

**THE EFFICACY OF NASOSINUS (HEPAR  
SULPHURIS CALCAREUM D3, NUX VOMICA D3  
AND PULSATILLA PRATENSIS D3) IN THE  
TREATMENT OF ACUTE 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 Sciences at the Durban Institute of Technology

I, Shelley Main, do declare that this mini dissertation is representative of my own work, both in conception and execution.

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## **DEDICATION**

THIS IS DEDICATED TO MY MOM AND DAD FOR ALWAYS DOING THE BEST THAT THEY COULD FOR ME. FOR THEIR LOVE, SUPPORT AND ENCOURAGEMENT THROUGHOUT MY LIFE.

AND TO WAYNE FOR HIS UNCONDITIONAL LOVE, UNDERSTANDING AND ENDLESS PATIENCE.

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- And last, but far from least, Wayne – There are no words. I will make up for all the madness one day.

## **ABSTRACT**

The purpose of this double blind placebo-controlled study was to determine the efficacy of Natura Homoeopathic Laboratory's Nasosinus (Hepar sulphuris calcareum D3, Nux vomica D3 and Pulsatilla pratensis D3) in the treatment of acute sinusitis, in terms of patients' perception of response to treatment.

A group of 30 patients were selected for the study according to inclusion and exclusion criteria. The patients were randomly divided into 2 equal groups (15 in the treatment group and 15 in the placebo group).

Each participant had 3 consultations with the researcher over a two week period. Patients completed the Patient Perception Questionnaire (Appendix C), in the presence of the researcher, during each consultation. Medication was dispensed on the first consultation only, in the form of capsules (1 capsule to be taken every 2 hours on the first day – to a maximum of 10 capsules, and then 1 capsule three times a day for days 2 to 7).

The data was statistically analysed using the SPSS Package – Version 9. Data was obtained from the Patient Perception Questionnaire (Appendix C). The intra-group analysis was done using Friedman's Test and Wilcoxon's Signed Rank Test. The inter-group analysis was done using the Kruskal-Wallis Test.

The Friedman's Test showed a significant improvement within both the Treatment and the Placebo Groups. For Group 1 (Treatment Group) there was a significant improvement in 14 of the 16 questions analysed. For Group 2 (Placebo Group) there was a significant improvement in 12 out of the 16 questions analysed.

The inter-group analysis that was done using the Kruskal-Wallis Test showed no significant difference between the treatment and placebo group. This was the case for all the questions analysed.

The conclusion derived from this study is that the homoeopathic complex Nasosinus is no more effective in the treatment of acute sinusitis than placebo and thus not effective in the treatment of acute sinusitis.

Factors that could possibly contribute to the likelihood of significant results in future studies include a larger sample size, an objective measurement tool as well as a longer treatment and measurement periods.

# **TABLE OF CONTENTS**

ACKNOWLEDGEMENTS	i
ABSTRACT	ii
TABLE OF CONTENTS	iv
LIST OF FIGURES	viii
LIST OF TABLES	xi
DEFINITION OF TERMS	xii

## **CHAPTER ONE      INTRODUCTION**

1.1 Introduction	1
1.2 Problem Statement	3
1.3 Assumptions	3

## **CHAPTER TWO      REVIEW OF RELATED LITERATURE**

2.1 Definition	4
2.2 Incidence	5
2.3 Aetiology	5
2.4 Diagnostic Criteria	6
2.5 Physiology and Pathophysiology	8
2.6 Signs and Symptoms	9
2.7 Complications	9
2.8 Treatment	

2.8.1 Medical	10
2.8.2 Complementary	12
2.8.3 Homoeopathic	13
2.8.3.1 Simplex Treatment	15
2.8.3.2 Complex Treatment	18
2.8.3.2.1 Nasosinus	20

## **CHAPTER THREE MATERIALS AND METHODS**

3.1 Sample Group	23
3.1.1 Inclusion Criteria	23
3.1.2 Exclusion Criteria	24
3.2 Randomisation and Blinding	25
3.3 Ethical Issues	25
3.4 Location of the Study	26
3.5 The Treatment	26
3.6 Measurement Tools	27
3.7 Consultation Procedures	28
3.8 Data Analysis	
3.8.1 Statistical Methods	28
3.8.2 Statistical Analysis	
3.8.2.1 Procedure 1 – Friedman’s Test	29
3.8.2.2 Procedure 2 – Wilcoxon’s Signed Rank Test	30



## **CONCLUSION AND RECOMMENDATIONS**

6.1 Conclusion	61
6.2 Recommendations	61

## **REFERENCES** 62

## **APPENDICES**

APPENDIX A	Subject Information Letter	69
APPENDIX B	Informed Consent Form	71
APPENDIX C1	Instructions for Questionnaire	72
APPENDIX C2	Patient Perception Questionnaire	73

## **LIST OF FIGURES**

<b>Figure 4.1</b>	33
Bar chart for Question 1 (patients' perception of headaches).	

<b>Figure 4.2</b>	34
Bar chart for Question 2a (patients' perception of facial pain / pressure on the forehead).	
<b>Figure 4.3</b>	34
Bar chart for Question 2b (patients' perception of facial pain / pressure in the cheeks).	
<b>Figure 4.4</b>	35
Bar chart for Question 2c (patients' perception of facial pain / pressure around the eyes).	
<b>Figure 4.5</b>	35
Bar chart for Question 2d (patients' perception of facial congestion / fullness).	
<b>Figure 4.6</b>	36
Bar chart for total score of Question 2 (patients' perception of facial pain / pressure).	
<b>Figure 4.7</b>	36
Bar chart for Question 3 (patients' perception of nasal discharge).	
<b>Figure 4.8</b>	37

Bar chart for Question 4 (patients' perception of post nasal drip).

**Figure 4.9** 37

Bar chart for Question 5a (patients' perception of nasal obstruction).

**Figure 4.10** 38

Bar chart for Question 5b (patients' perception of loss of taste).

**Figure 4.11** 38

Bar chart for Question 5c (patients' perception of loss of smell).

**Figure 4.12** 39

Bar chart for Question 5d (patients' perception of halitosis / offensive breath).

**Figure 4.13** 39

Bar chart for Question 5e (patients' perception of toothache).

**Figure 4.14** 40

Bar chart for Question 5f (patients' perception of earache).

**Figure 4.15** 40

Bar chart for total score of Question 5 (patients' perception of accompanying

symptoms).

**Figure 4.16**

41

Bar chart for total score of the Patient Perception Questionnaire.

## **LIST OF TABLES**

**Table 4.1**

42

Friedman's test for the Treatment Group.

**Table 4.2**

43

Wilcoxon's Signed Rank test for the Treatment Group.

<b>Table 4.3</b>	48
Friedman's test for the Placebo Group.	
<b>Table 4.4</b>	49
Wilcoxon's Signed Rank test for the Placebo Group.	
<b>Table 4.5</b>	54
Kruskal-Wallis test for inter-group analysis.	

## **DEFINITION OF TERMS**

**Anosmia** – Loss of the sense of smell (Berkow et al., 1995: 2347).

**Coryza** – An acute, usually without fever, viral condition of the respiratory tract, with inflammation in any or all airways, including the nose, paranasal sinuses, throat, larynx, and often the trachea and bronchi (Berkow et al., 1995: 190).

**Centesimal scale 'C'** – A method of potentising based on the principal that the first potency should contain one hundredth part of the base drug and each succeeding potency should contain one hundredth of the one immediately preceding. (Centesimal potencies are denoted by suffixing 'C' to the numerals denoting the deconcentration stage of the drug) (Gaier, 1991).

**Decimal scale 'D'** – A method of potentising based on the principal that the first potency should contain one tenth part of the base drug and each succeeding potency should contain one tenth part of the one immediately preceding. (Decimal potencies are denoted by suffixing 'D' to the numerals denoting the deconcentration stage of the drug) (Gaier, 1991).

**Drainage** – A Homoeopathic promotion of detoxication. The administration of a pathologically based (acting on a specific pathology) remedy in situations where the potential for healing by a constitutional remedy is obstructed (Gaier, 1991).

**Halitosis** – An unpleasant odour to the breath (Berkow et al., 1995: 757).

**Homoeopathy** – A system of therapeutics founded by Samuel Hahnemann, in which a disease is treated by drugs, which are capable of producing, in health, symptoms of that disease in the patient. These drugs are administered, as homoeopathic remedies, in small doses (Foubister, 1989: 1).

**Hyposmia** – Diminished sense of smell (Berkow et al., 1995: 1427).

**Nosode** – Remedies derived from the products of disease (e.g. sputum, pus), diseased tissue or pathogenic organisms (Boyd, 1989: 260).

**Placebo** – From Latin meaning ‘I shall please’. A ‘make-believe medicine’ allegedly inert and harmless. An inactive substance used in controlled studies for comparison with presumed active drugs (Berkow et al., 1995: 2647).

**Potency** – The stage of altered remedial activity to which a drug has been taken by means of a mathematico-mechanical process of deconcentration with succussion, or by trituration of the medicinal substance, which is thus brought to a state of diminutive or infinitesimal subdivision (Gaier, 1991).

**Proving** – Homoeopathic drug trials during which doses of a substance are administered to a healthy individual until a reaction to the substance occurs. These symptoms are then recorded and compiled into the remedy picture or materia medica (Ullman, 1991: 9 – 10).

**Rhinorrhea** – Profuse watery nasal discharge (Edwards and Bouchier, 1993: 354).

**Similimum** – A remedy or substance that would cause, in overdose, similar symptoms to those a sick person is exhibiting. This substance is matched to the sick person’s symptoms and administered, in minute doses, to treat the symptoms (Ullman, 1991: 6).

**Sinusitis** – A condition manifested by inflammation of the mucous membranes of the nasal cavity and paranasal sinuses, fluids within these cavities and or underlying bone (Lanza and Kennedy, 1997).

## **CHAPTER ONE**

### **1.1 INTRODUCTION**

Sinusitis is defined as inflammation of the mucous membranes lining the paranasal sinuses with associated symptoms (Casiano, 2000). Acute sinusitis is diagnosed if an episode has lasted less than three to four weeks and when the epithelial changes are usually reversible (Beavis, 2000). Sinusitis is one of the most common conditions presenting to primary care physicians in the United

States at a cost amounting to \$5.8 billion (Youngs, 2000).

Despite the fact that antibiotics have side effects, do not significantly shorten the duration or prevent complications of acute sinusitis, the allopathic use of antibiotics for respiratory tract infections is on the increase in Britain. Over prescribing has financial implications as well as the more serious development of microbial resistance (Hickner, 1996). Sinus sufferers often opt for surgical procedures, but these may have severe side effects (Heurter, 1992) or the patient may continue to suffer with sinusitis (Youngs, 2000).

Many people are becoming dissatisfied with orthodox medicine and are exploring alternative options. Investigations into safe and effective treatment options needs to be conducted, as there have been few studies of conditions relating to otolaryngology (Krouse and Krouse, 1999).

Homoeopathy is a system of medicine that has proven to be safe and effective over a period of 180 years. It is a system of medicine that treats a sick person as an individual and an integrated unity of body, soul and spirit (Koehler, 1989: 10). Homoeopathic medicines are given with the objective of stimulating the patient's own natural curative powers, as opposed to the use of drugs for their chemical or physical effects on humans or micro-organisms (Foubister, 1989: 13).

Homoeopathy is also considerably cheaper than conventional medicine (Ullman, 1991: 49), making it a desirable alternative to allopathic medication.

A review of the related literature found research done on sinusitis using homoeopathic treatment to be scarce. This is especially true of acute sinusitis. As a commercially available, over the counter product; Nasosinus consists of a complex of homoeopathic remedies the individual ingredients of which were chosen for their indications for sinusitis, based on the law of similars and stated in the Materia Medica (Stoffberg, 2003). There exists only anecdotal evidence as to the efficacy of the combination of these ingredients; no formal clinical trials have been performed, thus necessitating the conducting of this study.

A double-blind placebo-controlled study was conducted. Thirty volunteers were selected according to the inclusion and exclusion criteria listed in Chapter 3. Medication was dispensed according to the randomisation list drawn up by the research supervisor (15 patients received placebo and the other 15 received Nasosinus). Patients were evaluated using a Patient Perception Questionnaire (Appendix C2) adapted from The Short-Form McGill Pain Questionnaire (Melzack and Turk, 1992). Data was analysed using the Friedman's Test, Wilcoxon's Signed Rank Test and the Kruskal-Wallis Test.

## **1.2 PROBLEM STATEMENT**

The aim of this double-blind placebo controlled study was to determine the efficacy of Nasosinus (Hepar sulphuris calcareum D3, Nux vomica D3 and Pulsatilla pratensis D3) in the treatment of acute sinusitis in terms of patients' perceptions of response to treatment (Patient Perception Questionnaire).

## **1.3 ASSUMPTIONS**

- Patients took the medication as prescribed.
- Patients did not make use of other sinusitis medication during the trial as requested.

## **CHAPTER TWO**

### **REVIEW OF THE RELATED LITERATURE**

#### **2.1 DEFINITION**

Acute sinusitis is defined as inflammation of the paranasal sinuses lasting no longer than one month (Lindbaek et al., 1997).

In acute sinusitis the infection resolves (either spontaneously or with medical treatment) with no residual mucosal damage (Youngs, 2000).

The inflammatory process that causes sinusitis is also associated with inflammation of the nasal passages. It is almost impossible to evaluate problems relating to the sinuses without considering the nasal symptoms, as the nose and sinuses are contiguous. For this reason sinusitis may also be referred to as rhinosinusitis (Casiano, 2000).

Acute sinusitis may be superimposed on chronic sinusitis (Stafford, 1990) and may be difficult to distinguish from upper respiratory tract infection (Thistlethwaite, 1998). Sinusitis is considered chronic if symptoms last for more than 3 months or there are more than 3 or 4 episodes a year. Recurring acute sinusitis is when episodes (of less than 1 month duration) occur 3 or fewer times in a year (Beavis, 2000).

## **2.2 INCIDENCE**

Sinusitis is one of the most common conditions presenting to primary care physicians in the USA, with 31 million people being affected each year, each person losing an average of 4 days from work. Healthcare expenditure attributable to sinusitis amounts to \$5.8 billion (Youngs, 2000).

In Britain, acute and chronic sinusitis contributes to over 3 million hours of lost work per year (Loch et al., 1990). In a 1993 National Health Interview survey, rhinosinusitis was found to be the most frequently reported disease; its prevalence increasing dramatically between 1982 and 1993 (Casiano, 2000).

A study of the available data revealed South African statistics to be lacking.

## **2.3 AETIOLOGY**

The aetiology of sinusitis may be bacterial, fungal, physical and chemical trauma, antigen-antibody reactions, autoimmune disease and tumours. There may also be inherent structural abnormalities of the cilia (Loch et al., 1990).

Sinusitis develops depending on a variety of environmental [e.g. Infectious / viral agents; Trauma; Noxious chemicals; Iatrogenic (medications, surgery)] as well as host factors [e.g. Genetic / congenital conditions such as Cystic Fibrosis or Immotile Cilia Syndrome; Allergic / immune conditions; Anatomic abnormalities;

Systemic diseases such as endocrine or metabolic diseases; Neuromechanisms; Neoplasms] (Lanza and Kennedy, 1997).

Sinusitis often follows an upper respiratory tract infection and can be bacterial or viral in origin (Beavis, 2000).

## **2.4 DIAGNOSTIC CRITERIA**

Diagnosis of acute sinusitis is usually on the basis of history and physical examination. X-rays are unhelpful in confirming diagnosis and there are no blood tests of practical value. If treatment fails then further investigation such as CT scan or endoscopy is warranted (Mead, 1997). CT scan and endoscopy are accurate methods of diagnosis but cannot be justified on economic grounds

(Youngs, 2000).

In diagnosing a patient with sinusitis, history is important. Physicians use a cluster of symptoms and signs to diagnose acute sinusitis including headache, feeling of fullness in the face and pressure behind the eyes, facial pain (all exacerbated on bending forward) facial tenderness, purulent catarrh, nasal obstruction, toothache and post nasal drip. Examination may add little to clinical suspicion. Pain may be severe, the location of which will depend on the site of the infected sinus. Infection of the maxillary sinuses may cause pain in the cheeks, ethmoid sinuses pain in the bridge of the nose and frontal sinuses above the orbits of the eyes. The signs and symptoms of sinusitis are difficult to distinguish from an upper respiratory tract infection (Thistlethwaite, 1998). Other symptoms include anosmia, pain on chewing, bad breath, frequent tearing and oedema of eyelids as well as fever (Stafford, 1990).

According to Lanza and Kennedy (1997) patient history and physical examination should suffice for diagnosis of sinusitis. Endoscopy and CT scans are not required for initial diagnosis, but may be useful in more difficult, recurrent (chronic) cases. The subject must have had 2 or more major factors or 1 major and 2 minor factors for a duration of not more than 3 weeks.

Major factors:

- Facial pain / pressure
- Facial congestion / fullness

- Nasal obstruction / blockage
- Nasal discharge / purulence / discoloured post nasal drip
- Hyposmia / anosmia
- Purulent discharge in nasal cavity on examination
- Fever

Minor factors:

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

## **2.5 PHYSIOLOGY AND PATHOPHYSIOLOGY**

The sinuses are cavities in the bones of the head lined by mucous membranes.

There are four paranasal sinuses. They are the frontal, ethmoidal, sphenoidal and maxillary sinuses. Each of these has ostia through which mucous drains.

Secretions of the sinuses and nose are transported by the ciliary action. Mucous and debris are moved in this way towards the pharynx to be swallowed (Brewis et al., 1990: 461).

The sinuses normally drain via the ostia, which are natural ventilation holes. If these become obstructed as a result of mucosal swelling or mechanical

obstruction (such as local insult, polyps or deviated nasal septum), drainage is impaired and fluid collects in the sinuses. If the fluid becomes infected then sinusitis develops (Thistlethwaite, 1998).

In a normal situation, inhaled irritant matter is deposited into the mucous on the middle meatus and middle turbinate areas. The nasal mucous is produced by the mucous glands of the mucosa. If the cilia do not clear these secretions and related pathogens, then the mucous stagnates and becomes a medium for breeding bacteria and fungus, which then invades the mucosa. This then causes inflammation of the mucous membranes i.e. sinusitis (Loch et al., 1990).

Normal ciliary function, intact mucous membranes and normal mucous production are necessary for sinus clearance. Occlusion of the sinus ostia seems to initiate acute sinusitis, which, if untreated or inadequately treated, may develop into chronic sinusitis (Reilly, 1990).

## **2.6 SIGNS AND SYMPTOMS**

Acute sinusitis may present as a headache or facial pain, associated with a mucopurulent rhinorrhea and nasal obstruction. The pain may be dull, throbbing to severe lancinating and is aggravated by bending forward, straining or changes in pressure. There may be fever, halitosis, lethargy and malaise. On examination the sinuses are tender to light palpation, there may be eyelid or medial canthus oedema, loss of transillumination, erythema of turbinate mucosa, mucopurulent rhinorrhea, eczema of nostril and conjunctivitis (Loch et al., 1990).

The sinuses may be tender to percuss or on tapping the teeth (Van Shaik and Freeland, 1997) as well as disturbance of or loss of sense of smell (Mead, 1997).

## **2.7 COMPLICATIONS**

Complications usually occur after an acute exacerbation of a pre-existing chronic condition, when infection spreads into and beyond the bony boundaries of the sinuses. They may be extracranial (mucocele, osteomyelitis), orbital (eyelid oedema, orbital cellulitis, orbital abscess, subperiosteal abscess, cavernous sinus thrombosis) or intracranial (meningitis, cavernous vein thrombosis, subdural and frontal lobe abscess) (Loch et al., 1990). The most common complication being orbital cellulitis and the most rare being osteomyelitis of the maxillary bone, brain abscess and meningitis (Thistlethwaite, 1998).

Because of the intimate relationship between the sinuses and the eyes as well as the brain, infection and inflammation of the sinuses can lead to disabling or even fatal consequences (Casiano, 2000).

## **2.8 TREATMENT**

### **2.8.1 MEDICAL TREATMENT**

The allopathic treatment for acute sinusitis usually consists of a ten-day course of antibiotics often accompanied by additional treatments such as paracetamol-based analgesics, steam inhalations and local treatment with nasal sprays or

drops (Mead, 1997).

Antibiotics do not significantly shorten the duration of acute sinusitis or prevent complications and they have side effects. Over prescribing has financial implications as well as contributing to increasing microbial resistance (Butler et al., 1998).

Antibiotics have no benefit for most patients suffering with maxillary sinusitis, sore throats, acute otitis media and acute bronchitis. European and American studies have shown that 44 – 90% of adults and children that consult for a cold, upper respiratory tract infection, and acute bronchitis receive a prescription for antibiotics. This encourages people to consult for self-limiting conditions and has other implications (Butler et al., 1998). 98.4 % of patients receive antibiotics in the treatment of acute sinusitis (Little et al., 2000).

Nearly 80% of Americans believe that the presence of a discoloured nasal discharge requires treatment with an antibiotic, even though this is not a prediction of the effectiveness of the antimicrobial treatment (Hickner, 1996).

Patients with a confirmed acute bacterial sinusitis may benefit from an antibiotic, but not all patients in general practice can or should undergo the investigation by CT scan or radiography that this would require (Lindbaek et al., 1996).

Antihistamines, corticosteroids and mucolytics are of no proven benefit in the

treatment of bacterial sinusitis. Nasal decongestants confer some benefit although prolonged use leads to rebound congestion and chronic sinusitis. Most patients recover well without the use of antibiotics (Beavis, 2000).

Adjuncts to pharmacological treatment of acute sinusitis include non-pharmacological management such as steam, astringents, inhalations, saline solutions and hot, dry air (Druce, 1990).

Surgery (to correct anatomical abnormalities) is common practice for chronic sinusitis even though complications of surgery include blindness, cerebrospinal fluid leakage, haemorrhage, nasolacrimal duct obstruction, diplopia and orbital hematoma (Heurter, 1992). In some cases sinus ventilation has been improved with surgery, but patients usually continue to suffer with chronic or recurrent acute sinus infection (Youngs, 2000).

## 2.8.2 COMPLEMENTARY TREATMENT

Despite the fact that patients who are dissatisfied with traditional medicine are exploring alternate options, there have been few studies of conditions relating to otolaryngology. Investigation is needed into safety and efficacy of alternative techniques. Exercise, air filters and dietary manipulations are more commonly used than traditional medical therapies such as antihistamines and antibiotics (Krouse and Krouse, 1999).

It is estimated that 30 – 40 % of Americans use various alternative therapies for many illnesses, yet physicians frequently approach alternative and complementary therapies with scepticism and disdain. Controlled scientific studies are needed to demonstrate which alternative therapies have positive results and those that do not (Krouse, 1998).

In alternative therapies there are many natural substances and methods that are used to treat sinusitis. These include: Anise (Helps break up sinus congestion); Bromelain (Relieves sinus congestion); Cat's Claw (Stimulates immune defence against bacterial infection, relieves inflammation); Elderberry (Breaks up mucous, also prevents and treats flu); Horehound (Stimulates secretion of fluids to carry away congestion); Osha (Antibacterial, antiviral) and Wild Thyme (Breaks up congestion). Acupuncture can also be very effective in relieving pain and promoting sinus drainage. Aromatherapy oils such as eucalyptus are also widely used in the relief of sinusitis (Balch, 2002: 398).

Other natural supplements used successfully by sinusitis sufferers are Vitamin C, flavonoids (e.g. Quercetin), Echinacea, Astragalus, Reishi / Maitake mushrooms (Wilmot, 1999: 202 – 203).

It is evident that a safe, effective treatment for acute sinusitis needs to be found. If acute sinusitis is untreated or inefficiently treated it can lead to chronic sinusitis (Reilly, 1990).

## 2.8.3 HOMOEOPATHIC TREATMENT

There has been little research done on sinusitis using homoeopathic treatment. It can be seen from the studies described below that there is a need for research on acute sinusitis. Most of the research that has been conducted has been on chronic sinusitis.

Homoeopathy is a system of medicine that uses remedies that stimulate the bodies own immune and defence systems to heal itself. It is an approach that respects the wisdom of the body and is widely recognised to be safe (Ullman, 1991: 3).

Homoeopathic remedies speed a patient's recovery by stimulating the vital force. The vital force is the subtle energy within the body that enables the body to heal itself by boosting the defence mechanisms. The vital force responds to the tiny provocations of the homoeopathic medicines and thereby enables the body to rid itself of disease and return to its' healthy state (Lockie and Geddes, 1995: 18).

References to homoeopathy in conventional medicine are usually derogatory dismissing it as an anomaly in medicine, a science of placebos rather than 'real drugs', or a medical heresy (Ullman, 1991: 44). Skeptics assume that the microdoses used by homoeopaths could not possibly have any biological or

clinical effects (Ullman, 1991: 55). It is therefore important to undergo clinical, scientific trials that will evaluate the anecdotal evidence or claims made by homoeopaths over the past centuries.

According to Jouanny (1995:14) allopathic medicines are coercive and use an approach involving destruction, inhibition and substitution, whereas

homoeopathic remedies act together with the body's reactions to stimulate defence mechanisms.

According to Ullman (1991) homoeopathy is a natural pharmaceutical science in which the physician strives to find a substance that would cause, in overdose, similar symptoms to those a sick person is exhibiting. This same substance is then given to that sick person in very small, safe doses, often with dramatic results. This matching process is referred to as the 'Law of Similars' and is an underlying principle of homoeopathy.

This fundamental principle of "Like Cures Like" means 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 (Vithoukias, 1980: 92).

### **2.8.3.1 Simplex treatment**

For Homeopaths practicing strictly classical homoeopathy only one medicine can

be truly homoeopathic to the presenting illness at any one time, thus single remedies (and not combinations thereof) are administered to patients. This is so because remedies have been proved singly and not in combinations the effects of which may be different from their constituting medicines individually (Gaier, 1991). According to Ullman (1991:23) a combination of remedies serves only to improve symptoms of a condition and not to eliminate the cause.

Dlamini (2003) investigated the efficacy of the main miasmatic nosodes in the treatment of chronic sinusitis. This was also a double-blind placebo-controlled study and was conducted using a General Well-Being Questionnaire as well as a Sinus Symptom Visual Analogue Scale Questionnaire as measurement tools. Thirty patients were included in the study – 15 received placebo and 15 received medicated powders. They were assessed over a period of 3 weeks and data was analysed using the one-sample t-test and the Mann Whitney test. The conclusion reached was that the main miasmatic nosodes were not effective in the treatment of chronic sinusitis. There was significant improvement within both the treatment and placebo groups, but there was no statistical difference between the two groups. The researcher stated that this may have been due to the study being conducted over too short a period, the potency selected being too weak, as well as the influence of previous suppressive / allopathic therapy on the patients.

Ismail (2003) conducted a study to determine whether homoeopathic similimum was effective in the treatment of chronic sinusitis. This double-blind placebo-

controlled study included thirty patients (15 in the treatment group and 15 in the placebo group) who were seen over a 3-week period. The General Well-Being Questionnaire and the Visual Analogue Scale Questionnaire were used. Results were analysed using the one-sample t-test and the Mann Whitney test. The conclusion reached was that the homoeopathic simillimum is no more effective than placebo in the treatment of chronic sinusitis. There was, however, significant improvement within each group. The researcher recommended that the study be done over a longer period, that medication be repeated more frequently and that more objective measurement tools be used.

Smit (2002) conducted a study to determine the efficacy of a homoeopathic simillimum in the symptomatic treatment of chronic sinusitis. The patients were pre-diagnosed by a medical practitioner and were assessed over an eight-week period. The study was performed on matched pairs using a pre-test to post-test research design (i.e. each individual acted as his / her own control). Data was analysed by means of Wilcoxon's Signed Rank test and the conclusion reached was that the homoeopathic simillimum resulted in significant improvement. Only 15 patients were included and there was no placebo group, so the validity of this study is questionable.

Fleming (2001) compared the efficacy of *Hydrastis canadensis* mother tincture to that of the 3X potency in the treatment of sinusitis. This double-blind placebo-controlled study included 45 patients (who had been previously diagnosed) and

was conducted over a three-week period. 15 patients received placebo, 15 received the mother tincture and 15 received the 3X potency. Wilcoxon's Rank Sum, Mann Whitney, Kruskal-Wallis and goodness-of-fit tests were used to statistically analyse the data. The conclusion reached was that neither Hydrastis

Canadensis mother tincture nor 3X potency was effective in the treatment of sinusitis.

### **2.8.3.2 Complex treatment**

A complex is a combination of remedies (usually in low potency) that are commonly used to treat a specific disease or symptom. These combination remedies are freely available from health food stores for patients to self-medicate in the case of acute non-life-threatening conditions (such as sinusitis).

Complexes are often used when a similimum (individually prescribed) remedy is not available, or when a homoeopath is not certain which single homoeopathic remedy should be used (Ullman, 1991: 22 – 23).

The method of prescribing where more than one homoeopathic remedy is used simultaneously is known as disease based polypharmacy. This is done on the basis that the remedies all have a degree of similarity to that particular disease process (Watson, 1991: 71). A complex is usually prescribed so as to treat more than one symptom of the same condition (Kayne, 1997: 104 – 106).

The potencies of remedies in the combination can range from a tincture up to a

potency of usually not more than 30CH [CH representing a centesimal potency produced by the Hahnemannian method]. These combination remedies are in use by many homoeopaths worldwide, and through observation of their beneficial therapeutic effects have been accepted as an essential means of treatment (Gaier, 1991: 98).

According to Jouanny (1993) acute sinusitis responds well to homoeopathy. Low potencies administered several times a day is the most effective means of treatment in acute disease and will act on the level of local symptoms. The 3X (D3) potency is indicated for drainage.

In the case of acute sinusitis, the use of a complex such as Nasosinus could cause improvement of symptoms and therefore prevent development of chronic sinusitis or other complications.

Ebrahim (2003) investigated the efficacy of a homoeopathic complex (Hydrastis canadensis 9CH, Kalium bichromicum 9CH and Sambucus nigra 9CH) in the treatment of chronic sinusitis. This double-blind placebo-controlled study was done using a Patient Perception Questionnaire as well as a Sinus Symptom Visual Analogue Scale Questionnaire as measurement tools. Thirty patients were included and randomly divided into two groups – 15 patients in the placebo group and 15 in the treatment group. They were monitored over a 3-week period. The

one-sample t-test and Mann Whitney test were used to analyse the results. The conclusion was that the homoeopathic complex was not effective in the treatment of chronic sinusitis, as there was no significant difference between the two groups. There was, however, improvement within both groups. Recommendations of the study include using a larger sample size; using a homogenous sample; that more objective measurement tools be used; that the study be limited to one symptom; also that treatment should be done over a longer period and using different remedies and potencies in the complex.

Sengpiehl (1994) compared a specific homoeopathic remedy (*Luffa operculata* 4XH) to a combination of two remedies (*Kalium bichromicum* 5CH and *Cinnabaris* 5CH) in the treatment of chronic sinusitis. Forty patients were included in the study (20 in each group). Patients were assessed over a four-month period using a patient perception questionnaire as well as the physical appearance of the nasal mucosa. Data was analysed using the Mann Whitney test as well as the Wilcoxon's Signed Rank test. *Luffa operculata* was found to be more effective than the combination of the two remedies *Kalium bichromicum* and *Cinnabaris*. It is difficult to determine whether these results are valid as no placebo was used against which the results could be measured.

#### **2.8.3.2.1 Nasosinus**

Nasosinus was chosen for this study as it is available commercially and the validity of its use needed to be established, as there had been no clinical trials conducted to establish its efficacy (Stoffberg, 2003). Nasosinus is a complex of

homoeopathic remedies. The individual remedies of the complex have been chosen based on their ability, when applied according to the law of similars, to treat sinusitis. Only anecdotal evidence exists as to the efficacy of the complex i.e. a combination of the individual ingredients. The product contains a complex of remedies (see below) in a D3 potency making it useful for a wide range of symptoms of acute sinusitis and allowing for drainage. The symptoms below are listed in the Materia Medica under the respective remedy. It can be seen that the symptom picture is similar to that of acute sinusitis.

According to Van Wyk (1999) Nasosinus is indicated for congestive sinusitis, with thick catarrhal discharge, halitosis, ozaena, post nasal drip, blocked nose and congestive sinus headaches. It acts as a decongestant, promoting discharge of catarrh from the mucous membranes.

The complex contains the following remedies in a D3 potency:

Hepar sulphuris calcareum

Affinity for respiratory mucous membranes. Infected sinus and pus formation. Tendency to suppuration. Yellow expectoration. Headache as if nail were being driven into the right side of the head. Boring pain in right temple and in root of nose. Aching in the forehead. Boring pains in upper bones of orbit. Thick offensive nasal discharge. Earache. Hayfever. Pains in bones of face. (Vermeulen, 1994: 482).

Strychnos nux vomica

Headache in occiput or over eyes. Congestive headache. Pains and ringing in the ears. Nose stuffed up. Sneezing. Coryza. Acrid discharge. Swelling of the cheek. Sour odour from mouth. (Vermeulen, 1994: 709).

Pulsatilla pratensis

Discharges thick, bland and yellowish-green. Pains in head move to face and teeth. Frontal and supraorbital pains. Head seems heavy. Pulsating pain improved by pressure. Dull aching. Hearing difficult as if ears were stuffed. Earache. Coryza. Pressing pain at root of nose. Yellow mucous. Obstruction of nose. Frequent sneezing. Offensive odour from mouth. Throat covered with tenacious mucous. (Vermeulen, 1994: 796).

## **CHAPTER THREE**

### **MATERIALS AND METHODS**

#### **3.1 SAMPLE GROUP**

Patients were recruited via advertisements in local newspapers and posters and pamphlets that were distributed in local health shops and notice boards. Patient participation was on a voluntary basis and they were selected via convenience sampling. A group of 30 patients was selected according to the following inclusion and exclusion criteria:

##### **3.1.1 INCLUSION CRITERIA**

Patients were selected for the research according to the following criteria:

- Patients had to be between the ages of 18 and 65.
- Patients had to be English literate.
- Patients had to have taken no other sinus medication at least 48 hours prior to commencement of the study.
- Patients had to meet the diagnostic criteria (Lanza, 1997):

The patient had to have had 2 or more major factors or 1 major and 2 minor factors for a duration of not more than 3 weeks.

##### **Major factors:**

- Facial pain / pressure
- Facial congestion / fullness

- Nasal obstruction / blockage
- Nasal discharge / purulence / discoloured post nasal drip
- Hyposmia / anosmia
- Purulent discharge in nasal cavity on examination
- Fever

Minor factors:

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

### 3.1.2 EXCLUSION CRITERIA

Patients were excluded from the study according to the following criteria:

- Patient already receiving antibiotics.
- Pregnant females.
- Patients with serious respiratory conditions such as severe asthma.
- Patients who could not cease any sinusitis treatment that they were on (including homoeopathic and herbal remedies) 48 hours prior to commencing the study.

## **3.2 RANDOMISATION AND BLINDING**

This was a double-blind placebo-controlled study. As patients entered the study they were assigned numbers sequentially and received a corresponding medication according to the randomisation list that was drawn up, by picking numbers out of a hat, by research supervisor Dr. David Naude. The code was revealed after the data collection phase was complete.

Neither the patient nor the researcher was aware of which capsules were received (Nasosinus or Placebo) as dispensing was performed by an independent person according to the randomisation list drawn up by the Supervisor. The two sets of capsules and their corresponding packaging were indistinguishable to both the researcher and the patient.

## **3.3 ETHICAL ISSUES**

Nasosinus was compared to placebo in order to determine whether the homoeopathic complex was more effective than placebo. Apart from the fact that 50% received placebo and 50% the homeopathic complex; patients were treated equally in all other respects, therefore any improvement in the condition could be attributed to the homoeopathic remedy alone.

Placebo is a made of a medicinally inactive substance. It is allegedly inert and harmless. It is therefore used to illustrate the effects of a presumed active drug (Berkow et al., 1995: 2647).

The researcher explained the nature of the study to all the participants. Each

participant was given the Subject Information Letter (Appendix A) to read. This letter explained to all participants the need for the use of placebo to make the study scientifically acceptable, that there was a 50% chance that they would receive placebo capsules, that all information would be treated as confidential, that they were free to withdraw at any time, that no names would be used, and that all records would be destroyed. Informed consent was obtained in that all patients were asked to complete the Informed Consent Form (Appendix B). The placebo capsules were visibly indistinguishable from the Nasosinus capsules.

Acute sinusitis, although not without complications, is not considered a life threatening condition. Patients were therefore not placed at serious risk by receiving placebo capsules. All participants were offered free treatment at the end of the study if they turned out to be in the placebo group.

### **3.4 LOCATION OF THE STUDY**

The study was conducted in Scottburgh, Kwa-Zulu Natal at the consultation rooms of Dr Seedat. The dispensing of medication was done according to the randomisation list by Ms. V. Blanchard; Dr Seedat's receptionist.

### **3.5 THE TREATMENT**

Treatment consisted of either medicated capsules (Nasosinus) or unmedicated capsules (placebo). These were both made up by Natura Homoeopathic Laboratory (Pretoria). The unmedicated capsules contained lactose powder and were visibly indistinguishable from the Nasosinus capsules.

Patients were instructed to take one capsule every 2 hours on day one (to a maximum of 10 capsules) and then one capsule three times per day on days 2 to 7. They were instructed to take the capsules at least half an hour away from food and drink. They were also told to abstain from any other sinus treatment for the period of the study.

An assumption of the study was that the patients took the medicines as prescribed; every effort was made to provide clear instructions regarding the frequency and amount of capsules to be taken. The researcher emphasized the importance of adhering to these instructions.

### **3.6 MEASUREMENT TOOLS**

Quantitative measurement was conducted by means of a Patient Perception Questionnaire (Appendix C) adapted from the Short-Form McGill Pain Questionnaire (Melzack & Turk, 1992). This questionnaire was filled in at each consultation.

Scores were assigned in the following manner. Patients rated each symptom as either severe, moderate, slight or none. 'Severe' receiving a score of 1,

'moderate' a score of 2, 'slight' a score of 3 and 'none' a score of 4. A maximum total score being 52 and a minimum total score being 13.

## **3.7 CONSULTATION PROCEDURES**

Patients consulted with the researcher 3 times during the study. At the beginning of the first consultation patients were asked to read the Subject Information Letter (Appendix A) and sign the Informed Consent Form (Appendix B). Following this the researcher assessed the patients according to the inclusion and exclusion criteria and a diagnosis was made. A case history and systems review were conducted to eliminate any serious condition that may have existed. Vital signs were also measured. Patients then returned a week later for a follow-up consultation (Follow Up 1) and again after another week for a final consultation (Follow Up 2). Their involvement in the study ended after this two-week period. Patients were asked to fill in the Patient Perception Questionnaire (Appendix C2) adapted from the Short-Form McGill Pain Questionnaire (Melzack and Turk, 1992) on all three consultations.

## **3.8 DATA ANALYSIS**

### **3.8.1 STATISTICAL METHODS**

Patients were assessed using a Patient Perception Questionnaire (Appendix C2) adapted from the Short-Form McGill Pain Questionnaire (Melzack & Turk, 1992). The patients were graded according to the severity of their symptoms. The symptoms that were included in the questionnaire were: Headaches, Facial Pain or Pressure, Nasal Discharge, Post Nasal Drip, Nasal Obstruction and Accompanying Symptoms. Each question received a score according to whether

the patient graded it as 'severe', 'moderate', 'slight' or 'none'. The questionnaire was completed, and scores given, at the first consultation (baseline measurement), after second consultation (Follow Up 1) and after the third consultation (Follow Up 2). The information was analysed using non-parametric methods of data analysis. The statistical package that was used was SPSS Version 9.

## 3.8.2 STATISTICAL ANALYSIS

### 3.8.2.1 Procedure 1 – Friedman's Test

The intra-group analysis was done using the Friedman's ANOVA method i.e. the questionnaire scores between consultation one (baseline), consultation two (Follow Up 1) and consultation three (Follow Up 2) were compared. This was done for both the treatment group and the placebo group. Each question of the questionnaire was analysed separately: Question 1, Question 2a, 2b, 2c, 2d, Question 3, Question 4, Question 5a, 5b, 5c, 5d, 5e, 5f, as well as a total for Question 2, Question 5 and a total score for the entire questionnaire.

#### (i) Hypothesis testing

The null hypothesis  $H_0$ , states that there is no significant difference between the visits being compared at the  $\alpha = 0.05$  level of significance. The alternative hypothesis  $H_1$ , states that at least two of the visits will differ significantly at the same level of significance.

#### (ii) Decision rule

At the  $\alpha = 0.05$  level of significance, the null hypothesis is rejected if  $p \leq \alpha$  where

p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

### **3.8.2.2 Procedure 2 – Wilcoxon's Signed Rank Test**

The Wilcoxon's Signed Rank Test was done to determine between which two visits the difference lies. This was only done for the questions in which a significant difference (improvement) between visits was found i.e. Friedman's Test showed a significant difference.

#### **(i) Hypothesis testing**

The null hypothesis  $H_0$ , states that there is no significant difference between the two visits being compared at the  $\alpha = 0.05$  level of significance. The alternative hypothesis  $H_1$ , states that there is a significant difference between the two visits being compared.

#### **(ii) Decision rule**

At the  $\alpha = 0.05$  level of significance, the null hypothesis is rejected if  $p \leq \alpha/2$  where p is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

### **3.8.2.3 Procedure 3 – Kruskal-Wallis Test**

The inter-group analysis was done using the Kruskal-Wallis non-parametric Analysis of Variance (ANOVA) method. Groups one and two were compared to each other with regards to the scores given to the questions at each consultation.

#### **(i) Hypothesis testing**

In each test the null hypothesis  $H_0$ , states that there is no significant difference

between the two groups at the  $\alpha = 0.05$  level of significance. The alternative hypothesis  $H_1$ , states that at least two of the groups will differ significantly at the same level of significance.

**(ii) Decision rule**

At the  $\alpha = 0.05$  level of significance, the null hypothesis is rejected if  $p \leq \alpha$  where  $p$  is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

**3.8.2.4 Procedure 4 – Comparison using bar charts**

Analytical findings were summarised in a visual format by means of bar charts to compare the Treatment and Placebo Group with respect to the scores given to each question. Means were used to construct the bar charts.

## **CHAPTER FOUR**

## **4.1 INTRODUCTION**

In this chapter the results obtained from statistical analysis of the data from the two groups used in the trial will be discussed.

## **4.2 CRITERIA FOR ADMISSIBILITY OF THE DATA**

Only data collected from this trial was used in the results chapter and only data collected as was described in Chapter 3.

## **4.3 BAR CHARTS 4 – COMPARISONS OF MEAN SCORES.**

Figure 4.1 - Bar chart for Question 1 (patients' perception of headaches).

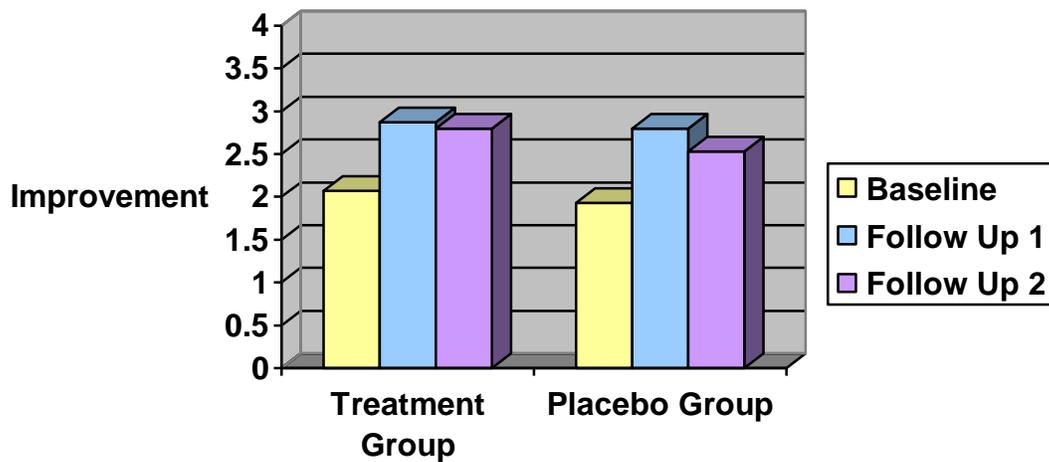


Figure 4.2 - Bar chart for Question 2a (patients' perception of facial pain / pressure on the forehead).

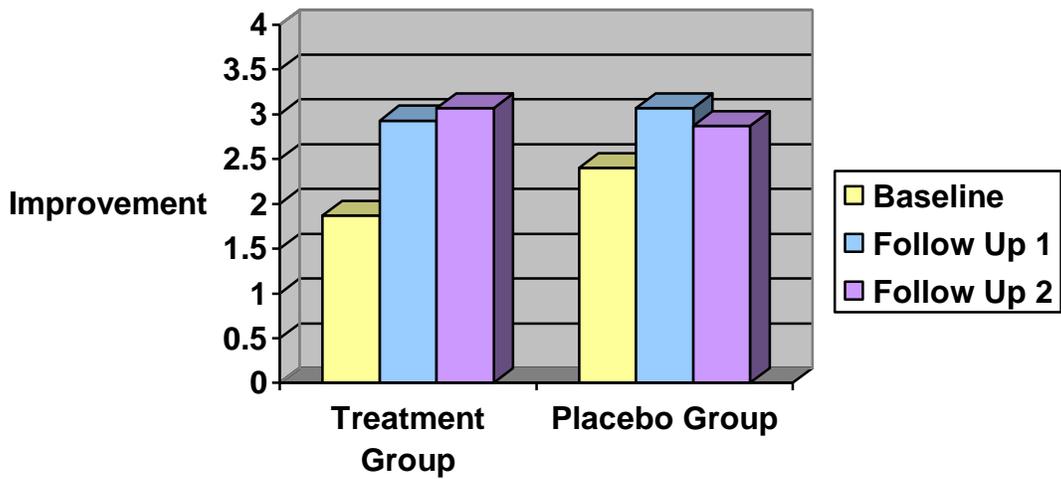


Figure 4.3 - Bar chart for Question 2b (patients' perception of facial pain / pressure in the cheeks).

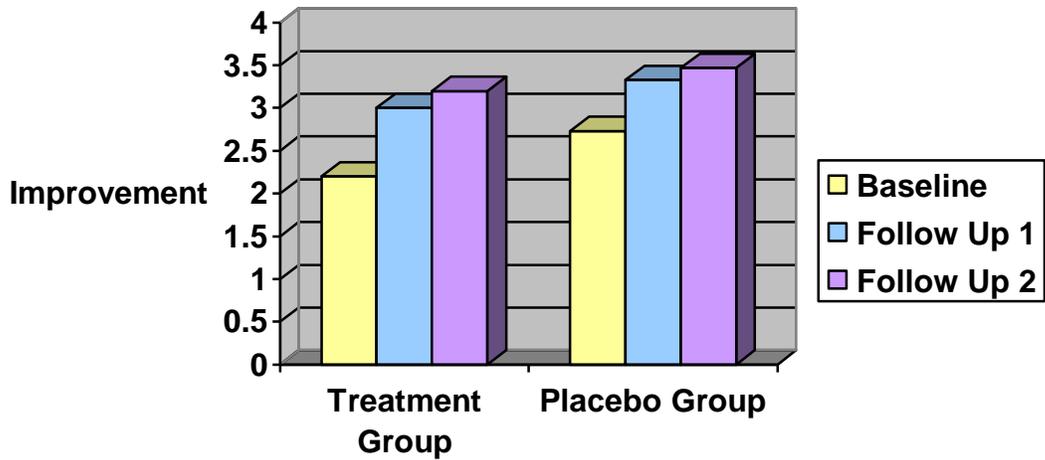


Figure 4.4 - Bar chart for Question 2c (patients' perception of facial pain / pressure around the eyes).

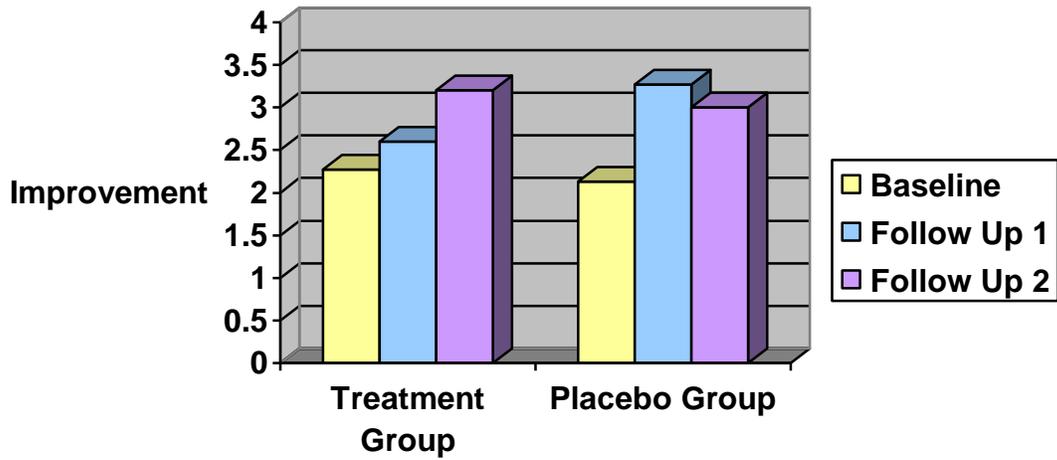


Figure 4.5 - Bar chart for Question 2d (patients' perception of facial congestion / fullness).

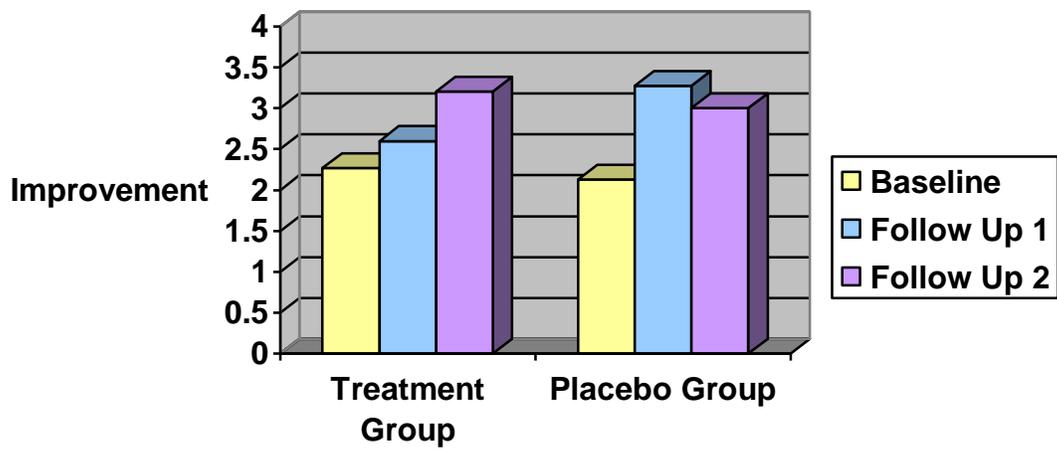


Figure 4.6 - Bar chart of total score for Question 2 (patients' perception of facial pain / pressure).

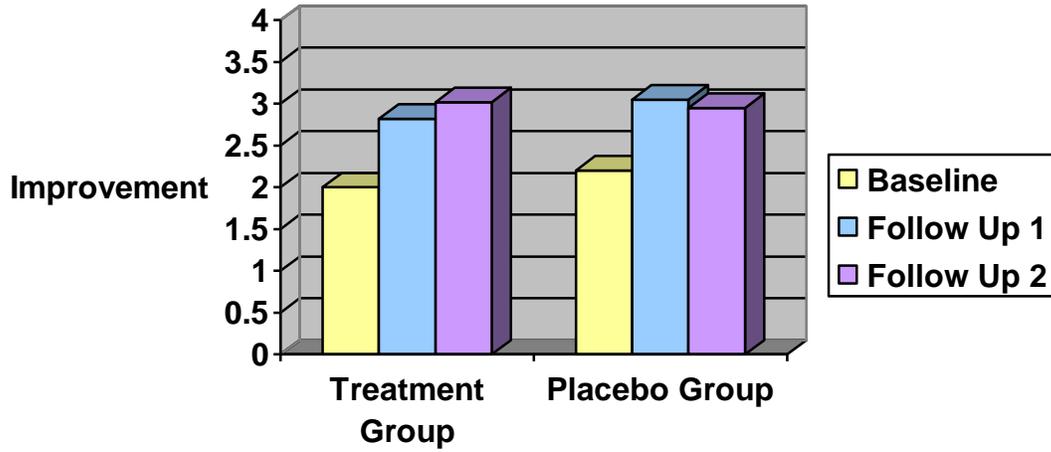


Figure 4.7 - Bar chart for Question 3 (patients' perception of nasal discharge).

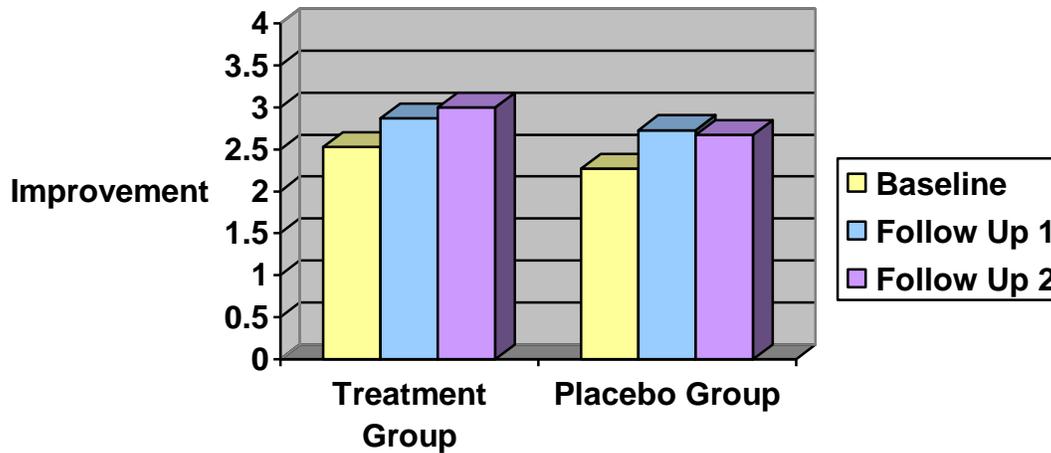


Figure 4.8 -Bar chart for Question 4 (patients' perception of post nasal drip).

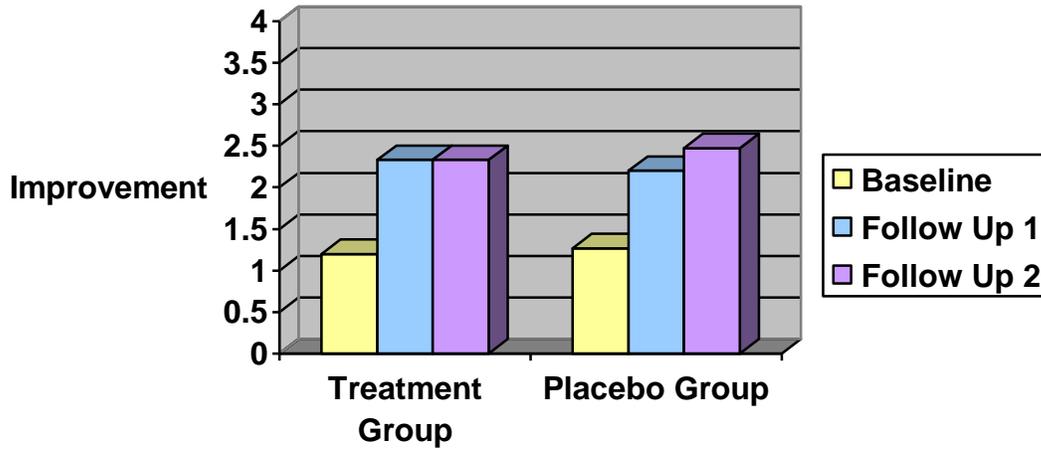


Figure 4.9 - Bar chart for Question 5a (patients' perception of nasal obstruction).

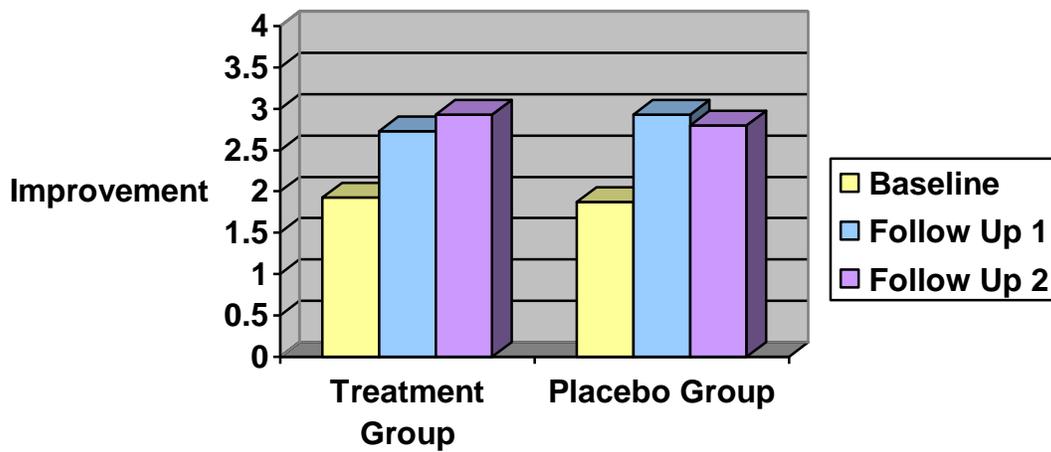


Figure 4.10 - Bar chart for Question 5b (patients' perception of loss of taste).

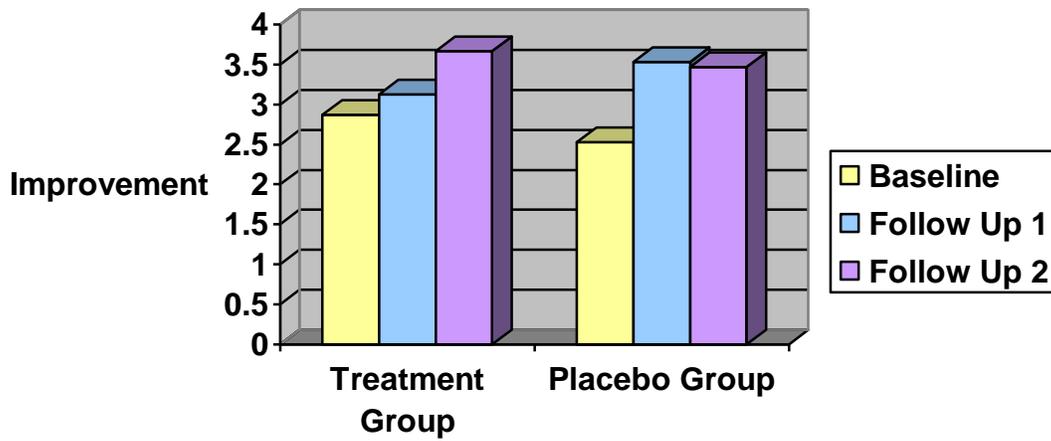


Figure 4.11 - Bar chart for Question 5c (patients' perception of loss of smell).

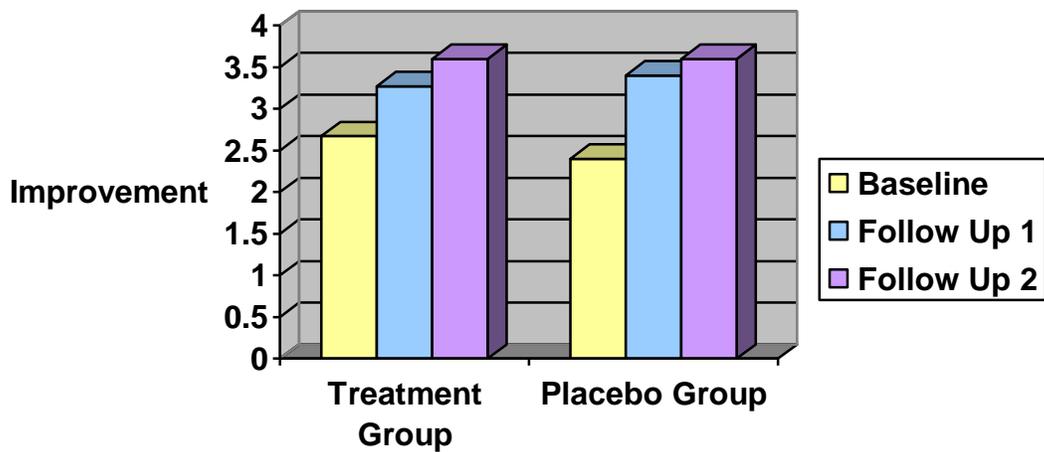


Figure 4.12 - Bar chart for Question 5d (patients' perception of halitosis / offensive breath).

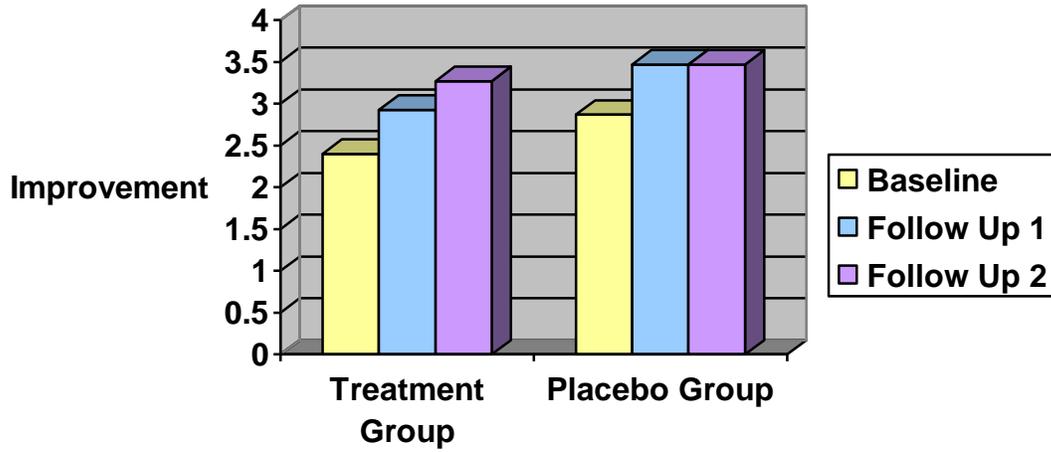


Figure 4.13 - Bar chart for Question 5e (patients' perception of toothache).

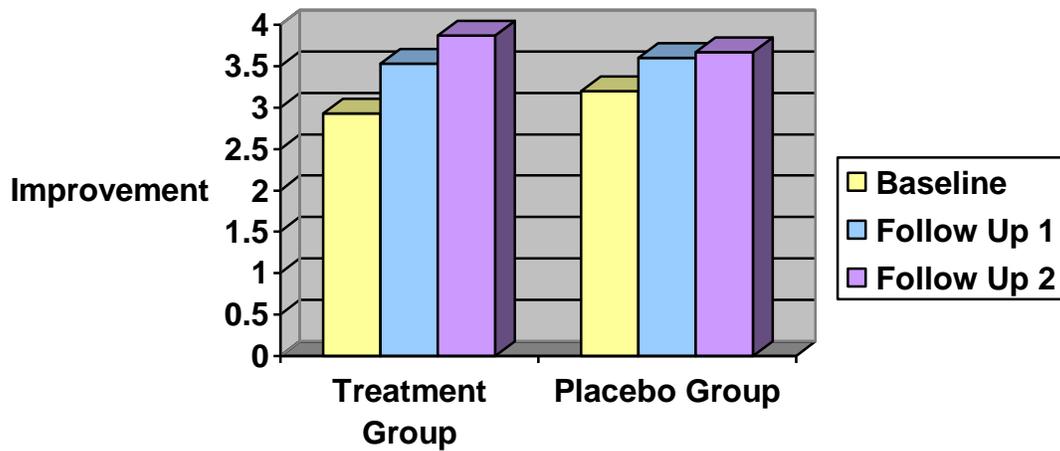


Figure 4.14 - Bar chart for Question 5f (patients' perception of earache).

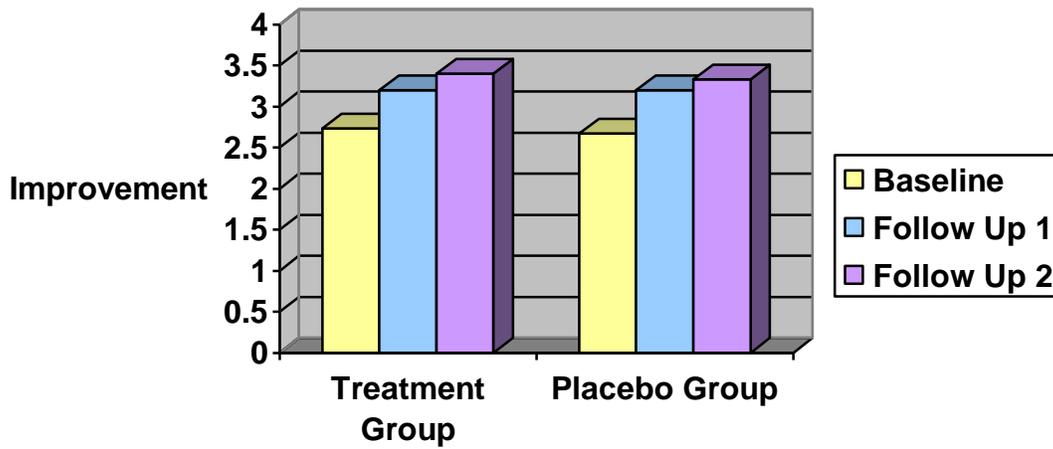


Figure 4.15 - Bar chart for total score of Question 5 (patients' perception of accompanying symptoms).

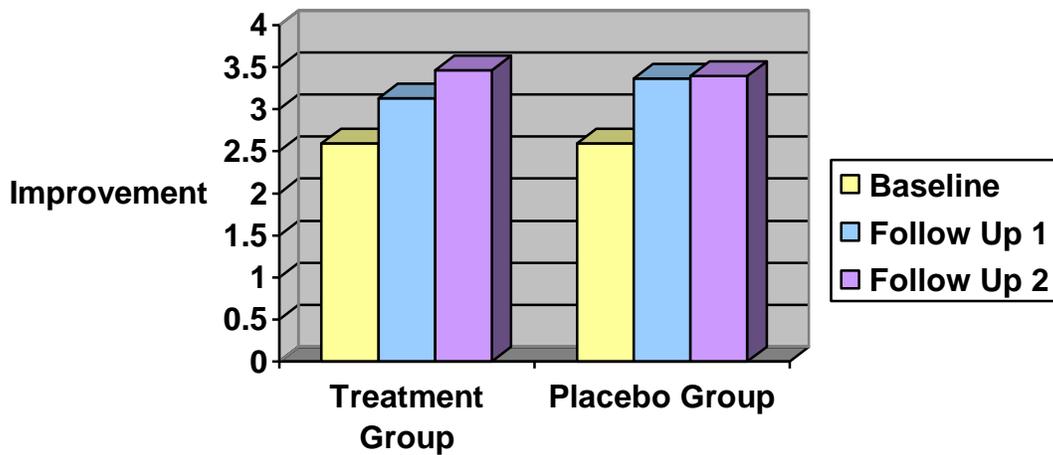
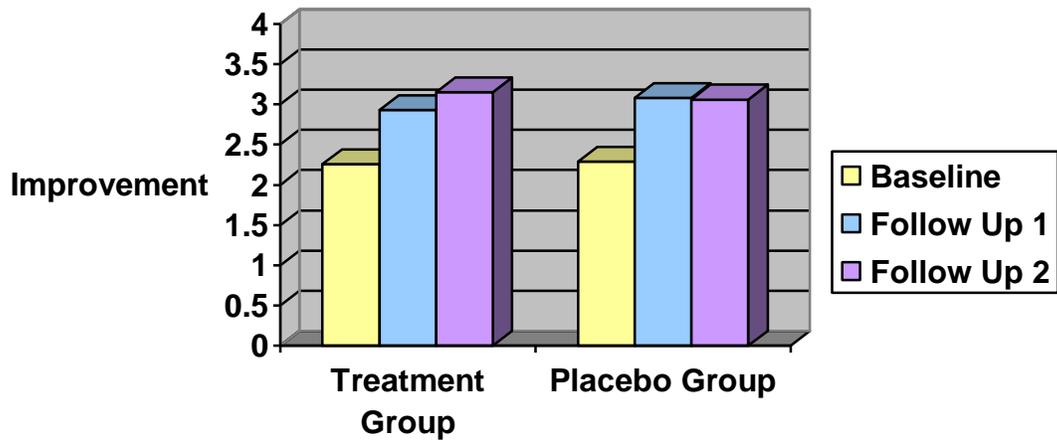


Figure 4.16 - Bar chart for total score of Patient Perception Questionnaire.



#### 4.4 INTRA-GROUP ANALYSIS

## 4.4.1 GROUP 1 – TREATMENT GROUP

Friedman's test was used to analyse difference in scores between consultations (see Table 4.1)

**Table 4.1 – Friedman's test for the Treatment Group**

Question	Means			P-Value
	Baseline	Follow Up 1	Follow Up 2	
1	2.07	2.87	2.80	<b>0.035 *</b>
2a	1.87	2.93	3.07	<b>0.001 *</b>
2b	2.20	3.00	3.20	<b>0.003 *</b>
2c	2.27	2.60	3.20	<b>0.001 *</b>
2d	1.67	2.73	2.60	<b>0.002 *</b>
3	2.53	2.87	3.00	0.325
4	1.20	2.33	2.33	<b>0.000 *</b>
5a	1.93	2.73	2.93	<b>0.009 *</b>
5b	2.87	3.13	3.67	<b>0.020 *</b>
5c	2.67	3.27	3.60	<b>0.001 *</b>
5d	2.40	2.93	3.27	<b>0.001 *</b>
5e	2.93	3.53	3.87	<b>0.001 *</b>
5f	2.73	3.20	3.40	0.060
2 Total	200	2.82	3.02	<b>0.000 *</b>
5 Total	2.59	3.13	3.46	<b>0.000 *</b>
1-5 Total	2.26	2.93	3.15	<b>0.000 *</b>

\* = P-Value of significance

Further analysis was done on the questions for which there was a significant difference i.e. the P-Value < 0.05 (those in bold type). This was done using Wilcoxon's Signed Rank Test, which determined between which consultation the significant difference lay.

**Table 4.2 – Wilcoxon's Signed Rank test for the Treatment Group**

Question	Consultations	Means	P-Value
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1	B – 1	2.07	2.87	<b>0.012 *</b>
	1 – 2	2.87	2.80	0.705
	B – 2	2.07	2.80	<b>0.046 *</b>
2a	B – 1	1.87	2.93	<b>0.003 *</b>
	1 – 2	2.93	3.07	0.564
	B – 2	1.87	3.07	<b>0.004 *</b>
2b	B – 1	2.20	3.00	<b>0.013 *</b>
	1 – 2	3.00	3.20	0.366
	B – 2	2.20	3.20	<b>0.007 *</b>
2c	B – 1	2.27	2.60	0.190
	1 – 2	2.60	3.20	<b>0.007 *</b>
	B – 2	2.27	3.20	<b>0.004 *</b>
2d	B – 1	1.67	2.73	<b>0.007 *</b>
	1 – 2	2.73	2.60	0.755
	B – 2	1.67	2.60	<b>0.004 *</b>
4	B – 1	1.20	2.33	<b>0.004 *</b>
	1 – 2	2.33	2.33	1.000
	B – 2	1.20	2.33	<b>0.002 *</b>
5a	B – 1	1.93	2.73	<b>0.017 *</b>
	1 – 2	2.73	2.93	0.366
	B – 2	1.93	2.93	<b>0.007 *</b>
5b	B – 1	2.87	3.13	0.157
	1 – 2	3.13	3.67	0.066
	B – 2	2.87	3.67	<b>0.020 *</b>
5c	B – 1	2.67	3.27	<b>0.003 *</b>
	1 – 2	3.27	3.60	0.129
	B – 2	2.67	3.60	<b>0.011 *</b>
5d	B – 1	2.40	2.93	<b>0.011 *</b>
	1 – 2	2.93	3.27	<b>0.025 *</b>
	B – 2	2.40	3.27	<b>0.006 *</b>
5e	B – 1	2.93	3.53	<b>0.021 *</b>
	1 – 2	3.53	3.87	0.157
	B – 2	2.93	3.87	<b>0.004 *</b>
2 Total	B – 1	2.00	2.82	<b>0.004 *</b>
	1 – 2	2.82	3.02	0.268
	B – 2	2.00	3.02	<b>0.002 *</b>
5 Total	B – 1	2.59	3.13	<b>0.001 *</b>
	1 – 2	3.13	3.46	<b>0.030 *</b>
	B – 2	2.59	3.46	<b>0.001 *</b>
1-5 Total	B – 1	2.26	2.93	<b>0.001 *</b>
	1 – 2	2.93	3.15	0.141
	B – 2	2.26	3.15	<b>0.001 *</b>

\* = *P-Value of significance*  
B = *Baseline (initial) consultation*  
1 = *1<sup>st</sup> follow-up consultation*  
2 = *2<sup>nd</sup> follow-up consultation*

The Wilcoxon's Signed Rank Test was used to determine between which consultations the significant difference lay. At the  $\alpha = 0.05$  level of significance, the tests revealed the following:

**Results for Question 1 (How would you describe your headache?):**

There was a significant improvement between the baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2a (How would you grade facial pain / pressure in the forehead?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2b (How would you grade facial pain / pressure in the cheeks?):**

There was a significant improvement between baseline and Follow Up 1 as well

as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2c (How would you grade facial pain / pressure around the eyes?):**

There was a significant improvement between baseline and Follow Up 2, as well as between Follow Up 1 and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between baseline and Follow Up 1 ( $p > 0.05$ ).

**Results for Question 2d (How would you grade facial congestion / fullness?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2 (Total score):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 4 (How would you grade post nasal drip?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5a (How would you grade nasal obstruction?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5b (How would you grade loss of taste?):**

There was a significant improvement between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between baseline and Follow Up 1 or between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5c (How would you grade loss of smell?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5d (How would you grade halitosis / offensive breath?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 and between Follow Up 1 and Follow Up 2 ( $p < 0.05$ ).

**Results for Question 5e (How would you grade toothache?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5 (Total score):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 and between Follow Up 1 and Follow Up 2 ( $p < 0.05$ ).

**Results for Questions 1 – 5 (Total score):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

## 4.4.2 GROUP 2 – PLACEBO GROUP

Friedman’s test was used to analyse difference in scores between consultations (see Table 4.3)

**Table 4.3 – Friedman’s test for the Placebo Group**

Question	Means			P-Value
	Baseline	Follow Up 1	Follow Up 2	
1	1.93	2.80	2.53	<b>0.009 *</b>

2a	2.40	3.07	2.87	0.262
2b	2.73	3.33	3.47	0.073
2c	2.13	3.27	3.00	<b>0.003</b> *
2d	1.53	2.53	2.47	<b>0.014</b> *
3	2.27	2.73	2.67	0.264
4	1.27	2.20	2.47	<b>0.000</b> *
5a	1.87	2.93	2.80	<b>0.006</b> *
5b	2.53	3.53	3.47	<b>0.002</b> *
5c	2.40	3.40	3.60	<b>0.000</b> *
5d	2.87	3.47	3.47	<b>0.005</b> *
5e	3.20	3.60	3.67	0.097
5f	2.67	3.20	3.33	<b>0.008</b> *
2 Total	2.2	3.05	2.95	<b>0.015</b> *
5 Total	2.59	3.36	3.39	<b>0.000</b> *
1-5 Total	2.29	3.08	3.06	<b>0.000</b> *

\* = P-Value of significance

Further analysis was done on the questions for which there was a significant difference i.e. the P-Value < 0.05 (those in bold type). This was done using Wilcoxon's Signed Rank Test, which determined between which consultation the significant difference lay.

**Table 4.4 – Wilcoxon's Signed Rank test for the Placebo Group**

Question	Consultations	Means		P-Value
1	B – 1	1.93	2.80	<b>0.008</b> *
	1 – 2	2.80	2.53	0.340
2c	B – 2	1.93	2.53	<b>0.038</b> *
	B – 1	2.13	3.27	<b>0.010</b> *
	1 – 2	3.27	3.00	0.380
2d	B – 2	2.13	3.00	0.070
	B – 1	1.53	2.53	<b>0.009</b> *
	1 – 2	2.53	2.47	0.942
4	B – 2	1.53	2.47	<b>0.014</b> *
	B – 1	1.27	2.20	<b>0.004</b> *
	1 – 2	2.20	2.47	0.206

	B – 2	1.27	2.47	<b>0.003 *</b>
5a	B – 1	1.87	2.93	<b>0.014 *</b>
	1 – 2	2.93	2.80	0.557
	B – 2	1.87	2.80	<b>0.006 *</b>
5b	B – 1	2.53	3.53	<b>0.002 *</b>
	1 – 2	3.53	3.47	0.739
	B – 2	2.53	3.47	<b>0.013 *</b>
5c	B – 1	2.40	3.40	<b>0.004 *</b>
	1 – 2	3.40	3.60	0.083
	B – 2	2.40	3.60	<b>0.004 *</b>
5d	B – 1	2.87	3.47	<b>0.024 *</b>
	1 – 2	3.47	3.47	1.000
	B – 2	2.87	3.47	<b>0.024 *</b>
5f	B – 1	2.67	3.20	<b>0.033 *</b>
	1 – 2	3.20	3.33	0.589
	B – 2	2.67	3.33	<b>0.008 *</b>
2 Total	B – 1	2.20	3.05	<b>0.004 *</b>
	1 – 2	3.05	2.95	0.932
	B – 2	2.20	2.95	<b>0.027 *</b>
5 Total	B – 1	2.59	3.36	<b>0.001 *</b>
	1 – 2	3.36	3.39	0.535
	B – 2	2.59	3.39	<b>0.002 *</b>
1-5 Total	B – 1	2.29	3.08	<b>0.001 *</b>
	1 – 2	3.08	3.06	0.733
	B – 2	2.29	3.06	<b>0.000 *</b>

\* = P-Value of significance

B = Baseline (initial) consultation

1 = 1<sup>st</sup> follow-up consultation

2 = 2<sup>nd</sup> follow-up consultation

The Wilcoxon's Signed Rank Test was used to determine between which consultations the significant difference lay. At the  $\alpha = 0.05$  level of significance, the tests revealed the following:

### **Results for Question 1 (How would you describe your headache?):**

There was a significant improvement between the baseline and Follow Up 1 as

well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2c (How would you grade facial pain / pressure around the eyes?):**

There was a significant improvement between baseline and Follow Up 1 ( $p < 0.05$ ). There was no significant improvement between baseline and Follow Up 2 or between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2d (How would you grade facial congestion / fullness?):**

There was a significant improvement baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 4 (How would you grade post nasal drip?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5a (How would you grade nasal obstruction?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant

improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5b (How would you grade loss of taste?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5c (How would you grade loss of smell?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5d (How would you grade halitosis / offensive breath?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5f (How would you grade earache?):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 2 (Total score):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Question 5 (Total score):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**Results for Questions 1 – 5 (Total score):**

There was a significant improvement between baseline and Follow Up 1 as well as between baseline and Follow Up 2 ( $p < 0.05$ ). There was no significant improvement between Follow Up 1 and Follow Up 2 ( $p > 0.05$ ).

**4.5 INTER-GROUP ANALYSIS**

Groups 1 and 2 were compared to each other with regards to all the questions in the Patient Perception Questionnaire using the Kruskal-Wallis non-parametric Analysis of Variance (ANOVA) method. It can be seen that there was no significant difference between the two groups for any of the questions that were asked i.e.  $p > 0.05$ .

**Table 4.5 – Kruskal-Wallis test for inter-group analysis**

		<b>Means</b>		<b>P-Values</b>
		<b>Group 1 (Treatment)</b>	<b>Group 2 (Placebo)</b>	
Question 1	Baseline	2.07	1.93	0.551
	Follow Up 1	2.87	2.80	0.982
	Follow Up 2	2.80	2.53	0.478
Question 2a	Baseline	1.87	2.40	0.134
	Follow Up 1	2.93	3.07	0.691
	Follow Up 2	3.07	2.87	0.639
Question 2b	Baseline	2.20	2.73	0.124
	Follow Up 1	3.00	3.33	0.350
	Follow Up 2	3.20	3.47	0.545
Question 2c	Baseline	2.27	2.13	0.695
	Follow Up 1	2.60	3.27	0.066
	Follow Up 2	3.20	3.00	0.502
Question 2d	Baseline	1.67	1.53	0.447
	Follow Up 1	2.73	2.53	0.423
	Follow Up 2	2.60	2.47	0.709
Question 3	Baseline	2.53	2.27	0.619

	Follow Up 1	2.87	2.73	0.650
	Follow Up 2	3.00	2.67	0.340
Question 4	Baseline	1.20	1.27	0.671
	Follow Up 1	2.33	2.20	0.698
	Follow Up 2	2.33	2.47	0.743
Question 5a	Baseline	1.93	1.87	0.947
	Follow Up 1	2.73	2.93	0.527
	Follow Up 2	2.93	2.80	0.665
Question 5b	Baseline	2.87	2.53	0.364
	Follow Up 1	3.13	3.53	0.209
	Follow Up 2	3.67	3.47	0.541
Question 5c	Baseline	2.67	2.40	0.521
	Follow Up 1	3.27	3.40	0.782
	Follow Up 2	3.60	3.60	1.000
Question 5d	Baseline	2.40	2.87	0.326
	Follow Up 1	2.93	3.47	0.199
	Follow Up 2	3.27	3.47	0.626
Question 5e	Baseline	2.93	3.20	0.375
	Follow Up 1	3.53	3.60	0.777
	Follow Up 2	3.87	3.67	0.340
Question 5f	Baseline	2.73	2.67	0.779
	Follow Up 1	3.20	3.20	0.805
	Follow Up 2	3.40	3.33	0.942
Q2 Total	Baseline	2.00	2.20	0.477
	Follow Up 1	2.82	3.05	0.437
	Follow Up 2	3.02	2.95	0.541
Q5 Total	Baseline	2.59	2.59	0.884
	Follow Up 1	3.13	3.36	0.531
	Follow Up 2	3.46	3.39	0.883
Q1- 5 Total	Baseline	2.26	2.29	0.967
	Follow Up 1	2.93	3.08	0.678
	Follow Up 2	3.15	3.06	0.547

## **CHAPTER FIVE**

### **DISCUSSION**

This double blind placebo-controlled study was conducted to determine the efficacy of Natura's Nasosinus (Hepar sulphuris calcareum D3, Nux vomica D3 and Pulsatilla pratensis D3) in the treatment of acute sinusitis, in terms of patients' perception of response to treatment.

The results of the Patient Perception Questionnaire indicate that for both groups there was a significant improvement within the group. In the Treatment Group (Group 1), the patients perceived significant improvement in 14 out of the 16 aspects of sinusitis on which they were graded. This was better than the Placebo Group (Group 2), which perceived significant improvement in only 12 out of the

16 questions.

However, statistical analysis of the scores, for all 16 questions, revealed that there was no significant difference between the two groups, indicating that the homoeopathic complex, Nasosinus, was no more effective than placebo in the treatment of acute sinusitis.

When the data was reviewed it was apparent that for many of the questions / symptoms, the Treatment Group did show a general positive trend throughout the measurement period. When the bar charts are studied, it is evident that for 13 out of the 16 questions, the Treatment Group showed an improvement from baseline to Follow Up 1 and then a further improvement by Follow Up 2. In the other 3 questions the patients' symptoms either seemed to stay the same or regress only slightly. When the bar charts are studied for the Placebo Group, it is evident that for only 6 out of the 16 questions was there an improvement from baseline to Follow Up 1 and then a further improvement by Follow Up 2. For 9 out of the 16 questions the patients' symptoms regressed from Follow Up one to Follow Up two and in one question the symptom score stayed the same from Follow Up one to Follow Up two. If the patients had been monitored for a longer period it may have revealed that the condition resolved to a significant degree for the Treatment Group, but not for the Placebo Group.

A review of the related literature revealed only one study similar to this one ( a

double blind, placebo controlled clinical trial evaluating the efficacy of a homoeopathic complex in the treatment of sinusitis); Ebrahim (2003).

Although the Ebrahim (2003) study made use of differing measurement tools, and a different homoeopathic complex it is however useful to compare the findings with this study in an attempt to critically evaluate the use of homoeopathic complexes in general for the treatment of sinusitis. The homoeopathic complex (Hydrastis canadensis 9CH, Kalium bichromicum and Sambucus nigra 9CH) although producing significant improvement within the treatment group (intra-group improvement) was shown to be no more effective than placebo when the two groups were compared with each other (inter-group analysis) i.e. the placebo group also improved to a statistically similar degree. Ebrahim (2003) concluded therefore that the homoeopathic complex in question was not effective in the treatment of chronic sinusitis. The findings of this study do thus concur with those of Ebrahim (2003).

If one were to compare the findings of this study with other homoeopathic placebo controlled sinusitis trials in general i.e. Dlamini (2003) and Ismail (2003) who tested the efficacy of the main miasmatic nosodes and homoeopathic similimum respectively one would find similar conclusions i.e. intra-group improvement of placebo and treatment groups and insignificant differences in improvement when comparing the two groups.

When formulating a homoeopathic complex such as Nasosinus the ingredients are selected on the basis that their symptomatology has a degree of similarity to that of the disease for which it is indicated i.e. each ingredient of this complex is strongly indicated in the treatment of acute sinusitis according to their materia medica and the law of similars. The materia medica from which the indications of each ingredient for the treatment of sinusitis are derived is compiled from homoeopathic drug provings of these substances. These substances are proven individually and never in combination or complex form.

No provings have been carried out on Nasosinus (or complexes in general) and little information exists with regards to the summative effects of mixing ingredients (polypharmacy) (Kayne, 1997). Thus one cannot be certain how the individual remedies interact with each other and thus cannot be certain of the effect a complex of remedies will have. Based on the results of this study one cannot assume that a complex of homoeopathic remedies will have an effect that equals the sum of its parts i.e. the complex will act by means of as each of the individual remedies or a combined summative effect.

Thus provings would need to be done on combination remedies such as Nasosinus so that their indication for use can be ascertained or confirmed. It may too have been beneficial to assess the remedies individually instead of in complex form.

The placebo effect also needs to be considered. This is when improvement occurs even though the patient is on placebo. This can be attributed to the patient's confidence in the research or researcher, their optimism and expectations that their symptoms will improve on the treatment. The patient may also desire to please the researcher and thus not reflect their symptoms accurately.

Another aspect is the possibility of attributing improvement in both groups to the fact that symptoms could have spontaneously changed or improved due to natural progression of the condition.

The subjectivity of the questionnaire may also be the reason for the lack of significant improvement between the two groups. A more objective method may have been a more accurate method to measure improvement.

Patients were given the homoeopathic complex for a period of 7 days. Patients may, however, have benefited from a longer treatment period.

A larger sample group may have yielded more significant results. In this study a sample size of only 30 patients was used.

It was assumed that all patients were compliant and took the medication as they were instructed to do. There is always the possibility that this was not done which could have affected the effectiveness of the Nasosinus.

## **CHAPTER SIX**

### **CONCLUSION AND RECOMMENDATIONS**

#### **6.1 CONCLUSION**

The results of this study lead to the conclusion that the homoeopathic complex Nasosinus (Hepar sulphuris calcareum D3, Nux vomica D3 and Pulsatilla pratensis D3) was shown to be statistically no more effective than placebo in the treatment of acute sinusitis and thus not effective in the treatment of acute sinusitis.

#### **6.2 RECOMMENDATIONS**

The following recommendations are made for further research:

1. Limit the study to one particular symptom of the condition.
2. Use a homogenous sample group i.e. same gender and age.
3. Increase the sample size of the study.
4. Take the medicines for longer than 7 days.
5. Monitor patients over a longer period.

6. Use objective measurement tools.

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## **SUBJECT INFORMATION LETTER:**

TITLE OF RESEARCH PROJECT: The efficacy of Nasosinus (Hepar sulphuris calcareum D3, Nux vomica D3 and Pulsatilla pratensis D3) in the treatment of acute sinusitis.

NAME OF SUPERVISOR: Dr. David Naude (M. Tech: Hom)

NAME OF RESEARCHER: Shelley Main

Dear participant

Thank you for taking the time to read this letter – with your help the efficacy of homoeopathic treatment in acute sinusitis can be investigated, increasing the safe and effective treatment options available to patients in the future.

I am a homoeopathy student at the Durban Institute of Technology. In order to qualify as a homoeopath, a mini-dissertation has to be completed. This mini dissertation takes the form of a research project in which I will test the efficacy of homoeopathic treatment in alleviating the symptoms of acute sinusitis. In order to test this I appeal to you to assist me by informing me of your symptoms before and during the study.

Each participant must comply with the following criteria before being selected to participate in the study:

1. Individuals must be between the ages of 18 and 65
2. Individuals must have been suffering from sinusitis for no longer than 3 weeks
3. Individuals must have taken no other sinus medication for at least 48 hours prior to commencement of the study
4. Individuals must be English literate

The following will be excluded:

1. Pregnant females
2. Individuals already taking antibiotics
3. Individuals with respiratory conditions such as severe asthma
4. For the duration of the study no other treatment will be permitted apart from chronic medication being used for an unrelated condition such as diabetes or hypertension

If you fulfill the criteria above (and are willing to participate), then you will be included in the study group. The study will last for 2 weeks and the researcher will need to see you 3 times during these 2 weeks i.e. at the beginning (1<sup>st</sup> consultation), after 1 week during which you will take capsules (2<sup>nd</sup> consultation), and then after the second week during which no capsules will be taken (3<sup>rd</sup>

consultation). I urge you to consult on all 3 occasions otherwise your results cannot be included in the study. During these consultations you will be asked to fill in a questionnaire about how you perceive your sinusitis. You will also be briefly examined to assess your sinuses. All information will be kept confidential. Once the dissertation is published the patient files will be destroyed and no names will appear on the dissertation.

In order for the study to be scientifically acceptable it is necessary to use a 'double blind placebo controlled' study. This means that 50% of the participants will receive medicated capsules and the other 50% of the participants will receive placebo (unmedicated) capsules that look identical. 'Double blind' means neither the patient nor the researcher will know who receives medicated or unmedicated capsules. This will only be revealed after the study has been completed and the data is analysed.

There will be 40 patients accepted into the study. 20 will receive placebo and the other 20 medicated capsules. There is a 50% chance that you may receive placebo. If this is the case, you will be entitled to free treatment at the end of the trial.

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

You are free to withdraw from the study at any time without giving reasons. If you have any questions please don't hesitate to contact me or my supervisor on the following numbers:

Shelley Main – 083-293-2390 or 039-976-2978 (W)

**Dr. Naude (M.Tech: Hom) – 031-204-2041**

Thank you  
Shelley Main  
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 Nasosinus (Hepar sulphuris calcareum D3, Nux vomica D3 and Pulastilla pratensis D3) in the treatment of acute sinusitis.

NAME OF SUPERVISOR: Dr. David Naude (M.Tech: Hom)

NAME OF RESEARCH STUDENT: Shelley Main

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: \_\_\_\_\_

### **APPENDIX C1**

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

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

Instructions:

- a) Please answer the questions as objectively and as accurately 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.

**APPENDIX C2**

Patient no.: \_\_\_\_\_  
Consultation no.: \_\_\_\_\_  
Date: \_\_\_\_\_

**PATIENT PERCEPTION QUESTIONNAIRE**  
Adapted from: *Short-Form McGill Pain Questionnaire*  
(Melzack and Turk, 1992)

**Each question is graded, using a scale consisting of four gradings, the highest (4) being the most severe.**



		2 moderate
		3 slight
		4 none
5c) Loss of smell		1 severe
		2 moderate
		3 slight
		4 none
5d) Halitosis (offensive breath)		1 severe
		2 moderate
		3 slight
		4 none
5e) Toothache		1 severe
		2 moderate
		3 slight
		4 none
5f) Earache		1 severe
		2 moderate
		3 slight
		4 none