

**THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM VERSUS
VITAMIN C (1000mg) IN THE TREATMENT OF INFLUENZA
TYPE SYNDROME.**

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Dissertation submitted in partial compliance with the requirements
for the Master's Degree in Technology in the Department of
Homoeopathy at Durban Institute of Technologies.

I, Carla Swan, do declare that this dissertation represents my own
work in both concept and execution.

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***I dedicate this study firstly to the Lord
who has blessed me with the
gifts and talents I have.
Thank you Father.***

***Secondly to my parents, Bryan and Bev,
Thank you for all of your love and support
For the six years of my studies.
And to a very special and faithful friend, Kirsten.
Thank you for standing by my side for many years.***

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ABSTRACT

The purpose of this double blind randomised study is to evaluate the efficacy of homoeopathic simillimum versus high doses of vitamin C in the treatment of Influenza Type Syndrome in terms of subjective symptoms assessed by the patient, and objective clinical signs assessed by the researcher.

It was hypothesised that the patients treated with homoeopathic simillimum treatment would respond favourably in terms of the presenting condition, subjective symptoms and objective clinical signs.

The study was a double blind randomised investigation. Convenience sampling was used to select 30 patients of both sexes and between the ages of 18 and 60 years of age, from the East London area. Volunteers responded to advertisements that had been placed in various advertising media.

30 patients were assessed and if they had an oral temperature of 37.8 degrees Celcius or more; coryza; myalgia; malaise; and cough they were accepted onto the study. If the patient had used any form of analgesic, antibiotic or anti-influenza medication; had complications of influenza, tracheitis, bronchitis, pneumonia; had presented with influenza type syndrome for longer than 48

hours; could not speak or understand English; had any form of gastric ulceration or irritation; or any form of renal pathology they were excluded from the study.

The subjects were randomly divided into two groups, i.e. homoeopathic and vitamin C. Fifteen patients received homoeopathic similimum treatment and fifteen received vitamin C treatment. The patients were assessed over a five-day period of which the first consultation was on day one, the second on day three and the third on day five. Patients completed a subjective questionnaire of clinical symptoms on day one, three and five of the treatment.

Patients were also required to take their oral temperature twice daily and recorded these values. An objective clinical evaluation sheet was completed by the researcher on days one, three and five of the study.

Non-parametric tests were used to make the statistical analysis. Inter group comparisons for the parameters measured were made using the Mann-Whitney unpaired two-tailed test at the level of $\alpha = 0.05$ level of significance.

The intra group comparisons for the parameters measured were made the Friedman's Test and if the null hypothesis was rejected, the Dunn procedure was used to determine where the difference lies.

All of the statistics show that there is valuable use in vitamin C for the treatment of Influenza Type Syndrome in terms of objective and subjective evaluation. The homoeopathic simillimum treatment has already been proven effective in a study conducted by Maharaj (1999).

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CHAPTER ONE

INTRODUCTION

Influenza is an acute viral infection involving the respiratory tract occurring in isolated cases in epidemics or in pandemics. It causes an acute necrotizing (and even haemorrhagic) inflammatory process involving the upper and lower respiratory tract. It is characterised by an abrupt fever, malaise, headache, and myalgia – also prostration, vomiting and depression with convalescence possibly being slow. (Hope, et al. 1998.)

Five pandemics have occurred during the past 100 years, the most severe of which being the Spanish pandemic in 1918 and 1919, which caused more than 20 million deaths. In Hong Kong in 1997 influenza A (H5N1), which had been known to cause outbreaks only in birds, jumped the species barrier for unknown reasons, resulting in 18 confirmed cases and 6 deaths. (Weir, 2000: 861.)

Influenza and influenza related illnesses are responsible for a considerable burden on the economy. In the USA, medical, pharmaceutical and hospitalisation costs along with the cost of loss of productivity is estimated at about 12 billion dollars annually. Debility and malaise that follow the acute illness further aggravate the loss of productivity. (Martin and Schoub, 1997.)

In a given community an epidemic may last up to 5 or 6 weeks and associated incidence as high as 10% - 20% of the population. Rates of infection are highest in the elderly and in the very young. Further, an increase in school absenteeism, visits to health care facilities, admissions to hospitals for pneumonia and deaths in certain groups of patients are noted yearly during epidemics of influenza. (Reese and Betts, 1996 : 240.)

Conventional allopathic treatment is essentially symptomatic and palliative, which can have an array of side effects. Amantadine hydrochloride and rimantadine have also been shown to be effective in prevention and treatment of influenza infections. Both of these drugs have been linked to severe side effects especially in the elderly. (Arden, et al. 1996.)

Recently the influenza vaccine has been used extensively for the prophylaxis and treatment of influenza. However, the influenza virus has the propensity for unpredictable change. (Bonn, 1997). Thus the effectiveness of influenza vaccine depends on the similarity between the virus strains included in the vaccine and those that circulate during the influenza season. Efficacy decreases if the match is not good. (Arden et al. 1996.) The vaccine has also been associated with numerous side effects. (Nichol et al. 1996).

Therefore an effective treatment which is not dependent on the unpredictability of the virus and having no side effects is desirable in the treatment of influenza type syndrome. Homoeopathy is an approach that uses

medicines that are believed to stimulate the patient's immunological system to initiate healing. (Ullman, 1991).

The reaction of the individual to the antigen is the guide to his/her homoeopathic remedy, therefore, it does not make a difference to the choice of drug, whether the causative strain is A, B, or C in influenza. (Ross, 1997).

In a placebo - controlled clinical study conducted by Maharaj (1999), a statistically significant improvement was observed at the end of the research trial when the homoeopathic simillimum treatment was compared to the placebo treatment with regards to patient's perception and clinical findings. The importance of lifestyle changes (e.g. exercise and low stress levels) and dietary advice (Vitamin C and anti-oxidant rich diets) need to be investigated. Their use in conjunction with homoeopathy must be studied further.

Among its many other uses, vitamin C is the first line of antioxidant protection in the body, working in aqueous (water) environments, (both plasma and inside human cells), thus making it the body's most important antioxidant. Its primary antioxidant partners are vitamin E and carotenes as these are fat-soluble. Vitamin C also works along with antioxidant enzymes such as glutathione peroxidase, catalase and superoxide dismutase. (Murry and Pizzorno, 1998:93.) Vitamin C is unquestionably the master immune-boosting nutrient. It helps immune cells to mature, improves the performance of antibodies and macrophages and is itself anti-viral and anti-bacterial, as well as able to destroy toxins produced by bacteria. While a gram vitamin C a day

helps to reduce the severity and incidence of colds, achieving 'tissue saturation' has even greater results. In order to take hold, a cold virus must get inside cells and reprogram them to make more cold viruses, which then infect other cells. If the bodies tissues are high in vitamin C the viruses cannot survive. To achieve this you need to take 3 grams of vitamin C immediately and then 2 grams every four hours. (Holford, 2000.)

Therefore the main purpose of this study was to establish the effectiveness of the homoeopathic simillimum versus high doses vitamin C in the treatment of influenza type syndrome in terms of subjective symptoms, being the patient's response to treatment; the patient's oral temperature and objective signs observed by the researcher.

CHAPTER TWO

REVIEW OF RELATED LITERATURE

2.1 INTRODUCTION

Influenza has a sudden onset of pyrexia associated with generalised aches and pains, anorexia, nausea and vomiting. Degree of ill health ranges from mild to rapidly fatal. Coryza, cough, headache, malaise, and inflamed respiratory mucous membranes are present. Most patients do not develop complications and acute symptoms subside within 3 – 5 days, but may be followed by 'post influenzal aesthenia' which can persist for several weeks. (Edwards, et al. 1995.)

Influenza is a highly contagious acute respiratory disease of global importance that has caused epidemics and pandemics of human disease for centuries. Most influenza infections are self-limiting, however, visits to clinics, physicians' offices, or hospital emergency rooms can increase greatly during epidemics. Lower-respiratory-tract and cardiac complications can lead to substantial increase in hospital admissions and deaths. Deaths after influenza occur in elderly people and in those with underlying pulmonary and cardiac diseases. Influenza is the most frequent cause of acute respiratory illness requiring medical intervention because it affects all age groups and because it can recur in any individual. (Cox and Subbarao, 1999.)

2.2 AETIOLOGY

Influenza viruses belong to a group of RNA viruses, orthomyxoviruses which have four genera: influenzavirus A, influenzavirus B and influenzavirus C and thogovirus. (Hope, et al. 1998.)

Influenza viruses are enveloped particles with two surface glycoproteins: haemagglutinin and neuraminidase. Influenza A viruses are further divided into subtypes on the basis of serological and genetic differences in their surface glycoproteins and genes that encode them. 15 subtypes of haemagglutinin (H1- H15) and nine subtypes of neuraminidase (N1- N9) have been identified. Influenza A virus with haemagglutinin proteins of the H1, H2 and H3 subtypes and neuraminidase proteins of the N1 and N2 subtypes have caused epidemic and pandemic activity in man since 1900. Frequent mutations give strains new antigenic properties. Minor changes, called antigenic drift, and major changes, called antigenic shift place whole areas at risk. (Cox and Subbarao, 1999.)

Antigenic drift refers to frequent, minor point mutations of the corresponding RNA segment. Antigenic shift occurs only in influenza viruses and results from the acquisition of new gene segments for haemagglutinin or neuraminidase. (Weir, 2000.)

2.3 EPIDEMIOLOGY AND PATHOGENESIS

Influenza viruses are unique in their ability to cause both recurrent annual epidemics and more serious pandemics that spread rapidly and may affect all or most age groups. The size of the epidemics and pandemics, and their relative impact, reflects the interplay between the extent of antigenic variation of the virus, the amount of protective immunity in the populations, and the relative virulence of the viruses. (Cox and Subbarao, 1999.)

Influenza pandemics usually arise in China and spread westwards to the rest of Asia, Europe and America. Influenza viruses have been isolated from many different animal species and recent evidence suggests that antigenic shift results from genetic re-assortment of viruses between animal and human reservoir. Farming practises in south east Asia, facilitate this process due to the close proximity between humans, ducks and domestic pigs. (Wiselka, 1994.)

Influenza viruses replicate in the columnar epithelial cells of the respiratory tract. From there they gain access to the respiratory secretions and are spread by small particle aerosols generated during sneezing, coughing and speaking. Spread of infection by direct contact is also possible. The incubation period for influenza (1 – 4 days) is short, and the explosive nature of influenza epidemics and pandemics, and simultaneous onset in communities, suggests that a single infected person can transmit the virus to a large number of susceptible individuals. (Cox and Subbarao, 1999.)

2.4 CLINICAL MANIFESTATIONS

Classic influenza is distinguished by abrupt onset of prominent systemic symptoms, including fever, chills, headache, myalgia, malaise and anorexia. Fever usually lasts for three days. Sore throat, sore eyes and photophobia are common early in the illness. As systemic illness abates, protracted cough becomes the most troubling respiratory symptom. Secondary bacterial pneumonia should be suspected when fever, increasing cough and sputum production develop after several days of improvement. (Weir, 2000.)

Physical signs include the appearance of being unwell, hot and moist skin, flushed face, injected eyes, hyperaemic mucous membranes and a clear nasal discharge. (Cox and Subbarao, 1999.)

2.5 COMPLICATIONS

The great majority of influenza cases are not associated with any significant complications if properly managed. However a variety of well recognised complications do occur. (Reese and Betts, 1996: 243.):

Pulmonary Complications:

- primary viral pneumonia
- secondary bacterial pneumonia
- chronic bronchitis
- croup and bronchiolitis in infants and young children

Non Pulmonary Complications:

- myositis
- toxic shock syndrome
- myoglobinuria
- Reye's syndrome
- neurological complications of post influenza encephalitis, encephalopathy with cerebral oedema , transverse myelitis and Guillain-Barre syndrome
- renal failure
- cardiac muscle damage. (Cox and Subbarao, 1999.)

2.6 DIAGNOSIS AND PHYSICAL EXAMINATION

2.6.1 Diagnosis

Diagnosis is easy during epidemics. (Hope et al., 1998.) A specific diagnosis can be made by isolating the virus through viral cultures and diagnostic techniques. Swabs from the mucosa of the nose and pharynx are taken and subjected to the relevant viral culture techniques. Thus the virus is isolated, details of the strain and the subtypes are deduced and a laboratory diagnosis of influenza is made. (Reese and Betts, 1996: 241.)

The diagnosis is made on the knowledge of a present epidemic and the presence of the cardinal symptoms of influenza: fever, malaise, headache, coryza, cough and myalgia. (Berkow et al., 1992.)

2.6.2 Physical Examination

In influenza type syndromes the ear, nose, throat and upper respiratory tract are examined thoroughly. Essential findings are:

- inflammation of the mucosa of the upper respiratory tract
- erythema of the oropharynx
- the skin may be warm and flushed especially around the nose
- conjunctival injection may be mild
- pain on palpation of the maxillary and frontal sinuses

- tonsillar and submandibular lymph nodes may be palpable
- the chest examination is usually normal
- body temperature up to 39.5 degrees celcius. (Berkow et al., 1992.)

2.7 ALLOPATHIC MANAGEMENT

In an effort to reduce influenza, two measures are currently being used:

- 1) Vaccination using inactivated virus
- 2) Prophylaxis or therapy using antiviral drugs.

2.7.1 Influenza vaccination

Specific recommendations for vaccine are made by national authorities with the vaccine being generally recommended for use in people with factors that predispose them to severe morbidity and mortality. Currently licensed influenza vaccines are trivalent inactivated formulations that contain 15mg each of the haemagglutinin of influenza A (H1 N1), influenza A (H3N2), and influenza B strains. (Cox and Subbarao, 1999.)

The inactivated vaccine is generally well tolerated; however, because the vaccine is grown in eggs, it is contraindicated in people with serious egg allergies. Some of the disadvantages of the inactivated vaccine are poor induction of mucosal IgA antibody and cell-mediated immune responses, and lower immunogenicity and efficacy in the elderly. (Cox and Subbarao, 1999.)

The effectiveness of influenza vaccine depends on the similarity between the virus strains included in the vaccine and those that circulate during the influenza season. If the match between the vaccine and the circulating virus is good, the influenza vaccine is shown to be 70% effective in healthy persons

under 65 years of age. But amongst the frail and elderly, efficacy ranges between 30% to 40%. Efficacy decreases if the match is not good. (Arden et al. 1996.)

The vaccine has also been associated with numerous side effects such as: local erythema and tenderness at the site of injection. Low grade fever, myalgia and headache have been reported in the first 24 hours after vaccinations. Allergic reactions, ranging from hives to systemic anaphylaxis, have also occurred due to hypersensitivity to vaccine components. Anecdotal cases of asthma attacks have been reported after vaccination. (Nichol et al. 1996.) In more recent studies, investigators have found an elevation in the overall relative risk for Guillian-Barre Syndrome during 6 weeks after vaccination. (Rose, 1998.)

2.7.2 Antiviral drugs

Two anti-influenza A drugs are currently licenced in some countries. They are amantadine hydrochloride and rimantadine hydrochloride, both of which are 70-90% effective in preventing illness caused by naturally occurring influenza A virus when administered prophylactically to healthy adults or to children during the period of exposure in normal epidemic or outbreak situation. When used within 48 hours of the onset of symptoms, these two compounds can reduce the severity and duration of signs and symptoms of illness caused by influenza A virus. (Cox and Subbarao, 1999.) Zanamivir has been approved to treat types A and B influenza. The major drug trials involved many more patients with type A, which is the most prevalent type and is associated with

the most serious epidemics. The drug was shown to shorten the course of typical flu episode by about a day and a half. (Robb-Nicholson, 2000.)

Amantadine is excreted renally and can cause substantial neurological side-effects. Drug resistant viruses have been isolated from patients when either amantadine or rimantadine is used for therapy. (Cox and Subbarao, 1999.) In drug trials done with zanamivir only a small portion of the number of patients selected came from the high risk group. Elderly patients were not recruited as their side effect profile may be worse. (Yamey, 1999.). Douglass states that the FDA ignored the recommendation of its own advisory panel, which voted 13-4 against approving Relenza (zanamivir). "This drug should never have been approved," explained Wolfe of the Public Citizen Health Research Group. He said the benefits are "close to zero." Relenza also can be dangerous. Asthmatics are advised to have medications on hand just in case Relenza causes bronchial spasms. Side effects of Relenza -- which occur in 3 out of 100 users or less -- include sinusitis, nausea and diarrhoea.²

2.8 HOMOEOPATHIC MANAGEMENT

2.8.1 Introduction

Homoeopathy is a therapeutic method which clinically applies the laws of similars and which uses medicinal substances in weak or infinitesimal doses in therapy. (Jouanny, 1991.)

2.8.2 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. There is a close resemblance between the patients symptom picture and the picture of the symptoms the remedy produced on healthy subjects. Thus the basis of homoeopathy is that the most successful remedy will be that one whose symptomatology presents the clearest and closest resemblance to the symptom complex of the patient i.e. Let like be treated with like. (Lt. Similia Similibus Curentur) (Boyd, 1982).

According to homoeopathic principles a remedy is chosen individually and specifically for each patient, based on full evaluation of the patient's physical, emotional, and mental characteristics. (Ullman, 1991.)

Homoeopathic medicines act as catalyst stimulating the body to heal its self. They do not weaken the defence mechanism of the body by suppression of signs and symptoms. Instead they act on an individual's energy patterns by stimulating the immune system to promote healing and resolution of a morbid state. (Castro, 1997.)

2.8.3 Perspectives of Homoeopathy in Influenza Type

Syndromes

According to Jouanny, influenza is clinically observed as an infectious syndrome, with catarrh of the mucous membranes, a nervous syndrome with a headache that predominates in encephalic forms and general arthralgia and myalgia and sometimes as a haemorrhagic syndrome in the form of epistaxis or purpura. (Jouanny, 1991.)

A double blind study by Porter (1995) showed the effectiveness of homoeopathic Oscillococcinum in the treatment and prevention of influenza type syndrome. In the research study, with reference to symptoms rated by the patient and physical findings by the researcher, there was greater improvement in the treatment group than in the placebo group. Furthermore, the treatment group showed a faster termination of their fever as opposed to the persisting fever of the placebo group's patients. Further results confirmed that over the 120 day follow-up treatment period, the treatment group had fewer and less frequently recurring symptoms than the placebo group.

In a further study by Maharaj (1999) the efficacy of homoeopathic simillimum treatment was tested in Influenza Type Syndrome. For that particular study the reaction of the individual patient is the guide to his or her homoeopathic remedy. It does not make much of a difference to the choice of the drug (homoeopathic remedy) whether the causative strain of influenza virus is A, B or C. Matching the symptom picture with that of the remedy is most important in homoeopathic simillimum prescribing.

The following names are a few examples of homeopathic remedies that have similar symptom picture as is the symptom picture of influenza type syndromes e.g. Aconitum napellus, Belladonna, Ferrum phosphoricum, Eupatorium perfoliatum, Gelsemium, Bryonia alba, Arsenicum album, Baptisia tinctoria. (Jouanny, 1991.) Some of them may come up as the simillimum remedy for many cases of influenza.

During an epidemic an “epidemic remedy” can sometimes be found i.e. one which covers a large majority of cases. To find this remedy one lists the prominent symptoms of a series of cases and finds the drug picture whose origin and development is closest to this composite symptom picture. The epidemic remedy may differ in different localities and may change as the epidemic progresses. (Ross, 1997.)

2.9 TREATMENT WITH VITAMIN C

Vitamin C known as ascorbic acid, serves several key functions in the body. It is involved in maintaining connective tissue; synthesizing neurotransmitters and hormones; maintaining the immune system; releasing stress hormones from the adrenal gland; absorbing iron; and providing antioxidant protection. (Smolin and Grosvenor, 1997:248.) Vitamin C works as antioxidant in aqueous (water) environments in the body, both outside and inside human cells. Vitamin C is the first line of antioxidant protection in the body. (Murry and Pizzorno, 1998:93.)

Vitamin C is unquestionably the master immune-boosting nutrient. It helps immune cells to mature, improves the performance of antibodies and macrophages and is itself anti-viral and anti-bacterial, as well as being able to destroy toxins produced by bacteria. In addition it is a natural anti-histamine, calming down inflammation, and stimulates another part of the immune defence system to produce interferon which boosts immunity. Vitamin C is an effective anti-viral agent. Viruses cannot survive in a vitamin C rich environment. To achieve this you need to take 3 grams of vitamin C immediately and then 2 grams every four hours. (Holford, 2000.)

While a gram of vitamin C a day helps to reduce the severity and incidence of colds, achieving 'tissue saturation' has even greater results. In order to take hold, a cold virus must get inside cells and reprogram them to make more cold viruses, which then infect other cells. However if the body's tissues are high in vitamin C the virus cannot survive. Tissue saturation is more likely to be achieved by taking in around 10-15 grams a day, or 3 grams every four hours. (Holford, 2000.)

Vitamin C levels are quickly depleted during the stress of an infection. A new study calculated that vitamin C at a dosage of 1 to 6 grams per day decreased the duration of the cold episodes by nearly a full day, or roughly twenty-one percent. (Murry and Pizzorno, 1998:375.) There is benefit in reducing the duration of cold symptoms from ingestion of relatively high doses of vitamin C. (Douglas et al. 2002.)

Cathcart believes that the ideal intake for any individual is the highest level they can tolerate without loose bowels. On the basis of his experience 11000 patients over 14 years this level may be 10 to 15 grams in a healthy person, 30 to 60 grams in a person with a cold, and 199 grams per day in a person with a serious infectious illness. Fortunately vitamin C is one of the least toxic substances known to man. Four studies gave 10 grams of vitamin C to over 3000 patients without a single reported incidence of toxicity. It is unlikely that any vitamin has been tested to such an extent for toxicity.¹

CHAPTER THREE

MATERIALS AND METHODS

3.1 STUDY DESIGN

The purpose of this double blind randomised study was to evaluate the efficacy of homoeopathic simillimum versus high doses of vitamin C in the treatment of Influenza Type Syndrome.

A total number of 30 patients participated in the study. Fifteen patients received Vitamin C treatment and fifteen received the valid homoeopathic treatment. The study was conducted over a five day period for each patient. The treatment took place at Berea Pharmacy in East London.

A list of numbers ranging from 1 to 30 was made, 30 pieces of paper were placed in a box, 15 were marked simillimum and 15 were marked vitamin C. An independent person drew one piece of paper at a time and allocated either simillimum or vitamin C to the randomisation list of numbers from 1 to 30. Each patient was allocated a number in a sequence.

The above-mentioned procedure of group division was carried out under standardised conditions by drawing the 30 pieces of paper randomly by an

independent person. These results (either simillimum or vitamin c) were transferred onto the blind randomisation list.

Each patient eligible for the study, in the first consultation, completed the Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C), under the supervision of the researcher. A complete homoeopathic and medical case - history was taken by the researcher using the case history format (Porter, 1995.) (Appendix E). A general physical examination was performed on each patient. The patient's temperature and physical signs were recorded on the Objective Clinical Evaluation Sheet (Nicholson, et al. 2000) (Appendix D).

The second consultation took place on day three of the study. The patient was re-assessed. The patient completed the Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C), during this second consultation. The patient's temperature and physical findings were recorded on the Objective Clinical Evaluation Sheet (Nicholson, et al. 2000) (Appendix D).

The final consultation took place on day five. The patient had to repeat the process of filling in the Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C). The researcher had to re-asses the patients physical condition and the results recorded on the Objective Clinical Evaluation Sheet (Nicholson, et al. 2000) (Appendix D).

Patients were also required to take their own oral temperature, mornings and evenings, during the five-day duration of the trial. The patients were taught how to take their own oral temperature with the thermometer provided during the first consultation. This result was recorded on the Home Oral Temperature Chart (Appendix F).

A dosage of 1000mg of vitamin C was decided upon after referencing the South African Medicines Formulary 3rd Edition, 1991. With a maximum daily dose of 300mg, 1g was considered to be a megadose, also within an acceptable dosage not to produce adverse effects. Vitamin C powder is an odourless white powder looking very similar to saccharum lactis powder. 500mg of saccharum lactus was mixed with 500mg of vitamin C in each powder given to the vitamin C group. This was to ensure that the dissolution rates between the two types of powders were equal.

Each case history was analysed using Synthesis, 7th Edition, Dr. Frans Schroyens. A few rubrics were extracted and compared for common remedies. These remedies were then referenced in Concordant Materia Medica, Frans Vermeulen. The researcher then decided upon the remedy which best fitted the symptom picture and decided upon the simillimum. This was then confirmed with the supervisor.

3.2 SUBJECTS

Advertisements requesting participation in a homoeopathic clinical trial for the treatment of influenza type syndrome were placed on notice boards at supermarkets, pamphlets handed out at many pharmacies and in local newspapers.

Patients were selected according to the inclusion and exclusion criteria set out by the study. The following criteria were used:

Inclusion criteria:

- Patients of both sexes are to be between 18 and 60 years of age;
- The patient must have an oral temperature of 37.8 degrees Celsius or more (Berkow and Fletcher, 1992:8);
- The patient must have muscle pain, a general feeling of illness and any two of the following symptoms: shivering, headache, coughing, irritation of nasal mucosa or a sore throat;

Exclusion criteria

- The patient had used any analgesic, antibiotic or anti-influenza medication for the presenting symptoms;
- The patient suffers from any complications of influenza, for example tracheitis, bronchitis, pneumonia;
- The patient has presented with influenza type syndrome for longer than 48 hours.

- The patient does not understand and speak the English language.
- The patient has any form of gastric ulceration or irritation.
- The patient has any form of renal pathology.

3.3 ETHICS

The nature of the study was explained to each patient at the outset by the researcher. Each patient was asked to read the letter to the patient (Appendix A), which stated that they were participating in the study at their own free will and could withdraw from the study at any time with out any cost or obligation. Thereafter the patients filled out and signed the Informed Consent Document (Appendix B).

3.4 INTERVENTIONS

An independent dispenser administered the appropriate homoeopathic remedy or the vitamin C. All patients in the simillimum group received their appropriate remedy to last the duration of the five-day study. The remedies were made up by the independent dispenser. The patients in the vitamin C group received sufficient vitamin C so that they took 1 gram each day for the five-day duration of the study.

Each patient was given 10 powders, one taken twice daily. The homoeopathic remedies were made up with the indicated remedy impregnated onto a base of saccharum lactis in granule form. The vitamin C group received sachets containing white vitamin C powder and a portion of saccharum lactis. This was

ensure that their dissolution rates were equal as both medications were to be taken in water. Each patient was instructed to dissolve the powder in a glass full of water which had been boiled and cooled. They then drank the mixture.

3.5 MEASUREMENTS AND OBSERVATIONS

Data for the study was collected using:

1. Subjective Questionnaire of Clinical Symptoms
(Nicholson, et al. 2000.) (Appendix C).
2. Objective Clinical Evaluation Sheet
(Nicholson, et al. 2000.) (Appendix D).
3. Patients Home Oral Temperature Chart (Appendix F)

The Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C) was to evaluate the patient's perception of the treatment and to qualify the symptoms experienced by the patient. The questionnaire was divided into two sections. Section A consisted of the symptoms the patient could experience during influenza, on a scale rating. Each symptom on the questionnaire was rated according to the degree of severity of the symptoms using the Likert scale i.e.

- 1 – severe
- 2 – moderate
- 3 – mild
- 4 – absent

The lower the score, the more severe the symptoms and visa versa for a higher score. Section B of the questionnaire consisted of three questions on the general state of the patient and their ability to do normal daily activities. It had a score rating, ranging from 1 through to 10, one being the most severe and 10 being back to good health. The patient filled in this questionnaire on days 1, 3 and 5. Section A and B were totalled and added together to get one score for each day on the Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C).

The Objective Clinical Evaluation Sheet (Nicholson, et al. 2000.) (Appendix D) was filled in by the researcher on days 1, 3 and 5. An oral temperature was recorded on the chart. Physical signs noted by the researcher were recorded. Similarly a Likert scale was used i.e.

- 1 – severe
- 2 – moderate
- 3 – mild
- 4 – absent

The lower the score, the more severe the symptoms and visa versa for a higher score.

3.6 STATISTICAL ANALYSIS

3.6.1 Procedure 1

Friedman's Test

The Friedman's ANOVA method was used to compare three related samples (subjective and objective data on days one, three and five respectively) for the homoeopathic and vitamin C groups.

***(i)* Hypothesis testing**

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

***(ii)* Decision rule**

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

3.6.2 Procedure 2

The Dunn Procedure

If the null hypothesis H_0 was rejected for the Friedman's Test, then multiple comparison procedure was applied using the Dunn procedure to determine between which two visits the difference lay.

(i) Hypothesis testing

The null hypothesis H_0 , states that there is no significant difference between the two visits being compared at the $\alpha = 0.10$ level of significance.

The alternative hypothesis H_1 , states that there is a significant difference between the two visits being compared.

(ii) Decision rule

At the $\alpha = 0.10$ level of significance, the null hypothesis is rejected if

$$\left| R_j - R_{j'} \right| \geq Z \sqrt{\frac{bk(k-1)}{6}}$$

Where R_j and $R_{j'}$ be the j^{th} and j'^{th} treatment rank totals.

b = the number of patients per group

k = the number of visits

z = value in the inverse normal distribution corresponding to $(1-[\alpha/k(k-1)])$

When $k = 3$, $\alpha = 0.10$; $z = 2.12$

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

3.6.3 Procedure 3

Mann-Whitney Test

The Mann-Whitney unpaired two-tailed test was used to compare the two groups (homoeopathic and vitamin C) with regard to each variable of interest. The two groups were treated as being independent of one another (unpaired). The purpose of this was to find out whether there was any significant difference between the two groups at the $\alpha = 0.05$ level of significance.

(i) Hypothesis testing

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

(ii) Decision rule

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

3.6.4 Procedure 4

Comparison using bar charts and pie charts

Selected visual summaries of analytical findings were given by use of bar charts and pie charts to compare the homeopathic and vitamin C groups. Means were used to construct the bar charts represented.

Statistical package

The statistical package STATISTICA 6.0 was used for data entry and analysis.

CHAPTER FOUR

RESULTS

INTRODUCTION

This chapter covers the results obtained from statistical analysis of the data collected from the three groups used in this trial.

CRITERIA FOR THE ADMISSIBILITY OF THE DATA

Only the data collected from this trial was accepted for use in the results chapter. The only data used in the analysis was collected in the manner described in chapter 3.

The data was collected from the measurement criteria used, namely:

- The Home Oral Temperature Chart (Appendix F)
- The researchers temperature reading (part of appendix D)
- The Subjective Questionnaire of Clinical Symptoms (Appendix C)
- The Objective Clinical Evaluation Sheet (Appendix D).

4.1 Data Analysis of Homoeopathic Group

4.1.1 Friedman’s Test

Table 4.1

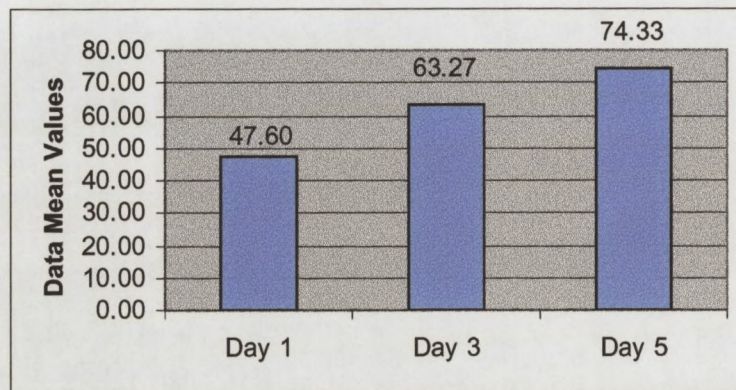
Subjective Data for Homoeopathic Group

	Day one Mean	Day three Mean	Day five Mean	P- value
Subjective Data	47.60	63.27	74.33	0.00019

Since the P-value < 0.05 for the variables further analysis will be done using the Dunn Procedure to determine between which visits the significant difference lies.

4.1.2 Bar Chart of Subjective Data for the Homoeopathic Group

Chart 1



The bar chart represents the improvement over the five day period for the Homoeopathic group. The “y” axis shows the mean values of the Homoeopathic subjective data.

4.1.3 The Dunn Procedure

$$\begin{aligned}
 |R_j - R_{j'}| &\geq Z \sqrt{\frac{bk(k-1)}{6}} \\
 &= 2.12 \sqrt{\frac{3.15(3+1)}{6}} \\
 &= 11.61
 \end{aligned}$$

4.1.3.1 Dunn Procedure between Day 1 and Day 3 for Homoeopathic Group - Subjective Data

R_{S1} = Rank totals for Day 1 subjective data

R_{S3} = Rank totals for Day 3 subjective data

$$|R_{S1} - R_{S3}| = |19.00 - 29.50| = 10.5$$

$$10.5 < 11.61$$

The null hypothesis is accepted at a $\alpha = 0.10$ level of significance.

There is no significant difference of the subjective data between day 1 and day 3 of the Homoeopathic group.

4.1.3.2 Dunn Procedure between Day 3 and Day 5 for Homoeopathic Group - Subjective Data

R_{S3} = Rank totals for Day 3 subjective data

R_{S5} = Rank totals for Day 5 subjective data

$$|R_{S3} - R_{S5}| = |29.5 - 41.5| = 12$$

$$12 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of subjective data between day 3 and day 5 of the Homoeopathic group.

4.1.3.3 Dunn Procedure between Day 1 and Day 5 for Homoeopathic Group - Subjective Data

R_{S1} = Rank totals for Day 1 subjective data

R_{S5} = Rank totals for Day 5 subjective data

$$|R_{S1} - R_{S5}| = |19 - 41.5| = 22.5$$

$$22.5 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of subjective data between day 1 and day 5 of the Homoeopathic group.

4.1.4 Friedman’s Test

Table 4.2

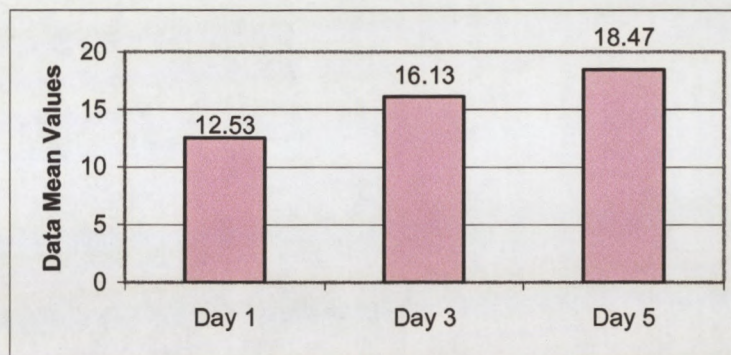
Objective Data for Homoeopathic Group

	Day one Mean	Day three Mean	Day five Mean	P- value
Objective Data	12.53	16.13	18.47	0.0000

Since the P-value < 0.05 for the variables further analysis will be done using the Dunn Procedure to determine between which visits the significant difference lies.

4.1.5 Bar Chart of Objective Data for the Homoeopathic Group

Chart 2



The bar chart represents the improvement over the five day period for the Homoeopathic group. The “y” axis shows the mean values of the Homoeopathic objective data.

4.1.6.1 Dunn Procedure between Day 1 and Day 3 for Homoeopathic Group - Objective Data

R_{01} = Rank totals for Day 1 objective data

R_{03} = Rank totals for Day 3 objective data

$$|R_{01} - R_{03}| = |15 - 30| = 15$$

$$15 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of objective data between day 1 and day 3 of the Homoeopathic group.

4.1.6.2 Dunn Procedure between Day 3 and Day 5 for Homoeopathic Group - Objective Data

R_{03} = Rank totals for Day 3 objective data

R_{05} = Rank totals for Day 5 objective data

$$|R_{03} - R_{05}| = |30 - 45| = 15$$

$$15 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of objective data between day 3 and day 5 of the Homoeopathic group.

4.1.6.3 Dunn Procedure between Day 1 and Day 5 for Homoeopathic Group - Objective Data

R_{01} = Rank totals for Day 1 objective data

R_{05} = Rank totals for Day 5 objective data

$$|R_{01} - R_{05}| = |15 - 45| = 30$$

$$30 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of objective data between day 1 and day 5 of the Homoeopathic group.

4.2 Data Analysis of Vitamin C Group

4.2.1 Friedman’s Test

Table 4.3

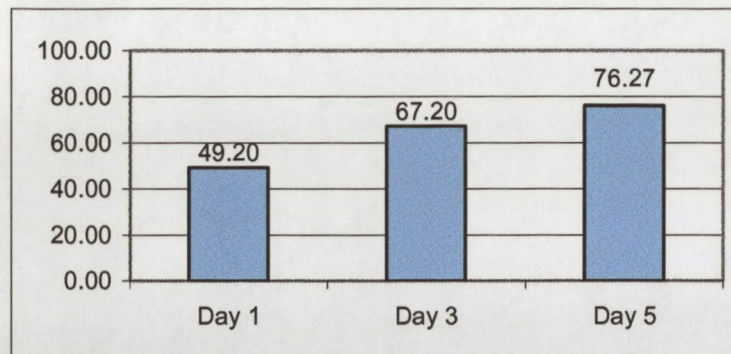
Subjective Data for Vitamin C Group

	Day one Mean	Day three Mean	Day five Mean	P- value
Subjective Data	49.20	67.20	76.27	0.0000

Since the P-value < 0.05 for the variables further analysis will be done using the Dunn Procedure to determine between which visits the significant difference lies.

4.2.2 Bar Chart of Subjective Data for Vitamin C Group

Chart 3



The bar chart represents the improvement over the five day period for the Vitamin C group. The “y” axis shows the mean values of the vitamin C subjective data.

4.2.3.1 Dunn Procedure between Day 1 and Day 3 for Vitamin C Group - Subjective Data

R_{S1} = Rank totals for Day 1 subjective data

R_{S3} = Rank totals for Day 3 subjective data

$$|R_{S1} - R_{S3}| = |64 - 74.5| = 10.5$$

$$10.5 < 11.61$$

The null hypothesis is accepted at a $\alpha = 0.10$ level of significance.

There is no significant difference of the subjective data between day 1 and day 3 of the vitamin C group.

4.2.3.2 Dunn Procedure between Day 3 and Day 5 for Vitamin C Group - Subjective Data

R_{S3} = Rank totals for Day 3 subjective data

R_{S5} = Rank totals for Day 5 subjective data

$$|R_{S3} - R_{S5}| = |74.5 - 86.5| = 12$$

$$12 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of subjective data between day 3 and day 5 of the vitamin C group.

4.2.3.3 Dunn Procedure between Day 1 and Day 5 for Vitamin C Group - Subjective Data

R_{S1} = Rank totals for Day 1 subjective data

R_{S5} = Rank totals for Day 5 subjective data

$$|R_{S1} - R_{S5}| = |64 - 86.5| = 22.5$$

$$22.5 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of subjective data between day 1 and day 5 of the vitamin C group.

4.2.4 Friedman's Test

Table 4.4

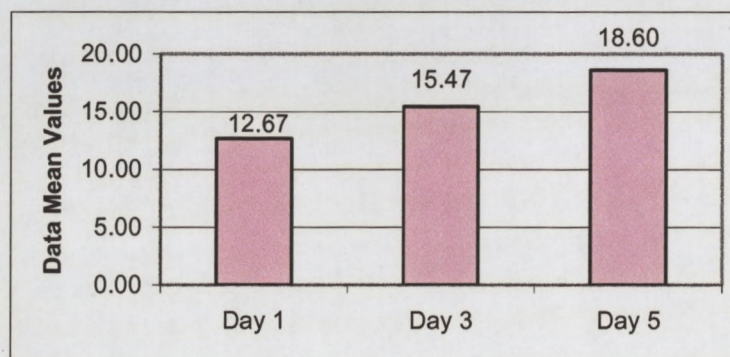
Objective Data for Vitamin C Group

	Day one Mean	Day three Mean	Day five Mean	P- value
Objective Data	49.20	67.20	76.27	0.0000

Since the P-value < 0.05 for the variables further analysis will be done using the Dunn Procedure to determine between which visits the significant difference lies.

4.2.5 Bar Chart of Objective Data for Vitamin C Group

Chart 4



The bar chart represents the improvement over the five day period for the Vitamin C group. The "y" axis shows the mean values of the vitamin C objective data.

4.2.6.1 Dunn Procedure between Day 1 and Day 3 for Vitamin C Group - Objective Data

R_{01} = Rank totals for Day 1 objective data

R_{03} = Rank totals for Day 3 objective data

$$|R_{01} - R_{03}| = |15 - 30| = 15$$

$$15 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of objective data between day 1 and day 3 of the vitamin C group.

4.2.6.2 Dunn Procedure between Day 3 and Day 5 for Vitamin C Group - Objective Data

R_{03} = Rank totals for Day 3 objective data

R_{05} = Rank totals for Day 5 objective data

$$|R_{03} - R_{05}| = |30 - 45| = 15$$

$$15 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of objective data between day 3 and day 5 of the Homoeopathic group.

4.2.6.3 Dunn Procedure between Day 1 and Day 5 for Vitamin C Group - Objective Data

R_{01} = Rank totals for Day 1 objective data

R_{05} = Rank totals for Day 5 objective data

$$|R_{01} - R_{05}| = |15 - 45| = 30$$

$$30 > 11.61$$

We fail to accept the null hypothesis, therefore the alternate hypothesis is accepted at a $\alpha = 0.10$ level of significance. There is a significant difference of objective data between day 1 and day 5 of the Homoeopathic group.

4.3 Inter-group Comparisons using the Mann – Whitney Test

4.3.1 Mann – Whitney Test : Subjective data for the Homoeopathic and Vitamin C Groups

Table 4.5

	Vitamin C Group	Homoeopathic Group	
	Mean Values		P - Values
Day 1	49.20	47.60	0.6186
Day 3	67.20	63.27	0.2997
Day 5	76.27	74.33	0.9174

The null hypothesis is accepted at the $\alpha = 0.05$ level of significance, as the test revealed that there was no statistically significant difference between the Homoeopathic and Vitamin C groups at all three visits. ($p > 0.025$)

4.3.2 Mann – Whitney Test : Objective data for the
Homoeopathic and Vitamin C Groups

Table 4.6

	Vitamin C Group	Homoeopathic Group	
	Mean Values		P - Values
Day 1	12.67	12.53	0.7244
Day 3	15.47	16.13	0.3951
Day 5	18.60	18.47	0.6333

The null hypothesis is accepted at the $\alpha = 0.05$ level of significance, as the test revealed that there was no statistically significant difference between the Homoeopathic and Vitamin C groups at all three visits. ($p > 0.025$)

4.3.3 Mann – Whitney Test : Researcher

Temperature readings for the Homoeopathic
and Vitamin C Groups

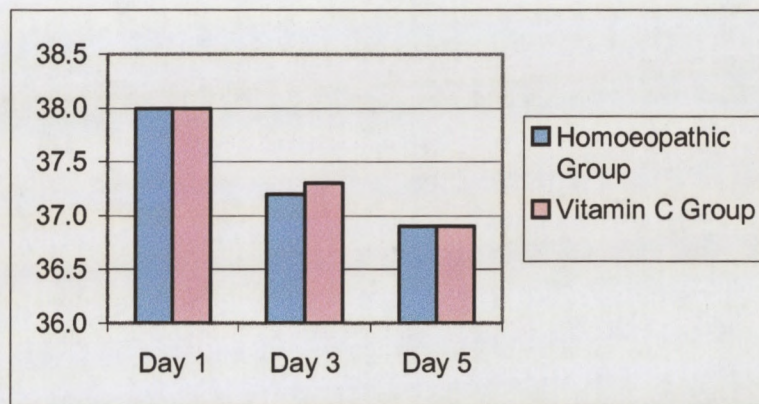
Table 4.7

	Vitamin C Group	Homoeopathic Group	
	Mean Values		P - Values
Day 1	38.0	38.0	0.5338
Day 3	37.3	37.2	0.0679
Day 5	36.9	36.9	0.3725

The null hypothesis is accepted at the $\alpha = 0.05$ level of significance, as the test revealed that there was no statistically significant difference between the researcher temperature readings for the Homoeopathic and Vitamin C groups at all three visits. ($p > 0.025$)

4.3.4 Bar Chart of Researcher Temperature readings over the five days.

Chart 5



The bar chart represents the temperatures recorded by the researcher over the five day period.

4.3.5 Mann – Whitney Test : Home Oral Temperature readings for the Homoeopathic and Vitamin C Groups

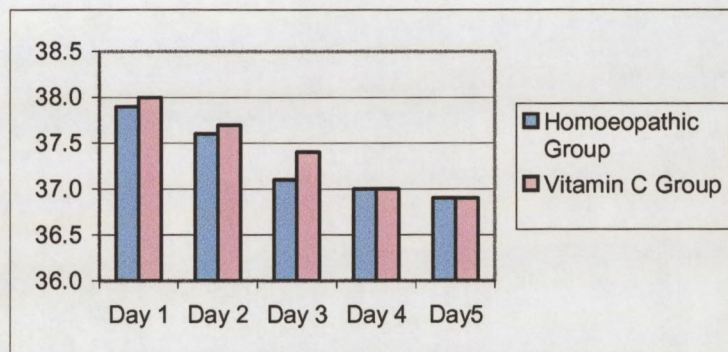
Table 4.8

	Vitamin C Group	Homoeopathic Group	
	Mean Values		P - Values
Day 1	38.0	37.9	0.7244
Day 2	37.7	37.6	0.5614
Day 3	37.4	37.1	0.0380
Day 4	37.0	37.0	0.5338
Day 5	36.9	36.9	0.2371

The null hypothesis is accepted at the $\alpha = 0.05$ level of significance, as the test revealed that there was no statistically significant difference between the home oral temperature readings for the Homoeopathic and Vitamin C groups on all five days. ($p > 0.025$)

4.3.6 Bar Chart of Home Oral Temperature Readings over the five days.

Chart 6

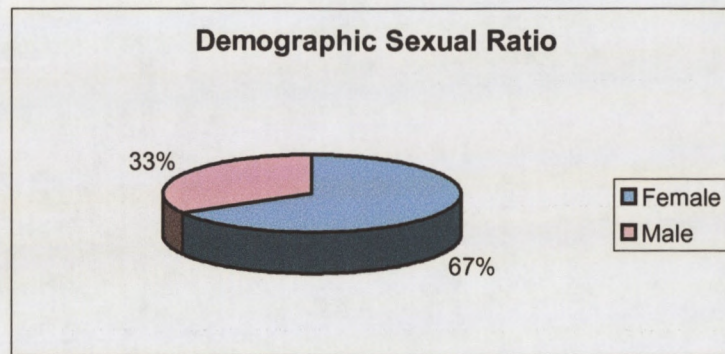


The bar chart represents the oral temperatures recorded by the patients over the five day period.

4.4 Pie Charts

4.4.1 Pie Chart of the Demographic Sexual Ratio

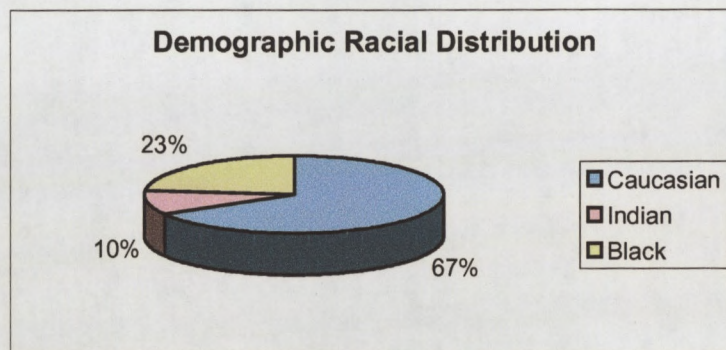
Chart 7



The pie chart illustrates the sexual ratio of the participants in this study.

4.4.2 Pie Chart of Demographic Racial Distribution

Chart 8



This pie chart illustrates the racial distribution of the participants in the study.

CHAPTER FIVE

THE DISCUSSION

5.1 INTRODUCTION

As evidenced in the previous chapter, very little statistical difference is shown between the two groups in relation to the various procedures done. Further discussion, interpretation and evaluation of these results have been dealt with in this chapter.

5.2 DISCUSSION

The subjective data from both of the research groups was worked with firstly, we looked at the results of the intra group comparisons. A statistically significant improvement was demonstrated between days 3 and 5 and 1 and 5 in terms of subjective data values for both of the homoeopathic and vitamin C groups. There was however, no significant improvement in between days 1 and 3 for both of the groups in terms of subjective data values.

The intra group comparison for the objective data, that which the researcher monitored, showed that there was a statistically significant improvement demonstrated between days 1 and 3, 3 and 5 and 1 and 5 in terms of objective data values for both of the homoeopathic and vitamin C groups.

The inter group comparisons taken from the Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C), showed that over the full five day period there was no statistical difference between the two groups. According to the Likert scale, the higher the score rating obtained in the questionnaire, the greater the improvement in the health of the patient.

With reference to the subjective data for both of the groups on day three, the mean value for the homoeopathic group was 63.27 and for the vitamin C group was 67.2. There was only a slight difference shown between the two groups.

Further inter group studies of the objective data, taken from the Objective Clinical Evaluation Sheet (Nicholson, et al. 2000) (Appendix D), showed that there was no statistical difference between the homoeopathic and vitamin C groups over the five day period.

The researcher temperature readings taken on days 1, 3 and 5 showed no statistical difference between the homoeopathic and vitamin C groups. The readings recorded were very similar for both groups.

The Home Oral Temperature Chart (Appendix F) showed that once again there was no statistical difference between the two groups on each of the five days when their own temperatures were recorded. The only day where there was a slight fluctuation, was on day three. The average homoeopathic group temperature had dropped to 37.1, where the vitamin C group temperature was still slightly raised at 37.4. A question must be asked at this point, even

though the researcher thoroughly went through the process of taking an oral temperature with the patient, there could still be an element of error from incorrect measurements on the thermometer.

During research done by Porter (1995), she discussed that both of the groups she treated received 1000mg of vitamin C during the trial. This could have contributed to both of her patient groups symptoms improving over the initial three day period.

Homoeopathic simillimum treatment was found to be effective in treating Influenza type syndrome, in a study by Maharaj (1999). Simillimum treatment requires that a full homoeopathic case is taken and the correctly indicated remedy given. Thus we have a very good indication that the homoeopathic treatment for this trial was effective. The group who received vitamin C treatment were given 1000mg per day, to be taken orally. The vitamin C was effective in the treatment of Influenza as there was little difference between the statistics of the two groups being compared. At some points the vitamin C group actually showed better statistical improvement.

The vitamin C given was only at 1000mg level per day. There definitely needs to be further research done to at higher levels of vitamin C.

Chart 3 in Chapter four showed a 33% were male participants and 67% were female participants. Chart 4 showed an interesting note that the largest percentage of research participants were Caucasians (67%), then following

that were that Black participants (23%) and lastly the Indian participants (10%). I would therefore speculate that this was due to the fact that advertisements were placed in the local English newspaper, where the widest reader coverage would be the Caucasians and therefore it would be anticipated that they would be the target group most likely to respond. It might be possible that this group of the population are the most informed about alternative health care in South Africa.

Subjectivity poses as the biggest problem in this type of study where a patient's perception was used as a means of measurement. This subjectivity means that the researcher had to rely on the patients ability to recall, rate and record the information required, as with the Subjective Questionnaire of Clinical Symptoms (Nicholson, et al. 2000.) (Appendix C). This could allow for the error in the authenticity of the information.

A similar homoeopathic study conducted by Papp et al. (1998) showed the effect of Osillococcinum in the Influenza like syndrome. In that study a larger sample size, i.e. 188 patients received treatment and 184 patients received placebo. From that study it was clear that if a larger sample size is used the chance of more statistically significant results are greater. With small trials there has to be a huge observed difference to be statistically significant. Therefore the results of this study would have been more clearly significant if a larger sample size was used.

An observation noted by the researcher, was that there were few cases of bronchitis or chest complications in the homoeopathic group of patients. In the vitamin C group, there were slightly more chest coughs remaining after the initial few days of Influenza.

Despite the problems encountered and shortfalls discovered, the vitamin C had a positive effect in reducing the initial Influenza signs and symptoms, as well as aiding in the recovery. Homoeopathic medicine has already been discussed as being effective, as long as it is given in simillimum form.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

This study attempted to evaluate the efficacy of homoeopathic simillimum versus high doses of vitamin C in the treatment of Influenza Type Syndrome. This was done in terms of subjective symptoms, using the Subjective Questionnaire of Clinical Symptoms (Appendix C) and objective symptoms using the Objective Clinical Evaluation Sheet (Appendix D).

Very few significant differences were found between the homoeopathic and vitamin C group according to subjective, objective and temperature statistics done in chapter four.

The intra group statistics done also showed that the improvement rates within each group were the same. No statistical difference was shown between day one and three subjective data for both homoeopathic and vitamin C groups.

The objective data showed identical reaction rates in both groups. Statistically there was a significant improvement between days 1 and 3, 3 and 5, and 1 and 5 in both groups. Thus we can see that the recovery times are equal.

It is thus concluded that homoeopathic simillimum treatment and vitamin C were equally effective in treating Influenza type syndrome.

6.2 RECOMMENDATIONS

During the study most of the homoeopathic group received the applicable homoeopathic remedy in a 30ch or a 200ch. A study using higher potencies such as M potencies is encouraged. A few guidelines should be given for prescribing in acute cases. Repetition may have to be frequent if the remedy action is quickly exhausted. It is best not to give potencies lower than 200; thus 200 to M potencies can be given, depending on the certainty of the medicine for the acute ailment (Vithoulkas, 1998).

With there being forthcoming changes in the vitamin C dosage levels, as from the Department of Health, this research needs to be repeated using a much higher dosage of vitamin C. A downfall of the research was that some of the patients could taste the vitamin C in their medicine, which could mean a slightly biased result on their subjective questionnaire, if they felt that the vitamin C was not effective. A recommendation would be that each group was given a mega dose of vitamin C accompanied with the applicable homoeopathic simillimum or placebo treatment. In this way one is able to see how much more effective the homoeopathic medicine would be.

There is definitely room for improvement with this homoeopathic research. Larger sample sizes are needed to get a better reflection on the effectiveness of treatment.

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APPENDIX A

COVERING LETTER

Technikon Natal
Department of Homoeopathy: Research

The efficacy of homoeopathic simillimum versus vitamin C (1000mg) in the treatment of Influenza Type Syndrome.

Dear participant

Thank you for your time and interest in reading the informed consent document. With your help, the effect of homoeopathy versus vitamin C in the treatment of influenza can be investigated. This study is important, as no research has been done to investigate the healing effects of vitamin C at a 1gram dosage, in relation to homoeopathic medicine.

I am a Master's Degree student at the Technikon Natal. In order to qualify as a Homoeopath a dissertation has to be completed. This is a legitimate study and aims to demonstrate the efficacy of the two forms of treatment in influenza.

Thirty patients will be selected and involved in this study. You will be assessed at the first consultation and if you fulfill the criteria of acceptance, you will be accepted into the study. The duration of the study is over five days. Your signs and symptoms will be assessed during three consultations. These will be on days one, three and five. Treatment will take place over the five-day period. In this study half of the participants will receive valid homoeopathic medication and the other half will receive doses of vitamin C (1 gram per day). The vitamin C will be given in divided doses each day. You will receive instructions on how to take the medication when you receive it.

Homoeopathic medication has been used, successfully, for many years to treat a variety of conditions. There are no known side effects from the treatment and you are unlikely to experience any discomfort from the medication. The only known side effect of vitamin C is diarrhoea. The dosage of vitamin C for this study should not cause any disturbance. If any discomfort is experienced, please do not hesitate to contact me. Any treatment in this study may involve an unanticipated risk.

Your participation in this research programme is on a voluntary basis and will not cost you anything. You will receive free treatment for influenza. All of your details will be kept confidential. You are free to decline your participation or to withdraw at any time, without obligation or without any negative consequences.

At any point if you have a formal complaint this may be lodged with the Technikon Research Ethics Committee. It must be noted that if the supervisor or any other authorities need to inspect your file, they may do so. You may

contact Dr AHA Ross, supervisor of this research and Head of Department at the Techikon Natal Homoeopathy Department if you feel you need to access a more knowledgeable person. You will be informed of any new findings during the course of the research. Most importantly, you are encouraged not to change from any of your normal daily activities.

Thank you for your assistance and I look forward to working with you.

Yours faithfully

*Carla Swan
Researcher, Master's Degree
Homoeopathic student.*

APPENDIX B

INFORMED CONSENT DOCUMENT

INFORMED CONSENT DOCUMENT

(To be completed in duplicate by patient)

Title of the research project:

The efficacy of homoeopathic simillimum versus vitamin C (1000mg) in the treatment of Influenza Type syndrome.

Name of supervisor:

Date of First appointment: _____

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO
2. Have you had an opportunity to ask questions regarding the 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?
 - a) at any time, and
 - b) without having to give reason for withdrawingYES/NO
9. Do you agree to voluntarily participate in this study? YES/NO
10. Do you understand that you may receive homoeopathic treatment or vitamin C during this study? YES/NO

If you have answered no to any of the above questions, please obtain the necessary information before signing.

PATIENT Name: _____ SIGNATURE _____

WITNESS Name: _____ SIGNATURE _____

RESEARCH STUDENT: _____ SIGNATURE _____

APPENDIX C

SUBJECTIVE QUESTIONNAIRE OF CLINICAL SYMPTOMS

(Nicholson, et al. 2000.)

SUBJECTIVE QUESTIONNAIRE OF CLINICAL
SYMPTOMS

PATIENT'S NAME:SURNAME:.....
DATE:

Please note:

IN THE FOLLOWING QUESTIONS MARK THE APPROPRIATE
DESCRIPTION.

SECTION A:

Rate the severity of the following symptoms as they are now:

	ABSENT	MILD	MODERATE	SEVERE
Fatigue				
Headache				
Muscle pain				
Feverishness				
Chills				
Nausea				
Vomiting				
Perspiration				
Sore throat				
Cough				
Hoarseness				
Blocked nose				
Runny nose				
Sneezing				
Nose bleeds				

SECTION B:

Answer the following questions on the scale of 1 to 10. Place a tick under the appropriate number.

1 – unable to do normal activities, worst health, worst sleep quality.

10 – fully able to do normal activities, best health, best possible sleep quality.

1. How is your ability to do normal activities affected?

[illegible]

2. What is your overall health status?

[illegible]

3. What is your sleep quality like?

[illegible]

APPENDIX D

OBJECTIVE CLINICAL EVALUATION SHEET

(Nicholson, et al. 2000.)

OBJECTIVE CLINICAL EVALUATION SHEET

Patients name and surname:.....

Date:.....

Temperature:.....

Skin temperature:

WARM		COOL	
------	--	------	--

	ABSENT	MILD	MODERATE	SEVERE
Flushed face				
Conjunctival irritation				
Pharyngeal inflammation				
Lymphadenitis				
Otitis				

APPENDIX E

CASE HISTORY

CASE HISTORY

Date : _____
Name : _____
Address : _____
Telephone No. : _____
Date of Birth : _____
Occupation : _____
Marital Status : _____

A. PAST MEDICAL HISTORY

1. Childhood illnesses _____

2. Adult illnesses _____

3. Surgical history _____

4. Other hospitalisations _____

5. Allergies _____

6. Immunizations _____

7. Current medical treatment _____

B. FAMILY HISTORY

Cancer: _____
Hypertension: _____
Diabetes: _____
Tuberculosis: _____
Other conditions: _____

C. SOCIAL HISTORY

- 1. Exercise/leisure activities: _____
- 2. Recent travel: _____
- 3. Smoking: _____
- 4. Alcohol: _____
- 5. Substance abuse: _____

D. MAIN COMPLAINT

History of the main complaint: _____

E. SYSTEMS HISTORY

- 1. General (weight gain, energy levels, etc.) _____
- 2. Integument (itching, discolouration, changes in skin, hair or nails) _____
- 3. Head (headache, vertigo, head injuries) _____
- 4. Eyes (vision, pain, tearing, redness, cataracts) _____
- 5. Ear, nose and throat:
 - a. Ears (hearing, tinnitus, earache, discharge) _____
 - b. Nose and sinuses (discharge, hayfever, congestion) _____
 - c. Throat (voice changes, soreness, dysphagia, tonsils, adenoids) _____

- _____

16. Miscellaneous _____

F. PHYSICAL EXAMINATION

Vital signs: Blood pressure: _____
 Temperature: _____
 Pulse rate: _____
 Respiratory rate: _____
 Height: _____
 Weight: _____

EXAMINATION OF RELATED SYSTEMS

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

APPENDIX F

**PATIENT’S HOME ORAL
TEMPERATURE CHART**

PATIENT'S HOME ORAL TEMPERATURE CHART

NAME: _____

Instructions to the patient concerning measuring procedure:

- 1. Shake the thermometer down to below 35.5 degrees celsius.
- 2. Insert it under the tongue, and close both lips.
- 3. Wait 3 to 5 minutes.
- 4. Then read the thermometer.
- 5. Re-insert the thermometer for one minute and read again. If the temperature is still rising, repeat this procedure until the reading remains stable.

	MORNING	EVENING
Day 1		
Day 2		
Day 3		
Day 4		
Day 5		