## THE HOMOEOPATHIC TREATMENT OF RECURRENT HEADACHES

#### BY

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology in the Department of Homoeopathy at Technikon Natal.

I, Dorian Lilley do declare that this dissertation represents my own work both in conception and execution.

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# ABSTRACT

The purpose of this placebo controlled study was to determine the efficacy of Similimum treatment on the treatment of recurrent headaches with reference to the patient's response and perception to treatment in order to determine the effectiveness of the treatment methods and the management of recurrent headaches in patients.

Thirty patients with recurrent headaches were admitted onto the study if they suffered from recurrent headaches at least one or more a month. Patients were recruited by means of advertising in local newspapers, shopping centres and libraries. After an initial consultation which included a detailed case history and physical examination, a double blind, random procedure assured that thirty patients were allocated to one of the two experimental groups ( i.e. fifteen in each group ). One of the groups received Similimum treatment and the other received placebo treatment for a period of three months. Treatment commenced one week after the initial consultation, in order to allow for time to evaluate the case and to prescribe the remedies accurately.

The patients were seen regularly during the three-month period (every two weeks) to evaluate their progress. The patients were given two questionnaires, one describing their headache characteristics and the other their perception changes towards their headaches. The questionnaire describing their headache characteristics (Appendix A) was filled in at the initial consultation and this information was used to select each patient's simillimum remedy, these characteristics tended to stay the stay the same throughout the study. The other

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questionnaire (Appendix B) described the patient's perception changes towards their headaches. Each patient took this questionnaire (Appendix B) home with them to recorded the details of their headaches during each two week period and this was evaluated at each repeat consultation.

The data was analysed by means of cross tabulation, frequency tables and bar graphs.

It was found that in each question of the patient perception questionnaire ( Appendix B ) the Similimum group showed a more positive reaction than the placebo group. The most positive of these can be seen in the patient's perception of the treatment and the patient's perception of their headaches where the Similimum group showed 40% more positive reaction to treatment that did the placebo group ( Refer to Graph 4.6 and 7.6 ).

This degree of positive reaction continues in the patient's perception of pain ( Refer to Graph 6.6 ) where the treatment group showed 13,33% greater number of patients experiencing no headaches and a 20% greater number of patients' experiencing very mild headaches as compared to the placebo group. The patient's duration of headache and number of headaches experienced in each two week period revealed a more positive reaction in the treatment group but it was not as significant as in the previously discussed questions. Similimum treatment, both chronic and symptomatic, seems to be the most effective treatment in the management of recurrent headaches as it allows for variation for each patient's specific symptom picture.

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## DEFINITIONS OF TERMS

Patients' perception: The patients' perception of the treatment as recorded from questionnaires. (i.e. changes in the physiological symptom picture as well as perception of headaches ).

Similimum treatment: Treatment of the patient by following the law of similars to find a remedy or remedies that correspond closely to a pathological picture of the patient in order to stimulate the patient back to health (Jouanny 1991 : 13).

Placebo: An inactive substance or preparation given to satisfy the patients symbolic need for drug therapy, and used in controlled studies to determine the efficacy of medicinal substances (Berkow 1992 : 2647).

# CHAPTER ONE

### INTRODUCTION

Headache is a term used to describe pains in the region of the cranial vault (Edwards and Boucher 1991: 849)

There are many factors that trigger headaches and play a role in patients suffering from recurrent headaches. The following are some examples: stress; chemical imbalances; blood pressure problems (Hypertension); poor diet, as well as excessive consumption of certain substances (eg.alcohol); drug abuse; emotional disorders; tension; tumours and sinusitis to name but a few. (Silberstein 1992.)

Recurrent headaches are one of the most common symptoms in patients today and are among one of the most difficult clinical problems to treat (Edwards and Boucher 1991). A search of medical literature from 1983-1991, revealed almost six thousand references to headaches which reflects the importance of this problem in medical practice (Fardy and Harris 1993). These patients need to be treated as this has a profound effect on the way in which they are able to function (Stewart <u>et al.</u> 1992). It affects their sleep and their work during the day, as well as their family lives (Rasmussen and Olesen 1994). The majority of these patients take painkillers and nonsteroidal anti-inflammatories to relieve their headaches, but the action of these is short lived and there are numerous side effects, such as rebound headaches and renal failure (Rapopart and Silberstein 1992).

These treatments are not a panacea and as said before have numerous side effects, infact overuse can often aggravate the patients whole condition (Fritz

1996).

Homoeopathy offers an effective and natural alternative to headache treatment. It is based on a principal ,that there is a similarity between the toxicological action of a substance and its therapeutic action. The homoeopathic remedy acts as a specific stimulant to the patient, it acts with the body's reactions and will not suppress or interfere with the body's systems. (Jouanny 1991:15.) Although Blackie (1990) provides a list of the most successfull homoeopathic remedies prescribed for headaches, a similimum remedy chosen from the entire range of homeopathic remedies listed in the materia medica, whose pathogenic action matches the symptom picture of the patient, is usually prescribed. (Jounnay 1991.)

The objective of this study is to find the Similimum for each participant and to assess the effect that this will have on the patient's symptomatology, with reference to patient perception to treatment in order to determine the effectiveness of the treatment methods and the management of recurrent headaches Because the Similimum will be used for each patient, it may be hypothesised that a deep action within the patient will result in significant relief from his or her headaches.

It is hypothesised that patients' perception of treatment with Similimum will be very positive and that the patients' perception of the treatment with placebo will be significantly less positive than the treatment group. Thus the Similimum treatment will be more effective in the management of recurrent headaches than the placebo treatment.

Headache is one of the universal complaints of mankind and is presently largely elusive to the public health professions. In the United States of America, 70% of the population experience headaches each year. (Silberstein 1992.) Headaches severely affect the quality of life of a large portion of the world's population and therefore needs urgent attention (Dubose <u>et al.</u>1995). Homoeopathy has a significant role to play in treating and alleviating this health problem.

# CHAPTER TWO review of the related literature

#### 2.1 DEFINITION

Headache is a term used to describe pains in the region of the cranial vault. Although the lines separating facial pain and headache are vague, they are considered separate. There are many causes of headaches and each one depending on the cause, will have a different definition eg Tension headache: a headache due to prolonged overwork, emotional strain or both, affecting especially the occipital region. (Edwards and Boucher 1991.)

#### 2.2 AETIOLOGY

Millions of people suffer from headaches. It is a common complete of the whole of man kind. In the U.S.A, in any given year 70% of the population suffer from headaches and over 1% of a physician's consultations and emergency visits are primarily for headaches. (Blaud 1990.) It is a symptom that accounts for more than 18 million visits to physicians each year (Dubose <u>et al</u> 1995). Even though it is one of the most common symptoms treated in practise, it is also one of the most difficult to treat. In the majority of patients, the cause is not serious and is reversible. (Edwards and Boucher 1991.) A careful clinical history and examination, will often lead to an accurate diagnosis, thereby avoiding an unnecessary investigation. Headaches can presage serious intercranial disease but the clinical features of raised intercranial pressure can

usually be distinguished from those of the more common forms of headaches. ( Edwards and Boucher 1991.)

In patients prone to headaches females suffer from headaches more frequently than males do and in both sexes headaches tend to decrease with age. This remains unexplained. (Blaud 1990.) Hormonal factors are thought to play a role in this but the mechanism is not clearly understood (Rasmussen and Olesen 1996). A headache is a common symptom of acute systemic or intercranial infection, intercranial tumour, sinusitis, head trauma, trigeminal neuralgia, hypertension, cerebral hypoxia, neck pathology and many diseases of the eye, nose, throat, teeth and ear (Silberstein 1992). However, these conditions account for only a couple of patients visiting physicians. The majority of patients suffer from migraine, muscle tension headache or head pain for which no cause can be found. The aetiology of headaches varies greatly but it is important for the clinician to determine precisely what hurts. (Berkow 1987.) It is important to note that the daily use of analgesics can actually aggravate headaches. It has been found that mixed analgesic compounds containing aspirin and paracetamol with barbiturates are the strongest inducers of chronic analgesic headaches. (Olesen 1995.)

Seymour<u>et al.</u> (1992) states that analgesic overuse in patients suffering from episodic migraine attacks can often cause the patients to develop chronic daily headaches. Headaches mainly result from stimulation of, or pressure on, any of the pain sensitive structures of the head: all tissues covering the cranium, the fifth, ninth and tenth cranial nerves and the upper cervical nerves; the large intercranial venous sinuses; the large arteries at the base of the brain and the

dura mater at the base of the skull. Dilation and contraction of blood vessel walls stimulate nerve endings causing pain which gives rise to the resultant headache (Berkow 1987).

#### 2.3 HEADACHE TRIGGERS

There are many trigger factors for headaches and these vary to a large degree. Dietary factors are very important as things like chocolate, alcohol, hunger and over indulgence can all trigger headaches. Visual stimuli and odours can also cause headaches, for example television, eye strain, florescent lighting, smoke and strong smells. Some other headache triggers include driving, menstruation , neck tension, temperature variations, lack of sleep or too much sleep, illness , stress and noise.(Blaud 1990; Seymour<u>et al.</u> 1992.)

#### 2.4 PATHOLOGY AND PATHOGENESIS

The trigeminal vascular system plays the most important role in the genesis of headaches. The primary sensory fibers of the intercranial contents and the c-fibers of the first division of the fith cranial nerve innervate the pial vessels. Stimulation of the trigeminal pathways causes dilatation of the extracranial vessels causing nasal congestion and flushing. Stimulation of the trigeminal nerve causes release of substance -P, histamine, serotonin and prostaglandins and sets up neurogenic inflammation. Parasympathetic fibers also release vasoactive intestinal peptide and enhance oedema production. (Gawell and Rothbart 1992.)

The pathology and pathogenesis of headaches vary greatly due to the variances

in the different causation factors. E.g. migraine - this is a vascular disorder, these headaches usually affect females more than males and are unilateral and throbbing in character. They last from 2 to 72 hours with one to two episodes per year to eight or more per month. (Dubose <u>et al.</u> 1995.)

There is a decrease of cerebral blood flow at the start of an attack and relative oligemia which may result in focal disturbance in cortical function giving the resultant prodromal symptoms. During the headache phase, there is dilatation of the extra cranial arteries leading to oedema and thus resulting in the sensation of pain. (Edwards and Boucher 1991.)

There is a strong genetic predisposition to migraine headaches whilst in tension type headaches and cluster headaches there is none (Stevens 1993). Dietary factors including chocolate, cheese, alcohol can precipitate attacks of headache, this is particularly true of migraine headaches. Other triggers that can give rise to headaches include sun, stress, anxiety, female hormones and contraceptive pills to name but a few. (Dubose <u>et al.</u> 1995.)

#### 2.5 CLINICAL MANIFESTATIONS

The clinical symptoms differ from headache to headache, depending on the nature of the headache as well as the causation factors. Due to these great variances in symptomatology, headaches are very difficult to treat. (Edwards and Boucher 1991.) The duration of a headache varies, they can be short lived or may last days, weeks, months or even years. Some headaches are episodic in nature, whilst others are chronic or constant in nature. Usually but not always, headaches are accompanied by associated symptoms, but these also depend on

the type, as well as the intensity of the headache. Some examples of associated features are: nausea, vomiting, photophobia, phonophobia, fatigue, dizziness and visual disturbances. (Stevens 1993.)

Some headaches like migraine headaches are preceded by an aura whilst other such as tension-type and cluster headaches have no warning symptoms at all (Berkow 1987).

The clinical manifestations of a headache differ mainly in cause, site, duration, character and association (Edwards and Boucher 1991). The following are some examples of this:

- A tension headache - these are said to be the most common headaches experienced. There is no prodrome, the headaches are bilateral and vary in severity from mild to severe. The character of pain experienced is normally a dull non-pulsatile pain. These headaches can have photophobia, precranial muscle tension and are normally associated with stress, anxiety and depression. (Stevens 1993.)

- Migraine - these headaches are also considered to be very common (Edwards and Boucher 1991). They are preceded by an aura, are usually unilateral and are moderate to severe in intensity. The character of pain experienced is a throbbing pulsatile pain, usually disabling in nature. These headaches are usually associated with nausea, vomiting, phonophobia and photophobia and are subject to many triggering factors (Stevens 1993).

#### 2.6 EVALUATION AND DIAGNOSIS

The evaluation and diagnosis of headaches is based predominantly on a

detailed case history as well as a detailed headache symptom picture. In the physical examination it is important to preform a detailed inspection of the head and neck as well as a full neurological examination. (Silberstein 1992.) A thorough history can decrease the possibility of misdiagnosis and rule out a potentially life threatening event (Stevens 1993). Some of the more routine examinations done on headache sufferers include a fundoscopy; full ear nose and throat examination; blood pressure reading; as well as an examination of the head and neck and a full neurological examination (Silberstein 1992). In the diagnosis of headaches it is important to separate headaches into different headache types. The International Headache Society (I.H.S. 1988) has done this by giving precise definitions of all headaches types including primary disorders, migraine, tension type headaches and cluster headaches as well as secondary organic headache disorders. (Silberstein 1992.) Seymour<u>et al.</u> (1992) states however that after attempting to classify patients suffering from chronic daily headaches using the I.H.S. criteria a significant proportion of these patients could not be classified. Seymour et al. (1992) felt that the I.H.S. should revise its criteria for headache diagnosis. All aspects of the patient's life should be explored in the case history, headaches often tend to be familial in nature so detail of the patients family history is vitally important. Details of the patients social and work circumstances are important to elicit in order to locate any possible stresses or precipitating factors, e.g. alcohol, tobacco. (Dubose et al. 1995.) It is also important to do a full systems history on each patient as headaches are often symptoms of many systemic diseases, e.g. hypothyroidism, hypertension,

asthma, drugs and head and neck trauma.

Most diagnoses can be made by the routine techniques discussed above but sometimes other methods are needed. It is very important to be careful when dealing with headaches as some could be the first signs of a serious organic problem. (Dubose <u>et al.</u> 1995.) The physical signs of neck stiffness, fever, hypertension, papilloedema, unequal pupils or persistence of neurological signs accompanied with a headache should always be investigated to rule out an underlying structural lesion. Some of the techniques used, are as follows: laboratory studies ( e.g. blood tests, cerebro-spinal fluid, etc. ), X-rays, Magnetic Resonance Imaging, and lumbar punctures CT scans

(Fritz 1996.)

#### 2.7 DIFFERENTIAL DIAGNOSIS

There are many different types of headaches and these can be differentiated from each other by their different symptom pictures. The International Headache Society (I.H.S.) has proposed and published a new classification of headaches that helps differentiate between the various headache types. (Silberstein 1992.)

Some examples of the more common headaches classified by the I.H.S. are as follows: Migraine is a common headache suffered by a great percentage of the worlds population (Patrick <u>et al.</u> 1992). It is an episodic headache and is more common in females than males. An attack is commonly initiated with a prodrome and may be preceded by an aura. These headaches are usually unilateral but can be bilateral and last from four to twenty four hours. They can

be aching or throbbing in character and there can be a sensitivity to light and sound. Vomiting and nausea as well as sensitivity to movement are also common symptoms. (Silberstein 1992.) Migraines have been divided by the I. H. S. into two different types, migraines with aura and migraines without aura (Silberstein and Lipton 1994).

Along with migraine tension type headaches are among the most common primary headaches experienced (Goadsby 1996). These headaches are bilateral and are dull, deep or band-like in character. There are not worse for motion and can last from half an hour to seven days. These headaches are normally mild to moderate in character.

The symptoms associated with these headaches include: anorexia, photophobia, phonophobia and muscle tenderness. (Silberstein 1992.)

Chronic daily headaches are similar to tension type headaches but they occur more frequently i.e.fifteen or more headaches a month (Seymour 1994). Another common headache classified by the I. H. S. are cluster headaches . These affect mostly males and the attacks are brief, frequent and strictly unilateral. They occur in clusters lasting weeks. The pain is very severe and commonly associated with unilateral autonomic signs such as nasal stuffiness and lacrimation. Movement does not aggravate these headaches and there is no nausea or vomiting. (Silberstein 1992.)

A Differential Diagnosis of headaches is as follows:

Acute single headache: subarachnoid haemorrhage, encephalitis, meningitis, systemic infection, sinusitis, optic neuritis, glaucoma and post concussion (Silberstein 1992).

Acute recurrent headache: migraine, cerebrovascular insufficiency, cluster, pheochromocytoma, cerebral tumours and idiopathic intracranial hypertension (Silberstein 1992).

Subacute headache (days or weeks): subdural haematoma, tumour, brain abscess and temporal arteritis (Silberstein 1992).

Chronic daily headache (months or years): tumor, psychiatric state, chronic tension-type headache, analgesic rebound, cervical spondylosis and eye strain (Silberstein 1992).

#### 2.8 TREATMENT

#### ALLOPATHIC

Besides attention to the cause, symptomatic analgesic therapy usually is indicated. Many of the headaches experienced are minor and do not need further treatment than this. The treatment of chronic psychogenic, post traumatic or migrainous headache is a more common and serious problem. Both psychotherapy and pharmacotherapy are necessary. (Berkow 1992.) Firstly in the treatment of headache a physician needs to be understanding and reassuring. The physician needs to show that they accept the patients pain as real. The patient should be allowed to discuss their emotional difficulties and the physician must also assure the patient that no organic lesion is present. Each patient must be educated in the role of stress and other irritants in the precipitation of headaches and should be urged to live as much of an active full life as possible. (Berkow 1992.) The pharmacology of headaches includes a variety of drugs. In most chronic headaches simple analgesics are effective. Aspirin is one of the most widely used analgesics used today as first line treatment. (Fritz 1996.) It may be given alone or in combination with other drugs (Silberstein 1992). Aspirin acts mainly at the peripheral or local level, the site or origin of pain, they do not alter consciousness or mood. They are most useful in mild to moderate pain from injury or inflammation in the skin, teeth and skeletal muscle. They are very effective as they are rapidly absorbed into the blood stream and transported to the site needed. Some of the side effects are as follows: respiratory alkalosis, gastrointestinal irritation and peptic ulceration. (Berkow 1992.) Acetaminophen is another commonly used analgesic, its mode of action is unknown but it has similar effects to aspirin without irritation to the bowel. It is also rapidly absorbed but an overdose can lead to hepatic necrosis. (Berkow 1992.)

Caffeine is also used in the treatment of headaches and is often used in combination with aspirin (Silberstein 1992).

Codeine is another analgesic that is widely used but it is an opium derivative. It acts as an analgesic when given orally and because of its central action it compliments aspirin. Codeine, although effective, has a great potential for overuse and addiction. (Fritz 1996.)

In the treatment of migraine headaches a new drug has been developed and has proved to be highly successful. This new drug is called Sumatriptan succinate and it significantly improves the quality of life of migraine sufferers. (Solomon <u>et al.</u> 1995.)

In chronic headaches or recurrent headaches many doctors combine the use of analgesics with tricyclic antidepressants or tranquillizers but these used over a long term period can cause serious problems (Berkow 1992).

Other examples of drugs used in the management of headaches are as follows: anti-emetics ,anxiolytics, butalbital, cortico steroids, narcotics, ergotamine and selective 5HT agonists (Silberstein and Lipton 1994).

Ergotamine is one of the most widely used and effective drugs used for acute migraine. It has many side effects though such as cramps, angina and abdominal pain. Analgesics and ergotamine have alot of short comings and one of the biggest problems is overuse which can aggravate headache problems. (Fritz 1996.)

There are many forms of non- pharmacological treatment available, the following are some examples: trans-cutaneous electronic nerve stimulation, biofeedback and various relaxation techniques (Fardy and Harris 1993). Prevention is better than cure and headaches can be reduced in patients if endogenous provoking factors are avoided (e.g. red wine, chocolate, alcohol, bright lights and oral contraceptives) (Fritz 1996).

#### HOMOEOPATHIC

Homoeopathy is a therapeutic method which clinically applies the law of similars and which uses medicinal substances in weak or infinitesimal doses (Jouanny 1991: 11). All information on headaches has been done through

provings ie. where a drug is administered to a group of healthy individuals and certain symptoms and signs of the toxicity are produced or from clinical experience. Therefore any medication which produces in a healthy person, headaches similar to those experienced by patients on this study can be used. This is the process used when prescribing Similimum (Jouanny 1991:13; Vithoulkas 1986).

Homoeopathic therapeutics act together with the body's reactions. Homoeopathy stimulates the body's defence mechanism and the remedy acts as a specific stimulant to the organism. Homoeopathic therapeutics are reactive, and the end result is strict individualization of treatment. (Jouanny 1991:14.) Homoeopathic remedies are always non- toxic due to the successive dilutions. They do not act chemically but rather according to a particular physical state and have the capacity of making the ill patient react to his disease. (Jouanny 1991:91.)

Examples of those used include: - Belladonna, Gelsemium sempervirens, Sanguinaria canadensis, Iris versicolor, Spigelia anthelmia, Bryonia alba, Silica , Lycopodium clavatum, Nux vomica, Sulphur, Natrum muriaticum, Sepia officinalis, Cimicifuga and Glonoine and Cocculus indicus (Blackie 1990). Remedies found to be of use in:

Acute symptoms: Aconite napellus, Belladonna, Gelemium sempervirens, Bryonia Apis mellifica, Nux vomica, Glonoinum, Iris versicolor, Spigelia anthelmia and Sanguinaria canadensis (Blackie 1990; Jouanny 1991). Chronic symptoms: Natrum muriaticum, Calarea carbonicum, Argentum nitricum, Lachesis, Silicea, Pulsatilla praetensis, Arsenicum album, Aurum

metallicum, Lycopodium clavatum, Nux vomica and Sepia officinalis (Blackie 1990).

The remedies used for headaches on this study are :

Bryonia alba: the patients that need this remedy have pressure headaches, particularly frontal, which are made worse by slightest movement ( even moving the eyes). These

patients are worse for warmth and their headaches are better for rest and pressure

(Boericke 1990).

Argentum Nitricum : headaches with coldness and trembling. Patients have a sensation as if they head were expanding accompanied with vertigo. There is aching in the front of the head. All of these symptoms are improved by pressure, cold and fresh air and aggrevated by warmth. (Boericke 1990.) Chelionium Majus : with this remedy there is neuralgia over the right eye accompanied with a sensation of the head being as heavy as lead and vertigo. These headaches are associated with hepatic disturbances, they are mainly right sided occuring behind the ear going down to the shoulder blade. These headaches are relieved by pressure. (Boericke 1990.)

Cimicifuga Racemosa : these are shooting, throbbing headaches specially after worry or stress. The patient has the sensation as if his brain were opening and shutting on the vertex. The patient feels that their brain is too large and also experiences tinnitis. (Boericke 1990.)

Cocculus Indicus : these headaches are accompanied with vertigo and nausea. They occur typically in the occipit and there is a sensation of opening and shutting in this area. These headaches are aggrevated by movement especially riding in a car, they are aggrevated by open air. (Boericke 1990.) Gelsimium Sempervirens : these are aching occipital headaches accompanied with vertigo, painful neck muscles and heavy eyes. These headaches are preceded by blindness and are improved by pressure and lying with the head held high. (Boericke 1990.)

Glonoine : these are sun headaches and are characterised by a heavy head, dizziness, and throbbing pain. There is a sensation as if the head is too large and they are aggravated by heat. (Boericke 1990.)

Iris Versicolor : this has frontal headaches with the right temple especially being affected. These headaches are always accompanied with nausea and they start off with a blurring of vision. They are aggravated by rest and are improved by motion. (Boericke 1990.)

Kalium Bichronicum : this has headaches over the eye brows which are preceded by blurred vision. The headaches are usually semilateral occuring in small spots. The bones on the scalp and over the sinuses feel painful and these headaches are generally aggravated by heat. This is the number one remedy for sinus headaches. (Boericke 1990.)

Nux Vomica : these headaches are characterised by occipital aching accompanied with vertigo. They can also be frontal headaches with a desire to press against something. These are congestive headaches with a very sensitive scalp. This remedy is also very good for headaches due to over indulgence. (Boericke 1990.)

Sanguinaria Canadensis : these are typically right sided headaches starting off in

the right occipital area moving over the top of the head to settle above the right eye. The headaches are usually accompanied with congestion of the face and burning in the eyes. (Boericke 1990.)

Spigelia : these headaches are typically left sided and start off in the left occipital area moving over the top of the head to settle above the left eye. These headaches are usually accompanied with palpitations. (Boericke 1990.)

#### **PROPHYLAXIS**

Elements in each patients lifestyle can influence the frequency, duration or severity of headaches. It is important for patients suffering from headaches to reduce their stress levels, to take more time off and to spend more time in relaxation as stress and tension can precipitate headaches. (De Benedittis and Lorenzetti 1992.)

Reduction or elimination of the precipitating factors may not stop patients getting headaches but it can reduce the number or severity of headaches. Some of the precipitating factors causing headache are as follows: certain foods(eg.tyramine containing substances, alcohol, chocolate, cheeses, processed meats), colorants and flavourants, strong environmental stimuli (eg. excessive sun, loud noises, smoke, weather changes) and lifestyle changes (excessive sleep, stressful events, over exertion, fatigue). (Dubose 1995.)

#### <u>CONCLUSION</u>

In conclusion it could be said that there exists a need for an effective treatment for recurrent headaches, a treatment that will decrease the frequency as well as the severity of patients headaches. A treatment that does not cause as many side affects as current treatments is also needed. This study aims to evaluate the efficiacy of Similimum Homoeopathic treatment in the management of

recurrent headaches.

## CHAPTER THREE

### MATERIALS AND METHODS

#### 3.1 THE STUDY DESIGN

The following steps were taking :

- Adverts were placed around the Durban area in shopping centres, librarys and newspapers.
- b) The patients underwent a initial consultation when they were assessed.
   Those that did not fit the criteria were told that they were not suitable for this study at this point.
- c) A sample of thirty patients were accepted for this study.
- d) The programme was explained to each patient and questions were answered. The patients were then signed a patient consent form
   (Appendix A).
- e) At the initial consultation the patients underwent a complete physical and homoeopathic case history performed by the researcher ( Appendix B ). The treatment then commenced one week after the initial consultation.
- f) The patients had to fill in two questionnaires (Appendix C and D).
  Appendix D was filled in under the researchers supervision and consisted of questions related to each patients specific headache picture. The other questionnaire (Appendix C) was taken home by the patient and was to be filled in at the time of any headaches during the periods between repeat visits. The patient recorded any changes experienced in their headaches characteristics.

- g) The case was then repertorised and checked before the prescription was given to the pharmacist, a neutral member of the study.
- h) The patients were devided randomly into two groups : a treatment group and a control group making it a double blind study . Neither the patients nor the researcher knew which group they were in.
- The medication was dispensed and the patients was informed how to take and store the medication.
- j) The patients underwent a twelve week treatment programme with a repeat consultation every two weeks to evaluate each patients progress. The patients were told to write down all the details of each headache they had during each two week period between repeat visits.
  Appendix C was given for this purpose. This questionnaire covered the number of headaches, severity of pain perceived, average duration of headaches and patients perception of their headaches and treatment for each two week period.
- k) All the data was collected from the questionnaires and case histories and was then analysed and interpreted and the hypothesis was tested.

### 3.2 THE SUBJECTS

Thirty patients recruited from the surrounding Durban area participated in this double blind placebo study. They were recruited from adverts in newspapers, libraries and shopping centres. The patients were admitted to the study if they had a history of recurrent headaches ( at least one headache every two weeks). Patients who suffered from any organic lesion or had a history of head trauma were not admitted on to the study. A detailed case history and physical examination was performed

to determine if each patient was suitable for the study. The patients were not recruited according to sex, age or race but all patients had to be older than eighteen years of age. Each patient filled in a patient consent form before treatment commenced.

#### 3.3 INTERVENTIONS

The case history ( Appendix B ) was obtained from the patients by the researcher. The case was then repertorised and checked and the homoeopathicwas prescribed for the treatment and control groups. The prescription wasthen given to the pharmacist , a neutral member in this study. The patients were randomly devided , using a table of randomization numbers , into two groups a control and treatment group. The researcher did not know what group the patients were in until the end of the study. The treatment group received Similimum remedy. This remedy is impregnated on to lactose pills and then allowed to dry. The control group received placebo pills ie. they received unimpregnated lactose pills . The patients were instructed to take these pills during their headaches until relief was obtained. The patients were also informed on how to take and store their medicine.

### 3.4 MEASUREMENTS

Before each patients received their medication they underwent an initial consultation. This was an assessment consisting of a complete case history, physical examination and a detailed picture of each patients headache characteristics. At this initial consultation each patient filled in a questionnaire (Appendix D) under the researchers supervision. This

questionnaire asked specific questions about each patients headache characteristics such as : location of headache, type of pain experienced, associated symptoms and various trigger factors. This information along with the information in the case history was also used to select the patients specific Similimum remedy . Each patients was then repertorised ( a process where by the Similimum remedy for each patient is found ) and a Similimum remedy was prescribed for both the control and treatment groups . Treatment commenced a week after the initial consultation and took place over a twelve week period with a repeat assessment every two weeks to follow their progress . The two questions were designed by the researcher based on existing tested questionnaires in related literature ( Russell <u>et al.</u> 1992; Brazier <u>et</u> <u>al.</u> 1992).

And these were used to assess the patients headaches as well as monitor each patients treatment progress. The first questionnaire (Appendix D) was filled in at the initial consultation and was represented in table form in the result section. The second questionnaire (Appendix C) was taken home by each patient and was brought in at the time of each visit. This questionnaire was used to evaluate the change in the patients perception towards their headaches during each two week period. This questionnaire asked information on any changes in the patients headaches perception, perception of treatment, severity of pain, duration of headache and number of headaches experienced in each two week period. These changes were put on to frequency tables and were represented graphically each week . The patients given a grading system of one to five, one being very bad and five being very good with three

being no change. This enabled the researcher to evaluate the patients progress from week to week over the twelve week period.

### 3.5 STATISTICAL PROCEDURES

The hypothesis was tested by :

transferring all the information collected from the questionnaires during the twelve week period on to spreadsheets. These values were put onto frequency tables which were represented graphically on bar graphs.

## CHAPTER 4

### RESULTS

#### The criteria governing the admissibility of the data.

Only data obtained from the case history and the questionnaires (Appendix C & D) was used in this study. At the initial consultation each patient under went a complete physical examination and homoeopathic case history. They were also given Appendix D to fill in under the researchers supervision. This questionnaire enabled each patient to describe the characteristics of their headaches according to the following criteria :

- a. Location of headaches
- b. Character of pain experienced
- c. Associated symptoms
- d. Triggering factors causing headaches

This information was represented in graph form and was compared with similar information in other headache articles. This information was also used to select each patients simillimum remedy.

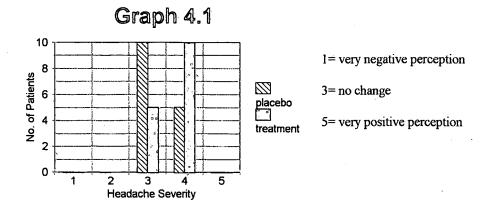
Appendix C was taken home by each patient at the initial consultation and each time a patient had a headache they recorded on this questionnaire and this was evaluated at each repeat visit ( every two weeks for three months ). This questionnaire enabled each patient to describe their perception of treatment during each two week period. The questions asked were as follows :

- a. Patients perception of treatment
- b. Patients perception of pain
- c. Patients perception of headaches

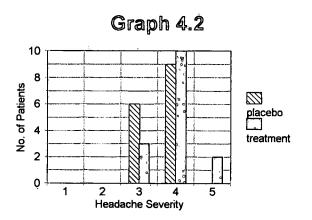
- d. Duration of headaches
- e. Number of headaches

This information was represented in graph form and the results were compared from week to week over the three month period. Question 1: Patients perception of treatment.



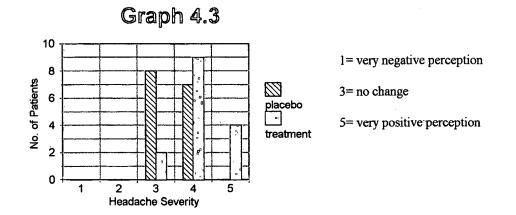


Graph 4.2 Patients perception of treatment after repeat 2.

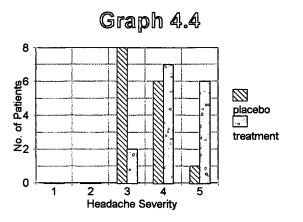


Graph 4.1 and 4.2 represents the patients perception of treatment over the first month. As can be seen in graph 4.1 66.66% of the placebo group experienced no change in their perception of treatment as opposed to only 33.33% of the treatment group. On the other hand it can be seen that as much as 66.66% of the treatment group experienced a positive perception to treatment as opposed to only 33.33% of the placebo group. After the second repeat (Graph 4.2) however 60% of the placebo group felt more positive towards treatment as opposed to 66.66% of the treatment group. Fourty percent of the placebo group felt no change in their perception as opposed to only 20% of the treatment group. It is important to note that 13.33% of the treatment group very positive towards treatment.

#### Graph 4.3 Patients perception of treatment after repeat 3.



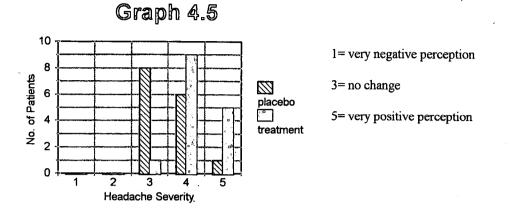
Graph 4.4 Patients perception of treatment after repeat 4.



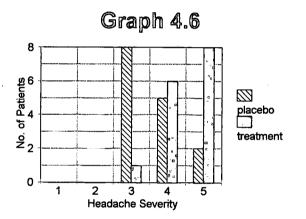
Graph 4.3 and 4.4 represent the results of the patient perception of treatment over the second month of treatment. In graph 4.3 it can be seen that 53.33% of the placebo group felt no change in their perception towards treatment whereas only 13.33% of the treatment group felt no change. The treatment group had 60% of patients experiencing a positive towards treatment as opposed to 46.66% of the placebo group. Twenty six percent of the treatment group experienced a very positive perception towards treatment after the third repeat(six weeks of treatment).

In graph 4.4 it can be seen that the amount of placebo and treatment patients remained the same but the great change in results occurred in the amount of treatment patients experiencing a very positive perception towards treatment.

#### Graph 4.5 Patients perception of treatment after repeat 5.

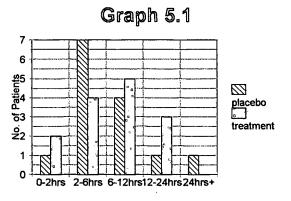


Graph 4.6 Patients perception of treatment after repeat 6.

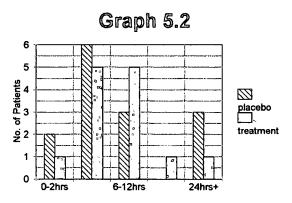


Graph 4.5 and 4.6 represents the patients perception of treatment over the third month . After the fifth and sixth repeat the degree of positive reaction of the treatment group can be seen more clearly, with 33.33% after the fifth repeat and 53.33% after the sixth repeat experiencing a very positive reaction towards treatment as opposed to 6.66% and 13.33% of the placebo group . The percentage of treatment patients experiencing a positive perception towards treatment was also higher. Sixty percent of the treatment group experienced a positive perception towards treatment after the fifth repeat and fourty percent after the sixth repeat as opposed to fourty percent and thirty three percent of the placebo group. As can be seen in graph 4.5 and 4.6 a large percentage of the placebo group (53.33%) experienced no change in their perception towards treatment over the last month. Question 2 : Patients duration of headache.

Graph 5.1 Patients duration of headache after repeat 1.

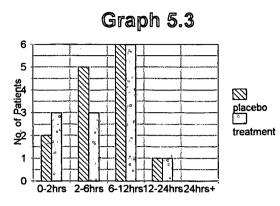


Graph 5.2 Patients duration of headache after repeat 2.

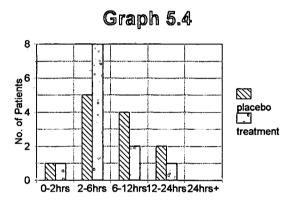


Graph 5.1 and 5.2 represents the duration of each patients headaches over the first month. After the first repeat (graph 5.1) the majority of the placebo group experienced headaches between 2-6 hours (46.66%) as opposed to 26.66% of the treatment group. The highest percentage of treatment patient's experienced headaches between 6-12 hours and 26.66% experienced headaches between 12-24 hours as opposed to only 6.66% of the placebo group. It is also important to note that one patient in each group experienced no headaches. After the second repeat (graph 5.2) it can be seen that 40% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the treatment group. Thirty three and a third percent of the treatment group also experienced headaches between 6-12 hours as opposed to 20% of the placebo group. It is important to note that one placebo patient and two treatment patient's experienced no headaches during the second two weeks of treatment

Graph 5.3 Patients duration of headache after repeat 3.

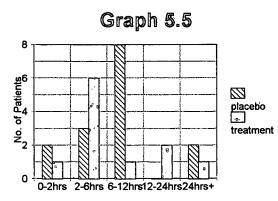


Graph 5.4 Patients duration of headache after repeat 4.

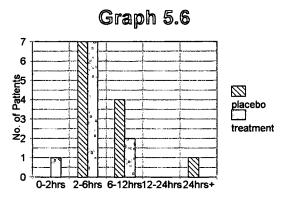


Graph 5.3 and 5.4 represents the duration of each patients headache over the second month of treatment. After the sixth week of treatment both the treatment and placebo group had 40% of their patients experiencing headaches between 6-12 hours. Twenty percent of the treatment group experienced headaches between 0-2 hours as opposed to 13.33% of the placebo group and as much as 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 20% of the treatment group. It is important to note that one placebo and two treatment patient's experienced no headaches. After the eighth week of treatment (graph 5.4) week of treatment 53.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group experienced headaches between 2-6 hours as opposed to 33.33% of the placebo group . One patient in each group experienced headaches between 0-6 hours and 26.66% of the placebo group experienced headaches between 6-12 hours as opposed to only 13.33% of the treatment group. In both groups 20% of patient's experienced no headaches at all.

Graph 5.5 Patients duration of headache after repeat 5.



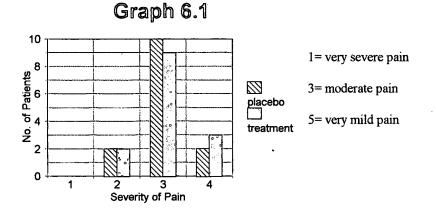
Graph 5.6 Patients duration of headache after repeat 6.



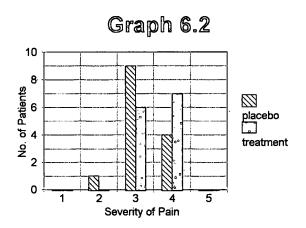
Graph 5.5 and 5.6 represents the duration of each patients headaches over the third month of treatment. After the fifth repeat (graph 5.5) it can be seen that 53.33% of the placebo patients experienced headaches between 6-12 hours as opposed to only 6.66% of the treatment group. Fourty percent of the treatment patients experienced headaches between 2-6 hours as opposed to only 20% of the placebo group and 13.33% of the placebo group experienced headaches between 0-2 hours as opposed to 6.66% of the treatment group. Four treatment patients (26.66%) experienced no headaches. At the end of treatment both groups had 46.66% of their patients experiencing headaches between 6-12 hours as opposed to only 13.33% of the treatment group. It is important to note that three placebo (20%) and five (33.33%) treatment patients experienced no headaches.

#### **QUESTION 3 : Patients perception of pain.**

Graph 6.1 Patients perception of pain after repeat 1.

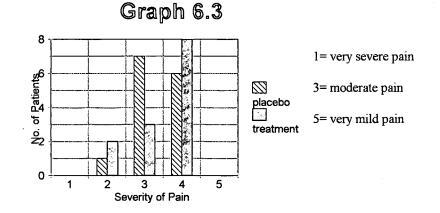


Graph 6.2 Patients perception of pain after repeat 2.



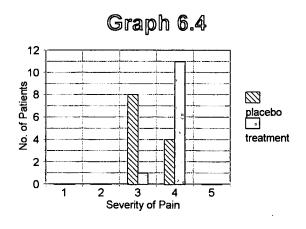
Graph 6.1 and 6.2 represents the patients perception of pain over the first month . In the first two week period 66.66% of the placebo group and 60% of the treatment group experienced moderate pain during their headaches whilst 13.33% of both groups experienced severe pain with their headaches. Twenty percent of the treatment group and 13.33% of the placebo group experienced mild pain with their headaches whilst one patient (13.33%) in each group experienced no headaches . After the second repeat (graph 6.2) it can be seen that a high percentage (46.66%) of the treatment group experienced mild pain with their headaches as opposed to 26.66% of the placebo group. The majority of the placebo group (60%) experienced moderate pain with their headaches as opposed to 40% of the treatment group. It is important to note that 6.66% of the placebo group experienced severe pain with their headaches and that 33.33% of the treatment patients and 6.66% of the placebo

patients experienced no headaches.





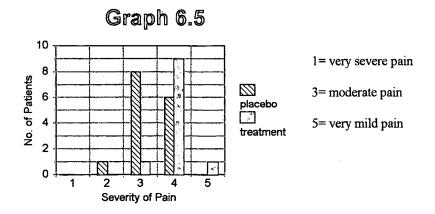




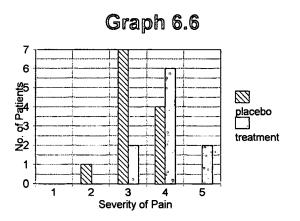
Graph 6.3 and 6.4 represents the

patients perception of pain over the second month. After the sixth week of treatment the treatment group had 53.33% of the patients experiencing headaches of a mild nature as opposed to 46.66% of the placebo group. A large percentage of the placebo group (40%) experienced moderate pain during their headaches as opposed to 20% of the treatment group. Severe pain was experienced by 13.33% of the treatment group and 6.66% of the placebo group. One placebo patient (6.66%) and two treatment patients (13.33%) experienced no headaches. After the fourth repeat (graph 6.4) it can be seen that 73.33% of the treatment group experienced mild pain with their headaches as opposed to only 26.66% of the placebo group. The majority of the placebo group (53.33%) experienced moderate pain with their headaches. Three patients (20%) in both groups experienced no headaches.

#### Graph 6.5 Patients perception of pain after repeat 5.



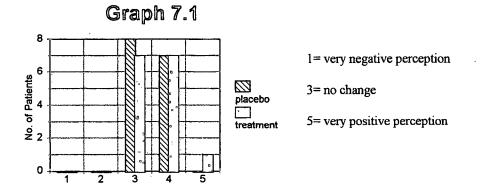
Graph 6.6 Patients perception of pain after repeat 6.



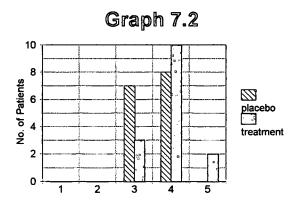
Graph 6.5 and 6.6 represents the patient perception of pain over the third month of treatment. After the fifth repeat (graph 6.5) 60% of the treatment group and 40% of the placebo group experienced milder pain with their headaches. The majority of the placebo group (53.33%) experienced moderate pain and one experienced severe pain with their headaches. Four treatment patients (26.66%) experienced no headaches and one experienced very mild headaches. At the end of the treatment period the majority of the placebo group (46.66%) still experienced moderate pain as opposed to only 13.33% of the treatment group. The treatment group however had 40% experiencing mild headaches as opposed to 26.66% of the placebo group and 13.33% experiencing very mild headaches. Three placebo patients (20%) and five treatment patients ( 33.33%) experienced no headaches.

#### **QUESTION 4 : Patients perception of headaches compared to before treatment.**

Graph 7.1 Patients perception of headaches after repeat 1.

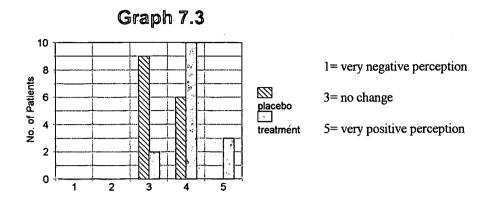


Graph 7.2 Patients perception of headaches after repeat 2.

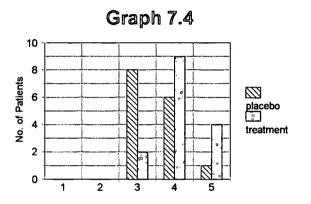


Graph 7.1 and 7.2 represents the patients perception of their headaches over the first month of treatment. As can be seen after the first repeat 46.66% of the treatment group experienced no change in their perception towards their headaches as opposed to 53.33% of the placebo group. The placebo group and the treatment group both had 46.66% experiencing a positive perception towards their headaches. One treatment patient experienced a very positive perception of treatment after the first two weeks of treatment. After the fourth week of treatment (graph 7.2) it can be seen that 66.66% the treatment group experienced a positive perception towards treatment as opposed to 53.33% of the placebo group. Of the placebo group 46.66% experienced no change in their perception towards their headaches as opposed to 20% of the treatment group. It is important to note that 13.33% of the treatment group experienced a very positive perception towards their headaches.

#### Graph 7.3 Patients perception of headaches after repeat 3.



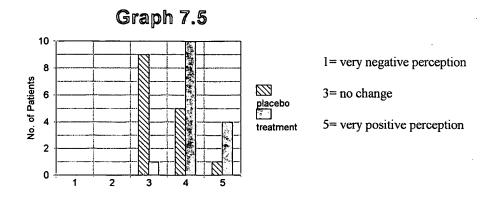
Graph 7.4 Patients perception of headache after repeat 4.



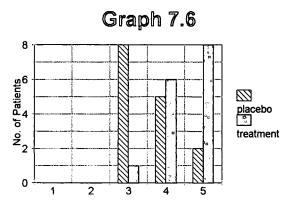
Graph 7.3 and 7.4 represents the patients perception towards their headaches over the second month of treatment. After the third repeat (graph 7.3) the placebo group had 60% of their patients experiencing no change in their perception as opposed to only 13.33% of the treatment group. On the other hand as much as 66.66% of the treatment group experienced a positive perception towards their headaches compared to only 40% of the placebo group. The treatment group had 20% experiencing a very positive perception towards their headaches.

After the fourth repeat (graph 7.4) 53.33% of the placebo group experienced no change in their perception as opposed to only 13.33% of the treatment group. However 60% of the treatment group experienced a positive perception compared to 40% of the treatment group. Four treatment patients (26.66%) and one (6.66%) placebo patient experienced a very positive perception towards their headaches.

Graph 7.5 Patients perception of headaches after repeat 5.



Graph 7.6 Patients perception of headaches after repeat 6.

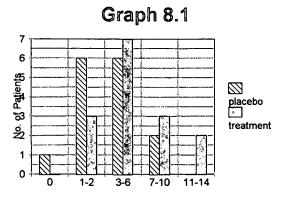


Graph 7.5 and 7.6 represents the patients perception towards their headaches over the third month of treatment. After the tenth week of treatment (graph 7.5) 60% of the placebo group and 6.66% of the treatment group experienced no change in their perception towards their headaches. The treatment group had 66.66% of them experiencing a positive perception towards their headaches compared to only 33.33% of the placebo group. Four treatment patients (26.66%) and one (6.66%) placebo patient experienced a very positive perception towards their headaches.

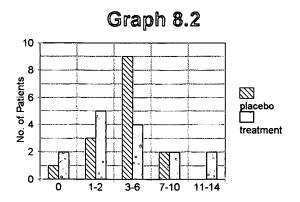
At the end of treatment 53.33% of the placebo group and 6.66% of the treatment group experienced no change in their perception whilst 40% of the treatment group and 33.33% of the placebo group experienced a positive perception towards their headaches. Two placebo patients (13.33%) and eight treatment patients (53.33%) experienced a very positive perception towards their headaches at the end of the treatment period.

#### **<u>OUESTION 5 : Number of headaches during each two week period.</u></u>**

Graph 8.1 Number of headaches during the first two week period.



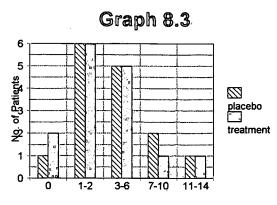
Graph 8.2 Number of headaches during the second two week period.



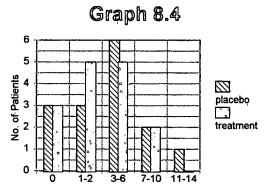
Graph 8.1 and 8.2 represents the number of headaches experienced over the first month of treatment. As can be seen after the first two weeks of treatment the majority of the treatment group experienced 3-6 headaches as opposed to the placebo group who had most of their patients experiencing 1-2 headaches during the first two weeks of treatment. A lot of the treatment patients experienced a high number of headaches, i.e. 20% experienced 7-10 headaches and 13.33% experienced 11-14 headaches.

After the second repeat (graph 8.2) it can be seen that the majority of the placebo group experienced 3-6 headaches (60%) and 1-2 headaches (20%) as opposed to the majority of the treatment group experiencing 3-6 headaches (26.66%) and 1-2 headaches (33.33%). It is important to note that 2 treatment patients (13.33%) and 1 placebo patient (6.66%) experienced no headaches.

Graph 8.3 Number of headaches during the third two week period.

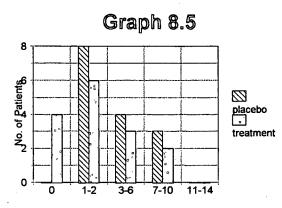


Graph 8.4 Number of headaches during the fourth two week period.

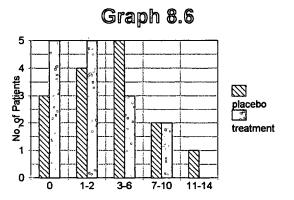


Graph 8.3 and 8.4 represents the number of headaches experienced over the second month. After the sixth week of treatment it can be seen that both the treatment and placebo groups had 33.33% of their patients experiencing 3-6 headaches and 40% experiencing 1-2 headaches during this period. A few placebo and treatment patients experienced between 7-14 headaches but it is important to note that two treatment (13.33%) and one placebo patient (6.66%) experienced no headaches. After the eighth week of treatment (graph.8.4) the majority of the placebo group (40%) experienced 3-6 headaches as opposed to 33.33% of the treatment group. Five treatment patients (33.33%) and three placebo patients (20%) experienced 1-2 headaches. Both the treatment and placebo groups had 20% experiencing no headaches.

Graph 8.5 Number of headaches during the fifth two week period.



Graph 8.6 Number of headaches during the sixth two week period.



Graph 8.5 and 8.6 represent the number of headaches experienced over the third month. After the tenth week of treatment the majority of the placebo group (53.33%) experienced 1-2 headaches as opposed to 40% of the treatment group. A few patients from both groups experienced 3-10 headaches. Four treatment patients (26.66%) experienced no headaches. At the end of the treatment period 33.33% of the placebo group and 20% of the treatment experienced 3-6 headaches. Five treatment patients (33.33%) and four placebo patients (46.66%) experienced 1-2 headaches whilst five treatment (33.33%) and three placebo patients (20%) experienced no headaches over this period.

# APPENDIX D:

QUESTIO	N 1 : Table 9	9.1 Location	of headaches	. )		
Group headache	Occipital	Bifrontal	Temporal	Vertex	Sides of head	Total
Placebo	4	6	2	1	2	15
Treatment	5	6	4			15

The majority of both the placebo and treatment groups experienced bifrontal and occipital headaches. A few patients in both groups experienced temporal headaches and the rest, three patients experienced headaches on their vertex and on the sides of the head.

QUESTION 2 : Table 10.1 Character of pain experienced						
Group	Throb	Severe	Dull Ache	Stabbing	Pressure	Total
headache		Ache				
Placebo	6	3	3	1	2	15
Treatment	5	6	1	2	1	15

A high number of patients in both groups experienced throbbing headaches and aching headaches. Very few

patients experienced stabbing or pressure type headaches and no other types of pain were reported.

QUESTION 3 : Table 11.1 Associated symptoms						
Group	nausea /	light/noise	dizzy	eye pain	neck pain	Total
Headache	vomiting	intolerance				
Placebo	2	3	. 2	5	3	15
Treatment	4	1	4	3	3	15

It can be seen from the table that the associated symptoms reported by the patients were quite evenly spread. The associated symptoms that predominated the most were eye pain, neck pain, nausea, vomiting and dizziness.

QUESTION 4 : Table 12.1 Trigger factors causing headaches						
Group	Stress/	alcohol	sun	fatigue	varied	Total
Headache	emotions					
Placebo	6		1	2	6	15
Treatment	4	2	•	1	8	15

As can be seen by the table the majority of patients in both groups experienced varied trigger factors from week to week. A high number of patients found that stress and emotions was the most common trigger for their headaches. Very few patients found that alcohol, sun, or fatigue triggered their headaches.

QUESTION 5: Table 13.1 Ratio of female to						
male	male					
Group	Male	Female	Total			
headache	headache					
Placebo	6	9	15			
Treatment	4	11	15			

The ratio of females to males was two to one.

Patients	Placebo patients	Treatment patients
1.	Gelsemium sempervirens	Bryonia alba
2.	Iris versicolor	Sanguinaria canadensis
3.	Belladonna	Nux vomica
4.	Bryonia alba	Argentum nitricum
5.	Nux vomica	Bryonia alba
6.	Gelsemium sempervirens	Spigelia anthelmia
7.	Bryonia alba	Kalium bichromicum
8.	Bryonia alba	Ignatia amara
9.	Spigelia anthelmia	Bryonia alba
10.	Kalium bichromicum	Iris versicolor
11.	Spigelia anthelmia	Cocculus indicus
12.	Bryonia alba	Belladona
13.	Ignatia amara	Spigelia anthelmia
14.	Apis mellifica	Bryonia alba
15.	Bryonia alba	Kalium bichromicum

### Table 14.1 Patients treatment profile

# CHAPTER FIVE

#### DISCUSSION

Headache is a term used to describe pains in the region of the cranial vault (Edwards and Boucher 1991). The purpose of this placebo controlled study was to determine the effectiveness of similimum treatment on recurrent headaches with reference to the patients perception and reaction to treatment.

The duration of headache varies greatly from patient to patient and headache type to headache type (Iversen et. al. 1990). The duration of headache also varies within certain headache types e.g. in migraine headache, attacks can vary between 2-72 hours (Silberstein 1992). Question two in Appendix C measured the duration of headache over the twelve week period. Both groups experienced a decrease in headache duration but the treatment groups improvement was more consistent over the entire period where as the control groups improvement was more erratic, fluctuating from week to week. The questionnaire should be modified to include a greater number of options when measuring the duration of headaches i.e. have closer measuring margins like 30 minutes between choices instead of one hour. This would allow for greater accuracy in analysis and would also show a greater difference in results. Another aspect that should also be considered here is the patients reliability when recording symptoms. There was not a statistical difference in the control versus treatment with regards to duration of headache. This was due to the fact that even though the treatment group were having less headaches and were feeling more positive towards their headaches,

they were still experiencing headaches and this was represented.

The greatest percentage of patients suffering from migraine, tension and chronic daily headache described their pain as being moderate in character (Iversen et.al, 1990). In question three the patients perception of pain was represented (refer to graph 6.1-6.6). It can be seen that at the start of treatment (graph 6.1) the majority of the patients experienced pain that was moderate in severity. At the end of the study (graph 6.6) the majority of the placebo patients experienced pain that was moderate to severe in character where as the treatment group experienced pain that was mild to very mild in nature.

However a modification to the questionnaire can be made to incorporate detail on the classification of each patients headache as established by the I.H.S. in 1988 (Silberstein 1992). This would enable the researcher to tabulate the number of patients experiencing certain headache types eg. migraine, tension or cluster headaches etc. This was left out of the study as it was irrelevant to the Homoeopathic treatment of recurrent headache in this study.

Question five represented the number of headache attacks experienced by each patient during each two week period. The results were more positive for the treatment group. Five of the treatment group experienced no headaches as apposed to three of the control group by the end of the study (refer to graph 8.6). The treatment group however also had a steady increase in the number of patients experiencing headaches of shorter duration compared to the control group which tended to fluctuate up and down from week to week ( refer to graphs 8.1 to 8.6).

The patients attitude towards their headaches and their perception of changes in how they are feeling on the treatment was very important in assessing the efficacy of the study. This was assessed in question 1 and question 4 of the questionnaire (refer to graphs 4.1 to 4.6 and 7.1 to 7.6).

Both sets of graphs in these questions started of f with the majority of the patients in the treatment group and control group feeling no change in their overall perception towards the treatment and their headaches after the first two weeks. But as can be seen by the last graphs in each question (refer to graphs 4:6 and 7.6) by the end of the study the treatment groups perception of positivity increased with over half of the treatment group feeling very positive perception as apposed to over half of the control group experiencing no change at all.

These two questions although very subjective reflect the true success of the study. This more positive perception in the Similimum group can be seen throughout the study to varying degrees and can be attributed to the fact that the Similimum treatment reacts on the person as a whole , improving the patients well being . The Similimum treatment is prescribed to fit the patients symptom picture precisely causing a positive reaction overall. On the other hand the control group having received unmedicated pills resulted in a less positive reaction to the treatment overall.

Appendix D is a questionnaire consisting of seven questions all of which involved each patients various headache symptoms. As these remain the same over the entire period the results were represented in table form . Seymour <u>et al.</u> (1992) reported that most patients with chronic daily headache had headaches bifrontal in location . In question one of this questionnaire the location of each patients headache was tabulated and as can be seen most of the patients on this study experienced headaches bifrontal in nature which was in concert with the report. Seymour <u>et al.</u> (1992) also reported that the second most common location of headaches were occipital which was also found to be the same on this study

Question two dealt with the character of pain experienced and it is important to note that a great percentage of patients experienced headaches of a throbbing or aching character. This was found to be the same in a study done by Seymour <u>et al.</u> (1992) where a great percentage of patients also experienced aching and throbbing headaches although the majority experienced nuchal stiffness which was not reported on this study. This could be attributed to the small sample size of this group which could have allowed for inaccuracy.

Seymour<u>et al.</u> (1992) states that the majority of patients in their study experienced fatigue, irritability and impaired concentration with their headaches. Question three tabulates the associated symptoms of all the patients and it can be seen that eye pain was the most common associated symptom , fatigue and impaired concentration were not even mentioned by the patients. The questionnaire should be modified to include a comprehensive list of associated symptoms to choose from instead of just a few examples. Patient reliability in recording their associated symptoms should also be considered. Blau (1990) reported that the majority of patients on their study had headaches triggered by lack of sleep , alcohol and mental stress. Question six tabulated the trigger factors for this study. The majority of the patients experienced varied trigger factors and a high percentage said that mental stress was the cause of their headaches which is in keeping with the article. The fact that no people mentioned lack of sleep and only two mentioned alcohol as trigger factors can be attributed to the small sample group as well as the inadequate list of trigger factors on the questionnaire. Patient reliability in recording their associated symptoms should also be considered.

Blau (1990) and Rasumrassen <u>et al.</u> (1996) reported that headaches tended to be more common in females than males, the ratio being 2 or 3:1. In this study the ratio of females to males was found to be 2:1 in keeping with these articles. The reasons behind this are thought to be hormonal in nature but the precise mechanisms are not clearly understood (Rasmussen <u>et al.</u> 1996).

Headaches are a very common health problem affecting as much as eighty percent in various population studies (Blau 1990). The current medication prescribed for this condition includes: analgesics , non steroidal anti inflammatory drugs, ergotamines and sumatriptan to name but a few all of these have numerous side effects , some of which are life threatening (Fritz 1996). These remedies are also extremely costly (Rasmussen 1996).

From the results in this study it can be seen that over all the Similimum group had a greater positive reaction to treatment than did the control group. The original hypothesis that the Similimum treatment would be more effective in the management of recurrent headaches and that the patients treated with placebo will have a far less positive reaction would have to be accepted.

Homoeopathy therefore offers a safe, effective treatment for recurrent headaches with no side effects.

The biggest problem with studies of this nature is the complete subjectivity of it. Nothing can be measured or seen, the researcher has to rely totally on each patients to recall and record the information needed and this could allow for error. This problem was encountered with the questionnaire provided. The questionnaire need to be revised and a more comprehensive headache diary needs to be developed. A more comprehensive questionnaire is essential to increase patient reliability in recalling headache symptoms accurately. The study would also have to be conducted over a far greater period of time, ( at least six months ) this would allow for far greater accuracy and the degree of possitivity would also be greater in the treatment group as can be seen by the consistent gradual improvement over the twelve week period.

The debilitating nature of headaches also needs to be evaluated and this was not covered in this study. So many people miss work each year due to headaches (Silberstein 1992) the evaluation of this would also show the effect the medication had on the quality of their daily lives, especially in the Similimum group, as they progressed through the treatment. Question one and question four of Appendix C attempted to test this but although given a general idea of the patients improvement it was not specific enough. The control and treatment group both showed improvement over the twelve week period but the treatment group showed a greater improvement over all which fits in with the hypothesis stated

# CHAPTER SIX

### CONCLUSIONS AND RECOMMENDATIONS

In this study the researcher attempted to evaluate the effect of Homoeopathic simillimum treatment compared to placebo treatment in the treatment of headache, with reference to the patients perception of the treatment in order to determine the efficacy of homoeopathic simillimum treatment of headaches.

A lot of unforseen problems were encountered along the way. One of these problems was the complete subjectivity of the study but due to the nature of this study this could not be helped. A more in depth headache questionnaire needs to be devised if this study were to be taken further.

Another problem was that the sample size was too small, this needs to be increased to at least sixty patients. This would improve the validity of the study, as analysis of small sample groups is often inaccurate.

The period of treatment should also be lengthened, this would also allow for more accurate analysis ( at least six months treatment period should be considered ). I anticipate that the Similimum group's reaction will show a far greater degree of positive reaction to treatment.

This was a difficult topic to research, as I had to rely on Subjective information from each patient in the results. This could have allowed for an inaccurate influence on the study.

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# APPENDIX A

**INFORMED CONSENT FORM(To** be completed in duplicate by patient/subject\*)\*Delete whichever is not applicable.

### TITLE OF RESEARCH REPORT

#### NAME OF SUPERVISOR

### NAME OF RESEARCH STUDENT

#### PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO

2. Have you had an opportunity to ask questions regarding this study? YES/NO

3. Have you received satisfactory answers to your questions? YES/NO

4. Have you had an opportunity to discuss this study? YES/NO

5. Have you received enough information about this study? YES/NO

#### 6. Who have you spoken to?

7. Do you understand the implications of your involvement in this study?YES/NO

8. Do you understand that you are free to withdraw from this stusy? YES/NO

a) at any time

b) without having to give a reason for withdrawing, and

c) without affecting your future health care.

9. Do you agree to voluntarily	participate in this study?	YES/NO
PATIENT/SUBJECT	Signature	

#### (in block letters)

PARENT/GUARDIAN		Signature	
	(in block letters)		
WITNESS NAME_		Signature	
	(in block letters)		
RESEARCH STUD	ENT	Signature	

(in block letters)

# APPENDIX B

Homoeopathic Case history and physical examination:

Patient details:

Name:

Address:

Tel.no:

Date of birth:

Occupation:

Marital status:

Past medical history:

# Past surgical history:

:

# Allergies:

# Family history:

# Present medication:

Smoker?

Recent travel:

Case history

Main complaint: Headache history.

First headache ever:

Pattern:

(change since first )

Duration

Frequency

Severity

How many headaches now?

Typical headache picture: (How many different headaches do you get?)

Describe typical headache.

Duration

Rate pain (mild /mod/severe)

Location (unilat/bilat)

Type of pain (pressure/throb/ache etc...)

How does activity effect it? (+ve/-ve)

Associated features:

Nausea

# Vomiting

Noise intolerance

•

Light intolerance

Other

Eye features:

Туре

Preceding headache

Accompanying headache

Family history of headache

Triggers: Precipitating factors (sun, heat, cold, climatic change, missing meal / going hungry, sleep to

much / little or stress - emotional / physical)

E.N.T

Tendency to otitis, sore throat, colds

Ears: Pain, itch, discharge, hearing

Nose: Bleeding, coryza, itching, cracks

Sinusitis

Throat: Pain, itch, dryness, voice

Mouth: Breath odour, jaw cracking, mouth ulcers

Respiratory

Tendency to bronchitis or asthma

Coryza, phlegm

Pain

Dyspnea

Digestive

Appetite, likes and dislikes

Pain

7 of 17

### Abdominal distention

٠,

# Nausea or vomiting

Change in weight

.Heartburn

Belching

Frequency of stool, constipation or diarrhoea

Flatulence

# Thirst

Urinary

Colour

Odour, sediment

Amount

Difficulty in micturition

.

Genital

Age period started

Regular

• .

0

Heavy / light flow

How many days apart?

Length of menstrual cycle, regularity

Change in emotions

Any other symptoms related

Circulatory

Palpitations

Oedema

### Weakness, tiredness, fainting, blackouts

Skin

Rashes, itches

Acne, boils, warts

Nails-break, split, flake

Perspiration

Locomotor

Pain

11 of 17

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# Joints-Cracking, nodosities

Trembling, swelling, tenderness, numbness, weakness

Cramps, stiffness, injuries or fractures

Nervous \ Mind

Emotions

Anxiety, intolerance

Sleep pattern

Fears

# Depression, tiredness

Co-ordination, tremor

General

Aggravation or improvement from cold\heat

damp\dry

sea\mountains

time of day

season

Physical examination

Gross Neurological

# Sensory:

.

Touch - Face

- Arms

# - Abdomen

- Legs

### Motor

.

# Power - eyes

- cheeks

0

- biceps

- legs

Fundoscopy

Vital signs: Blood pressure

Pulse: Rate and rhythm

Resp. rate

Temperature

Height

Weight

.

General:

General body inspection for abnormalities

Hand: Temperature, moisture, muscle tone, colour, callosities,

joint pain or deformity

Nails: Colour, clubbing, ridges, splinter haemorrhages

Head and neck: Auroscopy, ophthalmoscopy

Colour of skin

Mouth: tongue and throat

Bloodvessels and pulses

Salivary glands and lymph nodes

Position of trachea

### Thyroid

#### Neck stiffness

Chest and lungs: Chest shape and movement

Vibrations, pulsations

Breath sounds

Heart sounds

Abdomen: Lesions, scars, Distention

Muscle tone, tenderness, masses, viscera

Bowel sounds, arterial bruit

Legs: Lymph nodes, pulses

Venous or arterial distention, pain

#### Oedema

(A detailed examination of the particular system will be carried out if a problem is suspected)

#### 17 of 17

### <u>APPENDIX C</u>

### Patient perception questionnaire

Patients name: Thank you for participating in my study. This questionnaire determines your perception of the treatment you are receiving for your recurrent headaches. Your answers to the questions will be regarded as strictly confidential. Please answer the questions as objectively as possible.

To be completed at the end of each two week interval.

<u>INSTRUCTIONS</u>: Answer all the questions by circling the correct number or ticking the correct box. Complete all the questions.

1. I perceive the treatment to be:

. Not good at all ----- very good

2. How long did the headache last?:

0-30 1-3 6-12 12-24 more than

min hrs hrs hrs 24 hrs

3. How would you rate the pain of your headaches:?

severe pain ----- milder pain

#### 12345

4. Your perception of the headaches compared to them at the start of treatment?

worse ----- milder

### 1 of 1

<sup>12345</sup> 

#### 12345

5. How many headaches did you experience this last two week period.

### <u>APPENDIX D</u>

Detail of the patients headaches experienced in the three week period between repeat visits.

Please try to be precise as possible in your descriptions.

Patients name:

Date:

a. Location of the headache: e.g. frontal, behind eyes, temporal, vertex, occipital etc...

b. Character of pain: e.g. stabbing, throbbing, aching etc...

c. Radiation of headache: e.g. from occipit over the top of the head.

d. Associated phenomenon: e.g. ear pain, eye pain, nausea, blurred vision etc...

e. Time of occurrence: Try to see if the headaches appear at a certain time of day or type of weather.

f. Precipitating factors: what brings the headaches on?.