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A THREE WAY INVESTIGATION OF THE RELATIVE EFFECTIVENESS OF SPINAL MANIPULATIVE THERAPY, A HOMEOPATHIC MIGRAINE COMPLEX AND A COMBINATION OF THE TWO INTERVENTIONS IN THE MANAGEMENT OF MIGRAINE HEADACHES

By

Lelénia du Preez

Dissertation submitted to the Faculty of Health in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic at the Durban Institute of Technology.

I, Lelénia du Preez, do declare that this dissertation represents my own work in both concept and execution.

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M.Tech: Chiropractic (SA).

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M.Tech: Homeopathy (SA).

DEDICATION

I DEDICATE THIS WORK TO MY FAMILY AND TO DAWIE, WHO HAVE GIVEN ME UNCONDITIONAL LOVE AND SUPPORT THROUGHOUT MY ACADEMIC CAREER; AND TO THE LORD MY GOD FOR HIS AMAZING LOVE AND FOR GRANTING ME THE STRENGTH AND ABILITY TO STUDY.

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ABSTRACT

Migraine is a very common headache condition, with devastating influences on an individual's everyday life. In South Africa in particular the prevalence of migraine is between 10 and 15 percent. It has been shown that chiropractic and homeopathic treatment help in the management of migraine. No studies have been conducted to evaluate which is the better treatment, or whether a combination of chiropractic and homeopathy is even more effective in the management of migraine.

The aim of the study was to investigate the relative effectiveness of a manual intervention (spinal manipulative therapy) opposed to a homeopathic intervention (Migraine complex) opposed to a combination of these chiropractic and homeopathic interventions in the management of migraine headaches, in terms of patient perception, in order to determine the most effective treatment for migraine headache.

Thirty subjects diagnosed with migraine headaches according to the International Headache Society (1988), were randomly divided in 3 groups. Each group consisted of 10 subjects between the ages of 16 and 55, which were selected from the general population in Durban and surrounding areas. The first group received spinal manipulation therapy; the second group received a homeopathic migraine complex (*Iris versicolor* 9CH, *Spigelia anthelmia* 9CH and *Sanguinaria canadensis* 9CH) and the third group a combination of spinal manipulation therapy and the homeopathic migraine complex.

Group A received 8 spinal manipulation therapy treatments over a 6 week period. Group B was instructed to dissolve 5 pills of the migraine complex under the tongue, twice daily (on waking and at bedtime), when they were between attacks and hourly during attacks. The subjects had to undergo 8 assessments over the six week period. Group C received the same dosage of the homeopathic migraine

complex as well as 8 spinal manipulation therapy treatments over the six week period.

The study consisted of subjective measurements only. These included the Canadian Memorial Chiropractic Collage (CMCC) Neck Disability Index and the Glasgow Homeopathic Hospital Outcome Score (GHHOS), which were completed at every consultation. The subjects were asked to record their migraine headaches in a Headache diary each time they experienced a migraine, and on the last visit a Quality of Life Questionnaire was completed.

The data was then analysed statistically. Intra-group and inter-group comparisons were made. Inter-group comparison indicated that none of the three groups improved statistically significantly ($p>0.05$) more than any other of the groups. Intra-group results indicated no statistically significant improvement in terms of severity and duration in any of the three groups. However the frequency of migraine occurrence decreased significantly in the homeopathic migraine complex group (Group B) as well as in the combined group (Group C). The spinal manipulation group (Group A) showed a decrease in frequency, but this was not statistically significant. All three groups showed a marked improvement in the GHHOS and a decrease in the CMCC Neck Disability Index. Reduced medication consumption was noted in all three groups as well as an improvement in their quality of life.

From these results it seems that the three groups performed equally well. However the study was limited in its statistical strength due to the small sample size, leading to a high probability of type II errors. It is possible that statistically significant differences existed that were not detected by the analysis.

It is recommended that further studies are conducted, using a larger sample and that a four-week pre-treatment evaluation is done to strengthen the statistical results.

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Definition of terms

Manipulation

Passive maneuver in which specifically directed forces are applied to vertebral and extra-vertebral articulations of the body, with the object of restoring mobility to restricted areas (Gatterman, 1990:405).

1. Long lever manipulation - High velocity force exerted on a point of the body some distance from the area where it is expected to have its beneficial effect.
2. Short-lever manipulation - High-velocity thrust directed specifically at an isolated joint.

Adjustment

Specific form of direct articular manipulation utilising either long or short-leverage techniques with specific contacts, characterised by a dynamic thrust of controlled velocity, amplitude and direction (Gatterman, 1990:405).

Fixation

For the purpose of this study, the following definitions as listed by Gatterman, (1990:408) will apply:

1. Absence of motion of a joint in a position, usually at the extremity of such motion.
2. [Dynamic fault] State whereby a vertebra or pelvic bone has become temporarily immobilised in a position that it may normally occupy during any phase of physiological spinal movement.
3. Immobilisation of a vertebra in a position of movement when the spine is at rest or when the spine is in movement.

Chiropractic treatment or spinal manipulative therapy

For the purpose of this study, chiropractic treatment or spinal manipulative therapy refers to cervical and thoracic adjustments at fixated areas.

Complex homeopathy (polypharmacy)

"Complex" homeopathy is when multiple remedies were mixed into a standard formula to cover a persons symptoms and diagnosis (Linde, *et al.* 1997:835), provided each component is listed in the Homeopathic Pharmacopoeia of US (Gaier, 1991:97-100).

Homeopathic Migraine complex

For the purpose of this study the migraine complex consisted of *Iris versicolor* 9CH, *Spigelia anthelmia* 9CH and *Sanguinaria canadensis* 9CH (Aleotti,1997).

Dysarthria

A speech disorder in which the pronunciation is unclear although the linguistic content and meaning are normal (Oxford concise Medical Dictionary, 1998:198).

Vertigo

A disabling sensation in which the affected individual feels that either he himself or his surroundings are in a state of constant movement (e.g. spinning sensation) (Oxford concise Medical Dictionary, 1998:699).

Tinnitus

The sensation of sounds in the ears or head in the absence of an external sound source (Oxford concise Medical Dictionary, 1998:660).

Hypacusia (Hyperacusis)

Abnormal acute hearing or hypersensitivity to sounds (Oxford concise Medical Dictionary, 1998:315).

Diplopia

Double vision: the simultaneous awareness of two images of the one object. (Oxford concise Medical Dictionary, 1998:187).

Ataxia

Shaky movements and unsteady gait (Oxford concise Medical Dictionary, 1998:52).

Chapter 1

INTRODUCTION

1.1 Introduction

Migraine is a common condition and accounts for substantial morbidity and cost. In the United States migraine headaches affect approximately 11 million adults at any given time (Nelson *et al.* 1998:511). In South Africa in particular the prevalence of migraine is between 10-15% irrespective of race (Stang and Osterhaus, 1993:29-35).

Migraine is a headache that lasts 4-72 hours, is throbbing in quality, is moderate to severe in intensity, is unilateral, becomes worse with exertion, and is associated with nausea, vomiting, or sensitivity to light, sound, or smell (Beers and Berkow, 1999:1376).

There are two types of migraine, those with an aura and those without. An aura usually consists of homonymous visual disturbances, unilateral parethesias, numbness, unilateral weakness, aphasia or unclassifiable speech difficulty (Tuchin, *et al.* 2000:91).

Manipulation of the cervical and thoracic spine is widely used by chiropractors as a treatment for all types of migraine headaches, and there is sufficient evidence to support that it is a successful treatment method (Wright 1978:63 Whittle, 1995:1-65; Cullinan, 1998:1-111; Cattley and Tuchin, 1999:85-90; Tuchin, *et al.* 2000:91-95; Viti and Paris, 2000:25; and Grunnet-Nilsson, 2003:75).

The homeopathic approach to any condition involves remedies (Aleotti, 1997:35-43; Murphy, 1998:938, and Straumsheim *et al.* 2000:4-7), and thus was used in this trail for migraine prevention. "Complex" homeopathy is when multiple remedies are mixed into a standard formula to cover a person's symptoms and diagnosis (Linde, *et al.* 1997:835). In a study by Aleotti (1997), a homeopathic migraine complex - *Iris versicolor, Spigelia anthelmia* and *Sanguinaria canadensis* - was used for the treatment of migraine headache, successful results were obtained in terms of duration, frequency and intensity of the headache.

Although research has shown that the majority of patients respond to both chiropractic and homeopathic treatment, no research into the combined effect of the two treatment modalities i.e. chiropractic and homeopathy, has been done, to the best of the researchers knowledge, to date.

The aim of this study was therefore to investigate the relative effectiveness of chiropractic treatment opposed to homeopathic treatment, opposed to a combination of chiropractic and homeopathic treatment in the management of migraine headaches. This was conducted subjectively, in terms of patient perception (CMCC Neck Disability Index, Glasgow Homeopathic Hospital Outcome Scores (GHHOS), a headache diary and a quality of life assessment, in order to determine the most effective treatment regime for migraine sufferers.

All data was analysed using the SPSS package with an inter-group and intra-group comparison, to analyse if any, and where significant differences occurred across the population means.

1.2 The aim of the study

The aim of the study was to investigate the relative effectiveness of a manual intervention (spinal manipulative therapy) opposed to a homeopathic intervention (Migraine complex) opposed to a combination of chiropractic and homeopathic intervention in the management of migraine headaches, in terms of patient perception, in order to determine the most effective treatment for migraine headache.

1.3 The problem statement

The purpose of this investigation was to determine the medium-term effect of a chiropractic treatment and a homeopathic treatment and a combined chiropractic and homeopathic treatment on the frequency, duration and severity of migraine attacks in terms of patient's perception, the response to analgesic use and a quality of life outcome in migraine sufferers, in order to determine the most effective treatment.

1.4 Statements of the sub-problems

1.4.1 The first sub-problem

The first sub-problem was to determine the relative effectiveness of spinal manipulation therapy versus a homeopathic migraine complex in the treatment of migraine headaches in terms of frequency, severity and duration of attacks (subjective pain perception), the response of the subjects to analgesics, and the subject's quality of life outcome after the treatment.

1.4.2 The second sub-problem

The second sub-problem was to determine the relative effectiveness of spinal manipulation therapy alone versus a combination of spinal manipulative therapy and homeopathic migraine complex for the treatment of migraine headaches in terms of frequency, severity and duration of attacks (subjective pain perception), the response of the subjects to analgesics, and the subject's quality of life outcome after the treatment.

1.4.3 The third sub-problem

The third sub-problem was to determine the relative effectiveness of a homeopathic migraine complex alone versus a combination of spinal manipulation therapy and homeopathic migraine complex for the treatment of migraine headaches in terms of frequency, severity and duration of attacks (subjective pain perception), the response of the subjects to analgesics, and the subject's quality of life outcome after the treatment.

1.4.4 The fourth sub-problem

The fourth sub-problem was to determine the relative effectiveness of spinal manipulation versus a homeopathic migraine complex versus a combination of the two for the treatment for migraine headaches in terms of frequency, severity and duration of attacks (subjective pain perception), the response of the subjects to analgesics, and the subject's quality of life outcome after the treatment.

1.4.5 The fifth sub-problem

The fifth sub-problem was to integrate the data from the sub-problems 1 to 4, in order to determine the most beneficial management plan.

1.5 Potential benefits of the study

A high percentage of South Africans suffer from migraine headaches. The prevalence of migraine in South Africa is between 10 and 15% irrespective of race (Stang and Osterhaus, 1993:29-35). Although many controlled clinical trials have been conducted to evaluate the efficacy and effectiveness of different migraine treatments, there is still no therapeutic gold standard. Therefore more studies need to be conducted to measure the most effective method for the treatment of migraines.

It has been shown that chiropractic treatment (Tuchin *et al.* 2000:91-95) and homeopathic treatment (Aleotti, 1997:35-43) help in the management of migraine. In view of this it was thought to be beneficial to determine whether a combination of chiropractic and homeopathic treatment was not a better and more effective way to treat migraines, than the individual treatments alone.

Furthermore the study is beneficial as it serves to integrate the two professions, homeopathy and chiropractic, bringing about a greater awareness of what each profession can offer the patient and it will aid in total patient management and care.

1.6 Assumptions

1. It was assumed that a large enough sample size would be obtained (viz., 30 patients).

2. It was assumed that the patient's general lifestyle would remain unchanged for the duration of the study as alteration of diet and exercise may influence the migraine attacks.

3. It was assumed that the patient would continue to use allopathic medication for the treatment of their migraine headache, and that the dose, type and frequency of use would be indicated in their migraine diaries.

4. It was assumed that the patients would log their migraine headaches as required.

5. It was assumed that the patients would be compliant in terms of taking the homeopathic remedy as directed.

6. It was assumed that they would have received no other kind of treatment for migraine as has been discussed.

Chapter 2

LITERATURE REVIEW

2.1 Introduction

Headache is a fairly common condition that warrants no introduction, yet it is also a complex problem with a variety of manifestations. Migraine is just one of the many headache conditions that occur commonly, but can have devastating influence an individual's everyday life.

As headaches are one of the most commonly reported ailments [in excess of 18 million outpatient visits per year in the United States, (Osterhaus, *et al.* 1994:337)] and in particular migraine headaches [11 million adults in the United States are affected annually (Nelson *et al.* 1998:511)], the subject has been well researched. The condition is classified as common (Straumsheim, 2000:4) and accounts for substantial morbidity and monetary cost to patients (Osterhaus, *et al.* 1994:337).

2.2 Incidence of Migraine

Studies conducted in Australia indicate a similar pattern to South Africa, with 12% of the population, aged 15 years and older, experiencing migraine headaches (Tuchin, *et al.* 2000:91). In the general population the epidemiological information indicates that migraine affects between 12.9% and 17.6% of females and 3.4% to 6.1% of males (Phongphua, *et al.* 2000:109) however Wolff (1987:55), reported a much higher incidence of 10.3-30.1% females and 4.9-16.8 % males. In South Africa the prevalence of migraine has been found to be as high as 15% in all population groups (Stang and Osterhaus, 1993:29-35). In concurrence with this, the number of migraine

sufferers amongst high school children, in the greater KwaZulu Natal, has been found to be as high as 17% (Jansen, 2000:128).

2.2.1 Studies considering specific criteria revealed the following:

2.2.2.1 Age

Migraine prevalence varies with age, the occurrence increasing through early adult life, peaking at 30 to 40 years and then declining in the late forties to fifties years in both males and females (Steiner *et al.* 2003:522). It is rare for migraine to make its appearance after the age of 45 years (Lance, 1974:97). Although the occurrence of migraine is greatest in adulthood, it is one of the most common types of headache in children. In a 14 year longitudinal study of more than 9 000 school children, 5% suffered migraine attacks by 15 years of age (Singer, 1994:94). Further studies have established that migraine first appears at the age of 10 years and younger, in 25% of patients (Lance, 1974:97). Symptoms experienced by children vary from frequent, mild, bi-frontal attacks to severe, debilitating, unilateral pain associated with persistent motor and/or visual defects (Singer, 1994:100).

2.2.2.2 Gender

According to a recent survey of 30 000 participants by Lipton and colleagues, (2001:646-657), as cited by Johnson (2002:634), the prevalence of migraine in the United States is 18.2% amongst women and 6.5% amongst men. In the UK the prevalence of migraine in males is 7.6% and in females 18.3%. Migraine prevalence with aura is 5.8% (males 2.6% and females 4.2%), sensorimotor 1.2% (males 0.3% and females 1.7%) and visual and sensorimotor collectively 1.3% (males 0.4% and females 1.9%) (Steiner *et al.* 2003:522). Although women are more commonly affected than men, the prevalence of the disorder follows the same pattern and increases among both sexes between the ages of

12 and 40, peaking in midlife (between the age of 30 and 49 years) and declining thereafter (Johnson, 2002:634).
Before puberty migraine presents equally in both sexes, but after puberty the incidence is greater in females due to hormonal changes (Singer, 1994:95).

2.2.2.3 Family history

Migraine headaches are more common in patients with a genetic predisposition to migraine (Johnson, 2002:635). In 75% of migraine cases there is a family history of migraine (Singer, 1994:94).

2.2.2.4 Ethnic groups

The Lipton study, (2001: 646-657) viewed by Johnson, (2002:634) reported that migraine is more likely to affect Caucasian rather than Black people (Johnson, 2002:634). Similarly in the UK the prevalence of migraine is lower in the non-Caucasian races (5.1% male and 9.3% females) than in Caucasians (7.7% males and 19.0% females) (Steiner *et al.* 2003:522). No reason for this was stated in the literature.

2.2.2.5 Financial status

Migraine is more prevalent in lower income groups, perhaps due to increased financial stress (Johnson, 2002:634).

2.3. Diagnosis of Migraine

Since no test for migraine is yet available, physicians must rely on the patient's history and symptoms to make a clinical diagnosis (Johnson, 2002:636). Developing a set of valid diagnostic criteria for migraine is a challenge due to the disease entity that lacks objective defining markers. Without biological markers, there is no certainty that the migraine diagnosis reflects the underlying biological disorder. In an effort to develop diagnostic criteria in 1988, the Headache Classification Committee of the International Headache Society (IHS) had to rely on expert consensus, based on specific headache characteristics obtained from headache history records (Nash and Nash, 2003:322). In 2004 the Headache Classification Committee of the International Headache Society (IHS) updated the 1988 version.

2.3.1 Migraine Classification

The Headache Classification Committee of the International Headache Society (2004) lists six categories of migraine. They are:

1. Migraine without aura (common migraine).
2. Migraine with aura (classic migraine).
3. Childhood periodic syndromes that are commonly precursors of migraine.
4. Retinal migraine.
5. Complications of migraine.
6. Probable migraine.

This study concerned itself only with the first two categories, i.e. migraine without aura and migraine with aura.

2.3.1.1 Migraine without aura

Migraine without aura, also known as common migraine or hemicrania simplex, is defined by the Headache Classification Committee of the International Headache Society (2004:24/5) as: "Recurrent headache disorder manifesting in attacks lasting 4 to 72 hours. Typical characteristics of the headache are unilateral location, pulsating quality, moderate or severe intensity, aggravated by routine physical activity and association with nausea, photophobia and phonophobia."

The diagnostic criteria are as follows:

A: At least 5 attacks fulfilling criteria B-D below.

B. Headache lasting 4 to 72 hours.

C. Headache has at least 2 of the following characteristics:

1. Unilateral location
2. Pulsating quality
3. Moderate or severe intensity; affecting daily activity
4. Aggravated by or causing avoidance of routine activity (e.g. walking or climbing)

D. During the headache, at least one of the following symptoms occurs:

1. Nausea and/or vomiting
2. Photophobia and/or phonophobia

E. Not attributed to another disorder.

2.3.1.2 Migraine with aura

Migraine with aura, also known as classic migraine, is defined by the Headache Classification Committee of the International Headache Society (2004:25/6) as: "Recurrent headache disorder manifesting with attacks of reversible focal neurological symptoms that usually develops gradually over 5 to 20 minutes and last for less than 60 minutes. Headache with the features described in 2.3.1.1 Migraine without aura, usually follows the aura symptoms. Less commonly, headache lacks migrainous features or is completely absent."

The diagnostic criteria are as follows:

A. At least 2 attacks fulfilling criterion B below.

B. Migraine aura fulfilling criteria B and C for one of the subforms described below.

C. Not attributed to another disorder.

This definition encompasses six migraine with aura subtypes as listed by the Headache Classification Committee of the International Headache Society (2004).

2.3.2.2.1 Migraine with typical aura

The Headache Classification Committee of the International Headache Society (2004:26/7) describes this as follows: "Typical aura consisting of visual and/or sensory and/or speech symptoms. Gradual development, duration no longer than one hour, a mix of positive and negative features and with complete reversibility, characterise the aura which is associated with headache fulfilling criteria for migraine without aura."

Diagnostic criteria are as follows:

A. At least 2 attacks fulfilling criteria B to D

B. Aura consisting of at least one of the following but no motor weakness:

1. Fully reversible visual symptoms including positive features (e.g. flickering lights, spots or lines) and/or negative features (i.e. loss of vision).
2. Fully reversible sensory symptoms including positive features (e.g. pins and needles) and/or negative features (i.e. numbness).
3. Fully reversible dysphasic speech disturbances.

C. At least two of the following:

1. Homonymous visual symptoms and/or unilateral sensory symptoms.
2. At least one aura symptom develops gradually over $\geq$ 5 minutes and/or different aura symptoms occur in succession over $\geq$ 5 minutes.
3. Each symptom lasts $\geq$ 5 and $\leq$ 60 minutes.

D. Headache fulfilling criteria B –D, as described in 2.3.1.1 Migraine without aura begins during the aura or follows aura within 60 minutes.

E. Not attributed to another disorder.

2.3.2.2.2 Typical aura with non-migraine headache

The Headache Classification Committee of the International Headache Society (2004:27) describes this as follows "Typical aura consists of visual and/or sensory and/or speech symptoms. Gradual development, duration no longer than 1 hour, a mix of positive and negative features and complete reversibility characterise the aura which is associated with a headache that does not fulfil the criteria for migraine without aura."

The diagnostic criteria are the same as described in 2.3.2.2.1 Migraine with typical aura, except for D, which is:

D. Headache that does not fulfil criteria B –D, as described in 2.3.1.1 Migraine without aura begins during the aura or follows aura within 60 minutes.

2.3.2.2.3 Typical aura without headache

The Headache Classification Committee of the International Headache Society (2004:28) describes this as follows "Typical aura consists of visual and/or sensory symptoms with or without speech symptoms. Gradual development, duration no longer than 1 hour, a mix of positive and negative features and complete reversibility characterise the aura which is associated with headache."

The diagnostic criteria are the same as described in 2.3.2.2.1 Migraine with typical aura, except for D, which is:

D. Headache that does not occur during aura or follow aura within 60 minutes.

2.3.2.2.4 Familial hemiplegic migraine

The Headache Classification Committee of the International Headache Society (2004:28/9) describes this as follows: "Migraine with aura including motor weakness and at least one first or second degree relative has migraine aura including motor weakness."

The diagnostic criteria are the same as described in 2.3.2.2.1 Migraine with typical aura, except for C and D, which is:

C. At least two of the following:
   1. At least one aura symptom develops gradually over ≥5 minutes and/or different aura symptoms occur in succession over 5 minutes.
   2. Each aura symptom lasts ≥5 minutes and <24 hours.
   3. Headache fulfils criteria B to D as described in 2.3.1.1 Migraine without aura, begins during the aura or follows onset of aura within 60 minutes.

D. At least one first or second degree relatives has had attacks fulfilling criteria A to E.

2.3.2.2.5 Sporadic hemiplegic migraine

The Headache Classification Committee of the International Headache Society (2004:29) describes this as follows: "Migraine with aura including motor weakness, but no first or second degree relative has had aura including motor weakness."

The diagnostic criteria are the same as described in 2.3.2.2.4 Familial hemiplegic migraine except for D, which is:

D. No first or second degree relatives have attacks fulfilling criteria A to E.

2.3.2.2.6 Basilar Migraine

The Headache Classification Committee of the International Headache Society (2004:29/30) describes this as follows: "Migraine with aura symptoms clearly originating from the brainstem and/or from both hemispheres simultaneously affected, but no motor weakness."

The diagnostic criteria are as follows:

A. At least 2 attacks fulfilling criteria B to D

B. Aura consisting of at least two of the following reversible symptoms, but no motor weakness:

1. Dysarthria
2. Vertigo
3. Tinnitus
4. Hypacusia
5. Diplopia
6. Visual symptoms simultaneously in both temporal and nasal fields of both eye
7. Ataxia
8. Decreased level of consciousness
9. Simultaneously bilateral paraesthesias.

C. At least one of the following:

1. At least one aura symptom develops gradually over ≥5 minutes and/or different aura symptoms occur in succession over ≥5 minutes.
2. Each symptom lasts ≥5 and ≤60 minutes.

D. Headache that does not fulfil criteria B to D for 2.3.1.1 Migraine without aura begins during the aura or follows aura within 60 minutes.

E. Not attributed to another disorder.

The following classifications were mentioned in the IHS report of 1988, but are omitted in their 2004 report.

2.3.1.3. Migraine with acute onset aura

The Headache Classification Committee of the International Headache Society (1988) describes this as: "Migraine with aura developing fully in less than 5 minutes."

2.3.1.4. Migraine with complete aura

The Headache Classification Committee of the International Headache Society (1988) describes it as: "Migraine with one or more aura symptoms lasting >60 minutes and less than a week. Neuro-imaging is normal."

Since the 1988 criteria were published, different methods have been used to validate the diagnostic criteria in the IHS classification system. While most studies support the validity and usefulness of the IHS migraine diagnostic criteria, some findings differ and suggest that there is (1) a lack of uniform acceptance of the IHS criteria, (2) a lack of agreement about what the criteria considered most central and important in making the diagnosis, and (3) a lack of inclusion in the IHS system of some migraine characteristics that are considered important.

In the study by Nash and Nash (2003) the Structural Knowledge Assessment was utilised to evaluate the validity of the existing criteria. The fourteen concepts were used for the rating task included the 7 IHS diagnostic criteria for migraine headache as well as 7 non-IHS criteria that were deemed important in migraine diagnosis (Nash and Nash, 2003:322-323). These follow in the table below:

IHS Criteria	Non-IHS Criteria
Moderate/severe intensity	Family history
Nausea and vomiting	Female gender
Phonophobia	Food triggers
Photophobia	Hormonal relationship
Throbbing pain	Relief with sleep
Unilateral pain	Sensitivity to smells (osmophobia)
Worse with physical activity	Worse with stress

The most central concepts were unilateral pain, moderate to severe intensity and nausea/vomiting. Pain that worsens with physical activity was considered only relatively important. Sensitivity to smells (a non-IHS criterion) was found to be particularly good at distinguishing migraine from other headaches. The study provides strong support for the validity of the migraine diagnostic criteria in the IHS classification system (Nash and Nash, 2003:328).

In a survey by the American Headache Society members, it was found that headache specialists ranked the IHS criteria as no more important than other criteria in the diagnosis of migraine. They considered factors such as gender, hormonal association, dietary triggers, relationships to stress and menstruation, family history and onset in the second to third decade equally important (Nash, *et al.* 2003:3).

The second edition of the International Classification of Headache disorders by the International Headache Society was only published 15 years after the first edition, the reason being that the first edition was very well received by the health experts. New ideas and suggestions were included in the second edition. Every set of criteria, every number and every word had been weighted carefully, for it is important to have a generally accepted classification throughout the world especially as headache as a phenomenon is a young and developing field of research (IHS, 2004:9).

2.4. Clinical features

2.4.1 Site of headache

According to the recent prevalence study by Lipton, (2001:646-657) as reported by Johnson (2002:636), 59% of migraineurs experienced unilateral pain. Migraine headaches are chiefly unilateral in two-thirds of patients and bilateral in one third. The pain might be felt deeply behind the eye, but more commonly involves the frontal and temporal regions. It may extend over the entire head and radiate down the face or even to the neck and the shoulder. In other patients it starts as a dull ache in the upper neck and occipital region and radiates forwards. In some patients it may remain limited to the vascular territory of the frontal, temporal or occipital arteries (Lance, 1974:100).

2.4.2 Quality of headache

Migraine commonly starts as a dull headache which rapidly becomes more severe and assumes a pulsating to throbbing quality (Lance, 1974:100). Johnson substantiates this phenomenon in his finding of 85% of migraineurs experiencing pulsatile pain (Johnson, 2002:636).

2.4.3 Frequency of headache

More than half of patients that attend headache clinics experienced between one and four attacks each month, it has been found that, as emotional factors increase the frequency of the headache increases. In patients who experienced more than 10 attacks each month, tension headaches were often also present, and the patients found it difficult to distinguish between the two. Uncommonly patients may progress to 'status migrainosus' when they awaken each day with recrudescence of their migraine headache (Lance, 1974:100). In the United Kingdom, the median number of attacks per person is 12 per year with 13% of

migraineurs having one or more attacks per week and 54% of migraineurs having one or more attacks per month (Steiner *et al.* 2003:522).

2.4.4 Duration of attack

The headache persists for less than one day in about two-thirds of patients, although a feeling of exhaustion and lethargy may remain for several days afterwards (Lance, 1974:100). The median duration of a migraine attack is 24 hours (Steiner *et al.* 2003:523).

2.4.5 Time and mode of onset of migraine attack

Commonly, patients awaken in the morning with a migraine headache already present but it may start at any time of the day, and it may be preceded by focal neurological symptoms such as visual disturbances (Lance, 1974:100).

2.4.6 Vascular changes

The patient with migraine often notice increased pulsation and tenderness of the superficial temporal arteries during the headache and find that pressure over the vessel will reduce the intensity of the headache. Veins may become prominent over the forehead or temples and the conjunctival vessels are usually dilated. The skin may be flushed, but is more commonly pale, and sweating occurs in severe attacks. Hands and feet often feel cold. Patients with migraine may rarely have a fever (Lance, 1974:100-101).

2.4.7 Sodium and fluid retention

There is an increase in weight, with or without signs of general oedema, in 50% of patients before the migraine attack. Oliguria is common before the attack and roughly 30% of the patients notice polyuria as the headache subsides. The blood sodium level is increased before and during the attack and the serum

protein concentration falls. Sodium and water retention is associated with migraine and it is suggested that aldosterone is responsible for this retention. Sodium and water retention is however not the cause of migraine (Lance, 1974:101).

2.4.8 Gastrointestinal Disturbances

Patients feel nauseated by their migraine headache and the majority of patients report vomiting as well. The passage of one or more loose stools is noted by 20% of patients during an attack (Lance, 1974:101). According to the recent prevalence study by Lipton (2001:646-657), cited by Johnson (2002:636), 73% of migraineurs experienced nausea and 29% vomit.

2.4.9 Photophobia, phonophobia and osmophobia

Eighty percent (80%) of patients find light unpleasant during migraine headache and prefer to lie down in a darkened room. Photophobia may be a referred pain from irritation of the ophthalmic division of the trigeminal nerve. It may occur because of a manifestation of hyperactivity of the special senses, since the dislike of noise (photophobia) and strong odours (osmophobia) are also common complaints (Lance, 1974:104; Steiner *et al.* 2003:522). According to the Lipton study, (2001:646-657) described by Johnson (2002:636), 80% of migraineurs report sensitivity to light, and 76% of migraineurs report sensitivity to sound.

2.4.10 Hyperaesthesia

One third of patients suffer from undue sensitivity of the scalp during and after a migraine attack (Lance, 1974:104).

2.4.11 Focal neurological symptoms and signs

Aura is a complex of neurological symptoms that occurs just before or at the onset of migraine headache. Premonitory symptoms occur from hours to a day or two before the migraine attack. They include various combinations of fatigue, difficulty in concentration, neck stiffness, sensitivity to light and sound, nausea, blurred vision, yawning and pallor (IHS, 2004:26).

One third of patients experience transient disturbance of cerebral function. Visual hallucinations or scotomas are most frequent (33%). Fortification spectra (zig-zag appearance of the hallucination) are experienced by 10% and 25% who experience photopsia (unformed flashes of light which are white or coloured). Symptoms which originate in areas of the cortex other than the occipital lobe are much less common. Paraesthesiae around the mouth and tongue and in both hands may arise from the cortex or the long sensory tracts in the brainstem. Strictly unilateral paraesthesia associated with hemiparesis or dysphasia which is clearly of cortical origin is found in 4% of patients. Transient temporal or parietal lobe syndromes may be part of a migraine attack. Twenty five percent (25%) of patients experience symptoms arising from the brainstem such as diplopia, vertigo, inco-ordination, ataxia and dysarthria. Severe brainstem symptoms may be associated with faintness, fainting or sudden loss of consciousness (Lance, 1974:105).

Steiner *et al.* (2003:523) reported visual aura in 32% of migraineurs and 18% had sensorimotor aura.

According to the IHS (2004:27), the most common type of aura is the visual aura (e.g. fortification, scotomas) followed by sensory disturbances in the form of pins and needles and numbness, and less frequently dysphasic changes.

Blurred vision was noted in 44% of patients by Johnson, (2002:636) and in approximately one third of patients, the migraine attack is preceded (by 30 to 60 minutes) by an aura, which is a collection of transient focal neurologic

symptoms that include, among others, tingling in the extremities, visual changes and aphasia (Johnson, 2002:636)

2.4.12 Aggravating factors (Lance, 1974:109-111)

- Patients with the following personality are more susceptible to migraine attacks: tense, meticulous and obsessive, anxious, sensitive, depressed and stressed. Often it is the period of relaxation after a stressed period that will trigger the attack. Hormonal changes can also trigger the headache.
- Twenty five percent of patients consider that their attacks are provoked by eating certain foods, particularly fatty foods, chocolates and oranges. Tomatoes, onions and pineapples are occasionally mentioned. Thyramine (causes the release of seratonin from platelets) and amines (responsible for a sequence of biochemical changes) can trigger migraine. Missing a meal may precipitate migraine because of a lowered sugar level that stimulates noradrenaline and other biochemical changes.
- Glare and loud noises
- Alcohol and other vasodilators
- Exertion
- Hypertension
- Cervical spondylosis and compression of vertebral arteries or their sympathetic plexus.

2.5. Pathophysiology of migraine

2.5.1 Vascular theory

Migraine has been considered for many years to be a disturbance of vascular regulation in the cerebral circulation. There is an altered blood flow in all stages of the migraine attack, which are vasoconstriction, cerebral ischemia and then vasodilation (Vernon 1985:20).

In the classic vascular theory by Theisler, (1990:37) the sequence of the events in a prodromal migraine headache is as follows (Theisler, 1990:37):

Trigger factors such as stress, hypoglycemia, thyramine, and phenylethylamine initiates the release of epinephrine and noradrenaline before the attack

⇓⇓

Increasing platelet aggregation with release of pain-sensitizing agents and processes (e.g. bradykinin, histamine, sterile inflammation)

⇓⇓

Raise in serum serotonin levels

⇓⇓

Reactive cerebral vasoconstriction

⇓⇓

Cerebral ischemia

⇓⇓

Decrease in serum serotonin levels

⇓⇓

Reactive cerebral vasodilation

⇓⇓

Extracranial vasoditation

⇓⇓

Headpain

The aura that is perceived by the patient may also be due to blood flow. Before or simultaneously with the onset of aura symptoms, regional cerebral blood flow is decreased in the cerebral cortex corresponding to the clinically affected area, and often including an even wider area. Blood flow reduction usually starts posteriorly and spreads anteriorly and is usually above the ischeamic threshold. After one or several hours, gradual transition into hyperaemia occurs in the same area (IHS, 2004:26).

2.5.2 Neurogenic model of migraine:

2.5.2.1 Trigeminovascular system:

The Trigeminal nerve is central to the neurogenic model and is the most important component in the pathogenesis of migraine (Buzzi, 1995:277).

The neurogenic model of migraine pain implies that any stimulus which depolarizes trigeminal sensory fibres activates the trigeminovascular system (TVS) and induces changes in cephalic circulation, in the intra and extracranial tissues receiving trigeminal innervation. Metabolic changes in the brain or circulating factors may be responsible for triggering this system (Buzzi, 1995:277).

The TVS serves to alert and defend the brain. These fibres reside in the blood vessels, and can be activated by receptor-mediated or ionic mechanisms triggered by primary disturbances in the brain, or other events occurring in the circulation, or in the vessel wall. The brain is an insensitive organ whereas the meninges that protects the central nervous system, is innervated by the trigeminal nerve. Headaches are accompanied by autonomic responses which are made possible by anatomical connections between the TVS and autonomic structures in the brainstem (Buzzi, 1995:277).

Activation of the peripheral trigeminal fibres induces neurogenic inflammation in the dura mater, as well as vascular and mast cell changes. These changes cause an increase of vasodilation and permeability-promoting peptides in venous effluent of the cephalic circulation. The trigeminal pain pathway carries peripheral stimuli through the brainstem to the thalamus and the cortex, thus providing pain perception (Buzzi, 1995:277).

2.5.2.2 The new neural theory

A new neural theory of migraine was proposed by Eggers, (2001: 360-362). Single photon emission computed tomography (SPECTS) and positron-emission tomography (PET) have provided useful information about migraine pathophysiology. In most cases, SPECTS and PET scans performed during visual auras preceding the headache show focal areas of decreased blood flow that begin at the occipital lobe and progress forward across the cortex. SPECTS performed during the headache without aura often appear normal and SPECTS abnormalities of patients with aura can persist during asymptomatic periods. There are patients with aura who also have areas with hot spots (hyperfusion) and areas with cold spots (hypoperfusion). In other words there are focal areas of brain of activation and inhibition (Eggers, 2001:360-362).

Thus the theory is presented as follows:
Migraine is an electrical disease of the brain in which abnormally-functioning serotonergic pacemaker cells in the raphe nuclei inappropriately activate and inhibit wide areas of the brain, resulting in migrainous symptomatology, which consists of a mixture of positive and negative phenomena. Visual auras, for example, consist of both photopsias, which are a positive phenomena and scotomas which are negative phenomena. Activation of inhibitory cells, an inhibitory hot spot, could cause loss of neurological functions and negative symptoms. A

cold spot could represent loss of inhibition and lead to positive symptoms (Eggers, 2001:360-362).

Serotonergic neurons are limited to the raphe nuclei in the midbrain periaqueductal grey matter and project diffusely to the entire central nervous system. There are serotonergic receptors in the retina, which are involved in the migrainous process. There is considerable evidence implicating serotonin release in the periaqueductal grey matter with the onset of migraine attacks (Eggers, 2001:360-362).

2.5.2.3 Trigeminocervical complex

Another theory is the relationship between the trigeminocervical complex and migraine. These severe headaches involve the trigeminal and upper cervical dermatomes, sensory dysmodulation and, in one fifth of the patients, an aura with neurologic symptoms. Patients often complain of pain in the cutaneous distribution of the first (opthalmic) division of the trigeminal nerve. However the pain, in due course, frequently exceeds the trigeminal territory as pain from the back of the head is innervated by the greater occipital nerve (GON). This is the sole manifestation of pain in patients with migraine. Also other clinical features such as hypersensitivity of the skin of the scalp, neck muscle tenderness and hyperalgesia are often reported (Bartsch and Goadsby, 2003:371).

It has been shown that the spread and referral can be induced by stimulation of structures in the neck, which are innervated by upper cervical roots. Frontal head pain can be due to posterior fossa tumours, stimulation of infratentorial dura mater, and direct stimulation of cervical roots, vertical artery dissection and stimulation of subcutaneous tissue innervated by the GON. Similary, direct stimilation of the supratentorial dura mater leads to pain mostly referred to the opthalmic division of the trigeminal nerve, and may also refer to dermatomes supplied by the upper cervical roots (Bartsch and Goadsby, 2003:371).

This could be explained by the convergence of the trigeminal and cervical efferents on to neurons in the trigeminocervical complex in the brain stem. Convergence along with sensitisation of central trigeminal neurons provides a physiologic basis for the clinical phenomenon and referred pain by which pain originating from an affected tissue is perceived as originating from a distant receptive field (Bartsch and Goadsby, 2003:371).

2.5.3 Vertebral theory

At the level of the first and second cervical vertebrae is a two-to-three centimetre long structure called the superior cervical sympathetic ganglion (SCSG) (Moore, 1992:815). This structure controls smooth muscles and glands in the head. Postganglionic fibres travel upward from the SCSG and enter the cranium along with the internal carotid arteries through the cartilage-filled foramen lacerum, which is located anterior and lateral to the foramen magnum and just anterior to the first cervical vertebrae (Moore, 1992:815 and Clemente, 1987:645)

The superior cervical sympathetic ganglion controls blood vessel diameter in the head, and in the dilator pupillae muscles, which dilate the pupils of the eye. Subluxation of the first cervical vertebrae/occipital articulation can narrow the foramen lacerum and put pressure on the postganglionic sympathetic nerves, causing those nerves to fire. This leads to vasoconstriction of the blood vessels in the head and dilation of the pupils, which accounts for the photophobia many migraine sufferers experience (Hough, 2002).

Vasoconstriction of the blood vessels in the head results in hypoxia of the vascular system. Hypoxic tissues become acidic and release substance P, bradykinins and histamine, which cause vasodilation and increased capillary permeability. The vascular system in the head is then flooded with blood, causing the vascular headache (Hough, 2002).

Women often suffer from "hormonal" migraines. Prior to the beginning of menstruation, many women experience systemic inflammation (premenstrual syndrome) due to increased prostaglandin release. This inflammation further compromises the already narrowed foramen lacerum putting pressure on the postganglionic nerve fibres and resulting in a vascular headache. Eliminating vasoactive substances from the diet (chocolate, red wine, monosodium glutamate, etc.) has shown some success in reducing the number of headaches. These vasoactive substances result in dilation of the internal carotid arteries through the already narrowed foramen lacerum, putting pressure on the sympathetic nerves (Hough, 2002).

2.6. The impact of migraine

2.6.1 Disability caused by migraine

Migraine is a common episodic, temporarily disabling neurological disease. It imposes significant burdens on individuals and on the society (Steiner *et al.* 2003:519).

The World Health Organization (WHO) defines the functional consequence of illness in terms of impairment, functional limitations and disability. Impairment refers to the primary manifestation of illness and includes pain, limitations of range of motion, and effects on other sensations. Functional limitations are defined as the effect of the illness upon an individual's activities, such as walking. Disability refers to the consequences of illness on ability to work and function in other roles. Disability is the major determinant of the cost of illness. Migraine is a profound disability (Bigal *et al.* 2003:340-341).

The Lipton study, reported by Johnson, (2002:635), shows that among those who suffer from migraine, 32% of women and 43% of men had never consulted a physician regarding their headaches. Of the 68% of women and 57% of men who had consulted a physician, half of these patients had not been diagnosed with migraine. Of the 50% of patients who received a diagnosis of migraine, approximately 40% received prescription treatment for their headaches, 57% used over-the-counter medications and a small proportion received no treatment at all (Johnson, 2002:634/5). Despite treatment, a substantial percentage of patients remain dissatisfied because they continue to experience migraine pain with its associated symptoms as well as treatment-related side effects, including rebound headaches (Johnson, 2002:635).

Most (73%) migraineurs in the UK reported that the headache interferes with their daily activities (Steiner *et al.* 2003:524). In the survey by Lipton and colleagues, (2001:646-657) more than 90% of migraineurs reported some functional impairment caused by their headache, 53% stated their headaches severely limited their activities or forced them to seek bed rest. Approximately

31% of all migraineurs missed at least one day of work or school in the three months preceding the survey and more than 50% reported that their work or school productivity was reduced by at least 50% because of migraine headaches (Johnson, 2002:635). An estimated 5.7 workdays per year were missed by those who worked or attended school in the UK (this average includes the most disabled). Females were 25% more likely than males to miss time off work or school. Almost half (>45%) of males and females who rarely or never missed work or school, nevertheless required bed rest with a median duration of 2 hours (Steiner *et al.* 2002:524).

2.6.2 Cost of migraine

The direct cost of the treatment of migraine exceeds $1 billion per year in the United States. The indirect cost associated with morbidity, diminished quality of life, expensive employee absenteeism, and reduced work productivity is substantially higher, and an estimated $13 billion per year is lost (Johnson, 2002:634). Due to the dissatisfaction of treatment patients seek additional relief with other medications, physicians or emergency care facilities, adding further to the direct costs associated with migraine (Johnson, 2002:635).

In congruence with this, a significant economic burden was observed by a recent study conducted by Gerth (2001:197-206). Annual workdays lost were estimated from the patient's reports and productivity data was collected during a 4 week period. The investigation showed that each clinic-based patient with migraine lost 19.5 workdays (8.3 days because of absenteeism, 11.2 days because of reduced workday equivalents). The total cost of migraine-related productivity loss borne by employers in the United States is estimated to be $3,309 per patient per year (Johnson, 2002:635).

2.7 Migraine and it association to other disorders

2.7.1 Depression

Migraneurs often display symptoms of depression, including apathy, insomnia and loss of appetite. The relationship between migraine and depression is strongest in patients with prominent auras, including paresis, dysarthria and loss of consciousness. A common observation is that migraine is caused by stress and constitutes a symptom of depression. Several antidepressant drugs are effective in migraine prophylaxis such as tricyclines and seratonin reuptake inhibitors (Eggers, 2001:362).

2.7.2 Allergy and childhood vomiting

Migraine is linked to allergic disorders such as asthma, hayfever, hives and eczema and also to cyclical vomiting or 'bilious attacks' in children (Lance, 1974:97).

2.7.3 Epilepsy

Many reports in the past have linked migraine with epilepsy (Lance, 1974:97). Migraine hotspots in the brain may reflect network oscillations of cortical circuitry similar to those seen in epilepsy. In adolescents migraine can be associated with electroencephalographic abnormalities. Sometimes seizures follow immediately upon the migraine attacks. This happens less frequently in adults, because the oscillatory neuronal discharge involved in a migraine attack that occasionally transforms into frank epilepsy in the immature brain, is usually inhibited in the adult brain. Anti-epileptic drugs such as valproate are effective in migraine prophylaxis (Eggers, 2001:361-362).

2.8 Hormonal influence

Migraine occurs more frequently in adult women than adult men. It develops most frequently in the second decade with a peak incidence occurring around or after adolescence. In addition, women report more frequent and severe headaches than men. This could be due to the cyclic changes in female sex hormones that occur following menarche. This factor can precipitate headache attacks or condition the central nervous system (CNS) to be more susceptible to attacks. It is more likely to occur premenstrually.

The term Menstrual Headaches refers to migraine attacks that occur with menstruation (IHS, 2004:138). The International Headache Society (IHS) suggest that migraine without aura is the predominant variant associated with the menstrual cycle and precipitates that 90% of the attacks should occur between 2 days before menses and the last day of menses (Steward *et al.* 2000:1517). Clinical evidence suggests that migraine without aura, rather than with aura, is associated with menstruation (Steward *et al.* 2000:1517; Mattsson, 2003:27).

In a population-based diary study, there was a 60% increase in migraine headaches without aura during the first 3 days of menstruation. The excess risk peaks on the first and second days with the lowest risk at the time of ovulation (Steward *et al.* 2000:1520). The risk of experiencing migraine attacks during 3 consecutive menstrual cycles and at no other time was estimated at 7.2%. American studies indicate that the risk of experiencing migraine without aura is approximately doubled on the first two days of the menstrual cycle in comparison to all other days (Mattsson, 2003:27).

The menstrual cycle is the result of a carefully orchestrated sequence of interactions between the hypothalamus, pituitary, ovary and endometrium, with the sex hormones acting as modulators and effectors at each level. Oestrogen and progestin's have potent effects on central serotonergic and opioid neurons,

modulating both neuronal activity and receptor density. The primary trigger for migraine occurring during menses may be the withdrawal of oestrogen rather than the maintenance of sustained high or low oestrogen levels. Oestrogen given premenstrually delays the onset of migraine but not menstruation. In contrast, progesterone administration delays menstruation but does not prevent migraine. Oestrogen withdrawal might trigger migraine attacks in susceptible women. Menstrual migraines do not constitute a unique headache type any more than alcohol or chocolate triggered responses. Menstrual migraine is therefore difficult to treat (Steward *et al.* 2000:1522).

Although the prevalence of migraine headaches peak at around the age of 40 years and declines thereafter, little information is available on why this happens. Middle age women undergo physical, mental and social changes that may be relevant to the prevalence of migraine. To date there is no information on the relationship between migraine and symptoms related to menopause and no association has been made between the usage of hormonal replacement therapy and migraine headaches (Mattsson, 2003:27).

2.9 Differential diagnosis of migraine headaches:

2.9.1 Functional headaches

1. Cluster headaches

Also known as "migrainous neuralgia". Males are more commonly affected, with a peak onset of 20 - 50 years. It is a paroxysmal, explosive, unilateral, temporal and periorbital pain, which commences quickly without any warning signs. The attack follows a cycadian regularity, often nocturnal. The cluster cycles usually last weeks with pain-free intervals lasting months. Associating signs and symptoms are ipsilateral nasal stuffiness, soft tissue swelling, forehead sweating, lacrimation, hyperermic eye and Horner's syndrome (Raskin, 1988:229-234).

Although migraine and cluster headache are two distinct and different entities, occasionally some patients present with characteristics of both headache disorders occurring simultaneously during attacks. Either migrainous features can be seen in patients with cluster headaches or unilateral cranial autonomic symptoms can be seen in migraine headaches, or both can be mixed together without one being more predominant. To differentiate between cluster and migraine headaches the symptoms must be carefully viewed (Dora, 2003:561-562).

The symptom patterns are as follows (Dora, 2003:561-562):

Migraine	Cluster headaches
Switches sides even if they preferentially occur on the same side. Side locked migraines have also been reported.	Strictly unilaterally
Almost never accompanies autonomic symptoms.	Accompanied by autonomic symptoms
Last 2-72 hours	Seldom last longer than 3 hours
	Occurs in bouts which last around 8 weeks
Patient prefers to lie down in a dark quiet room and try to sleep.	Patients are restless and unwilling to lie down as this results in an increased pain
Sleep relieves the headache	Sleep has little impact on cluster headaches
Nausea, vomiting, photophobia, phonophobia, pulsating headache	Nausea, vomiting, photophobia, phonophobia, pulsating headache

Although migraine and cluster headaches are considered to be two different entities with different, but not yet fully understood, pathophysiology, it is possible that both share a common pathophysiological step, probably a functional alteration in hypothalamic or brainstem circuits (Dora, 2003:562).

2. Tension headaches (Muscle contraction)

The headache lasts minutes to days. The pain is typically bilateral, pressing or tightening in quality and of mild to moderate intensity. It does not worsen with routine activity. There is no nausea but photophobia or phonophobia may be present. Mild nausea may be present in chronic tension type headache (IHS, 2004).

3. Transformed Migraine and Chronic Daily Headaches

Patients with chronic migraine often have a past history of episodic migraine that progresses to a process of transformation characterised by headaches that become more frequent over months to years, with associated symptoms that become less severe (Bigal *et al.* 2003:337). This is called transformed migraine. Transformed migraine is a diagnosis not recognized by the IHS system, but two thirds of the American Headache Society (AHS) members are using this diagnosis (Nash *et al.* 2003:11).

Patients then develop a pattern of chronic daily headaches that phenomenologically may resemble that of chronic tension-type headache, with a few attacks of full-blown migraine superimposed. The impact of CDH depends more on the frequency than on the severity of the headache attack (Bigal *et al.* 2003:337).

4. Analgesic Overuse Headache

Analgesic rebound headache was diagnosed in at least 20% of patients with headaches by the American Headache Society (AHS). The AHS members do not support the IHS criteria for diagnosing headaches associated with analgesic overuse. They prefer to base their diagnosis on the number of days of analgesic medication use rather than the quantity of analgesic medication used (Nash *et al.* 2003:11). Chronic migraine can lead to the overuse of analgesic medication which leads to rebound headaches (Johnson, 2002:635).

5. Post traumatic headache

Acute post traumatic headache is attributed to moderate or severe head injury. Chronic post traumatic headache is often part of post traumatic syndrome. It can include symptoms such as equilibrium disturbances, poor concentration, decreased work ability, irritability and sleep disturbances (IHS, 2004).

6. Fibromyalgia

A form of non-articular rheumatism characterised by widespread musculoskeletal pain and stiffness, as well as tenderness on palpation at characteristic sites, called tender points (Meyer, 1997:32).

7. Psychogenic

Patient complains of pain which 'hurts all the time, is felt all over and is the worst pain ever" yet they do not respond to any treatment (Gatterman, 1990:251).

8. Sinus headache

The inflammation/infection of one or more paranasal sinuses and occurs with obstruction of the normal drainage mechanism. It is associated with intermittent daily headache attacks (Gatterman, 1990:251).

9. Vertebrogenic headache

It is a structural dysfunction of the cervical spine e.g. subluxation (Schafer & Faye 1989:118).

10. Miscellaneous

- Drug associated headache - too many analgesics or headache medication can cause daily headaches (Johnson, 2002:635).
- Allergic Headache - Usually seasonal, rarely associated with food (Gatterman, 1990:251).
- Hangover - Due to excessive alcohol intake has migraine like symptoms (Gatterman, 1990:251).

- Eyestrain - Frontal headache with visual acuity that may require attention, glasses may by necessary (Gatterman, 1990:251).

2.9.2 Pathological Headaches

1. Structural tumour or brain abscess

Rapidly progressive headache, with signs and symptoms of raised intercranial pressure (Gatterman, 1990:251).

2. Structural Aneurysm

Headache due to small bleeds, usually felt in vertex, described as the worst headache ever (Gatterman, 1990:251).

3. Hypertension

Headache associated with an elevated blood pressure of 200/110mmHg (Gatterman, 1990:251).

4. Giant Cell Arthritis

Signs and symptoms are headache and scalp tenderness, malaise, loss of weight, fever, muscle tenderness and stiffness, visual impairment, arm and jaw claudication, brainstem ischaemia and cerebral hemisphere infarction (Edwards and Bouchier, 1993:867). Stroke may occur, so signs and symptoms are vital (Gatterman, 1990:251).

2.10 Warning signs

Differential diagnosis of benign headaches should only begin after ruling out more threatening conditions including intracranial disorders, neoplasms, infections and ocular disorders. Gatterman, (1990) lists the following red-flag warnings of organic disease (Gatterman, 1990:252):

- Episodic fainting in relation to headache,
- Abrupt onset of a severe headache for the first time,
- Neurological abnormalities associated with headache,
- Elevation in body temperature associated with headache,
- Onset of headache after age 50,
- Headaches associated with an increased in pressure (coughing, bending, valsalva, coitus),
- History of recent blood pressure elevation,
- Personality change,
- Headache following history of head trauma,
- Disturbances of pulse rate and respiration,
- Constant sensory disturbances,
- Onset of visual field defects.

2.11 Treatment

Once the clinician has established the diagnosis of migraine it is important to determine the most effective mode of long-term migraine management. Overall the goals of long-term treatment are to reduce the frequency and severity of migraine attacks, to improve quality of life and productivity; discontinue poorly tolerated, ineffective or unwanted acute-migraine medications; and educate and enable patients to take control of their disorder. It is important that, in learning about their condition, patients develop realistic goals and a proper understanding of the benefits of treatment (Johnson, 2002:636).

2.11.1 Preventative therapy

Preventative treatment that includes nonpharmacologic and pharmacologic measures are indicated for patients who cannot tolerate or do not respond adequately to treatment for acute migraine; and who continue to experience moderate to severe migraine attacks that are profoundly disabling and occur more than twice a month (Johnson, 2002:636).

Nonpharmacological measures include (Johnson, 2002:636):

- Education about the disease and its treatment
- Changes in lifestyle and habits to avoid migraine triggers.
- Triggers may include:
  - Excessively stressful or extreme activities
  - Caffeine and certain foods
- Patient should adhere to a regular sleeping, eating and exercising schedule and use relaxation techniques.

Nonpharmalogical treatment for the relief of migraine may include (Ives, 2003:131):

- Rest in a dark and cool room
- Applying either hot or cold compresses to the head and neck
- Taking a leisurely warm shower or bath
- Massage of the head and neck.
- Stretching neck and shoulder muscles.
- Relaxing
- Drinking water and natural juice
- Doing self ischemic compression at the suboccipital triggerpoints for about a minute or two to release endorphins that relieves pain
- Avoiding excessive exercise

2.11.2 Medical Treatment:

- *Beta-blockers* - e.g. propanol.

  Not all Beta-blockers are effective. They work by their effects on the bloodvessels, controlling their dilation and constriction.

  Side-effects are: drowsiness, lethargy, mild dizziness, upset stomach and depression (Ostov, 1977:62 and Findley *et al.*1992:10-11).

- *5-HT antagonists*: - e.g. pizotifen.

  Work against the effect of 5-HT (seratonoin) and raises the threshold for migraine triggers.

  Side-effect: Increased appetite, drowsiness, dry mouth, dizziness and nausea (Ostrov, 1977:62).

- *Anti-depressants*: e.g. tricyclics, prozac®, Aropax®.

  Usually given in low dosages, to relieve the depression migraine sufferers might experience.

  Side-effects: Dry mouth, constipation, blurred vision and dizziness. They often settle down after days/weeks of treatment (Ostrov, 1977:62; MIMS Medical specialities, 1997:12, 13).

- *Anti-emetics:* (e.g. betaclopramide)

  Helps in relieving nausea and/or vomiting.

  Side-effects: drowsiness, lethargy, dizziness, insomnia and diarrhoea, (Ostrov, 1977:62; MIMS Medical Specialists, 1997:25).

- *Simple analgesics*: e.g. asprin, paracetamol, etc.

  Most patients, before consulting a physician, try over-counter drugs. In practice many migraine patients find simple analgesics inadequate, and frequent administration is necessary to control their symptoms. Side-effects: Frequent administration can lead to analgesic dependence, deterioration of pain control and renal impairment (Findley *et al.* 1992:10-11; Johnson, 2002:635).

- *Non-steroidal anti-inflammatory drugs (NSAID):* e.g. naproxen, ibuprofen.

  Often these are taken by patients with chronic pain. They work by inhibiting the production of prostaglandins and decrease the inflammatory process.

Side-effects: nausea, vomiting, heartburn, indigestion and can cause gastrointestinal bleeding (Ostrov, 1977:59 and Findley *et al.* 1992:10-11).

- *Ergotamine*:

  Ergotamine is a more or less specific treatment for acute migraine attacks. Its actions include constriction of the smooth muscle of the dilated blood vessels in migraine sufferers (Wolff, 1987:88-90).

  Side-effects: It affects blood vessels all around the body, so it is contra-indicated for patients with cardiovascular disorders. Other side effects are nausea, vomiting, drowsiness and rebound headaches (Ostrov, 1977:59 and Findley *et al.* 1992:10-11)

- *Sumatriptan*: eg (Imigran®)

  Works by constriction of the cranial blood vessels, and is very effective in the treatment of migraines, but is extremely costly.

  Side-effects: Fluttering or tightness of the chest or throat, nausea and vomiting. Rarely swelling or a rash may develop (Ostrov, 1977:60 and Findley *et al.* 1992:10-11; MIMS Medical specialities, 1997:28).

2.11.3 Chiropractic Treatment

Manipulation of the spine is widely used by chiropractors as a treatment for migraine headaches (Parker, 1978:589). Wright (1978:63) attempted to measure the improvement of migraines after an adjustment of the cervical spine, when he performed a retrospective analysis on 87 migraine sufferers. This was not a controlled study, as he did not compare his treatment with any other form of treatment; however his study did show a general improvement of 74.4% in pain perception by the patient.

This result is supported by a randomised controlled trial that was conducted by the Chiropractic Research Centre of Macquarie University, to assess the efficacy of chiropractic spinal manipulative therapy (SMT) in the treatment of migraines. In the treatment group, patients were treated over an 8 week period with a maximum of 16 spinal manipulations. The control group received detuned interferential therapy. It was found that the average response of the treatment group (n=83) showed a statistical significant improvement in migraine frequency ($p<0.01$), duration ($p<0.01$), disability ($p<0.05$) and medication use ($p<0.01$) when compared to the control group (n=40). Of the participants, 22% reported more than a 19% reduction in their migraine frequency and duration and more than 50% of the participants reported significant improvement in the morbidity of each episode (Tuchin, *et al.* 2000:91).

These results support the findings of a study by Whittle (1995:1-65), who conducted a trial to determine the most effective chiropractic management programme with respect to the frequency of treatments for migraine headaches. Two groups received chiropractic adjustments of fixations found in the cervical and thoracic spine, and soft tissue management to the above-mentioned areas. One group received 9 treatments in 3 weeks and the other 9 treatments in 9 weeks. Both groups showed positive results (as was the case in the study by Tuchin, *et al.* (2000:91-93)), however neither group fared better than the other, even though the intense treatment group showed a significant decrease in the frequency of migraine attacks and received greater benefit from the treatment

than the conservative group who showed a difference in duration and frequency only during the treatment period (Whittle, 1995:1-65).

This can be compared to Cattley and Tuchins' (1999:85-90) study, which assessed the response of a patient with chronic migraines to a short program of chiropractic care on spinal manipulative therapy on a once weekly schedule for 5 weeks, followed by an 8 week re-evaluation. A marked improvement in the migraine symptoms following the chiropractic care was noted. The patients reported an improvement in frequency, intensity, duration and use of medication (Cattley and Tuchin, 1999:85-90). In this respect Hough (2002) found that the occipital lift adjustment to be the most effective to treat migraine headaches and most patients were found to be headache free within four to six treatments.

In contrast to this Grunnet-Nilsson (2003:75) recommends that chiropractors can expect patients with migraine headaches to show an improvement only after 14 sessions of spinal manipulation over an 8 week period, with an improvement of 40% (Grunnet-Nilsson, 2003:75).

Thus one would be able to derive a consensus from the above literature stating that a treatment protocol between 3 and 9 weeks with 4 – 14 adjustments is indicated for the treatment of migraine patients (Whittle, 1995:1-65; Cattley and Tuchin, 1999:85-90; Grunnet-Nilsson, 2003:75).

Further in 1998, Cullinan compared two different types of treatment for migraine headaches: acupuncture with vertebral adjustment (cervical and upper thoracic spine) versus vertebral adjustment alone. Both types of treatment showed significant improvement, but neither was more successful than the other (Cullinan, 1998:109-111).

In the same year, a prospective, randomised, parallel-group comparison of 218 individuals with migraine headaches was conducted (Nelson *et al.* 1998:511-519). The patients were assigned to two groups, one received spinal

manipulation, one a daily medication (amitryptilene - a drug used to prevent pain in chronic conditions such as migraine headache), and one a combination of both. No advantage to combining amitriptyline and spinal manipulation for the treatment of migraine headache was found. Spinal manipulation seemed to be as effective as a well-established and efficacious treatment (amitriptyline), and on the basis of a benign side effects profile, spinal manipulation should be considered a treatment option for patients with frequent migraine headaches (Nelson *et al.* 1998:511-519).

The first cervical/occipital articulation manipulation:

Intersegmental dysfunction has been found in almost 100% of migraine subjects at C0-C1 (Vernon, 1995:615). Chiropractic treatment (adjustment of the first cervical/occipital articulation) eliminates migraine headaches by repositioning the occiput upon the first cervical vertebrae, removing pressure on the postganglionic sympathetic nerve fibres that pass through the foramen lacerum (Hough, 2002).

Cervical spine Manipulation:

Migraine is sometimes called 'Migraine cervicale' due to the notion that migraine could be associated with cervical dysfunction (Vernon, 1995:614). Manipulation of the cervical spine increases the cervial range of motion, greatly reducing the levels of intersegmental dysfunction in the cervical spine, reducing the dizziness levels in most patients (Vernon, 1995:615) and restoring nerve function (Parker, 1978:589).

Thoracic spine manipulation:

There is an inter-relationship between the upper thoracic spine and the symptoms of headache and there are definite benefits of a thrust manipulation in the upper thoracic spine for headache symptoms. The reason for that is one

of the following, or a combination of the following potential theories (Viti and Paris, 2000:25).

- Mechanical / Postural: By stretching the restricted joint capsule. Range of motion will be improved in all directions. An improvement in the upper thoracic extension would reduce the forward head posture and subcranial bending that accompanies this posture. This could reduce compression in the subcranial region and reduce the patient's symptoms (Viti and Paris, 2000:27).
- Reflex / Muscular: The semispinalis capitis arises from the transverse processes of C7 and T1-6 or 7 and inserts into the inferior and superior nuchal line of the occiput. The longissimus capitis arises by tendinous attachment from the transverse processes of T1-4 or 5 and inserts into the posterior margin of the mastoid process. Golgi tendon organs are inhibitory to a muscle when placed on a stretch, causing reflex relaxation of the entire muscle. The thrust stimulates the Golgi tendon organs of the surrounding musculature and reflexely inhibits these muscles. Also the greater occipital nerve pierces the semispinalis capitis near the attachment of the occipital bone. Thus the reflex relaxation of the muscle could theoretically reduce compression of the greater occipital nerve (Viti and Paris, 2000:27).
- Reflexive / Sympathetic: The sympathetic innervation of the head and neck originates from T1-2 spinal levels (Viti and Paris, 2000:27).
- Placebo Effect: The "audible pop" can have a significant psychological effect (Viti and Paris, 2000:28).

2.11.4 Homeopathic treatment

Although literature about Homeopathic remedies used to treat headaches and migraines exists, few controlled studies on the subject have been conducted (Aleotti, 1997:3). The object of homeopathy is to stimulate the patients' defence mechanism, which changes the established reaction patterns (migraine) to a more favourable way of dealing with stress (Straumsheim *et al.* 2000:4). Homeopathic medical practitioners maintain that homeopathy is an effective form of therapy (Muscari-Tomaioli *et al.* 2001:189), which is safe, and without the side effects of allopathic medication (Ferder, 2002).

For the purpose of this dissertation, 2 types of homeopathic treatments need to be explained.

- Classical homeopathy is when a single remedy (similimum) is selected based on the total symptom picture. It is an individualised treatment (Linde, *et al.* 1997:835).
- Complex homeopathy is the application of multiple remedies (polypharmacy) mixed into a standard formula to cover a person symptoms and diagnosis (Linde, *et al.* 1997:835), provided each component is listed in the Homeopathic Pharmacopoeia of the US (Gaier, 1991:97-100).

In order to evaluate the efficacy of homeopathy in the prevention and cure of migraine attacks and accompanying symptoms, a randomised, double blinded, placebo controlled clinical trial was conducted with a sample of 68 patients who received homeopathic similimum (indvidualised) treatment. Both the homeopathic and the placebo groups had a reduction in attack frequency, pain intensity and drug consumption, with a statistically non -significant difference favouring the homeopathic group. However at the 5 month follow up the patients underwent a neurological test, where a statistically significant reduction in attack frequency in the homeopathic group ($p=0.005$) was shown (Straumsheim *et al.* 2000:5).

Aleotti (1997) conducted a 3 month placebo controlled clinical trial to determine the efficiency of a homeopathic migraine complex in the treatment of migraines. The complex consisted of *Iris versicolor* 9CH, *Spigelia anthelmia* 9CH and *Sanguinaria canadensis* 9CH. She found that the use of the migraine complex was successful in reducing the frequency (p=.0007), duration (p=0.007) and severity (p=0.0004) of migraine headaches in the patients as well as alleviating the symptoms related to migraine such as nausea, vomiting, photophobia, phonophobia and visual disturbances (Aleotti, 1997:1-1-48). A limitation to this study was that no migraine diary was used. The use of such a diary would ensure a higher degree of accuracy of information received from the patient.

Aleotti's (1997) study differed from Straumsheim's (2000:4-7) study in that complex homeopathic therapy (polypharmacy) addresses the patient's particular stress factors rather than his or her constitutional type. The remedies are further combined in a specific way to cover the highest number of toxic and functional disturbances (Gaier, 1991:97-100).

According to the Homeopathic Medical Repertory in the rubric "Headaches - Migraine" the remedies *Iris versicolor* and *Sanguinaria canadensis* are among the major remedies indicated for migraine (graded 3/3) as well as *Spigelia anthelmia,* graded 1/3 (Murphy, 1998:938). These remedies were chosen with care as the symptoms of these remedies correspond closely to the signs and symptoms experienced by a migraine sufferer during a migraine attack (Aleotti, 1997:13).

A combination of the following homeopathic remedies was utilized in this study; each has been presented with the symptomatology for which it is indicated:

Iris versicolor:

"Sick headache in forehead and eyes beginning with a blur before the eye, especially after relaxing from a mental strain; intense noises in the ear; constriction around forehead, dull throbbing; constant nausea and vomiting; deficient appetite; constipation; weakness; symptoms worse on the right and in the evenings; periodical; a walk outside and a cold cloth on the head bring relief". (Ferder, 2000; Hering 1991:266 and Boericke, 1992:365)

Spigelia anthelmia:

"Throbbing pain in the head beginning in the occiput and radiating to the vertex and frontal region, finally coming to rest above the left eye with violent throbbing, or stitching pains above or through the eyeball; vertigo; aggravated by noise, motion, jolts; photophobia; periodical; redness and lacrimation of eye on affected side. Begins at sunrise, worse at noon and better at sunset; painful stiffness of neck and shoulders" (Ferder, 2000; Mathur, 1989:838 and Jouanny 1984:380).

Sanguinaria canadensis:

"Congestive headache with throbbing pain; hurting as if eyes would be pressed out; begins in the occipital region and spreads upwards, settling over the right eye; veins and temples are distended; periodical; begins in the morning, increases during the day, and lasts until the evening; aggravated by noise, smells, motion and light. Tired headache from mental or physical exertion. Pain in the back of the head 'like flash of lightning' Headaches improve with sleep, pressure, quiet dark room; nausea with salivation; burning vomiting passing of gas of burping. A person who needs this remedy often comes down with migraines after missing meals, and also suffers from digestive problems and allergies" (Ferder, 2000; Mathur, 1989:798; Jouanny, 1984:357 and Boericke 1992:542).

2.12 Conclusion

In as much as the aforementioned studies have shown benefits, the need for rigorous clinically controlled trials remain as there are to date no therapeutic gold standards for the treatment of migraines.

Despite the advent of newer, highly effective therapies (such as chiropractic, homeopathy, acupuncture, allopathic medication etc.) more than 70% of patients that undergo therapy are dissatisfied with their treatment. This dissatisfaction is a primary reason why patients seek additional healthcare services, change healthcare providers and report dissatisfaction with their health plan (Johnson, 2002:634).

We have to keep in mind that migraine is a complex condition and an effective treatment for one patient might not be effective for another. Although research has shown that the majority of patients respond to both chiropractic and homeopathic treatment, no research into the combined effect of the two treatment modalities i.e. chiropractic and homeopathy, has been done to date, thus there may be a group of patients that will respond better to a combined treatment regime. A study into this realm will further be beneficial as it could serve to integrate the two professions, bringing about a greater awareness of what each of the professions can offer the patient contributing to improved patient management and care, i.e. constituting a holistic approach.

This research therefore evaluates each of the treatments on its own, i.e. spinal manipulation, homeopathic remedy complex and a combination of the two in order to assist with the search for a more effective treatment method that could benefit a large number of migraine sufferers, resulting in a treatment that is conservative and bears no side effects.

Chapter 3

MATERIALS AND METHODS

3.1 Introduction

This chapter covers the method in which the study was conducted, including the study design, the subjects (patients) used, the interventions (treatment) they received as well as the method of data collecting and the statistical procedures the data was subjected to.

3.2 Study design

This study was designed as a randomised, comparative pilot clinical trial.

3.2.1 Object of the study

The object of the study was to determine the relative effectiveness of each treatment protocol in terms of certain subjective measurements.

The aim of the study was to investigate the relative effectiveness of a manual intervention (spinal manipulative therapy) opposed to a homeopathic intervention (Migraine complex) opposed to a combination of chiropractic and homeopathic intervention in the management of migraine headaches, in terms of patient perception, in order to determine the more effective treatment for migraine headache.

The study attempted to identify whether the combination of chiropractic and homeopathic interventions had a relative greater effect in the treatment of migraine headaches than the individual treatments alone.

3.2.2 Selection of subjects

This study was limited to patients residing in Durban and surrounding areas. Patients were notified of the research via advertising. Advertisements (Appendix H) inviting participation in the clinical trial were placed on notice boards at the Chiropractic Day Clinic at Durban Institute of Technology. Three thousand five hundred flyers were distributed all over the greater Durban area.

Patients who phoned to inquire then received a telephonic interview. The following questions were asked to confirm the diagnosis of migraine headaches:

- Unilateral location (IHS, 1988)?
- Pulsating quality (IHS, 1988)?
- During the headache the person must also experience either nausea or vomiting or both (IHS, 1988)?
- Photophobia, phonophobia, or both (IHS, 1988)?
- Between the ages of 16 - 55?
- Experience at least two migraine attacks per month (Cullinan, 1998)?
- Been suffering with migraine headaches for a minimum of twelve months (Cullinan, 1998)?

Patients who complied with the above mentioned criteria where then scheduled for an initial consultation. To confirm a diagnosis of migraine headaches, a case history and a Migraine History questionnaire was completed for each subject.

Hence a non-probability convenience sampling technique was applied. The patients had to fulfil the diagnostic requirements for migraine, *either with aura or without aura*, as determined by the Headache Classification Committee of the International Headache Society (IHS) (1988).

Inclusion Criteria:

1. Minimum age:

   Headaches are a common complaint in children. It is estimated that at the age of 15 years as many as 75% of children will have experienced headaches (Jansen, 1998:128). In Scotland the prevalence of migraine in children aged 5-15 was 10.6% and it caused significant reduced school attendance (Jansen, 1998:128). The above age distribution was an indicator of the prevalence of this condition in school children, but the minimum age for the study was 16 due to the constraints of patient compliance (which could bias the results) and to obviate the need for parental consent.

2. Maximum age:

   Once again, this age was obtained from the age of other studies carried out on migraine patients. Cullinan (1995:32) had a maximum age limit of 60 and Cartwright (2001:39), an age limit of 65. Patients older than 65 years of age were excluded due to the likelihood of phase three degeneration (Kirkaldy-Willis, 1992:111,419) being present in their cervical spine. To make sure there were no complications with early degeneration the maximum age limit used in this study was 55. Therefore the patients were to be between the ages of 16 and 55.

3. Patients had to fit the definition of migraine according to the International Headache Society (IHS) (1988), whose diagnostic criteria are as follows:

Migraine without aura	Migraine with Aura
▫ Idiopathic recurring headaches in attacks lasting 2-72 hours. ▫ At least 2 of the following - Unilateral - Pulsating - Moderate or severe; affecting daily activity - Aggravated by physical activity ▫ At least one of the following: - Nausea - Vomiting - Photophobia - Phonophobia	▫ At least 2 attacks fulfilling 3 of the 4 criteria below - One or more reversible aura symptoms - At least 1 aura symptom lasting for more than 4 minutes or 2 or more successive symptoms - One aura symptom never lasting more than 60 minutes - Free interval of less than 60 minutes of headache before or with aura.

4. Patients must experience at least two migraine attacks per month, and been suffering with migraine headaches for a minimum of twelve months (Cullinan, 1998:32?

Exclusion Criteria:

The following exclusions were assessed by means of a case history, physical examination and regional examination. If x-rays were warranted for diagnostic confirmation of a condition, the patient was excluded.

1. Patients that had exhibited any of the following contra-indications to spinal manipulation were excluded like: (Gatterman, 1990:59-61)
   - ▫ Tumours.
   - ▫ Arthritides.
   - ▫ Bone infections.
   - ▫ Traumatic injuries.

2. Patients with any vascular complications were excluded such as: (Gatterman, 1990:55-58)
   - ▫ Vertebral-basilar insufficiency (a positive Wallenbergs).
   - ▫ Artherosclerosis of major vessels.
   - ▫ Aneurysms.

3. Patients with any hard neurological signs of the cervical spine were excluded: (Gatterman, 1990:66)
   - Non-intact dermatomes, myotomes and reflexes of upper extremities.
   - Nerve root damage.
   - Cervical disc lesion.

4. Patients with any illness or condition that affected, perpetuated or caused their headaches were excluded. For example, influenza, sinusitis, raised intracranial pressure, meningitis, pregnancy or elevated blood pressure (Cartwright, 2001:40).

5. Chiropractic and Homeopathic Interns were excluded because they might bias the outcome.

3.2.3 Allocation of subjects

After the patients had signed the Informed Consent Form (Appendix I), they were randomly divided into three equal groups (10 per group). Thirty numbers were placed in a hat. Number 1-10 represented group A (Chiropractic treatment - spinal manipulative therapy), number 11-20 represented group B (Homeopathy - homeopathic migraine complex) and number 21-30 represented group C (A combination of spinal manipulative therapy and homeopathic migraine complex). All the numbers were mixed and the patients were asked to pick one out of the hat.

3.3 Intervention

After being accepted into the study, the patients were treated as follows:
Each group was given eight treatments over a period of six weeks.

At the first visit, each subject underwent the following examination:

- Detailed case history (Appendix A),
- Physical examination which included a full head and cranial nerve examination(Appendix A),

- A cervical spine regional examination(Appendix A),
- Migraine History questionnaire (Appendix B).

They were also required to complete the following at every visit:

- The CMCC Neck Disability Index (Appendix C),
- Glasgow Homeopathic Hospital Outcome Score (Appendix D)

In addition to this the patients were asked to keep a headache diary (Appendix E) to be filled in every time they experienced a migraine attack, and at the end of the study he/she had to complete a Quality of Life Assessment Questionnaire (Appendix F).

From the above literature (Chapter 2), it was deduced that a treatment protocol between 4 – 14 adjustments was indicated for the treatment of migraine patients (Whittle, 1995:1-65; Cattley and Tuchin, 1999:85-90; Hough, 2002; and Grunnet-Nilsson, 2003:75).

The average time period over which these treatments where spaced varied from 3 to 9 weeks, with the research results varying from excellent to inconclusive (Whittle, 1995:1-65; Cattley, 1999; Tuchin, *et al.* 2000:91; and Grunnet-Nilsson, 2003:75). Therefore no indication is given in the literature as to the optimal time period for such a study. The average treatment period was chosen for this study was 6 weeks.

- Group A received spinal manipulation at vertebral fixated areas of the cervical and thoracic spine. Fixated areas were determined by means of motion palpation (Schafer and Faye, 1990:98). Techniques taught by Szaraz (1990) in the *Compendium of Chiropractic techniques* were used to manipulate the cervical and thoracic spine. No manipulation was given if no fixation was found.

  They received 8 treatments over a 6-week period (i.e. 2 treatments in the first 2 weeks and 1 treatment per week thereafter).

- Group B was instructed to dissolve 5 pills of migraine complex (consisting of *Iris versicolor* 9CH, *Spigelia anthelmia* 9CH and *Sanguinaria canadensis* 9CH) under the tongue, twice a day on waking and at bedtime, when they were between attacks and hourly during attacks (Aleotti, 1997).

The patients had to come in for 8 assessments over the six week treatment period to fill in the questionnaires and to collect their weeks supply.

To evaluate the effectivity of the remedy, a six week period was sufficient (Naude,2003).

Preparation of Homoeopathic Complex

The homoeopathic complex (*Iris versicolor* 9CH, *Spigelia anthelmia* 9CH and *Sanguinaria Canadensis)* was manufactured by the Laboratory Technician in the Homoeopathic Laboratory at the Department of Homoeopathy, Durban Institute of Technology. The methodology used to manufacture the complex was obtained from the German Homoeopathic Pharmacopea (1991).

Each individual constituent of the complex was individually prepared from the relevant mother tinctures and potentised using the Hahnemanian centesimal scale up to the 8CH potency as per method 5a (German Homoeopathic Pharmacopoea, 1991) Each constituent of the complex in their relevant 8CH potency was then combined in equal parts; one part of this was then added to 99 parts of 96% ethanol and potentised to produce the homoeopathic complex in 9CH potency.

Neutral pillules where then impregnated at a 1%v/v means of a triple impregnation procedure with the homoeopathic complex as per method 10 (German Homoeopathic Pharmacopoea, 1991).

- Group C received the same dosage of the homeopathic migraine complex plus 8 chiropractic treatments (spinal adjustment) over the six week period.

The participants were requested not to change their lifestyle (e.g. exercise, smoking) and eating habits for the duration of the trial in order to minimise sources of variation.

- All three groups were required to document their migraine headaches for the duration of the study in the headache diaries that were provided.
- All three groups were required to complete a Migraine History Questionnaire supervised by the researcher before the commencement of the treatment.
- All groups had to fill in subjective measurement questionnaires at every visit and a Quality of Life Assessment Questionnaire at the end of the treatment period.

3.4 Methods of measurement

Subjective measurements were taken to measure any changes related to the treatment, with regard to migraineurs.

The Subjective measurements used were the Migraine History Questionnaire (Appendix B), CMCC Neck Disability Index (Appendix C), Glasgow Homeopathic Hospital Outcome Score (GHHOS) (Appendix D), Headache diary (Appendix E), and the Quality of Life Assessment Questionnaire (Appendix F).

The Migraine History Questionnaires were filled in at the initial consultation. The CMCC Neck Disability Index and the Glasgow Homeopathic Hospital Outcome Score (GHHOS) were completed at every visit (a total of 8 readings were taken). At the final consultation the patient was required to fill in the Quality of Life Assessment Questionnaire. This was done before the actual treatment proceeded.

The Headache diary was filled in over a period of 6 weeks and completed every time the patient experienced a migraine attack. A baseline measure was taken at the first consultation (Migraine History Questionnaire) with regards to the headache frequency, average duration and average intensity of their migraine attacks.

3.4.1 Subjective measurements

3.4.1. Migraine History Questionnaire (Appendix B)

The Migraine History Questionnaire was derived from Aleotti (1997) and Whittle (1995). The patient had to complete it as thoroughly as possible to get a clear picture of the patient's headache as a baseline measure.

3.4.1.2 CMCC Neck Disability Index (Appendix C)

The CMCC Pain Disability Index Questionnaire indicated how the day to day life of the patient was affected by the neck pain and headache experienced. Ten questions were required to be answered by the patient. These questions were scored from a minimum of zero to a maximum of six. The results obtained were represented as a percentage disability and were calculated by scoring the questionnaire out of 60 (Vernon and Mior, 1991: 418-428).

3.4.1.3 Glasgow Homeopathic Hospital Outcome Score (GHHOS) (Appendix D)

The questionnaire was used to determine the subjective improvement of the patient. It measured the patients own estimate of improvement or deterioration since starting the treatment. Patients were asked to note their perceived level of improvement according to the scale (Richardson, 2001:158-162).

+4 = Cured / back to normal
+3 = Significant improvement
+2 = Moderate improvement, affecting daily living
+1 = Slight improvement, no effect on daily living
0 = no change/unsure
-1 = Slight deterioration, no effect on daily living
-2 = Moderate deterioration, affecting daily living
-3 = Severe deterioration
-4 = Disastrous deterioration

3.4.1.4 Headache diary (Appendix E)

The headache diary was used to determine the frequency, intensity and duration of the headaches over the research period (Cartwright, 2001). This subjective rating was thought to be the "gold standard" of measuring head pain (Andrasik, 1992:353). The headache diary was adapted from Aleotti (1997).

Headache frequency pertains to the number of discreet migraines over a specified interval.
Peak intensity pertains to the highest intensity value out of 5 for a given migraine period.
The duration pertains to the length of time in hours between headache onset and offset.

3.4.1.5 Quality of Life Assessment Questionnaire (Appendix F)

Quality of Life Assessment Questionnaire determined whether there was any change in quality of life after the treatment, whether the treatment was successful and had made any difference in the patients every day lifestyle.

3.5 Statistical Analysis

Statistical Analysis was conducted using the SPSS (version 9) software suite. This Statistical software program is manufactured by SPSS Inc, 444N. Michigan Avenue, Chicago, Illinois, USA.

All tests set the type 1 error at 5%, or mentioned differently $\alpha = 0.05$. If the p value as reported was less than 0.05 a significant result was declared and the Null Hypothesis was rejected.

3.5.1 The Null Hypothesis

H_o: There is no difference between the variables (e.g. $\mu_1 = \mu_2 = \mu_3$)

H_1: There is an difference between all variables (μ_1, μ_2 and μ_3 are significantly different to each other).

α = 0.05 level of significance of test.

Note: The p-value is the probability of H_o being true.

Note: α = probability of rejecting H_o when is true (Type 1: error)

Reject the H_0 if $p \leq 0.05$

Accept the H_0 if $p > 0.05$

3.5.2 The Chi-square test.

The Chi-Square Test is used in situations where sets of observed and theoretical frequencies are to be compared. χ^2 is defined by:

$$\chi^2 = \Sigma((O - E)^2) / E$$

where O and E denote the observed and expected, or theoretical frequencies, respectively. Inspection of the definition shows that χ^2 is a descriptive measure of the magnitude of the discrepancies between the observed and expected frequencies. The larger the discrepancies the larger χ^2 will be. The observed frequencies are equal to (row total × column total)/ grand total). Note that ideally in the Chi-Square Test all cells should be greater than or equal to five (Ferguson,1976:189).

The likelihood ratio for the Chi-Square Test is:

$$\chi^2 = \Sigma O \log (O/E)^2$$

3.5.3 Kruskal-Wallis test

The Kruskal-Wallis test is a rank test for *K* independent samples; it is a one way sample analysis of variance by rank (Ferguson, 1976:392).

3.5.4 Spearman's Coefficient of Rank correlation *p*

A coefficient of rank correlation is a statistic defined in such a way as to take a value of +1 when the paired ranks are in the same order, a value of -1 when the ranks are in an inverse order and an expected value of 0 when the ranks are arranged at random with respect to each other. A definition of rank correlation which meets these requirements is:

$p = 1 - 2\sum d^2 / \sum d^2_{max}$

Where *p* is the Greek letter for Rho (Ferguson, 1976:365).

3.5.5 Analysis of variance (ANOVA)

The analysis of variance is a method for dividing the variation observed in experimental data into different parts, each part assignable to a known source, cause or factor. The relative magnitude of variation resulting from different sources is assessed and ascertains whether a particular part of the variation is greater than expectation under the null-hypothesis. The analysis of variance is inextricably associated with the design of experiments (Ferguson, 1976:223).

Chapter 4

THE RESULTS

4.1 Introduction

This chapter covers the results obtained following the statistical analysis of the figures secured from the Headache Questionnaire (Appendix B), the CMCC Neck Disability Index (Appendix C), Glasgow Homeopathic Hospital Outcome Score (Appendix D), the Headache diaries (Appendix E) and the Quality of Life Assessment Questionnaire (Appendix F). It also contains information regarding demographics of the sample population and information related to the nature of migraines experienced by the subjects.

The results have been tabulated and/or graphically displayed, and significant findings reported.

Note:
Group A = Chiropractic treatment group.
Group B =Homeopathic treatment group.
Group C = Combined Chiropractic and Homeopathic treatment group.

4.2 Demographic data

4.2.1 Age

Table 1: Age

Age	Group A	Group B	Group C	Total
16-25	3	2	4	9
26-35	5	1	1	7
36-45	2	3	1	6
46-55	0	4	4	8
Total	10	10	10	30
Mean age:	29.1	39.9	36.3	35.1

4.2.2 Gender distribution

Table 2: Gender distribution

Sex	Group A	Group B	Group C	Total
Male	2	2	3	7
Female	8	8	7	23
Total	10	10	10	30

The proportion of females was substantially higher in each of the three groups.

4.2.3 Ethnic distribution

Table 3: Ethnic distribution

Ethnic group	Group A	Group B	Group C	Total
Black	1	1	1	3
Indian	4	2	2	8
White	5	7	7	19
Total	10	10	10	30

The sample population consisted predominantly of Whites, with relatively few Indians and Blacks.

4.3 Migraine history reported by the patient on the Migraine history questionnaire at the initial visit.

4.3.1 Migraine with and without aura

Table 4: Migraine with aura verses migraine without aura

	Group A	Group B	Group C	Total
MwA	4	4	8	16
MwoA	6	6	2	14
Total	10	10	10	30

The number of subjects that reported suffering from migraine with aura (n=16) was very similar to the number that reported suffering from migraine without aura (n=14).

4.3.2 Length of time suffered with migraine headaches

Table 5: Length of time suffered with migraine headaches

Years	Group A	Group B	Group C	Total
> 5 years	8	9	6	23
≤ 5 years	2	1	4	7
Total	10	10	10	30

Most of the subjects in each group had been suffering with migraine headaches for more than 5 years.

The Chi-Square Test = 2.626. The p-value (0.269) is greater than 0.05 and therefore H_0 was accepted, which suggests that there is no significant difference in the proportion of subjects who suffered from migraines longer than 5 years and those who had experienced migraine for less than or equal to 5 years.

4.3.3 Location of the headache

Table 6: Location of headache

Side	Group A	Group B	Group C	Total
Left	3	4	4	11
Right	7	5	6	18
Total	10	10	10	30

Table 6 shows the number of subjects that experienced left and right sided headaches for each group.

The Chi-Square Test = 0.453. The p-value (0.797) is greater than 0.05 and therefore H_0 was accepted. This suggests that there is no significant difference between the groups regarding the usual location of their headache.

4.3.4 Frequency of occurrence on one side.

Table 7: Unilateral headache

	Group A	Group B	Group C	% of subjects
Never or sometimes	2	6	3	36.7%
Usually or always	8	4	7	63.3%
Total	10	10	10	100%

Table 7 shows the number of subjects that experienced unilateral headache for each of the 3 groups. Most of the subjects (63%) experienced unilateral headaches during a migraine attack (n=19).

The Chi-Square Test = 3.744. The p-value (0.154) is greater than 0.05 and therefore H_0 was accepted, suggesting that there is no significant difference between the groups.

4.3.5 Migraine symptoms

Table 8: Symptoms during the migraine attack

	Symptoms		Group A	Group B	Group C	% of subjects
1	**Nausea**	M-S	8	7	6	70
		N-L	2	3	4	
2	**Vomiting**	M-S	5	5	4	46
		N-L	5	5	6	
3	**Dizziness**	M-S	7	8	6	70
		N-L	3	2	4	
4	**Sleepiness**	M-S	7	8	5	66
		N-L	3	2	5	
5	**Loss of appetite**	M-S	7	9	7	76
		N-L	3	1	3	
6	**Ringing in ear**	M-S	3	7	3	43
		N-L	7	3	7	
7	**Photophobia**	M-S	9	8	8	83
		N-L	1	2	2	
8	**Tingling / strange sensation**	M-S	6	6	4	53
		N-L	4	4	6	

M-S = moderate to severe
N-L = none or little

The subjects were asked to rate the severity of associated symptoms on a scale 0 to 4 (0 being least severe and 4 most severe), for each of 8 symptoms. In order to test for differences in severity of associated symptoms between the groups, the ratings 0 and 1 were combined into a category called "none or little" and the ratings 2 to 4 into a category "moderate to severe". Table 8 shows the counts per category for each of the 3 groups. A percentage of occurrence for each symptom is also displayed which indicates that photophobia (80%) was the most common associated symptom.

Table 9: Results of tests for the difference between proportions of symptoms in all three groups.

	1	2	3	4	5	6	7	8
Chi-Square	0.966	0.269	0.966	2.103	1.660	4.402	0.516	1.072
p-value	0.617	0.874	0.617	0.349	0.436	0.111	0.773	0.584

A separate Chi-Square Test was performed for each of the 8 associated symptoms by subdividing Table 8 into 8 different 3 x 2 tables. The results are shown in Table 9. No statistically significant differences were noted between the 3 groups. In all 8 associated symptoms the p-value was more than 0.05 and therefore H_0 was accepted in all.

4.3.6 Causative factors

Table 10: Causative factors

	Factor		Group A	Group B	Group C	% of subjects
1	**Hunger**	Yes	6	3	4	43
		No	4	7	6	
2	**Tension/stress**	Yes	10	10	7	90
		No	0	0	3	
3	**Fatigue**	Yes	4	3	3	33
		No	6	7	7	
4	**Weather changes**	Yes	2	4	3	30
		No	8	6	7	
5	**Head movements**	Yes	3	4	1	26
		No	7	6	9	
6	**Certain foods**	Yes	6	5	4	50
		No	4	5	6	

Table 10 shows the counts for each of the 6 causative factors for the 3 groups, and a percentage of occurrences for each of the causative factor experienced by the sample population.

The Chi-Square Test = 3.333. The p-value (0.972) is greater than 0.05 and therefore H_0 was accepted. This suggests that there is no significant difference between the 3 groups.

The proportion of "yes" answers that exceeds the proportion of "no" answers, in all three groups, only occurs with tension/stress. The Chi-square Test for tension and stress = 7.288 with the p-value of (0.026) which is less than 0.05, therefore H_0 was rejected. This indicates that tension and stress is a major causative factor in migraine headaches.

4.3.7 Aggravating factors

Table 11: Aggravating factors 1

	Factor		Group A	Group B	Group C	% of subjects
1	**Menstruation (females only)**	Yes	3	4	4	48
		No	4	4	4	
2	**Sneeze/cough**	Yes	3	5	5	43.3
		No	7	5	5	
3	**Exertion**	Yes	7	4	5	53.3
		No	3	6	5	
4	**Head movements**	Yes	5	8	6	63.3
		No	5	2	4	

Table 11 shows a summary of the counts for each of the 4 aggravating factors for the 3 groups. A percentage of occurrence for each aggravating factors experienced by the sample population is also displayed.

The Chi-Square Tests = 2.659. The p-value (0.850) is more than 0.05 and therefore H_0 was accepted. This suggests that there are no significant differences in the proportions of "yes" answers between the three groups.

Table 12: Aggravating factors 2

	Factor	Rating	Group A	Group B	Group C	% of subjects rated 2-4
5	Motion	0	3	3	2	
		1	0	1	2	
		2	0	3	3	
		3	2	3	1	
		4	5	0	1	56
6	Noise	0	2	3	1	
		1	1	0	1	
		2	0	2	2	
		3	0	1	2	
		4	7	4	3	73
7	Light	0	1	1	1	
		1	0	0	0	
		2	0	2	1	
		3	1	3	2	
		4	8	4	5	86

Table 12 shows the counts for the 3 aggravating factors that were rated on a scale of 0-4. (0=not at all, 4=severely). A percentage of occurrences per aggravating factors experienced by the sample population are also displayed (for severity rating 2 – 4). The results suggest that light (86%) and noise (73%) are more likely to aggravate migraine headaches than motion.

Table 13: ANOVA results for ratings for the aggravating factors 5, 6 and 7 in table 12. Tests of Between-Subjects Effects.

Dependent Variable: RATING

Source	Type III Sum of Squares	Df	Mean Square	F	Sig.
Corrected Model	30.953(a)	8	3.869	1.712	.109
Intercept	573.376	1	573.376	253.662	.000
FACTOR	21.356	2	10.678	4.724	.012
GROUP	8.731	2	4.366	1.931	.152
FACTOR * GROUP	1.096	4	.274	.121	.975
Error	176.311	78	2.260		
Total	784.000	87			
Corrected Total	207.264	86			

a R Squared = .149 (Adjusted R Squared = .062)

Table 13 displays the analysis of variance between the aggravating factors and shows no statistically significant difference in rating between the groups (p=0.152) for the various aggravating factors, but that the ratings for the factors are significantly different (p=0.012). Factor 7 (light) is rated as most severe, followed by factors 6 and 5 (motion which is least severe).

4.3.8 Menstruation

Table 14: Menstruation as an aggravating factor in females suffering with migraine with aura or migraine without aura.

Menstruation	Group A	Group B	Group C	Total
MwA	1	1	3	5
MwoA	2	3	1	6
Total	3	4	4	11

Table 14 shows the counts of females that stated that menstruation was an aggravating factor.

4.3.9 Relieving factors

Table 15: Relieving factors

	Factor		Group A	Group B	Group C	% of subjects
1	Medication	Yes	8	8	9	83
		No	2	2	1	
2	Lying down	Yes	9	8	6	76
		No	1	2	4	
3	Massage	Yes	6	6	6	60
		No	4	4	4	
4	Heat	Yes	1	0	1	6.6
		No	9	10	9	
5	Cold	Yes	3	2	2	23
		No	7	8	8	
6	Food	Yes	2	0	0	6.6
		No	8	10	10	

Table 15 shows the counts for the 6 relieving factors for each of the 3 groups. From the table above it is suggested that medication, lying down and massage usually improve migraine headaches, and that heat, cold and food less commonly improve migraine headaches in the sample population. No significant differences were noted between the 3 groups.

4.3.10 Doctor Consultation

Table 16: Number of patients who consulted a doctor about their headaches before.

	Group A	Group B	Group C	Total
Yes	8	7	5	66.7%
No	2	3	5	33.3%
Total	10	10	10	100%

Most of the subjects in each group (8, 7 and 5 respectively), had consulted a doctor about there headaches before. These 3 groups do not differ significantly. (Chi-Square = 2.103, p-value = 0.349) and H_0 was accepted.

4.3.11 Family history of migraine

Table 17: Family history of migraine

	Group A	Group B	Group C	Total
Yes	5	9	5	29
No	5	1	5	11
Total	10	10	10	30

The majority of subjects in each group have a family history of migraine headaches.

4.3.12 Job Stress

Table 18: Results of ANOVA of job stress for the 3 groups:

Tests of Between-Subjects Effects

Dependent Variable: STRESS

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	7.400(a)	2	3.700	2.390	.111
Intercept	346.800	1	346.800	224.010	.000
GROUP	7.400	2	3.700	2.390	.111
Error	41.800	27	1.548		
Total	396.000	30			
Corrected Total	49.200	29			

a) R Squared = .150 (Adjusted R Squared = .087)

Table 18, an analysis of variance (ANOVA), suggests that there were no statistically significant differences between the 3 groups regarding there job stress. The p-value (0.111) is more than 0.05 and therefore H_0 was accepted.

Table 19: Job stress between groups

	1	2	3	4	5	Total
Group A	0	0	3	3	4	10
Group B	2	1	3	3	1	10
Group C	2	1	3	2	2	10
Total	4	2	9	8	7	30

Table 19 shows the count of subjects rating their job stress between 0 and 5 (0=no stress, 5=severely stressful). Most of the subjects rated their job stress level between 3 and 5.

4.4 Results from subjective tests

4.4.1 The Glasgow Homeopathic Hospital Outcome Score

The GHHOS is a score measuring subjective outcome of the patient. It measured the patients own estimate of improvement or deterioration since starting the treatment. Eight readings were taken.

Table 20: Report of the GHHOS over time

GROUP		T1	T2	T3	T4	T5	T6	T7	T8
1	Mean	.00	1.50	1.80	1.90	2.40	1.80	2.60	2.50
	N	10	10	10	10	10	10	10	10
	Std. Deviation	.000	.972	.919	2.025	1.776	2.150	1.350	1.509
2	Mean	.00	.40	1.00	2.00	2.00	2.30	1.60	2.20
	N	10	10	10	10	10	10	10	10
	Std. Deviation	.000	1.350	1.563	1.333	1.563	1.252	2.503	1.932
3	Mean	.00	1.70	2.40	2.00	2.30	2.50	2.80	3.10
	N	10	10	10	10	10	10	10	10
	Std. Deviation	.000	1.160	.966	1.563	1.160	.972	.919	.876
Total	Mean	.00	1.20	1.73	1.97	2.23	2.20	2.33	2.60
	N	30	30	30	30	30	30	30	30
	Std. Deviation	.000	1.270	1.285	1.608	1.478	1.518	1.749	1.499

Table 20 shows a summary of the GHOSS for the 8 treatments between the 3 groups.

Table 21: Percentage improvement in the GHOSS

		-4	-3	-2	-1	0	+1	+2	+3	+4	% Improved	% scoring +2 to +4
Group A	**80**	0	0	4	3	12	11	13	29	8	76.3%	62.5%
Group B	**80**	0	3	2	1	20	14	12	21	7	67.5%	50%
Group C	**80**				1	14	10	15	31	9	81.3%	68.8%

Table 21 shows the percentage of improvement per group using the same method as Richardson (2001:158-162). Group A improved with 76%; group B with 67.5% and Group C with 68.8%.

Figure 1: Outcome scores for group A over the 8 treatments.

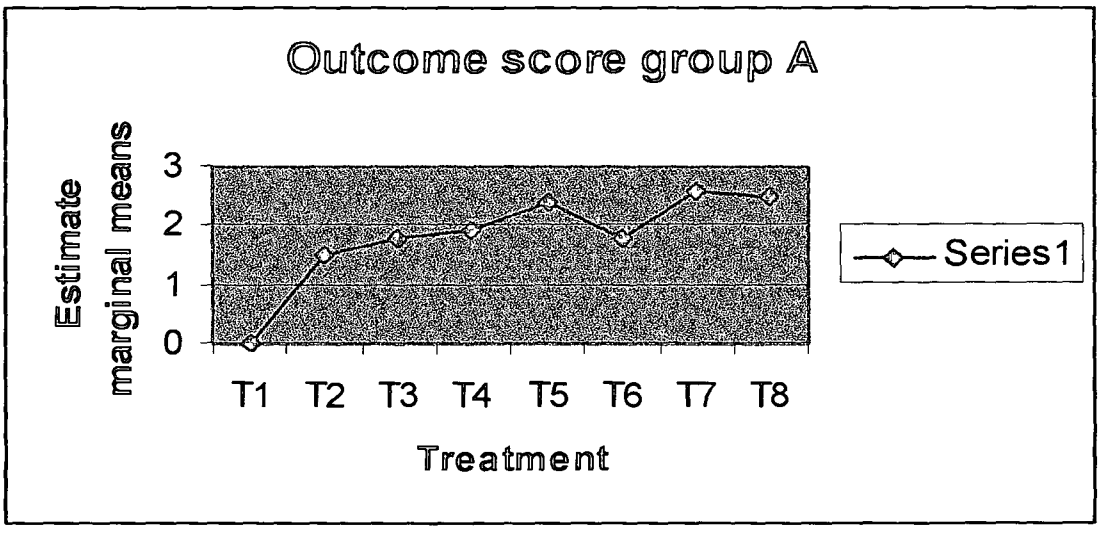


Figure 1 shows the outcome score for group A over the treatment period. The average gradient of improvement is 0.657

Figure2: Outcome scores for group B over the 8 treatments

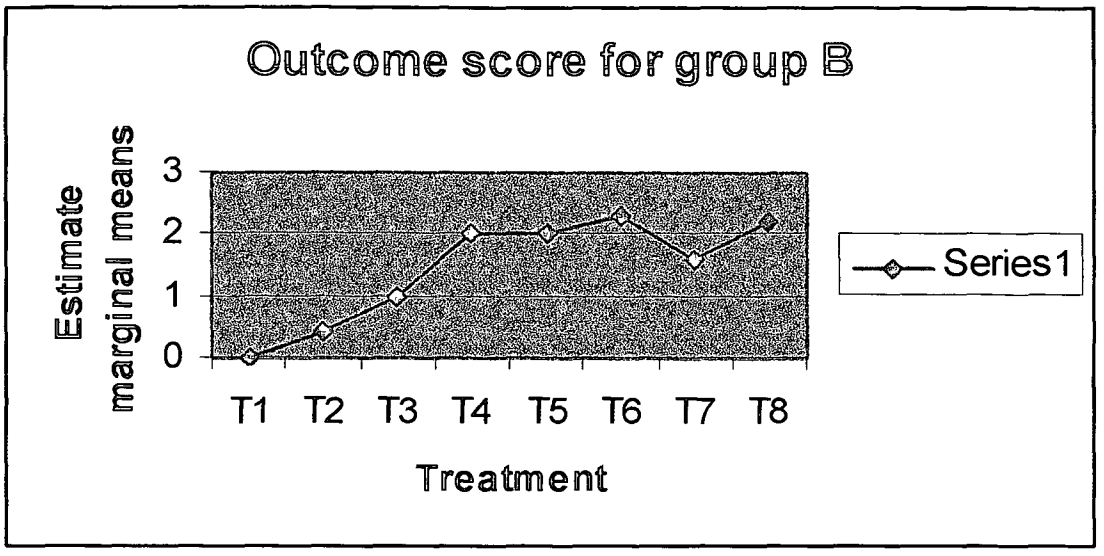


Figure 2 shows the outcome score for group A over the treatment period. The average gradient of improvement is 0.246

Figure 3: Outcome score for group C over the 8 treatments

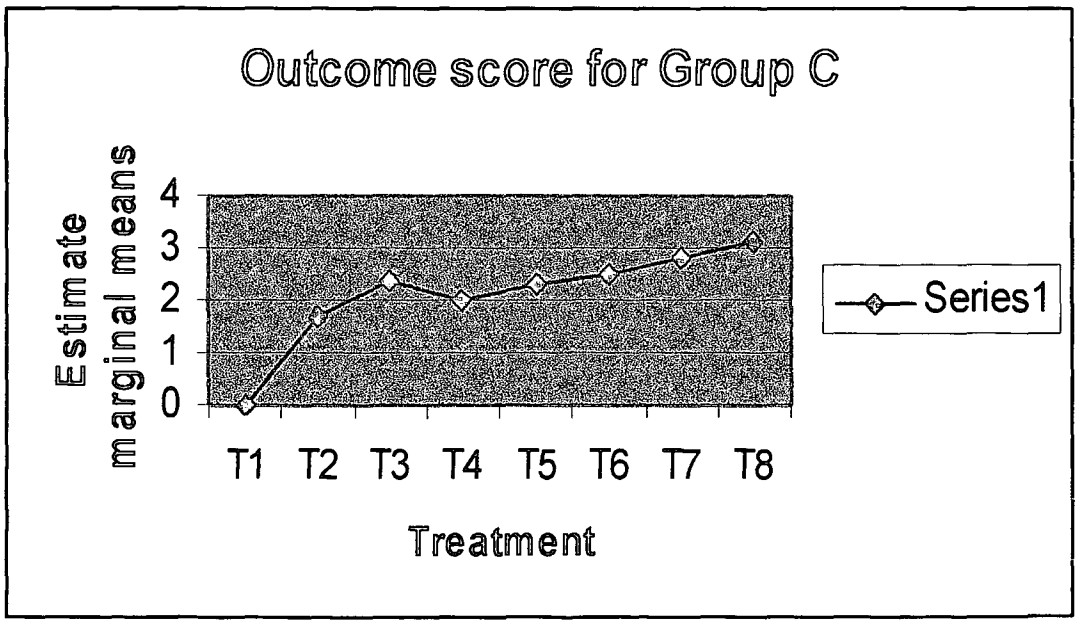


Figure 3 shows the outcome score for group A over the treatment period. The average gradient of improvement is 0.196

Table 22: ANOVA tables of repeated measures design for GHHOS migraine outcome score for the within-subjects effects.

Measure: Outcome Score

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
TIME	Sphericity Assumed	147.067	7	21.010	13.544	.000
	Greenhouse-Geisser	147.067	4.200	35.016	13.544	.000
	Huynh-Feldt	147.067	5.439	27.041	13.544	.000
	Lower-bound	147.067	1.000	147.067	13.544	.001
TIME * GROUP	Sphericity Assumed	18.008	14	1.286	.829	.637
	Greenhouse-Geisser	18.008	8.400	2.144	.829	.584
	Huynh-Feldt	18.008	10.877	1.656	.829	.610
	Lower-bound	18.008	2.000	9.004	.829	.447
Error(TIME)	Sphericity Assumed	293.175	189	1.551		
	Greenhouse-Geisser	293.175	113.400	2.585		
	Huynh-Feldt	293.175	146.842	1.997		
	Lower-bound	293.175	27.000	10.858		

Table 23: ANOVA tables of repeated measures design for migraine outcome score for the between-subjects effects

Measure: Outcome score

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	763.267	1	763.267	165.097	.000
GROUP	17.658	2	8.829	1.910	.168
Error	124.825	27	4.623		

Table 22 and 23 was obtained by performing a repeated measures analysis of variance (ANOVA) on these total scores (indices). In the analysis "Time" is the "within subjects factor", and "Groups" the "between subjects factor".

From the above tables it is clear that there was a statistically significant change over time in the outcome of the subjects (p=.000). The p-value is less than 0.05, and therefore H_0 was rejected, suggesting that the outcome score improved over time. There was however not a statistically significant difference between the three groups. As the p-value (0.168) was greater than 0.05, H_0 was accepted.

Figure 4 Plot of mean outcome score over time of all three groups

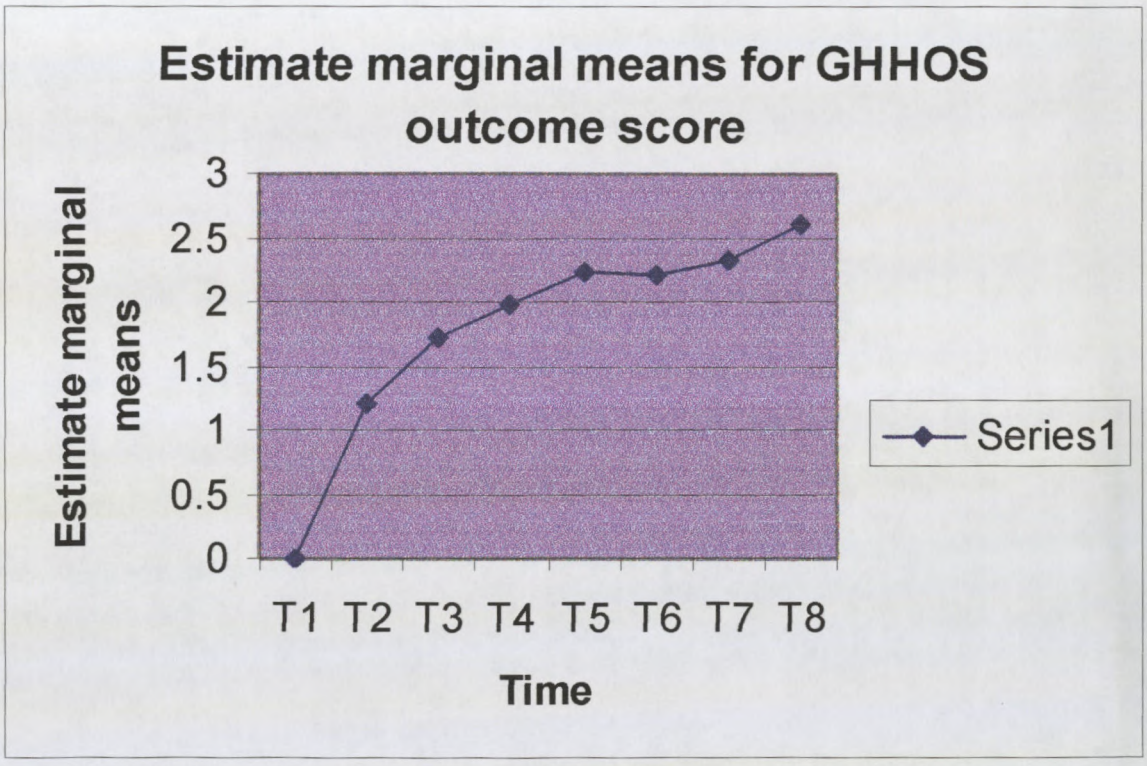


Figure 4 shows an increase in the outcome score for all 3 groups over time, which suggests an improvement in the study population (N=30) as a whole.

4.4.2 CMCC Neck Disability Index

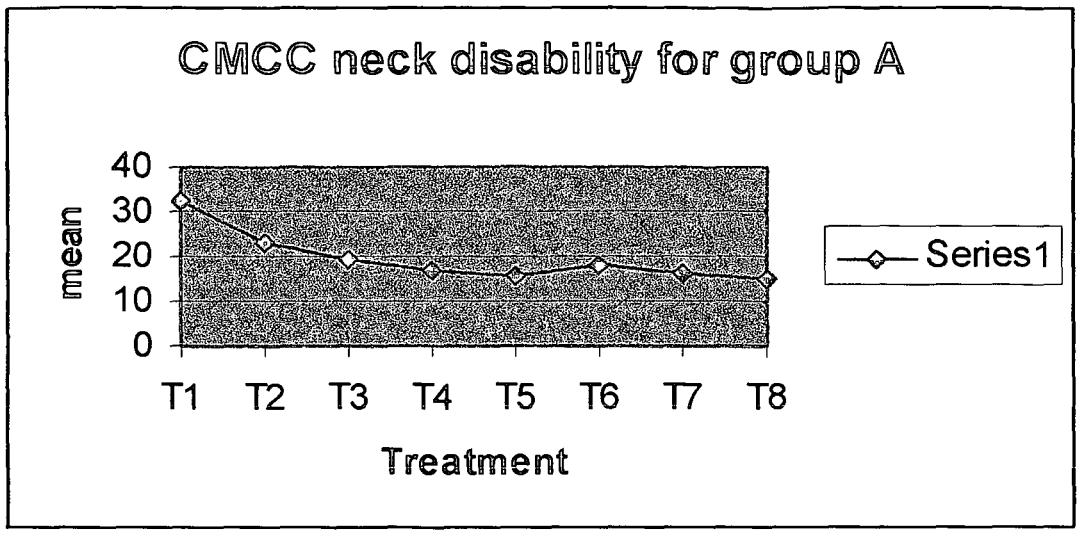
The CMCC Neck Disability Index Questionnaire indicated how the day to day life of the patient was affected by the neck pain and headaches experienced. Ten questions were required to be answered by each subject at every visit. A score of 1 indicates the least disability and 6 the most disability. A total score (disability index) ranging from 10 to 60 was calculated for each subject on each visit.

Table 24: Report of the CMCC Disability Index

GROUP		T1	T2	T3	T4	T5	T6	T7	T8
A	Mean	32.56	23.00	19.67	16.67	15.78	18.33	16.22	15.11
	N	9	9	9	9	9	9	9	9
	Std. Deviation	9.248	6.164	9.836	6.021	5.044	9.644	5.783	4.702
B	Mean	33.00	22.75	23.00	15.63	20.38	18.00	18.88	14.50
	N	8	8	8	8	8	8	8	8
	Std. Deviation	10.461	12.045	15.128	7.615	12.738	9.943	10.855	4.276
C	Mean	30.00	17.22	14.00	13.44	17.44	14.22	13.00	12.22
	N	9	9	9	9	9	9	9	9
	Std. Deviation	14.335	5.215	4.610	4.333	6.560	4.177	5.431	3.346
Total	Mean	31.81	20.92	18.73	15.23	17.77	16.81	15.92	13.92
	N	26	26	26	26	26	26	26	26
	Std. Deviation	11.207	8.309	10.772	5.982	8.425	8.168	7.683	4.175

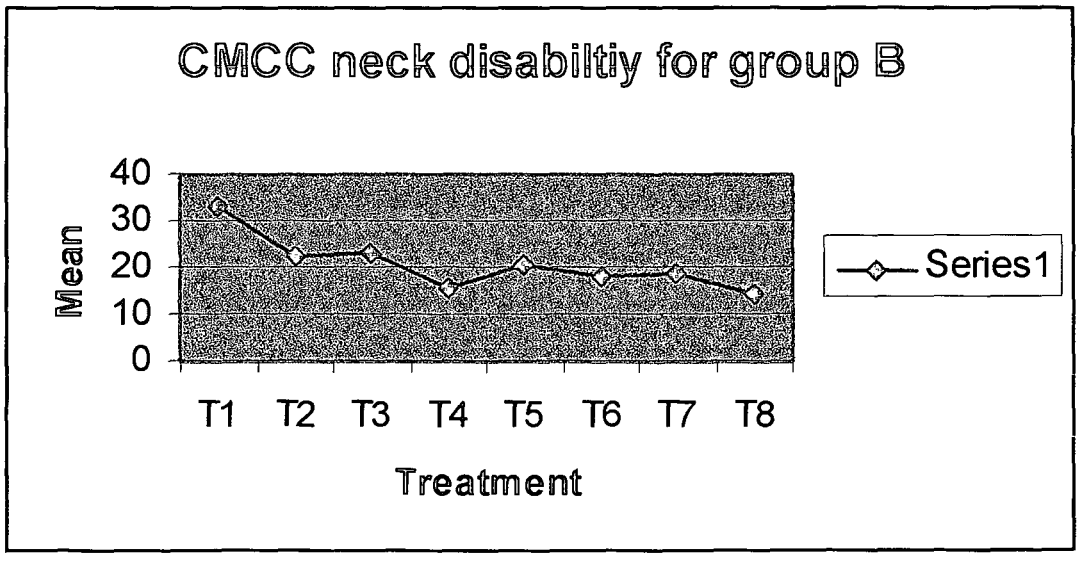
Table 24 indicates the mean disability experienced per group per treatment period. Note: Due to the failure of the some subjects to answer all the questions the number of patients per group varies. (4 subjects were not included in this statistical test).

Figure 5: Change over time in the CMCC Neck Disability Index for group A



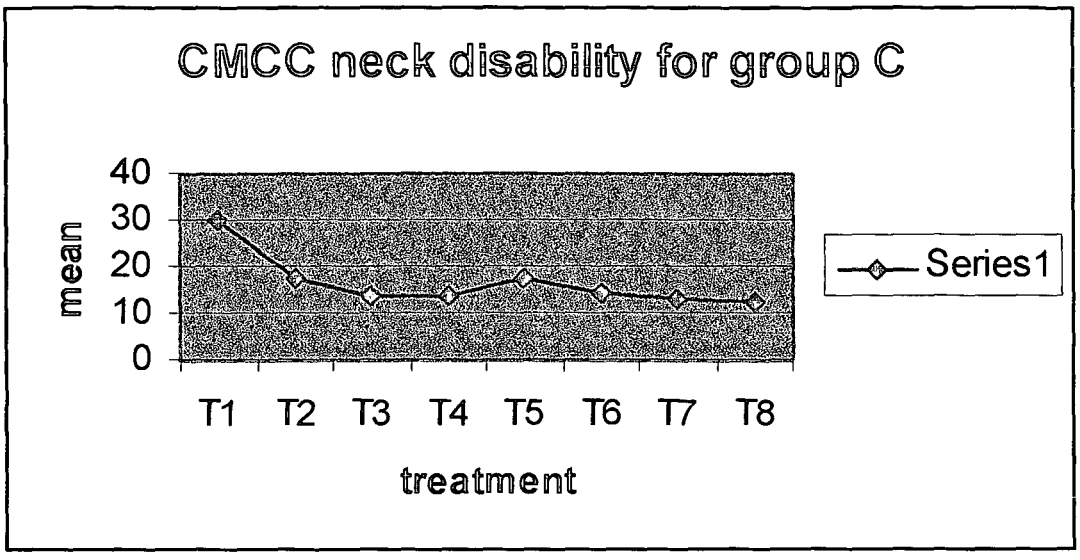
Group A showed a decrease in the disability over the treatment period.

Figure 6: Change over time in the CMCC Neck Disability Index for group B



Group B showed a decrease in the disability over the treatment period.

Figure 7 Change over time in the CMCC Neck Disability Index for group C



Group C showed a decrease in the disability over the treatment period.

On visual inspection it is clear that there was a decrease in neck disability in all three groups. Due to the small sample size, no statistical test was run to determine the percentage of decrease in each of the group.

Table 25: ANOVA tables of repeated measures design for CMCC Neck Disability Index: Tests of Within-Subjects Effects

Measure: INDEX

Source		Type III Sum of Squares	Df	Mean Square	F	Sig.
TIME	Sphericity Assumed	5793.005	7	827.572	16.799	.000
	Greenhouse-Geisser	5793.005	3.347	1730.714	16.799	.000
	Huynh-Feldt	5793.005	4.326	1338.980	16.799	.000
	Lower-bound	5793.005	1.000	5793.005	16.799	.000
TIME * GROUP	Sphericity Assumed	311.309	14	22.236	.451	.955
	Greenhouse-Geisser	311.309	6.694	46.503	.451	.859
	Huynh-Feldt	311.309	8.653	35.978	.451	.898
	Lower-bound	311.309	2.000	155.654	.451	.642
Error(TIME)	Sphericity Assumed	7931.321	161	49.263		
	Greenhouse-Geisser	7931.321	76.985	103.024		
	Huynh-Feldt	7931.321	99.508	79.705		
	Lower-bound	7931.321	23.000	344.840		

Table 26: ANOVA tables of repeated measures design for CMCC neck disability index: Tests of Between-Subjects Effects

Measure: INDEX

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	74533.550	1	74533.550	337.845	.000
GROUP	699.195	2	349.597	1.585	.227
Error	5074.137	23	220.615		

Table 25 and 26 was obtained by performing a repeated measures analysis of variance (ANOVA) on these total scores (indices). In the analysis "Time" is the "within subjects factor", and "Groups" the "between subjects factor".

From the above tables it is clear that there was a statistically significant change over time in the disability of the subjects (p=0.000). The p-value is less than 0.05 and therefore H_0 was rejected, suggesting that there was a significant decrease in the subjects' disability. However there was not a statistically significant difference between the 3 groups (p=0.227). The p-value is more than 0.05 and therefore H_0 was accepted.

Figure 8: Plot of mean disability indices over time for all three groups

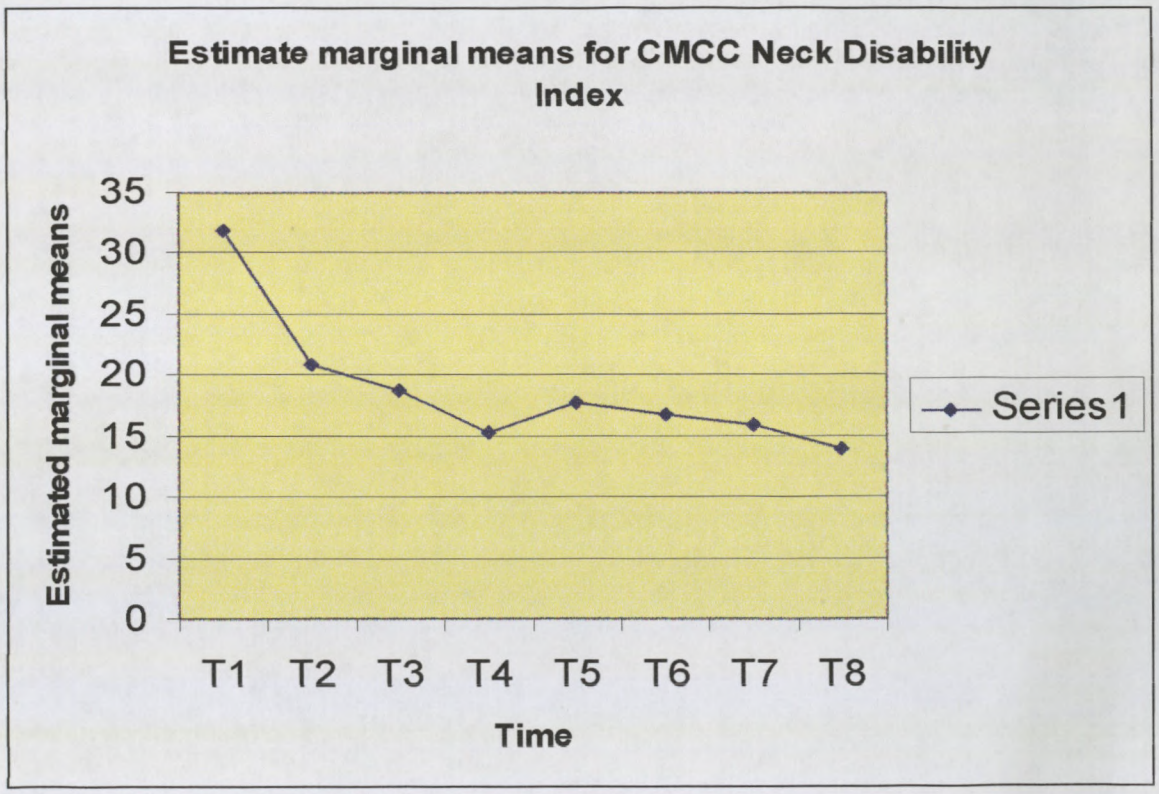


Figure 8 indicates a decrease in disability for all 3 groups over time, which suggests an improvement in the study population (N=30) as a whole.

4.4.3 Subjective findings for the severity of migraine

4.4.3.1 Intra-group analysis for the severity of migraine.

Table 27: Patterns of severity ratings over time for Group A

Patient	No of afterwards migraines	Rho statistic	p-value	Comment on pattern
1	2	n/a	n/a	Cannot say
2	3	n/a	n/a	No change
3	5	-0.088	0.434	No change
4	5	0.206	0.348	No change
5	4	0.051	0.467	No change
6	5	-0.559	0.124	No change
7	2	n/a	n/a	Cannot say
8	4	0.444	0.227	No change
9	5	0	0.500	No change
10	4	-0.354	0.280	No change

Table 28: Pattern of severity rating over time for Group B

Patient	No of afterwards migraines	Rho statistic	p-value	Comment on pattern
1	14	-0.109	0.349	No change
2	13	-0.217	0.228	No change
3	1	n/a	n/a	Cannot say
4	1	n/a	n/a	Cannot say
5	1	n/a	n/a	Cannot say
6	4	-0.632	0.126	No change
7	1	n/a	n/a	Cannot say
8	14	0.126	0.328	No change
9	6	-0.767	0.022	Decrease over time
10	12	0.082	0.394	No change

Table 29: Pattern of severity rating over time for Group C

Patient	No of afterwards migraines	Rho statistic	p-value	Comment on pattern
1	10	-0.158	0.321	No change
2	5	-0.207	0.347	No change
3	9	0.461	0.090	No change
4	2	n/a	n/a	Cannot say
5	1	n/a	n/a	Cannot say
6	4	-0.894	0.02	Decrease over time
7	7	-0.380	0.176	No change
8	6	-0.124	0.396	No change
9	15	0.110	0.343	No change
10	4	-0.264	0.334	No change

Table 30: Summary of pattern comments in tables 27 – 29.

	No change	Decrease	Cannot say	p-value	Chi-Square
Group A	8	0	2	0.000	22.181
Group B	5	1	4	0.08	5.822
Group C	7	1	2	0.01	10.124

The migraine severity rating of the first visit was compared with those that occurred afterwards. The number of subsequent migraines varied between 1 and 15. The purpose of the analysis was to determine whether the severity rating patterns change over time. Tables 27 to 29 show the results of tests and visual inspections of data over time. Table 30 is a summary of the comments in tables 27 to 30. For cases with 4 or more subsequent migraines, the change over time was tested by means of calculating the Spearman Rho Statistic. For cases with less than 4 subsequent migraines the changes were determined (where possible) by means of visual inspections of plots over time.

Note that it was not statistically possible to comment on a pattern on the basis of 2 or 3 time points ("cannot say" subjects).

The intra-group analysis for group A, comparing the "no change in pain" subjects to the "decrease in pain" subject showed no statistically significant differences between the 3 groups. The p-value (0.000) is less than 0.05 and therefore H_0 is rejected, which indicates that a significant difference exists between the "no

change in pain" subjects and the "decrease in pain" subjects, favoring the "no change" in pain subjects. The same was found for group C which has a p-value of (0.01). However in group B the p-value was 0.080 which indicates that there is no significant difference between the "no change in pain" subjects and the "decrease in pain" subjects.

There appears to be little or no evidence of change in severity over time in all three groups

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4.4.3.2 Inter-group analysis of the severity of migraine.

The Chi-Square Test was done to determine if there was any significant difference between the three groups. The number of "no change in pain" subjects versus "decrease in pain" between all three groups was used for this test.

Chi-Square = 1.969. The p-value of (0.374) is more than 0.05 and therefore H_0 was accepted, which suggest that there is no statistically significant difference between the three groups.

The inter-group analysis after the treatment period was done by means of the Chi-Square Test. The inter-group analysis between groups A and B is tabulated in table 31, between Groups A and C in table 32 and between B and C in table 33.

Table 31:Chi-Square Tests between Group A and Group B for the severity rating

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.436(b)	1	.231	.429	.429	
Continuity Correction(a)	.022	1	.881			
Likelihood Ratio	1.798	1	.180	.429	.429	
Fisher's Exact Test				.429	.429	
Linear-by-Linear Association	1.333(c)	1	.248	.429	.429	.429
N of Valid Cases	14					

a Computed only for a 2x2 table
b 2 cells (50.0%) have expected count less than 5. The minimum expected count is .43.
c The standardized statistic is 1.155.

The p-value (0.180) is more than 0.05 and therefore H_0 was accepted, which indicates that there is no statistically significant difference between Group A and B regarding the severity of the migraine headaches.

Table 32:Chi-Square Tests between Group A and Group C for the severity rating

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.067(b)	1	.302	1.000	.500	
Continuity Correction(a)	.000	1	1.000			
Likelihood Ratio	1.453	1	.228	1.000	.500	
Fisher's Exact Test				1.000	.500	
Linear-by-Linear Association	1.000(c)	1	.317	1.000	.500	.500
N of Valid Cases	16					

a Computed only for a 2x2 table
b 2 cells (50.0%) have expected count less than 5. The minimum expected count is .50.
c The standardized statistic is 1.000.

The p-value (0.228) is more than 0.05 and therefore H_0 was accepted, which indicates that there is no statistically significant difference between Group A and C regarding the severity of the migraine headaches.

Table 33:Chi-Square Tests between Group B and Group C for the severity rating

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	.049(b)	1	.825	1.000	.692	
Continuity Correction(a)	.000	1	1.000			
Likelihood Ratio	.048	1	.826	1.000	.692	
Fisher's Exact Test				1.000	.692	
Linear-by-Linear Association	.045(c)	1	.832	1.000	.692	.527
N of Valid Cases	14					

a Computed only for a 2x2 table
b 2 cells (50.0%) have expected count less than 5. The minimum expected count is .86.
c The standardized statistic is -.212.

The p-value (0.826) is more than 0.05 and therefore H_0 was accepted, which indicates that there is no statistically significant difference between Group B and C regarding the severity of the migraine headaches.

4.4.4 Subjective findings for the frequency of migraine attacks

4.4.4.1 Intra-group Analysis for the frequency of migraine attacks

Table 34: Patterns of migraine frequency over time for Group A

Patient	Estimated frequency over 6 weeks (baseline)	Actual frequency over the treatment period	Difference	Comment
1	12	2	10	Improvement
2	9	3	6	Improvement
3	6	5	1	Improvement
4	3	5	-2	Worse
5	3	4	-1	Worse
6	7.5	5	2.5	Improvement
7	6	2	4	Improvement
8	6	4	2	Improvement
9	3	5	-2	Worse
10	12	4	8	Improvement
Mean	6.75	3.9		Improvement

Binomial Test

		Category	N	Observed Prop.	Test Prop.	Exact Sig. (2-tailed)
R	Group 1	1	7	.70	.50	.344
	Group 2	0	3	.30		
	Total		10	1.00		

Table 35: Patterns of migraine frequency over time for Group B

Patient	Estimated frequency over 6 weeks (baseline)	Actual frequency over the treatment period	Difference	Comment
1	45	14	31	Improvement
2	13.5	13	.5	Improvement
3	3	1	2	Improvement
4	9	1	8	Improvement
5	7.5	1	6.5	Improvement
6	3	4	-1	Worse
7	7.5	1	6.5	Improvement
8	24	4	20	Improvement
9	6	6	0	No change
10	32	12	20	Improvement
Mean	28	5.7		Improvement

Binomial Test

		Category	N	Observed Prop.	Test Prop.	Exact Sig. (2-tailed)
R	Group 1	1	8	.89	.50	.039
	Group 2	0	1	.11		
	Total		9	1.00		

Table 36: Patterns of migraine frequency over time for Group c

Patient	Estimated frequency over 6 weeks (baseline)	Actual frequency over the treatment period	Difference	Comment
1	3	10	-7	Worse
2	6	5	1	Improvement
3	9	9	0	No change
4	3	2	1	Improvement
5	4.5	1	3.5	Improvement
6	15	4	11	Improvement
7	9	7	2	Improvement
8	12	6	6	Improvement
9	22.5	15	7.5	Improvement
10	6	4	2	Improvement
Mean	11.6	6.3		

Binomial Test

		Category	N	Observed Prop.	Test Prop.	Exact Sig. (2-tailed)
R	Group 1	1	8	.89	.50	.039
	Group 2	0	1	.11		
	Total		9	1.00		

Table 37: Summary of migraine frequency changes over time

	Improvement	No change	Worse	p-value
Group A	7	0	3	0.334
Group B	8	1	1	0.039
Group C	8	1	1	0.039

The migraine frequency of the first visit (an estimate) was compared with the subsequent number of migraine headaches in the treatment period. The purpose of the analysis was to determine whether the frequency rating patterns changed over time. The number of migraine headaches within each group and the significance of improvement of each (Binomial Test) are illustrated in Table 34 to 36 and a summary is given in Table 37.

The p-value (0.344) for group A is more than 0.05 and therefore H_0 was accepted, which indicates that there was no statistically significant change in the frequency of migraine headaches over the treatment period. Group B and C both have p-values of 0.039. This is smaller than 0.05 and H_0 was rejected. This indicates a significant improvement in the migraine headache frequency of both group B and C.

4.4.4.2 Inter-group Analysis of the frequency of migraine attacks

The inter-group analysis using the Chi-Square Test for the frequency patterns between all three groups is illustrated in Table 38 and the frequency pattern between groups A and B and group A and C is illustrated in Table 39 (the two tables look exactly the same). No differences between group B and C were noted, therefore no Chi-Square Test was done.

Table 38: Chi-Square Tests between all three groups for the frequency patterns

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.564(a)	2	.458
Likelihood Ratio	1.501	2	.472
Linear-by-Linear Association	1.150	1	.284
N of Valid Cases	28		

a 3 cells (50.0%) have expected count less than 5. The minimum expected count is 1.61.

Chi-Square = 1.501. The p-value (0.472) is higher than 0.05, which indicates no significant differences between the three groups.

Table 39: Inter-group analysis of the frequency patterns for Group A and B using the Chi-Square Tests.

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.017(b)	1	.313	.582	.333	
Continuity Correction(a)	.198	1	.656			
Likelihood Ratio	1.061	1	.303	.582	.333	
Fisher's Exact Test				.582	.333	
Linear-by-Linear Association	.963(c)	1	.326	.582	.333	.279
N of Valid Cases	19					

a Computed only for a 2x2 table
b 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.89.
c The standardized statistic is -.981.

The table illustrating inter-group analysis of the frequency patterns for Group A and C appears exactly the same as Table 39, and was therefore not included.

4.4.4.3 The mean of the subsequent number of migraine

Table 40: Results of Kruskal-Wallis test for comparing the mean of subsequent number of migraines for the 3 groups.

Ranks

	Group	N	Mean Rank
NMIGR	A	10	13.25
	B	10	15.60
	C	10	17.65
	Total	30	

Test Statistics (a,b)

	NMIGR
Chi-Square	1.274
Df	2
Asymp. Sig.	0.529

a Kruskal Wallis Test
b Grouping Variable: TRTMT

Kruskal-Wallis test was used to compare the means of the subsequent number of migraines (denoted by nmigr) for the 3 groups. The result of the test is shown in Table 40.

Chi-Square = 1.274. The p-value (0.529) is more than 0.05 and therefore H_0 is rejected. This suggests that the means do not differ significantly between the groups.

4.4.5 Duration of migraine episodes

The mean duration of migraine at baseline was 47 hours for group A, 23.5 hours for group B and 29.6 hours for group C.

4.4.5.1 Intra-group analysis for the duration of the migraine attacks over time

Table 41: Pattern of duration over time for Group A

Patient	Rho statistic	p-value	Comment on pattern
1	n/a	n/a	Cannot say
2	n/a	n/a	Cannot say
3	0.829	0.021	Increase over time
4	0.736	0.048	Increase over time
5	0.667	0.110	No change
6	-0.883	0.010	Decrease over time
7	n/a	n/a	Cannot say
8	0.803	0.051	Increase over time
9	-0.086	0.436	No change
10	0.5	0.196	No change

Table 42: Pattern of duration over time for Group B

Patient	Rho statistic	p-value	Comment on pattern
1	-0.493	0.029	Decrease over time
2	-0.777	0.001	Decrease over time
3	n/a	n/a	Cannot say
4	n/a	n/a	Cannot say
5	n/a	n/a	Cannot say
6	0.154	0.402	No change
7	n/a	n/a	Cannot say
8	-0.069	0.403	No change
9	-0.252	0.293	No change
10	-0.231	0.224	No change

Table 43: Pattern of duration over time for Group C

Patient	Rho statistic	p-value	Comment on pattern
1	-0.215	0.263	No change
2	-0.091	0.432	No change
3	0.153	0.336	No change
4	n/a	n/a	Cannot say
5	n/a	n/a	Cannot say
6	-0.4	0.252	No change
7	-0.75	0.016	Decrease over time
8	-0.083	0.429	No change
9	0.235	0.19	No change
10	0.975	0.002	Increase over time

Table 44: Summary of duration pattern comments in tables 41 to 43

	No change	Increase	Decrease	Cannot say	p-value	Chi-Square
Group A	3	3	1	3	0.602	1.871
Group B	4	0	2	4	0.085	7.638
Group C	6	1	1	2	0.016	9.499

Tables 41 to 43 show the results of tests and visual inspections of duration data over time. For cases with 5 or more headaches, the change over time with regards to the duration was tested by calculating the Spearman Rho Statistic. For cases with less than 5 durations the changes were determined (when possible) by means of visual inspections of plots over time. Table 44 is a summary of the results of Tables 41-43

Note that it was not statistically possible to comment on a pattern on the basis of 2 or 3 time points ("cannot say" subjects).

The intra-group analysis for group A, comparing the "no change in duration" subjects to the "decrease in duration" subjects to the "increase in duration" subject showed no statistically significant differences between the categories. The p-value (0602) for group A, (0.085) for group B, is more than 0.05 and therefore H_0 is accepted, which indicates that there is no significant difference exists between the "no change in duration" subjects, the "decrease in duration" subjects and the

"increase in duration" subject. However in group C the p-value was 0.016 which indicates that there is a significant difference between the categories, favoring the "no change in duration" subjects.

There appears to be little or no evidence of change in duration over time in all three groups.

4.4.5.2 Inter-group analysis for the duration of the migraine attacks over time

Table 46: Chi-Square Tests for the duration over time between group A and group B

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	3.420(a)	2	.181	.339		
Likelihood Ratio	4.565	2	.102	.339		
Fisher's Exact Test	3.118			.339		
Linear-by-Linear Association	.010(b)	1	.920	1.000	.587	.245
N of Valid Cases	13					

a 6 cells (100.0%) have expected count less than 5. The minimum expected count is 1.38.
b The standardized statistic is -.100.

Table47: Chi-Square Tests for the duration over time between group A and group C

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.942(a)	2	.379	.608		
Likelihood Ratio	1.999	2	.368	.608		
Fisher's Exact Test	2.056			.491		
Linear-by-Linear Association	.778(b)	1	.378	.497	.296	.183
N of Valid Cases	15					

a 6 cells (100.0%) have expected count less than 5. The minimum expected count is .93.
b The standardized statistic is -.882.

Table 48: Chi-Square Tests for the duration over time between Group B and group C

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	1.478(a)	2	.478	.748		
Likelihood Ratio	1.842	2	.398	.748		
Fisher's Exact Test	1.499			.748		
Linear-by-Linear Association	.399(b)	1	.528	.790	.385	.210
N of Valid Cases	14					

a 5 cells (83.3%) have expected count less than 5. The minimum expected count is .43.
b The standardized statistic is -.632.

Inter-group analysis using the Chi-Square Test between groups A and B is illustrated in Table 45, between groups A and C in Table 46 and between groups B and C in Table 47.The p-value between group A and B is (0.102) and between group A and C is (0.368) and between group B and C is (0.398), therefore H_0 was accepted in all cases, which indicates no statistically significant differences in the inter-group analysis.

Overall there is no evidence of different patterns for the 3 groups (Chi- Square = 5.533 with a p-value of 0.237).

4.4.6 Link between severity and duration of a migraine

Figure 9: Box plot of duration for each severity rating

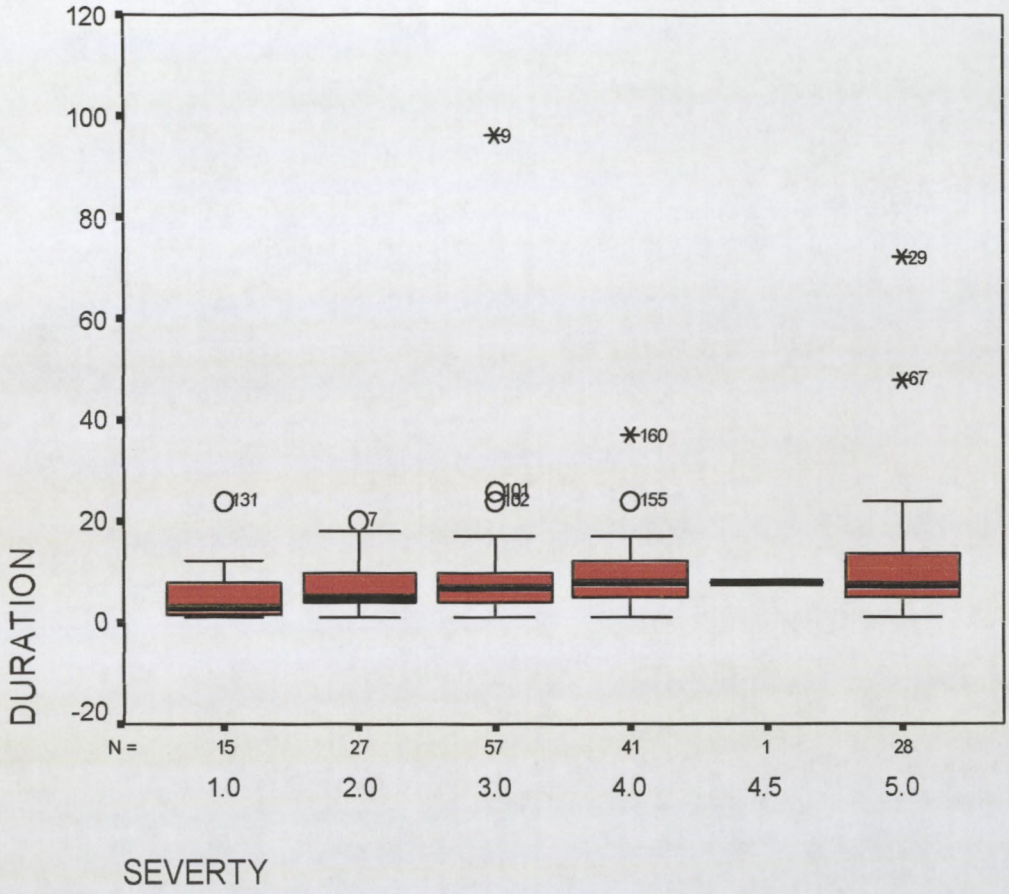
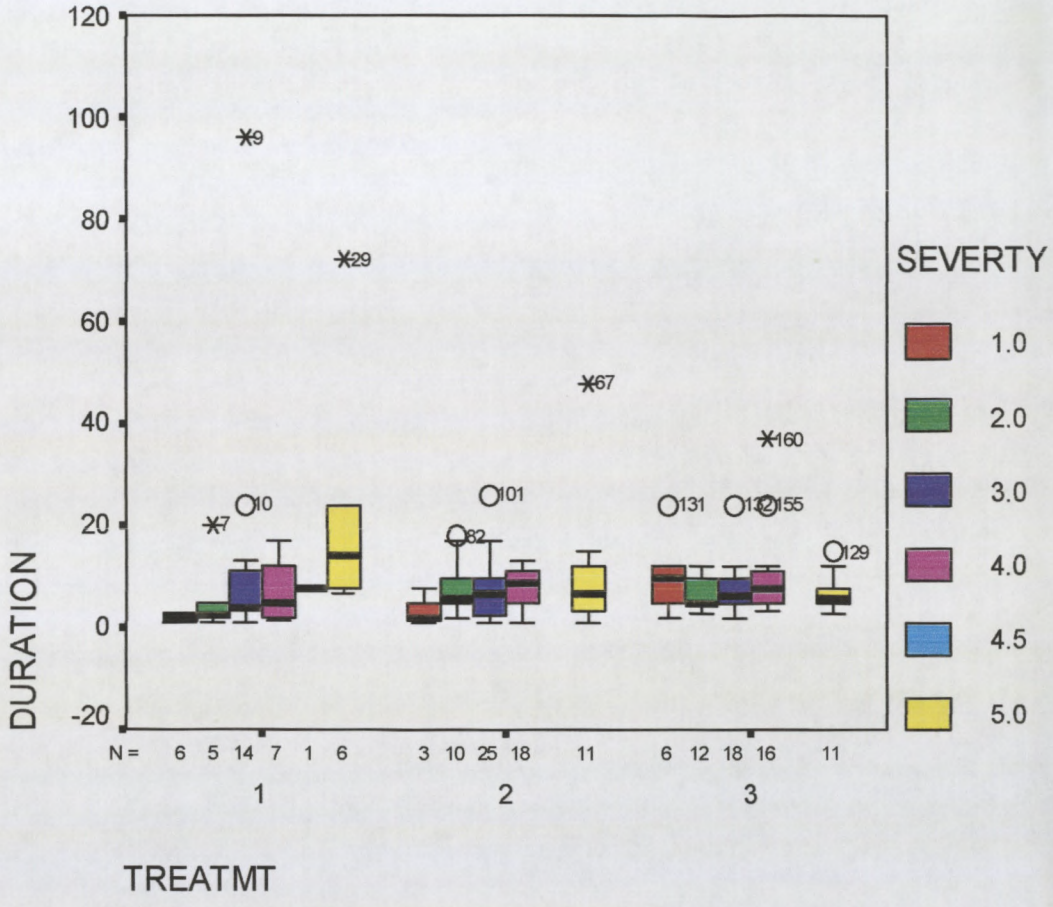


Figure 9 shows a box plot of the duration of a migraine episode for each severity rating. From the box plot it is clear that median duration of a migraine episode does not change much for the different severity ratings. However, more outliers (extreme values) seem to exist at the higher severity ratings (3 to 5) than at lower ones (1 to 2). The collapsed box at 4.5 is due to there being only 1 severity rating (and hence no variation) at that rating. It is clear that extremely longer durations are more likely to occur at higher severity ratings (3 to 5) than at lower ones (1 to 2).

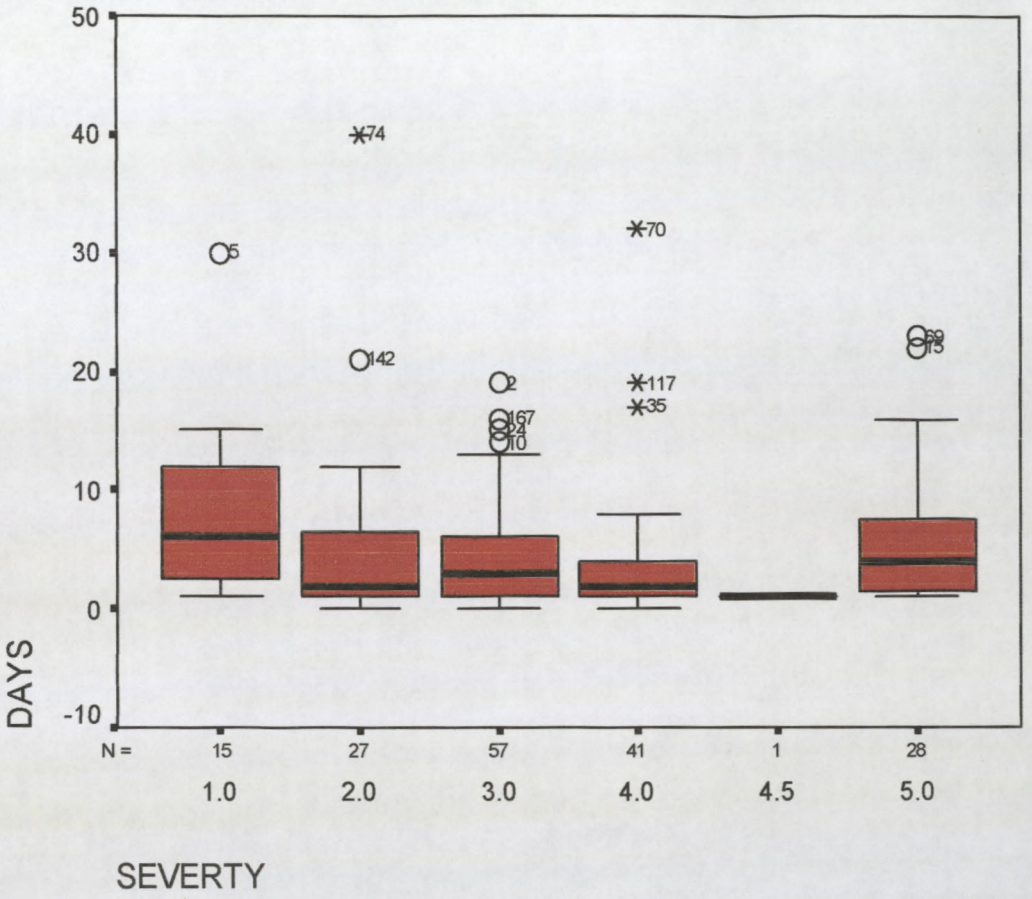
Figure 10: Box plot of the duration of migraine episodes for each severity rating.



Note: Duration is in hours

From figure 10 it is clear that in Group A the median duration and the variation in duration increases with an increase in severity rating. This does not appear to happen in the other two treatment groups.

Figure 11: Box plot of days for each severity rating



4.4.7 Link between severity and days between migraines

From the box plot in Figure 11 it can be deduced that there is slightly more time between migraines with a severity rating of 1 (the lowest) than for the other ratings. The time between migraines for the other ratings appear to be the same.

4.5 Medication consumption

4.5.1 After the treatment report

Table 49: Overall medication consumption improvement

	Group A	Group B	Group C
Better	5 out of 10	4 out of 10	7 out of 10

On the Quality of Life Questionnaire subjects have indicated a 5/10 improvement in medication consumption in group A, 4/10 in group B and 7/10 in group C.

Chi-Square = 1.915

With a p-value (0.384), H_0 was accepted; which indicates that the "better" proportions for the 3 groups are not statistically significantly different.

4.5.2 Home medication patterns as indicated on the Migraine diary

Table 50: Home medications patterns for Group A

	Frequency of taking medication			
	1	2	3	4
Quantity of medication				
1	3	1	0	0
2	17	2	1	2
3	0	1	0	0

Table 51: Home medications patterns for Group B

	Frequency of taking medication			
	1	2	3	4
Quantity of medication				
1	12	2	0	0
2	23	12	3	0
3	0	0	1	0
4	1	0	0	0

Table 52: Home medications patterns for Group C

	Frequency of taking medication					
	1	2	3	4	5	6
Quantity of medication						
1	4	0	0	0	0	1
2	14	8	1	1	2	1
3	0	2	1	0	0	0
4	4	3	0	2	0	0
6	1	0	0	0	0	0

Tables 50 to 52 show a summary in counts of the amounts and frequencies of medication taken for each of the 3 groups. This was obtained in the migraine diaries.

The quantity of medication and the frequency of taking the medication depended on the recommended dosage of the medication. A lot of migraine medications e.g. Adco-Dol®, Betapyn®, Brupfen®, Dispirin®, Dolorol®, Grandpa®, Myprodo®l, Panado®, Pynstop®, Sinutab®, Syndol® and Tylenol®, have a recommended dosage of two tablets as needed. Some of the medications on this list also have a recommended dosage of two tablets twice a day. For this reason these two combinations of quantity and frequency occur most in all three groups.

Table 53: Counts of using and not using medication

	Group A	Group B	Group C
Using medication	27	54	45
Not using medication	12 - (30.8%)	12 - (18.1%)	14 - (23.7%)
Total headaches	39	66	59

Table 53 shows the numbers of times medication were used and not used for each migraine episode.

Although the proportion of cases where medication was not used appears to be more for group A(30.8%) than for the group B (18.1%) and for group C (23.7%), a

formal test indicates that these proportions for the 3 groups are statistically not different (Chi-Square = 2.169 with p-value = 0.338).

4.6 Quality of life results

At the end of the treatment each of the subjects within the 3 groups had to indicate whether they were doing better (a score of 1 was allocated in such a case), the same (a score of 0 was allocated in such a case) or worse (a score of -1 was allocated in such a case) on 16 different issues on the Quality of Life Questionnaire. These 16 issues were grouped into the 5 categories shown below.

1 General health after treatment (issues 1 and 2).
2 Physical condition after treatment (issues 3, 4 and 15).
3 Coping with daily routine after treatment (issues 5, 6, 7 and 9).
4 Coping socially after treatment (issues 8 and 16).
5 Intake of foods, fluids or drugs after treatment (issues 10, 11, 12, 13 and 14).

For each of the 5 categories a total score was obtained for each subject. An analysis of the results is shown below.

4.6.1 General health:

Table 54: Cross tabulation results for "general health" totals counts

	General health denoted by numbers of patient responses as a combined score for issue (1 and 2)			Total
	0	1	2	
Group A	0	2	8	10
Group B	2	2	6	10
Group C	0	2	8	10
Total	2	6	22	30

Table 54 shows the counts of the "general health" as a combined score for issue 1 and 2 for each of the 3 groups.

Chi-Square = 4.771

The p-value (0.312) is greater than 0.05 and therefore H_0 was accepted, which suggests that there were no statistically significant difference between the three groups. All three groups showed a general improvement.

4.6.2 Physical health:

Table 55: Cross tabulation for "physical health" condition totals counts

		Physical Condition denoted by numbers of patient responses as a combined score for questions (3,4 and 15)				Total
		0	1	2	3	
GROUP	A	1	0	6	3	10
	B	1	2	6	1	10
	C	0	4	6	0	10
Total		2	6	18	4	30

Table 55 shows the counts of the "physical health" totals as a combined score for issue 3, 4 and 15 for each of the 3 groups.

Chi-square = 11.457

p-value = 0.075

The p-value (0.075) is greater than 0.05 and therefore Ho was accepted, which suggests that there was no statistically significant difference between the three groups. The table indicates a general improvement in all three groups.

4.6.3 Daily activity:

Table 56: Cross tabulation for "daily activity" total counts

		Coping with daily activities denoted by numbers of patient responses as a combined score for questions (5, 6, 7 and 9)						Total
		-2	0	1	2	3	4	
GROUP	A	1	2	2	4	1	0	10
	B	0	2	1	4	1	2	10
	C	0	1	2	3	3	1	10
Total		1	5	5	11	5	3	30

Table 56 shows the counts of the "daily activity" totals as a combined score for issue 5, 6, 7 and 9 for each of the 3 groups.

Chi-Square = 7.515

The p-value (0.676) is greater than 0.05 and therefore Ho was accepted, which suggests that there was no statistically significant difference between the three groups. The table indicates a slight improvement in all three groups.

4.6.4 Social:

Table 57: Cross tabulation for "social" total count

		Coping with social life, denoted by numbers of patient responses as a combined score for questions (8 and 16)			Total
		0	1	2	
GROUP	A	6	4	0	10
	B	5	4	1	10
	C	6	4	0	10
Total		17	12	1	30

Table 57 shows the counts of the "social" totals as a combined score for issue 8 and 16 for each of the 3 groups.

Chi-Square = 2.317

The p-value (0.678) is greater than 0.05 and therefore H_0 was accepted, which suggests that there was no statistically significant difference between the three groups. The table suggests that there was virtually no improvement in their social life.

4.6.5 Intake of foods, fluids and drugs:

Table 58: Cross classification for "intake" total counts

		Intake, denoted by numbers of patient responses as a combined score for questions (10, 11, 12, 13 and 14).				Total
		0	1	2	3	
GROUP	A	4	3	2	1	10
	B	2	5	2	1	10
	C	1	2	5	2	10
Total		7	10	9	4	30

Table 58 shows the counts of the "intake" totals as a combined score for issue 10 to 14) for each of the 3 groups

Chi-Square = 5.716

The p-value (0.456) is greater than 0.05 and therefore H_0 was accepted, which suggests that there was no statistically significant difference between the three groups. The table suggests that there was no change in the intake of foods, fluids and drugs.

Chapter 5

DISCUSSION OF THE RESULTS

5.1 Introduction

This chapter focuses on two main areas of analysis, namely: demographic analysis and subjective questionnaire data analysis. Analysis of the subjective data includes intra-group and inter-group comparisons. The results of this study were compared with published research to determine whether the study compared favourably with previous documented trends in migraine research.

5.3 Demographic Data

5.2.1 Sample size

Thirty five people were provisionally accepted, fulfilling the criteria of the IHS for migraine. Five people were excluded, because they did not arrive for their follow-up treatments. Group A, group B and group C were randomly allocated 10 subjects each.

5.2.2 Age (Table 1)

The age range of group A was 21-38 years with the mean age of 29.1, group B was 22-55 years with the mean age of 39.9 and group C was 21-55 with the mean age of 36.3. The groups were not similar with regard to age, thus weakening the statistical results obtained for the study. The combined mean age of this study was 35.1 years of age. This can be compared with Steiner *et al.* (2003:522) who stated that migraine headaches peak between the ages of 30 and 40 years.

5.2.3Gender (Table 2)

The prevalence of migraine in the United States is 18.2% amongst women and 6.5% amongst men (Johnson, 2002:634). In the UK the prevalence of migraine in females is 18.3% and in males 7.6%. (Steiner *et al.* 2003:522). In this study the male to female ratio was 2:8 in group A, 2:8 in group B and 3:7 in group C. This supports the hypothesis that migraine headaches more commonly affect females (Johnson, 2002:634).

5.2.4 Ethnicity (Table 3)

The Black, Indian, Caucasian ratio revealed a ratio of 1:4:5 for Group A, 1:2:7 for Group B and 1:2:7 for group C. This supports the hypothesis that migraine headaches are more prevalent in Caucasians than Non-Caucasians (Johnson, 2002:634 and Steiner *et al.* 2003:522).

5.3 Baseline measurements

The baseline measurements in this study showed no significant statistical difference between the three groups. For all the baseline measurements, the null hypothesis (H_0) was accepted as $p > 0.05$ in all the categories. This indicated that the distribution of patients in each group was equal, which strengthens the statistical analysis.

5.3.1 Time suffered with migraine (Table 5)

The subjects that had suffered with migraines for longer than 5 years were 8/10 for group A, 9/10 for group B and 6/10 for group C. The groups were not significantly different with respect to the duration suffered with migraine headaches ($p=0.269$).

5.3.2 Headache location (Tables 6 and 7)

Headache location for all three groups was similar with the majority of subjects complaining of unilateral pain. (8/10, 4/10 and 7/10 respectively, with p=0.154). The mean percentage for unilateral head pain for this study was 63.3%. This is comparable with the literature where Johnson (2002:636) stated that 59% of migraneurs experienced unilateral pain, and Lance (1974:100) stated that migraine is chiefly unilateral in two thirds of patients. The proportion of left and right sided location of the headache in this study were similar in the three groups (p=0.797).

5.3.3 Pain character

The most common pain description in the sample group was throbbing pain. This supports the literature that 85% of migraineurs experience pulsatile (throbbing) pain (Johnson, 2002:636).

5.3.4 Frequency of migraine episodes (Tables 34 to Table 36)

The mean frequency of migraine episodes per month reported by the patients at baseline was 6.75 for group A, 28 for Group B and 11.6 for group C. The groups were not similar with regard to frequency of migraine, thus weakening the statistical results obtained for the study. Steiner (2003:522) reported that 54% of migraineurs have one or more migraines per month. In another report by Lance (1974:100), it was mentioned that most people experience between one and 4 migraines per month, which can increase with emotional factors. In patients that experienced more than 10 attacks each month, tension headaches were often also present (Lance 1974:100). At baseline, 3 subjects in group B and 1 in group C reported more than 10 migraines per month. It is possible that tension type headaches might have been present combined with the migraine headaches in those individuals, or even 'status migrainosus' in one subject from group B.

5.3.5 Duration of migraine episodes (Section 4.4.5)

At baseline, the mean duration of a migraine attack was reported at 47 hours for group A, 23.5 hours for group B, and 29.6 hours for group C. The mean duration between the three groups was 33.36 hours. Lance, (1974:100) stated that migraines persist for less than a day in two thirds of the patients, and Steiner *et al.* (2003:523) stated that the median duration of an attack is 24 hours. When the results in this study were compared with the literature, it was noted that the mean duration in this study was longer than the results in other studies. The baseline duration used in this study was estimated by the patients, which could be the reason for the difference.

5.3.6 Associated symptoms (Table 8 and Table 9)

The associated symptoms of migraine reported by the participants on their initial visit seemed to be similar and comparable between the 3 groups. The associated symptoms reported by all the participants were photophobia (p=0.773, 83% of subjects); loss of appetite (p=0.436, 76% of subjects); nausea (p=0.617, 70% of subjects); dizziness (p=0.617, 70% of subjects) sleepiness (p=0.349, 66% of participants); tingling and other sensations (p-value = 0.584, 53% of subjects); vomiting (p=0.874, 46% of subjects) and tinnitus (ringing in ears) (p=0.111, 43% of subjects). This is similar to the literature where Lance (1974:104); Steiner *et al.* (2003:522) and Johnson (2002:636) reported that 80% of patients find light unpleasant and report sensitivity to light during a migraine attack. A recent prevalence study performed by Johnson (2002:636) reported that 73% of migraineurs experienced nausea and 29% vomit; this is similar to the findings from this study. Eggers (2001:362) stated that migraneurs often display loss of appetite and Dora (2003:561-562) reported that patients prefer to lie down and try to sleep during a migraine, although on review of the literature no exact statistics were found, the hypothesis is consistent with the results of this study. On review of the

literature no exact statistics on dizziness and tinnitus associated with migraine was found.

5.3.7 Causative factors (Tables 10,18 and 19)

Possible causative factors for the onset of migraine were described at the first consultation by the patients as the following: tension and stress (90%); certain foods (50%); hunger (43%); fatigue (33%); the weather (30%) and head movements (26%). No significant differences were noted between the 3 groups (p=0.972) thus strengthening the statistical results. In the literature, Nash and Nash, (2003:322/3) emphasised that the cause of a migraine might be due to stress and certain foods, which is consistent with the results in this study. It is also noted that most of the subjects in this sample group rated their job stress levels fairly high (Tables 18 and 19). No statistically significant differences between the 3 groups regarding their job stress was noted (p=0.111). Stress might be a major causative factor in migraine headaches, as 90% of the subjects rated stress as a causative factor.

5.3.8 Aggravating factors (Table 11 to Table 13)

Aggravating factors for migraine headaches as described at the first visit by the patients were as follows: light (86% of subjects); noise (73% of subjects); head movements (63% of subjects); motion (56% of subjects); exertion (53% of subjects); menstruation (48% of female subjects); sneezing and coughing (43% of the subjects). No significant differences were noted between the 3 groups (p=0.850), which strengthens the statistical results of the study. Literature confirms that 80% of migraine sufferers reported sensitivity to light and 76% to noise during a migraine attack (Johnson, 2002:636); this is consistent with the results in this study.

The IHS, (2004:24) states that migraine gets worse with physical activity; although on review of the literature no exact statistics were found, the hypothesis is consistent with the results of this study

5.3.9 Menstruation (Table 14)

Migraine associated with menstruation was reported in 47.8% of female subjects. Of the 11 subjects 5 had migraine with aura and 6 migraines without aura. Literature suggests that migraine without aura, rather than with aura, is associated with menstruation (Steward *et al.* 2000:1517; Mattsson, 2003:27). In this study the sample size was too small to make such a conclusion.

5.3.10 Relieving factors (Table 15)

Relieving factors reported by the subjects at the initial visit were medication (83% of subjects); lying down (76% of subjects) and massage (60% of subjects). Heat, cold and food did not seem to relieve migraine headaches in the sample group. No significant differences between the three groups where noted which strengthens the results in the study. On review of the literature Dora (2003:561-562) states that sleep relieves migraine headaches.

5.3.11 Doctor consultation (Table 16)

Thirty percent of the participants had never consulted a doctor about their headaches. This is similar to the literature that states that among those who suffer with migraine headaches, 32% of women and 43% of men had never consulted a physician regarding their headaches (Johnson, 2002:634).

5.3.12 Family history of migraine (Table 17)

For the 3 groups, 50%, 90% and 50% of the subjects respectively, had a family history of migraine headaches which is consistent with Johnson (2002:635) and Singer (1994:94) who stated that migraine headaches are more common in patients with a genetic predisposition to migraine.

5.4 Subjective data

The subjective data comprised of the Homeopathic Hospital Outcome score, the CMCC neck disability index, headache diary results and the Quality of Life Questionnaire. The diary results consisted of severity, frequency and duration categories.

5.4.1 The Glasgow Homeopathic Hospital Outcome Score

The GHHOS indicated the improvement or deterioration in the outcome of the patients condition (Richardson, 2001:158).

5.4.1.1Intra-group data analysis for the GHHOS (Tables 20 to 22 and Figures 1-4)

Comparison of the initial consultation and the follow-up consultations indicated a significant statistical improvement in group A, group B and group C. All three groups had an increase in the average gradient with 0.657, 0.246 and 0.196 respectively and showed a general improvement of 76.3%, 67.5% and 81.3% respectively. Thus a general improvement was noted in all groups.

5.4.1.2 Inter group data analysis for the GHHOS (Table 23)

No significant differences were noted between the 3 groups. All three groups showed a general improvement ($p=0.168$).

To the best of the researcher's knowledge, the GHHOS had only previously been used to measure the outcome of homeopathic treatment. In a study by the Department of Homeopathic Medicine in Liverpool, the overall outcome for all types of headaches treated with homeopathy had a general improvement of 77.4% (Richardson, 2001:161). Although in previous literature the GHHOS only showed improvement in homeopathy, in this study it showed an improvement in all 3

groups, with the best results for the combined group (C) with 81.3%, followed by the chiropractic group (A) with 76.3% and lastly the homeopathic group (B) with 67.5%.

5.4.2 The CMCC Neck Disability Index

The CMCC neck disability index indicated how the day to day life of the patient was affected by neck pain experienced.

5.4.2.1Intra-group data analysis for the CMCC Neck Disability Index (Tables 24 to 25 and figures 5 to 8)

In comparison between the initial consultation and the follow-up consultation for the CMCC questionnaire, it was found that all three groups showed significant statistical improvements over time (p=0.000). On visual inspection (Table 24 and Figures 5-7), it was clear that there was a decrease in the neck disability in all three groups. Due to the low sample size per group, no statistical tests could have been done to determine the exact percentage of decrease in each group.

5.4.2.2 Inter-group data analysis for the CMCC Neck Disability Index (Table 26)

There were no statistically significant differences between the 3 groups (p=0.227); all three showed a general decrease in the CMCC disability, but neither performed better than the other.

To the best of the researcher's knowledge, the CMCC Neck Disability Index is usually used with neck manipulation research. It had never been used in homeopathic research. Cullinan (1998:92) used the CMCC Neck Disability Index for migraine research, comparing manipulation to combined acupuncture and manipulation for the treatment of migraine. A statistically significant improvement in his manipulation group was shown when compared with the combined adjustment

and acupuncture group. Kidson (2001:101), also used the CMCC Neck Disablility Index, and showed that manipulation was able to reduce neck disability. In this study the CMCC Neck Disability Index showed a reduction in neck disability not only in the manipulation group, but also in the homeopathic (group B) and combined group (group C).

5.4.3. Headache diary

5.4.3.1 Severity rating of migraine

5.4.3.1.1 Intra-group data analysis for the severity rating of migraine (Table 27 to 30)

- Group A (Table 27 and 30) did not report any significant changes in the severity of their migraine headaches over the treatment period. Eight subjects showed no change at all, and due to statistical reasons 2 subjects cannot be reported on. The p-value (0.000) indicated that there was a significant statistical difference between the "no change in pain" subjects and "decreased in pain" subjects, favouring the "no change" in pain subjects.

  In a clinical trial assessing the response of patients with chronic migraines to a short program of spinal manipulation, a marked improvement in the patients intensity of the migraines was noted (Cattley and Tuchin's, 1999:85-90). In a study by Cullinan (1998:95), a significant decrease in the intensity of migraine was noted in the manipulation group. The same result was not found in this study. Group A showed no statistically significant improvement in the intensity of their migraine headaches.

- Group B (Table 28 and 30) did not report any significant changes in the severity of their migraine headaches over the treatment period. Five subjects showed no change at all, 1 subject showed a decrease in severity and due to statistical reasons 4 subjects cannot be reported on. The p-value (0.080) indicated that there was no significant statistical difference between the "no change in pain" subjects and "decreased in pain" subjects.

With regards to the homeopathic group, Alleoti, (1997) found the use of the migraine complex very successful in reducing the severity of migraine headaches (p=0.004). The same result was not found in this study.

- Group C (Table 29 and 30) did not report any significant changes in the severity of their migraine headaches over the treatment period. Seven subjects showed no change at all, 1 subject showed a decrease and due to statistical reasons 2 subjects cannot be reported on. The p-value (0.01) indicated that there was a significant statistical difference between "no change in pain" subjects and "decrease in pain" subjects, favouring the "no change" subjects.

  Group C cannot be compared with literature as no research has been done on a combined spinal manipulation therapy (SMT) and a homeopathic migraine complex treatment.

5.4.3.1.2 Inter-group data analysis for the severity rating of migraine (Table 31 to 33)

Between all three groups (section 4.4.3.2) there was no significant statistical difference, with little or no evidence of change over time in the severity of their migraine headaches. (Chi-Square Test =1.969 and p=0.374).

- No significant statistical difference in the severity of the migraine headache was noted between group A and group B (Table 31) with a p-value of 0.180.

- No significant statistical difference in the severity of the migraine headache was noted between group A and group C (Table 32) with a p-value of 0.228.

- No significant statistical difference in the severity of the migraine headache was noted between group B and group C (Table 33) with a p-value of 0.826.

To the best of the researcher's knowledge no studies had been done comparing a spinal manipulation therapy, with a homeopathic migraine complex, or spinal manipulation therapy with a combined spinal manipulation therapy and homeopathic migraine complex, or a homeopathic migraine complex with a combined spinal manipulation therapy and homeopathic migraine complex to date, therefore this inter group analysis regarding severity could not be compared with past literature.

5.4.3.2 Frequency of migraine occurrence

5.4.3.2.1 Intra-group analysis for frequency of migraine occurrence (Table 34 to 37)

- Group A (Table 34 and 37) did not report statistically significant changes in the frequency of their migraine headaches over the treatment period. Seven subjects showed an improvement, whereas 2 subjects showed deterioration and 1 subject showed no change in the frequency of their migraine headaches. ($p=0.344$).

  The Chiropractor Research Center of Macquiarie University conducted a clinically controlled trial to assess the effectiveness of spinal manipulation in the treatment of migraine headaches. An average response to the treatment showed a statistically significant improvement in migraine frequency ($p<0.01$) (Tuchin *et al.* 2000:91). A marked improvement in the migraine frequency after spinal manipulation was also noted in a study by Cattley and Tuchin (1999:85-90), and in a study by Cullinan (1997:95). Whittle (1995:65) showed a significant decrease in the frequency of migraine attacks in the intense manipulation group (9 treatments in 3 weeks) compared with the conservative group (9 treatments in 9 weeks).
  In this study, group A showed a decrease in frequency but was not statistically significant. This could be due to the small sample size, and the chance of missing possible statistically significant results is high (Type II error).

- Group B (Table 35 and 37) reported a statistically significant improvement in the frequency of their migraine headaches over the treatment period. Eight subjects showed an improvement, whereas one showed a deterioration and one showed no change in the frequency of their migraine headaches. ($p=0.039$).

The effect of homeopathy treatment regarding the reduction in frequency of migraine was found to be very successful (p=0.007) in a study by Aleotti (1997:i-v), using the same migraine complex that was used in this study. A reduction in frequency was also noted using a similimum treatment for migraine (Strausheim, 2000:4-7). This is in keeping with this study where group B (homeopathic group) showed a statistically significant reduction in frequency (p=0.039).

- Group C (Table 36 and 37) showed the same pattern to group B (p=0.039), with a statistically significant reduction in migraine frequency.

Group C cannot be compared with literature as no research has been done on a combined spinal manipulation therapy and homeopathic migraine complex treatment.

5.4.3.2.2 Inter group analysis for the frequency of migraine occurrence (Tables 38 to 40)

- The inter-group analysis of the frequency patterns between all three groups (Table 38) was not significant different between the groups (p=0.472). There was also no significantly difference in the mean number of migraines during the treatment period (Table 40). All three groups were significantly similar. (Chi-Square = 1.274; p=0.529)

- No significant differences in the frequency pattern of the migraine headaches were noted between group A and group B (Table 39) with a p-value of 0.303.

- No significant differences in the frequency pattern of the migraine headaches were noted between group A and group C (Table 39) with a p-value of 0.303.

- No significant differences in the frequency pattern of the migraine headaches were noted between group B and group C. The patterns in group B and group C were exactly the same; therefore no table was included in chapter 4.

To the best of the researcher's knowledge no similar studies had been conducted, therefore the inter group analysis regarding migraine frequency could not be compared with past literature.

5.4.3.3 Duration of migraine episodes

5.4.3.3.1 Intra-group data analysis for the duration of migraine episodes (Tables 41 to 44)

- Group A (Tables 41 and 44) did not report any significant changes in the duration of their migraine headaches over the treatment period. Three subjects reported increased duration of their migraine headaches, one subject reported a decrease in duration, 3 subjects reported no change in duration at all, and due to statistical reasons 3 subjects could not be reported on. The generated p-value (0.602) indicated that there was no significant statistical difference between the three categories recorded for the duration of migraine headaches over time (Chi-Square = 1.871).

  In a clinical trial by Tuchin, *et al.* (2000:91), spinal manipulation therapy was proven to decrease the duration of migraine headaches significantly ($p<0.01$). Similar results were found in a study by Calltey and Tuchin, (1999:85-90) and in a study by Cullinan, (1997:96). The same result was not obtained in this study, where no statistically significant changes were detected in the spinal manipulation group (group A).

- Group B (Tables 42 and 44) did not report any significant changes in the duration of their migraine headaches over the treatment period. None of the subjects showed an increased duration of their migraine headaches, 2 subjects showed a decreased duration, 4 subjects showed no change in duration at all and due to statistical reasons 4 subjects could not be reported on. The generated p-value (0.085) indicated that there was no significant statistical difference between the three categories recorded for the duration of migraines over time (Chi-Square = 7.638).

Aleotti (1997:i-v) showed a reduction in duration of migraine headaches (p=0.007) in a clinical trial using the same migraine complex as in this study. Different results were obtained in this study. No statistically significant changes were found in group B.

- Group C (Tables 43 and 44) did not report any significant changes in the duration of their migraine headaches over the treatment period. One subject showed an increased duration of migraine headaches, 1 subject showed decreased duration, 6 subjects showed no change in the duration at all, and due to statistical reasons 2 subjects could not be reported on. The generated p-value (0.016) indicated that there was a significant statistical difference between the three categories recorded for the duration of migraines over time, with preference for the "no change in duration" category in this group (Chi-Square = 9.499).

  Group C cannot be compared with literature as no research has been done on the same combined chiropractic and homeopathy treatment.

5.4.3.3.2 Inter-group data analysis for the duration of migraine episodes (Tables 46 to 48)

- There is no evidence of significantly statistical different patterns for the duration of migraine headaches over the treatment period between the 3 groups (Chi-square = 5.533 with p=0.237).

- No significant statistical differences in the duration of migraine headaches were noted between group A and group B (Table 46) with a p-value of 0.102.

- No significant statistical differences in the duration of migraine headaches were noted between group A and group C (Table 47) with a p-value of 0.368.

- No significant statistical differences in the duration of migraine headaches were noted between group B and group C (Table 48) with a p-value of 0.398.

To the best of the researcher's knowledge no similar studies had been conducted, therefore the inter group analysis regarding migraine duration could not be compared with past literature.

5.4.4 Link between the severity and the duration of a migraine attack (Figure 9)

It is clear that median duration did not change much for the different severity ratings. However, there were a few exceptions where extreme durations were more likely to occur with higher severity ratings. For group A (SMT) it is clear that the median duration and variation in duration increased with an increase in severity rating. This did not appear to happen for the other 2 treatments (homeopathic migraine complex and combined groups). To the best of the researcher's knowledge, no literature relating the link between the severity and the duration of a migraine attack was found. Due to the small sample size no statistically significant conclusion could be made regarding the different treatment modalities.

5.4.5 Link between duration of migraine and severity of migraine. (Figure 10)

In group A the duration of the migraine increased with an increase in severity. Group B and group C showed no link between the severity and duration. To the best of the researcher's knowledge, no literature relating the link between the severity and duration of migraine attacks was found. Due to the small sample size no statistically significant conclusion could be made regarding any of the treatment modalities.

5.4.6 Link between severity and days between migraines (Figure 11)

There was a longer duration between migraine attacks of lower severity ratings, but no significant differences between the higher severity ratings and duration between attacks. To the best of the researcher's knowledge, no literature relating the link between the severity and days between migraine attacks was found. Due to the small sample size no statistically significant conclusion could be made regarding any of the treatment modalities.

5.4.7 Allopathic medication consumption (Tables 49 to 53)

In the Quality of Life Questionnaire, patients reported an overall improvement in their allopathic medication consumption (Table 49). Group A reported a 50% improvement in their medication intake, Group B 40% and Group C 70%.

The patients were asked to note their allopathic medication consumption on the Migraine diary, every time they had a migraine.

It was assumed that allopathic medication was frequently taken with every headache at baseline, of which 83% reported that they found relief with medication (Table15). In Table 53 it is illustrated that after the treatment less medication was consumed. Of the 39 migraine headaches that occurred in Group A, 12 required no medication (30.8%). In Group B 12 out of 66 headaches required no medication (18.1%) and in Group C 14 out of 45 (23.7%). The proportion of cases where medication was not used appears to be higher in group A than the other 2 groups, but a formal test indicated that these proportions for the 3 groups are the same (Chi-square = 2.169, p= 0.338).

A significant reduction in allopathic medication consumption for migraine headaches has been shown in a clinical trail with spinal manipulation ($p<0.01$) (Tuchin, *et al.* 2000:91). Cattley and Tuchin, (1999:85-90) showed similar results. This can be compared with group A, which showed a reduction in allopathic medication consumption.

Similar to above, a reduction in medication consumption was noted using a similimum treatment for migraine (Strausheim, 2000:4-7). This can be compared with group B, which also showed a reduction in allopathic medication consumption.

Group C cannot be compared with literature as no research has been done on a combined chiropractic and homeopathy treatment.

5.5 Quality of life

5.5.1 Quality of life results (Tables 54 to 58)

In the survey by Lipton and colleagues (2001:646-657), reviewed by Johnson, more than 90% of migraineurs reported some functional impairment caused by their headaches, 53% stated their headaches severely limited their activities or forced them to seek bed rest. Approximately 31% of all migraineurs missed at least one day of work or school in the three months preceding the survey and more than 50% reported that their work or school productivity was reduced by at least 50% because of migraine headaches (Johnson, 2002:635). Seventy three percent of migraineurs in the UK reported that migraine interferes with their daily activities (Steiner *et al.* 2003:524).

In this study it was noted that the quality of life of the patients, in terms of general health, physical health and daily activity improved in all three treatment groups.

With respect to their general health (Table 54), a statistically significant improvement in the general health of the subjects, in all three groups was noted. Group A reported an 80% significant improvement, group B a 60% significant improvement and group C an 80% significant improvement. There was no difference between the levels of improvement for the 3 groups, (Chi-square = 4.771, p=0.312).

With regards to their physical improvement (Table 55), patients noted a statistically significant improvement in their physical health in all three groups (i.e. Improvement in migraine headaches, physical activities and muscular skeletal pain). The mean improvement for group A, appears to be slightly larger than those for groups B and C, but no significant changes between the three groups were noted (Chi-square = 11.457, p=0.075). The literature stated that statistical

significant improvement was noted in the disability of patients after spinal manipulation (Tuchin *et al.* 2000:91).

In terms of their daily activity (Table 56), (i.e. sleep, job satisfaction, coping with job load and coping with stress), a slight improvement in each of the 3 groups was found (Chi-square = 7.515, p=0.676), and no real changes in social life (Table 57), were detected after the treatment in any of the 3 groups (Chi-square = 2.317, p=0.678).

5.6 Summary

5.6.1 Summary for Group A

For group A there were no statistically significant changes for the severity and duration of the migraine attacks during the study. There was a slight decrease in frequency of attacks, but was statistically insignificant. The GHHOS and the CMCC Neck Disability Index showed a significant improvement over time. Patients reported a 50% improvement in their medication consumption with an actual decrease of 30.8%. Their quality of life had also improved with respect to their general health, physical condition (more than group B and C) and daily activity.

From the literature it is clear that the frequency, intensity and duration in the different studies improved with spinal manipulation; however in this study no significant improvement was noted. The following reasons could have had an effect on the outcome:

- The small sample size and the chance of missing possible statistically significant results are high (Type II error).

- The results relied purely on the patients own perception of their improvement. This is subjective, as no objective measurements were made. Headaches cannot be measured objectively.

- Grunnet-Nilsson (2003:75) recommends that chiropractors can expect patients with migraine headaches to show an improvement only after 14 sessions of spinal manipulation over an 8 week period, as this type of treatment protocol can reduce their migraine attacks by 40% (Grunnet-Nilsson, 2003:75). Eight treatments over a 6 weeks period were given in this study.

- There is no complete explanation of the pathophysiology for the migraine which has numerous different aetiologies. Migraines might be aggravated or potentially caused by cervical spine conditions (Tuchin *et al.* 2000:92). Subjects in this study were randomly allocated to the three groups. Not all subjects in group A's migraines were caused by muscular skeletal, or cervical spine conditions, and this could be the reason why not all subjects responded to manipulation.

5.6.2 Summary for Group B

For group B there were no statistically significant changes for the severity and duration of migraine attacks during the study. There was a statistically significant decrease in the frequency ($p=0.039$) of attacks. The GHHOS and the CMCC Neck Disability Index showed a significant improvement over time. Patients reported a 40% improvement in their medication consumption with an actual decrease of 18.1%. Their quality of life had improved with respect to their general health, physical condition and daily activity.

Although the same method and remedy was used as in a study by Aleotti (1997:i-v) the results of this study did not echo the results of Alleoti's study.

Possible reasons for this:

- The homeopathic trial was not done in a homeopathic clinic and the researcher was not a homeopath but a chiropractor. This could have influenced the result, as the patients first choice of treatment would have been chiropractic, as they had come to a chiropractic clinic. Patients might have had more confidence in the treatment if their first choice of treatment was homeopathy and the remedy was administered by a homeopath.

- Patients might not have been compliant enough in taking the remedy.

- Due to the small sample size, the chance of missing possible statistically significant results is high (Type II error).

- Again, the results relied purely on the patients own perception of their improvement. It is subjective, as no objective measurements were made. Headaches cannot be measured objectively.

- Migraine has many pathophysiologies (e.g. vascular, neurogenic and cervicogenic). Subjects were randomly allocated to groups and not all types of migraine will respond to homeopathy. With the poor understanding of the pathophysiology it is very difficult to treat migraine (Straumsheim, 2000:4)

5.6.3 Summary for Group C

For group B there were no statistical significantly changes for the severity and duration of the migraine attacks during the study. There was a statistically significant decrease in the frequency of attacks (p=0.039). The GHHOS and the CMCC Neck Disability Index showed a significant improvement over time. Patients reported a 40% improvement in their medication consumption with an actual decrease of 18.1%. Their quality of life had improved with respect to their general health, physical condition and daily activity.

It was hypothesised that group C would have had better results than groups A and B due to the combination of the two treatment protocols. It did not perform statistically better or worse than the other 2 groups.

5.7 Limitations of the study

A limitation of the study may have been the small sample size of 30 (10 in a group), which did not show meaningful results. Due to the small size of the sample, there is a predilection for a Type II error (Freidman *et al.* 1992:358).

With regard to the CMCC Neck Disability Index and the GHHOS, which were filled in at the consultations, the unconscious desire to please the examiner by recording lower scores to indicate an improvement, could have been present.

With regard to the headache diary, there may have been the problem of not listing their headaches accurately or compliantly in the diaries.

An important part of the measurement of variables in this study was getting the baseline measurements. This is particularly important with regards to the headache diary. The baseline measurement for this study was taken at the first consultation. Patients gave an estimate of the migraines they had had in the previous month in terms of severity, frequency and duration. A far more accurate approach would have been, to first assess them for a month before the treatment in terms of severity, frequency and duration, using a headache diary.

With respect to the homeopathic treatment (Migraine complex), this homeopathic trial was not done in a homeopathic clinic and the researcher was not a homeopath but a chiropractor. This could have influenced the result, as the patients first choice of treatment would have been chiropractic, as they had come to a chiropractic clinic. Patients might have had more confidence in the treatment if their first choice of treatment was homeopathy and the remedy was administered by a homeopath.

Chapter 6

CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The results of the study indicate statistically insignificant differences between the three groups with regards to various categories of inter-group and intra-group analysis.

None of the three groups showed a statistically significant difference in terms of severity and duration of their migraine headaches, which is in contrast to previous studies. However the frequency of migraine occurrence decreased significantly in the homeopathic migraine complex group (Group B) and the combined group (Group C). The spinal manipulation group (Group A) showed a decrease in the frequency of migraines, but this was not statistically significant. All three groups showed a marked improvement in the GHHOS and a decrease in the CMCC Neck Disability Index. Reduced medication consumption was noted in all three groups as well as an improvement in their quality of life.

In conclusion, comparison of the three different treatments: spinal manipulation therapy alone, homeopathic migraine complex alone and spinal manipulation therapy combined with homeopathic migraine complex; did not find any of these treatments to be more successful than the others. However the study was limited in its statistical strength due to the small sample size, leading to a high probability of type II errors. It is possible that statistically significant differences existed that were not detected by the analysis.

6.2 Recommendations

A larger sample size is recommended allowing for parametric statistical analysis to be performed. This would make trends in the results more apparent and sensitive to subtle change in data. This study, with a sample size of thirty and treatment groups of 10, can only be considered a pilot study. It therefore does not have the strength of a study of a study with a larger sample size.

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

For further studies it is recommended that an individualised homeopathic remedy (similimum), instead of a migraine complex, be used. But in order to do so, a homeopath or a homeopathic intern will be required to prescribe the remedy for each individual participant.

It is recommended that further studies be stratified according to the type of migraine (migraine with aura or migraine without aura), for the sake of scientific accuracy and simplicity.

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CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:..... Date:.....

File # :..... Age: .....

Sex : ..... Occupation: .....

Intern :..... Signature .....

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature :

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

CASE STATUS:

PTT:	Signature:	Date:

CONDITIONAL:

Reason for Conditional:

Signature: Date:

Conditions met in Visit No:	Signed into PTT:	Date:
Case Summary signed off:		Date:

Intern's Case History:

1. **Source of History:**

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

3. **Present Illness:**

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

4. **Other Complaints:**

5. **Past Medical History:**

< General Health Status

< Childhood Illnesses

< Adult Illnesses

< Psychiatric Illnesses

< Accidents/Injuries

< Surgery

< Hospitalizations

6. **Current health status and life-style:**

< Allergies

< Immunizations

< Screening Tests incl. xrays

< Environmental Hazards (Home, School, Work)

< Exercise and Leisure

< Sleep Patterns

< Diet

< Current Medication
Analgesics/week:

< Tobacco
< Alcohol
< Social Drugs

7. **Immediate Family Medical History:**

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

8. **Psychosocial history:**

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

9. **Review of Systems:**

< General

< Skin

< Head

< Eyes

< Ears

< Nose/Sinuses

< Mouth/Throat

< Neck

< Breasts

< Respiratory

< Cardiac

< Gastro-intestinal

< Urinary

< Genital

< Vascular

< Musculoskeletal

< Neurologic

< Haematologic

< Endocrine

< Psychiatric

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CHIROPRACTIC DAY CLINIC
PHYSICAL EXAMINATION

Patient:_____File#:_____Date:_____

Clinician:_____Signature:_____

Student:_____Signature:_____

1. VITALS

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

2. GENERAL EXAMINATION

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

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

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

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

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

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

Percussion: - borders of heart

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

4. RESPIRATORY EXAMINATION

1) Is this patient in **Respiratory Distress** ?

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

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

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

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

5. ABDOMINAL EXAMINATION

1) Is this patient in **Liver Failure** ?

Inspection - Shape:
- Scars:
- Hernias:

Palpation - Superficial:
- Deep = Organomegally:
- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

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

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

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

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

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

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

Evidence of head trauma:

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

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

II External examination of eye:
- Visual Acuity:
- Visual fields by confrontation:
- Pupillary light reflexes = Direct:
= Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

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

b. Motor
- Masseter:
- Jaw lateral movement:

c. Reflexes
- Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

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

b. Taste - Anterior two-thirds of tongue:

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

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

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

XII Inspection of tongue (deviation):

Motor System:

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

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

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

Sensory System:

a.	Dermatomes	- Light touch:
		- Crude touch:
		- Pain:
		- Temperature:
		- Two point discrimination:
b.	Joint position sense	- Finger:
		- Toe:
c.	Vibration:	- Big toe:
		- Tibial tuberosity:
		- ASIS:
		- Interphalangeal Joint:
		- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:
= Intention Tremor:
= Nystagmus:
= Truncal Ataxia:
Finger-nose test (Dysmetria):
Rapid alternating movements (Dysdiadochokinesia):
Heel-shin test:
Heel-toe gait:
Reflexes:
Signs of Parkinsons:

8. <u>SPINAL EXAMINATION:</u>(See Regional examination)

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

9. <u>BREAST EXAMINATION:</u>

Summon female chaperon.

Inspection	- Hands rested in lap:
	- Hands pressed on hips:
	- Arms above head:
	- Leaning forward:
Palpation	- masses:
	- tenderness:
	- axillary tail:
	- nipple:
	- regional lymph nodes:

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REGIONAL EXAMINATION - CERVICAL SPINE

Patient: _____ File No: _____

Date: _____ Student: _____

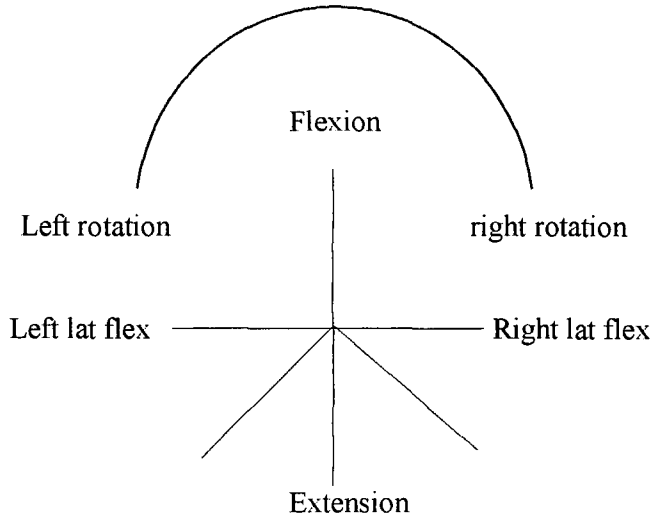
Clinician: _____ Sign: _____

OBSERVATION:

Posture
Swellings
Scars, discolouration
Hair line
Body and soft tissue contours

Shoulder position
Left :
Right :
Shoulder dominance (hand):
Facial expression:

RANGE OF MOTION:
Extension (70°):
L/R Rotation (70°):
L/R Lat flex (45°):
Flexion (45°):



PALPATION:
Lymph nodes
Thyroid Gland
Trachea

ORTHOPAEDIC EXAMINATION:

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

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

NEUROLOGICAL EXAMINATION:

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

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

MOTION PALPATION & JOINT PLAY:

Left: Motion Palpation:
Joint Play:
Right: Motion Palpation:
Joint Play:

Upper Thoracics:
Motion Palpation:
Joint Play:

BASIC EXAM: SHOULDER:
Case History:

BASIC EXAM: THORACIC SPINE:
Case History:

ROM: Active:
Passive:
RIM:
Orthopaedic:
Neuro:
Vascular:
Observ/Palpation:

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

Headache Questionnaire

1. How long have you suffered from migraine headaches?

6 months - 1 year	1	3 - 4 years	4
1 - 2 years	2	4 - 5 years	5
2 - 3 years	3	Longer than 5 years	6

1.1 If you have answered 6 months to 1 year, how many migraine headaches have you had in that time?_____

2. How often do you get migraine headaches?

About ones a month	1	About ones a week	3
Several times a month	2	Several times a week	4

2.1 How often in the last month have you had a migraine? _____

3. Please rate the severity of your migraine headache (1=Mild, 3=moderate, 5=severe)

1 2 3 4 5

---

4. How long do your headaches usually last?_____

5. Are your headaches on one side only?

Never	1	Usually	3
Sometimes	2	Always	4

5.1 If so, which side is more common? **Left** **Right**

6. Before you have a headache, do you know that one is coming? **Yes** **No**

6.1 If you answered yes to no 6, please describe what you notice?

_____

_____

_____

7. How would you describe the character of your headaches?

Pressure	1	Throbbing	3
Steady ache	2	Stabbing	4

8. During your headache, do you (0 = not at all, 4 = severely)

8.1 Feel nauseous? **1 2 3 4**
8.2 Vomit? **1 2 3 4**
8.3 Feel dizzy? **1 2 3 4**
8.4 Feel sleepy? **1 2 3 4**
8.5 Loss of appetite? **1 2 3 4**
8.6 Hear ringing in the ear? **1 2 3 4**
8.7 Find that light hurts your eyes? **1 2 3 4**
8.8 Notice tingling or any strange sensation in any part of your body? **1 2 3 4**

9. When you have a headache, do you notice any changes in your sight? **Yes** **No**

9.1 If yes, describe what you notice

_____

_____

10. When do your headache usually occur?

Wakes up at night	1	Evening	4
Morning	2	All day	5
Afternoon	3	Variable	6

11. Do any of the following bring on a migraine headache?

11.1 Hunger	**Yes**	**No**	11.2 Tension / stress	**Yes** **No**
11.3 Fatigue	**Yes**	**No**	11.4 Weather changes	**Yes** **No**
11.5 Head movements	**Yes**	**No**	11.6 Certain foods	**Yes** **No**

12. Do any of the following aggravate your migraine?

12.1 Menstruation	**Yes**	**No**	12.2 Sneeze / cough	**Yes**	**No**	
12.3 Exertion	**Yes**	**No**	12.4 Head movements	**Yes**	**No**	
12.5 Motion	1	2	3	4		
12.6 Noise	1	2	3	4		
12.7 Light	1	2	3	4		

13. Do any of the following improve your migraine?

13.1 Medication	**Yes**	**No**	13.2 Lying down	**Yes** **No**
13.3 Massage	**Yes**	**No**	13.4 Heat	**Yes** **No**
13.5 Cold	**Yes**	**No**	13.6 Food	**Yes** **No**

14. Have you ever seen a doctor about your headaches? **Yes** **No**

15. Are you on any medication? (for any reason) **Yes** **No**

15.1 Please state which ones and for what.

_____

_____

16. Does any one in your family suffer from migraines?

Mother	1	Sibling	4
Father	2	Children	5
Grand parent	3		

17. Are you married? **Yes** **No**

18. Do you have children? **Yes** **No**

19. Do you smoke? **Yes** **No**

19.1 How many?_____

20. How would you rate your job stress? **1** **2** **3** **4** **5**

21. Have you had any illnesses or operations? **Yes** **No**

21.1 If yes, please state what.

_____

_____

22. Do you suffer from any allergies? **Yes** **No**

22.1 If yes, please state what.

_____

_____

CMCC NECK DISABILITY INDEX

Patient Name:_____File no.:_____Date:_____

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

Section 1 - Pain Intensity

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

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

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

Section 3 - Lifting

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

Section 4 - Reading

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

Section 5 – Headaches

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

Section 6 - Concentration

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

Section 7 - Work

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

Section 8 - Driving

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

Section 9 - Sleeping

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

Section 10 - Recreation

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

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

Glasgow Homeopathic Hospital Outcome Score

Patient name: _____

Date: _____

File number: _____

Outcome score

Treatment	-4	-3	-2	-1	0	1	2	3	4	Notes

Tick in appropriate block

+4 = Cured / back to normal

+3 = Significant improvement

+2 = Moderate improvement, affecting daily living

+1 = Slight improvement, no effect on daily living

0 = no change/unsure

-1 = Slight deterioration, no effect on daily living

-2 = Moderate deterioration, affecting daily living

-3 = Severe deterioration

-4 = Disastrous deterioration

Migraine Diary

Headache onset:
Date: _____
Time began: _____ Time ended: _____

Preceding symptoms:
Visual disturbances of aura? _____
Numbness/tingling? _____
Motor disturbances? _____
Nausea and vomiting? _____
Any other symptoms? _____
_____
_____

Headache Symptoms?
Pain severity scale (1=not severe, 5=most severe)_____
Describing of pain (throbbing, stabbing, pounding, dull ache, palsating)?_____
Location of pain:_____
Other symptoms (nausea, vomiting, sensitivity to light and sound):_____

Home treatment:
Medication taken? (except homeopathic complex) _____
What type?_____
How much?_____
How often?_____
Non medical treatment (sleep, darkness, heat, cold, compression, ice, relaxation, etc.) _____
_____

Headache onset:
Date: _____
Time began: _____ Time ended: _____

Preceding symptoms:
Visual disturbances of aura? _____
Numbness/tingling? _____
Motor disturbances? _____
Nausea and vomiting? _____
Any other symptoms? _____
_____
_____

Headache Symptoms?
Pain severity scale (1=not severe, 5=most severe)_____
Describing of pain (throbbing, stabbing, pounding, dull ache, palsating)?_____
Location of pain:_____
Other symptoms (nausea, vomiting, sensitivity to light and sound):_____

Home treatment:
Medication taken? (except homeopathic complex) _____
What type?_____
How much?_____
How often?_____
Non medical treatment (sleep, darkness, heat, cold, compression, ice, relaxation, etc.) _____

Quality of life Assessment Questionnaire

		AFTER THE TREATMENT			
		Worse	Same	Better	Comments
1	How do you feel after the treatment?				
2	How do you feel your general health is?				
3	Is there a improvement in your migraine headaches?				
4	Are you able to do more physical activities after the treatment?				
5	Do you sleep better at night?				
6	Are you enjoying your job?				
7	Are you able to cope with your work load?				
8	How is your relationship with family members and work colleges?				
9	How do you cope with stress?				
10	Has your intake of alcohol, caffeine and tobacco changed?				
11	Nutrition. Do you eat healthy?				
12	Has anything change in your diet?				
13	Has your headache medication consumption changed?				
14	Have you taken any social drugs, and what effects has it had on your condition?				
15	Do you have any neck pain or other muscularskeletal pain after the treatment?				
16	Any change in your libido or sex life?				

Appendix F

DURBAN INSTITUTE OF TECHNOLOGY CHIROPRACTIC CLINIC
Letter of information

"A three way investigation of the relative effectiveness of spinal manipulative therapy, a homeopathic migraine complex and a combination of the two interventions in the management of migraine headaches."

Dear Participant

You have been invited to participate in a research study, designed to determine the most effective way to treat migraine headaches. It has been shown that chiropractic and homeopathic treatment both help in the treatment of migraines headaches. It would be beneficial to determine which treatment method is a better and more effective way to treat migraines.

Forty-five patients will be used for this study, who will randomly be divided into 3 groups. All 45 will undergo a comprehensive history, physical examination and a head and neck examination from the researcher and be asked to fill in a headache questionnaire prior to examination. Group 1 will receive chiropractic manipulation at fixated areas of the neck and mid back. Group 2 will be instructed to dissolve 5 pills of migraine complex (consisting of *Iris versicolor* 9CH, *Spigelia anthelmia* 9CH and *Sanguinaria canadensis* 9CH) twice a day on waking and at bedtime, when they are between attacks and hourly during attacks, and group 3 will receive a combination of both chiropractic manipulation and the homeopathic migraine complex.

Patients will be required to come in for 8 visits over a 6 week period. At every visit questionnaires will be filled in by the participants. Participants will also be required to document their migraine attacks by means of a headache diary for the duration of the study. A quality of life assessment will be taken at the end of the study.

The first consultation will take about an hour and all the follow-up visits between 15 and 30 minutes.

The case history and physical examinations and the headache questionnaire will serve to screen you for any signs and symptoms or conditions that are unfavourable for spinal manipulation. If so, you will be excluded from this study. If you present with any illness that may affect, perpetuate or cause your headaches, you will be excluded (For example, influenza, sinusitis, raised intracranial pressure, meningitis, pregnancy or elevated blood pressure).
If you are suffering from any of the above or might be pregnant, please inform the researcher immediately.

Both the chiropractic and homeopathic treatment is a conservative form of treatment. The homeopathic complex is very safe to use and have no side effects. You may experience some discomfort during the chiropractic treatment and some post treatment soreness after a manipulation, but this will be transient in nature. Should you wish to, you are however free to withdraw from the study at any stage, without any prejudice.

The consultation is free of charge and your participation is voluntary. Confidentiality is always maintained although your records must be open for inspection by clinic supervisory staff. Should you wish to ask any questions to my supervisor, you can phone her at the number provided, or should you be interested in the results, you have the right to be informed of the outcome of the study.

If you have any concerns with any area of the study, please feel free to ask questions or to forward complaints to the Durban Institute of Technology Ethics Committee (Dr. D Naude tel. 2042041).

Thank you for your interest and participation.

.....
Miss Lelénia du Preez

Tel: 2042205

.....
Dr. T. MacDougall (Supervisor)
M.Tech. Chiropractic
Tel: 2028991

Informed Consent

Date:_____

Title of research project: A three way investigation of the relative effectiveness of spinal manipulative therapy, a homeopathic migraine complex and a combination of the two interventions in the management of migraine headaches.

Name of Supervisors: Dr. T. Macdougall
Dr. D. Naude

Name of Research Student: Lelénia du Preez

Name of Institution: Durban Institute of Technology

Please circle the appropriate answer

1. Have you read the patient information sheet? YES/NO
2. Have you had opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to regarding this study? _____
7. Do you understand the implications of your involvement in this study? YES/NO
8. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time?
   b) Without having to give a reason for withdrawing?
   c) Without affecting your future health care?
9. Do you agree to voluntarily participate in this study? YES/NO

IF YOU HAVE ANSWERED NO TO ANY OF THE ABOVE, PLEASE OBTAIN THE NECESSARY INFORMATION FROM THE RESEARCHER AND / OR SUPERVISOR BEFORE SIGNING. THANK YOU.

PLEASE PRINT IN BLOCK LETTERS

SUBJECTS NAME_____SIGNATURE_____

WITNESS' NAME _____SIGNATURE_____

RESEARCHERS' NAME _____SIGNATURE_____

Appendix H

Do you suffer from **Migraines?**

Are you between 16 and 55?

!!!!!! Headaches !!!!!!!

Research is currently being carried out at the Durban Institute of Technology Chiropractic Day Clinic

Treatment is ***FREE*** should you qualify for this study!!

Please contact: Lelénia du Preez on 031 204 2205 / 2512 for more information