The efficacy of the main miasmatic nosodes in the treatment of chronic sinusitis.

by

NOMTHANDAZO DLAMINI

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I, Nomthandazo Dlamini, do hereby declare that this dissertation represents my own work both in concept and execution.

Signature of student	Date of signature

APPROVED FOR FINAL SUBMISSION

Signature of Supervisor	Date of signature
Dr R. Steele B.A., H.D.E., M.Tech. Hom. (T.N.)	

DEDICATION

This dissertation is dedicated to my family:

Mom, dad, Sphamandla, Sthembiso, and my late brother Sokesimbone Dlamini.

ISETHULO

Kumalunga omndeni:

u Mama, u baba, u Sphamandla, u Sthembiso, kanye

nomfowethu ongasekho u Sokesimbone Dlamini.

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Thank You Almighty God for giving me the words of encouragement during difficult moments:

Psalm 27:1,3,5 and 14

The Lord is my light and my salvation; whom shall I fear?

The Lord is the strength of my life; of whom shall I be afraid?

Though an army may encamp against me, my heart shall not fear;

Though war may arise against me, in this I will be confident.

For in the time of trouble He shall hide me in His pavilion;

Wait on the Lord, be of good courage, and He shall strengthen

Your heart; wait, I say, on the Lord.

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Ngithanda ukudlulisa amazwi okubonga kulabantu abagisingathile kulolucwaningo:

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Noma impi imisa ngakimi, inhliziyo yami ayesabi

Noma ngivukelwa ngukulwa, nokho nginethemba.

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ABSTRACT

The purpose of this double blind placebo controlled study was to evaluate the efficacy of the main miasmatic nosodes in the treatment of chronic sinusitis in terms of the patients' perception of the treatment.

The study was conducted at the Durban Institute of Technology Homoeopathy Day Clinic.

Thirty participants were selected for this double blind placebo controlled study, with fifteen being randomly assigned to the treatment group and fifteen to the placebo group. Treatment consisted of powders that were administered three times a day over a period of five days, with follow-up after three weeks.

The patients' perception of the treatment was assessed using the General Well-Being Questionnaire (McDowell and Newell, 1996) (Appendix C1) and Sinus Symptom Visual Analogue Scale (Walker and White, 2000) (Appendix C2) that were answered before and after treatment period.

All data obtained from questionnaires was statistically analysed using a one-sample t-test, and Mann-Whitney U test.

The General Well-Being Questionnaire results showed that there were elements of improvement within the treatment group before and after treatment, but there was no significant difference between the treatment group and the placebo group.

The Sinus Symptom Visual Analogue Scale results showed that in both groups, the scores before and after treatment showed a significant difference, but there was no significant difference between the treatment and the placebo group.

Thus it was concluded that that the main miasmatic nosodes are not effective in the treatment of chronic sinusitis.

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DEFINITION OF TERMS

Rhinitis: is an inflammation of the mucous membrane of the nose (Solomon et al., 1990: 826).

Kartagener's syndrome: An autosomal recessive disorder, is frequently associated with abnormalities of the cilia that impair mucociliary clearance in the airways, leading to persistent infections (Kumar, 1997: 403).

Ostiomeatus: is the outflow tract from the sinuses and includes the ostium (a tubular organ, or between distinct cavities within the body of each sinus) (Tichenor, 2003) as well as the meati (a canal that enters a structure) (Moore, 1992: 13).

Aspergillosis: opportunistic infections caused by *Aspergillus* species and inhaled as mould conidia, leading to hyphal growth and invasion of blood vessels, hemorrhagic necrosis, infarction, and potential dissemination to other sites in susceptible patients (Berkow and Beers, 1999:668).

Conchae: are uneven scroll-shaped elevations that form the lateral wall of the nasal cavity (Moore, 1992: 758).

Anosmia: loss of the sense of smell (Solomon et al., 1990: 1153).

Oedema: is the swelling that occurs as a result of an increase in the interstitial fluid (Solomon et al., 1990: 794).

Transillumination: the passage of light through body tissues for the purpose

of examination (Bates, 1995: 192).

Halitosis: offensive breath (Edwards, 1995: 415).

Somnoplasty: Radiofrequency tissue ablation of the inferior turbinates using a thermocouple feedback electrode procedure to relieve chronic nasal obstruction (Doctors Guide, 2003).

CHAPTER ONE

1.1 INTRODUCTION

Sinusitis is defined as a condition manifested by inflammation of the mucous membranes (possibly including neuroepithelium) of the nasal cavity and paranasal sinuses, fluids within these cavities, and/or underlying bone (Lanza and Kennedy, 1997).

Approximately thirty percent of the population is affected by sinusitis at some point in their lifetime. Sinusitis is one of the most commonly increasing health problems worldwide. (Tichenor, 2000.) Often, people with chronic sinusitis complain of fatigue, lack of concentration, poor productivity, and general discomfort (Ullman, 2002: 11-23).

Sinusitis was the 5th leading cause for antibiotic prescriptions between 1985 and 1992. (Kaliner et al., 1997: S1-20).

Antibiotics do not always bring medium to long-term relief, and are often followed by persistence of symptoms leading to a chronic state of sinusitis that is very difficult to treat successfully (National Allergy and Infectious Diseases, 2001).

Corticosteroids are amongst the potent drugs used for chronic sinusitis in conventional medicine that often lead to conditions such as growth retardation and poor immune systems as a result of long term treatment (McDonogh, 1999).

Even surgery gives only temporary relief and does not guarantee a permanent

recovery from sinusitis as many patients experience more congestion and swelling of the nasal passages following this procedure (Adler, M. 1999).

Homoeopathic medicines may produce additional symptoms during the course of treatment, but these are rarely serious or harmful, and disappear quickly (the so called “Homoeopathic aggravation”) (Hahnemann, 1997: 220). Homoeopathy attempts to bring each individual to the highest level of health possible on the physical, mental, and emotional levels. In acute and chronic disease, whether the symptoms are physical, mental, or emotional, homoeopathy produces subtle, yet often dramatic, healing and elimination of the underlying susceptibility to developing a disease state.
(Ullman, 1995:11-23.)

Samuel Hahnemann affirmed that, “the ideal cure is rapid, gentle and permanent restoration of health in the shortest, most reliable, and most harmless way” (Hahnemann, 1997: 92).

Implicit in this approach is the idea formulated by Hahnemann that it is impossible to fundamentally and permanently cure a chronic disease state unless treatment is directed towards the underlying miasm/s (Watson, 1991: 41).

Therefore the main aim of this double blind placebo controlled study was to determine the efficacy of the main miasmatic nosodes in improving the symptoms of chronic sinusitis in terms of the patient's perception of the treatment.

1.2 HYPOTHESIS

It is hypothesised that the main miasmatic nosodes are not effective in the treatment of chronic sinusitis.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

Sinusitis is defined as a condition manifested by inflammation of the mucous membranes (possibly including neuroepithelium) of the nasal cavity and paranasal sinuses, fluids within these cavities, and/or underlying bone (Lanza and Kennedy, 1997).

Chronic sinusitis is diagnosed if the sinus condition occurs for more than 4 weeks in duration (Carr, 2002).

2.2 AETIOLOGY

The precise aetiology and phathophysiology for sinusitis is not perfectly clear as it is commonplace to have a clinical setting in which sinusitis coexists with other conditions such as allergic rhinitis, cystic fibrosis and/or asthma (Lanza and Kennedy, 1997).

Inhalation of airborne allergens such as dust, pollen, mould, often sets off allergic reactions such as allergic rhinitis that in turn, may contribute towards chronic sinusitis. Certain weather conditions such as humidity, especially in the northern hemisphere can affect people with chronic sinusitis. (National allergy and infectious diseases, 2000.)

The development of sinusitis depends on a variety of inciting factors that lead to either anatomical or functional sinus outflow obstruction (Lanza and Kennedy, 1997).

Table 2.1 Multifactorial causes of sinusitis (Lanza and Kennedy, 1997:S2)

Host factors:

- Genetic/ congenital conditions:
  - Cystic fibrosis
  - Immotile cilia syndrome
- Allergic/ immune conditions
- Anatomic abnormalities
- Systemic diseases:
  - Endocrine
  - Metabolic
- Neoplasm

Environmental factors:

- Infectious/viral agents
- Trauma
- Noxious chemicals
- Iatrogenic
  - Medications
  - Surgery

2.3 PHYSIOLOGY AND PATHOPHYSIOLOGY

The sinuses are pneumatic or air-filled extensions of the respiratory part of the nasal cavity into the following cranial bones: frontal, ethmoid, sphenoid, and maxilla (Moore, 1992:758). They are named according to the bones that they lie in, namely the ethmoidal, frontal, maxillary, and sphenoidal sinuses (Giles, 1995:39).

2.3.1 GENETIC FACTORS

Two genetic disorders, cystic fibrosis (CF) and immotile cilia syndrome (Kartagener's syndrome) are associated with a chronic sinus disease state where the CF transmembrane conductance regulator (cAMP dependent chloride channels) are defective as a result of genetic mutation (Kaliner et al., 1997). This results in impaired clearance of secretions and abnormal viscidity of airway secretions that may result in colonisation and secondary infections caused by two common pathogens, *Staphylococcus aureus* and *Pseudomonas aeruginosa* (Kumar, 1997:208).

2.3.2 ALLERGIC AND IMMUNE FACTORS

A role for allergies in the development of sinusitis has been suggested but not proven (Benninger, 1997).

It has been suggested that in allergic fungal sinusitis, the progressive epithelial damage resulting from eosinophil influx associated with the presence of fungi and apparent allergic responses may initiate a self

perpetuating, cyclical inflammatory/immunologic response (Kaliner et al., 1997).

Histamine is the most prominent mediator of inflammation released as a result of inhalation of airborne allergens such as dust, pollen and mould that cause antigen-antibody reactions, followed by increased vascular permeability, destabilised lysosomal membranes, and other reactions that produce inflammation and mucosal swelling (Benninger, 1997).

This leads to obstruction of the sinus ostia, preventing mucus outflow, reduction in oxygen tension, changes in mucociliary transport, and a transudation of fluid into the sinuses, creating a suitable environment for bacterial overgrowth (Benninger, 1997).

A gram-negative rod or anaerobic microorganism may cause exacerbations of chronic sinusitis (Berkow and Beers, 1999: 688).

2.3.3 SINUSITIS IN METABOLICALLY OR IMMUNOLOGICALLY COMPROMISED PATIENTS

In patients with poorly controlled diabetes or with immunodeficiency, aggressive and even fatal fungal or bacterial sinusitis can occur (Berkow and Beers, 1999:688).

Mucormycosis (phycomycosis) is a mycosis caused by fungi of the order *mucorales* that may develop in patients with poorly controlled diabetes that is characterized by black, devitalised tissue in the nasal cavity (Berkow and Beers, 1999:688).

Aspergillosis and candidiasis of the paranasal sinuses may occur in a patient who is immunologically compromised as a result of therapy with cytotoxic drugs or the underlying disease process in leukemia, lymphoma, multiple myeloma, AIDS, or other immunosuppressive diseases. Aspergillosis is characterized by polypoid tissue in the nose and paranasal sinuses (Brekow and Beers, 1999:688).

2.3.4 ANATOMIC ABNORMALITIES

Anatomic abnormalities such as nasal septal spurs or deviations, hypertrophic or paradoxic middle turbinates, and concha bullosa can affect sinus ostia outflow so that minimal mucosal swelling or inflammation from an upper respiratory tract infection or an allergy intermittently obstructs the sinus causing sinusitis (Benninger, 1997).

2.3.5 INFECTIOUS AGENTS

Sinusitis is often a sequela of an upper respiratory tract infection followed by mucosal swelling that obstructs sinus outflow resulting in infection (Benninger, 1997). The oxygen in the sinus is absorbed into the blood vessels of the mucous membrane resulting in relative negative pressure (vacuum) that can be painful
(Berkow and Beers, 1999: 687).

Chronic sinusitis with or without polyposis is characterised by inflammatory thickening and polypoid changes in the sinus mucosa. Epithelial cells produce cytokines, such as interleukins that recruit neutrophils and other T-lymphocytes, and GM-CSF (granulocyte macrophage colony stimulating factor) that primes the eosinophils for enhanced responses to activating stimuli by altering epithelial ion transport processes and inducing ciliostasis. (Kaliner et al., 1997.)

This can result in bacterial colonisation by microorganisms that enter directly through the nasal passages, spreading cellulitis or thrombophlebitis in the lamina propria of the mucous membrane lining the nasal passages being influenced by production of nitric oxide, which is generated by the nasal epithelium (Berkow and Beers, 1999: 687).

Furthermore, bacterial products can affect both epithelial function and cytokine production resulting in long term epithelial thickening and goblet cell hyperplasia (Kaliner et al., 1997).

2.4 CLINICAL FEATURES

- Headache located either frontally, interorbitally, temporally or on the vertex.
- Nasal obstruction, purulent nasal discharge, and anosmia, alteration in the sense of smell.
- Facial pain, upper dental pain, pain in and behind the eyes.

- Postnasal discharge in the pharynx which looks like a thick strand or a solid band of discoloured mucous causing continual throat clearing or hawking, and is an important cause of secondary respiratory and gastric disorders such as pharyngitis, earache, deafness, nausea and vomiting of clear mucous and cough.
- There can also be breath odour, and fatigue present (McDonogh, 1999).

2.5 PHYSICAL EXAMINATION

Diagnosis is based on a careful medical history and thorough physical examination of the head and neck. All sinuses must be palpated for tenderness (Bates, 1995:182-184).

The nasal mucosa and septum are examined using an otoscope; a nasal speculum; or a nasal endoscope to find signs such as hyperemia, oedema, crusts, purulence, concha bullosa, polypoid mucosa, or cysts protruding into the meatus (Carr, 2002). Anatomic anomalies such as deviated septum, concha bullosa, and middle meatal polyps that cause narrowing of the osteomeatal units should also be noted (McDonogh, 1999).

Transillumination may be a handy diagnostic tool for diagnosis, but is not a reliable examination (McDonogh, 1999).

X-rays of the apices of the teeth are required in chronic maxillary sinusitis to exclude a periapical abscess (Berkow and Beers, 1999: 688). Normal radiographs of the sinuses only show gross abnormalities within

the sinuses and do not give any idea of the extent of the disease (McDonogh, 1999).

CT scanning (coronal computed tomography) of the paranasal sinuses is superior to radiography, and is very helpful in diagnosing difficult or recalcitrant cases of sinusitis (Lanza andKennedy, 1997). One cut through the frontal sinus, two cuts in the anterior ethmoid and maxillary sinuses and one cut each in the posterior ethmoids and sphenoid sinuses will give a fairly comprehensive picture of the extent of the disease (McDonogh, 1999).

Microscopy, culture and sensitivity (MCS) of the postnasal drip, the sputum, and any pus from the middle meatus is another useful investigation (McDonogh, 1999).

If necessary, other local and systemic causes should be excluded by means of a full blood count, immunoglobulin evaluation and skin tests for allergies. Assessment of the ESR (erythrocyte sedimentation rate), can indicate whether the symptoms are caused by an infection or not, especially in complicated cases involving surrounding bone inflammation. (McDonogh, 1999.)

2.6 CLINICAL DIAGNOSIS

According to Lanza and Kennedy (1997), and Carr (2002), the basis for diagnosis of chronic sinusitis is as follows:

The patient must have more than 2 major factors or 1 major and 2 minor factors occurring for more than 4 weeks in duration.

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

2.7 COMPLICATIONS

Swelling of the upper eyelid, proptosis, loss of visual acuity, loss of eye movement, swelling over the frontal sinus, signs of meningeal irritation and secondary chest problems (McDonogh, 1999).

Sinusitis frequently complicates asthma, and medical and/or surgical therapy for underlying sinusitis can improve asthma (Kaliner et al., 1997).

Infection from the nasal passages can spread into the surrounding bones of the face if left untreated, resulting in osteomyelitis (Giles et al., 1995:40), and intracranial abscesses (Edwards, 1995: 1098).

2.8 DIFFERENTIAL DIAGNOSIS

- Rhinitis
- Common cold
- Barre syndrome
- Upper dental sepsis
- Temporomandibular joint disease
- Cervical muscular disease
- Old neck injuries (McDonough, 1999).

2.9 TREATMENT

Treatment is aimed at restoring the health of the mucous membrane of the osteomeatal unit, and combating infection of the sinuses and the complications or secondary effects of these infections. It must decrease oedema of the mucosa, thereby opening airspaces of the infendibulum and stimulating the movement of secretion from the sinuses, and must have bactericidal components. (McDonogh, 1999.)

2.9.1 MEDICAL TREATMENT

Local decongestants such as oxymetazoline or xylometazoline are advisable for a limited period only (McDonogh, 1999).

Methylxanthines are said to stimulate ciliary activity and relieve the associated cough. Pseudoephedrine sulphate is a sympathomimetic that helps to shrink the mucous membrane and has no effect on the viscocity of the mucous produced. (McDonogh, 1999.)

Among antibiotics, penicillin is the drug of first choice, especially amoxycillin clavulanic acid preparations. They are broad-spectrum bactericidal agents and should be used for a minimum of ten days initially, but for up to four weeks if necessary. After the initial course, a further three weeks of antibiotic therapy is permissible or a sulphonamide-based product can be prescribed for one month. (McDonogh, 1999.)

Prolonged antibiotic courses are usually prescribed in unresolved cases and for patients with complications. Tetracyclines, macrolides, antifungal agents and metronidazole are prescribed only if indicated by the MCS (microscopy, culture and sensitivity) results, or if the patient is allergic to penicillin. (McDonogh, 1999.)

If there is an allergic component, patients are advised to avoid allergens, they are given antihistamines, systemic steroids and immunotherapy (Carr, 2002). Anti-inflammatory agents such as corticosteroids decrease oedema of the mucous membrane, inflammatory

infiltrate of the membranes and also stimulate ciliary activity (McDonogh, 1999).

Prednisone should be used as a single morning dose for five days and then on alternate days for further five doses. Such drugs are not prescribed in immunocompromised patients, since they lower then immunity and can cause growth retardation in children if used continuously for longer than seven days. (McDonogh, 1999.)

Patients with a nasal obstruction are advised to inhale steam from a vaporiser or a hot cup of water to lessen the discomfort and soothe inflamed sinuses. Hot wet compresses are applied over the inflamed area to alleviate symptoms of congestion (National allergy and infectious diseases, 2000).

2.9.2 PHYSIOTHERAPY

Physiotherapy usually entails up to 8 treatments sessions with nasal douches, or nebulisation with normal saline and in a non-asthmatic patient, sodium 2-mercaptoethane-sulphonate solution to help remove and break down thick mucous plugs in the nasal cavity and middle meatus. Ultrasound and laser treatment of the sinus cavities promotes movement of viscid mucous in the sinus cavities and promotes blood flow through the mucous membrane thereby aiding action of medication.
(McDonogh, 1999.)

2.9.3 SURGERY

Surgical treatment simply allows the sinuses, which previously did not drain, to drain through the ostia (Tichenor, 2003) as in cases of failed medical treatment of the primary disease and its complications, and for lesions of the osteomeatal unit that cause persistent disease. Functional endoscopic sinus surgery (FESS) is the only surgery that can be used with accuracy in this region and which does not destroy normal ventilatory and drainage tracts. (McDonogh, 1999.) Some patients will develop new areas of sinusitis post-surgically which may or may not be able to be visualized on endoscopy and sometimes require repeat CT scans. In those cases, oral antibiotics are more likely to be necessary and in some cases surgical revision may be necessary. In some patients, scar tissue may form after surgery. (Tichenor, 2003.)

In some cases, nasal obstruction is typically caused by enlargement of the inferior nasal turbinates. Normally, turbinates swell and humidify air as it is inhaled. Chronic turbinate enlargement blocks the air passage leading to chronic sinusitis. (Doctors guide, 2003.)

The somnoplasty technique was developed as a means of reducing some of the obstruction caused by the turbinates. This technique gently heats the turbinates. As a result the turbinate will shrink down in size over the course of 6-8 weeks. There may be minimal crusting and bleeding as a result. (Tichenor, 2003.)

2.10 HOMOEOPATHIC TREATMENT

Homoeopathy is based on the fundamental principle of "*Like cures like"*, meaning that," any substance which can produce a totality of symptoms in a healthy human being can cure the totality of symptoms in a sick human being" (Vithoulkas, 1998:92).

According to homoeopathic principles, disease is not considered as something local, or an affection of the parts, but is the state of being of the whole person at the time, the way he/she feels, thinks and behaves. This is the state that needs to be treated and reversed for the local body parts to function normally. (Sankaran, 1991:10.)

Homoeopathy attempts to bring each individual to the highest level of health possible on the physical, mental, and emotional levels. In acute and chronic disease, whether the symptoms are physical, mental, or emotional, homoeopathy produces subtle, yet often dramatic, healing and elimination of the underlying susceptibility to developing a disease state. (Ullman, 1995:11-23.)

Implicit in this approach is the idea formulated by Hahnemann that it is impossible to fundamentally and permanently cure a chronic disease state unless treatment is directed towards the underlying miasm/s (Watson, 1991: 41).

A miasm is a predisposition toward chronic disease underlying the acute manifestation of illness, which is transmissible from generation to

generation, and which may respond beneficially to the corresponding nosode (Vithoulkas, 1998: 133).

A nosode is a substance that is prepared from either pathological tissue or from the appropriate drug or vaccine (Vithoulkas, 1998:133).

The pathological tissues are collected and mixed with equal parts of spirits of wine. The next step in preparation of nosodes involves dilution and potentisation. (Vithoulkas, 1998:160-61.) This procedure involves a serial dilution wherein one part by volume of a medicinal substance is diluted with 99 parts of distilled water or ethyl alcohol, which then is shaken vigorously. One part of this solution is diluted further with 99 parts of diluted water or ethyl alcohol and then shaken forcefully for a definite number of successions. (Ullman, 1991:12.)

The true natural chronic diseases are those that arise from a chronic miasm, which when left unchecked by the employment of those homoeopathic medicines that are specific for them, always go on growing worse (Hahnemann, 1997:166).

Miasmatic treatment is a method of prescription that is based on the assumption that there exists in virtually everyone an inherited or an acquired energy blockage that produces a predisposition towards a particular and recognisable pattern of illness (Watson, 1991:41).

Eizayaga states that if a patient has ‘never been well since’ a specific disease, the acquired miasmatic layer should be treated with the

corresponding disease nosode in the same way as an active miasm would be treated (Watson, 1991:35).

From clinical experience of other Homoeopaths, it is evident that the nosodes are in fact amongst the most frequently indicated homoeopathic medicines (Watson, 1991:41).

There are different situations in which a major nosode ought to be considered when prescribing such as:

- When the nosode is the indicated medicine (i.e. the simillimum medicine);
- When all well selected and indicated medicine fail to work;
- When a patient's ailments relapse;
- When acute diseases fail to resolve;
- When the miasm obscures the symptom picture (Watson, 1991:41).

There are five major miasmatic nosodes indicated for the homoeopathic treatment of chronic sinusitis namely; *Psorinum*, *Medorrhinum,* *Syphilinum*, *Tuberculinum*, and *Carcinosinum* (Watson, 1991:42).

2.10.1 *Psorinum*

Psorinum is the major medicine associated with the Psoric miasm. This miasm arises from a history of the itch-mite or scabies infection. It is made up of sero-purulent matter of scabies vesicle (Vermeulen, 1994: 1336).

Psorinum is indicated for sinusitis which presents chronic catarrh, coryza, and loss of smell, offensive odours, and purulent

discharges (Vermeulen, 1994:1338), and for sinusitis with nasal ulcers that are slow to heal (Farrington, 1995:147).

This nosode is indicated in cases where there is frequent dry or fluent coryza, long continued obstruction of one or both nostrils, weak or lost sense of smell and polypi of the nose (Choudhury, 1997:14-22).

2.10.2 ***Medorhinum***

Medorhinum is the major medicine associated with the Sycotic miasm and it arises from a history of suppressed gonorrhoeal infection. Gonorrhoeal secretions are used to make up this medicine (Vermeulen, 1994:1092).

Medorhinum is indicated for thick yellow discharges, obstruction of the posterior nares, chronic nasal and pharyngeal catarrhs (Vermeulen, 1994:1092).

It is also indicated for suppression of ailments as a result of improper medication, overproduction of secretions in the nasal passages and overgrowth of tissues like polyps (Coulter, 1998:157-242).

There is often an association with tumourous growths and a peculiar odour of fish brine or stale fish (Choudhury, 1997:61).

This remedy is indicated for obstinate nasal catarrh, nose that is sensitive to inhaled air, itching and crawling sensation in the nose (Kent, 1999: 728).

2.10.3 *Syphilinum*

Syphilinum is the major medicine associated with the Syphilitic miasm. This miasm arises from a history of a venereal disease infection by *Treponema Pallidum*. The Syphilitic Virus is used to make up this nosode (Vermeulen, 1994: 1564).

Syphilinum is indicated for nasal ulceration; suppuration and bone affections as a result of complications (Vermeulen, 1994:1565).
There is loss of smell, snuffles in children, dark, greenish black or brown thick crusts that are not always offensive (Choudhury, 1997:45).

2.10.4 *Tuberculinum*

Turbeculinum is the major medicine associated with the Tubercular miasm. This miasm arises from a family history of tuberculosis. *Tuberculinum Bovinum* is used to make up this medicine (Vermeulen, 1994: 1618).

Turbeculinum is indicated for green fetid pus (Vermeulen, 1994:1619), and for patients who suffer from repeated exacerbations of local symptoms, usually accompanied by catarrhal condition in the chest (Coulter, 1998:157-242).

There is much sneezing and yellow thick discharges smelling like old cheese constantly dropping down the throat (Choudhury, 1997:86).

There is often an association with adenopathy and hard glands of the head and neck region (Morrison, 1993:391).

2.10.5 *Carcinosinum*

Carsinosinum is the major medicine associated with the Cancer miasm and it arises from cases where a history of carcinoma can be elicited or where the symptoms of the carcinoma itself exist (Vermeulen, 1994: 447).

Carsinosinum is usually indicated for frequent tendency to coryza and recurrent sinusitis (Vermeulen, 1994:447), and to those who have a family history of cancer (Coulter, 1998:157-242), diabetes, tuberculosis, and pernicious anaemia (Choudhury, 1997:119).

As in all homoeopathic prescribing, the administration of nosodes is subordinated to the principle of individualisation, of finding the simillimum from the patient's idiosyncratic features, including the patient's inheritance (family history) and personal medical history, which must be taken into account to determine the dominant miasm to prescribe on (Coulter, 1998:159-160).

2.11 THE PLACEBO EFFECT

The word placebo means, "I will please"(Newman, 1994:1298).
It is made up of a medicinal inactive substance such as a starch or sugar used in controlled studies for comparison with presumed active drugs or prescribed with the intent to relieve symptoms or meet a patient's

demands, i.e. it is a “make-believe medicine”, and it is allegedly inert and harmless (Berkow and Beers, 1999:2585).

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

The subjective and objective, desirable and undesirable effects of placebos appear to be related to two components of the placebo reaction. The first is anticipation (usually optimistic) of results because drugs are expected to work; it can be called "suggestibility," "faith," or "hope." The second is spontaneous change, which is at times even more important. A placebo may be credited for spontaneous improvement or blamed for spontaneous deterioration or an entirely new problem (eg, headache, rash) (Berkow and Beers, 1999:2586.)

In studies, effects of placebo must be subtracted from those of the active drug. The active drug must perform significantly better than the placebo to demonstrate efficacy. (Berkow and Beers, 1999:2586.)

2.12 RELATED HOMOEOPATHIC RESEARCH

Sengpiehl (1994) evaluated the reaction of homoeopathic *Luffa Operculata* 4X and a combination of *Kalium Bichromium* 5CH and *Cinnabaris* 5CH. Forty patients were randomly selected and divided into 2 experimental groups. The study was carried over a period of four months. One group received *Luffa Operculata* 4X and the other group received a combination of *Kalium Bichromium* 5CH and *Cinnabaris* 5CH. The statistical results form questionnaires were analysed using Mann-Whitney U test and Wilcoxon Signed Rank test. The Mann-Whitney U test results showed values of $p = 0.033$ and $p = 0.31$ within each group. The conclusion was that *Luffa Operculata* was a more effective mode of treatment for chronic sinusitis than a combination of *Kalium Bichromium* and *Cinnabaris*. (Sengpiehl, 1994.) However, it is difficult to assess the validity of these results, because, there was no placebo control group in this study**.**

Smit (2002) conducted a study to determine the efficacy of a homoeopathic simillimum in the symptomatic treatment of chronic sinusitis over a period of eight weeks. Fifteen patients were selected and diagnosed with chronic sinusitis by a medical doctor via case history taking and an endoscopic examination. Data collected from evaluation forms completed by participants and objective medical assessment was statistically analysed using Wilcoxon Signed Rank test. The results indicated a highly significant improvement in all the determinants measured (primary, associated ,and secondary symptoms of sinusitis, mood, vitality, and medical improvement). The validity of these results is difficult to assess, because there was no placebo control group in this study and the sample size was very small.

Fleming (2001) investigated the efficacy of *Hydrastis Canadensis* mother tincture and 3X potency in the treatment of sinusitis. This double blind placebo controlled study was carried over a three week period. Forty-five patients between the ages of 13 and 50 years with pre-diagnosed sinusitis were randomly selected into three groups . The control group received placebo. One experimental group received *Hydrastis Canadensis* mother tincture, and the one experimental group received *Hydrastis Canadensis* 3X. The data from questionnaires was analysed using Wilcoxon-Rank-Sum test, Kruskal-Wallis test, Mann-Whitney U test and goodness-of-fit tests. There was a generally observed reduction in symptom severity for all three groups between days 1 and 11 of the study. *Hydrastis Canadensis* 3X group showed a symptom severity reduction between days 11 and 21. There was however no significant difference between the three groups. It was concluded that neither *Hydrastis Canadensis* mother tincture nor *Hydrastis Canadensis* 3X was effective in the treatment of sinusitis.

Van Niekerk (1999) conducted a double blind study comparing miasmatic treatment and simillimum in the treatment of acne vulgaris in terms of the objective clinical findings. Thirty-five patients were divided into two treatment groups of which eighteen constituted the simillimum group and seventeen the miasmatic group. The effect of the homoepathic treatment was measured in terms of the reduction in the total number of lesions. The treatment period was nine weeks. The standardised statistical techniques for non-parametric data used were the Wilcoxon Matched Pair test and the Mann-Whitney U test. A Friedman ANOVA was also performed. The results showed that there was no statistically significant difference between the reduction in the number

of lesions in the two treatment groups. The Friedman ANOVA showed a statistical significant reduction in the non-inflamed and inflamed lesions ($p < 0.00013$ as well as $p < 0.00001$ respectively). Both treatment groups showed a statistically significant improvement. The miasmatic treatment for patients with acne vulgaris was found to be as significant as the simillimum treatment. There was no placebo control group in this study.

Two other studies on homoeopathic treatment of sinusitis were conducted at the same time as this study, using the same protocol and methodology.

Ismail (2003) investigated the efficacy of homoeopathic simillimum in the treatment of chronic sinusitis. This double blind placebo controlled study was conducted over a three-week period. Thirty participants were selected for this study and were divided into two experimental groups – simillimum and placebo group. The data collected from questionnaires was statistically analysed using a one-sample t-test and Mann-Whitney U test.
The one-sample t-test results showed that both treatment groups showed a statistically significant improvement , however the Mann-Whitney U test results showed that there was no statistically significant difference between the two groups. Therefore the simillimum treatment was found to be as significant as the placebo group. It was concluded that simillimum treatment was not effective in the treatment of chronic sinusitis.

Ebrahim (2003) investigated the efficacy of a homoeopathic complex (*Hydrastis Canadensis* 9CH, *Kalium Bichromium* 9CH and *Sambucus nigra* 9CH) in the treatment of chronic sinusitis over a period of three weeks. This

was a double blind placebo controlled study. Thirty participants were selected for this study and were divided into two groups, one receiving complex treatment and the other receiving placebo. Data collected from questionnaires was statistically analysed using one-sample t-test and Mann-Whitney U test. The one-sample t-test results showed that both treatment groups showed a statistically significant improvement. Mann-Whitney U test results showed that there was no significant difference between the two groups. Therefore the complex treatment was found to be as significant as the placebo group. It was concluded that homoeopathic complex treatment was not effective in the treatment of chronic sinusitis.

CHAPTER THREE

MATERIALS AND METHODS

3.1 OBJECTIVES

The purpose of this double blind placebo controlled study was to evaluate the efficacy of the main miasmatic nosodes in the treatment of chronic sinusitis in terms of the patients' perception of the treatment.

3.2 ADVERTISEMENTS

Advertisements 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.

3.3 SAMPLING METHOD

Thirty volunteering participants were selected according to inclusion and exclusion criteria (see 3.4) for this double blind study. Fifteen participants were randomly assigned to the nosode treatment group and fifteen participants were randomly assigned to the placebo group.

3.4 THE SUBJECTS

Inclusion 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.

Exclusion criteria

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.

3.5 METHODOLOGY

Patients that were accepted in this study received a full explanation of the purpose of the study prior to their participation. They were also made aware about the 50% possibility of being placed into either a placebo or a treatment group (see Appendices A and B).

Each of the thirty participants were asked to complete the following documentation in the presence of the researcher

- Subject information letter (Appendix A) before receiving treatment,
- Consent form (Appendix B) before receiving treatment,
- General Well-Being Questionnaire (McDowell and Newell, 1996) (Appendix C1) before and after receiving treatment,
- Sinus Symptom Visual Analogue Scale (Walker and White, 2000) (Appendix C2) before and after receiving treatment.

The researcher then took a full homoeopathic medical case history, and performed a general physical examination (Bates, 1995) (Appendix D).

Patients were advised to not change their lifestyle and diet during the course of the study.

3.6 TREATMENT

Based on the extensive case history taken by the researcher the dominant miasmatic predisposition of each case was determined according to homoeopathic principles. The following were taken into account in the selection of the nosode treatment, based on Watson's (1991:44) recommendations:

- Family history: when there is a prevalence of disease in the ancestors of the patient, it can give clues as to the probable miasmatic inheritance;
- Personal medical history: the pattern of illness throughout the patient's life including the presenting disorder can usually be matched to a particular miasm.

Each miasm has one nosode. The appropriate nosode was therefore selected as the miasmatic treatment. This is one of the accepted methods of miasmatic prescribing (Watson, 1991:41).

An independent dispenser was provided with a script in which either a placebo or a miasmatic nosode was administered using the randomisation list.

The treatment was administered in the form of 15 powders (indistinguishable

from each other) where 14 powders contained unmedicated granules and 1 powder contained the active ingredient (i.e. nosode granules). This is based on the homoeopathic principles of nosode prescription, which states that only

one, simple single medicine should be given to the patient at one time (Hahnemann, 1997:296).

Patients were seen after 3 weeks for their follow up consultation and evaluation of the treatment. During this consultation, the participants were assessed and results were recorded using questionnaires.
No treatment was given during this consultation.

3.7 MEASURING INSTRUMENTS

The General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) was used as an indicator of subjective feelings of psychological well being and distress before and after treatment.

The researcher used the Sinus Symptom Visual Analogue Scale (Walker and White, 2000; Appendix C2) to measure the severity of symptoms as experienced by patients before and after treatment (Walker and White, 2000).

Both questionnaires were available in English and Zulu.

3.8 STATISTICAL ANALYSIS

GROUPS ANALYSED

Group one constitutes the nosode group (nos).

Group four constitute the placebo group (plcb).

3.8.1 General Well-Being Questionnaire

The subjective data obtained from the General Well-Being Questionnaire (McDowell and Newell, 1996; Appendix C1) were used to look for the differences between the “before treatment” and “after treatment” results for each question within each group by using a one-sample t-test.

The Mann-Whitney U test was carried out to test for differences between the nosode and the placebo groups.

3.8.2 Sinus Symptom Visual Analogue Scale questionnaire

The Sinus Symptom Visual Analogue Scale Questionnaire (Walker and White, 2000; Appendix C2) data was analysed using the one-sample t-test to test for the differences between the “before treatment” and “after treatment” scores within each group.

The Mann-Whitney U test was carried out to test for differences between the placebo and nosode groups.

3.9 DATA ANALYSIS

3.9.1 GENERAL WELL-BEING QUESTIONNAIRE DATA:

3.9.1.1 One-sample t-test

This test was used to test for differences between the “before treatment” and “after treatment” results for each question within each experimental group:

H_0: There is no difference between before and after results for each question within each group

H_1 : There is a difference between before and after results for each question within each group

In each case α = 0.05 level of significance, or α = 0.01 level of significance

H_0 was rejected if $p < \alpha/2$ and H_0 was accepted if $p > \alpha/2$ since the test is two tailed.

P is the observed significance level or p-value

* indicates significant at α = 0.05

** indicates more significant at α = 0.01

3.9.1.2 Mann-Whitney U test

This test was used to test for the differences between the nosode and placebo groups:

H_0 : There is no significant difference between the nosode and placebo groups

H_1 : There is a significant difference between the nosode and placebo groups

In each case α = 0.05 level of significance, or α = 0.01 level of significance

H_0 was rejected if $p < \alpha/2$ and H_0 was accepted if $p > \alpha/2$ since the test is two tailed.

P is the observed significance level or p-value

* indicates significant at $\alpha = 0.05$

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

3.9.2 SINUS SYMPTOM VISUAL ANALOGUE SCALE QUESTIONNAIRE DATA:

3.9.2.1. <u>One-sample t-test</u>

This test was used to compare the differences between total scores before and after treatment for groups

H_0: There is no difference between before and after total scores for groups

H_1: There is a difference between before and after total scores for groups

In each case $\alpha = 0.05$ level of significance, or $\alpha = 0.01$ level of significance

H_0 was rejected if $p < \alpha/2$ and H_0 was accepted if $p > \alpha/2$ since the test is two tailed.

P is the observed significance level or p-value

* indicates significant at $\alpha = 0.05$

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

3.9.2.2 <u>Mann-Whitney U test</u>

This test was used to test for the differences between the nosode and placebo groups:

H_0 : There is no significant difference between the nosode and placebo groups

H_1 : There is a significant difference between the nosode and placebo groups

In each case $\alpha = 0.05$ level of significance, or $\alpha = 0.01$ level of significance

H_0 was rejected if $p < \alpha/2$ and H_0 was accepted if $p > \alpha/2$ since the test is two

tailed.

P is the observed significance level or p-value

* indicates significant at $\alpha = 0.05$

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

CHAPTER FOUR

RESULTS

The subjective data obtained 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. The one-sample t-test and Mann-Whitney U test were carried out for the purpose of this research using the SPSS version 9.

4.1 The criteria governing the admissibility of the data

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

4.2 General Well-Being Questionnaire (GW-BQ) results:

The data obtained from the General Well-Being Questionnaire consisted of the differences between “before” and “after “ treatment scores that were calculated for each individual in each group for each question. The raw data for the nosode and placebo groups and fourteen questions are shown in Appendix E. Statistical results are shown in Tables 4.1 – 4.4, and Figure 4.1.

Table 4.1 (GW-BQ) One-sample t-test showing differences between before and after treatment results for each question within nosode group (nos).

Question	P - value	Mean Difference	95% confidence interval of the difference	95%% confidence interval of the difference
			Lower	Upper
Q1	0.384	0.4000	-0.4831	1.2831
Q2	0.002**	1.4000	0.5948	2.2052
Q3	1.000	0.0000	-0.6942	0.6942
Q4	0.604	0.2667	-0.8101	1.3435
Q5	0.372	0.4667	-0.6182	1.5516
Q6	0.604	0.2667	-0.8101	1.3435
Q7	0.898	0.0667	-1.0303	1.1636
Q8	0.097	0.8667	-0.1771	1.9104
Q9	0.143	0.7333	-0.2806	1.7473
Q10	0.271	0.4000	-0.3488	1.1488
Q11	0.769	-0.1333	-1.0895	0.8228
Q12	0.264	0.4667	-0.3929	1.3263
Q13	0.011*	1.1333	0.2996	1.9671
Q14	0.212	0.4000	-0.2552	1.0552

α = 0.05 level of significance, or α = 0.01 level of significance

As can be seen from the table above, only Question 2 (p = 0.002) and Question 13 (p = 0.011) showed a statistical significance.

Table 4.2 (GW-BQ) One-sample t-test showing differences between before and after treatment results for each question within the placebo group (plcb).

Question	P - value	Mean difference	95% confidence interval of the difference	95%% confidence interval of the difference
			Lower	Upper
Q1	0.028*	0.8000	0.0995	1.5005
Q2	0.016*	1.3333	0.2938	2.3729
Q3	0.565	0.3333	-0.8811	1.5478
Q4	0.294	0.7333	-0.7087	2.1754
Q5	0.056	1.0667	-0.0303	2.1636
Q6	0.894	-0.0997	-1.1229	0.9896
Q7	0.527	0.3333	-0.7676	1.4343
Q8	0.036*	1.2000	0.0885	2.3115
Q9	0.010**	1.0000	0.2749	1.7251
Q10	0.903	0.0667	-1.0887	1.2220
Q11	0.531	-0.2000	-0.8685	0.4685
Q12	0.096	0.6667	-0.1349	1.4683
Q13	0.178	0.5333	-0.2737	1.3404
Q14	0.086	0.6667	-0.1071	1.4405

α = 0.05 level of significance, or α = 0.01 level of significance

The results from the table above show that the placebo group had a statistical significance for Questions 1 (p = 0.028), 2 (p = 0.016), 8 (p = 0.036), and Question 9 (p = 0.010).

Table 4.3 (GW-BQ) Mann-Whitney U test showing the differences between the mean ranks for the nosode and placebo groups.

Group		Mean Rank	Sum of Ranks
Q1	**Nosode**	13.60	204.00
	Placebo	17.40	261.00
Q2	**Nosode**	14.60	219.00
	Placebo	16.40	246.00
Q3	**Nosode**	14.67	220.00
	Placebo	16.33	245.00
Q4	**Nosode**	14.37	215.50
	Placebo	16.63	249.50
Q5	**Nosode**	13.47	202.00
	Placebo	17.53	263.00
Q6	**Nosode**	16.57	248.50
	Placebo	14.43	216.50
Q7	**Nosode**	15.00	225.00
	Placebo	16.00	240.00
Q8	**Nosode**	14.70	220.50
	Placebo	16.30	244.50
Q9	**Nosode**	14.67	220.00
	Placebo	16.33	245.00
Q10	**Nosode**	16.30	244.50
	Placebo	14.70	220.50
Q11	**Nosode**	15.70	235.50
	Placebo	15.30	229.50
Q12	**Nosode**	14.90	223.50
	Placebo	16.10	241.50
Q13	**Nosode**	17.43	261.50
	Placebo	13.57	203.50
Q14	**Nosode**	14.87	223.00
	Placebo	16.13	242.00

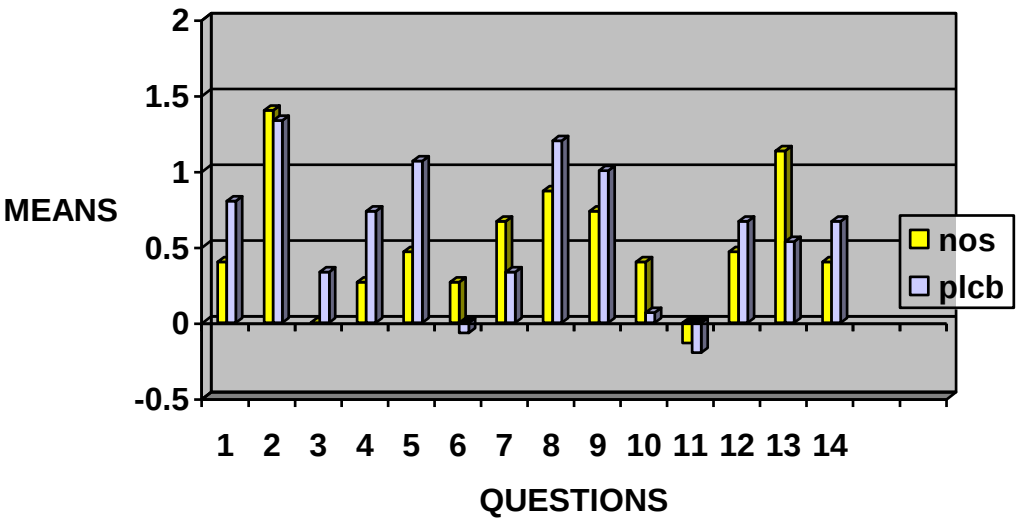

Figure 4.1 (GW-BQ) Graph showing the mean differences between the nosode (nos) and placebo (plcb) groups.

Table 4.4 (GW-BQ) Mann-Whitney U test showing p-values of each question between the nosode and placebo groups.

	p-value	**H_0**
Q1	0.220	Accepted
Q2	0.567	Accepted
Q3	0.584	Accepted
Q4	0.476	Accepted
Q5	0.200	Accepted
Q6	0.501	Accepted
Q7	0.745	Accepted
Q8	0.913	Accepted
Q9	0.594	Accepted
Q10	0.612	Accepted
Q11	0.892	Accepted
Q12	0.698	Accepted
Q13	0.216	Accepted
Q14	0.683	Accepted

H_0 = null hypothesis

α = 0.05 level of significance, or α = 0.01 level of significance

Since all p-values were > 0.025, the null hypothesis was accepted. Therefore, there is no significant difference between the nosode and placebo groups.

4.3 Sinus Symptom Visual Analogue Scale (SSVAS) questionnaire results:

For the Sinus Symptom Visual Analogue Scale data, the difference between the scores "before" and "after" treatment for each question was found for each of the 30 individuals in the nosode and placebo groups. The raw data for the individuals in the two groups are shown in Appendix F. Statistical results are shown in Tables 4.5 – 4.8, and Figures 4.2.

Table 4.5 (SSVAS) One-sample t-test showing differences between before and after treatment results for each question within the nosode group (nos).

	P-value	Mean difference	95% Confidence Interval of Difference	95% Confidence Interval of Difference
			Lower	Upper
Q1	0.158	1.2857	-0.5705	3.1419
Q2	0.019	2.2500	0.4391	4.0609
Q3	0.050	2.2143	-9.22E-04	4.4295
Q4	0.015	2.1786	0.5005	3.8566
Q5	0.007	2.5357	0.8242	4.2473
Q6	0.001	3.0357	1.5530	4.5185
TP	0.001	13.1429	6.7680	19.5177

TP = Total points

α = 0.05 level of significance, or α = 0.01 level of significance

The table above show that only Question 1 (p = 0.158) had no statistical significance since the p-value > 0.025, however for the total points p-value < 0.025. This shows a statistical significance for the nosode treatment.

Table 4.6 (SSVAS) One-sample t-test showing differences between before and after treatment results for each question within the placebo group (plcb).

	P-value	Mean difference	95% Confidence Interval of Difference	95% Confidence Interval of Difference
			Lower	Upper
Q1	0.035	2.3000	0.1814	4.4186
Q2	0.009	2.5000	0.7209	4.2791
Q3	0.000	3.6667	2.0533	5.2801
Q4	0.208	1.2333	-0.7712	3.2379
Q5	0.019	2.2667	0.4393	4.0940
Q6	0.002	3.4333	1.5211	5.3456
TP	0.001	15.4000	7.2697	23.5303

TP = Total points

α = 0.05 level of significance, or α = 0.01 level of significance

The table above shows that only Question 4 (p =0.208) had no statistical significance since the p-value > 0.025. The total points show a statistical significance since the p = < 0.025.

Table 4.7 (SSVAS) Mann-Whitney U test showing the mean ranks differences for the nosode and placebo groups.

GRP	Mean Rank	Sum of Ranks
Q1 nos	14.93	224.00
plcb	16.07	241.00
Q2 nos	15.50	232.50
plcb	15.50	232.50
Q3 nos	14.20	213.00
plcb	16.80	252.00
Q4 nos	17.23	258.50
plcb	13.77	206.50
Q5 nos	16.30	244.50
plcb	14.70	220.50
Q6 nos	15.43	231.50
plcb	15.57	233.50
Nos	15.70	235.50
plcb	15.30	229.50

GRP = group nos = nosode plcb = placebo TP = Total points

Table 4.8 (SSVAS) Mann-Whitney U test showing the differences of the p-values of each question between the nosode and placebo groups.

	p-values	**H_0**
Q1	0.721	accepted
Q2	1.000	accepted
Q3	0.416	accepted
Q4	0.274	accepted
Q5	0.609	accepted
Q6	0.697	accepted
TP	0.901	accepted

TP = Total points

α = 0.05 level of significance, or α = 0.01 level of significance

Since all p-values were > 0.025, the null hypothesis was accepted. Therefore, there is no significant difference between the nosode and placebo groups.

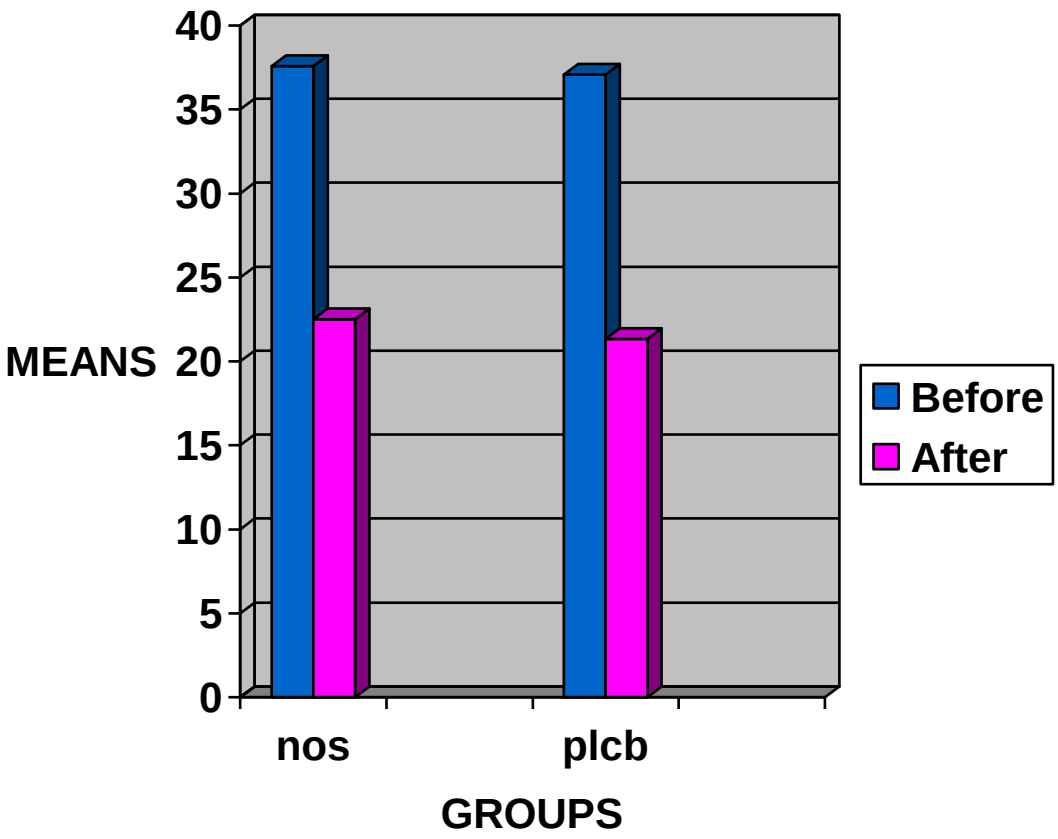

Figure 4.2 (SSVAS) Graph showing the comparison of the mean differences between the nosode (nos) and placebo (plcb) groups before and after treatment.

4.4 Randomisation List

Table 4.9 Table showing nosodes and potencies prescribed and dispensed.

Patient number	Nosode precribed	Dispensed	Placebo
1	*CARCINOSINUM* 200 CH	X	
2	*CARCINOSINUM* 30 CH		X
3	*CARCINOSINUM* 30 CH	X	
4	*TUBERCULINUM* 30 CH	X	
5	*CARCINOSINUM* 1 M		X
6	*MEDORRHINUM* 30 CH	X	
7	*SYPHILLINUM* 30 CH		X
8	*CARCINOSINUM* 1M	X	
9	*TUBERCULINUM* 200 CH		X
10	*CARCINOSINUM* 30 CH	X	
11	*MEDORRHINUM* 30 CH	X	
12	*TUBERCULINUM* 200 CH		X
13	*CARCINOSINUM* 200 CH	X	
14	*CARCINOSINUM* 200 CH	X	
15	*CARCINOSINUM* 30 CH	X	
16	*TUBERCULINUM* 30 CH	X	
17	*MEDORRHINUM* 30 CH		X
18	*CARCINOSINUM* 200 CH		X
19	*MEDORRHINUM* 30 CH	X	
20	*CARCINOSINUM* 30 CH		X
21	*MEDORRHINUM* 30 CH		X
22	*MEDORRHINUM* 30 CH		X
23	*CARCINOSINUM* 200 CH	X	
24	*CARCINOSINUM* 30 CH		X
25	*CARCINOSINUM* 200 CH		X
26	*CARCINOSINUM* 30 CH	X	
27	*MEDORRHINUM* 30 CH		X
28	*CARCINOSINUM* 30 CH		X
29	*CARCINOSINUM* 200 CH		X
30	*CARCINOSINUM* 30 CH	X	

The table above shows that there were an equal number of participants in each group that were allocated with either a nosode or a placebo according to the randomisation list. The most common nosode prescribed was *Carcinosinum* (18 participants). The most common nosode dispensed was also *Carcinosinum* (10 participants).

CHAPTER FIVE

DISCUSSION

The results show that there was no significant difference between the nosode

treatment and placebo groups .Therefore, according to this study, miasmatic

nosodes are not effective in the treatment of chronic sinusitis.

The reason for the placebo effect in this investigation could be due to the

following factors (Peters, 2001):

- The clinical environment was private and procedures taken during the

  consultation might have contributed towards the patient's trust in the

  therapist, including the amount of time spent with the patient.

- Most of the participants were self motivated and may have been

  convinced by the therapist's knowlegde, empathy, and confidence in

  the treatment.

- Patients were being grateful for the researchers efforts and this was

  reflected in an exaggeration of the benefits of the treatment.

- The extended patient doctor interaction during consultations.

- "Experimental subordination" meaning that in an experiment, subjects

  say what they thought was expected of them rather than what they

  really experienced.

- Psychoneuroimmunological response, meaning that the brain can

  influence the body's defence against infection.

Failure of miasmatic nosodes in the treatment of chronic sinusitis could be

due to the following:

- All participants selected for this study had been exposed at some point

  or other to "Suppressive Therapapy" or allopathic medication

  (Vithoulkas, 1998). Such cases do not present a clear picture about

  the nature of the disease state to prescribe on.

- Most cases were lying in the "dormant miasm" where the prescription

  was based only on family history and past medical history

  (Roberts, 1993), therefore nosode was not simillimum. A history of

  cancer and other serious chronic diseases

  was present for most cases in which case the prognosis is poor, and

  patients with such background can be expected to encounter problems

on the way to cure (Vithoulkas, 1998).

- Unlike Simillimum, the principle of "Individualisation" of each case

was not applicable since participants were classified into five major

nosode prescripition categories.

- Only one powder with an active ingredient (nosode) was prescribed.

- The potency selected might have been too weak to cause a reaction.

- Being a chronic illness, sinusitis could have relapsed despite good

therapy (Vithoulkas, 1998).

- The study period was too short to observe a miasmatic response that

is expected to occur over a one or two year period (Vithoulkas, 1998).

- The researcher observed from case taking, that many of the

participants had improved notably on the mental and emotional level,

even though the sinus symptoms may have showed no or little

improvement. Should there have been a longer observation period,

one might have been able to observe a greater improvement in the

sinus condition.

- This study was conducted during the winter season, t herefore partial

perpetuation of their sinusitis may have been influe nced by the

co-existence of the common cold and flu during the t hree-week

observation period.

One had expected *Medorrhinum* to be the most indicated nosode in this study since chronic sinusitis clinical presentation is often classified as “an over active secretion of the mucous membranes” (Roberts, 1993). However

Carcinosinum was the most commonly prescribed nosode (se e Table 4.9).

The most commonly dispensed nosode was also *Carcinosinum*. This could be

due to the fact that so many participants (n=10) had a fa mily history of cancer

and diabetes, both being factors that strongly point to *C arcinosinum*

(Watson,1991: 42).

Only three nosodes were indicated for participants in this study. Ten participants received the cancer nosode (*Carcinosinum*), two participants received the tubercular nosode (*Tuberculinum*), and three participants received the sycotic nosode (*Medorrhinum*).

Eight participants that received *Carcinosinum* had complained of a history of headaches during the first consultation before treatment. All these participants

reported that they were headache-free during the three-week treatment period.
Carcinosinum is known to be relevant in the treatment of headache

(Vermeulen, 1994: 447).

Compared to other related research studies, Sengpiehl (1994) and Smit (2002) conducted their studies over a four-month and two-month period respectively. However, both studies were not placebo controlled. Their results showed a significant improvement in sinusitis symptoms. This could have been due to a longer observation treatment period, but it is difficult to assess the validity of these results, because there was no placebo group.

Like this study, Fleming (2001), Ismail (2003) and Ebrahim (2003) conducted double blind placebo controlled studies over a period of three weeks. Their results showed a significant improvement in each mode of treatment investigated. However, there was no statistical significance when compared to the placebo groups.

The outcome of these studies could have been due to the similar weaknesses as the ones mentioned above for the miasmatic nosodes, such as, the short treatment period. There was a placebo effect in these studies which could have been due
to the same factors mentioned above for the study on miasmatic nosodes .

In addition, the use of subjective outcome measures only may have been insufficient to adequately evaluate the effectiveness of miasmatic nosode treatment of chronic sinusitis. In future, objective clinical evaluation should be

included in any similar study.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIOS

6.1 CONCLUSION:

Based on the results of this study one must conclude that the main miasmatic nosodes are not effective in the treatment of chronic sinusitis.

6.2 RECOMMENDATIONS FOR FURTHER STUDIES:

- It is recommended that a larger sample size be studied.

- It is recommended that the study should be conducted over a longer period.

- The inclusion criteria should state that only those who have been diagnosed by a specialist prior to engagement in the study will be

included.

- Investigation of homoeopathic treatment in both acute and chronic sinusitis should be done.

- As sinusitis is affected by seasonal changes, it would be beneficial to have the study taking place in different season, comparing the results.

- Prescription should be done on at least two occasions.

- It will be ideal to have an investigation based on the objective clinical findings of the nasal mucosa rather than patient's perception only.

- It would offer a great advantage to have a study evaluating the efficacy of homoeopathic miasmatic nosodes and major anti-miasmatic medicines in the treatment of chronic sinusitis.

- It would be interesting to investigate a comparison between miasmatic nosodes and homoeopathically prepared cortisone in the treatment of sinusitis.

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APPENDIX G: Ukuthathwa kwemithi yesi Homoeopathy

APPENDIX A

SUBJECT INFORMATION LETTER

TITLE OF RESEARCH PROJECT: The efficacy of the main miasmatic nosodes in the treatment of chronic sinusitis.

NAME OF SUPERVISOR: Dr Richard Steele

NAME OF CO-SUPERVISOR: Dr Corne Hall

NAME OF INVESTIGATOR: Nomthandazo Dlamini

NAME OF CO-INVESTIGATORS: Shaida Ismail, Shera Ebrahim

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 is 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 Sinus Symptom Visual Analogue Questionnaires 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. This means that patients will receive either the active medicine or the placebo, which looks and tastes the same but is neutral. “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. There is a 50% chance that you may receive placebo, and if that is the case you will be entitled to free homoeopathic treatment at the end of the trial. Treatment will be available in a form of homoeopathic powders and will be dispensed by the homoeopathic clinic dispenser.

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

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

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

Dr Steele – 2042041(031)

Nomthandazo Dlamini – 0825331369

Thank you for the courtesy of your assistance.
Nomthandazo Dlamini
Department of Homoeopathy, Durban Institute of Technology.

APHENDIKSI A
INCWADI YEMININGWANE EBALULEKILE

ISIHLOKO SOCWANINGO PHROJEKTHI: Ukubaluleka kwamanosodi asemqoka ekwelapheni isifo se khronikhi sanusaythisi.

IGAMA LOMPHATHI HLELO: Dokotela Richard Steele
IGAMA LESEKELA LOMPHATHI: Dokotela Corne Hall
IGAMA LOMCWANINGI: Nomthandazo Dlamini

ABANYE ABACWANINGI: Shaida Ismail, Shera Ebrahim

Usuku:

Sawubona

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

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

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

Uma uzozimbandakanya kuloluhlelo kumele ube ngumuntu onalokhu okulandelayo:

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

Labo abanalokhu okulandelayo bazohoxiswa kuloluhlelo:

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

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

Loluhlelo lusingathwa umthetho owenza ukuba umcwaningi, nomphathi hlelo, bangazi ukuba yilowo nalowo muntu welashwa ngaluphi uhlobo lomuthi wokwelapha phecelezi l”double blind placebo control study”. Abantu abazimbandakanyayo kuloluhlelo, bazocazwa kumaqembu amabili okwelashwa (phecelezi i plasibo noma i thrithmenti) ngendlela engabandlululi.Umuntu ngamunye usethubeni elingamaphesenti angu 25 okuba kwiqembu elibizwa nge plasibo kanye nethuba elingamaphesenti angu 75 lokuba kwiqembu le thrithmenti. Yonke imithi yokwelapha izobe itholakala ngendlela efanayo kulamaqembu womabili ngendlela yesihomoeopathi.

Amavolontiya angu 15 azofakwa kwiqembu lethrithmenti, kanti amavolovtiya angu 5 azofakwa kwiqembu leplasibo. Labo abazobe bekwiqembu leplasibo bayokwaziswa ekupheleni kohlelo, futhi bayonikwa ithuba lokwelashwa uma seluphelile lolucwaningo.

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

Uma unemibuzo noma ungacaciselwa ngokweneliskile, ungathintana nalaba abalandelayo kulezinombolo:

Nomthandazo Dlamini - 0825335369

Dokotela Steele- 2042041

Siyabonga ngosizo lwakho.

Umnyango wakwa homoeopathy e 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 the main miasmatic nosodes in the treatment of chronic sinusitis.

NAME OF SUPERVISOR: Dr Richard Steele

NAME OF CO-SUPERVISOR: Dr Corne Hall

NAME OF RESEARCH STUDENT: Nomthandazo Dlamini

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_____

APHENDIKSI B

IFOMU YESIVUMELWANO

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

ISIHLOKO SOCWANINGO PHROJEKTHI
Ukubaluleka kwamanosodi asemqoka ekwelapheni isifo se khronikhi sanusaythisi

IGAMA LOMPHATHI HLELO WOCWANINGO PHROJEKTHI: Dokotela Richard Steele

IGAMA LESEKELA LOMPHATHI: Dokotela Corne Hall.

IGAMA LOMFUNDI WOCWANINGO PHROJEKTHI: Nomthandazo Dlamini

ABANYE ABACWANINGI: Shaida Ismail no Shera Ebrahim

KOKELEZELA IMPENDULO YAKHO KULEMIBUZO ELANDELAYO:

1) Usulifundile uhla olumayelana nemininingwane yalolu cwaningo? YEBO/CHA
2) Ulitholile ithuba lokubuza kabanzi ngalolu cwaningo? YEBO/CHA
3) Ukwazile ukuthola izimpendulo ezenelisayo kulemibuzo? YEBO/CHA
4) Ulitholile ithuba lokudingida ngalolu cwaningo? YEBO/CHA
5) Ulithole lonke ulwazi oludingayo ngalolu cwaningo? YEBO/CHA

6) Usuke waxhumana nobani ngalolu hlelo?_____
7) Uyiqondisisa yonke imibandela yokuzimbandakanya kwakho kulolu hlelo?
YEBO/CHA

8)Uyazi ukuthi wamukelekile ukuhoxa kulolucwaningo? YEBO/CHA

a) noma yinini
b) ngaphandle kokunika isizathu sokuhoxa
c) ngaphandle kokuzibangela ukukhubazeka kwempilo yakho esikhathini esizayo

9) Uyavuma ukuzimbandakanya ngokuba yivolontiya kulolucwaningo phrojekthi?

YEBO/CHA

Uma uphendule ngo CHA kwenye yemibuzo elapha ngenhla, uyacelwa ukuba uthole imininingwane efanele ngaphambi kokusayina.

IGAMA LESIGULI/ LOMUNTU OZIMBANDAKANYAYO*_____

(amagama amakhulu)

SAYINA_____

IGAMA LIKAFAKAZI_____

(amagama amakhulu)

SAYINA_____

IGAMA LOMFUNDI OWENZA UCWANINGO _____

(amagama amakhulu)

SAYINA_____

APPENDIX C

DURBAN INSTITUTE OF TECHNOLOGY

DEPARTMENT OF HOMOEOPATHY: RESEARCH

QUESTIONS TO PATIENTS WITH CHRONIC SINUSITIS

Instructions:

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

b. Please answer the questions as objectively and as honestly as possible

c. Please read each question carefully before answering it.

d. Please make sure that you answer all the questions and that you do not leave any out accidentally.

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

APHENDIKSI C

DURBAN INSTITUTE OF TECHNOLOGYUMNYANGO WEZOCWANINGO WAKWA HOMOEOPATHYIMIBUZO EQONDENE NALABO ABAPHETHWE ISIFO SE KHRONIKHI SANUSAYTHISI

Imithetho:

a. Impendulo yakho kuloluhla lwemibuzo elandelayo izoba YIMFIHLO, futhi izosetshenziselwa ucwaningo kuphela.

b. Uyacelwa ukuba uphendule imibuzo ngendlela eqinisekile nethembekile.

c. Uyacelwa ukuba ufunde umbuzo ngamunye ngaphambi kokuwuphendula.

d. Qiniseka ukuthi uphendula yonke imibuzo futhi awukho owushiye ngephutha.

e. Uyacelwa ukuba uphendule imibuzo ezolandela lemithetho. Uma unemibuzo noma ungaqondisisi kahle,ungabuza umphathi wocwaningo ongumsingathi wohlelo.

The General Well-Being Questionnaire

(McDowell and Newell, 1996)

Purpose:

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

APPENDIX C1 **Date:_____**
Patient no.:_____

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
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 behavior, thoughts, emotions, OR feelings? (DURING THE PAST 3 WEEKS)

1 Yes, definitely so
2 Yes, for the most part

3 Generally so
4 Not too well
5 No, and I am somewhat disturbed
6 No, and I am very disturbed

4) Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile? (DURING THE PAST 3 WEEKS)

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

5) Have you been under or felt you were under any strain, stress, or pressure? (DURING THE PAST 3 WEEKS)

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 bit
6 Not at all

6) How happy, satisfied, or pleased have you been with your personal life? (DURING THE PAST 3 WEEKS)

1 Extremely happy- could not have been more satisfied or pleased
2 Very happy
3 Fairly happy
4 Satisfied- pleased
5 Somewhat dissatisfied
6 Very dissatisfied

7) Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel, or of your memory? (DURING THE PAST 3 WEEKS)

1. Yes – very much so and I am very concerned

2. Some and I am quite concerned
3. Some and I have been a little concerned
4. Some – But not enough to be concerned or worried about
5. Only a little
6. Not at all

8) Have you been anxious, worried or upset? (DURING THE PAST 3 WEEKS)

1 Extremely so- to the point of being sick or almost sick
2 Very much so
3 Quite a bit
4 Some- enough to bother me
5 A little bit
6 Not at all

9) Have you been waking up fresh and rested? (DURING THE PAST 3 WEEKS)

1 Every day
2 Most every day
3 Fairly often
4 Less than half the time
5 Rarely
6 None of the time

10) Have you been bothered by any illness, bodily disorder, pains, or fears about your health? (DURING THE PAST 3 WEEKS)

1 All the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

11) Have you been feeling emotionally stable and sure of yourself? (DURING THE PAST 3 WEEKS)

1 All the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

12) Have you felt tired, worn out, used-up, or exhausted? (DURING THE PAST
3 WEEKS)

1 All the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

13) How concerned or worried about your HEALTH have you been? (DURING
THE PAST 3 WEEKS)

1 Extremely concerned
2 Very much concerned
3 Quite a bit concerned
4 Some- enough to bother me
5 A little bit concerned
6 Not concerned at all

14) How much energy have you felt? (DURING THE PAST 3 WEEKS)

1 Extremely energetic
2 Very energetic
3 Fairly good amount of energy
4 Satisfactory amount of energy
5 A little bit of energy
6 No energy at all

IMIBUZO EPHATHELENE NESIMO SEMPILO YAKHO
(Ngokuka McDowell no Newell, 1996)

Inhloso:

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

\

APHENDIKSI C1 **Inombolo yesiguli:**
Usuku:

IMIBUZO EPHATHELENE NESIMO SEMPILO YAKHO
(Ngokuka McDowell no Newell, 1996)

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

1) Uzizwa uphatheke kanjani empilweni?
(KULAMASONTO AMATHATHU ADLULE)

1 Ngizizwa ngiwumqemane
2 Ngizizwa ngigculisekile empilweni
3 Ngizizwa ngisesimweni esikahle sempilo
4 Ngiba nentokozo ngibuye ngizizwe ngiphansi
5 Ngizizwa ngiphansi empilwemi
6 Ngizizwa ngintekenteke

2) Sikuphatha kabi kangakanani lesifo se sinusitis?
(KULAMASONTO AMATHATHU ADLULE)

1 Ngiphatheke kabi ngokweqile- angisakwazi ukuzinakekela
2 Ngiphatheke kabi kakhulu impela
3 Ngiphatheke kabi kakhudlwana
4 Kona kungiphatha kabi
5 Ngiphatheke kabi kancanyana
6 Akungiphathi kabi

3) Ubukwazi ukulawula imicabango kanye nemizwa yakho?
(KULAMASONTO AMATHATHU ADLULE)

1Yebo, kakhulu
2 Yebo, ngokuvamile
3 Yebo, ngokwenelisekile
4 Angikwazi kangako
5 Cha, angikwazi ukuzilawula
6 Cha, angisalawuleki

4) Uke ube nokudumala, ukudikibala, ukulahla ithemba noma ube nezinkinga uze ungazi ukuthi zingaxazululeka?
(KULAMASONTO AMATHATHU ADLULE)

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

5) Uke waba nengcindezi (phecelezi istresi)?
(KULAMASONTO AMATHATHU ADLULE)

1 Yebo, ngokwedlulele
2 Yebo, kakhulu impela
3 Yebo, kakhudlwana
4 Yebo, kancane
5 Yebo,kancanyana
6 Cha akunjalo

6) Ujabule kangakanani empilweni?
(KULAMASONTO AMATHATHU ADLULE)

1 Ngijabule ngokweqile
2 Ngijabule kakhulu impela
3 Ngijabule kakhudlwana
4 Ngijabule ngokwenelisayo
5 Angijabule kangako
6 Angijabule kwasampela

7) Uke uzizwe sengathi ulahlekelwa ingqondo, ukulawula indlela owenza ngayo izinto, imicabango kanye nendlela ozizwa ngayo?
(KULAMASONTO AMATHATHU ADLULE)

1 Yebo, ngokwedlulele futhi ngikhathazeke kakhulu
2 Ngikhathazekile kakhulu impela
3 Nginokukhathazeka okuncane
4 Ngikhathazekile, kodwa hhayi ngaleyondlela
5 Kona kuyangikhathaza kancanyana
6 Angikhathazekile kwasampela

8) Uke waba nexhala, ukukhathazeka, noma ukudinwa?
(KULAMASONTO AMATHATHU ADLULE)

1 Ngokwedlulele - kuze kungigulise
2 Kakhulu impela
3 Kakhudlwana
4 Kancane - kodwa ngikhathazekile
5 kancanyana
6 Angihlangabezananga nalesimo

9) Uke uvuke izizwa ungumqemane?
(KULAMASONTO AMATHATHU ADLULE)

1 Zinsuku zonke

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

10) Uke wakhathazwa yisifo, ukukhubazeka komzimba, izinhlungu, noma ukwesabela impilo yakho?
(KULAMASONTO AMATHATHU ADLULE)
1 Njalonje
2 Ngezikhathi eziningi impela
3 Ngezikhathi eziningana
4 Kwesinye isikhathi
5 Kwesinye isikhashana
6 Angizange

11) Uke wazizwa ugculisekile emphefumulweni?
(KULAMASONTO AMATHATHU ADLULE)
1 Njalonje
2 Ngezikhathi eziningi impela
3 Ngezikhathi eziningana
4 Kwesinye isikhathi
5 Kwesinye isikhashana
6 Angizange

12) Uke wazizwa ukhathele?
(KULAMASONTO AMATHATHU ADLULE)
1 Njalonje
2 Ngezikhathi eziningi impela
3 Ngezikhathi eziningana
4 Kwesinye isikhathi
5 Kwesinye isikhashana
6 Angizange

13) Uke wakhathazeka kangakanani ngempilo yakho?
(KULAMASONTO AMATHATHU ADLULE)
1 Ngikhathazeke ngokwedlulele
2 Ngikhathazeke kakhulu impela
3 Ngikhathazeke kakhudlwana
4 Ngikhathazeke ngokwamukelekile
5 Ngikhathazeke kancane
6 Angikhathazekile

14) Uzizwa unomdlandla noma umfutho ongakanani?
(KULAMASONTO AMATHATHU ADLULE)
1 Nginomdlandla owedlulele
2 Nginomdlandla omkhulu impela

3 Nginomdlandla omkhudlwana
4 Nginomdlandla ofanelekile
5 Nginomdlandla omncane
6 Anginawo umdalndla

APPENDIX C2 **Patient no:____**
Date:_____

Sinus Symptom Visual Analogue Scale
(Walker and White, 2000)

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

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

Symptom	Symptom score – visual analogue scales
0 = none	10 = extreme
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 Total Points Score out of 60

APPENDIX C2 **Patient no:____**
Date:_____

Sinus Symptom Visual Analogue Scale
(Ngokuka Walker no White, 2000)

Kuloluhla lwezimpawuezilandelayo, yilolo nalolo phawulunikezwe isikali esisuka ku 0 kuya ku 10 ngendlela ozizwa ngayo, lapho u 0 echaza ukuthi awuzwa lutho olukhombisa lolophawukanti uma sekugcina ku 10 kuchaza ukuthi uzizwa unalo lolophawu futhi lisezingeni eliphezulu kakhulu.

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

Uphawu Isikali sezimpawu – visual analogue scales 0 = alu(ku)kho ……10 = lu(ku)khona kakhulu
1. Ubu(izin)nhlungu noma ukucinana ebusweni 0……10 2. Ubuhlungu bekhanda 0……..10 3. Ukucinana kwamakhala 0……..10 4. Ukuphuma kwamafinyila 0……..10 5. Inkinga yokuzwa ngamakhala 0……..10

6. Ukungazizwa kahle kuphelele

0……..10

Amaphuzu aphelele Isibalo emephuzwini angu 60

APPENDIX D

CASE HISTORY QUESTIONAIRE

(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 WHERE BORN?

CHILDHOOD DISEASES/ILLNESSES:
(MUMPS, MEASLES, CHICKEN POX, GERMAN MEASLES, TUBERCULOSIS)

TONSILS:
ALLERGIES:
VACCINATION HISTORY:

FAMILY HISTORY:
(TB, DIABETES, HEART DISEASE, HYPERTENSION, STROKE, ASTHMA, ARTHRITIS, ANEMIA, HEADACHES, EPILEPSY, ECZEMA, KIDNEY DISEASE, HAYFEVER, CANCER, MENTAL ILLNESSES)

MOTHER: FATHER:

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, tumour)

ENDOCRINE SYSTEM:

(dysthyroid, diabetes)

ON EXAMINATION:

VITAL SIGNS:

PULSE
BLOOD PRESSURE
RESPIRATORY RATE
TEMPERATURE
WEIGHT AND HEIGHT

GENERAL OBSERVATION:

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

GENERAL OBSERVATION:

HEAD **inspection and palpation**
Note any –deformities
-lumps
-tenderness, other lesions.

FACE **inspection and palpation**
Note facial expression and contours, symmetry, involuntary
Movements. Oedema, masses and facial pain.

EYES inspection and palpation
Note position and alignment.
Note pupil size, shape, equality.
Note any redness, swelling, vascular pattern, nodules.

NOSE AND PARANASAL SINUSES

inspection and palpation
External surface –asymmetry, deformity, inflammation.
Internal surface –Nasal mucosa –colour, swelling, exudates, bleeding.
Nasal septum –bleeding, crusting, perforation or
Deviation
Inferior, medial turbinate and middle meatus –colour, swelling,
exudates and polyps.
Palpate the sinuses –Frontal sinus tenderness
Maxillary sinus tenderness
Postnasal drip –colour, odour, quantity, frequency**.**

MOUTH AND PHARYNX

Lips –colour, moisture, swelling.
Mouth –breath, taste, pain, lesions.
Teeth –caries, pain, abnormalities in shape, colour and position.
Pharynx –tonsils, swellings, lesions, colour, ulceration, uvula.

EARS

Ear drum and canal –discharge, foreign bodies, redness and swelling, cerum,
colour and contour
-handle of malleus
-cone of light
-perforations.

NECK

Stiffness and pain
thyroid gland
tracheal deviation
JVP
lymph nodes

THORAX **-**inspection, palpation and auscultation
-chest wall movement and shape
-auscultation of heart and lungs

ABDOMEN -**inspection, palpation and auscultation**
-pain, tenderness, guarding, spleen, liver, kidneys.

BACK -**inspection and auscultation**
-symmetry of body
-curvature and orientation of spine
-posture, any restricted movements

UPPER AND LOWER LIMBS

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

AXILLAE -**inspection and palpation**
4 areas - Central –Apical
Distal
Pectoral/anterior
Subscapular/posterior
Also -Supraclavicular
Infraclavicular

APPENDIX G

HOW TO TAKE HOMOEOPATHIC MEDICATION

- If you are taking powders – just open one end of the powder and tip under your tongue, allow it to dissolve and DO NOT TAKE IT WITH WATER.
- If you are taking pills or granules – do not touch them with your fingers. Count the pills or granules into the lid of the vial and place them under your tongue and allow them to dissolve.
- Take your remedies away from meals – at least half an hour or one hour after eating. Avoid eating mint before or after taking medication.
- The remedies must be stored in a cool, dark place. Keep away from radiation, e.g. computers, television, radios, etc.
- Avoid the use of camphor during the treatment period (Vicks, camphor cream).
- Try to avoid the intake of coffee during the treatment period.

APPENDIX G

UKUTHATHWA KWEMITHI YESI HOMOEOPATHY

- Uma usebenzisa ophawuda – vula kwicala elilodwa bese uthela emlonyeni, ngaphansi kolimi, dedela kuncibilike futhi UNGAPHUZI NAMANZI.

- Uma usebenzisa amaphilisi noma amagranuli – ungawathinti ngeminwe. Thela amaphilisi ambalwa esivalweni bese uwathela ngaphansi kolimi uwadedele azincibilikalele.

- Hlukanisa ukuthatha imithi yakho kanye nokudla - kube uhhafu wehora noma ihora elilodwa ngaphambi, noma ngemuva kokudla. Qaphela ukudla iminti kulesisikhathi esibaliwe.

- Gcina imithi yakho endaweni epholile, engenalanga. Qhelisa imithi yakho kumakhompyutha, amradio, omabonakude, njalo-njalo.

- Qhaphela ukusebenzisa izinto ezine khemfangesikhathi usebenzisa imithi (njengo Viksi kanye no khemfa khrimu).
- Qaphela ukuphuza ikhofi ngesikhathi sokwelashwa.

APPENDIX E

Raw data layout for the General Well-being Questionnaire

Nosode Group

No.	*Q1*	*Q2*	*Q3*	*Q4*	*Q5*	*Q6*	*Q7*	*Q8*	*Q9*	*Q10*	*Q11*	*Q12*	*Q13*	*Q14*
1	0	1	0	-3	-1	1	1	4	0	0	2	0	1	0
2	0	1	-3	1	3	0	0	4	-2	2	0	-2	0	0
3	-3	3	0	-2	-2	-2	-5	-2	2	-1	0	1	-2	2
4	0	0	1	2	-1	-1	2	0	0	1	-1	0	3	-2
5	1	0	0	0	1	1	0	0	1	0	-1	2	1	0
6	4	5	3	4	5	3	4	4	4	3	3	3	3	2
7	-2	1	0	0	0	-1	0	-1	0	-1	0	-1	0	-1
8	1	0	0	-1	-1	1	0	1	0	0	-5	0	0	0
9	1	2	-1	0	1	1	0	-1	2	-1	0	2	1	1
10	0	2	0	1	-2	2	0	1	0	0	0	0	2	1
11	0	3	0	0	2	-5	0	0	1	2	0	0	2	0
12	0	0	0	2	2	1	0	1	-1	1	0	1	1	1
13	21	1	-1	-2	0	0	-2	0	-2	1	-1	-2	0	1
14	1	0	0	-1	-1	1	-1	0	4	-2	0	0	1	-1
15	2	2	1	3	1	2	2	2	2	1	1	3	4	2

Control group

No.	*Q1*	*Q2*	*Q3*	*Q4*	*Q5*	*Q6*	*Q7*	*Q8*	*Q9*	*Q10*	*Q11*	*Q12*	*Q13*	*Q14*
16	-1	2	-2	-4	-4	2	-3	-2	2	-2	1	-1	0	-2
17	2	3	-4	2	0	0	-2	3	4	-2	-3	3	-1	1
18	1	2	0	0	1	-3	0	1	1	1	0	0	0	0
19	0	-2	0	-3	-1	0	0	0	0	1	0	1	2	0
20	-2	-3	-1	-3	0	-2	-2	-2	-1	-2	-2	0	-2	2
21	2	2	1	0	2	2	3	2	1	3	1	1	1	1
22	1	3	2	3	2	-1	1	1	0	0	0	1	0	0
23	2	3	3	4	3	2	3	4	1	4	2	3	3	1
24	2	0	2	3	3	2	3	2	2	1	0	-2	3	-1
25	1	0	1	2	2	3	2	3	0	0	0	0	2	1
26	-1	3	0	0	1	0	0	0	0	0	0	0	0	0
27	1	1	0	3	3	0	2	0	0	2	0	1	0	0
28	1	1	-2	1	-1	-2	-2	-1	1	-1	-1	0	-1	-1
29	2	2	5	4	2	-2	0	4	3	-4	-1	0	0	2
30	1	3	0	-1	3	-2	0	3	1	0	0	3	1	0

Appendix F

Raw data layout for Sinus Symptom Visual Analogue Scale Questionnaire

Nosode group

Patients numbers

	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*
Q1	0	4	-1	-1	0	7	2.5	-1	4	3	4	2.5	-6	0	5
Q2	0	4	0	-3	-1	7.5	0.5	4.5	-1	4	5.5	0	2	7	5
Q3	0	-6	2	1.5	3.5	8.5	8	-1	1.5	6	0	1	5	0	6
Q4	0	4	0.5	8	2	5	6	-2	4	1	0	-1	3	0	7
Q5	6	0	0	7.5	0	6	2	-1	5	3	6	1	0	0	6
Q6	0	7	2	2.5	3	7	2.5	-2	5	3	6	2	3	4	6
TP	**6**	**13**	**3.5**	**16**	**8**	**41**	**22**	**64**	**19**	**20**	**22**	**5.5**	**7**	**11**	**35**

Placebo group

Patients numbers

	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*
Q1	6	-2	0	0	0	10	4	0.5	0	5	0	1	-1	10	1
Q2	10	-3	0	4	0	6	3	5.5	3	2	0	0	0	4	3
Q3	6	8	0	1	0	7	5	6.5	1	4.5	2	0	2	5	7
Q4	0	1	0	-3	0	6	7	7	-5	6	0	0	0.5	0	-1
Q5	0	5	0	0.5	0	0	3	0	-2	8.5	0	0	3	5	9
Q6	6	3	0	0.5	0	10	5	1.5	-2	5	2	3	-1	5	8
TP	**28**	**12**	**0**	**3**	**0**	**39**	**27**	**21**	**-5**	**31**	**4**	**4**	**4**	**29**	**27**