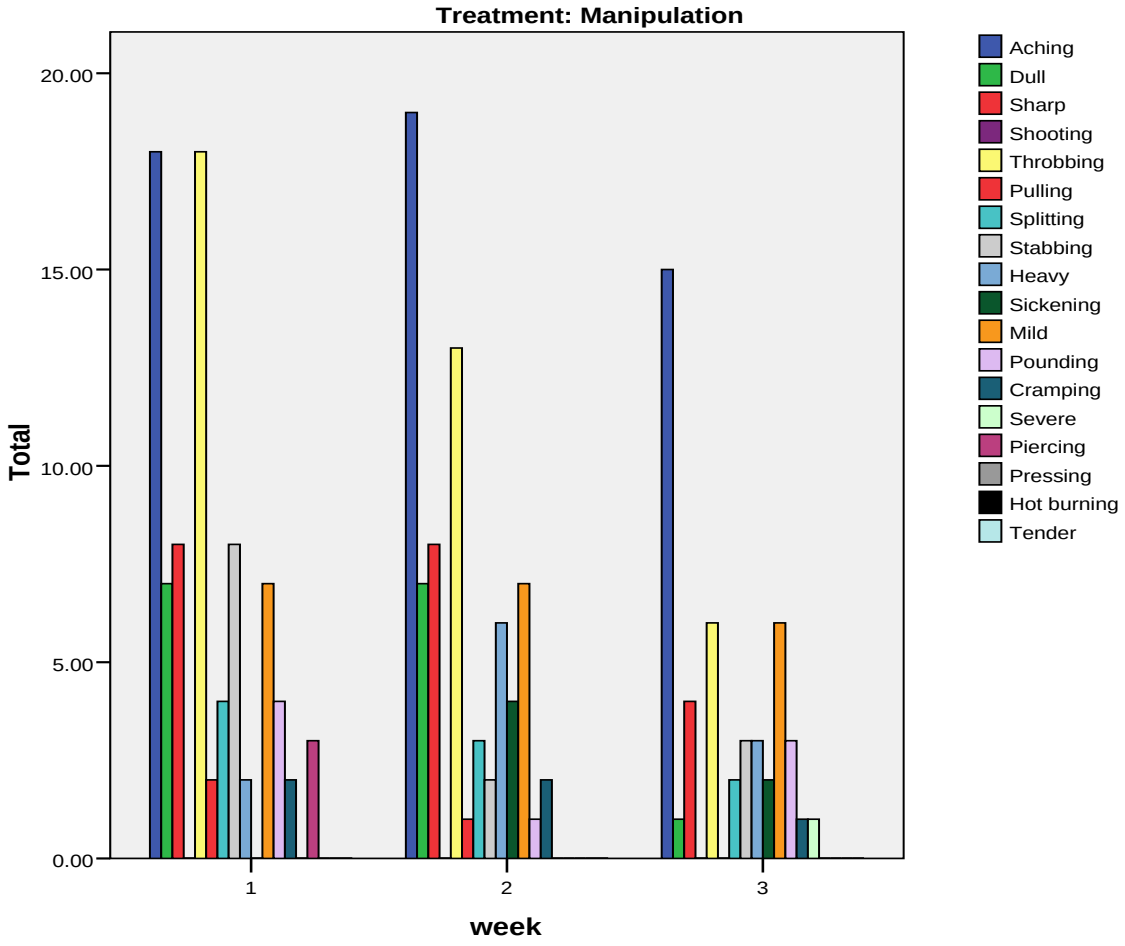

Figure 4.10.1: Total episodes of each type of pain experienced by the manipulation group per week

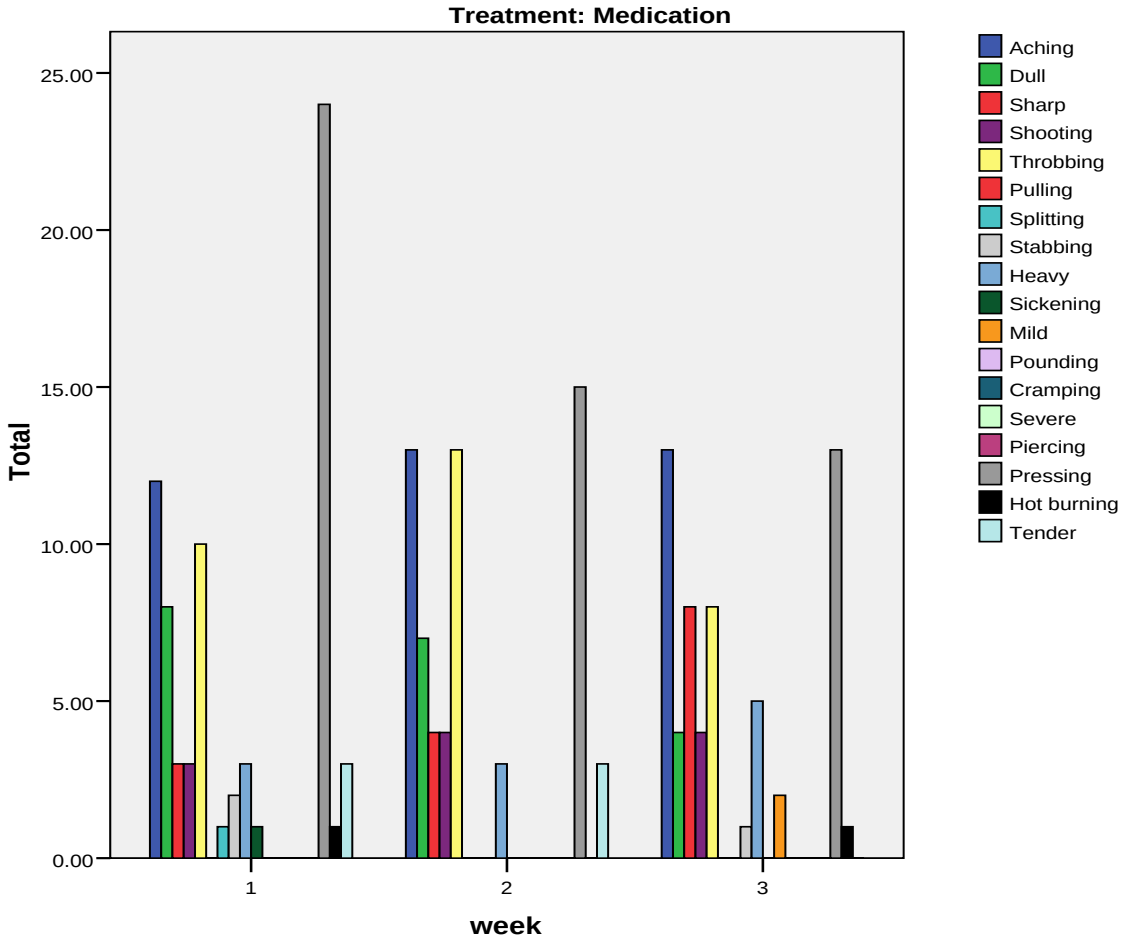

Figure 4.10.2: Total episodes of each type of pain experienced by the medication group per week

4.11: Review of the objectives

Objectives were to determine:

Objective One

- The effectiveness of Ibuprofen in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in lifestyle.

  Hypothesis one: Ibuprofen was effective in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in life style.

  This hypothesis was ***not rejected (accepted)*** –only accepted for the significant changes.

Objective Two

- The effectiveness of a spinal manipulation in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in lifestyle.

  Hypothesis two: Spinal manipulation was effective in the treatment of ETTH in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated signs and symptoms and changes in life style.

  This hypothesis was ***not rejected (accepted)*** –only accepted for the significant changes.

Objective Three

A comparison between the trends in subjective clinical measures in cervical spine manipulation and Ibuprofen groups in the treatment of ETTH.

Hypothesis three: Spinal manipulation would be more effective in the treatment of ETTH than Ibuprofen in terms of subjective clinical measures which included intensity of the headache, duration, frequency, associated symptoms and changes in lifestyle.

The hypothesis was ***accepted*** in terms of several subjective outcomes namely: pain intensity (NRS-101), the presence, the frequency, the duration of headache per day and photophobia.

The hypothesis was ***rejected*** in terms of several subjective outcomes namely: CMCC Neck Disability Index and associated symptoms.

CHAPTER 5 : Conclusions and Recommendations

5.1 Conclusions

The subjective measurements of the CMCC Neck Disability Index revealed a decrease in the scores over the duration of the study for both treatment groups. The rate of decrease for both groups was the same and the time effect was highly significant which meant both groups decreased significantly (p<0.001). There was however no significant treatment effect (p=0.167). Only the manipulation group completed the SF-MPQ.

There was a significant time effect which meant that manipulation was effective in reducing the pain character (p=*0.002*). Several of the subjective Headaches Diary outcomes followed this trend with significant time effect but no statistical treatment effect for both groups. Some of the Headache Diary outcomes could not be modelled due to the fact that there were no reported episodes in either the spinal manipulation group or the medication group.

There was a significant treatment effect for the NRS-101. The manipulation group showed a linear decrease in pain over the duration of the study where as the medication group this was the case up to time point 3 (3rd consultation) when the pain level started to increase.

Several subjective outcomes from the headache diary showed a significant treatment effect in favour of manipulation. These were number of headaches per day (p=0.018), duration of headaches (p=0.0456), and photophobia (p=0.027).

The findings have shown that cervical spine manipulation is superior in some instances to Ibuprofen® for treatment of ETTH in terms of several subjective outcomes namely: pain (NRS- 101), the presence, the frequency, the duration of headache per day and photophobia.

Therefore, cervical spine manipulation is shown to be effective in the treatment of ETTH and can be considered as a possible alternative treatment option for ETTH

5.2 Recommendations

5.2.1 Subjective Data

The CMCC Neck Disability Index, NRS-101, SF-MPQ and the Headache Diary were easy to administer and were understood by the participants. They are recommended for use in future studies.

It is recommended that the McGill Pain Questionnaire be translated into Zulu in a study which includes a large population of Zulu speaking people as some of the descriptive words were not understood and had to be explained to the participants. This will assist in reaching a more accurate collection of data. In this case where the participants were allowed to take the headache diary home, it would be recommended for the researcher to keep a close eye on the responses of the participants in the Headache Diary at every consultation. This is to make sure that the participant is responding correctly and that they are keeping the diary up to date.

5.2.2 Other Recommendations

This study included thirty two participants. A larger sample size is recommended as it would yield more accurate results and would better represent the ETTH population.

A sham procedure for the manipulation group is also recommended in future, to more accurately test the real treatment value of manipulation.

In this study only subjective data was collected. A combination of subjective and objective would yield more accurate results and is recommended for future studies, although it is acknowledged that there are very few objective measures when measuring headache syndromes.

Future studies could investigate the effects of manipulation in the treatment of TTH among different occupations and different levels of education. Additionally it is suggested that a more stratified approach to the patients at the outset of the clinical trial be taken to minimise the impact of these (at present) unknown variables on treatment outcome.

Future research needs to be done to determine if the plateau effect seen in CMCC Neck Disability Index, NRS-101 and the SF-MPQ data outcome was due to the assumptions with regards to post manipulation sequelae or other reasons.

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