

**THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM TREATMENT
OF ORAL MALODOUR**

BY AZIZA MUHAMMED RANDEREE

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I, Aziza Muhammed Randeree, do hereby declare that this dissertation represents my own work in both conception and execution.

—

Aziza Muhammed Randeree

11/11/97

Date

APPROVED FOR FINAL SUBMISSION

Supervisor

Monique Lee M. Tech. (Hom)

11/11/1999

Date

*TO MY HUSBAND, EBRAHIM FOR HIS INTEREST, SUPPORT
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ABSTRACT

The purpose of this placebo-controlled study was to evaluate the efficacy of the homoeopathic simillimum treatment in halitosis in terms of the volatile sulphur compounds being measured objectively by the portable sulphide monitor and subjectively by organoleptic measurement.

It was hypothesized that the patients treated with the homoeopathic simillimum treatment would respond favourably in terms of the presenting complaint. The study was a clinical trial, in which a placebo group was compared to an experimental group. Convenience sampling was used to gather subjects for the trial. Volunteers responded to advertisements that had been placed in various advertising media. Thirty patients were selected from the Durban area. The patients were of both sexes, all race groups and over sixteen years of age.

Thirty subjects who were assessed by the panel of odour judges and by the portable sulphide monitor were accepted into trial. The subjects were randomly divided into two groups i.e. placebo and experimental group. The study was a double blinded study that lasted three months.

Each patient was treated for an initial period of three weeks followed by a final follow up, a month later. Fifteen patients received placebo and fifteen patients received valid homoeopathic simillimum treatment.

All the data obtained by the researcher through the portable sulphide monitor and organoleptic judges were analysed and interpreted by means of parametric statistical tests. The two major tests used were the two-sample unpaired t-test and the two-paired sample t-test.

Using the two-sample paired t-test, it was shown that at the end of the trial period there was a significant difference between the experimental and placebo group at the 5% level of significance.

Using the two-sample unpaired t-test, it was found that there was significant differences in the experimental group between the beginning and the end of the research trial at a 5% level of significance.

From the results it was apparent that the homoeopathic simillimum treatment is effective in treating halitosis.

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DEFINITION OF TERMS

1. **HALITOSIS** : From the Latin word , halitus- meaning exhalation- in this case of offensive breath from the oral cavity, called also fetor ex ore, fetor oris and stomatodysdodia (Dorland and Newman 1994: 729).

2. **ORGANOLEPTIC** : Making an impression on an organ of special sense. Capable of receiving a sense impression. (Dorland and Newman 1994: 1190.)

3. **PLACEBO** : Any dummy medical treatment administered to a control group in a controlled clinical trial in order that the specific and the nonspecific effects of the experimental group can be distinguished (Dorland and Newman 1994: 1298).

4. **REPERTORISATION** : From the Latin meaning to find out, obtain, devise or procedure. It describes the reference book that schematically indexes the symptoms sought to be in the materia medica. These symptoms are classified in a logical structured way, related to each appropriate medicine, offering around each general or particular symptom and its modalities one, or a clutch of potentially suitable remedies. A patient is said to have been repertorised when the total symptom complex has been matched against the listings in such a repertory and the drug that best parallels the majority of the symptoms has been identified. (Gaier 1991: 493- 494.)

5. **SIMILLIMUM** : A homoeopathic remedy specifically chosen from the entire range of homoeopathic remedies, and the pathogenic action matches the total symptom picture of the patient (Jouanny 1993: 91).

CHAPTER ONE

INTRODUCTION

Halitosis is derived from the Latin word 'halitus' meaning bad breath and the Greek word 'osis' meaning disease or condition (Iwu and Akpata. 1990).

Halitosis defined as an unpleasant oral malodour has become a health concern among the general public (Iwakura *et al.* 1994). Halitosis affects a large proportion of the population and may be the cause of significant social and psychological handicap to those who suffer from it (Bosy *et al.* 1994). Oral malodour is a common social and economical problem especially in industrialised countries. In a national survey in Japan carried out in 1993, for example, 24% of the examined persons above the age of 30 years complained about bad breath (Quirynen *et al.* 1998). More than half of the United States population will at some time be affected by halitosis. Annual sales of mouthwashes and related over the counter products in the United States exceed 500 million dollars (Replogle and Beebe. 1996.)

Oral malodour may be caused by a number of factors both intra and extra-orally. In most cases bad breath originates from the oral cavity itself (Quirynen *et al.* 1998). Halitosis of oral aetiology may result from periodontal disease, poor saliva flow, improper dental restorations, excessive microbial colonization of the tongue, or unclean dentures. Non-oral aetiologies include upper and lower respiratory tract conditions, gastrointestinal and

neurological disorders, various systemic diseases and use of certain drugs. (Rosenberg et al. 1991.)

One of the most intriguing problems regarding bad breath is the apparent inability of knowing whether one has it, and to what extent. Many people emit bad breath for years without at all being aware of it. Others greatly overestimate their own oral malodour and are consequently prone to obsessive behaviour such as to avoid social interaction and may even contemplate suicide. (Rosenberg et al. 1995.)

For the assessment of oral malodour, 2 methods are generally used. One method is subjective organoleptic examination and the other is quantitative measurement of volatile sulphide compounds, i.e., gas chromatography and portable sulphide monitor (Shimura et al. 1996).

Rosenberg et al. (1992) and Yaekagi and Sanada (1992) conducted studies on two-phase oil water mouth rinses. These proved effective in reducing oral malodour for a short period of time. Although mouth rinses have been tested for their effectiveness in reducing oral malodour parameters in a variety of studies, few investigations have been conducted using other kinds of oral products (Greenstein et al. 1997).

Homoeopathy is a therapeutic method which clinically applies the law of similars and which uses the medicinal substances in weak or infinitesimal doses in therapy (Jouanny 1993: 11).

To date there has been only one controlled homoeopathic research study done on halitosis. Neumann (1997) conducted a clinical trial on the effect of a halitosis complex (consisting of potentised homoeopathic remedies such as Arnica Montana 4CH, Carbo Vegetabilis 4CH, Arsinicum Album 4CH, Bryonia Alba 4CH, Nitricum Acidum 4CH and Mercurius Solubilis 4CH) on oral malodour. Volatile sulphur compounds were measured by a portable sulphide monitor and organoleptically by three odour judges who then recorded their results on a visual analogue scale (Aker 1995). Non-parametric tests were used to analyse the results. The results showed a significant decrease in volatile sulphur compounds over a three-week period, however an increase in the amount of volatile sulphur compounds was observed during the fourth week of the trial.

The method of treatment used in that study, i.e. the complex method, did not provide long term relief in patients. A shortfall of that study is that the homoeopathic principle of individualised treatment was intentionally overlooked.

The Law of Similars states 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 (Vithoukias 1986: 98).

Thus the researcher was presented with the opportunity of assessing the value of a single homoeopathic remedy as compared to a complex (Neumann 1997) in the treatment of halitosis.

The aim of this placebo-controlled study was to evaluate the efficacy of the homoeopathic simillimum treatment in halitosis, in terms of the quality of mouth air assessed organoleptically and the concentration of the volatile sulphur compounds in the oral cavity measured quantitatively by a portable sulphide monitor.

The potential benefit of the study was most importantly the improvement of the psychological state of the patient and a subsequent improvement in the individual sense of well being.

CHAPTER TWO

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

Twenty- first century technology is providing a growing number of entrepreneurs with big profits. Promoting new cures for one of societies oldest and most troublesome social maladies, people are being coaxed to solve a problem of such a personal nature that those afflicted often will not discuss it even with family and friends. This affliction commonly known as halitosis, could ignite a multimillion-dollar enterprise if permanent treatment is discovered. (Meskin. 1996.)

Halitosis, defined as offensive breath or bad breath (Dorland and Newman 1994: 729), is a common human condition affecting primarily the adult population (Rosenberg *et al.* 1991). Oral malodour, which is commonly noticed by the patients themselves, is an important clinical sign and symptom which often aids clinicians in establishing a diagnosis of underlying pathology (Touyz. 1993).

Halitosis is a prevalent affliction, affecting 25 to 85 million Americans. Ninety two percent of dentists surveyed at the American Dental Associations 1995 annual session

reported that they had patients with chronic bad breath. Almost half reported seeing six or more patients weekly with unpleasant breath. Based on that statistic, those dentists would encounter roughly 500,000 halitosis patients a week. (Meskin. 1996.)

2.2. PATHOGENESIS

The exact pathophysiological mechanism is not clear, but several conditions have been deemed responsible for septic or putrefactive changes in the mouth, nose, nasal sinuses, or lungs. Smoking or ingestion of garlic, onions or paraldehyde, whose volatile products are excreted by the lungs or in saliva may be causes of bad breath. There are also some psychiatric cases in which the patients suffer from imaginary halitosis (Tiomny *et al.* 1992.)

Halitosis is caused mainly by volatile sulphur compounds (VSC) including hydrogen sulphides, methyl mercaptan, and dimethyl sulphide (Yaekagi and Sanada. 1992). VSC increases the permeability of the oral mucosa and collagen solubility and decrease protein and collagen synthesis. Microbiological studies have demonstrated that periodontal pathogenic microorganisms contribute to increased VSC production, in particular that of methyl mercaptan, in the oral cavity. Therefore it has been suggested that *Fusobacterium*, *Porphyromonas gingivalis* and other microorganisms have important roles in the pathogenesis of halitosis. (Yaekagi and Sanada.1992.)

2.3. AETIOLOGY

Halitosis is a condition that is easy to recognise but the cause can be difficult to discover. The commonest causes are found in the mouth. If they are not present in the mouth then an extra oral source should be sought. (Symposium. 1990.) A recent report on experience gained in a Multidisciplinary Breath Odour Clinic indicated that in 87% of the consulting patients, oral malodour could be related to an oral cause (Quirynen *et al.* 1998).

Chronic periodontal disease and gingivitis are perhaps the most common causes of halitosis. These conditions flourish in a confined, anaerobic environment, protected from the flow of saliva. Periodontal disease and gingivitis are therefore conducive to bacterial overgrowth. Stomatitis and glossitis resulting from underlying systemic disease, medication or vitamin deficiencies may cause odour when ulcers or fissures develop trapping food particles and desquamated tissue. (Replogle and Beebe. 1996.)

Saliva from individuals with periodontitis putrefies more rapidly and the odour is more disagreeable in comparison to saliva in healthy individuals. This is attributable in part to the degradation of blood and host cellular products that provide substrates for generation of volatile sulphur compounds. (Bosy *et al.* 1994.)

Reduced salivary flow leading to a dry mouth (xerostomia) contributes to conditions favouring oral malodour production. . Decrease in saliva can be caused by many factors; for example, dehydration, aging, anemia, metabolic disease, autoimmune disease of the salivary glands, malignancy and medication. (McDowell *et al.* 1993.)

Chronic xerostomia may also cause caries, infection, mucosal dehydration and atrophy. The bacteria on the tongue also correlates strongly with malodour. A growing body of research indicates that tongue coating also plays a significant role in odour formation. (Quiryne *et al.* 1998.)

Tobacco smokers and garlic eaters may have peculiar breath of varying intensity, which is made more objectionable if the individuals oral hygiene is also poor (Iwu and Akpata. 1990).

Ozostomia refers to a putrid smell that is detected from the mouth but is derived from the upper respiratory tract, in particular the nasal and sinus cavities, the pharynx and larynx. Thus the aetiologies include rhinitis, sinusitis, pharyngitis, laryngitis, tonsillitis and nasal polyp or carcinoma. Foul breath from the mouth originating from the lower respiratory tract, also known as stomadysdodia may be caused by infective or necrotic processes of the lower respiratory tract. For example, bronchitis, bronchiectasis, tuberculosis, carcinoma of the lung, lung abscess, emphysema and pulmonary infarcts. (Touyz. 1993.)

In older literature, diseases of the gastrointestinal tract have been mentioned as possible causes along with pyloric stenosis and gastrocolic fistulas. In a study conducted by Tiomny *et al* (1992), subjects suffering from halitosis and with evidence of *Helicobacter pylori* were treated with a course of colloidal bismuth subcitrate. The halitosis had disappeared along with eradication of the organism in all subjects.

Persons suffering from dyspepsia, reflux, hiatus hernia, gastric cancer, malabsorption syndrome and enteric infections may also have halitosis. Systemic diseases such as diabetes mellitus, kidney failure, several liver disorders, gallbladder dysfunctions and blood dyscrasias, e.g. leukemia may cause bad breath. (Replogle and Beebe. 1996.)

2.4. THE HALITOSIS SOCIAL HANDICAP

There are apparently healthy individuals who complain of having bad breath which no one else can smell and for which no local or systemic condition can be found (Iwu and Akpata. 1990).

Some patients may suffer from halitophobia or imaginary bad breath. Although various psychological states have been used to describe this population, (e.g. delusion, hypochondria, obsessive compulsive disorder, olfactory reference syndrome), none are satisfactory. The current success rate in dealing with such individuals appears low and indicates the need for collaboration with psychological and/or psychiatric counseling. (Quirynen et al. 1998.) Halitophobics are driven to social isolations, may have their teeth extracted and occasionally even commit suicide (Rosenberg et al. 1995).

2.5. ASSESSMENT OF HALITOSIS

For the assessment of oral malodour in scientific investigations, reliable methods of measurements are required. Previous methods of assessing oral malodour have been based upon subjective, organoleptic scales or quantitative measurement of volatile sulphur compounds or both. Quantitative measurements by gas chromatography, cryoscopy and

culture of plaque and periodontal exudates require laboratory facilities, are time consuming and expensive. Recent studies have investigated the use of a simple, rapid technique for measurement of halitosis related sulphides by using a portable sulphide monitor. (Rosenberg et al. 1991.)

Shimura et al. (1996) conducted a study on a new volatile sulphide compound (VSC) monitor with a zinc-oxide, thin film semiconductor sensor by comparing it with other means of measurement. They reported its characteristics as rapid in warming up, simple to handle with high reproducibility and a good specificity and sensitivity. The volatile sulphide monitor, which is small in size, simple to handle and has sensitive correspondence to the organoleptic assessment, can be used to measure halitosis without much restriction (Shimura et al. 1997).

2.6. MANAGEMENT OF HALITOSIS

2.6.1 Oral hygiene

Since halitosis often originates in the oral cavity, proper oral hygiene must be stressed. Patients should be instructed to brush their teeth at least twice a day and floss once a day. Tongue brushing, as well as palatal brushing, is an important method of reducing mouth odour. Regular dental consultations may be appropriate. (Replogle and Beebe. 1996.)

Dental health care is mandatory and dentures should not be worn during sleep, but kept clean by overnight soaking. Strict attention should be given to diet and the elimination if possible, of smoking and alcohol intake. (Symposium. 1990.)

2.6.2 Allopathic management

Much research has been reported on mouthwashes eliminating oral bacteria and therefore reducing oral malodour. Yaekagi and Sanada (1992) experimented with an oil-water mouthwash to determine the effect on sulphides in mouth air, showing that volatile sulphides are consistently reduced.

Rosenberg *et al.* (1991) used chlorexidene mouth rinse regimens to show reductions in mouth odour. Chlorexidene was effective in reducing microbial levels for longer than 3 hours as measured by the rinsing technique.

The Department of National Health and Population and Development (1994) suggest that antiseptic mouthwashes reduce the bacterial count by letting in oxygen, which is toxic to the Gram- negative bacteria, thereby retarding bacterial growth. Aromatic mouthwashes can also temporarily mask malodour and stimulate salivation.

In a study conducted by Greenstein *et al.* (1997), the anti malodour properties of oxidising lozenges was compared to breath mints and chewing gum. It was concluded that sucking of a full strength lozenge with oxidising properties reduces tongue dorsum malodour for 3 hours following use.

Most mouthwashes only mask odours for a short time and alcohol containing mouthwashes can dry oral tissues (Replogle and Beebe. 1996).

However, in America, over the counter “cure” (mouth rinses, chewing gum, mints and sprays) for those seeking temporary solutions for their breath problem have created a billion dollar industry (Meskin. 1996).

2.7. Homoeopathic Management

2.7.1 Introduction

Homoeopathy is a therapeutic method which clinically applies the law of similars and which uses medicinal substances in weak or infinitesimal doses in therapy (Jouanny 1993: 11).

Homoeopathy is an exceptionally safe form of medicine that treats the whole individual. It relies on the body’s own powers of self-regulation and self-healing. Since it’s development nearly two hundred years ago, it has benefited millions of people, all over the world. (Lockie and Geddes 1992: 15.)

2.7.2 Homoeopathic Simillimum Treatment

Simillimum treatment is based on the comparison of the symptom complex presented by the patient with the symptom complex presented by the remedies (Boyd 1989: 20).

The Law of Similars (*Similia Similibus Curentur*) was a new principle uncovered by Hahneman over two hundred years ago. He called it “like cures like”, and this is now the fundamental pillar of the science of homoeopathy. This principle states that any substance that can produce a totality of symptoms in a healthy human being can cure that totality of

symptoms in a sick human being. Simillimum is the name given to the medicine or remedy that best corresponds to the patient's symptoms. Most homoeopathic prescriptions are based on the simillimum principle. In other words, there are no medicines for specific conditions or diseases. Therefore when two patients, suffering from the same condition, consult a homoeopath, they receive different prescriptions depending on the symptoms they present with. (Vithoukas 1986: 92.)

2.7.3 Perspectives in Homoeopathy in Halitosis Management

A double-blind study conducted by Neumann (1997) demonstrated that the use of a homoeopathic complex led to a reduction in volatile sulphur compounds in mouth air and a significant improvement in oral malodour. However this study (Neumann 1997) was conducted over a short period of time and it was a recommendation by the researcher that a long-term treatment be investigated.

As far as it could be ascertained no other research has been done in the field of treating halitosis homoeopathically.

Information from provings of homoeopathic remedies in the *Materia Medicas* indicate that bad breath can be treated depending on similarity of symptoms to the remedy (Jouanny 1984: 38, Boericke 1990: 77, Morrison 1993: 46).

2.8 SUMMARY

Bad breath is a cause of concern, embarrassment and frustration on the part of the general public. Oral malodour, whether real or perceived, can lead to social isolation and even contemplation of suicide. Considering human preoccupation with pleasing social appearances, a permanent treatment for halitosis could prove a landmark breakthrough in medical science.

Homoeopathy is a safe and effective therapeutic method as it acts by stimulating the body's immunological system to initiate healing (Ullman 1991: 99). It is therefore very effective in the treatment of psychosocial conditions like halitosis.

This study aims to evaluate the efficacy of the homoeopathic simillimum in the management of halitosis.

CHAPTER 3

MATERIALS AND METHODS

3.1. THE STUDY DESIGN

This study was a double-blind placebo controlled clinical trial. In this study a treatment group was compared to a placebo group in order to evaluate the efficacy of the homoeopathic simillimum treatment on halitosis (oral malodour).

A total number of 30 patients participated in the study. Fifteen patients received placebo treatment and fifteen patients received the valid homoeopathic treatment.

The following steps were taken in the execution of the study:

3.1.1. Patients were recruited by advertising in local newspapers and at the health shops.

3.1.2. 30 patients were selected according to the inclusion and exclusion criteria as set out by the study as discussed in section 3.2.

3.1.3. Consultation with each patient was according to the following steps:

3.1.3.1. Day one = Consultation one

Each patient was screened according to the inclusion and exclusion criteria as discussed in section 3.2. If selected into the study each patient was required to complete the informed consent document (Appendix A).

Thereafter the researcher using the case history format (Appendix B) took a complete homoeopathic and medical case history.

The researcher performed a complete physical examination. Thereafter a dentist performed an oral examination. The patients breath was measured using the portable sulphide monitor and recorded in parts per million (ppm) (Appendix C).

The breath was also tested organoleptically by three odour judges who recorded their findings on a visual analogue scale (Aker 1995) (Appendix D).

Each case was then repertorized using the Synthesis Repertory (1995). A prescription was then formulated and checked by a qualified homoeopathic clinician.

The prescription was then submitted to the research clinician, who randomly divided the sample of 30 patients into 2 groups i.e. 15 patients in the experimental group and 15 patients in the placebo group. Randomization was achieved by using ballot papers. Each number chosen by a patient corresponded to the same number on a list drawn up by the research clinician. This number decided whether the patient received placebo or the valid homoeopathic medication. The respective medication was then dispensed to each patient. The patients were asked to refrain from smoking, drinking, eating, chewing, brushing, flossing and mouth rinsing at least two hours prior to each follow up consultation.

3.1.3.2. Week two = Consultation two

Each patient was reassessed. The patients breath was measured using the portable sulphide monitor and the results were recorded (Appendix C).

The breath was also measured by the organoleptic method and the results were recorded (Appendix D).

3.1.3.3. Week three = Consultation three

The patients breath was reassessed using the portable sulphide monitor and by the organoleptic method. Results were then recorded. (Appendix C, D) respectively.

3.1.3.4. Week seven = Consultation four

Each patient was reassessed and the results were recorded.

3.2. SUBJECTS

Patients were recruited by advertising in the local newspapers and health shops. Each patient was screened by the researcher according to the inclusion and exclusion criteria as set out by the research.

3.2.1. Inclusion Criteria

3.2.3.4. Patients had to be above the age of 16 years.

3.2.3.5. Patients from all race groups were included in the study.

3.2.3.6. Patients of both sexes were included in the study.

3.2.2. Exclusion criteria

Patients were excluded from the study if they were known to be suffering from the following disorders:

Malignancies

Brochiectasis

Renal disorders

Diabetes Mellitus

Diabetes Insipidus

Wegeners Granulomatosis

Pulmonary Tuberculosis

Abscess of the Lung

Throat and Sinus infection

3.3. ETHICS

The nature of the study was explained to each participant at the outset by the researcher. Each participant was asked to read and complete the informed consent form (Appendix A), which stated that they were participating in the study of their own free will and could withdraw from the study at any time without any cost or obligation.

3.4. INTERVENTIONS

3.4.1. Homoeopathic simillimum treatment

The medicine used in the study was obtained from W. Last and Company in Cape Town. The medication was prescribed in pillule form and was to be taken via the oral route sublingually. The medication was dispensed as hard lactose granules and was impregnated at a rate of 2% with the prescribed homoeopathic simillimum remedy.

A homoeopathic clinician dispensed each participant's medication, as set out in the prescription by the researcher. The clinician was a neutral member of the study and exclusively had access to the randomization list, which determined which patient, received placebo and which patient received valid homoeopathic medication.

Patients were instructed on how to take the medication by the researcher. Medication was to be taken twenty minutes before meals and not in association with coffee or tea. Patients were instructed to store medicines in a dark place away from any strong smelling substances.

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

Patients were given a vial of medication from which 3 pillules were to be taken twice a week for three weeks.

3.4.2. Placebo treatment

The medicine in this group was identical to the medication in the experimental group in all respects, with the exception that the pillules dispensed were unmedicated or unpregnated with any remedy. The placebo medicine was in the form of neutral pillules, which was prepared from *sacchrum lactis*.

The placebo medicines were also taken orally and sublingually. The placebo medicines were dispensed in the same manner as were the valid homoeopathic medication.

3.5. MEASUREMENTS AND OBSERVATIONS

Two kinds of data were needed for this study:

- 3.5.1. The physiological response of patients with halitosis to the treatment with the homoeopathic simillimum as measured by an organoleptic method.

3.5.2. The physiological response of patients with halitosis to treatment with the homoeopathic simillimum as measured by a portable sulphide monitor.

3.5.1. The organoleptic measurement

A panel of at least 3 odour judges obtained the data needed for organoleptic measurement. This involved the training of individuals to recognise different degrees of offensive mouth odour. Training was done using the triangular test method (Lyon *et al.* 1992: 24). The individuals were presented with 3 samples of alcohol and advised that the percentage of one of the three samples of alcohol was different, and was asked to identify the different sample. The percentages of two of the samples of alcohol used were 60% and the percentage of the third sample of alcohol used was 30%. Training was done over a two-week period prior to seeing the patient for halitosis. The odour judges recorded their organoleptic assessment on a 10cm visual analogue scale (Aker 1995) (Appendix D). The judges were asked to refrain from drinking coffee, smoking or wearing scented personal products prior to the examination (Rosenberg *et al.* 1991). The odour judges were unaware of their and the other odour judges previous organoleptic scorings of the patient.

3.5.3. The measurement by the portable sulphide monitor

The data needed for measurement of hydrogen sulphide in mouth air was obtained from a portable sulphide monitor pm 700 series (single gas monitor) ordered from Metrosonics Inc. The subjects were asked to hold the sensor of the monitor at least 1 cm from his slightly open mouth and exhale briefly through his mouth. The monitoring unit then displayed data of an individual exposure in parts per million and the results were recorded. (Appendix C).

3.6. STATISTICAL PROCEDURES

Procedure one: Comparison between 2 unpaired (independent) samples

As both variables of study were continuous, the two-sample unpaired t-test was used to compare 2 independent samples with respect to each continuous variable. In each test, the null hypothesis states that there is no significant difference between Groups 1 and 2 (i.e. experimental group and placebo group respectively), with respect to the variable in charge, at the $\alpha = 0.05$ level of significance. The alternative hypothesis states that there is a significant difference.

Decision Rule: The null hypothesis is rejected at the alpha level of significance if $p < 0$ where p is the observed significance level or p-value. Otherwise, the null hypothesis is accepted at the same level.

Remark: The Mann-Whitney U test was not used because the variables were continuous, and not categorical. However, results from the Mann-Whitney U test were similar to those obtained from the two-sample unpaired t-tests.

Procedure Two: Comparison between 2 related samples within group 1 (experimental group)

As both variables were continuous, the two-sample paired t-test was used to compare results from related samples. In each test, the null hypothesis states that there is no

significant improvement between 2 related samples being compared, at the alpha level of significance. The alternative hypothesis states that there is a significant improvement.

Decision Rule: The null hypothesis is rejected at the alpha level of significance if $p < \alpha$ where p is the observed significance level or p -value. Otherwise, the null hypothesis is accepted at the same level.

Remark: Wilcoxin's signed rank test was not used because the variables were continuous, and not categorical. However, results from Wilcoxin's tests were similar to those obtained from the two-sample paired t -tests.

Procedure Three: Comparison between related samples within group 2 (placebo group)

Procedure 2 is repeated within group 2 with the same decision rule.

Procedure Four: Summary statistics

Means and variances for continuous variables

Averages and variances were computed for continuous variables only, and were used for the construction of barcharts.

Procedure five: Comparison using barcharts

Visual summaries of analytical findings will be given by use of barcharts to compare Groups 1 and 2 with respect to the variables. Average (mean) readings was be used to construct barcharts.

Statistical Package:

The statistical package **SPSS** was used for data entry and analysis.

CHAPTER FOUR

RESULTS

4.1. INTRODUCTION

This chapter covers the results obtained after statistically analysing the data collected from the measurement criteria used, namely:

The Hydrogen Sulphide Monitor (Appendix C)

The Visual Analogue Scale

Comparisons were made between the two groups (experimental and placebo groups), using the two sample unpaired t-test. Thereafter comparisons were made within each group, using the two-sample paired t-test. The use of these parametric tests showed whether there was a significant difference between the two groups (experimental and placebo groups).

Bar graphs were compiled using the median values of the portable sulphide monitor readings on four consultations. Another set of bar graphs were drawn up using the median values of the visual analogue scale on four consultations.

These sets of graphs were used to compare and contrast the findings between the experimental group and the placebo group before and after treatment.

4.1.1. The two-sample unpaired t-test

This test was used to make comparison between the experimental and placebo group. In each test, the null hypothesis states that there is no significance difference between the two groups within the 5% level of significance of the test. The decision rule states :

1. Reject the null hypothesis at the alpha level of significance if $p < 0$ were p is the observed significance level or p-value. Other wise, the null hypothesis is accepted at the same level.

4.1.2. The two-sample paired t-test

This test was to make comparison within the experimental and placebo group. In each test, the null hypothesis states that there is no significant difference within each group, within the 5% level of significance of the test. The decision rule states:

1. Reject the null hypothesis at the alpha level of significance if $p < 0$ were p is the observed significance level or p-value. Otherwise, the null hypothesis is accepted at the same level.

4.2. Criteria for the admissibility of data

- a) Only the data collected from the trial were accepted.
- b) Data was obtained from the portable sulphide monitor and the visual analogue scale completed by the researcher and the organoleptic judges.

4.3. The Results

4.3.1. Table 4.1

COMPARISON BETWEEN PLACEBO AND EXPERIMENTAL GROUPS ACCORDING TO DATA FROM THE PORTABLE MONITOR (in parts per million) USING THE TWO-SAMPLE UNPAIRED T-TEST.

GROUPS	CONSULTATION	ALPHA	P-VALUE	DECISION
EXP VS PLACEBO	1	0.05	0.029	REJECT
EXP VS PLACEBO	2	0.05	0.074	ACCEPT
EXP VS PLACEBO	3	0.05	0.018	REJECT
EXP VS PLACEBO	4	0.05	0.003	REJECT

Exp = Experimental

Alpha = Significance Level

Alpha = 0.05

Decision = Ho

Ho = There is no significant improvement between the consultations at the alpha = 0.05 level of significance.

In consultation 1, 3, 4, there was significant difference between the experimental group and the placebo group with regards to the mean values of the portable sulphide monitor.

And 1 & 3 with regards to the hydrogen sulphide monitor.

4.3.2. Table 4.2

**COMPARISON BETWEEN PLACEBO AND EXPERIMENTAL GROUPS
ACCORDING TO DATA FROM THE VISUAL ANALOGUE SCALE
(ORGANOLEPTIC READINGS) USING THE TWO-SAMPLE UNPAIRED
T-TEST.**

GROUPS	CONSULTATION	ALPHA	P-VALUE	DECISION
EXP VS PLACEBO	1	0.05	0.283	ACCEPT
EXP VS PLACEBO	2	0.05	0.166	ACCEPT
EXP VS PLACEBO	3	0.05	0.004	REJECT
EXP VS PLACEBO	4	0.05	0.008	REJECT

Exp = Experimental

Alpha = Significance Level

Alpha = 0.05

Decision = Ho

Ho = There is no significant difference between the consultations at the alpha = 0.05 level of significance.

In consultations 3 and 4 there were significant differences between the placebo and experimental groups with regards to the mean values in terms of organoleptic readings.

4.3.3. Table 4.3

COMPARISON OF SAMPLES WITHIN THE EXPERIMENTAL GROUP AS RECORDED ON THE PORTABLE SULPHIDE MONITOR (in parts per million) USING THE TWO-SAMPLE PAIRED T-TEST.

CONSULTATION	P-VALUES	ALPHA	Ho
1 & 2	0.104	0.05	ACCEPT
1 & 3	0.005	0.05	REJECT
1 & 4	0.01	0.05	REJECT
2 & 3	0.229	0.05	ACCEPT
2 & 4	0.284	0.05	ACCEPT
3 & 4	0.67	0.05	ACCEPT

Alpha = Level of Significance

Ho = There is no significant difference between the consultations at the
Alpha = 0.05 level of significance

There was significant differences in the experimental group between

Consultations 1 & 3 and 1 & 4 (i.e. before and after treatment).

4.3.4. Table 4.4

COMPARISON OF SAMPLES WITHIN THE EXPERIMENTAL GROUP AS RECORDED ON THE VISUAL ANALOGUE SCALE (ORGANOLEPTIC READINGS) USING THE TWO-PAIRED SAMPLE T-TEST.

CONSULTATION	P-VALUES	ALPHA	Ho
1 & 2	0.002	0.05	REJECT
1 & 3	0.001	0.05	REJECT
1 & 4	0.012	0.05	REJECT
2 & 3	0.146	0.05	ACCEPT
2 & 4	0.529	0.05	ACCEPT
3 & 4	0.539	0.05	ACCEPT

Alpha = Level of Significance

Ho = There is no significant difference between the consultations at the
alpha = 0.05 level of significance

There was significant difference in the experimental group between consultations 1 & 2, 1 & 3 and 1 & 4 with regards to the organoleptic readings.

4.3.5. Table 4.5

COMPARISON OF SAMPLES WITH THE PLACEBO GROUP AS RECORDED ON THE PORTABLE SULPHIDE MONITOR (in parts per million) USING THE TWO-PAIRED SAMPLE T-TEST

CONSULTATION	P-VALUES	ALPHA	Ho
1 & 2	0.027	0.05	REJECT
1 & 3	0.004	0.05	REJECT
1 & 4	0.055	0.05	ACCEPT
2 & 3	0.424	0.05	ACCEPT
2 & 4	0.207	0.05	ACCEPT
3 & 4	0.072	0.05	ACCEPT

Alpha = Level of Significance

Ho = There is no significant difference between the consultations at the alpha = 0.05 level of significance

There was significant difference in the placebo group between consultations 1 & 2 and 1 & 3 with regards to the portable sulphide monitor readings.

4.3.6. Table 4.6

COMPARISON OF SAMPLES WITHIN THE PLACEBO GROUP AS RECORDED ON THE VISUAL ANALOGUE SCALE (ORGANOLEPTIC READINGS) USING THE TWO-PAIRED SAMPLE T-TEST.

CONSULTATION	P-VALUES	ALPHA	Ho
1 & 2	0.006	0.05	REJECT
1 & 3	0.123	0.05	ACCEPT
1 & 4	0.679	0.05	ACCEPT
2 & 3	0.094	0.05	ACCEPT
2 & 4	0.038	0.05	REJECT
3 & 4	0.257	0.05	ACCEPT

Alpha = Level of Significance

Ho = There is no significant difference between the consultations at the alpha = 0.05 level of significance

There was significant difference in the placebo group between consultations 1 & 2 and 2 & 4 with regards to the organoleptic readings.

4.3.7. Table 4.7

SUMMARY STATISTICS OF THE PORTABLE SULPHIDE MONITOR READINGS FOR THE EXPERIMENTAL GROUP (GROUP 1) AND PLACEBO GROUP (GROUP 2) FOR FOUR CONSECUTIVE CONSULTATIONS.

	CONSULT	ONE	CONSULT	TWO	CONSULT	THREE	CONSULT	FOUR
	GROUP 1	GROUP 2	GROUP 1	GROUP 2	GROUP 1	GROUP 2	GROUP 1	GROUP 2
MEAN	0.0368	0.036763	0.02906	0.04899	0.03207	0.04577	0.04667	0.04458
VARIANCE	0.01952	0.02124	0.01267	0.036	0.01543	0.03143	0.03267	0.02981
RANGE	0.5	0.5	0.4	0.6	0.5	0.5	0.6	0.7

4.3.8. Table 4.8

SUMMARY STATISTICS OF THE ORGANOLEPTIC READINGS (VISUAL ANALOGUE SCALE) FOR THE EXPERIMENTAL GROUP (GROUP 1) AND PLACEBO GROUP (GROUP 2) FOR FOUR CONSECUTIVE CONSULTATIONS.

	CONSULT	ONE	CONSULT	TWO	CONSULT	THREE	CONSULT	FOUR
	GROUP 1	GROUP 2	GROUP 1	GROUP 2	GROUP 1	GROUP 2	GROUP 1	GROUP 2
MEAN	1.0204	0.9133	0.7896	1.0862	0.6126	0.9799	0.9407	1.0778
VARIANCE	1.041	0.834	0.624	1.18	0.375	0.96	0.885	1.162
RANGE	3.9	2.9	2.8	3.2	1.8	3	2.8	3.5

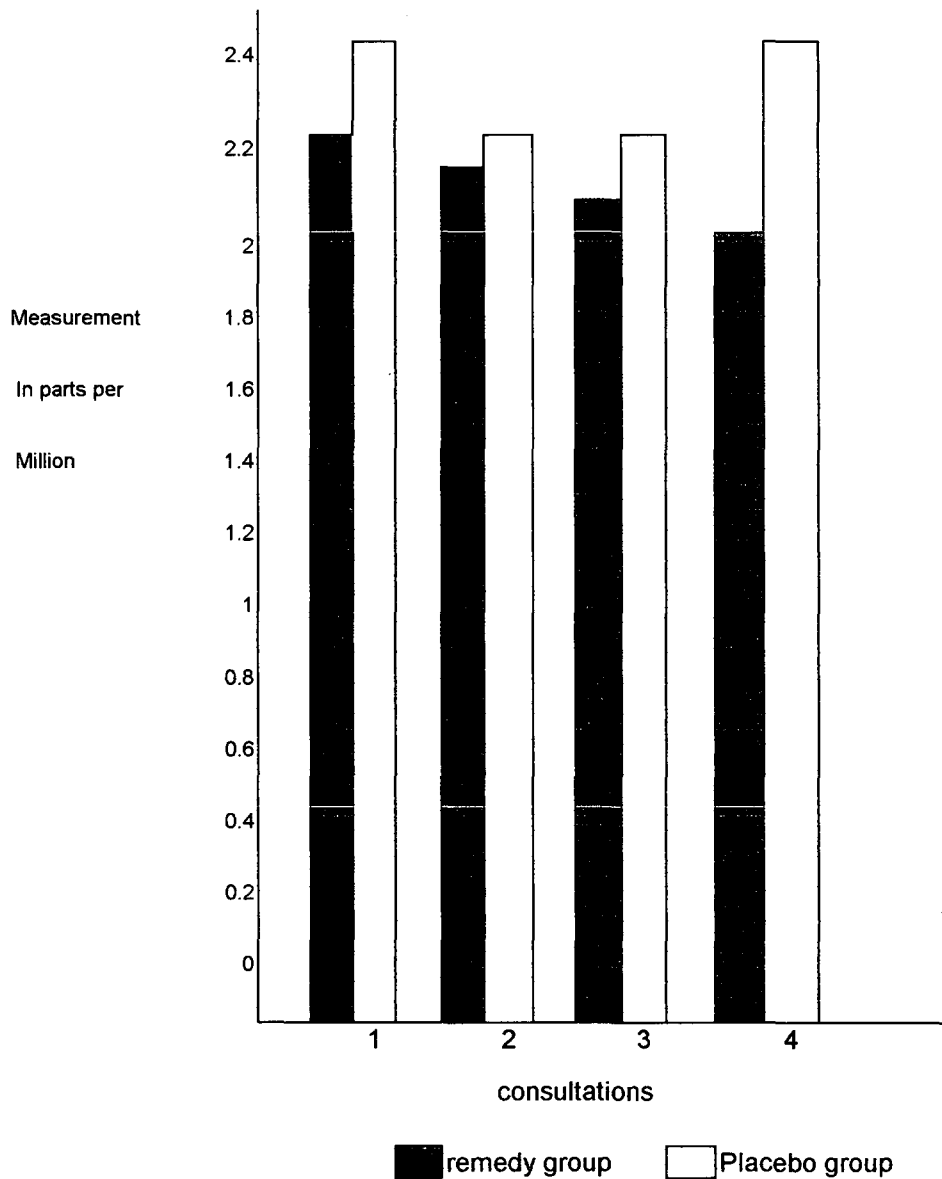
4.3.9. Table 4.9

REMEDY SELECTION AND PATIENT PROFILE

REMEDY	EXPERIMENTAL	PLACEBO
ARGENTUM NITRICUM	1	1
ARSENICUM ALBUM	1	1
BARYTA CARBONICUM	0	1
CALCAREA CARBONICUM	1	0
CARBO VEGETABILIS	1	0
FLOURICUM ACIDUM	1	1
HEPAR SULPHURIS CALCAREUM	0	1
KALIUM BICHROMICUM	0	2
KREOSOTUM	1	1
LYCOPodium	0	1
LACHESIS	1	0
MERCURIUS SOLUBILIS	3	1
NATRUM MURIATICUM	0	1
NITRICUM ACIDUM	1	2
NUX VOMICA	1	1
PHOSPHORUS	2	1
SULPHUR	1	0

The patient profiles indicate that the most popular remedies used were Mercurius Solubilis (4 patients), Nitricum Acidum (3 patients) and Phosphorus (3 patients).

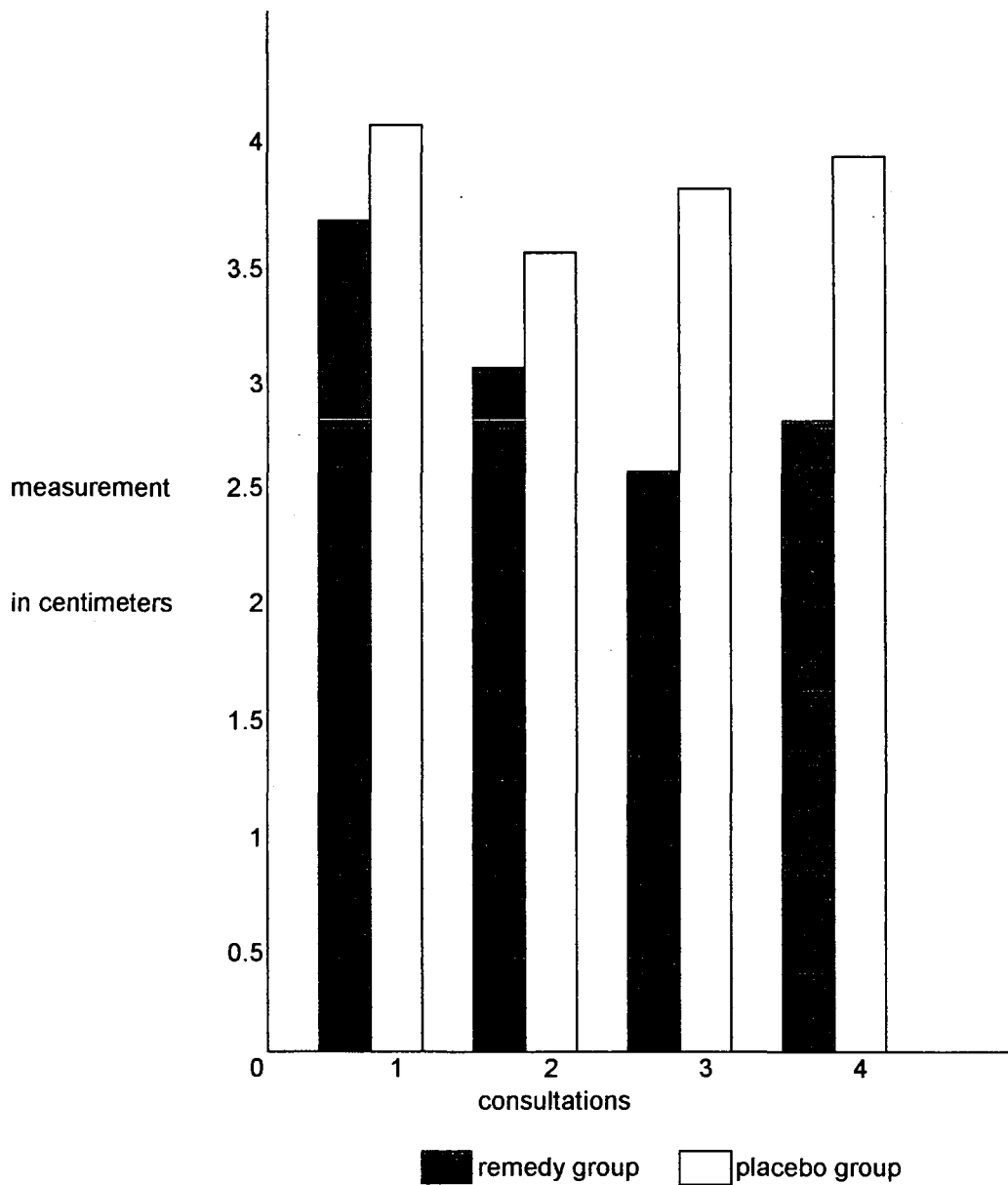
4.3.10. Figure 4.1

COMPARISON BETWEEN THE PLACEBO AND EXPERIMENTAL GROUPS WITH RESPECT TO THE MEAN READINGS OBTAINED FROM THE PORTABLE SULPHIDE MONITOR (in parts per million)

This graph illustrates the median values of the portable sulphide monitor readings of both groups over the four consultations.

4.3.10. Figure 4.2

COMPARISON BETWEEN THE PLACEBO AND EXPERIMENTAL GROUPS WITH RESPECT TO THE MEAN READINGS OBTAINED FROM THE VISUAL ANALOGUE SCALE (organoleptic readings)



This graph illustrates the median values of the organoleptic readings of both groups over the four consultations.

CHAPTER FIVE

DISCUSSION

5.1. INTERPRETATION

Halitosis, a general term denoting unpleasant breath arising from physiological and pathological causes from oral and systemic sources (Tonzetich.1977).

This study was designed to evaluate the efficacy of the homoeopathic simillimum treatment in halitosis, in terms of the volatile sulphur compounds being measured objectively by a portable sulphide monitor and subjectively by organoleptic measurement.

Intergroup comparisons show that there was significant differences in the p-values between the experimental and placebo groups after treatment as shown in tables 4.1 and 4.2.

Table 4.1 shows that there was a significant difference between the experimental and placebo group at consultation one (i.e. before treatment), and at consultations three and four (i.e. after treatment) with regard to the organoleptic readings.

The organoleptic readings were recorded on a visual analogue scale (Aker 1995). Table 4.2 depicts that there were significant differences between the experimental and placebo group at consultation three and four (i.e. after treatment) with regard to the organoleptic readings.

Intragroup comparisons revealed that there was a significant decrease in oral malodour after treatment in the experimental group using both the portable sulphide monitor and organoleptic readings as shown in tables 4.3 and 4.4.

Within the experimental group the p-values were significantly different between consultations one and three and one and four, i.e. before and after treatment according to readings obtained from the portable sulphide monitor as shown in table 4.3.

The p-values calculated from the organoleptic readings within the experimental group showed a significant difference between consultations one and two, one and three and one and four. It should be noted that the difference was seen after the treatment as displayed in table 4.4.

Intragroup comparison of the placebo group showed significant differences between consultations one and two essentially using both the portable sulphide monitor and organoleptic readings as shown in tables 4.5 and 4.6. Yet no significant difference was seen between consultations one and four, i.e. before and after treatment.

Within the placebo group there was a significant difference between consultations one and two, and, one and three according to the portable sulphide monitor readings shown in table 4.5.

The p-values of the organoleptic readings within the placebo group is displayed in table 4.6. Here a significant difference was shown between consultations one and two, and, two and four.

The median readings with respect to the organoleptic readings show no significant change before and after treatment in the placebo group. It should be noted that there is a discrepancy in the experimental group before and after treatment, i.e. the median decreased on the fourth consultation.

The medians of the portable sulphide monitor readings were calculated as illustrated in figure 4.2. Here the medians of the placebo group remained the same i.e. before and after treatment. The medians of the experimental group decreased after treatment as shown in figure 4.2.

The patient profiles in table 4.9 found in this study were indicated by the remedy prescribed to the patients in both groups. It was found that Mercurius solubilis was the most popular remedy. Nitricum acidum and Phosphorus also featured often in the prescription. It should be highlighted that Mercurius solubilis was used in the experimental group which subsequently showed significant improvement.

According to the results tabulated and illustrated it is apparent that there was a statistically significant improvement in the experimental group after the treatment. Thus, the homoeopathic simillimum treatment was found to be effective in treating halitosis which is in accordance with the homoeopathic principle of similars. (Boyd 1989. 11.)

5.2. ARGUMENT

One major obstacle to oral malodour research has been scientific measurement. Since oral malodour is a perceived olfactory stimulus, assessment by human judges may be the most

logical one. However this poses the problem of subjectivity were an individuals perception is used as a means of measurement. To counterbalance this problem the portable sulphide monitor was used as modern objective means of calculation. This subjectivity implies that the research has to rely on the individuals ability to recall, rate and record the information required. This could allow for error in authenticity of information. If the organoleptic method of measurement could be revised to include an objective element for further studies, a more tangible objective means of recording information may be used.

In a similar study conducted by Neumann (1997), the complex method of treatment was used and it was found that this method of treatment did not provide relief over a long period of time i.e. to chronic halitosis.

The period of treatment used in this study was two months and the homoeopathic simillimum treatment appeared to have provided lasting relief to chronic sufferers. Therefore it is important for homoeopaths to consider the homoeopathic simillimum treatment method in halitosis.

In the past, dentists had often circumvented patients questions regarding this problem. (Rosenberg *et al.* 1995). This study was conducted in a dental clinic in a medical center where it was incidentally found that the majority of the patients were diagnosed with periodontal disease, thus portraying that this study is of direct importance to dental practitioners and researchers where homoeopathic remedies may be used as complimentary treatment to dental practices.

5.3. SPECULATION

This study was conducted using a small sample size of thirty patients. Small trials require large observed differences to be statistically significant (Lewith and Aldridge, 1993:21).

The results of this study could have been more significant if a large sample size was used.

Patient education and compliance must be enforced as most patients use breath mints, mouthwashes daily out of habit and chew gum constantly. This could alter readings on the portable sulphide monitor and would also affect the ratings of the organoleptic judges.

During the study it was seen that patients have imagined halitosis due to presumptions based upon others attitudes. According to Iwakura *et al* (1994), patients complaining of halitosis should be categorised by a questionnaire before treatment into three types: Type 1; self conscious, Type 2; conscious by the indication of others and Type 3; conscious by presumption from the attitudes of others.

It was apparent that the causes of halitosis are many (refer chapter two). Therefore it should be considered to every health care practitioner to screen each patient suffering from halitosis in order to find the proper aetiology of the condition. These patients should then be referred to the respective practitioners e.g. dentist, physician, etc. to aid in management.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1. CONCLUSION

The subject of halitosis is a sensitive one, especially for the people suffering from it who invariably fall prey to the odd wry comment from friends and colleagues. This embarrassing problem is only masked by commercial mouthwashes as these often only compound the problem. Immaculate oral hygiene such as repeated brushing and flossing which may logically seem to be the answer, unfortunately do not help eliminate bad breath.

This study attempted to evaluate the efficacy of the homoeopathic simillimum treatment compared to placebo treatment in halitosis in terms of the volatile sulphur compounds measured objectively by the portable sulphide monitor and subjectively by organoleptic measurement.

A statistically significant improvement was observed at the end of the research trial when the homoeopathic simillimum treatment was compared to the placebo treatment. A significant decrease in the portable sulphide monitor readings and organoleptic readings over the four consultations was observed at the end of the study. It was thus concluded that the homoeopathic simillimum treatment was effective in treating halitosis both objectively and subjectively.

6.2. RECOMMENDATIONS

This study has proven the effectiveness of the homoeopathic simillimum treatment.

Further studies could highlight this by changing the potency and dosage of the chosen simillimum e.g. ascending potencies of the remedy i.e. 30CH, 200CH, M and 10M.

Seeing that halitosis is often a long-term complaint, the study period should be of a longer period of time to prove its lasting effects.

Many patients suffer from delusional halitosis. Thus for further studies the patients perception should be considered and recorded in a questionnaire for more comprehensive findings.

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APPENDIX A

INFORMED CONSENT DOCUMENT

INFORMATION TO SUBJECTS

Thank you for your interest in this study. The study is being conducted to test the effectiveness of the homoeopathic simillimum treatment on halitosis (bad breath). You will be assessed at the first consultation and if you fulfill the criteria of acceptance, you will be accepted into the study. If you are accepted into study your treatment will have to be taken over a period of three weeks. There will be three follow-up consultations of which two will be one week apart and the third follow up consultation will be one month later. Your condition will be reassessed at each consultation.

In this study half the patients will receive placebo i.e. unmedicated pillules, and the other half of the participants will receive valid homoeopathic medication. Instructions will be given to you on how to take the medication.

Homoeopathic medication has been used successfully for many years to treat a variety of conditions. There are no known side effects to the treatment and you are unlikely to experience any discomfort from the medication.

If you are placed in the placebo group, you will qualify for the homoeopathic treatment at the end of the research study.

Your participation in this research program is on a voluntary basis and will not cost you anything. You are free to withdraw from the research study at any time, without any obligation.

Thank you for your assistance.

Yours truly,
A. RANDEREE

INFORMED CONSENT FORM

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

TITLE OF RESEARCH PROJECT

NAME OF SUPERVISOR

NAME OF RESEARCH STUDENT

DATE: _____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO
2. Have you had opportunity to ask question 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 reason for withdrawing, and
 - c) without affecting your future health care.
9. Do you agree to voluntarily participate in this study? YES/NO

PATIENT/SUBJECT* Name _____ **Signature** _____
(in block letters)

PATIENT/GUARDIAN*Name _____ **Signature** _____
(in block letters)

WITNESS Name _____ **Signature** _____
(in block letters)

RESEARCH STUDENT Name _____ **Signature** _____

APPENDIX B

CASE HISTORY FORMAT

PAST HISTORY AND TREATMENT:

CHILDHOOD DEVELOPMENT/MILESTONES

ALLERGIES:

VACCINATION HISTORY:

FAMILY BACKGROUND:

FAMILY MALE/FEMALE

ILLNESS:

TB

CA

DIABETES

HEART

PATIENT:

PORPHYRIA

SIBLINGS:

MENSES:

F.M.P

SEXUAL:

CONTRACEPTION:

PREGNANCY-LABOUR:

LEUCORRHOEA:

M/F INFECTIONS:

M/F S.T.D.
SEXUAL:
PROSTRATE:
G.I.T.:
DESIRE:
AVERSIONS:
APPETITE:
THIRST:
BOWELS:
URINE:
PERSPIRATION:
BIORYTHM
METABOLISM:
WEATHER MODALITIES:
SLEEP:
DREAMS:
HEAD:
EYES:
U.R.I & E.N.T.
EARS:
NOSE:
THROAT:
TONSILS:IN/OUT
CHEST:
HEART:
MUSCULOSKELETAL:
SKIN:
HAIR:

APPENDIX C

PORATBLE SULPHIDE MONITOR READINGS

PORTABLE SULPHIDE MONITOR READINGS

PATIENT NAME _____

CONSULTATION ONE

DATE _____

Amount of sulphides present in mouth air _____ ppm

CONSULTATION TWO

DATE _____

Amount of sulphides present in mouth air _____ ppm

CONSULTATION THREE

DATE _____

Amount of sulphides present in mouth air _____ ppm

CONSULTATION FOUR

DATE _____

Amount of sulphides present in mouth air _____ ppm

APPENDIX D

VISUAL ANALOGUE SCALE

VISUAL ANALOGUE SCALE

PATIENT NAME _____

CONSULTATION ONE

DATE _____

	NO ODOUR	ODOUR
JUDGE 1.	1 _____	10 _____
JUDGE 2.	1 _____	10 _____
JUDGE 3.	1 _____	10 _____

CONSULTATION TWO

DATE _____

	NO ODOUR	ODOUR
JUDGE 1.	1 _____	10 _____
JUDGE 2.	1 _____	10 _____
JUDGE 3.	1 _____	10 _____

CONSULTATION THREE

DATE _____

	NO ODOUR	ODOUR
JUDGE 1.	1 _____	10 _____
JUDGE 2.	1 _____	10 _____
JUDGE 3.	1 _____	10 _____

CONSULTATION FOUR

DATE _____

	NO ODOUR	ODOUR
JUDGE 1.	1 _____	10
JUDGE 2.	1 _____	10
JUDGE 3.	1 _____	10