ACKNOWLEDGEMENTS

I would like to express my gratitude to the following people:

- Dr Richard Steele For his invaluable advice, guidance, encouragement and patience as a supervisor.
- Dr Corne Hall For her support, encouragement and assistance as a co-supervisor.
- Dr Madhu Maharaj, Dr Ingrid Couchman, and Dr David Naude For their support and assistance as clinicians.

In Particular I would like to thank:

- My parents, who have always guided, inspired and have moulded me into the person that I am today. Thank you for all your patience and especially giving me the opportunity to pursue my ambitions.
- My siblings, Thank you for being my strength in times of adversity.
- My grandparents, who have always shown me their endless support and motivation. Thank you for all your blessings and words of wisdom.
- All those relatives and friends who have always supported and encouraged me throughout my studies.
- The Almighty, for giving me the courage, strength and ability to achieve all that I have and may he continue to brighten up the path that I have chosen, Insha-allah, Ameen.

ABSTRACT

The purpose of this placebo-controlled study was to evaluate the efficacy of homoeopathic simillimum treatment of patients suffering from chronic sinusitis, in terms of the patient's perception of the treatment.

A sample of 30 patients was selected for the study on the basis of inclusion and exclusion criteria. These patients were randomly divided into 2 groups (15 patients for the treatment group and 15 patients for the placebo group).

Each participant had 2 consultations with the researcher over a period of 3 weeks. Patients completed the General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) and Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2) during each consultation in the presence of the researcher. The treatment consisted of 15 powders containing either an active ingredient (i.e. simillimum) or placebo, dispensed at the first consultation. Each patient was required to take one powder three times a day, 30 minutes before meals, for 5 days.

The data was statistically analysed using the one-sample t-test and the non-parametric Mann-Whitney test. Both these test were performed at the 5% level of significance.

The one-sample t-test was used to compare before and after treatment results within each group for the General Well-Being Questionnaire and the Sinus Symptom Visual

Analogue Scale Questionnaire. There was a significant improvement after treatment in some of the variables of the questionnaires within each group.

The Mann-Whitney test was used to determine if there was a significant difference between the simillimum treatment group and the placebo group for the General Well-Being Questionnaire and the Sinus Symptom Visual Analogue Scale Questionnaire. The results showed that there were no statistical significant differences between the groups.

A summary of the patient profile (Table 4.8) showed that the most commonly prescribed medicines were <u>Causticum</u> and <u>Natrum Muriaticum</u> (4 patients) followed by <u>Calcarea carbonica</u>, <u>Lycopodium</u> and <u>Phosphorus</u> (3 patients). The most commonly dispensed medicines were <u>Calcarea carbonica</u> and <u>Phosphorus</u> (3 patients) followed by <u>Lycopodium</u>.

According to the results obtained from this study, it is apparent that the simillimum treatment was effective in some of the aspects of chronic sinusitis, but no more than the placebo. Therefore, the conclusion is that the simillimum treatment is not effective in the treatment of chronic sinusitis.

TABLE OF CONTENTS [see table of contents file]

ACKNOWLEDGEMENTS	i
ABSTRACT	
TABLE OF CONTENTS	iv
LIST OF TABLES	vii
LIST OF FIGURES	viii
DEFINITION OF TERMS	iy

LIST OF TABLES

[See table of contents file]

LIST OF FIGURES

Figure 4.1	Bar chart representing the comparison between the mean differences within each group with regards to the 14 questions (variables) of the General Well-Being Questionnaire derived from the One-Sample T-Test	30
Figure 4.2	Bar chart representing the comparison between before and after treatment for the groups with regards to the total scores of the Sinus Symptom Visual Analogue Scale Questionnaire	35

DEFINITION OF TERMS

Anosmia – refers to a loss of the sense of smell (Berkow and Beers, 1999:687).

Catarrh – increased mucus discharge from the mucous membranes of the nose, fauces and bronchia, which have been inflamed by any variety of irritants (Yasgur, 1998:43).

Halitosis - (foetor ex ore) refers to bad breath (Yasgur, 1998:105).

Homoeopathy – a therapeutic method which clinically applies the "LAW OF SIMILARS" and which uses medicinal substances in weak or infinitesimal doses (Jouanny, 1993:11).

Homoeopathic Materia Medica – this is composed of the sum-total of pathogenetic knowledge. It is the collection of symptoms, that is, "changes in the way of feeling and acting" of healthy individuals. These are local, general, functional or behavioural symptoms produced by pharmacologically active substances. It is a vast reactional symptomatology of "individuals" considered as a whole, as a psychosomatic unit and as a biological unit (Jouanny, 1993:16).

Hyposmia - refers to a diminished sense of smell (Berkow and Beers, 1999:687).

Nosode – is a homoeopathic medicine from the products of disease or diseased tissues (Watson, 1991:41).

Placebo – a non-medicated substance, that is relatively inert pharmacodynamically administered to contract the effects of relative non-medication in controlled experiments with those of medication in two comparable groups of patients (Gaier, 1991:187).

Repertorization – from the Latin "reperio, -ire, repperi, -tum" meaning to find out, obtain, devise or procure. It describes the reference book that schematically indexes the symptoms sought to be located in the Materia Medica. These symptoms are classified in a logically structured way, and related to each appropriate medicine, offering around each general or particular symptom and its modalities, or a clutch of potentially suitable medicines. A patient is said to be "repetorized" when the total symptom complex has been matched against the listings in such a repertory and the drug that best parallels the majority of the symptoms has been identified (Gaier, 1991:493-494).

Simillimum – the homoeopathic medicine that most closely corresponds to the totality of symptoms. It is the most similar medicine corresponding to a case, the one best covering the true totality of symptoms, and when found, is always curative (or in incurable cases, it is the best possible palliative medicine) (Yasgur, 1998:234-235).

Sinusitis - is a condition manifested by inflammation of the mucous membranes of the nasal cavity and para nasal sinuses, fluids within these cavities, and/or the underlying bone (Lanza and Kennedy, 1997).

THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM IN THE TREATMENT OF CHRONIC SINUSITIS

<u>BY</u>

SHAIDA ISMAIL

Mini-dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Homoeopathy, in the Faculty of Health Sciences at the Durban Institute of Technology.			
I, Shaida Ismail, do hereby declare that th both in conception and execution.	is dissertation represents my own work,		
Signature of Student	Date of Signature		
APPROVED FOR FINAL SUBMISSION			
Signature of Supervisor Supervisor: Dr R. Steele B. A., H. D. E., M. Tech. (Hom.)(TN)	Date of Signature		

DEDICATION

THIS IS DEDICATED TO MY FAMILY FOR ALL THEIR LOVE, HELP AND MOTIVATION THROUGHOUT MY LIFE.

THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM IN THE TREATMENT OF CHRONIC SINUSITIS

SHAIDA ISMAIL

2003

CHAPTER ONE

1.1 INTRODUCTION

Sinusitis is defined as a condition manifested by inflammation of the mucous membranes of the nasal cavity and para nasal sinuses, fluids within these cavities, and/or the underlying bone (Lanza and Kennedy, 1997). **Chronic sinusitis** is diagnosed if the condition has been present for more than 4 weeks (Carr, 2001). It is the most commonly reported diseases in the United States, affecting more than 14% of the population (Chrostowski and Pongracic, 2002).

Health care experts estimate that 37 million Americans are affected by sinusitis every year. Health care workers report 33 million cases of chronic sinusitis to the United States Centre for Disease Control and Prevention annually (National Allergy and Infectious Diseases, 2001).

Americans spend millions of dollars each year for the medications that promise relief from their sinus symptoms (National Allergy and Infectious Diseases, 2001).

In recent years many people have become increasingly aware of the limitations of conventional medicine. Though medical science has found cures for many troubling health problems, it has been less successful in combating chronic illnesses. Likewise, medicines often offer potent treatments for numerous ailments, but they also pose the risk of powerful and distressing side effects. In addition, these medications can be very expensive, and the cost particularly if long-term therapy is required may be prohibitive for many patients. As awareness of the shortcomings of modern medicine

has grown, people have become more enthusiastic about complementary approaches to treating ailments. Complementary therapies are also typically less expensive than conventional treatment. (Shepherd, 1999.)

Homoeopathy is a holistic form of medicine. In treating an illness, it takes into account the unique emotional and physical traits of the individual concerned. Homoeopathic medicines work by helping the body's defence system to heal itself. (Lockie and Geddes, 1995:6.) There is much literature about homoeopathic medicines used to treat sinusitis but very few controlled studies on the subject exist.

In homoeopathic practice medicines are given with the object of stimulating the patients' natural curative powers, as opposed to the use of the drugs for their chemical or physical effects on humans or microorganisms (Foubister, 1989:13).

A double blind study of the homoeopathic treatment of chronic sinusitis by Sengpiehl (1994) was conducted at Technikon Natal, which evaluated two modes of treatment. The reaction of the homoeopathic medicine <u>Luffa operculata</u> 4XH and a combination of Kalium bichromicum 5CH and Cinnabaris 5CH were compared. Forty patients were randomly selected and divided into their respective groups. The statistical results were obtained by performing the Mann-Whitney-U-Test within each group. The result of the study showed that Luffa operculata 4XH was a more effective mode of treatment for chronic sinusitis than a combination of Kalium bichromicum 5CH and Cinnabaris 5CH. (Sengpiehl, 1994.) However it is difficult to assess the validity of these results, because there was no placebo control group. Sengpiehl recommended that simillimum treatment should be investigated.

The purpose of this double blind placebo controlled study was to evaluate the efficacy of homoeopathic simillimum in the treatment of chronic sinusitis in terms of the patient's perception of the treatment.

According to various sources the cost of sinusitis appears to be staggering (Lanza and Kennedy, 1997). Homoeopathy is considerably cheaper than conventional medicine (Ullman, 1991:49). This form of treatment can have potential benefits to patients resulting in less medical costs and a better socio-economic well-being.

1.2 HYPOTHESIS

It is hypothesized that the homoeopathic simillimum treatment will have no significant therapeutic effect in the treatment of chronic sinusitis.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

Sinusitis is a leading health-care problem believed to be increasing in both incidence and prevalence (Lanza and Kennedy, 1997). For instance, a number of national data sets shed light on the great expense and increasing health care burden that sinusitis places on the American population (Kaliner et al., 1997).

Among the commonest problems encountered by general practitioners are patients who complain of sinusitis (McDonogh, 1999).

The patients are depressed and often desperate because, more often than not, they will have had the problem for months or even years and various forms of treatment would not have helped for long (McDonogh, 1999).

2.2 <u>AETIOLOGY</u>

A number of conditions can predispose an individual to have sinusitis (Benninger, Anon, and Mabry, 1997). Inhalation of airborne allergens such as dust, fungi, mould, and pollen may contribute to sinusitis. Damp weather, especially in northern temperate climates, or pollutants in the air and in buildings also can affect people subject to chronic sinusitis (National Allergy and Infectious Diseases, 2001).

Chronic sinusitis also develops in patients with immune deficiency diseases or abnormalities of mucus secretion or movement (e.g. HIV infection, cystic fibrosis) (National Allergy and Infectious Diseases, 2001).

Gram-negative rods (e.g. <u>Haemophilus influenzae</u>) or anaerobic micro organisms (e.g. <u>Fusobacterium nucleatum</u>) may cause exacerbations of chronic sinusitis. In a minority of cases, chronic maxillary sinusitis is secondary to dental infection (Berkow and Beers, 1999:688; Delost, 1997:277).

2.3 PATHOPHYSIOLOGY

The para nasal sinuses are air filled cavities extending from the nasal cavities. The sinuses are named according to the bones where they are located, namely the frontal, ethmoidal, sphenoidal and maxillary sinuses (Giles, 1995:39).

With an upper respiratory infection, the swollen nasal mucous membrane obstructs the ostium of the para nasal sinuses, and the oxygen in the sinus is absorbed into the blood vessels in the mucous membrane. The resulting relative negative pressure in the sinus (vacuum sinusitis) is painful (Berkow and Beers, 1999:688). If the vacuum is maintained, a transudate from the mucous membrane develops and fills the sinus, where it serves as a medium for bacteria that enter through the ostium or through a spreading cellulitus or thrombophlebitis in the lamina propria of the mucous membrane. An outpouring of serum and leukocytes to combat the infection results, and painful positive pressure develops in the obstructed sinus. The mucous membrane becomes hyperaemic and oedematous (Berkow and Beers, 1999:687).

Prolonged obstruction results in mucus stasis with bacterial and occasionally fungal colonization and infection (Benninger, Anon, and Mabry, 1999).

2.4 CLINICAL CRITERIA FOR DIAGNOSIS

The patient's clinical history for chronic sinusitis is considered either to be strong or suggestive on the basis of major and minor factors (Lanza and Kennedy, 1997).

Major factors

Facial pain/pressure

Facial congestion/fullness

Nasal obstruction

Nasal discharge: purulent, or discoloured postnasal drainage

Hyposmia/anosmia

Purulent discharge in nose

Minor factors

Headache

Halitosis

Fatigue

Dental pain

Cough

Ear pressure/fullness

According to Lanza and Kennedy (1997), and Carr (2001), the criteria for diagnosis of chronic sinusitis is as follows: the patient must have more than 2 major factors or 2 major and 1 minor factor occurring for more than 4 weeks in duration.

2.5 COMPLICATIONS

There are severe complications that can occur if not treated early.

The infection can spread into the bones of the face resulting in osteomyelitis.

Intracranial spread to produce a subdural or extradural abscess, meningitis or brain abscess.

Cavernous sinus thrombosis can occur but is a rare complication. (Giles, 1995:40.)

2.6 INVESTIGATIONS

Radiographic imaging such as computed tomography (coronal and axial) of the para nasal sinuses may be performed. This can demonstrate mucosal thickening, polyps, fluid levels in sinuses, as well as underlying anatomical abnormalities predisposing to sinusitis. Plain sinus films may show opacification related to air-fluid levels (Carr, 2001).

Flexible or rigid nasal endoscopy can be used to diagnose nasal and sinus disease and to assess the response to medical and surgical therapy (Kaliner et al., 1997). Another useful investigation is microscopy, culture and sensitivity (MCS) of the postnasal drip, the sputum and any pus from the middle meatus. Assessment of the erythrocyte sedimentation rate (ESR) is a very handy examination as it can indicate whether the symptoms that the patient has are the result of infection or not. (McDonogh, 1999.)

2.7 CONVENTIONAL MEDICAL TREATMENT

Medical treatment is aimed at promoting normal ventilation and drainage of mucus in the region of the ostiomeatal unit. It seeks to decrease oedema of the mucosa and thereby open the airspace of the infundibulum, and to stimulate the movement of secretions from the sinuses. It should not promote the production of thick mucus and it must have an antibacterial component (McDonogh, 1999).

2.7.1 <u>DECONGESTANTS AND MUCOEVACUANTS</u>

Topical and systemic decongestants therapies have been recommended to treat chronic sinusitis. Decongestants are vasoconstrictor agents that reduce the thickness of the nasal mucosa (Kaliner et al., 1997).

2.7.2 ANTIBIOTICS AND ANTI-INFLAMMATORY AGENTS

Penicillin is the drug of first choice, especially the amoxycillin-clavulonic acid preparations. They are broad-spectrum bacterial products. Antibiotics are used for a minimum of ten days initially but up to four weeks if necessary. Prolonged antibiotic courses are usually prescribed in unresolved cases and for patients with complications. Tetracyclines, macrolides, antifungal agents and metronidazole are prescribed only if indicated by the MCS results and if the patient is allergic to penicillin. (McDonogh, 1999.)

Corticosteroids are used as an anti-inflammatory agent to reduce swelling and facilitate drainage of sinuses. There is a reduction in tissue eosinophilia accompanying

the administration of corticosteroids. Coticosteroids are also efficient in shrinking nasal polyps. (Kaliner et al., 1997.)

2.7.3 ADJUNCTIVE THERAPY

Adjunctive therapy is used to promote sinus drainage by reducing obstruction caused by inflammation and secretions (Snyman, 2001). Clinicians generally agree that in principle the adjunctive use of systemic mucolytic agents or physical mucoevacuant measures should benefit patients with chronic sinusitis (Kaliner et al., 1997).

2.7.4 <u>SURGERY</u>

Surgery for chronic sinusitis is indicated in cases of failed medical treatment of the primary disease and its complications and for lesions of the ostiomeatal unit that cause recurrent or persistent disease (McDonogh, 1999).

Sinusitis not responsive to antibiotic therapy may require an operation such as maxillary sinusotomy, ethmoidectomy, or sphenoid sinusotomy to improve ventilation and drainage and to remove inspissated mucopurulent material, epithelial debris, and hypertrophic mucous membrane. These operations are performed intranasally with the aid of an endoscope (functional endoscopic sinus surgery) (Berkow and Beers, 1999:688).

2.7.5 SIDE EFFECTS

One of the major concerns regarding conventional medical treatment is the extent of the side effects caused by the drugs used to treat chronic sinusitis. The following are some commonly used drugs and their side effects:

2.7.5.1 <u>Local decongestants</u> (e.g. oxymetazoline or xylometazoline)

These drugs cause headaches, light-headedness, insomnia, palpitations, rebound congestion, local stinging and irritation, epistaxis, nausea and skin rashes (Snyman, 2001).

2.7.5.2 Antimicrobial drugs (e.g. penicillin such as amoxycillin)

Penicillin has a low toxicity but high concentrations can produce encephalopathy, which is fatal. One of the most serious side effects of penicillin is hypersensitivity causing severe rashes and anaphylactic reactions. (Neal, 1997:83.)

Other side effects include hepatitis, blood dyscrasis, gastrointestinal disturbances, sore mouth and black hairy tongue, thrush and vaginitis (Snyman, 2001).

2.7.5.3 <u>Corticosteroids</u> (e.g. prednisone or prednisolone)

The predominant disadvantage of systemic corticosteroids is that they suppress the hypothalamic-pituitary-adrenal axis. Long-term use of these agents can cause adrenal suppression. The more common side effects of short-term systemic corticosteroid therapy include mucosal itching, superficial gastric ulcerations, changes in affect or temperament, sleep disturbances, and, occasionally, premature ventricular contractions. With longer use these agents have more significant side effects including osteoporosis, myopathy, peptic ulcer disease, hypertension, ocular effects and weight gain. (Benninger, Anon and Mabry, 1997.)

2.8 HOMOEOPATHIC TREATMENT

2.8.1 INTRODUCTION

Homoeopathy is a medical approach that respects the wisdom of the body. It is an approach that utilizes medicines that stimulate the body's own immune and defence systems to initiate the healing process. It is an approach that individualizes medicines according to the totality of the person's physical, emotional and mental symptoms. (Ullman, 1991:3.)

Homoeopathy is based on the fundamental principle of "LIKE CURES LIKE", that is, "Any substance which can produce a totality of symptoms in a healthy human being can cure that totality of symptoms in a sick human being" (Vithoulkas, 1980:92).

2.8.2 HOMOEOPATHIC SIMILLIMUM TREATMENT

In simillimum treatment the homoeopath will choose a medicine that matches as accurately as possible the symptom picture presented by the patient. This is why the homoeopathic assessment takes into account a person's character, stress levels, lifestyle, level of exercise, diet, food preferences, family medical history and the effects of general factors, to provide a unique symptom picture. Each individual is given a medicine that best suites him/her as a whole, therefore many different medicines may be indicated for different patients, even though they may have the same main complaint. (Lockie and Geddes, 1995:19.)

No matter what the individual symptoms are, they are recognised as primarily an intrinsic effort of the organism to adapt to and deal with various internal or external

stresses. Methods that simply suppress, control, or manage symptoms should be avoided, since such therapies compromise the innate tendency of the organism to defend and heal itself. The side effects that these suppressive treatments cause are actually direct effects of the treatment. (Ullman, 1991:28-29.)

To prescribe homoeopathic medicines for chronic sinusitis it is important to pay special attention to the type of pain and its distribution, the type of catarrh, together with those physical conditions that either worsen or improve them (Gemmell, 1997).

2.8.3 HOMOEOPATHIC MATERIA MEDICA FOR SINUSITIS

These are some commonly used medicines to treat sinusitis (Ullman, 1997; Jouanny, 1993).

- Arsenicum album (arsenic): People who need this medicine feel throbbing and burning pains in the sinuses. Their pains are aggravated by light, noise, movement, after midnight, and may be triggered by anxiety, exertion, and excitability. They may feel relief by lying quietly in a dark room with the head raised on pillows and exposed to cool air. Their teeth may feel long and painful. They may feel nausea and experience vomiting concurrent with their sinusitis. They tend to have a great thirst, but they tend to drink frequent sips, rather than gulps.
- Belladonna (deadly nightshade): This medicine is effective for people whose head feels full, as if it could burst. The pain usually resides in the forehead or around the eyes. There is throbbing pain that is worse by jarring, touch, bending forward, lying flat, or motion of the eyes and is relieved by gradually applied pressure, sitting up, or bending the head backwards. Another characteristic

- symptom of people who need this medicine are when the sinus pains appear strongly and rapidly but then disappear temporarily, only to repeat the process of coming and going pain. The eyes are also sensitive to light and the face is flushed. They are apt to feel dizzy which becomes worse when stooping.
- Hepar sulphuris calcareum (Hahnemann's calcium sulphide): Rarely indicated at the beginning of a sinusitis condition, people who need Hepar sulphuris begin sneezing and then develop sinusitis from the least exposure to cold air. Their nasal discharge is thick and yellow. The nostrils become very sore from the acrid discharge, and their nasal passages become sensitive to cold air. Concurrently, they may have a headache with a sense of a nail or a plug that is thrust into the head along with a boring or bursting pain. The headache above the nose is worse from shaking the head, motion, riding in a car, stooping, moving the eyes, or simply from the weight of a hat, but is relieved by the firm pressure of a tight bandage. The scalp is so sensitive that simply combing the hair may be painful.
- Kali bichromicum (potassium dichromate): The distinguishing feature of people with sinusitis who need this medicine is that they have a thick, stringy, yellow or greenish-yellow nasal discharge. They have extreme pain at the root of the nose that is better by applying pressure there. The bones and scalp feel sore. They experience dizziness and nausea when rising from sitting, and the severe pain may lead to dimmed vision. The pains are worse from cold, light, noise, walking, stooping, and in the morning (especially on waking or at 9 am) or at night. They prefer to lie down in a darkened room and feel better by warmth, warm drinks, or overeating.
- Mercurius (mercury): People who will benefit from this medicine feel as though their head is in a vase. The pains are worse in open air, from sleeping, and after

eating and drinking. The pains are also aggravated by extremes of hot and cold temperature. The scalp and the nose become very sensitive to the touch. Their teeth feel long and painful, and they may salivate excessively. The nasal discharge is usually green and too thick to run. It is offensive smelling and acrid.

• Pulsatilla (windflower): When the head pain is worse when lying down and in a warm room and is better in cool air, this medicine should be considered. The sinusitis may begin after being overheated. Stooping, sitting, rising from lying down, and eating can aggravate the head pain, which is often in the front part of the head and accompanied with digestive problems. They get some relief from slow walking in the open air or by wrapping the head tightly in a bandage. This condition is commonly experienced when the child is in school or the adult is at work. The nasal discharge is often thick and yellow or green.

2.8.4 HOMOEOPATHIC RESEARCH ON SINUSITIS

This study was conducted at the same time with 2 other double-blind placebo-controlled studies, namely, Dlamini (nosode prescribing) (2003) and Ebrahim (complex prescribing) (2003). Each study consisted of a sample size of 30 randomly selected patients. These studies were similar in research methodology and treatment regime and the same questionnaires (Appendix C1 and C2) were used to determine the patient's perception of treatment of chronic sinusitis.

Dlamini (2003) determined the efficacy of main miasmatic nosodes in the treatment of chronic sinusitis. It was found that there was a significant improvement in some of the variables of the questionnaires. However, there was no significant difference between

the nosode and placebo group. It was concluded that the main miasmatic nosodes were not effective in the treatment of chronic sinusitis.

Ebrahim (2003) prescribed a homoeopathic complex which consisted of <u>Hydrastis</u> canadensis 9CH, <u>Sambucus</u> 9CH, and <u>Kali bichromicum</u> 9CH. This study also showed an improvement in some of the variables of the questionnaires but there was no significant difference between the complex and placebo groups. Thus, the homoeopathic complex was also not effective in the treatment of chronic sinusitis.

A double blind study of the homoeopathic treatment of chronic sinusitis was conducted by Sengpiehl (1994), which compared the reaction of the homoeopathic medicine <u>Luffa operculata</u> 4XH and a combination of Kalium bichromicum 5CH and Cinnabaris 5CH. The sample group consisted of forty patients. The result of the study showed that <u>Luffa operculata</u> 4XH was a more effective mode of treatment for chronic sinusitis than a combination of Kalium bichromicum 5CH and Cinnabaris 5CH. Since there was no placebo control group, it was difficult to assess the validity of these results. The researcher recommended that simillimum treatment should be investigated in order to obtain lasting results.

Smit conducted a study in 2002 wherein the efficacy of a homoeopathic simillimum remedy in the symptomatic treatment of chronic sinusitis was determined. Fifteen patients who were pre-diagnosed with sinusitis by a medical doctor participated in the study. The study was performed on matched pairs using a pre-test to post-test research design. In this type of study each individual acted as his/her own control, before and after receiving the individualized remedy. The determinants used for the

study were symptoms of sinusitis (such as the primary symptoms, secondary symptoms, associating symptoms, mood and vitality), and a medical evaluation of each patient before and after the treatment. The results indicated a significant improvement in all the determinants measured at a 0.05 level of significance. However a highly statistical significant improvement was found in the secondary symptoms and vitality determinants. This was observed at a 0.01 level of significance. The most common simillimum medicines prescribed were Pulsatilla pratensis 30C and 200C, and Phosphorus 200C. Smit recommended that a larger sample group be used to have more accurate results.

In another double-blind study, Fleming (2001) compared <u>Hydrastis canadensis</u> tincture to <u>Hydrastis canadensis</u> 3X potency in the treatment of sinusitis. Forty-five patients were randomly selected. The results indicated a reduction in the symptom severity over the course of the study. However there was no significant difference in the subjective perception of the participant to their symptoms of sinusitis.

Although there have not yet been any other formal controlled studies testing the use of homeopathic medicines to treat sinusitis, there are 200 years of successful and safe clinical experience in treating people with homoeopathic medicine. A review of 89 double-blind, randomised clinical studies testing homoeopathic medicines showed that it was 2.45 times more effective than placebo (Ullman, 1997).

Homeopathic medicines are often effective in treating the acute symptoms of sinusitis, although professional simillimum management is usually necessary to cure chronic sinusitis. This professional homeopathic treatment can lead to a significant reduction

in the frequency and intensity of acute sinusitis attacks and can often even lead to a total elimination of their occurrence (Ullman, 1997).

2.9 THE PLACEBO EFFECT

The word placebo means, "I will please" (Dorland and Newman, 1994:1298). It is made of a medicinally inactive substance used in controlled studies for comparison with presumed active drugs or prescribed with the intent to relieve symptoms or meet a patient's demand i.e. it is a "make believe medicine", and it is allegedly inert and harmless (Berkow and Beers, 1999:2585). This placebo has shown repeatedly to have an effect on patients, involving both improvement and deterioration in functioning.

There is a placebo element in every manoeuvre, including surgical and psychological techniques or medication in any form. Thus the effect of any drug will vary from patient to patient and doctor to doctor, depending on the placebo reactivity. Studies to determine whether or not certain personality characteristics correlate with responses to placebo have disagreed extravagantly with one another (Berkow and Beers, 1999:2586).

The remarkable list of subjective and objective changes due to placebo has been put down to two possible components of the placebo response. The first component is that of anticipation and expectation associated with medication i.e. the "faith", or "hope" patients have. The second component is spontaneous change or natural history of the condition (Berkow and Beers, 1999:2585).

2.10 SUMMARY

From the literature reviewed in this chapter it is evident that chronic sinusitis is a widespread problem (McDonogh, 1999) and it is the most frequently reported chronic disease (Chrostowski and Pongracic, 2002). Its prevalence is rising and generates significant health care costs (Kaliner <u>et al.</u>, 1997). One of the principle aims of the treatment of chronic sinusitis is the achievement of a subjective improvement in the patient's condition (Walker and White, 2000).

Homoeopathy offers a different philosophy, since its medicines are not simply intended to be antibacterial, antiviral or antihistamines but to stimulate the person's overall resistance to infection. Homoeopathic medicines strengthen the organism so that it is more capable of defending itself. Such treatment provides a more ecological approach to curing infectious disease, since it aids the body's natural homoeostasis without suppressing the organism's inherent self-protective responses. (Ullman, 1991:xxix.)

The 'totality of symptoms' and their relationship to each other guides the selection of the simillimum, which provides the stimulus for recovery (Boyd, 1989:3). The homoeopathic approach respects the body's wisdom, thus making it a potentially safer medicine (Ullman, 1991:29).

CHAPTER THREE

MATERIALS AND METHODS

3.1 OBJECTIVES

The objective of this double-blind placebo controlled study was to evaluate the efficacy of homoeopathic simillimum treatment of chronic sinusitis in terms of the patient's perception of the treatment as assessed by the General Well-Being Questionnaire (McDowell and Newell, 1996; see Appendix C1) and Sinus Symptom Visual Analogue Questionnaire (Walker and White, 2000; Appendix C2).

3.2 STUDY DESIGN

A sample group of 30 patients were selected for the study on the basis of the inclusion and exclusion criteria listed in section 3.3. These patients were randomly divided into 2 groups (15 patients for the treatment group and 15 patients for the placebo group). Each patient had 2 consultations, which was conducted at the Durban Institute of Technology Homoeopathic Day Clinic.

During the first consultation each patient was given the subject information letter (Appendix A) to read and the consent form (Appendix B) to sign. During this consultation the researcher took a full homoeopathic case history and performed a physical examination (Bates, 1995; Appendix D).

Patients were required to complete the General Well-Being Questionnaire (McDowell and Newell, 1996; see Appendix C1) and the Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2).

The homoeopathic dispenser on duty in the Homoeopathic Day Clinic dispensed medication to the respective groups according to the randomization sheet drawn up by the Homoeopathic Day Clinic laboratory technician.

The treatment consisted of 15 powders containing either an active ingredient (i.e. simillimum) or placebo. Each patient was required to take one powder three times a day, 30 minutes before meals, for 5 days. Patients were asked to return for the second consultation in 3 weeks time. In the second consultation the researcher reassessed the patient and the patients were required to complete the General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) and the Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2) for the final time.

3.3 SUBJECTS

Participation in this study was on a voluntary basis. Participants were obtained through advertisements placed in the local newspaper and on the notice boards at the Durban Institute of Technology and other Durban tertiary institutions, health shops, as well as through pamphlet distribution. The researcher selected participants according to the inclusion and exclusion criteria listed in 3.3.1.

3.3.1 INCLUSION CRITERIA

- Participants had to be between the ages of 18 years to 65 years.
- Participants had to fall within the criteria for diagnosis:

The patient had to have more than 2 major factors or 2 major and 1 minor factor for the duration of more than 4 weeks.

Major factors	Minor factors	
*Facial pain/ pressure	*Headache	
*Facial congestion/ fullness	*Halitosis	
*Nasal obstruction	*Fatigue	
*Nasal discharge: purulent,	*Dental pain	
or discoloured postnasal drainage	*Cough	
*Hyposmia/ anosmia	*Ear pressure/ fullness	
*Purulent discharge in the nose		
(Adapted from Lanza and Kennedy (1997), and Carr (2001).		

- Participants had to have taken no other sinusitis medication for at least one week before the commencement of the study.
- Patients had to be literate.

3.3.2 EXCLUSION CRITERIA

- Pregnant females.
- Patients with chronic respiratory condition e.g. severe asthma.
- For the duration of the study, no other forms of treatment were permitted except for chronic medication used for unrelated conditions e.g. hypertension, diabetes, and hypercholesterolaemia.
- Patients with a history of lactose intolerance.

3.4 ETHICS

The researcher explained the nature of the study to each participant who met the selection criteria. Each participant was asked to read the subject information letter (Appendix A) and complete the consent form (Appendix B). Free treatment was offered to participants in the placebo group at the end of the study.

3.5 TREATMENT

3.5.1 HOMOEOPATHIC SIMILLIMUM TREATMENT

The medicine used in this study was prepared at the Durban Institute of Technology Homoeopathic Day Clinic dispensary. Patients were instructed on how to take the medication by the researcher. Patients were given fifteen powders from which three powders were to be taken thirty minutes before meals each day for 5 days. The simillimum group received the indicated simillimum in powders numbered 1, 4 and 7 with the remaining powders been placebo. In classical homoeopathy, it is traditional to give only a few doses of the simillimum medicine (Speight, 1979:7).

Simillimum treatment was based on the homoeopathic principles and each case was carefully analysed in order to select the correct simillimum medicine. The researcher took a full homoeopathic case history (Bates, 1995; Appendix D) from each patient. Once this was done, the researcher repertorized the most appropriate symptoms in order to find the simillimum medicine that best matched the symptom picture presented by the patient. The researcher used the Homoeopathic Materia Medica to confirm the selection of the appropriate simillimum medicine.

There was no standardization of potency for the medication as it varied for each patient as stipulated by the simillimum principle of individualisation.

3.5.2 PLACEBO TREATMENT

The placebo powders contained lactose granules that were impregnated with 96 percent ethanol only, which was the same ethanol percentage contained in the impregnating potencies used to prepare the homoeopathic simillimum powders. The placebo powders were indistinguishable in appearance and taste from the simillimum powders. The placebo medication was dispensed in the same manner as the homoeopathic simillimum medication.

3.6 MEASUREMENTS

Patients were given the General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) and Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2) to complete in the first and second consultations.

The General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) consisted of 14 variables, each indicating a subjective feeling of the psychological well-being and distress of each participant. Each variable was allocated a rating of 1 to 6, giving the participant the opportunity to choose the number that best applied to them.

The Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2) was used to assess the severity of symptoms of sinusitis using a scale

of 0-10, where zero represented no symptom and 10 represented the most severe symptom imaginable.

These questionnaires were used to determine the relative efficacy of homoeopathic simillimum treatment in terms of the patient's perception of the treatment.

3.7 STATISTICAL ANALYSIS

Only data collected from the General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) and the Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2) were used.

3.7.1 DATA ANALYSIS

a) One sample T-test

This test was used to determine the differences between the initial consultation (before treatment) and follow-up consultation (after treatment) for each question (variable) within each group.

Hypothesis Testing:

The null hypothesis H₀, states that there is no difference between before and after treatment results for each question within each group.

The alternative hypothesis H₁, states that there is a difference between before and after treatment results for each question within each group.

All tests were done at α = 0.05 level of significance.

If $\alpha = 0.01$ level of significance this indicates a more significant difference.

Decision Rule:

For two - tailed test:

Reject H_0 if $p < \alpha/2$

Accept H_0 if $p > \alpha/2$

P is the observed significance level or p-value.

b) Mann- Whitney Test

This is a non-parametric test used to determine if there are any significant differences between the simillimum group and placebo group.

Hypothesis Testing:

The null hypothesis H_0 , states that there is no difference between the groups.

The alternative hypothesis H_1 , states that there is a difference between the groups.

 α = 0.05 level of significance

Decision Rule:

For two - tailed test:

Reject H_0 if $p < \alpha/2$

Accept H_0 if $p > \alpha/2$

P is the observed significance level or p-value.

3.7.2 STATISTICAL PACKAGE

The statistical package, Statistical Package for Social Sciences (SPSS) version 9 was used for data entry and analysis.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

The results were obtained after statistically analysing the data collected from the General Well-Being Questionnaire and Visual Analogue Scale Questionnaire.

Comparisons were made within each group using the one sample t-test for the General Well-Being Questionnaire and the Visual Analogue Scale Questionnaire.

The Mann-Whitney test was a non-parametric test used to determine if there was a significant difference between the simillimum and placebo groups for the General Well-Being Questionnaire and the Visual Analogue Scale Questionnaire.

Bar charts were used to demonstrate the differences in the means of each individual variable of the General Well-Being Questionnaire and to compare the total scores of the Visual Analogue Scale Questionnaire before and after treatment for each treatment group.

4.2 CRITERIA FOR ADMISSIBILITY OF DATA

The data obtained from the General Well-Being Questionnaire consisted of differences between" before treatment" and "after treatment" scores (or "before – after" such that an improvement in condition is shown as a positive difference between scores), that were calculated for each individual in each group for each question. The data obtained from the Visual Analogue Scale Questionnaire consisted of differences between

"before treatment" and "after treatment" scores for each question and the total scores of each individual in each group.

4.3 General Well-Being Questionnaire Data

4.3.1 One-Sample T- Test Results

Tables 4.1 to 4.3 contain results for each group. Refer to Appendix C1 for the General Well-Being Questionnaire.

Table 4.1 - One-Sample T- Test comparison between before and after treatment results for each question within the Simillimum group

			95%confiden the Differenc	ce Interval of e
Question	P-value	Mean Difference	Lower	Upper
Q1	0.006	1.0000	0.3381	1.6619
Q2	0.005	1.4667	0.5337	2.3996
Q3	0.719	-0.1333	-0.9128	0.6461
Q4	0.041	1.0667	0.0527	2.0806
Q5	0.191	0.6667	-0.3729	1.7062
Q6	0.719	0.1333	-0.6461	0.9128
Q7	0.027	0.5333	0.0716	0.9951
Q8	0.001	0.8667	0.4049	1.3284
Q9	0.150	0.4667	-0.1308	1.1241
Q10	0.085	0.7333	-0.1160	1.5827
Q11	0.265	0.3333	-0.2829	0.9495
Q12	0.009	1.1333	0.3263	1.9404
Q13	0.060	0.8667	-0.0425	1.7758
Q14	0.364	0.2667	-0.3424	0.8757

All tests were done at α = 0.05 level of significance.

If $\alpha = 0.01$ level of significance this indicates a more significant difference.

There is a significant difference in the simillimum treatment group with regards to Questions 1, 2, 4, 7, 8, and 12 before and after treatment.

P is the observed significance level or p-value.

Table 4.2 - One-Sample T-Test comparison between before and after treatment results for each question within the Placebo group

			95%confider the Difference	nce Interval of
Question	P-value	Mean Difference	Lower	Upper
Q1	0.028	0.8000	0.0995	1.5005
Q2	0.016	1.3333	0.2938	2.3729
Q3	0.565	0.3333	-0.8811	1.5478
Q4	0.294	0.7333	-0.7887	2.1754
Q5	0.056	1.0667	-0.0303	2.1636
Q6	0.894	-0.0607	-1.1229	0.9896
Q7	0.527	0.3333	-0.7676	1.4343
Q8	0.036	1.2000	0.0885	2.3115
Q9	0.010	1.0000	0.2749	1.7251
Q10	0.903	0.0667	-1.0887	1.2220
Q11	0.531	-0.2000	-0.8885	0.4685
Q12	0.096	0.6667	-0.1349	1.4683
Q13	0.178	0.5333	-0.2737	1.3404
Q14	0.086	0.6667	-0.1071	1.4405

All tests were done at α = 0.05 level of significance. If α = 0.01 level of significance this indicates a more significant difference.

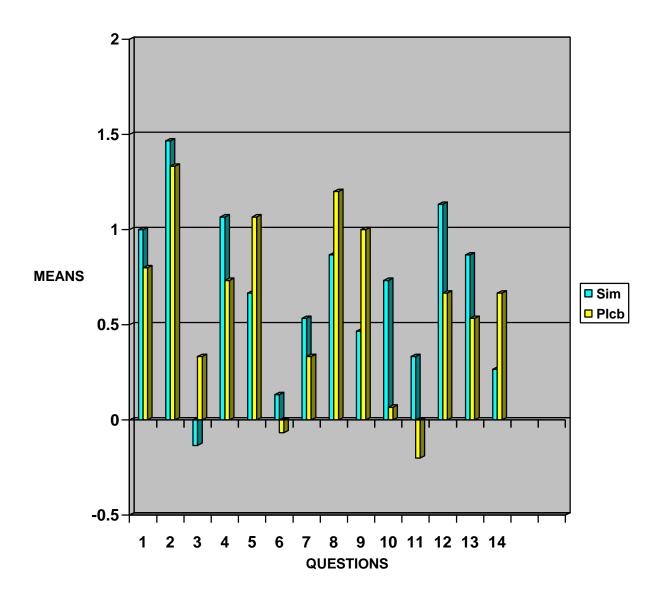
P is the observed significance level or p-value.

There is a significant difference in the placebo group with regards to Questions 1, 2, 8, and 9 before and after treatment.

Table 4.3 - One-Sample T-Test: Summary of p-values for General Well-Being Questionnaire

Question/ Group	Simillimum	Placebo
1	0.006**	0.028*
2	0.005**	0.016*
3	0.719	0.565
4	0.041*	0.294
5	0.191	0.056
6	0.719	0.894
7	0.027*	0.527
8	0.001**	0.036*
9	0.150	0.010**
10	0.085	0.903
11	0.265	0.531
12	0.009**	0.096
13	0.060	0.178
14	0.364	0.086

^{*} Significant at 5% level ** more significant at 1% level



Sim- Simillimum group Plcb - Placebo group

Table 4.1 – Bar chart representing the comparison between the mean differences within each group with regards to the 14 questions (variables) of the General Well-Being Questionnaire derived from the One-Sample T-Test

4.3.2 Mann-Whitney Test Results

This test indicates if there is any significant difference between the simillimum and placebo groups with regards to the 14 questions (variables) of the General Well-Being Questionnaire.

Table 4.4 - Mann-Whitney Test comparison between the Simillimum and Placebo groups with regards to the 14 questions of the General Well-Being Questionnaire

Question	P-values	H ₀ Decision
1	0.777	Accept
2	0.983	Accept
3	0.318	Accept
4	0.597	Accept
5	0.100	Accept
6	0.424	Accept
7	0.729	Accept
8	0.241	Accept
9	0.575	Accept
10	0.642	Accept
11	0.101	Accept
12	0.863	Accept
13	0.655	Accept
14	0.795	Accept

All tests were done at α = 0.05 level of significance.

If $\alpha = 0.01$ level of significance this indicates a more significant difference.

P is the observed significance level or p-value.

There are no significant differences between the simillimum and placebo groups with regards to the 14 questions (variables) of the General Well-Being Questionnaire.

4.4 <u>Sinus Symptom Visual Analogue Scale Questionnaire</u> <u>Data</u>

4.4.1 One Sample T-Test Results

Table 4.5 and 4.6 contain results for each group. Refer to Appendix C2 for Sinus Symptom Visual Analogue Scale Questionnaire.

Table 4.5 - One Sample T-Test comparison between before and after treatment results with regards to each question and total score within the Simillimum group

			95%confiden the Difference	
Question	P-value	Mean Difference	Lower	Upper
1	0.000	2.8000	1.5021	4.0979
2	0.009	3.0000	0.8939	5.1061
3	0.001	2.3333	1.1837	3.4830
4	0.003	2.7333	1.1295	4.3372
5	0.076	1.8333	-0.2219	3.8886
6	0.001	3.7667	1.9604	5.5729
Total score	0.000	16.4667	9.4435	23.4898

All tests were done at α = 0.05 level of significance.

If $\alpha = 0.01$ level of significance this indicates a more significant difference.

P is the observed significance level or p-value.

There is a significant difference between the before and after treatment results within the simillimum group for all of the questions except for Question 5.

Table 4.6 - One Sample T-Test comparison between before and after treatment with regards to each question and total score in the Placebo group

			95%confident the Difference	
Question	P-value	Mean Difference	Lower	Upper
1	0.035	2.3000	0.1814	4.4186
2	0.009	2.5000	0.7209	4.2791
3	0.000	3.6667	2.0533	5.2801
4	0.208	1.2333	-0.7712	3.2379
5	0.019	2.2667	0.4393	4.0940
6	0.002	3.4333	1.5211	5.3456
Total score	0.001	15.4000	7.2697	23.5303

All tests were done at α = 0.05 level of significance.

If $\alpha = 0.01$ level of significance this indicates a more significant difference.

P is the observed significance level or p-value.

There is a significant difference between the before and after treatment results within the placebo group for all of the questions except for Question 4.

4.4.2 Mann-Whitney Test

This test indicates if there is any significant difference between the simillimum and placebo groups with regards to the 6 questions (variables) and the total score of the Sinus Symptom Visual Analogue Scale Questionnaire.

Table 4.7 - Mann-Whitney Test comparison between Simillimum and Placebo groups for each question and total score of the Sinus Symptom Visual Analogue Scale Questionnaire

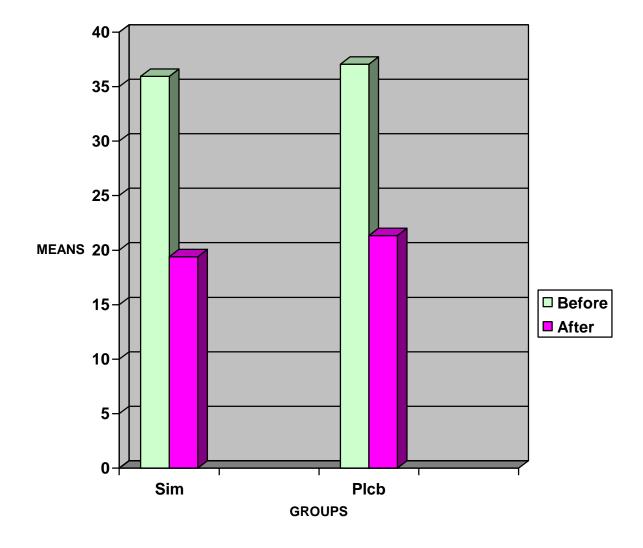
Question	P-values	H ₀ Decision
1	0.315	Accept
2	0.516	Accept
3	0.195	Accept
4	0.264	Accept
5	0.866	Accept
6	0.835	Accept
Total score	0.724	Accept

All tests were done at $\alpha = 0.05$ level of significance.

If $\alpha = 0.01$ level of significance this indicates a more significant difference.

P is the observed significance level or p-value.

There is no significant difference between the simillimum and placebo groups with regards to the Sinus Symptom Visual Analogue Scale Questionnaire.



Sim – Simillimum group Plcb – Placebo group

Table 4.2 – Bar chart representing the comparison between before and after treatment for the groups with regards to the total scores of the Sinus Symptom Visual Analogue Scale Questionnaire derived from the One-Sample T-Test

4.5 Medicines prescribed

TABLE 4.8 - Summary of patient profile including medicines

Remedy	Indicated Simillimum	Simillimum group with potencies (Dispensed)	Placebo group (Not Dispensed)
Arsenicum album	2	1: *30CH - 200CH -M	1
Calcarea carbonica	3	3: *30CH - 200CH *200CH *30CH - 200CH -M	0
Causticum	4	1: *30CH - 200CH -M	3
Carcinosin	2	1: *200CH	1
Lachesis	1	1: *30CH - 200CH -M	0
Lycopodium	2	2: *30CH *30CH - 200CH -M	0
Natrum muriaticum	4	1: *30CH - 200CH -M	3
Nux vomica	1	0	1
Phosphorus	3	2: *M *200CH - M	1
Pulsatilla pratensis	1	1: *30CH - 200CH -M	0
Sepia	2	1: *30CH - 200CH -M	1
Silicea	2	0	2
Staphysagria	1	0	1
Sulphur	1	0	1
Thuja	1	1: *30CH - 200CH -M	0

The patient profile shows that the most commonly indicated medicines were

<u>Causticum</u> and <u>Natrum muriaticum</u> (4 patients) followed by <u>Calcarea carbonica</u> and

<u>Phosphorous</u> (3 patients).

The most commonly dispensed medicines were <u>Calcarea carbonica</u> 30CH, 200CH, M, <u>Lycopodium</u> 30CH, 200CH, M and <u>Phosphorus</u> 200CH, M.

CHAPTER FIVE

DISCUSSION

This double-blind placebo-controlled study was designed to evaluate the efficacy of homoeopathic simillimum in the treatment of chronic sinusitis in terms of the patient's perception of the treatment.

Intragroup comparisons showed that there was a significant difference between the initial (before treatment) consultation and follow-up (after treatment) consultation within each group for some of the variables of the General Well-Being Questionnaire (Table 4.1, 4.2 and 4.3).

Table 4.1 demonstrates that the simillimum treatment group had a significant beneficial effect on 6 variables of well-being. Patients in this group experienced a significant improvement in their mental, emotional and physical well-being as well as a marked improvement in the "bother" of their sinus condition. There was an overall significant improvement in their general feeling of well-being.

The placebo group had a significant effect on 4 variables of well-being (Table 4.2). In this group patients experienced an improvement their mental, physical and general well-being as well as an improvement in the bother of their sinus condition.

The difference between the means within each group is graphically demonstrated in Figure 4.1. It can be seen in the bar chart that there is a difference between the

means within the simillimum and placebo groups with regards to the 14 variables (questions) of the General Well-Being Questionnaire.

Table 4.5 and 4.6 demonstrates that both the simillimum treatment group and placebo group showed a significant difference between the initial consultation (before treatment) and follow-up consultation (after treatment) for all of the variables except for one with regards to the Sinus Symptom Visual Analogue Scale Questionnaire. It can be seen in Table 4.5 that the simillimum treatment group had a significant improvement in all the symptoms of sinusitis except for the disturbance of smell. The placebo group (Table 4.6) also showed a significant improvement in all the symptoms of sinusitis except for nasal discharge.

In Figure 4.2, the bar chart demonstrates the before and after treatment of the simillimum treatment group and placebo group with regards to the total scores of the Sinus Symptom Visual Analogue Scale Questionnaire.

Intergroup comparisons showed that there were no statistical significant differences between the simillimum treatment group and the placebo group with regards to the General Well-Being Questionnaire (Table 4.4) and the Sinus Symptom Visual Analogue Scale Questionnaire (Tables 4.7).

The patient profile (Table 15) shows that the most commonly indicated simillimum medicines were <u>Causticum</u> and <u>Natrum muriaticum</u> and the most commonly dispensed simillimum medicines were <u>Calcarea carbonica</u>, <u>Lycopodium</u> and Phosphorus.

It is interesting to note that Phosphorus, which was one of the commonly dispensed simillimum medicines in this study, was also one of the commonly prescribed simillimum medicines in the study conducted by Smit (2002).

This double-blind study was conducted at the same time with Dlamini (nosode prescribing) (2003) and Ebrahim (complex prescribing) (2003). It was found that there was significant improvement in some of the variables measured but no statistical significant differences between the treatment groups (i.e. nosode and complex) and the placebo group. Therefore both of these treatments were not effective in the treatment of chronic sinusitis.

This study adds further knowledge to the evaluation of homoeopathy in the treatment of sinusitis. The findings of this study are similar to those of Sengpiehl (1994), Fleming (2001), Dlamini (2003) and Ebrahim (2003) i.e. that homoeopathic medication is not effective in the treatment of sinusitis. The only study, which demonstrated a positive effect, is that of Smit (2002).

This study used a sample size of 30 patients. The results of this study could have been more significant if a larger sample size was used.

During the study, some patients had reported that they felt better at an earlier stage of the treatment, but regressed by the time of the follow-up consultation. In order to assess this, future studies should have an earlier follow-up consultation, or medication could be more frequently repeated.

The fact that there was significant improvement in a number of variables in both groups as assessed by "before" and "after" testing, is most likely to be due to the placebo effect as described by Berkow and Beers (1999:2585). An additional factor could have been that the participants had an opportunity to explain their whole medical condition and were listened to in a caring way, which had a positive effect on their well-being and sinus symptoms.

Since this is a chronic condition, patients should be monitored over a longer period of time to evaluate the effect of the medication. In addition, the dose could be repeated after a certain period e.g. one month.

In this study, the efficacy of the treatment, was subjectively measured by the patient perception questionnaires (Appendix C1 and C2). The researcher had to rely on the patient's ability to recall and rate the information required. More objective means of evaluation, such as clinical findings e.g. changes in nasal mucosa (Bates, 1995:183), could be used in future studies to overcome this problem.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

Chronic sinusitis is a widespread problem (McDonogh, 1999). One of the principle aims of the treatment of chronic sinusitis is the achievement of a subjective improvement in the patient's condition (Walker and White, 2000).

The purpose of this study was to evaluate the efficacy of homoeopathic simillimum in the treatment of chronic sinusitis in terms of the patient's perception of the treatment.

A statistically significant improvement occurred in some of the variables of the questionnaires in both the simillimum treatment group and the placebo group.

However, there was no significant difference between the simillimum treatment group and placebo group.

Thus, it can be concluded that the homoeopathic simillimum treatment was not effective in the treatment of chronic sinusitis.

6.2 RECOMMENDATIONS

- A study should be carried out over an extended period of time in order to evaluate a sustained improvement e.g. 3 months.
- This study used only subjective data (patient's perception questionnaires) as a means of measurement; other studies should also use objective clinical findings e.g. changes in nasal mucosa (Bates, 1995:183).
- Future studies should have follow-up consultations sooner and more frequent repetition of the medication.
- A larger sample group should be used to get more significant results.
- An expanded age group to include children and the elderly should be considered, as this would show a variety of responses between age groups.

<u>REFERENCES</u>

- Bates, B. 1995. <u>A guide to physical examination and history taking</u>. 6th edition Philadelphia: Lippincott Company.711p. ISBN 0 397 55053 7.
- Beers, M.H. and Berkow, R. 1999. <u>The Merck Manual</u>. 17th edition. Whitehouse Station, W.J: Merck Research Laboratories. 2834p. ISBN 0911910-10-7.
- Benninger M.S., Anon J. and Mabry R.L. 1997. The medical management of Rhinosinusitis. <u>Otolaryngology Head and Neck Surgery</u>.

 117: S41-49.
- Boyd, H. 1989. <u>Introduction to Homoeopathic Medicine</u>. 2nd edition.

 Beaconsfield: Beaconsfield Publishers Ltd. 285p. ISBN: 0-906584-21-3.
- Carr, M.M. 2001. Sinusitis. [Online] Available from:

 http://www.icarus.med.utoronto.ca/carr/manual/outline.html
 [Accessed on 21 February 2002].
- Chrostowski, D. and Pongracic, J. 2002. Control of Chronic Nasal Symptoms.

 <u>Postgraduate Medicine</u>. 101(6): 77-95.
- Delost, M.D. 1997. <u>Introduction to Diagnostic Microbiology: a text and workbook.</u>
 Missouri: Mosby-Year Book, Inc. 552p.ISBN 0-8016-7853-6.

- Dlamini, N. 2003. The Efficacy of Main Miasmatic Nosodes in the Treatment of Chronic Sinusitis. M. Tech. Dissertation, Durban Institute of Technology, Durban. (In Process).
- Dorland, I. Newman, W.A. (eds) <u>Dorland's Illustrated Medical Dictionary.</u> 1994. 28th ed. Philadelphia: W.B. Saunders Company. 1940p. ISBN 0-7216-53235.
- Ebrahim, S. 2003. The Efficacy of Homoeopathic Complex (Hydrastis canadensis 9CH, Sambucus 9CH, Kali bichromicum 9CH) in the Treatment of Chronic Sinusitis. M. Tech. Dissertation, Durban Institute of Technology, Durban. (In Process).
- Fleming, C. 2001. The Efficacy of Hydrastis canadensis Tincture and 3X Potency
 In the Treatment of Sinusitis. M.Tech. Dissertation, Witswaterstrand
 Technikon, Witswaterstrand.
- Foubister, D.N. 1989. <u>Tutorials on Homoeopathy</u>. Beaconsfield: Beaconsfield Publishers Ltd. 202p.ISBN 0-906584-25-6.
- Gaier, H.C. 1991. <u>Thorson's Encyclopaedic Dictionary of Homoeopathy</u>
 London: Thorsons. 601p. ISBN 0-7225-1823-4.
- Gemmell, D.1997. Sinusitis and Catarrh. Homoeopathic Links. 47(3).

- Giles, L. 1995. Sinusitis. <u>The South African Journal of Homoeopathy</u>. 1(1): 39-42.
- Jouanny, J. 1993. The Essentials of Homoeopathic Therapeutics.

 Sainte Foy Les Lyon: Editions Boiron. 417p. ISBN 2-85742-014-5.
- Kaliner, M.A., Osguthorpe, D.J., Fireman, P., Anon, J., Georgitis, J., Davis, M.L.,Naclerio, R., and Kennedy, D. 1997 Sinusitis: Bench to Bedside.Otolaryngology Head and Neck Surgery. 116:S1-20.
- Lanza, D. and Kennedy, D.W. 1997. Adult rhinosinusitis defined.

 Otolaryngology Head and Neck Surgery. 117 (3 pt 2): S1-7.
- Lockie, A. and Geddes, N. 1995. <u>The Complete Guide to Homoeopathy,</u>

 <u>The Principles and Practice of Treatment</u>. London: Dorling

 Kindersley Limited. 240p. ISBN 0-7513-0209-0.
- McDonogh, M.B. 1999. Chronic Sinusitis. <u>MIMS Disease Review</u>. 112-119. Pretoria: MIMS.
- McDowell, I. and Newell, C. 1996. <u>Measuring health: Guide to rating scales and questionnaires</u>. 2nd edition. New York: Oxford University Press. 523p.

 ISBN 0-19-510371-8.

- National Allergy and Infectious Diseases. 2001. <u>Sinusitis</u>. [Online].

 Available from: http://www.niaid.nih.gov/factsheets/sinusitis.htm
 [Accessed on 21 February 2002].
- Neal, M.J. 1997. <u>Medical Pharmacology at a Glance</u>. 3rd edition. London: Blackwell Science Ltd. 103p. ISBN 0-86542-719-4.
- Sengpiehl, M. 1994. The Homoeopathic Treatment of Chronic Sinusitis. M.Tech.

 Dissertation, Technikon Natal, Durban.
- Shepherd, S. (ed.) 1999. <u>Reader's Digest. The Healing Power of Vitamins, Minerals and Herbs</u>. Newlands: Heritage Publishers. 416p. ISBN: 1-874912-63-7.
- Smit, S. 2002. A Study to Determine the Efficacy of a Homoeopathic Simillimum Remedy in the Symptomatic Treatment of Chronic Sinusitis. M. Tech.

 Dissertation, Witswaterstrand Technikon, Witswaterstrand.
- Snyman J.R. (ed) 2001. Sinusitis. MIMS Medical Specialities. 41(1): 171-288.
- Speight, P. 1979. <u>A Study Course in Homoeopathy</u>. London: Health Science Press. 144p.
- Ullman, D. 1991. <u>Homoeopathic Medicine for Children and Infants</u>.

 New York: G.P. Putman and Sons.225p. ISBN: 0-87477-692-9.

- Ullman, D. 1991. <u>Discovering Homoeopathy</u>. Berkley: North Atlantic Books. 277p. ISBN: 1-55643-108-2.
- Ullman, D. 1997. <u>Homeopathy and sinusitis: Safer Remedies</u>. [Online]

 Available form: http://www.healthy.net/asp/templates/Articles.htm
 [Accessed on 21 April 2003].
- Vithoulkas, G. 1998. <u>The Science of Homoeopathy</u>. New Delhi-India: B Jain Publishers (P) Ltd. 331p. ISBN 81-7021-221-9.
- Walker, F.D. and White, P.S. 2000. Sinus symptom sores: what is the range in healthy individuals? <u>Clinical Otolaryngology and Allied Sciences</u>.25(6): 482-4.
- Watson, I. 1991. A guide to the Methodologies of Homoeopathy. Kendal, Cumbria: Miller Turner Printers Ltd. 115p. ISBN 0 9517657 0 1.
- Yasgur, J. 1998. <u>Homoeopathic Dictionary and Holistic Health Reference</u>.

 4th Edition. Philadelphia: Van Hoy Publishers. 422p.ISBN 1-886149-04-6.

APPENDICES

APPENDIX A Subject Information Letter (Zulu and English)

APPENDIX B Information Consent Form (Zulu and English)

APPENDIX C Instructions of Questionnaires (Zulu and English)

APPENDIX C1 General Well-Being Questionnaire (Zulu and English)

APPENDIX C2 Visual Analogue Scale Questionnaire (Zulu and English)

APPENDIX D Case History Questionnaire

THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM IN THE TREATMENT OF CHRONIC SINSUITIS

BY SHAIDA ISMAIL

APPENDIX A SUBJECT INFORMATION LETTER

TITLE OF RESEARCH PROJECT: <u>The efficacy of homoeopathic simillimum</u> (a medicine that closely matches the totality of a patient's mental, emotional and physical symptoms) in the treatment of chronic sinusitis.

NAME OF SUPERVISOR: <u>Dr Richard Steele</u>

NAME OF CO-SUPERVISOR: <u>Dr Corne Hall</u>

NAME OF INVESTIGATOR: <u>Shaida Ismail</u>

NAME OF CO-INVESTIGATORS: <u>Nomthandazo Dlamini</u>, <u>Shera Ebrahim</u>

Date:

Dear participant

Thank you for your time and interest in reading this letter. With your assistance the efficacy of the Homoeopathic treatment in chronic sinusitis can be investigated.

I am a homoeopathy student of the Durban Institute of Technology. In order to qualify as a Homoeopath, a mini-dissertation has to be completed. This study will test the efficacy of the homoeopathic treatment in alleviating symptoms of chronic sinusitis. In order to do this, we appeal to you for your assistance by becoming actively involved and informing us about your symptoms before and during the study as well as their effect on your daily lives.

This clinical trial will be conducted at the Homoeopathy Day Clinic under the supervision of a qualified and registered homoeopath with a practise number.

Each participant must comply with the selection criteria in order to participate in this study. The study will include those that fulfil the following criteria:

- a) Individuals must be between the ages of 18 years to 65 years
- b) Individuals must have been suffering from chronic sinusitis for a period of more than 4 weeks in duration,
- c) Individuals must have taken no other sinusitis medication for at least 1 week before the commencement of the study.
- d) Individuals must be literate.

Those with the following conditions will be excluded from this study:

- a) Pregnant females.
- b) Individuals with chronic respiratory conditions e.g. asthma.
- c) For the duration of the study, no other treatment will be permitted except the chronic medication used for unrelated conditions e.g. hypertension, diabetes, hypercholesterolaemia.
- d) Individuals with a history of lactose intolerance.

Once you have fulfilled these selection criteria, and are willing to participate, you will be accepted into the study group. This study will last for three weeks and the researcher will need to see you for two consultations during these weeks i.e. the first

consultation and the second consultation. During these consultations, you will be required to fill in a general well-being and a sinus symptom visual analogue scale questionnaire available in Zulu and English languages. All the information given by the participant will be kept confidential. Once the dissertation is published the case files will be destroyed and no name will appear in the dissertation.

One of the elements of this study that makes it scientifically acceptable is that it is a "double blind placebo controlled" study. "Double blind" refers to the fact that neither the researcher nor the patients will know who is receiving what. This will only be known at the end of the data collection phase of the study, when the code is broken in order to analyse the data statistically.

In this study the participants will be divided randomly into two groups i.e. the treatment and placebo groups. There is a chance that you may receive placebo, and if that is the case you will be entitled to free homoeopathic treatment at the end of the trial. Treatment will be available in a form of homoeopathic powders and will be dispensed by the homoeopathic clinic dispenser.

Your participation in this study is on a voluntary basis and the consultation and treatment costs will be covered by the Durban Institute of Technology.

There is a possibility that there might be a slight aggravation of the original symptoms but homoeopaths regard this as a good sign, which indicates a homoeopathic response to the stimulus of the homoeopathic medicine. You are welcome to withdraw from this study at anytime and without giving any reasons.

If you have any questions about the study or are experiencing any problems during the course if the study, please contact me or my supervisor on the following numbers:

<u>Dr Steele – 2042041(031)</u> Shaida Ismail– 0833403635

Thank you for the courtesy of your assistance.
Shaida Ismail
Department of Homoeopathy, Durban Institute of Technology.

APPENDIX B

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject)
*Delete whichever is not applicable

TITLE OF RESEARCH PROJECT: The efficacy of homoeopathic simillimum in the treatment of chronic sinusitis.

NAME OF SUPERVISOR: <u>Dr Richard Steele</u>	
NAME OF CO-SUPERVISOR: <u>Dr Corne Hall</u>	
NAME OF RESEARCH STUDENT: Shaida Ismail	
PLEASE <u>CIRCLE</u> THE APPROPRIATE ANSWER:	
 Have you read the subject information letter? Have you had an opportunity to ask questions regarding this study? Have you received satisfactory answers to your questions? Have you had an opportunity to discuss this study? Have you received enough information about this study? Who have you spoken to? Do you understand the implications of your involvement in this study? 	YES/NO YES/NO YES/NO YES/NO YES/NO
8) Do you understand that you are free to withdraw from this study? a) at any time b) without having to give a reason for withdrawing, and c) without affecting your future health care	YES/NO
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 inforn before signing.	ation
PATIENT/ SUBJECT* NAME:	_
(in block letters) SIGNATURE	
WITNESS NAME:(in block letters)	_
SIGNATURE	
RESEARCH STUDENT NAME:(in block letters) SIGNATURE	-
DIOINITORE	

APPENDIX C 1

Patient	number:	
Date:		

GENERAL WELL-BEING QUESTIONNAIRE

(McDowell and Newell, 1996)

READ- this section contains questions about how you feel and how things have been going with you. For each question please circle the number that best applies to you.

- 1) How have you been feeling in general? (DURING THE PAST 3 WEEKS)
 - 1 In excellent spirits
 - 2 In very good spirits
 - 3 In good spirits mostly
 - 4 I have been up and down in spirits a lot
 - 5 In low spirits mostly
 - 6 In very low spirits
- 2) Have you been bothered by your sinus condition? (DURING THE PAST 3 WEEKS)
 - 1 Extremely so to the point where I could not work or take care of things
 - 2 Very much so
 - 3 Quite a bit
 - 4 Some enough to bother me
 - 5 A little
 - 6 Not at all
- 3) Have you been in firm control of your behaviour, thoughts, emotions, OR feelings?

(DURING THE PAST 3 WEEKS)

- 1 Yes, definitely so
- 2 Yes, for the most part
- 3 Generally so
- 4 Not too well
- 5 No. and I am somewhat disturbed
- 6 No, and I am very disturbed
- 4) Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?

(DURING THE PAST 3 WEEKS)

- 1 Extremely so to the point that I have just about given up
- 2 Very much so
- 3 Quite a bit
- 4 Some enough to bother me
- 5 A little bit
- 6 Not at all

5) Have you been under or felt you were under any strain, stress, or pressure?

(DURING THE PAST 3 WEEKS)

- 1Yes almost more than I could bear or stand
- 2 Yes quite a bit of pressure
- 3 Yes some, more than usual
- 4 Yes some, but about usual
- 5 Yes a little
- 6 Not at all
- 6) How happy, satisfied, or pleased have you been with your personal life? (DURING THE PAST 3 WEEKS)
 - 1 Extremely happy could not have been more satisfied or pleased
 - 2 Very happy
 - 3 Fairly happy
 - 4 Satisfied pleased
 - 5 Somewhat dissatisfied
 - 6 Very dissatisfied
- 7) Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel or of your memory? (DURING THE PAST 3 WEEKS)
 - 1 Yes, very much so and I am very concerned
 - 2 Some and I am quite concerned
 - 3 Some and I have been a little concerned
 - 4 Some but not enough to be concerned or worried about
 - 5 Only a little
 - 6 Not at all
- 8) Have you been anxious, worried, or upset? (DURING THE PAST 3 WEEKS)
 - 1 Extremely so to the point of being sick or almost sick
 - 2 Very much so
 - 3 Quite a bit
 - 4 Some enough to bother me
 - 5 A little bit
 - 6 Not at all
- 9) Have you been waking up fresh and rested? (DURING THE PAST 3 WEEKS)
 - 1 Every day
 - 2 Most every day
 - 3 Fairly often
 - 4 Less than half the time
 - 5 Rarely
 - 6 None of the time

10) Have you been bothered by any illness, bodily disorder, pains, or fears about your health?

(DURING THE PAST 3 WEEKS)

- 1 All the time
- 2 Most of the time
- 3 A good bit of the time
- 4 Some of the time
- 5 A little of the time
- 6 None of the time
- 11) Have you been feeling emotionally stable and sure of yourself? (DURING THE PAST 3 WEEKS)
 - 1 All the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 None of the time
- 12) Have you felt tired, worn out, used up, or exhausted? (DURING THE PAST 3 WEEKS)
 - 1 All the time
 - 2 Most of the time
 - 3 A good bit of the time
 - 4 Some of the time
 - 5 A little of the time
 - 6 None of the time
- 13) How concerned or worried about your HEALTH have you been? (DURING THE PAST 3 WEEKS)
 - 1 Extremely concerned
 - 2 Very much concerned
 - 3 Quite a bit concerned
 - 4 Some enough to bother me
 - 5 A little bit concerned
 - 6 Not concerned at all
- 14) How much ENERGY have you felt? (DURING THE PAST 3 WEEKS)
 - 1 Extremely energetic
 - 2 Very much energetic
 - 3 Fairly good amount of energy
 - 4 Satisfactory amount of energy
 - 5 A little bit of energy
 - 6 No energy at all

APPENDIX C

DURBAN INSTITUTE OF TECHNOLOGY DEPARTMENT OF HOMOEOPATHY: RESEARCH QUESTIONS TO PATIENTS WITH CHRONIC SINUSITIS

Your answer to the questions in this questionnaire will be regarded as strictly CONFIDENTIAL and will be used for research purposes only

Ins

S	struc	ctions:
	a.	Please answer the questions as objectively and as accurate as possible
	b.	Please read each question carefully before answering it.
	C.	Please make sure that you answer all the questions and that you do not leave any out accidentally.

d. Please answer all questions following the instructions given. If you have any queries, please ask for assistance from the researcher

conducting the questionnaire.

The General Well-Being Questionnaire

(McDowell and Newell, 1996)

Purpose:

The General Well-Being Questionnaire offers a brief but broadranging indicator of subjective feelings of psychological well-being and distress for use in community surveys.

APPENDIX D	Patient No Date:	
CASE I	<u>HISTORY QUESTIONAIRE</u> (Bates, 1995)	
SURNAME: FIRST NAMES: AGE: OCCUPATION:	PATIENT NO.:	
TELEPHONE:		
MAIN COMPLAINT: \	WHAT SEEMS TO BE THE PROBLEM?	
	COMPLAINT: AETIOLOGY, DURATION, CHARACTER, OMITANTS, RADIATION, PATIENTS RESPONSE TO	
PAST MEDICAL HIST (RHEUMATIC FEVER BLOOD PRESSURE)	ORY: R, PNEUMONIA, TUBERCULOSIS, JAUNDICE, HIGH	
PAST SURGICAL HIS DID YOU HAVE ANY	STORY: OPERATION SINCE YOU WHERE BORN?	
CHILDHOOD DISEASES/ILLNESSES: (MUMPS, MEASLES, CHICKEN POX, GERMAN MEASLES, TUBERCULOSIS)		
TONSILS: ALLERGIES: VACCINATION HISTORY:		
FAMILY HISTORY: (TB, DIABETES, HEART DISEASE, HYPERTENSION, STROKE, ASTHMA ARTHRITIS, ANEMIA, HEADACHES, EPILEPSY, ECZEMA, KIDNEY DISEASE, HAYFEVER, CANCER, MENTAL ILLNESSES)		

MOTHER: FATHER: GRANDPARENTS (MOTHER AND FATHER SIDE) SIBLINGS:

SOCIAL HISTORY:

- 1. WHAT ARE YOUR HOBBIES, LEISURE ACTIVITIES AND EXERCISE?
- 2. DO YOU SMOKE? HOW MANY?
- 3. DO YOU DRINK ALCOHOL? HOW MUCH? HOW OFTEN?

GENERALS:

ENERGY LEVELS

SLEEP

DREAMS

APPETITE

FOOD LIKES/DISLIKES

WEATHER LIKES/DISLIKES

THIRST

PERSPIRATION

SEXUAL LIBIDO

MENSES

STDS

SUPPLEMENTS AND OTHER MEDICATIONS

SYSTEMS REVIEW:

HEAD:

HEADACHES -Types?

- -Location?
- -Frequency?
- -What makes it better/worse?
- -Associating symptoms?

EYES:

(Vision, glasses, contact lenses, pain, redness, double vision, cataracts)

EARS:

(Hearing problems, vertigo, tinnitus, earaches, infections, discharge)

NOSE AND SINUSES:

(Pain, congestion, nosebleed, frequency of colds, hayfever, loss of smell)

MOUTH AND THROAT:

(Frequency of sore throat, bleeding gums, sore tongue, breath odour, loss of taste)

NECK:

(Swollen glands, pain or stiffness in the neck)

RESPIRATORY SYSTEM:

(Cough, sputum, haemoptysis, wheezing, asthma, bronchitis, TB)

CARDIC SYSTEM:

(Chest pain or discomfort, hypertension, rheumatic fever, murmurs)

GASTROINTESTINAL SYSTEM:

(Heartburn, anorexia, nausea, vomiting, abdominal pains, haemorrhoids, constipation, and diarrhoea)

URINARY SYSTEM:

(Infection, burning and pain on urination)

GENITAL SYSTEM:

Female –menses -discharge/leucorrhoea

Male –impotence -libido

MUSCULOSKELETAL SYSTEM:

(Joint pain, stiffness, arthritis, gout, backache)

NEUROLOGICAL SYSTEM:

(Numbness, paralysis, weakness, fainting, tumour)

ENDOCRINE SYSTEM:

(Dysthyroid, diabetes)

ON EXAMINATION:

VITAL SIGNS:

PULSE BLOOD PRESSURE RESPIRATORY RATE TEMPERATURE WEIGHT AND HEIGHT

GENERAL OBSERVATION:

(State of health, signs of distress, skin colour and possible lesions, sexual development, posture, motor activity and gait, dress, grooming and hygiene, odours of the body and breath. Facial expression, note state of awareness and level of consciousness, listen to the patient's speech).

GENERAL OBSERVATION:

HEAD inspection and palpation

Note any –deformities

-lumps

-tenderness, other lesions.

FACE inspection and palpation

Note facial expression and contours, symmetry, involuntary Movements. Oedema, masses and facial pain.

EYES inspection and palpation

Note position and alignment.

Note pupil size, shape, equality.

Note any redness, swelling, vascular pattern, nodules.

NOSE AND PARANASAL SINUSES

inspection and palpation

External surface –asymmetry, deformity, inflammation.

Internal surface –Nasal mucosa –colour, swelling, exudates, bleeding.

Nasal septum –bleeding, crusting, perforation or Deviation

Inferior, medial turbinate and middle meatus -colour, swelling,

exudates and polyps.

Palpate the sinuses – Frontal sinus tenderness

Maxillary sinus tenderness

Postnasal drip -colour, odour, quantity, frequency.

MOUTH AND PHARYNX

Lips -colour, moisture, swelling.

Mouth -breath, taste, pain, lesions.

Teeth –caries, pain, abnormalities in shape, colour and position.

Pharynx –tonsils, swellings, lesions, colour, ulceration, uvula.

EARS

Ear drum and canal -discharge, foreign bodies, redness and swelling, cerum,

colour and contour

- -handle of malleus
- -cone of light
- -perforations.

NECK

Stiffness and pain thyroid gland tracheal deviation JVP lymph nodes

THORAX -inspection, palpation and auscultation

-chest wall movement and shape-auscultation of heart and lungs

ABDOMEN -inspection, palpation and auscultation

-pain, tenderness, guarding, spleen, liver, kidneys.

BACK -inspection and auscultation

- -symmetry of body
- -curvature and orientation of spine -posture, any restricted movements

UPPER AND LOWER LIMBS

-Hair distribution, colour, temperature, any lesion any pain and muscle conditions.

AXILLAE -inspection and palpation

4 areas - Central -Deep

Apical

Pectoral/anterior

Subscapular/posterior

Also -Supraclavicular

Infraclavicular

APHENDIKSI A INCWADI YEMINININGWANE EBALULEKILE

ISIHLOKO SOCWANINGO PHROJEKTHI: <u>Ukubaluleka kwe similimamu</u> (<u>Umuthi okhethwe ngokuhlaziya isimo sengqondo, somphefumulo, kanye nesomzimba kulowo nalowo muntu) ekwelapheni isifo sekhroniki sanusaythisi.</u>

IGAMA LOMPHATHI HLELO: <u>Dokotela Richard Steele</u>

IGAMA LOMCWANINGI: <u>Shaida Ismail</u>

ABANYE ABACWANINGI: <u>Nomthandazo Dlamini, Shera Ebrahim</u>

Usuku:_____

Sawubona

Siyabonga ngokuzinika isikhathi kanye nentshisekelo yakho ekufundeni lencwadi. Ngosizo lwakho, ukubaluleka kwe Homoeopathy ekwelapheni i chronic sinusitis kungacwaningwa.

Ngingumfundi owenza ihomoeopathy e Durban Institute of Technology. Ukuze ngigogode kulomkhakha, kumele ngenze ucwaningo. Lolu wuhlelo olusemthethweni oluzoletha ulwazi mayelana nokubaluleka kwe Homoeopathy ekwehliseni izinga lezimpawu ze chonic sinusitis. Ukuze lokhu kufezeke, uyacelwa ukuba uzimbandakanye kuloluhlelo lwamahhala mayelana nokusixoxela ngesifo sakho sechronic sinusitis, nanokuba sikuphatha kanjani empilweni yakho.

Lolucwaningo phrojekthi luzobe lusingathwe ngu Dokotela oyi homoeopath orejistiwe kuwo lomnyango. Lonke ulwazi ongahle usonike lona kulolucwaningo, luzogcinwa luyimfihlo yakho kanye nomcwaningi kuphela.

Uma uzozimbandakanya kuloluhlelo kumele ube ngumuntu onalokhu okulandelayo:

- a) ube neminyaka ephakathi kweyishumi nesishiyagalombili kuya kwiminyaka engamashumini ayisithupha nanhlanu.
- b) kumele ube ukade uphethwe yilesifo esikhathini esingamasonto amane elandelana,
- c) kumele ube ngumuntu obengathathi muthi wokwelapha isinusitis esikhathini esingangesonto ngaphambi kokuzimbandakanya kulolucwaningo.
- d) Kumele ube ngumuntu okwaziyo ukufunda kanye nokubhala.

Labo abanalokhu okulandelayo bazohoxiswa kuloluhlelo:

- a) abesifazane abakhulelwe
- b) labo abanesifo esiqondene nesifuba njege asma.
- c) Kusukela luqala loluhlelo, awuvumelekile ukuthatha olunye uhlobo lomuthi wokwelapha, ngaphandle kwaleyo yezifo ezibucayi ezinjengesofo sikashukela, isifo esiphathelene nenhliziyo kanye nakholesteroli.
- d) Labo abangazwani nemikhigizo yobisi, ilakthozi.

Uma usuyifezile lemigomo ebhaliwe futhi uzimisele ngokubandakanyeka, usungaba kuloluhlelo oluzothatha amasonto amathathu, lapho umcwaningi edinga ukuba akubone ezikhathini ezimbili lapho kudingeke ukuba ugcwalise ifomu yemibuzo ephathelene nesimo sempilo yakho kanye neye sanusaythisi. Leli fomu lizobe libhalwe ngolimi lwesiZulu nesi Ngisi . Yonke imininingwane ezobe igcwaliswe kulelifomu izobe iyimfihlo.

Loluhlelo lusingathwa umthetho owenza ukuba umcwaningi, nomphathi hlelo, bangazi ukuba yilowo nalowo muntu welashwa ngaluphi uhlobo lomuthi wokwelapha phecelezi l'double blind placebo control study". Abantu abazimbandakanyayo kuloluhlelo, bazocazwa kumaqembu amabili okwelashwa (phecelezi i plasibo noma i thrithmenti) ngendlela engabandlululi. Yonke imithi yokwelapha izobe itholakala ngendlela efanayo kulamaqembu womabili ngendlela yesihomoeopathi.

Labo abazobe bekwiqembu leplasibo bayokwaziswa ekupheleni kohlelo, futhi bayonikwa ithuba lokwelashwa uma seluphelile lolucwaningo.

Uyaziswa ukuba ukuzimbandakanya kwakho kuloluhlelo lwamahhala kungukuvolontiya, futhi wamukelekile ukuba uhoxe kuloluhlelo noma yinini, nangaphandle kokusinika isizathu. Ukuzimbandakanya kwakho kulolu hlelo akuzuba nomphumela olimazanayo, kepha ungazizwa ungekho esimweni esejwayelekile ezinsukwini zokuqala esikuthatha njengophawu olujwayelekile uma welashwa ngokwesihomoeopathi.

Uma unemibuzo noma ungacaciselwa ngokweneliskile, ungathintana nalaba abalandelayo kulezinombolo:

Shaida Ismail- 0833403635

Dokotela Steele- 2042041

Siyabonga ngosizo lwakho.

Umnyango wakwa homoeopathy e Durban Institute of Technology

APHENDIKSI B

SAYINA.....

IFOMU YESIVUMELWANO

(Lefomu mayigcwaliswe isiguli / noma umuntu ozozimbandakanya ku cwaningo phrojekthi) * kuchaza ukuthi <u>cisha</u> lapho kungafanelekile khona

ISIHLOKO SOCWANINGO PHROJEKTHI: Ukubaluleka kwe similimamu (Umuthi okhethwe ngokuhlaziya isimo sengqondo, somphefumulo, kanye nesomzimba kulowo nalowo muntu) ekwelapheni isifo sekhroniki sanusaythisi.

IGAMA LOMPHATHI HLELO WOCWANINGO PHROJEKTHI: <u>Dokotela Richard</u> <u>Steele</u>

IGAMA LOMSINGATHI WOHLELO: Dokotela Corne Hall.

IGAMA LOMFUNDI WOCWANINGO PHROJEKTHI: Shaida Ismail

KOKELEZELA IMPENDULO YAKHO KULEMIBUZO ELANDELAYO:

NORELEGICA IVII ENDOLO TARRITO ROLLINIDOLO ELI INDELLA	110.
1) Usulifundile uhla olumayelana nemininingwane yalolu cwaningo? 2) Ulitholile ithuba lokubuza kabanzi ngalolu cwaningo? 3) Ukwazile ukuthola izimpendulo ezenelisayo kulemibuzo? 4) Ulitholile ithuba lokudingida ngalolu cwaningo?	YEBO/CHA YEBO/CHA YEBO/CHA YEBO/CHA
5) Ulithole lonke ulwazi oludingayo ngalolu cwaningo?	YEBO/CHA
6) Usuke waxhumana nobani ngalolu hlelo? 7) Uyiqondisisa yonke imibandela yokuzimbandakanya kwakho kulolu	hlelo? YEBO/CHA
8)Uyazi ukuthi wamukelekile ukuhoxa kulolucwaningo? a) noma yinini b) ngaphandle kokunika isizathu sokuhoxa c) ngaphandle kokuzibangela ukukhubazeka kwempilo yakho esik 9) Uyavuma ukuzimbandakanya ngokuba yivolontiya kulolucwaningo	
II	
Uma uphendule ngo CHA kwenye yemibuzo elapha ngenhla, uyace	eiwa ukuba
uthole imininingwane efanele ngaphambi kokusayina.	
IGAMA LESIGULI/ LOMUNTU OZIMBANDAKANYAYO*	
	agama amakhulu)
SAYINA	
IGAMA LIKAFAKAZI———————————————————————————————————	
(amagama amakhulu)	
SAYINA	
	
IGAMA LOMFUNDI OWENZA UCWANINGO	
(amagama an	nakhulu)

APHENDIKSI C

DURBAN INSTITUTE OF TECHNOLOGY UMNYANGO WEZOCWANINGO WAKWA HOMOEOPATHY IMIBUZO EQONDENE NALABO ABAPHETHWE ISIFO SE KHRONIKHI SANUSAYTHISI

Impandulo vakho kuloluhla lwamibuzo alandalayo izoba VIMEIHI O futbi

	zosetshenziselwa ucwaningo kuphela.
Imitl	netho:
a	. Uyacelwa ukuba uphendule imibuzo ngendlela eqinisekile nethembekile.
b	. Uyacelwa ukuba ufunde umbuzo ngamunye ngaphambi kokuwuphendula.
C	. Qiniseka ukuthi uphendula yonke imibuzo futhi awukho owushiye ngephutha
d	. Uyacelwa ukuba uphendule imibuzo ezolandela lemithetho. Uma unemibuzo noma ungaqondisisi kahle,ungabuza umphathi wocwaningo ongumsingathi wohlelo.

IMIBUZO EPHATHELENE NESIMO SEMPILO YAKHO

(Ngokuka McDowell no Newell, 1996)

Inhloso:

Uhla lwemibuzo ephathelene nesimo sempilo yakho lubekelwe ucwaningo oluxhumene nabantu bomphakathi, futhi luzosinika uvo lwakho mayelana nesimo sengqondo kanye nesomphefumulo kanye nokukhathazeka empilweni yakho.

APHENDIKSI C1

Inombo	o yes	iguli: ₋	
Usuku:_			

IMIBUZO EPHATHELENE NESIMO SEMPILO YAKHO

(Ngokuka McDowell no Newell, 1996)

FUNDA LAPHA: Lengxenye iqukethe uhla lwemibuzo emayelana nendlela ozizwa ngayo kanye nesimo obukade ukuso kulenyanga eyedlule. Beka indilinga kuleyonombolo eqondene nempendulo yakho

1) Uzizwa uphatheke kanjani empilweni?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Ngizizwa ngiwumqemane
- 2 Ngizizwa ngigculisekile empilweni
- 3 Ngizizwa ngisesimweni esikahle sempilo
- 4 Ngiba nentokozo ngibuye ngizizwe ngiphansi
- 5 Ngizizwa ngiphansi empilwemi
- 6 Ngizizwa ngintekenteke
- 2) Sikuphatha kabi kangakanani lesifo se sinusitis?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Ngiphatheke kabi ngokweqile- angisakwazi ukuzinakekela
- 2 Ngiphatheke kabi kakhulu impela
- 3 Ngiphatheke kabi kakhudlwana
- 4 Kona kungiphatha kabi
- 5 Ngiphatheke kabi kancanyana
- 6 Akungiphathi kabi
- 3) Ubukwazi ukulawula imicabango kanye nemizwa yakho?

(KULAMASONTO AMATHATHU ADLULE)

- 1Yebo, kakhulu
- 2 Yebo, ngokuvamile
- 3 Yebo, ngokwenelisekile
- 4 Angikwazi kangako
- 5 Cha, angikwazi ukuzilawula
- 6 Cha, angisalawuleki
- 4) Uke ube nokudumala, ukudikibala, ukulahla ithemba noma ube nezinkinga uze ungazi ukuthi zingaxazululeka?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Ngidikibele ngokweqile
- 2 Ngidikibele kakhulu impela
- 3 Ngidikibele kakhudlwana
- 4 Ngidikibele kancane
- 5 Ngidikibele kancanyana
- 6 Angizange ngibe kulesimo

- 5) Uke waba nengcindezi (phecelezi istresi)?
 - (KULAMASONTO AMATHATHU ADLULE)
 - 1 Yebo, ngokwedlulele
 - 2 Yebo, kakhulu impela
 - 3 Yebo, kakhudlwana
 - 4 Yebo, kancane
 - 5 Yebo,kancanyana
 - 6 Cha akunjalo
- 6) Ujabule kangakanani empilweni?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Ngijabule ngokweqile
- 2 Ngijabule kakhulu impela
- 3 Ngijabule kakhudlwana
- 4 Ngijabule ngokwenelisayo
- 5 Angijabule kangako
- 6 Angijabule kwasampela
- 7) Uke uzizwe sengathi ulahlekelwa ingqondo, ukulawula indlela owenza ngayo izinto, imicabango kanye nendlela ozizwa ngayo?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Yebo, ngokwedlulele futhi ngikhathazeke kakhulu
- 2 Ngikhathazekile kakhulu impela
- 3 Nginokukhathazeka okuncane
- 4 Ngikhathazekile, kodwa hhayi ngaleyondlela
- 5 Kona kuyangikhathaza kancanyana
- 6 Angikhathazekile kwasampela
- 8) Uke waba nexhala, ukukhathazeka, noma ukudinwa?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Ngokwedlulele kuze kungigulise
- 2 Kakhulu impela
- 3 Kakhudlwana
- 4 Kancane kodwa ngikhathazekile
- 5 kancanyana
- 6 Angihlangabezananga nalesimo
- 9) Uke uvuke izizwa ungumqemane?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Zinsuku zonke
- 2 Cishe kube njalo ngosuku
- 3 Kona kuvamile
- 4 Kwenzeka ngalezozinsuku ezimbalwa
- 5 Kona akuvamile kangako
- 6 Akukaze kwenzeke

10) Uke wakhathazwa yisifo, ukukhubazeka komzimba, izinhlungu, noma ukwesabela impilo yakho?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Njalonje
- 2 Ngezikhathi eziningi impela
- 3 Ngezikhathi eziningana
- 4 Kwesinye isikhathi
- 5 Kwesinye isikhashana
- 6 Angizange

11) Uke wazizwa ugculisekile emphefumulweni?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Njalonje
- 2 Ngezikhathi eziningi impela
- 3 Ngezikhathi eziningana
- 4 Kwesinye isikhathi
- 5 Kwesinye isikhashana
- 6 Angizange

12) Uke wazizwa ukhathele?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Njalonje
- 2 Ngezikhathi eziningi impela
- 3 Ngezikhathi eziningana
- 4 Kwesinye isikhathi
- 5 Kwesinye isikhashana
- 6 Angizange

13) Uke wakhathazeka kangakanani ngempilo yakho?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Ngikhathazeke ngokwedlulele
- 2 Ngikhathazeke kakhulu impela
- 3 Ngikhathazeke kakhudlwana
- 4 Ngikhathazeke ngokwamukelekile
- 5 Ngikhathazeke kancane
- 6 Angikhathazekile

14) Uzizwa unomdlandla noma umfutho ongakanani?

(KULAMASONTO AMATHATHU ADLULE)

- 1 Nginomdlandla owedlulele
- 2 Nginomdlandla omkhulu impela
- 3 Nginomdlandla omkhudlwana
- 4 Nginomdlandla ofanelekile
- 5 Nginomdlandla omncane
- 6 Anginawo umdalndla

APPENDIKSI C 2

Inombolo	yesiguli:	
Usuku:		

Sinus Symptom Visual Analogue Scale

(Ngokuka Walker no White, 2000)

Kuloluhla lwezimpawu ezilandelayo, yilolo nalolo phawu lunikezwe isikali esisuka ku 0 kuya ku 10 ngendlela ozizwa ngayo, lapho u 0 echaza ukuthi awuzwa lutho olukhombisa lolophawu kanti uma sekugcina ku 10 kuchaza ukuthi uzizwa unalo lolophaphawu futhi lisezingeni eliphezulu kakhulu.

Umthetho: Dweba umugqa KUSUKELA ku 0 kuze kugcine lapho ucabanga khona ukuthi izinga lophawu lwakho onalo lizwakala liphezulu.

Uphawu	Isikali sezimpawu – visual analogue scale	
0 = alu(ku)kho	10 = lu(ku)khona kakhulu	
Ubu(izin)hlungu noma ukucinana ebusweni		
0	10	
2. Ubuhlungu bekhanda		
0	10	
3. Ukucinana kwamakhala		
0	10	
4. ukuphuma kwamafinyila		
0	10	
5. Inkinga yokuzwa ngamakh	nala	
0	10	
6. Ukungazizwa kahle kuphelele		
0	10	
Amaphuzu aphelele Is	sibalo emaphuzwini angu 60	

APPENDIX C 2

Patient	number:	
Date:		

Sinus Symptom Visual Analogue Scale

(Walker and White, 2000)

Each symptom below is assessed using a scale of 0-10, where zero represents no symptom and 10 represents the most severe symptom imaginable.

Instruction- Draw a line STARTING from 0 up to a point that best indicates the severity of your symptom.

Symptom	Symptom score - visual analogue scales	
0 = none	10 = extreme	
Facial pain or pressure		
0	10	
2. Headache		
0	10	
3. Nasal blockage or congestion		
0	10	
4. Nasal discharge		
0	10	
5. Disturbance of smell		
0	10	
6. Overall discomfort		
0	10	
Total Points	Score out of 60	