

**A STUDY INVESTIGATING THE EFFICACY OF A HOMOEOPATHIC  
COMPLEX (*HYDRASTIS CANADENSIS* 9CH, *KALIUM BICHROMICUM*  
9CH, *SAMBUCUS NIGRA* 9CH) ON THE TREATMENT OF CHRONIC  
SINUSITIS.**

**BY**

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Mini-dissertation submitted in partial compliance with the requirements of the  
Master's Degree in Technology: Homoeopathy in the Faculty of Health  
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I, Shera Ebrahim do declare that this mini-dissertation represents my own  
work in both conception and execution.

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## **Dedication**

*This work is dedicated to my mother.*

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## **Abstract**

Chronic Sinusitis is defined as a condition manifested by the inflammation of the mucous membranes of the nasal cavity and the paranasal sinuses, fluids within these sinuses, and/or the underlying bone (Lanza and Kennedy, 1997). It is diagnosed if the condition has been present for 4 weeks or more (Carr, 2001).

The demand for non-invasive, harmless and successful treatment for this condition is quite evident and increasing (Mayo Health Clinic Oasis, 2000).

The aim of the study was to evaluate the efficacy of a homoeopathic complex in the treatment of chronic sinusitis in terms of the patients' perception (Appendices C1 & C2) of the treatment.

The homoeopathic complex used in this double-blind study was made up of *Hydrastis canadensis* 9CH, *Kalium bichromicum* 9CH and *Sambucus nigra* 9CH.

This study was a double-blind placebo-controlled study. A sample of 30 participants was selected for this double blind placebo controlled study on the basis of inclusion and exclusion criteria listed in section 6.1. The participants were randomly divided into 2 groups (15 participants for the treatment group and 15 participants for the placebo group).

Each patient had 2 consultations with the researcher over a period of 3 weeks. Medication was prescribed in the first consultation in the form of 15 powders (3 powders to be taken daily for 5 days) and was dispensed according to the randomisation sheet compiled by an independent figure.

The data accumulated via the questionnaires was evaluated and analysed statistically using the One-Sample t-test and the Mann-Whitney test. The statistical package used was the SPSS Package - Version 9.

The One-Sample t-test (data from General Well-Being Questionnaire, Appendix C1) showed a significant positive effect for one element out of fourteen for patients treated with the homoeopathic complex while the placebo group showed significant positive effects for four elements out of fourteen. The Mann-Whitney test showed no significant differences between the treatment and placebo groups (data from Appendix C1).

The data from the Sinus Symptom Visual Analogue Scale Questionnaire (Appendix C2) was analysed using a One-Sample t-test (based on assumption of normality) and the Mann-Whitney test (non-parametric) to test whether the mean differences between the before and after treatment were significantly different within each group. The results indicate that within both the groups the mean differences were significantly different. However, the Mann-Whitney test for differences between the groups indicated no significant difference.

Therefore, the conclusion derived from this study is that the homoeopathic complex studied is not effective in the treatment of chronic sinusitis.

## **Definition of Terms**

### ***Chronic Sinusitis***

A condition manifested by inflammation of the mucous membranes of the nasal cavity and the paranasal sinuses, fluids within these cavities, and/or the underlying bone (Lanza and Kennedy, 1997:S1-2). It is diagnosed if the condition has been present for 4 weeks or more (Carr, 2001).

### ***Homoeopathy***

Homoeopathy is based on the fundamental principle of “*like cures like*”, that is, “Any substance that can produce a totality of symptoms in a healthy human being can cure that totality of symptoms in a sick human being” (Vitoulkas, 1980:92).

### ***Simillimum***

This is the medicine that matches the presenting symptom picture of the patient most accurately. A homoeopath observes the patient acutely and takes into consideration the patient’s character, stress levels, level of exercise, diet, food preferences, family medical history, sleep patterns and the effects of general factors eg. Weather, temperature, etc to obtain a unique symptom picture (Lockie and Geddies, 1995:19). After careful assessment, the medicine most similar to the patient’s symptoms is prescribed. Therefore many different medicines may be prescribed for patients having the same ailment.

***Polypharmacy***

This is a method of homoeopathic prescribing where more than one homoeopathic medicine is prescribed simultaneously. This is done solely on the basis that they all have a degree of similarity to the particular disease process being treated. (Watson, 1991:71).

***Potency***

The especially produced capability in a medicine to effect a dynamic stimulus in the appropriate patient (Gaier, 1991:432).



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# Chapter 1

## Introduction

Chronic Sinusitis is defined as a condition manifested by inflammation of the mucous membranes of the nasal cavity and the paranasal sinuses, fluids within these cavities, and/or the underlying bone (Lanza and Kennedy, 1997). It is diagnosed if the condition has been present for 4 weeks or more (Carr, 2001).

The incidence of chronic sinusitis is higher in areas where the climate is damp and humid, and where there are high concentrations of pollutants (dust, smoke, etc.) in the environment both indoors and outdoors (Berkow and Beers, 1999:688). In patients who are immune deficient, infected with HIV, cystic fibrosis, Kartagener's syndrome or have abnormalities in mucus secretion or movement, the incidence of chronic sinusitis is greater. Patients who have asthmatic responses to non-steroidal anti-inflammatory drugs have a high incidence of chronic sinusitis and those who have histories of allergies or allergic rhinitis are more susceptible to developing chronic sinusitis.

(National Institute of Allergies and Infectious Diseases, 1999).

In the United States of America, in 2001, 32 million persons (aged 18 and older) were diagnosed with sinusitis. This amounted to 16.3 percent of the



adult population with the highest rates being among women and people living in the South (Centers for Disease Control and Prevention, 2003). The incidence of chronic sinusitis in patients with AIDS may be as high as 64% (Rivera, 2003). The incidence of chronic sinusitis is believed to be increasing because of the proliferation of air pollution and household chemicals (Southside Regional Medical Centre, 2002).

Internationally, chronic sinusitis is prevalent. It is particularly common in places where atmospheric pollution levels are high and where the climate is damp and temperate. Higher pollen concentrations are associated with a higher prevalence of the disease in the northern hemisphere (Rivera, 2003).

Quality of life is reduced and the productivity of the sufferer is affected if the disease is untreated. The disease is associated with exacerbation of asthma and serious complications such as meningitis and brain abscess which can produce significant morbidity and mortality. (Rivera, 2003).

A study of the homoeopathic treatment of chronic sinusitis that evaluated two modes of treatment was previously carried out at Technikon Natal (Durban Institute of Technology). The reactions of the homoeopathic medicine Luffa operculata 4XH and a combination of Kalium bichromicum 5CH and Cinnabaris 5CH were compared. Both treatments acted on the symptoms of chronic sinusitis to varying degrees. (Sengpiehl, 1994:27). Forty patients were randomly selected and divided into their respective groups. The statistical results were obtained by performing the Mann-Whitney-U-Test for each

group. The results 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.

Smit conducted a study to determine the efficacy of a homoeopathic simillimum medicine in the symptomatic treatment of chronic sinusitis at Technikon Witwatersrand in 2002. This was not a placebo-controlled study. The primary aim of the research was to evaluate the changes in the vital force as expressed in the energy level and emotional well being of the patient. The study utilized a pre-test and post-test research design and was performed on matched pairs. The Wilcoxon Rank Test was used to analyse the data statistically. Results of this study indicated a significance level of 1% for improvement of primary symptoms from day 14 up to the end of 8 weeks and this trend persisted for the associated symptoms of chronic sinusitis. Medical reports suggested that 4 of the 15 patients showed a 25 –50% improvement and 7 showed a 75-100% improvement. This study clearly indicated that the homoeopathic simillimum provided a safe alternative for the treatment of chronic sinusitis. (Smit, 2002).

Fleming (2001) conducted a study at Technikon Witwatersrand to determine the efficacy of *Hydrastis canadensis* mother tincture and 3X potency on the treatment of sinusitis. There were 45 participants in this study and they were divided into 1 Control Group (placebo) and 2 Experimental Groups. One Experimental Group was treated with *Hydrastis canadensis* mother tincture and the other with the 3X potency. This was a double-blind study with a

duration of 3 weeks. The Wilcoxon-Rank-Sum tests, Kruskal-Wallis tests, Mann-Whitney tests and goodness-of-fit tests were used to statistically analyse the data accumulated. The Kruskal-Wallis test showed that symptom severity did not differ significantly for the three groups and also showed that there was no significant difference in the reduction of symptom severity. The Mann-Whitney test showed no difference in symptom severity between the Control Group and the Experimental Groups. The goodness-of-fit tests revealed no statistical evidence to suggest relief or worsening of the symptoms by the treatment in the study. Symptom severity showed significant reductions over the course of the study, however there was no evidence to suggest that this was caused primarily by the treatment. (Fleming, 2001).

Dlamini (2003) conducted a placebo-controlled study investigating the efficacy of homeopathic nosode medicines in the treatment of chronic sinusitis. The results indicated no positive significant differences between the treatment and placebo groups thus indicating that the treatment was not effective in the treatment of chronic sinusitis.

Ismail (2003) conducted a placebo-controlled study investigating the efficacy of the homeopathic simillimum in the treatment of chronic sinusitis. There were no positive significant differences between the treatment and placebo groups thus indicating that the treatment was not effective in the treatment of chronic sinusitis.

## **1.1 Hypothesis**

The homoeopathic complex (*Hydrastis Canadensis* 9CH, *Kalium bichromicum* 9CH, *Sambucus nigra* 9CH) is not effective in the treatment of chronic sinusitis.

## Chapter 2

### Literature Review

#### 2.1 Aetiology

The aetiologies of chronic sinusitis include the following:

- Inhaling airborne allergens such as dust, mould, pollen, housemite, animal hair, etc. which causes allergic rhinitis. This can lead to sinusitis (Institute of Allergies and Infectious Diseases, 2001).
- Pollutants in the air and in buildings, and damp weather conditions and environments can also affect those with chronic sinusitis adversely (National Institute of Allergies and Infectious Diseases, 2001).
- Gram-negative rod or anaerobic micro-organisms may be responsible for many exacerbations of this condition (Berkow and Beers, 1999:688).
- Chronic maxillary sinusitis is secondary to dental infections in a minority of cases. (Berkow and Beers, 1999:688).

Factors that lead to sinusitis may be classified as host or environmental factors (Carr, 2001).

a). Host Factors

- Allergic/ Immune conditions
- Anatomic abnormalities
- Genetic conditions
  - Cystic fibrosis
  - Immotile cilia syndrome
  
- Systemic diseases
- Neoplasm

b). Environmental Factors

- Infections/ Viral agents
- Trauma
- Noxious chemicals
- Iatrogenic
  - Medications
  - Surgery

## **2.2 Physiology and Pathophysiology**

The paranasal sinuses extend from the nasal cavities and are filled with air.

These sinuses are named according to the bones they lie in, viz. frontal, ethmoidal, sphenoidal and maxillary sinuses. (Giles, 1995:39).

When there is an upper respiratory infection, the nasal mucus membranes swell and obstruct the ostium of the paranasal sinuses, and the oxygen in these sinuses is absorbed into the blood vessels in the mucus membranes. This results in a relative negative pressure in the sinuses (vacuum sinus) and is very painful (Berkow and Beers, 1999:688).

A transudate from the mucus membrane develops and fills the sinus if the vacuum is maintained. This serves as a medium for bacteria that enter through the ostium or through a spreading thrombophlebitis or cellulitis in the lamina propria of the mucus membrane. An outpouring of serum and leukocytes results in order to combat the infection and a painful positive pressure develops in the obstructed sinus. Hyperaemia and oedema of the mucus membranes also results (Berkow and Beers, 1999:687).

Kern states that fungal growth was found in 96% of patients with chronic sinusitis attending the Mayo Clinic and those who are allergic to fungi can develop an allergic fungal sinusitis (1999). An article published in the Mayo Clinic Proceedings in September 1999, by Gene of the Mayo Clinic suggests that the difference between those with chronic sinusitis and the normal population was that their eosinophils had become infected. These infected eosinophils release a product called Major Basic Protein which attacks the fungus but is very irritating to the lining of the sinuses. It is then suggested that it is this injury that allows the bacteria to proliferate thus resulting in inflammation.

## **2.3 Diagnosis**

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 1 major and 2 minor factors for a duration of more than 4 weeks.

### 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

The above is determined by taking a careful medical case history and doing a physical exam (Tichenor, 2000). On physical exam, palpation and percussion



over the sinuses show tenderness. Transillumination also indicates sinusitis if the frontal and maxillary sinuses appear opaque. (Bates, 1995:192-3).

## **2.4 Complications**

If the condition is not treated early, severe complications can result (Giles, 1995:40):

- Osteomyelitis – this occurs when the infection spreads to the bones of the face;
- Subdural or extradural abscess, meningitis or brain abscess – this occurs when the infections spreads intracranially;
- Cavernous sinus thrombosis may occur but this is a rare complication.

## **2.5 Investigations**

Radiography of paranasal sinuses can be used for diagnosis of chronic sinusitis as it defines the sites and degree of involvement of the sinuses more reliably (Berkow and Beers, 1999:687).

A sinus or head X-ray, cranial CT (Computed Tomography) scan or cranial MRI (Magnetic Resonant Imaging) shows sinusitis or thickening of the membranes of the sinuses. X-rays of the apices of the teeth are required in chronic maxillary sinusitis to exclude a periapical abscess. A Full Blood Count (FBC) shows an elevated white cell count and microscopy, culture and sensitivity (MCS) investigations of drainage can also be done to determine

which pathogens (bacteria, virus, fungi) are involved. (Berkow and Beers, 1999:688).

## **2.6 Treatment**

The goals of treatment are the cure of the infection and relief of symptoms of chronic sinusitis.

### **2.6.1 Medical Treatment**

The medical treatment of chronic sinusitis with antibiotics and decongestants is similar to that of acute sinusitis generally, but the role of bacterial infections and hence the usefulness of antibiotics in treating chronic sinusitis is debatable (National Institute of Allergy and Infectious Diseases, 2001).

When there is intense inflammation of the sinuses, corticosteroids are administered by injection or in pill form. They are also commonly contained in nasal sprays (Mayo Health Clinic Oasis, 2000). They decrease the inflammatory infiltrate in the mucus membrane, decrease oedema of the membranes and also stimulate ciliary activity (McDonogh, 1999:117). The discomfort of sinusitis can be reduced by inhaling steam from a vapourizer or a cup of hot water can soothe the inflamed sinuses. Hot water bottles, hot wet compresses, or an electric heating pad applied over the inflamed area can also be comforting (National Institute of Allergy and Infectious Diseases, 2001).

Although topical decongestants are used because they stimulate the alpha-adrenergic receptors in the nasal mucosa thereby causing vasoconstriction and shrinkage of swollen mucosa, there is evidence to suggest that they increase mucosal inflammation in the long term presumably by decreasing blood flow. Therefore only temporary relief is obtained. Systemic decongestants relieve symptoms quickly with minimal drying effects but patients with other medical conditions must be careful (Carr, 2001).

Oxymetazoline or xylometazline are local decongestants but are to be used for limited periods only. Methylxanthines are used to stimulate ciliary activity and relieve the associated cough. Pseudoephedrine sulfate is a sympathomimetic and is used to help shrink the inflamed mucosa, and does not increase the thickness or affect the viscosity of the mucus produced like antihistamines. (McDonogh, 1999:116-117).

Penicillin is the first choice for antibiotic treatment, especially amoxicillin-clavulanic acid preparations. These are broad-spectrum bactericidal products and should only be used for a minimum of 10 days initially but up to 4 weeks if necessary. Sulphonamide-based products can be prescribed for a month. Unusually, prolonged courses of antibiotics are prescribed for unresolved cases or for cases with complications. (McDonogh, 1999:116-117). Antibiotics such as clindamycin and metronidazole are used to treat chronic sinusitis because anaerobic bacteria are associated with the condition. The course of treatment with antibiotics is usually 10 – 14 days (Carr, 2001).

For allergic sinusitis, patients must avoid allergens. Topical nasal steroids, topical cromolyn sodium, antihistamines, systemic steroids and immunotherapy are the available treatment protocols for allergic chronic sinusitis (Carr, 2001).

Physiotherapy is also an important factor in the treatment of this condition and the combination of physiotherapy and medical treatment has proved beneficial to patients. It entails the use of nebulisation or nasal douches with normal saline solutions and in the non-asthmatic patient, sodium 2-mercaptoethane sulphonate solutions. Thick mucus plugs are helped to be broken down and removed from the nasal cavity and middle meatus. The movement of viscid mucus in the sinuses and the flow of blood through the membranes are promoted by using laser and ultrasound treatment during physiotherapy. This helps the action of the medication. Usually a minimum of 8 treatments is prescribed but the physiotherapist may recommend more or less depending on the response of the patient. (McDonogh, 1999:117, 118).

Surgery is an alternative when medical treatment fails. The problem in children is often eliminated by removing the adenoids obstructing the nasal passages. Adults with a history of allergic and infectious conditions sometimes develop nasal polyps that interfere with proper drainage. Removal of these polyps and/ or repair of a deviated septum to ensure an open airway often provides considerable relief from sinusitis symptom (National Institute of Allergy and Infectious Diseases, 2001).

The aim of surgical treatment is to remove anatomical lesions and restore ventilation and mucus clearance of the ostiomeatal units (McDonogh, 1999:117).

Follow-up management of patients is exceedingly important after medical treatment, physiotherapy and surgery to help patients deal with recurrence of symptoms, complications if they arise and to advise patients on after-treatment protocol (McDonogh, 1999:118, 119).

### **2.6.2 Phytotherapy**

Phytotherapy is an empirical system of medicine that employs plant remedies only (derived from trees, ferns, seaweeds, lichens or other vegetation) destined to support the healing life force (Gaier, 1991:423).

According to Balch in the Prescription for Nutritional Healing (2000:626) there are many herbs that are used to treat sinusitis. These are:

- *Aniseed (Pimpinella anisum), Fenugreek (Trigonella foenum-graecum), Marshmallow (Althea officinalis) and Red Clover (Trifolium praetense)* – they help to clear congestion and loosen phlegm.
- *Bayberry (Myrica cerifera)* – this acts as an astringent and a decongestant.

- *Echinacea* is used to boost the immune system and fight viral infection.
- *Crushed Ginger Root (Zingiber officinale)* can be used as a poultice to the forehead and nose. This stimulates circulation and drainage of these areas.
- *Goldenseal (Hydrastis canadensis)* is also effective and works well in conjunction with *Bromelain* (an enzyme found in fresh pineapple). *Goldenseal* must not be taken internally for more than a week at a time and should not be taken during pregnancy.
- *Mullein (Verbascum thapsus)* is used to reduce inflammation and soothe irritation.
- *Olive Leaf Extract* has both antibacterial and anti-inflammatory qualities and is thus effective in relieving symptoms.
- *Rose Hips (Rosa canina)* are a good source of vitamin C.

### **2.6.3 Homoeopathic Treatment**

Homoeopathy is based on the fundamental principle of *“like cures like”*. This principle expounds that *“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).

Homoeopathy aims to stimulate the intrinsic self-healing mechanisms into action by administering substances that cause a slight increase in the symptoms (Lockie and Geddes, 1995:14–15).

Homoeopathic medicines help to hasten recovery by stimulating the vital force (subtle energy within the body that responds to the tiny provocations of the medicines and enables the body to heal itself.) The medicines help the body to return to its healthy state by energizing the vital force to rid the body of disease. (Lockie and Geddes, 1995:18).

Polypharmacy is the method of homoeopathic prescribing where more than one medicine is prescribed simultaneously on the basis that they all have a degree of similarity to the particular disease process. (Watson, 1991:71). A combination of medicines (Complex) is usually prescribed so as to treat more than one symptom of the same condition (Kayne, 1997:104,105,106).

The potencies of combination homoeopathic medicines usually range from tinctures to 30CH [CH representing a centesimal potency (1:99) produced by the Hahnemannian method] and are in general use by many homoeopaths

worldwide. This has been accepted as an essential method of treatment as the therapeutic effects it generates has been observed. (Gaier, 1991:98).

The homoeopathic preparation of ultra high dilutions includes stepwise decimal (1:9), centesimal (1:99) or quinquagenimillesimal (1: 50 000) serial dilution with succussion at every step. Succussion is a process of vigorous shaking with impact. The solvent used is distilled water or alcohol. Insoluble substances are first triturated with lactose powder up to 4CH when they become soluble (Kayne, 1997:49).

According to the French Pluralistic school of thinking, the potency of the medicine is selected according to the severity of the symptoms as well as the level at which the symptoms occur:

-If the homoeopathic relationship of the medicine corresponds to the level of local symptoms, then low dilutions of the medicine are utilized i.e. 4CH or 5CH;

-If the correspondence is at the level of general symptoms and modalities, then medium dilutions are utilized i.e. 7CH or 9CH; and

-If the correspondence is at the level of nervous symptoms, then high dilutions of 15CH to 30CH are utilized. (Jouanny, 1980:93).

Polypharmacy was the method of homoeopathic prescribing used in this study. As there were specific inclusion and exclusion criteria that corresponded closest to the level of general symptoms and modalities, 9CH was selected as the potency for the medicines in the complex.



The medicines in the complex used for the study are:

*Hydrastis canadensis* :

This plant belongs to the genus Ranunculaceae and is also known as Goldenseal. Its main alkaloid constituents are hydrastine, berberine and canadine. It is a potent medicine for disorders of the mucous membranes especially the ear, nose and throat, also helps counter infections, digestive problems and has gynaecological uses (Chevallier, 1996:107).

Promotes discharge and expectoration of thick, yellow, tenacious catarrh from the nasal passages and bronchi. Specifically acts on thick, yellow, ropey catarrh, white excoriating discharge, and thick tenacious secretion from the posterior nares to throat. Covers the symptomatology of sinusitis (Vermeulen, 1997:846).

*Kalium bichromicum (K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub>)* :

This is potassium dichromate or bichromate of potash. It is used in industry for dyeing fabrics, calico-painting, woodstaining, photography and for producing current in electric batteries. Homoeopathically, it is used for disorders of the mucous membranes, treating localized pain and for the treatment of perforating ulcers (Clarke, 1996:86,87).

It has a special affinity for mucous membranes of the respiratory and digestive tracts. Especially for tough, stringy, viscid, greenish-yellow catarrh of the pharynx, larynx, bronchi and nose (Vermeulen, 1997:923).

*Sambucus nigra* :

This plant is also known as Elder and belongs to the genus Caprifoliaceae. Its main constituents are flavonoids, phenolic acids, triterpenes, sterols, tannins, cyanogenic glycosides, anthocyanins and vitamins A and C. It is used medicinally for colds and flu, catarrh and allergies, arthritis and skin disorders (Chevallier, 1996:132).

Dry coryza. Snuffles. Inflammation of nasal membranes. Hoarseness with tenacious mucus in the larynx. Suffocating cough with blocked nose (Vermeulen, 1997:1418-1419).

## **2.7 The Placebo Effect**

Placebo is made of a medicinal inactive substance and is used in controlled studies for comparison purposes with presumed active drugs. It is prescribed with the intention to relieve symptoms or to meet a patient's demands, i.e. "make-believe medicine." Placebo is allegedly inert and harmless. (Berkow and Beers, 1999:2585-6).

The placebo effect is present in all medical environments and procedures including surgery, psychological techniques and medication in any form.

Therefore the effects of any drug will vary from patient to patient and doctor to doctor, depending on the placebo reactivity. Studies conducted 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 the placebo effect has been divided into 2 components of the placebo response.

1. The anticipation and expectation associated with medication i.e. the “faith” or “hope” patients have when seeking treatment.
2. The spontaneous change or natural history of the condition (Berkow and Beers, 1999:2585).

In order to obtain non-biased objective results, placebo was administered to one of the groups in this study.

The placebo powders used in this study were prepared with ethanol of the same percentage as the impregnating potencies used to prepare the treatment powders. This was done to make the placebo powders indistinguishable from the treatment powders.

## Previous Homoeopathic Research

A study of the homoeopathic treatment of chronic sinusitis that evaluated two modes of treatment was previously carried out at Technikon Natal (now Durban Institute of Technology). The reactions of the homoeopathic medicine *Luffa operculata* 4XH and a combination of *Kalium bichromicum* 5CH and *Cinnabaris* 5CH were compared. Both treatments acted on the symptoms of chronic sinusitis to varying degrees (Sengpiehl, 1994:27). Forty patients were randomly selected and divided into their respective groups. The statistical results were obtained by performing the Mann-Whitney-U-Test for each group. The results 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.

Smit conducted a study to determine the efficacy of a homoeopathic simillimum medicine in the symptomatic treatment of chronic sinusitis at Technikon Witwatersrand in 2002. Each patient was required to fill in evaluation forms on a daily basis for the first week of the study and thereafter on a daily basis for the duration of the study. The form contained a table with the following as headings: primary symptoms, secondary symptoms and associated symptoms of chronic sinusitis. There was no placebo group so the patients acted as their own control and had to be previously diagnosed with chronic sinusitis by a medical practitioner. Also included in the form were sections on general well being, moods, vitality/ energy and severity of symptoms. The primary aim of the research was to evaluate the changes in

the vital force as expressed in the energy level and emotional well being of the patient. The study utilized a pre-test and post-test research design and was performed on matched pairs. Data was accumulated using the self-report evaluation forms that were filled in on 14 occasions by each of the 15 patients. The Wilcoxon Rank Test was used to analyse the data statistically. Values from this test obtained on the final day were ranked in relation to values obtained on the starting day. The significance level for each series was determined by summation of the rank values and these were read off published tables.

Results of this study indicated a significance level of 1% for improvement of primary symptoms from day 14 up to the end of 8 weeks and this trend persisted for the associated symptoms of chronic sinusitis. Although the patients in the trial were not affected by secondary symptoms beyond the level of mild inconvenience, 10 out of the 15 patients reported improvement over the 8 weeks resulting in a significance level of 1%. Two of the 15 patients reported a markedly lowered mood (as rated by the evaluation form), the other 13 felt good, with 9 of these reporting maximum mood scores at the end of the study. Eleven of the 15 patients scored 4 or 5 for vitality (1 = lousy and 5 = feeling great). Medical reports suggested that 4 of the 15 patients showed a 25 –50% improvement and 7 showed a 75-100% improvement. Clinical improvement was noted by a medical doctor. This study clearly indicated that the homoeopathic simillimum provided a safe alternative for the treatment of chronic sinusitis (Smit, 2002).

Fleming (2001) conducted a study at Technikon Witwatersrand to determine the efficacy of *Hydrastis canadensis* mother tincture and 3X potency on the treatment of sinusitis. There were 45 participants in this study and they were divided into 1 Control Group (placebo) and 2 Experimental Groups. One Experimental Group was treated with *Hydrastis canadensis* mother tincture and the other with the 3X potency. This was a double-blind study. Participants filled in questionnaires and patients could remain anonymous if they so desired. Follow-ups were done telephonically on a weekly basis and patients were encouraged to contact the researcher at any stage if they experienced any problems. Initial questionnaires were completed before commencement of treatment under the supervision of the research supervisor. The duration of the study was 3 weeks. The Wilcoxon-Rank-Sum tests, Kruskal-Wallis tests, Mann-Whitney tests and goodness-of-fit tests were used to statistically analyse the data accumulated. Medication was in liquid form and all groups were instructed to take 10 drops twice daily. The Kruskal-Wallis test showed that symptom severity did not differ significantly for the three groups and also showed that there was no significant difference in the reduction of symptom severity. This was consistent for both the first and last days of the study. The Mann-Whitney test showed no difference in symptom severity between the Control Group and the Experimental Groups. The goodness-of-fit tests revealed no statistical evidence to suggest relief or worsening of the symptoms by the treatment in the study. Symptom severity showed significant reductions over the course of the study, however there was no evidence to suggest that this was caused primarily by the treatment. (Fleming, 2001).

Dlamini (2003) and Ismail (2003) conducted placebo-controlled studies at the Durban Institute of Technology investigating the efficacy of the main homoeopathic nosodes and homoeopathic simillimum medicines, in the treatment of chronic sinusitis respectively. Both studies utilized the One-Sample t-test to determine if the differences between the before and after treatment results for each question in the placebo and treatment groups for the questionnaires were positively significant and the Mann-Whitney test to determine if there were significant differences between the groups after the treatment. Significance was decided to be at 5% and decisions were made using p-values i.e. if  $p < 0.05$ , the null hypothesis was rejected. Both tests indicated no positive significant differences thus concluding that the homoeopathic nosode and homoeopathic simillimum medicines were not effective in treating chronic sinusitis.

The studies conducted by Sengpiehl and Smit were not placebo-controlled trials. Although the studies conducted by Fleming, Dlamini and Ismail were placebo controlled, the results were not significant. The use of a homoeopathic complex in the treatment of chronic sinusitis has not been previously researched using this combination of remedies in a placebo-controlled trial. All of the above created gaps for further research that were attempted to be addressed in this study.

## Chapter 3

### Research Methodology

#### 3.1 Selection

- Volunteers were obtained through advertisements that were placed on the notice boards at the Durban Institute of Technology and other Durban tertiary institutions, pharmacies, health shops, local sport clubs, libraries and notice boards of public places and in local newspapers.
- There were 30 participants selected for the study on the basis of inclusion and exclusion criteria listed below.

##### 3.1.1 Inclusion criteria

- a) Participants were between the ages of 18 years to 65 years.
- b) Participants met the criteria for diagnosis:

The patient must have more than 2 major factors or 2 major factors  
and

1 minor factor for the duration of more than 4 weeks.



### Major Factors

- \*Facial pain/ pressure
- \*Facial congestion/ fullness
- \*Nasal obstruction
- \*Nasal discharge: purulent,  
or discoloured postnasal drainage
- \*Hyposmia/ anosmia
- \*Purulent discharge in the nose

### Minor Factors

- \*Headache
- \*Halitosis
- \*Fatigue
- \*Dental pain
- \*Cough
- \*Ear pressure/ fullness

(Adapted from Lanza and Kennedy (1997), and Carr (2001).

- c) Participants did take any other sinusitis medication for at least one week before the commencement of the study.
- d) Patients were literate.

### **3.1.2 Exclusion criteria**

- a) Pregnant females were excluded.
- b) Patients with chronic respiratory condition e.g. severe asthma were not allowed to participate in this study.
- c) For the duration of the study, no other form of treatment was permitted except for the chronic medication used for unrelated conditions e.g. hypertension, diabetes, hypercholesterolaemia.
- d) Patients with a history of lactose intolerance were also excluded.

### **3.2 Preparation of Experimental Medicines**

- a) The researcher prepared the placebo and treatment powders in the Homoeopathic Day Clinic dispensary. The homoeopathic dispenser dispensed 15 powders to each participant depending on which group they belonged to (i.e. treatment or placebo group).
- b) All 15 treatment powders contained the active ingredient (i.e. the homoeopathic complex). The powders were numbered from 1 to 15.
- c) The placebo powders were also numbered and contained 96% ethanol which was similar to the impregnating potencies used to prepare the treatment powders. These powders were then indistinguishable from the treatment powders.
- d) The powders were placed into 2 separate boxes labeled 'treatment powders' and 'placebo powders'. Once the research commenced, only the homoeopathic dispenser on duty dispensed the necessary powders.

### **3.3 Consultations**

- Consultations were conducted at the Homoeopathic Day Clinic of the Durban Institute of Technology.
- Before selection, the participants were given the subject information letter (Appendix A) to read, and when selected the consent form (Appendix B) to sign.

- The participants were randomly divided between the treatment and placebo groups (15 participants for the treatment group and 15 participants for the placebo group).

### **3.3.1 First Consultation**

- a) This began as soon as the consent form (Appendix B) was signed.
- b) During this consultation the researcher took a full homoeopathic case history and performed a physical examination (Bates, 1995; Appendix D).
- c) Participants filled in a General Well-Being Questionnaire (McDowell and Newell, 1996; see Appendix C1) and the Sinus Symptom Visual Analogue Scale (Walker and White, 2000; see Appendix C2).
- d) Participants were then sent to the clinic reception area to collect their prescription.
- e) The homoeopathic dispenser on duty at the Homoeopathic day Clinic dispensed the medication to the respective groups according the randomization sheet that was drawn up by the Homoeopathic Day Clinic laboratory technician.
- f) Treatment consisted of 15 powders that contained either the treatment (i.e. complex) or placebo.
- g) Each participant was required to take one powder 3 times a day for 5 days, 30 minutes before meals.
- h) Participants were then instructed to return for the second consultation that took place 3 weeks later.

### **3.3.2 Second Consultation**

- a) During this consultation, participants filled in the General Well Being (McDowell and Newell, 1996; Appendix C1) and the Sinus Symptom Visual Analogue Scale (Walker and White, 2000; Appendix C2) for the final time.
- b) They were later informed as to which groups they were placed in the study, and those who were in the placebo group were offered free homoeopathic treatment at the Homoeopathic Day Clinic.

### **3.4 Data Collection**

The data required for this study was based on the patients' perception of the treatment. This was assessed by the answers to the questionnaires (Appendices C1 and C2).

### **3.5 Methodology of Data Analysis**

- a) For each group (treatment and placebo) the One-Sample t-test was done to compare results before and after the treatment.
- b) Comparison of results between the 2 groups i.e. complex treatment and placebo was done using the Mann-Whitney U-test.

### **3.6 Statistical Analysis**

Only data 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.

#### **3.6.1 General Well-Being Questionnaire Data**

Data from this questionnaire (Appendix C1) was analysed using the One-Sample t-test and Mann-Whitney tests.

##### **a) One-Sample t-test**

The differences between before and after treatment results for each question within each group were determined using this test.

##### Hypothesis Testing:

- $H_0$  (null hypothesis) states that there is no difference between the before and after treatment results for each question within each group.
- $H_1$  (alternative hypothesis) states that there is a significant difference between before and after treatment results for each question within each group.

$\alpha = 0.05$  level of significance

$\alpha = 0.01$  level of more 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 significant level or p value.

\* indicates significant at  $\alpha = 0.05$

\*\* indicates significant at  $\alpha = 0.01$

### b) **Mann-Whitney U-test**

To test for significant differences between the treatment and placebo Groups, the Mann-Whitney U-test was carried out.

#### Hypothesis Testing:

- $H_0$  (null hypothesis) states that there is no difference between the before and after treatment results for the groups.
- $H_1$  (alternative hypothesis) states that there is a significant difference between before and after treatment results for the groups.

$\alpha = 0.05$  level of significance

$\alpha = 0.01$  level of more significance

### Decision Rule

For one-tailed test:

Reject  $H_0$  if  $p < \alpha$

Accept  $H_0$  if  $p > \alpha$

P is the observed significant level or p value.

\* indicates significant at  $\alpha = 0.05$

\*\* indicates significant at  $\alpha = 0.01$

### **3.6.2 Sinus Symptom Visual Analogue Scale Questionnaire Data**

Data from this questionnaire (Appendix C2) was analysed using the One-Sample t-test and Mann-Whitney tests.

#### **a) One-Sample t-test**

This was used to compare the differences between the total scores before and after treatment for the groups as well as to compare the differences in the scores for each question before and after the treatment.

#### Hypothesis Testing:

- $H_0$  (null hypothesis) states that there is no difference between the before and after treatment total scores for the groups.

- $H_1$  (alternative hypothesis) states that there is a significant difference between before and after treatment total scores for the groups.

$\alpha = 0.05$  level of significance

$\alpha = 0.01$  level of more 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 significant level or p value.

\* indicates significant at  $\alpha = 0.05$

\*\* indicates significant at  $\alpha = 0.01$

#### **b) Mann-Whitney U-test**

This was used to determine the difference between the initial (before treatment) consultation and follow-up (after treatment) consultation within each group.



### Hypothesis Testing:

- $H_0$  (null hypothesis) states that there is no improvement before and after treatment.
- $H_1$  (alternative hypothesis) states that there is an improvement before and after treatment.

$\alpha = 0.05$  level of significance

$\alpha = 0.01$  level of more significance

### Decision Rule

For one-tailed test:

Reject  $H_0$  if  $p < \alpha$

Accept  $H_0$  if  $p > \alpha$

P is the observed significant level or p value.

\* indicates significant at  $\alpha = 0.05$

\*\* indicates significant at  $\alpha = 0.01$

## **Chapter 4**

### **Statistical Analysis of results**

#### **4.1 Statistical analysis of responses from the General Well-Being Questionnaire (GB-WQ)**

##### **4.1.1 One-Sample t-test**

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 the treatment and the placebo group for each question. The results are shown in Table 4.1 and 4.2.

**Table 4.1**  
**GW-BQ: One-Sample t-test**  
**Treatment Group**

Question	Test Value = 0			
	Mean Difference	P-value	95% Confidence Interval of the Difference	
			Lower	Upper
Q1	.6667	.036	.0505	1.2829
Q2	.8000	.138	-.2916	1.8916
Q3	.4000	.233	-.2879	1.0879
Q4	.8000	.075	-.0929	1.6929
Q5	.1333	.698	-.5877	.8544
Q6	.2667	.389	-.3773	.9107
Q7	.3333	.371	-.4405	1.1071
Q8	.6667	.096	-.1349	1.4683
Q9	.4000	.305	-.4052	1.2052
Q10	.4000	.305	-.4052	1.2052
Q11	.6000	.167	-.2831	1.4831
Q12	.4667	.250	-.3671	1.3004
Q13	.4667	.169	-.2233	1.1566
Q14	.5333	.056	-.0151	1.0818

As can be seen from Table 4.1, only Question 1 showed a significant improvement.

**Table 4.2**  
**GW-BQ: One-Sample t-test**  
**Control Group**

Question	Test Value = 0			
	Mean Difference	P-value	95% Confidence Interval of the Difference	
			Lower	Upper
Q1	.8000	.028	.0995	1.5005
Q2	1.3333	.016	.2938	2.3729
Q3	.3333	.565	-.8811	1.5478
Q4	.7333	.294	-.7087	2.1754
Q5	1.0667	.056	-.0303	2.1636
Q6	-.0667	.894	-1.1229	.9896
Q7	.3333	.527	-.7676	1.4343
Q8	1.2000	.036	.0885	2.3115
Q9	1.0000	.010	.2749	1.7251
Q10	.0667	.903	-1.0887	1.2220
Q11	-.2000	.531	-.8685	.4685
Q12	.6667	.096	-.1349	1.4683
Q13	.5333	.178	-.2737	1.3404
Q14	.6667	.086	-.1071	1.4405

As can be seen from Table 4.2, Questions 1, 2, 8 and 9 showed significant improvement.

#### 4.1.2 Mann-Whitney U-test

The results obtained from the treatment and placebo groups were compared (See Table 4.3).

**Table 4.3**  
**GW-BQ: Mann-Whitney U-test**  
**Ranks**

<b>GROUP</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of Ranks</b>
Treatment	15	14.67	220.00
Placebo	15	16.33	245.00
<b>Total</b>	30		

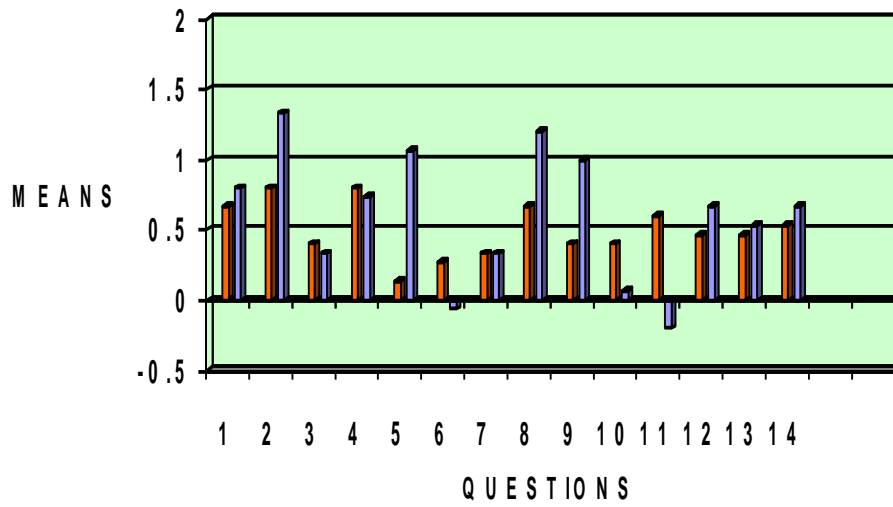
#### **Test Statistics<sup>b</sup>**

	<b>WB</b>
Mann-Whitney U	100.000
Wilcoxon W	220.000
Z	-.519
Asymp. Sig. (2-tailed)	.604
Exact Sig. [2*(1-tailed Sig.)]	.624 <sup>a</sup>

- a. Not corrected for ties.
- b. Grouping Variable: GROUP

As can be seen from Table 4.3, there is no significant difference between the results of the 2 groups. Therefore the hypothesis is accepted i.e. the homoeopathic complex utilized in this study is not effective in improving general well-being of sinusitis patients.

Figure 4.1 is a graphic representation of the “before” and “after” results from the General Well-Being Questionnaire.



**Figure 4.1**  
**Graphic Representation of Results from General Well-Being Questionnaire**  
 This graph clearly illustrates the difference in the results for the two groups before and after treatment.

## 4.2 Statistical Analysis of Responses from the Sinus Symptom Visual Analogue Scale (SSVAS)

The data obtained from the SSVAS 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 the treatment and the placebo group for each question. The results are shown in Tables 4.4, 4.5 and 4.6.

### 4.2.1 One-Sample t-test

As indicated by Table 4.4 below, there was no significant difference between the results of the 2 groups.

**Table 4.4**  
**SSVAS: One-Sample t-test**  
**Differences between Before and After Scores for Individual Questions**  
**Treatment Group**

Question	Test Value = 0			
	Mean Difference	P-value	95% Confidence Interval of the Difference	
			Lower	Upper
Q1	2.5333	.010	.7012	4.3654
Q2	2.0000	.041	.0902	3.9098
Q3	3.3000	.007	1.0583	5.5417
Q4	2.0667	.007	.6709	3.4624
Q5	.5000	.654	-1.8402	2.8402
Q6	2.6667	.001	1.2955	4.0379

Table 4.4 indicates that the results were significant for Questions 1, 2, 3, 4 and 6.

**Table 4.5**  
**SSVAS: One-Sample t-test**  
**Differences between Before and After Scores for Individual Questions**  
**Placebo Group**

Question	Test Value = 0			
	Mean Difference	P-value	95% Confidence Interval of the Difference	
			Lower	Upper
Q1	2.5000	.021	.4412	4.5588
Q2	2.5000	.009	.7209	4.2791
Q3	3.6667	.000	2.0533	5.2801
Q4	1.2000	.324	-1.3156	3.7156
Q5	2.6667	.019	.4393	4.0940
Q6	3.4333	.002	1.5211	5.3456

Table 4.5 indicates that the results were significant for Questions 1, 2, 3, 5 and 6.

**Table 4.6**  
**SSVAS: One-Sample t-test**  
**Differences Between Before and After Scores for the Groups**

Group	Test Value = 0			
	Mean Difference	P-value	95% Confidence Interval of the Difference	
			Lower	Upper
Control	15.7333	.001	7.7810	23.6856
Treatment	13.0667	.005	4.6279	21.5054

The total before and after scores were calculated for each group and are shown in Table 4.6. Results for both the treatment and placebo groups were very significant from the beginning to the end of the study.



#### 4.2.2 Mann-Whitney U-test

The results from the treatment and placebo groups were compared (see Table 4.7).

**Table 4.7**  
**SSVAS: Mann-Whitney U-test**  
**Ranks**

<b>GROUP</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of Ranks</b>
Treatment	15	14.47	217.00
Placebo	15	16.53	248.00
<b>Total</b>	30		

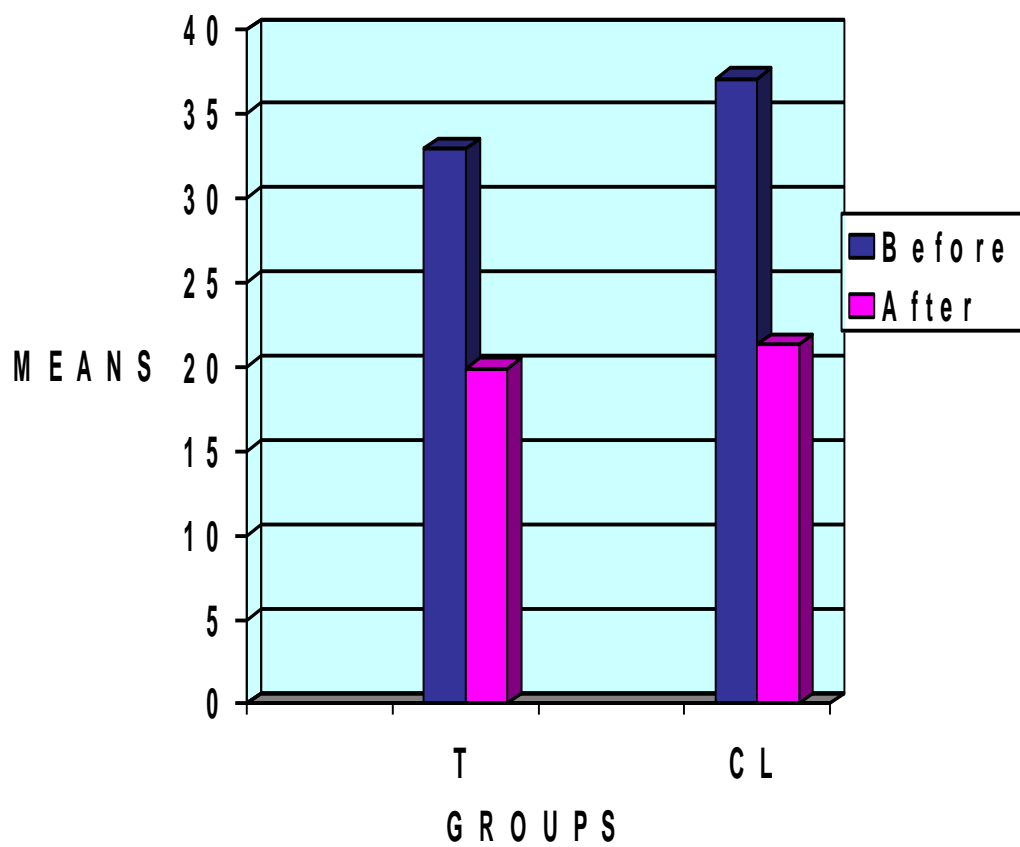
#### **Test Statistics<sup>b</sup>**

	<b>WB</b>
Mann-Whitney U	97.000
Wilcoxon W	217.000
Z	-.644
Asymp. Sig. (2-tailed)	.519
Exact Sig. [2*(1-tailed Sig.)]	.539 <sup>a</sup>

- a. Not corrected for ties.
- b. Grouping Variable: GROUP

As can be seen from Table 4.7, there is no significant difference between the results of the 2 groups. Therefore the hypothesis is accepted i.e. the homoeopathic complex utilized in this study was not effective in improving general well being of sinusitis patients.

Figure 4.2 is a graphic representation of the overall “before” and “after” results from the Sinus Symptom Visual Analogue Scale.



**Figure 4.2**  
**Graphic Representation of Results from the Sinus Symptom Visual Analogue Scale**  
(T = Treatment, CL = Control)

## Chapter 5

### Discussion of Results

This study was conducted to determine the efficacy of a homoeopathic complex (*Hydrastis Canadensis* 9CH, *Kalium bichromicum* 9CH, *Sambucus nigra* 9CH) in the treatment of chronic sinusitis.

The results for the General Well-Being Questionnaire indicate that in the treatment group well-being was significantly improved on one level out of fourteen, and in the placebo group well-being significantly improved on four levels out of fourteen, so outperforming the homoeopathic complex.

The scores for the Sinus Symptom Visual Analogue Scale indicate that both the treatment and placebo groups showed significant improvement in sinusitis symptoms at the end of the study.

However, statistical analysis of differences between the groups in the two questionnaires demonstrated that there were no significant differences, so the homoeopathic complex was no more effective in the treatment of chronic sinusitis than the placebo.

The limited effects on the treatment group can be attributed to the subjectivity of the questionnaire and also on the treatment mode (homoeopathic complex) chosen for the study. This can be substantiated by Vithoulkas in 'The Science of Homoeopathy' (1980:91, 92) that a combination of remedies (complex) is used for symptomatic treatment of conditions and does not aim to eliminate the cause of the ailment.

The positive significance in the placebo group can be attributed to the patients' confidence in the research, their optimism and hope that homoeopathic treatment will improve their symptoms. Most patients had not consulted with homoeopaths prior to the research and were very pleased to discover how in-depth the case history and physical examination was and felt good about talking about what was bothering them. Positive results in this group can also be attributed to the patients' desire to please the researcher.

The remarkable list of subjective and objective changes due to the placebo effect has been divided into 2 components of the placebo response.

1. The anticipation and expectation associated with medication i.e. the "faith" or "hope" patients have when seeking treatment.
2. The spontaneous change or natural history of the condition (Berkow and Beers, 1999:2585).

Although the Sinus Symptom Visual Analogue Scale Questionnaire showed positive significant differences before and after treatment indicating that the

treatment and placebo were successful in improving the symptoms of chronic sinusitis, the inter-group comparison showed no significant difference.

When individual case histories and follow-up consultations were reviewed after the completion of the study, it was apparent that most patients experienced amelioration of symptoms during the course of the treatment but these symptoms returned before the end of the treatment thus indicating that the relief experienced was transient.

A single remedy (medicine) is used to treat a totality of symptoms in classical homoeopathy. For instance, Vithoukias (1980:91) states: "Fever, malaise, loss of appetite, pain, emotional reactions, mental confusion as well as more refined and individualistic responses of each person are not problems in themselves but are rather the defense mechanism's best possible attempt to produce cure of a disturbance which originated upon the dynamic plane. To affect directly the dynamic plane, we must find **a substance** similar enough to the resultant frequency of the dynamic plane to produce resonance."

This can to an extent explain why the homoeopathic complex did not improve symptoms completely and in effect result in a cure of the condition. As homoeopathic medicines are proved individually and not in groups, their interactions with each other are not certain and it is impossible to tell how they will react in the body and which medicine in the combination actually effected the improvement or cure. It is then also impossible to tell which medicine is

the cause of the aggravation or adverse effects if these occur during the course of the treatment and anti-doting the substance will prove difficult.

Homoeopathic treatment is usually very specific to each individual but even though the patients in this study had varied symptom-pictures, they were treated with the same combination of medicines. This may also explain the participants' poor response to the treatment.

The study by Fleming (2001) provided no statistical evidence in favor of homoeopathy for the treatment of chronic sinusitis. The General Well-Being Questionnaire was utilized in studies by both Dlamini (2003) and Ismail (2003) to collect data from the participants. Results indicated that there was no significant positive effect on the treatment of chronic sinusitis. The study by Sengpiehl (1994) did not have a control group but the results indicated that use of the single medicine was more effective in the treatment of chronic sinusitis than the combination of two medicines.

Smit (2002) utilised clinical data for the study on the efficacy of the homoeopathic simillimum (without a control group) in the treatment of the condition and the results obtained indicated statistically positive significant improvement in the symptoms.

All the studies mentioned above indicate that the development of more objective tools for measuring the improvement of symptoms in chronic sinusitis will make research in the area more valuable.

## Chapter 6

### Conclusion and Recommendations

The results of this study lead to the conclusion that the homoeopathic complex utilized is not effective in the treatment of chronic sinusitis.

Recommendations for further research include the following:

1. Follow-up consultations should be sooner i.e. 1 or 2 weeks after the initial consultation.
2. Increase the duration of the trial as chronic conditions can take longer to resolve.
3. Use different potencies of the medicines in the complex, e.g. 30CH, 12CH, etc.
4. Use a different combination of medicines in the complex, e.g. Allium cepa, Arsenicum album, Natrum muriaticum.
5. Use homogenous sample groups for the study i.e. same gender and age.
6. Limit the study to particular symptoms of the condition.
7. Increase the sample size for the study.
8. Initiate studies during the different seasons.
9. Medicines in this study were taken over a period of 5 days. Medicines should be taken over a longer period in future studies.

10. Tools utilized for evaluation of participants' responses should be clinically objective.



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**APPENDIX A**  
**SUBJECT INFORMATION LETTER**

TITLE OF RESEARCH PROJECT: The efficacy of a homoeopathic complex (*Hydrastis Canadensis* 9CH, *Kalium bichromicum* 9CH and *Sambucus nigra* 9CH) in the treatment of chronic sinusitis.

NAME OF SUPERVISOR: Dr Richard Steele

NAME OF CO-SUPERVISOR: Dr Corne Hall

NAME OF INVESTIGATOR: Shera Ebrahim

NAME OF CO-INVESTIGATORS: Nomthandazo Dlamini, Shaida Ismail

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. severe 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 patient's perception 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: 15 participants will be placed in the treatment group and 15 participants will be placed in the placebo group. If you are in the placebo group 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 of the study, please contact me or my supervisor on the following numbers:

***Dr Steele – (031) 204 2041***  
***Shera Ebrahim – 082 51 888 33***

Thank you for the courtesy of your assistance.

Shera Ebrahim  
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 a homoeopathic complex  
(Hydrastis Canadensis 9CH, Kalium bichromicum 9CH and Sambucus nigra 9CH) in  
the treatment of chronic sinusitis.

NAME OF SUPERVISOR: Dr Richard Steele

NAME OF CO-SUPERVISOR: Dr Corne Hall

NAME OF RESEARCH STUDENT: Shera Ebrahim

PLEASE CIRCLE THE APPROPRIATE ANSWER:

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

**If you have answered NO to any of the above, please obtain the information before signing.**

PATIENT/ SUBJECT\* NAME: \_\_\_\_\_  
(in block letters)

SIGNATURE \_\_\_\_\_

WITNESS NAME: \_\_\_\_\_  
(in block letters)

SIGNATURE \_\_\_\_\_

RESEARCH STUDENT NAME: \_\_\_\_\_  
(in block letters)

SIGNATURE \_\_\_\_\_



**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 WEEKS)

- 1 Yes - 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 tome
- 5 A little of the tome
- 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 2**

**Patient No:** .....

**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 symptoms and 10 represents the most severe symptom imaginable.**

**Instruction:** Draw a line STARTING from zero up to a point that best indicates the severity of your symptom.

Symptom	Symptom Score – Visual Analogue Scale
	0 = none ..... 10 = extreme
1. 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
<b>Total Points</b>	<b>Score out of 60</b>

## **APPENDIX D**

### **CASE HISTORY QUESTIONNAIRE**

(Bates, 1995)

DATE OF HISTORY: \_\_\_\_\_  
SURNAME: \_\_\_\_\_ PATIENT NO.: \_\_\_\_\_  
FIRST NAMES: \_\_\_\_\_  
AGE: \_\_\_\_\_ SEX: \_\_\_\_\_  
OCCUPATION: \_\_\_\_\_  
MARITAL STATUS: \_\_\_\_\_  
CHILDREN: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
TELEPHONE: \_\_\_\_\_ (\_\_\_\_\_) \_\_\_\_\_

### **MAIN COMPLAINT: WHAT SEEMS TO BE THE PROBLEM?**

#### **HISTORY OF MAIN COMPLAINT:**

(ONSET, LOCATION, AETIOLOGY, DURATION, CHARACTER, MODALITIES, CONCOMITANTS, RADIATION, PATIENTS RESPONSE TO SYMPTOMS)

#### **PAST MEDICAL HISTORY:**

(RHEUMATIC FEVER, PNEUMONIA, TUBERCULOSIS, JAUNDICE, HIGH BLOOD PRESSURE)

#### **PAST SURGICAL HISTORY:**

DID YOU HAVE ANY OPERATION SINCE YOU WERE 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:  
SIBLINGS:                    GRANDPARENTS (MOTHER AND FATHER SIDE)  
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)

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