

THE EFFICACY OF HOMOEOPATHIC SIMILLIMUM IN
THE TREATMENT OF COMMON AND FLAT
VERRUCAE

by

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*THIS DISSERTATION IS DEDICATED TO MY PARENTS FOR
ALL THEIR SUPPORT, GUIDANCE AND PATIENCE OVER THE
YEARS, AND TO KIRSTEN FOR ALWAYS ENCOURAGING ME
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ABSTRACT

The purpose of this placebo-controlled study was to evaluate the efficacy of homoeopathic simillimum treatment of common and flat verrucae, in terms of its clinical manifestations, and the patient's perception to the treatment.

It was hypothesized that the patients treated with homoeopathic simillimum would respond favourably in terms of the presenting condition and that their perception of the treatment received would be positive.

The study was a clinical trial, in which a placebo group was compared with an experimental group. Convenience sampling was used to gather patients for the trial. Volunteers responded to advertisements that had been placed in various advertising media. Thirty patients were selected from the Greater Durban area. The subjects were of both sexes, all race groups and over ten years of age.

The thirty subjects were assessed and if they complied with the criteria for the admissibility of a subject they were accepted into the study. The subjects were divided into two groups, one experimental and the other placebo, according to simple random sampling. The study was conducted under a double-blind protocol that lasted for three months for each patient.

The patients were required to complete a Patient Perception Questionnaire during each follow-up consultation in the presence of the researcher.

Results were statistically analyzed using the Analysis of Variance test, the Mann-Whitney U-test (inter-group comparison), the Wilcoxon Signed Rank test (intra-group comparison) and the Correlation test.

When the results for the clinical manifestations of the verrucae were compared it was found that there was no significant difference between the two variables, namely the *control* and *treatment groups*.

When the questionnaires for each patient was compared, using the Mann-Whitney U-test (inter-group comparison) and the Wilcoxon Signed Rank Test (intra-group comparison), it was found that the *placebo group* did not improve significantly. The *experimental group* however did improve significantly with regards to the patient's perception of the treatment received.

When the comparative analysis was done between the clinical manifestations of the verrucae and the patient's perception to the treatment, in both the *control* and *treatment groups*, there was a poor correlation between the two variables and no significant difference in the *control group*. The *treatment group*, on the other hand, showed a positive correlation and a significant difference between the two variables.

The results of this clinical trial demonstrated that homoeopathic simillimum treatment is not effective in the treatment of the clinical manifestations of verrucae, but is, however, effective in the treatment of verrucae in terms of patient's perception to the treatment received.

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DEFINITION OF TERMS

Allopathic: A term loosely applied to the practice of mainstream (orthodox) medicine. (Gaier, 1991:30.) A term applied to that system of therapeutics in which diseases are treated by producing a condition incompatible with or antagonistic to the condition to be cured or alleviated. (Dorland's, 1988:50.)

Materia Medica: Contents of a reference book containing all the necessary information for the proper use of medicines. Deals with the origin, composition and properties, sometimes also the classification and reference source (authority), of medicinal agents. These properties also include physical, chemical and biological, where appropriate, toxicological characters of the drug, as well as its reactive propensity as a homoeopathic therapeutic agent. Also the appellation of the academic subject, the origin and mode of preparation of the drugs, their pathogenetically, toxicologically and clinically established characteristics and indications, the potencies commonly used, the preferred route of administration and dosage which are taught at homoeopathic medical schools. (Gaier, 1991:337-338.)

Repertorization: It describes the reference book that schematically indexes the symptoms sought to be located in the Materia Medica. These symptoms are classified in a logically structured way, related to each appropriate medicine, offering around each general or particular symptom and its modalities a clutch of potentially suitable remedies. A patient is said to have been "repertorized"

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.)

Simillimum: The single homoeopathic medicine, or the drug picture of which most nearly approaches the total symptom complex of the patient, which will certainly cure that patient, if the patient's condition is within reversible limits. (Gaier 1991:509.)

CHAPTER 1

INTRODUCTION

Although the skin acts as a protective organ surrounding the body, it frequently endures and succumbs to the attack of various microorganisms, parasites and insects. (Cotran et al. 1999:1208.)

The verrucae, or warts, represent thickenings or projections of epidermis. They occur singly or in groups. The possibility that these lesions are caused by viruses is fortified by evidence obtained by electron microscopy of viral particles. (Kissane, 1985:1608.)

Viruses consist of one nucleic acid only, either ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) and a capsid. They are completely dependent on a vital host in order for the duplication process to proceed. Most RNA viruses are incapable of duplication in the epidermis of the skin and consequently cannot cause an actual, noticeable skin disease. DNA viruses, on the other hand, are very capable of duplication and proliferation in the epidermis and cause skin lesions determined by the type of reaction. (Heyl & Swart, 1990:73.)

The term "wart" is often applied loosely to any small tumour of a horny nature arising from the skin. It is wrongly used when referring to such dissimilar conditions as cellular naevi (moles), skin tags and keratoses. (Wilkinson, 1977:173.)

Warts are amongst the most common of disorders of the skin and rarely cause any significant threat to the health of the infected person. They are however regarded as ugly and excite the usual distaste and revulsion associated with so many other diseases of the skin.

Consequently, they illicit a variety of illogical responses from teachers and local authorities, which results in children being banned from some communal activities. These lesions are somewhat self-limiting and do not require heroic efforts for their removal. They are, however, notoriously stubborn in resisting superficial treatment. (Marks, 1996:14-15.)

The homoeopathic method, for the treatment of warts and other dis-eases, produces an individualization of treatment. It constitutes an individual terrain therapy and the homoeopathic drug appears as a specific stimulant to the organism as opposed to allopathic medicines, which are coercive. (Jouanny, 1984:20.)

Successful homoeopathic treatment should stimulate the body's own defence mechanism to give systemic support to its self-healing effort. The highest ideal of cure is rapid, gentle and permanent restoration of health, or the removal and annihilation of the disease in its whole extent, in the shortest, most reliable, and most harmless way. (Hahnemann, 1989:10.)

The purpose of this placebo-controlled clinical trial is therefore to determine the efficacy of the homoeopathic simillimum in the treatment of common and flat verrucae in terms of its clinical manifestations and the patient's perception to the treatment.

Therefore, if this study shows that the homoeopathic simillimum is effective in the treatment of common and flat verrucae, by reducing the size of the verrucae, there could be several potential benefits involved : not only could it relieve the suffering of the individual, but it could become a preferred method of treatment that would leave the patient healthier, with less medical costs and with an increased socio-economic well-being.

CHAPTER 2

REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

There are no simple, routinely effective treatment options available for the treatment of warts; the lack of such therapies often makes the treatment of warts frustrating both to the patient and the consulting physician. Although experience indicates that most of the current therapies employed by orthodox medicine eventually remove warts, recurrences are common. (Beutner & Ferenczy, 1997.)

Although non-genital warts are generally self-limited, patients may find them distressing and eventually seek treatment for what ever reason or purpose. Unfortunately, modern medicine and most of our popular therapies offer little, if any, advantage over normal keratolytics, or placebo for that matter. Nature often eradicates the warts without the patient having to endure any pain, inconvenience, and the cost associated with the many treatment methods available today. Thus, before the physician devises a treatment program, physicians may find it useful to discuss the natural history of viral warts with the patient to dispel unrealistic expectations and make the patient aware of what they may be letting themselves in for. (Landow, 1996.)

2.2 DEFINITION

Warts are common, contagious, epithelial tumours caused by at least 35 types of human papillomaviruses (HPV), some of which can become malignant, with the risk of infection increasing in immunosuppressed and transplant patients. Regression of warts can occur within months or years, with or without treatment. (Berkow et al., 1987:2274.)

2.3 AETIOLOGY

Papillomaviruses are a genera of viruses grouped together by their tumorigenicity and homogeneity of deoxyribonucleic acid (DNA). They infect a wide variety of vertebrates, including man. Each type shows a particular tropism to specific anatomic sites. Cutaneous infections of the skin and mucosal infections of anogenital, oral and respiratory epithelia are common. (Hines, 1996.)

2.4 EPIDEMIOLOGY

Common warts are found in as much as 25 percent of some groups in a well-defined population and are most prevalent among young children. Plantar warts are also widely prevalent and occur most commonly among adolescents and young adults. The dramatic rise in the incidence of venereal warts (condylomata acuminata) over the last 15 to 20 years has seen it become the most common sexually transmitted disease in the United States. (Reichman, 1994:801.)

The classification of human papillomaviruses (HPV) type with disease is as follows:
(Reichman, 1994:801.)

<u>DISEASE</u>	<u>ASSOCIATED HPV TYPES</u>
Deep plantar warts	1,2,4
Common warts	1,2,4,26,27,29
Flat warts	3,10,27,28
Condylomata acuminata	6,11,30
Epidemodysplasia verruciformis	5,8,9,12,14,15,17,19-25

2.5 PATHOGENESIS

A HPV infection is spread most commonly by close personal contact and is facilitated by minor trauma at the site of inoculation. It may result from direct contact with another individual or, less commonly, from autoinoculation or contact with fomites. All types of squamous epithelium may be infected by HPV, and gross and histological appearances of lesions vary with the site of the infection and the particular virus type of HPV, of which there are at least 35 types capable of producing the common wart. (Reichman, 1994:802.)

2.6 MEDICAL TREATMENT AND RESEARCH

The medical treatment of warts is very vast and it has been developed over quite a number of years. There are many conflicting views about which approach is appropriate or if treatment is even warranted. Other suggestions for the management of warts is to "amuse" the patient while nature does the healing. This results in minimal discomfort to the patient without being subjected to an invasive therapy that could lead to scarring.

According to a task force of the American Academy of Dermatology's Guidelines of Care, acceptable indications for the treatment of warts include: (1) the patient's desire for therapy, (2) presence of such symptoms as pain, bleeding, itching, or burning, (3) lesions that are disabling or disfiguring, (4) large number of lesions or large-sized lesions, (5) a desire to prevent spread to unblemished skin, and (6) an immunocompromised state. (Landow, 1996.)

Bolton (1991) describes the treatment options available in the conventional medical management of warts, which includes therapies such as: cryotherapy, topical applications of keratolytics, occlusive taping, surgery, laser therapy, chemotherapy and immunotherapy. All

of the above therapies can be used on the majority of warts. Some of the options are more invasive, destructive, expensive and painful, leaving behind scar tissue and no guarantee that recurrence of the warts will not re-occur.

2.6.1 The major treatment options

2.6.1.1 Podophyllin

A plant compound that causes tissue necrosis due to the antimitotic action which prevents cell division. Commonly used in the treatment of anogenital warts. Current recommendations advise that application be limited to < 0.5 ml or < 10 cm² per session to decrease the potential for systemic effects, including bone marrow depression. The systemic toxicity of podophyllin precludes its use during pregnancy. Treatment can cause local skin reactions, including redness, tenderness, itching, burning, pain, and swelling. (Beutner & Ferenczy, 1997.)

2.6.1.2 Bleomycin

An intralesional injection of the chemotherapeutic agent bleomycin sulphate is one of the few treatment options that may actually be virucidal. Its efficacy as a wart treatment depends, in part, on the reduced activity in the skin of the enzyme charged with inactivating this compound. The injection must be strictly limited to the wart. Local pain, a haemorrhagic eschar, and scarring may result. (Landow, 1996.)

2.6.1.3 Salicylic acid

Bunney (1982) states that simple topical agents are just as effective and successful as more invasive treatment methods. Patient-directed treatments with non-prescription salicylic acid preparations continue to offer a variety of advantages unsurpassed by newer therapeutic options.

2.6.1.4 Cantharidin

Cantharidin is a vesicating agent extracted from the blister beetle and seems best suited to periungual warts. Several treatments at 14-day intervals clear the affected areas around the nails. This painless, expedient, office-based method is ideal for young children. (Landow, 1996.)

2.6.1.5 Trichloroacetic acid (TCA)

It is a chemodestructive agent that causes chemical coagulation of warts. Although TCA has little systemic toxicity, lack of control over the depth of penetration and breadth of the treatment area may result in discomfort and, in rare cases, ulcers and scarring. (Beutner & Ferenczy, 1997.)

According to Landow (1996): nitric acid, silver nitrate, and monochloroacetic, dichloroacetic, and trichloroacetic acid should be enshrined in the proverbial history book as applications of these agents often cause pain and discomfort, scarring, blistering, and skin discolouration.

2.6.1.6 Cryotherapy

Landow (1996) states that this form of treatment continues to be the main weapon in the fight against warts and according to proponents, liquid nitrogen provides unsurpassed therapeutic benefits in two or more applications. Pain, scarring, dyspigmentation, and infection are some of the discomforts that a patient must be informed about.

2.6.1.7 Surgical removal

Surgery is also an option in the treatment regime and includes total excision, blunt dissection and curettage. The treatment can be performed under local anaesthesia and is relatively non-traumatic but scarring usually results. (Bolton, 1991.)

2.6.1.8 Laser therapy

Laser treatment is a popular choice for the treatment of lesions that have not responded to other therapies and for extensive HPV disease. Because of the precision involved in this particular treatment this technique allows normal adjacent tissue to be spared. The major drawbacks of laser therapy is the special training and expensive equipment required for this treatment. (Beutner & Ferenczy, 1997.)

2.6.2 Some documented medical research

In a randomised clinical trial comparing podophyllin, cryotherapy, and electrodesiccation, 450 patients were enrolled in a public clinic for the treatment of external genital warts. Complete clearance of warts was observed in 41%, 79% and 94% of patients who received up to six weekly treatments of podophyllin, cryotherapy and electrodesiccation respectively. Relapses occurred in 25% of all patients, yielding three-month clearance rates of 17%, 55% and 71% for podophyllin, cryotherapy, and electrodesiccation respectively. In conclusion it was stated that none of these three treatments were highly successful even though the treatment initially showed a great deal of promise. (Stone et al., 1990.)

A study evaluating the treatment of intractable palmar, plantar and periungual warts, using a new technique of bleomycin injection following a local topical anaesthetic cream, demonstrated a 92% success rate after an average of four treatments. Sixty two patients were treated, 57 cleared with 10% of these subsequently relapsing, 3% of the patients failed to show any improvement after 10-13 treatments, 2% of the patients developed Raynaud's phenomenon, and 4% of the patients withdrew because they were unable to tolerate the treatment. (Munn et al., 1996.)

In a blinded observer comparative study, 130 men with penile warts were randomly allocated to treatment with either cryotherapy or trichloroacetic acid (TCAA). There was no significant difference in response to treatment, side effects, or recurrence rates between the two treatments. Warts resolved in 81% of patients treated with TCAA compared with 88% of those treated with cryotherapy. Early recurrence (two months) occurred in 36% of patients treated with TCAA and in 39% of those treated with cryotherapy. (Godley *et al.*, 1987.)

According to Benton (1991), the potential side effects of conventional treatment, which include: post-operative pain, onycholysis, scarring, Raynaud's phenomenon, irritation of the skin at the site of application and possible inhalation of viral particles affiliated with procedures such as blunt dissection or curettage and cautery. These effects should always be weighed against the disability caused by the wart, as well as, the recurrences of warts in other sites on the body.

2.7 HOMOEOPATHY

2.7.1 The historical background to homoeopathy

The basis of homoeopathy is by no means a recent concept. As long ago as the fifth century B.C., Hippocrates had stated that there were two methods of treating disease: on the one hand there was treatment by opposites (when a medicine was used to oppose or counteract the symptoms and signs of disease) and on the other hand there was treatment by similars. The latter method would stimulate healing in the body by giving a substance that would mimic the symptoms and signs of disease. In treatment by similars the remedy was in effect stimulating the body's own healing capabilities, thus strengthening the body. (Gibson, 1991:84.)

2.7.2 The founder of homoeopathy

Samuel Hahnemann, a German medical doctor, formulated for the first time in the history of medicine the complete laws and principles governing health and disease, and proven in actual clinical experience. (Vithoulkas, 1986:5.)

He began experimenting around 1790 with *Cinchona* (Peruvian Bark) from which quinine is derived. He used the substance to experiment on himself and to his surprise he developed the signs and symptoms of intermittent fever. Knowing that *Cinchona* was an effective treatment in malaria Hahnemann went on to experiment with other substances in use at the time. He formulated extensive drug pictures of many remedies and in so doing laid down the principles for homoeopathy, which are still as valid today as they were 208 years ago. (Gibson, 1991:72.)

2.7.3 The principles of homoeopathy

2.7.3.1 Homoeopathic simillimum treatment

The principle of similars states that patients with particular signs and symptoms can be cured if given a drug that produces the same symptom-complex in a healthy individual. (Linde et al. 1997:834.) The basis of homoeopathy is that the most successful remedy, for any given occasion, is the one whose symptomatology closely and clearly resembles the symptom-complex of the sick person in question. That is "let likes be treated by likes". (Boyd, 1989:2.)

Homoeopaths therefore need to select an individual remedy based on a full evaluation of the patient's physical, emotional and mental characteristics as well as his/her genetic endowment in order to realise optimum results for the patient. (Ullman, 1991:99.)

2.7.3.2 The concept of provings

No one could ever predict with certainty the exact effect of a drug on all the subjects in a population sample. To be able to approximate that, a way had to be devised to assess fully the anticipated effects of a substance on individuals in all their diversity. Hahnemann attacked the problem from an all together new angle. He was the first to investigate the effects of drugs on individuals, healthy human organisms, then collected all the subjective and objective responses to the drugs. The healthy volunteers (provers) note in their diaries any signs and symptoms that develop, such as any changes in temperament, or in intellectual acuity, or fatigability, or tussive irritation, or thermalgesia, or absolutely any other altered state(s). At the end of the proving all diaries are collected and compared and a drug picture is built up. (Gaier, 1991:390.)

Today there are hundreds of remedies which have been proven in this way and which cover the major part of all possible disturbances in the human being. Fortunately, for the science of therapeutics, it happens that the symptom pictures quite accurately match the pictures of virtually all illnesses in all their variety. (Vithoulkas, 1986.)

2.7.3.3 The concept of the minimum dose

The concept that the remedy acts as a "trigger effect" to the body's natural immune system points to the necessity for a single dose – the minimum stimulus required to set healing in progress. The effect of some doses may last only hours in severe acute cases and need to be repeated at regular intervals, or may extend to months in the more chronic cases. So long as improvement is continuing no further doses should be administered to the patient. (Boyd, 1989:56.)

2.7.3.4 The concept of potency

Hahnemann discovered that remedies prepared by means of dilution and succussion often became more powerful therapeutic agents than the original crude material. Moreover, remedies prepared by dilution without succussion did not display this increased therapeutic power. Hahnemann therefore named this process of dilution and succussion of his solutions, potentisation. (Gibson, 1991:74.)

2.7.3.5 The concept of the single remedy

The concept that the remedy acts as a stimulus to the body and that its selection is based on the materia medica picture, supports the view that wherever possible a single homoeopathic remedy should be prescribed. The single-remedy method of prescribing is based largely on the views of Hahnemann and Kent and is the one used to a large extent in the British Isles, USA and South America. In many other countries many doctors use a system of polypharmacy. Here several remedies are combined into one preparation and are prescribed mainly on the pathological indications, apparently with considerable success. (Boyd, 1989:56.)

2.7.3.6 Hering's law of cure

Hering stated that "if cure is in progress, symptoms will manifest at levels which are progressively of less crucial importance to the freedom of the individual to express fullness and creativity of life". (Vithoukas, 1986.)

During homoeopathic treatment of an illness, symptoms disappear in an orderly manner. That is, symptoms will improve from above downwards, from vital organs to less vital organs, from the most recent to earliest symptoms and healing progresses in reverse chronological order of the appearance of symptoms. (Yasgur, 1992:69.)

2.7.4 The placebo enigma

The literal meaning of placebo is: I shall please. Placebo can be regarded as a form of treatment without demonstrable substance. (Pearce, 1995.) Shapiro (1978) defined it as "any treatment deliberately used for non-specific psychological or psychophysiological effect".

Many scientists believe that homoeopathy violates natural laws and thus any effect produced by the treatment is purely a placebo effect. But the use of and growing belief in the effectiveness of homoeopathy is widespread and growing among allopathic physicians and the public, and advocates claim that there are measurable and reproducible effects over placebo. (Linde et al., 1997:834.)

It is often considered as a classic example of mind-body relation that depends on largely subconscious interactions between the doctor, the treatment process, and the patient. Evidence shows that it depends on the patient's belief or expectation that the treatment is effective; that it often operates without deliberate intention; and, it affects physiological and pathological processes. (Pearce, 1995.)

2.7.4.1 The clinical spectrum of placebo reaction

It is a complex response affecting not only subjective pain and many other symptoms, but also objective signs of pathology and physiology. The only thing learned from a placebo trial is whether or not the patient is placebo-positive. The trial is of no assistance in separating psychogenic from organic pain. (Pearce, 1995.)

2.7.4.2 What treatments act as placebos?

The type of placebo agent is varied. A physician's personality attributes, dress, demeanour, voice and body language, may each contribute to a marked placebo effect. Perceived clinical interest, caring and sympathy in the attending physician similarly have considerable therapeutic impact, irrespective of the material nature of the treatment. Placebo effects play a role in: drugs, homoeopathic remedies, acupuncture, psychotherapy, biofeedback and transcutaneous electric nerve stimulators. The benefit of placebo is often considered transient, but the effect is not always short-lived. (Pearce, 1995.)

2.7.4.3 "Pharmacological profile"

In the symptomatic treatment of pain, the degree of improvement may vary from none to complete relief. Some patients receiving placebo respond with abrupt improvements, while others show a gradual response. The abrupt improvements occur significantly earlier in the trial and seem less likely to persist. (Pearce, 1995.)

2.7.4.4 The use and exploitation of placebo

Individuals are not consistent in their placebo responses, and we cannot accurately predict the placebo-responder. Independently evaluated randomised controlled trials are essential in prospective drug trials and physical treatments. In most instances they must include a placebo component. The placebo effect is therefore a very controversial topic in the various medical professions and much has been written on it. (Pearce, 1995.)

2.7.5 How is homoeopathy different from orthodox medicine?

Homoeopathy has recently burst upon the international health care scene with some renewed

vigour. Over the past decade, patients have become increasingly aware of the shortcomings and drawbacks of conventional medicine and the treatments offered that tend to suppress diseases without actually curing them. People from all walks of life are actively seeking safer and more effective forms of medicine. As a result, homoeopathy and other medical alternatives are receiving a vast amount of media attention. (O'Reilly, 1998.)

According to Gibson (1991), orthodox medicine over the long term tends to be palliative rather than curative. It succeeds in its endeavours by easing the symptoms of the patient or by replacing substances that are lacking in the patient. None of which actually result in the cure of the initial cause or problem. Homoeopathy, on the other hand, stimulates the body to heal itself and its use can be truly curative.

The possibility of homoeopathy becoming the dominant medical paradigm in the future, with allopathic treatments as "add ons" would hopefully result in the majority of the medical practitioners gaining a homoeopathic understanding of what causes and cures disease. They will no longer revert to curing diseases with antibiotics, corticosteroids and surgery. Instead, they will understand that these approaches suppress and suspend the manifestation of the dynamic disease. (O'Reilly, 1998.)

2.8 HOMOEOPATHIC TREATMENT AND RESEARCH

Homoeopathy is a system of medical therapy that concentrates on treating the whole person. This means that the practitioner recognises that the patient is not just a physical entity but that there is an emotional, mental and spiritual aspect – all or any of which may need treatment. It also recognises that this complex individual does not live in isolation but is in continual

interaction with his/her environment. All these factors must be taken into account when both assessing the problem and planning the treatment. (Gibson, 1991.)

Schultz's (1994:66) study, using the double-blind protocol, endeavoured to determine whether homoeopathy had a role to play in the treatment of external warts (excluding genital warts). A sample group of 30 patients was used, 15 of which received homoeopathic treatment and 15 received placebo treatment over a period of six months. Every 26 days, for the duration of the six-month trial, patient's warts were re-photographed and questionnaires completed regarding the patient's perception to the treatment. Trace outlines of the warts, from the photographs, were scanned into a computer that calculated the surface area of warts. When comparing the surface area of the warts treated with homoeopathy as opposed to those treated with placebo, using the unpaired T-test, no significant difference ($p = 0,947$) was found between the two groups. Height of the wart was not taken into consideration. The above mentioned clinical trial paved the way with regards to accurate measurement of the surface area of the wart using computer scanning equipment. The trial, however, fell short in the sphere of homoeopathic philosophy, in the choice of using up to 6 - 10 different remedies on a patient, in order to see positive results, if any. It is impossible to say with certainty which remedy may have been curative or suppressive in each individual research patient due to the fact that many remedies were used in the investigation.

Giles' (1995:69) study to evaluate the efficacy of Thuja occidentalis tincture and Thuja occidentalis tablets in the treatment of warts (excluding genital warts) was conducted over a three-month period using the double-blind protocol. A sample group of 30 patients was selected and randomised into two groups. The first group of 15 patients was administered

Thuja occidentalis 9CH tablets which were taken twice daily. The second group were administered the tablets, to be taken twice daily, as well as Thuja occidentalis tincture which was applied twice daily to the warts. Every 21 days the warts were re-photographed and questionnaires completed regarding the patient's perception to the treatment. Trace outlines of the warts, from the photographs, were scanned into the computer, which calculated the surface area of the wart. When comparing the two groups, using the unpaired T-test, there was no significant difference ($p = 0,078$) between the two groups. There was little difference in the correlation of the two treatment groups. With regards to the tablet group: $p = 0,479$; $r = - 0,178$ and the tablet and tincture group: $p = 0,53$; $r = 0,17$. It must be emphasized that no placebo-control group was used which could have strengthened this study.

Gupta et al. (1991) conducted a study, with a sample size of 60 patients suffering from common and plantar warts. The study spanned from December 1986 to August 1989. Cases were treated with the simillimum, in the Korsakovian potency, with no external applications and no dietary restrictions. In this study no patients were taken as control. The results of the study revealed from the 66 patients, 21% of which dropped out, that the warts completely disappeared in 71% of the cases, no change was observed in 5% and in 3% of the cases the number of warts increased. No mention is made of the recurrence rate of the warts or of a measuring technique. The researchers concluded by saying that in order to prove the efficacy of homoeopathic drugs, an in-depth study using the double-blind method should be employed.

According to clinical experience, Jouanny (1980:408) concludes that 80% of verrucae disappear completely with the use of homoeopathic remedies. Jouanny also stated that it is

almost certain that they will re-occur when allopathic treatment is resorted to and thus worsen the underlying predisposition of the patient.

An analysis of the indexes of the Alternative Medical Journals, the British Homoeopathic Journals as well as a thorough literature search from 1982 - 1998 revealed no research done on verrucae treatment using a homoeopathic simillimum in centesimal potency.

In conclusion, none of the allopathic therapies studied to date purports to be a "cure" for HPV infection. By prompting the host to join the fight against HPV infection new immunomodulatory therapies hold promise for increasing the success rate of treating warts. (Beutner & Ferenczy, 1997.) As homoeopathy is thought to be an immune-stimulating therapy and holds a great deal of promise in the treatment of warts, research such as what is being proposed, will hopefully contribute in bringing homoeopathy to the forefront of immunomodulatory therapies.

CHAPTER 3

MATERIALS AND METHODS

3.1 Objectives

The objectives of this placebo-controlled investigation were to determine the efficacy of homoeopathic simillimum in the treatment of common and flat verrucae with regards to their clinical manifestations and the patient's perception of the treatment.

3.2 Study design

In this experimental study the single variable design was used for its "before and after with control". In this method we are determining the influence of an independent variable (homoeopathic treatment) on a dependent variable (the clinical manifestations of the warts as presented by the patient) whereby the independent variable is manipulated to measure the effect on the dependent variable.

Thirty patients were selected, fifteen patients were allocated to the treatment group and the other fifteen to the placebo group. Simple random sampling was used, which gave each element in the population an equal chance of being included in a sample and makes the selection of every possible combination of the desired number of subjects equally likely. The problem with this experimental method is that there is no control over the influence of extraneous forces that will cause secondary variations. This is overcome by selecting a

sufficient number of test units at random. All sources of extraneous variations are largely controlled because treatment variables are equally exposed and equally affected by extraneous factors.

The sample subjects were selected as follows: A list of numbers ranging from 1-30 was made, 30 pieces of paper were placed in a box, 15 were marked placebo and 15 experimental. An independent person drew one piece of paper at a time and allocated either placebo or experimental to the list of numbers from 1-30. Each patient was then allocated a number in sequence.

3.3 Subjects

A minimum of thirty patients was included in the study. Patients were made aware of the study by advertising on bulletinboards and in the newspapers. Patient participation in the study was voluntary, and each patient had to sign the required "Patient Consent Form". All the patients resided in the greater Durban area with easy access to the Technikon Natal Homoeopathic Day Clinic. Patients were asked not to change their lifestyles for the duration of the study to minimise variations.

3.3.1 Exclusion criteria

- Undergone dermatological therapy up to six months prior to the study.
- Undergoing a course of antibiotic medicine.
- Use of other homoeopathic medication other than the treatment prescribed by the researcher.

- Undergoing Schussler Tissue Salt therapy.
- Patients who present with anal, vaginal and internal warts will be excluded.
- Patients under the age of ten years.
- Alcohol or drug abuse or any condition e.g. mental illness or dementia associated with poor compliance.

3.3.2 Inclusion criteria

Any patient will be included into the trial who presents with common and flat warts and meets the inclusion criteria.

3.4 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 document (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.

3.5 Treatment

The sample of thirty patients were divided equally into two groups. Group one received placebo medication, but were otherwise treated exactly the same as Group two. Group two received homoeopathic simillimum treatment (Appendix G), prepared according to the British Homoeopathic Pharmacopoeia (Association's Scientific Committee 1993) by a homoeopathic pharmacist. The homoeopathic pharmacist was a neutral member in the study and randomly divided the sample of thirty into two groups according to simple random sampling. Neither the researcher nor the patients knew in which particular group, placebo or treatment, they were allocated to.

Therefore, this study is using the double-blind protocol. The medicine given to the experimental group (group two) consisted of lactose powders, impregnated at 1% volume / volume, with each patient's simillimum medication. The medication itself was made up in 73% alcohol. The patients in the placebo group received neutral lactose powders; these powders look exactly like the medicated powders, but do not contain any medication.

The remedies were prescribed in an individualistic manner; the basic principle of homoeopathy. Every patient received a different remedy and potency, prescribed only after taking into account every patient's unique case history and the results of the physical examination.

3.6 Measurements

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

- (1) Patients were obtained by advertising in the local media.
- (2) The researcher assessed the patients to see if they were suitable for the study (see 3.3.1 and 3.3.2). If the patient was accepted into the study the researcher went ahead with the first visit:
 - (a) After careful explanation, by the researcher, informing the patient about the study and how it would be conducted the patient was required to sign a consent form.
 - (b) The researcher conducted a complete medical and homoeopathic case history at the initial consultation.
 - (c) A complete general physical examination was conducted by the researcher.

- (3) The warts of all 30 patients were photographed in colour (vertically above) and the size determined as described later (number 12). The warts were photographed using a Chinon CM-7 SLR camera, a pentax macro lens, AGFA portrait spools (100 ASA) and a kobol 252 computer/slave flash. The following parameters on the camera were adhered to: (1) aperture between 16 and 22; (2) magnification factor of 2; (3) shutter speed of 125; (4) patient's distance from the camera would be recorded and standardised between 25 and 30cm.
- (4) Each patient's case was repertorised and compared with several Materia Medicas to find the most suitable remedy for each individual patient.
- (5) The completed documentation and final prescriptions were checked and signed by a qualified homoeopath.
- (6) Following that, the signed prescriptions were submitted to the neutral homoeopathic pharmacist, who prepared the necessary medication or placebo.
- (7) The researcher then handed the medication to each patient, with the necessary instructions as how to take, handle and store the medicine.
- (8) The patients took the medication / placebo for a period of 30 days before the next consultation took place.
- (9) The study will last for last for 3 months.

(10) At the subsequent three follow-up consultations each patient's case history and physical examinations were reviewed to assess whether they should continue with the current medication or whether the prescription should be altered in accordance with their presenting clinical manifestations. The patients also completed a questionnaire (Schultz, 1994), in the presence of the researcher, determining their perception of the treatment.

(11) Should the researcher feel the need to change the medication, a new prescription, signed by a qualified homoeopath, was handed to the neutral homoeopathic pharmacist and the necessary changes were made, depending whether the patient was in the placebo or treatment group.

(12) On completion of the study, clear transparency paper will be placed over the colour photographs (where a standard magnification factor is to be used) and the outline (from the outer border) of the wart traced on, using a fine transparency pen – Rotring 0.25mm tip. These transparency sheets will be placed in a flatbed image scanner, which is linked to an IBM personal computer, which calculates the surface area of the warts in square millimeters using the Allycad image-processing program. A margin of error of between 1 and 2 mm squared will be taken into account.

3.7 Statistical analysis

Statistical analysis of the data was conducted by using Statgraphics, version six plus by Manugistics Inc. (2115 East Jefferson Street, Rockville, Maryland, USA).

Methods of data analysis

(2) With respect to the size of the verrucae.

There are two groups: placebo and treatment.

In each group there are 15 patients. This is a small sample size, and hence, no parametric test will be done. In each group there are four readings which are taken at four different time periods.

Notations

- μ_1, μ_2, μ_3 and μ_4 are true values of the 4 subgroup means.
- H_0 is the null hypothesis
- H_1 is the alternative hypothesis

Procedure 1:

If the null hypothesis is rejected, the alternative hypothesis will be automatically accepted at the α level of significance.

α is the level of significance of the test

Comparison of 4 group means using the one-way ANOVA (analysis of variance) method.

$$H_0 : \mu_1 = \mu_2 = \mu_3 = \mu_4$$

H_1 : At least two means are significantly different

$\alpha = 0.05$ = level of significance of the test

Decision Rule :

Reject H_0 at the α level of significance if the P-value $< \alpha$

Accept H_0 at the α level of significance if the P-value $\geq \alpha$

Procedure 2:

If the null hypothesis H_0 is accepted, then the process stops by the end of procedure 1. In this case, it will be concluded that there is no significant difference between the 4 subgroups with respect to "time factor".

If the null hypothesis H_0 is rejected, then it will be concluded that there is a significant difference between the 4 subgroups with respect to "time factor". In such a case, subsequent analyses will be performed to identify the means that differ from each other. For every "rejection" of this type, six two-tailed Mann-Whitney unpaired tests will be done.

(2) $H_0 : \mu_1 = \mu_2$ versus $H_1 : \mu_1 \neq \mu_2$

(2) $H_0 : \mu_1 = \mu_3$ versus $H_1 : \mu_1 \neq \mu_3$

(3) $H_0 : \mu_1 = \mu_4$ versus $H_1 : \mu_1 \neq \mu_4$

(4) $H_0 : \mu_2 = \mu_3$ versus $H_1 : \mu_2 \neq \mu_3$

(5) $H_0 : \mu_2 = \mu_4$ versus $H_1 : \mu_2 \neq \mu_4$

(6) $H_0 : \mu_3 = \mu_4$ versus $H_1 : \mu_3 \neq \mu_4$

Decision Rule:

Reject H_0 at the α level of significance if the P-value $< \alpha/2$

Accept H_0 at the α level of significance if the P-value $\geq \alpha/2$

All tests will be carried out at the $\alpha = 0.05$ level of significance

(2) Analysis with respect to the questionnaire.

- Mann-Whitney U-test (Intra-group comparisons),
- Wilcoxon Signed Rank Test (Inter-group comparisons).
- Pearson Coefficient of Correlation Test

CHAPTER 4

RESULTS

4.1 INTRODUCTION

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

- The clinical manifestations (surface area) of the verrucae (Appendix A and B),
- The Patient Perception Questionnaire (Appendix C),
- Correlation between clinical manifestation and patient perception.

Comparisons were made between the two groups with regard to the clinical manifestations, using the Analysis of Variance test, to determine the spread of the data about the mean.

Comparisons were also employed *within* the two groups, using the Mann-Whitney U-test, and also *between* the two groups using the Wilcoxon Signed Rank test. The use of these non-parametric tests showed whether there was a significant difference between the two groups with regards to the Patient Perception Questionnaire i.e. the *control group* (group 1) and the *treatment group* (group 2).

The Pearson Coefficient of Correlation Test was also employed to determine if there was a correlation between the clinical manifestations and the Patient Perception Questionnaire.

4.1.1 The Analysis of Variance test (ANOVA)

The test is used to test the significance of difference, between the spread of data about the mean, of more than two samples. The null hypothesis states that there is no significant difference between the two groups within the 5% level of significance of the test. The decision rule states:

- Reject the null hypothesis if the P value is less than or equal to 0.025,
- Accept the null hypothesis if the P value is greater than 0.025.

The P value represents the two-tailed probability value.

4.1.2 The Mann-Whitney U-test (Inter-group comparison)

This test was used to make comparisons between the *treatment group* and the *control group*. The null hypothesis states that there is no significant difference between the two groups within the 5% level of significance of the test. The decision rule states:

- Reject the null hypothesis if the P value is less than or equal to 0.025,
- Accept the null hypothesis if the P value is greater than 0.025.

The P value represents the two-tailed probability value.

4.1.3 The Wilcoxon Signed Rank test (Intra-group comparison)

This test was used to make comparisons within the *treatment group* and the *control group*. The null hypothesis states that there is no significant difference between the two groups within the 5% level of significance of the test. The decision rule states:

- Reject the null hypothesis if the P value is less than or equal to 0.025,
- Accept the null hypothesis if the P value is greater than 0.025.

The P value represents the two-tailed probability value.

4.1.4 The Pearson Coefficient of Correlation Test

This test was used to make comparisons, or to describe the degree to which one variable is linearly related to another, between the clinical manifestations (x) and the patient's perception to the treatment (y), in the *treatment* and *control groups*.

The *correlation coefficient* can only assume values between -1 to $+1$. This value is denoted by r .

- As r nears either ± 1 there exists a strong, linear relationship between the variables x and y .
- As r nears 0 there exists a weak or non-linear relationship between the variables x and y .

Any interpretation of r should always consider the following:

- A low correlation does not necessarily imply that the variables are unrelated, but simply that the relationship is poorly defined. A non-linear relationship may exist.
- A correlation does not necessarily imply a cause-and-effect relationship, merely an observed association. (Govender, 2000.)

The null hypothesis states that there is no significant difference between the two groups within the 5% level of significance of the test. The decision rule states:

- Reject the null hypothesis if the P value is less than or equal to 0.025,
- Accept the null hypothesis if the P value is greater than 0.025.

The P value represents the two-tailed probability value.

Statistical significance testing is a method employed to see if a difference between groups is likely to be due to chance. Investigators must resort to a method of proof by elimination. This method is known as statistical significance testing (P-values). The method works on the

principle that a hypothesis must be either true or false, we assume the hypothesis is false and see how the data is explained. If there is only a small probability (5%) that the false, or null, hypothesis could explain the data then we reject the null hypothesis and by elimination accept the study hypothesis. (Govender, 2000.)

4.2 CRITERIA FOR THE ADMISSIBILITY OF THE DATA

- Only the data collected from the trial was accepted.
- All case histories and external examinations were performed by the researcher.
- All questionnaires were completed under the supervision of the researcher.
- All photographs were taken by the researcher.

4.3 The Results

4.3.1 Clinical manifestations of the verrucae

4.3.1.1 TABLE 4.1

The ANALYSIS OF VARIANCE, with respect to 4.1.1, of the four sample means calculated within the *control group*.

GROUP	COUNT	SUM	AVERAGE	VARIANCE
Column 1	15	7.1979	0.47986	0.068103
Column 2	15	6.8635	0.457567	0.060797
Column 3	15	5.8924	0.392827	0.068716
Column 4	15	5.9752	0.398347	0.077321

Column = visit

Count = number of patients in the control group

Sum = sum of the wart surface areas after each visit

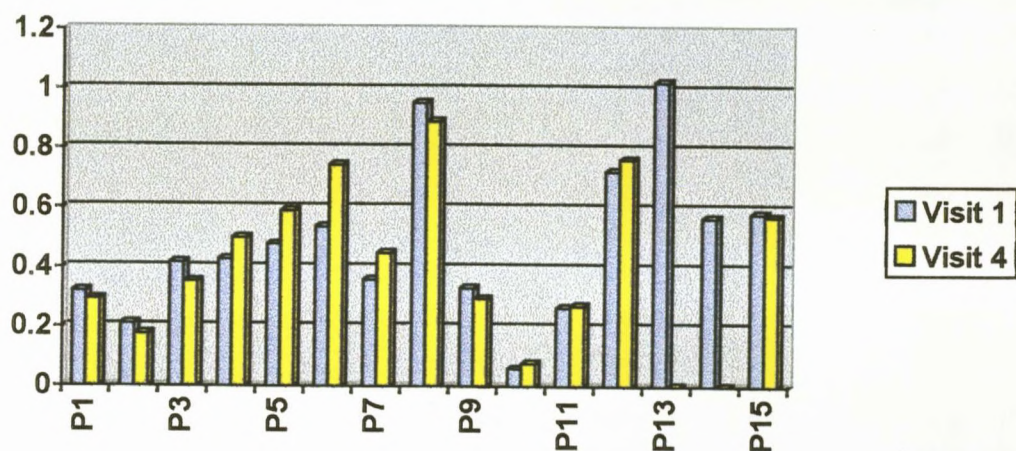
Average = the *sum* divided by the *count*

Variance = the sum of squared differences between each observation and the mean

The results of the Analysis of Variance test showed that $p = 0.7477$. The P-value was greater than 0.025, the null hypothesis was accepted at the 5% level of significance, it was concluded that there was no significant difference between the sample means.

4.3.1.2 FIGURE 4.1

The following graph is derived from the values in Appendix A and it demonstrates the change in wart surface area for each patient in the **control group**. V1 representing the initial consultation and V4 representing the final consultation. The values are derived by the difference recorded between the two visits.



x-axis = patients within the control group

y-axis = surface area of the wart in cm²

4.3.1.3 TABLE 4.2

This frequency table displays the rates of occurrence for the **control group**.

GROUP	IMPROVED	NO CHANGE	WORSENE	TOTAL
Control group	7 (46.67%)	0	8 (53.33%)	15 (100%)

4.3.1.4 TABLE 4.3

The ANALYSIS OF VARIANCE, with respect to 4.1.1, of the four sample means calculated within the *treatment group*.

GROUPS	COUNT	SUM	AVERAGE	VARIANCE
Column 1	15	11.623	0.774867	0.512996
Column 2	15	10.3523	0.690153	0.355401
Column 3	15	6.709	0.447267	0.292137
Column 4	15	6.4842	0.43228	0.226909

Column = visit

Count = number of patients in the control group

Sum = sum of the wart surface areas after each visit

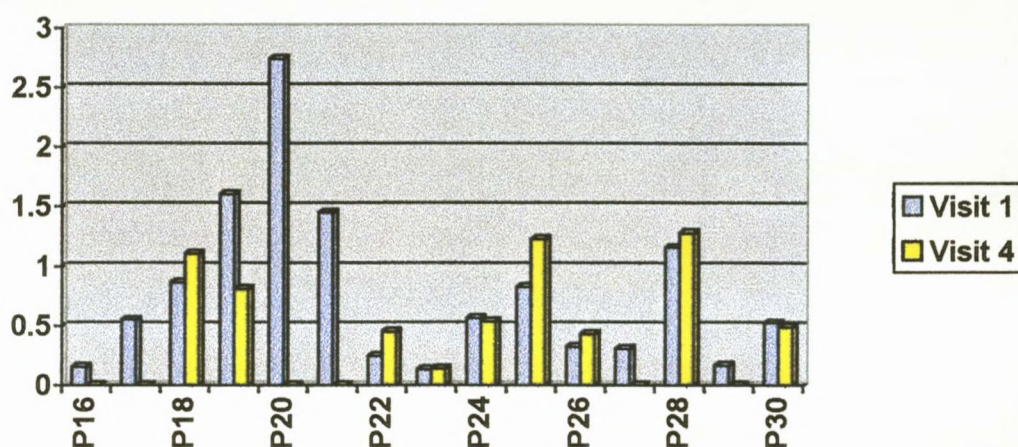
Average = the *sum* divided by the *count*

Variance = the sum of squared differences between each
observation and the mean

The results of the Analysis of Variance test showed that $p = 0.2872$. The P-value was greater than 0.025, the null hypothesis was accepted at the 5% level of significance, it was concluded that there was no significant difference between the sample means.

4.3.1.5 FIGURE 4.2

The following graph is derived from the values in Appendix B and it demonstrates the change in wart surface area for each patient in the **treatment group**. V1 representing the initial consultation and V4 representing the final consultation. The values are derived by the difference recorded between the two visits.



x-axis = patients within the treatment group

y-axis = surface area of the wart in cm²

4.3.1.6 TABLE 4.4

This frequency table displays the rate of occurrence for the **treatment group**.

GROUP	IMPROVED	NO CHANGE	WORSENER	TOTAL
Treatment group	9 (60%)	0	6 (40%)	15 (100%)

4.3.1.7 TABLE 4.5

The values in this table represent the sum of the differences between each visit found within the *control* and *treatment group*. These values represent the rate of change of the sum of the wart surface areas that occurred between the time frame of each visit.

Difference between visits	Control group	Treatment group
Visit 1 – Visit 2	0.3344	1.2707
Visit 2 – Visit 3	0.9711	3.6435
Visit 3 – Visit 4	- 0.0828	0.2246

The Unpaired T-test (2-tailed) was used to compare the change in clinical manifestations of the verrucae (surface areas) found within the *control group* against that of the *treatment group* using the values from Table 4.5. The P-value was calculated to be **0.2840** and therefore there was no significant difference between the *control* and *treatment groups*.

4.3.2 Patient Perception Questionnaire

4.3.2.1 TABLE 4.6

Comparison of the P-values calculated from the Patient Perception Questionnaire values between the *control group* and the *treatment group*.

	Visit 1	Visit 2	Visit 3
Treatment vs. control	0.0740	0.0560	0.0370

The P-values of the results of the Mann-Whitney U-test (Inter-group comparison), with respect to 4.1.2, were calculated and tabulated for Visit 1, Visit 2 and Visit 3, between the *treatment* and *control group*.

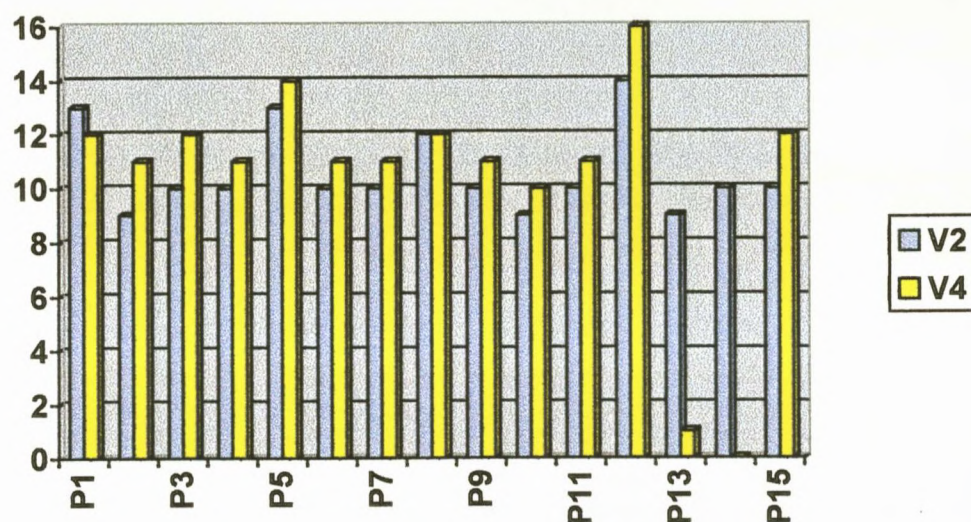
Visit 1: The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant difference between the *treatment* and *control groups* during Visit 1.

Visit 2: The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant difference between the *treatment* and *control groups* during Visit 2.

Visit 3: The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant difference between the *treatment* and *control groups* during Visit 3.

4.3.2.2 FIGURE 4.3

The following graph is derived from values in Appendix C and it demonstrates the change in each patient's perception to the treatment received in the **control group**. V2 representing the first time the questionnaire was completed and V4 representing the final consultation. The values are derived by the differences recorded between the two visits.



x-axis = patients within the control group

y-axis = scores from the Patient Perception Questionnaire

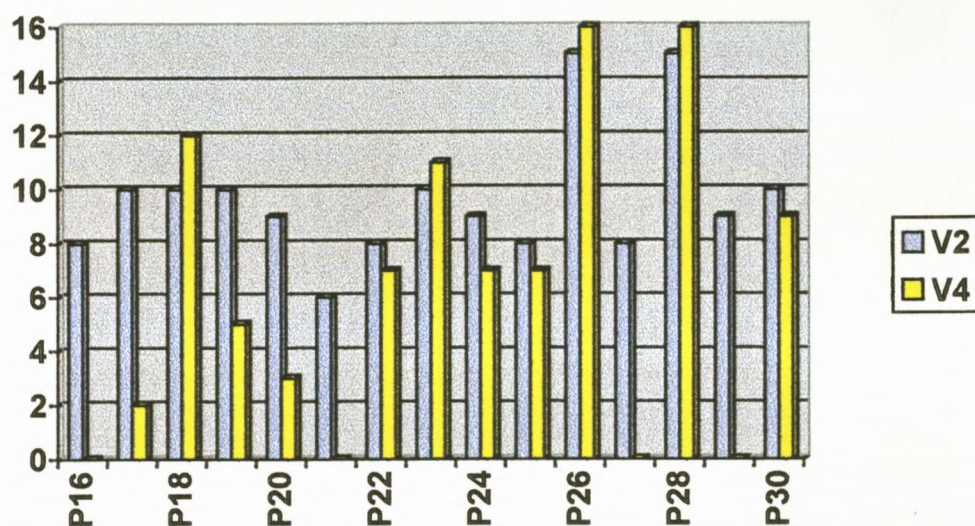
4.3.2.3 TABLE 4.7

Frequency table displaying rates of occurrence for the **control group**.

GROUP	IMPROVED	NO CHANGE	WORSENE	TOTAL
Control group	3 (20%)	1 (6.67%)	11 (73.33%)	15 (100%)

4.3.2.4 FIGURE 4.4

The following graph is derived from values in Appendix D and it demonstrates the change in each patient's perception to the treatment received in the *treatment group*. V2 representing the first time the questionnaire was completed and V4 representing the final consultation. The values are derived by the differences recorded between the two visits.



x-axis = patients within the control group

y-axis = scores from the Patient Perception Questionnaire

4.3.2.5 TABLE 4.8

Frequency table displaying rates of occurrence for the *treatment group*.

GROUP	IMPROVED	NO CHANGE	WORSENE	TOTAL
Treatment group	11 (73.33%)	0	4 (26.67%)	15 (100%)

4.3.2.6 TABLE 4.9

Comparison of the P-values calculated from the Patient Perception Questionnaire values within the *control group* and the *treatment group*. V2 representing the first time the questionnaire was completed and V4 representing the final consultation.

	Control group	Treatment group
Visit 2 vs. Visit 3	0.4930	0.0150
Visit 3 vs. Visit 4	0.3310	0.0770
Visit 2 vs. Visit 4	0.1770	0.0160

The P-values of the results of the Wilcoxon Signed Rank Test (Intra-group comparison), with respect to 4.1.3, were calculated and tabulated above.

Visit 2 vs. Visit 3

- The *control group*

The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant improvement between Visit 2 and Visit 3 in the *control group* with respect to the patient's perception to the treatment.

- The *treatment group*

The P-value was less than 0.025. The null hypothesis must be rejected at the 5% level of significance. Thus it was concluded that there was a significant improvement between Visit 2 and Visit 3 in the *treatment group* with respect to the patient's perception to the treatment.

Visit 3 vs. Visit 4

- The *control group*

The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant improvement between Visit 3 and Visit 4 in the *control group* with respect to the patient's perception to the treatment.

- The *treatment group*

The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant improvement between Visit 3 and Visit 4 in the *treatment group* with respect to the patient's perception to the treatment.

Visit 2 vs Visit 4

- The *control group*

The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant improvement between Visit 2 and Visit 4 in the *control group* with respect to the patient's perception to the treatment.

- The *treatment group*

The P-value was less than 0.025. The null hypothesis must be rejected at the 5% level of significance. Thus it was concluded that there was a significant improvement between Visit 2 and Visit 4 in the *treatment group* with respect to the patient's perception to the treatment.

4.3.3 CORRELATION

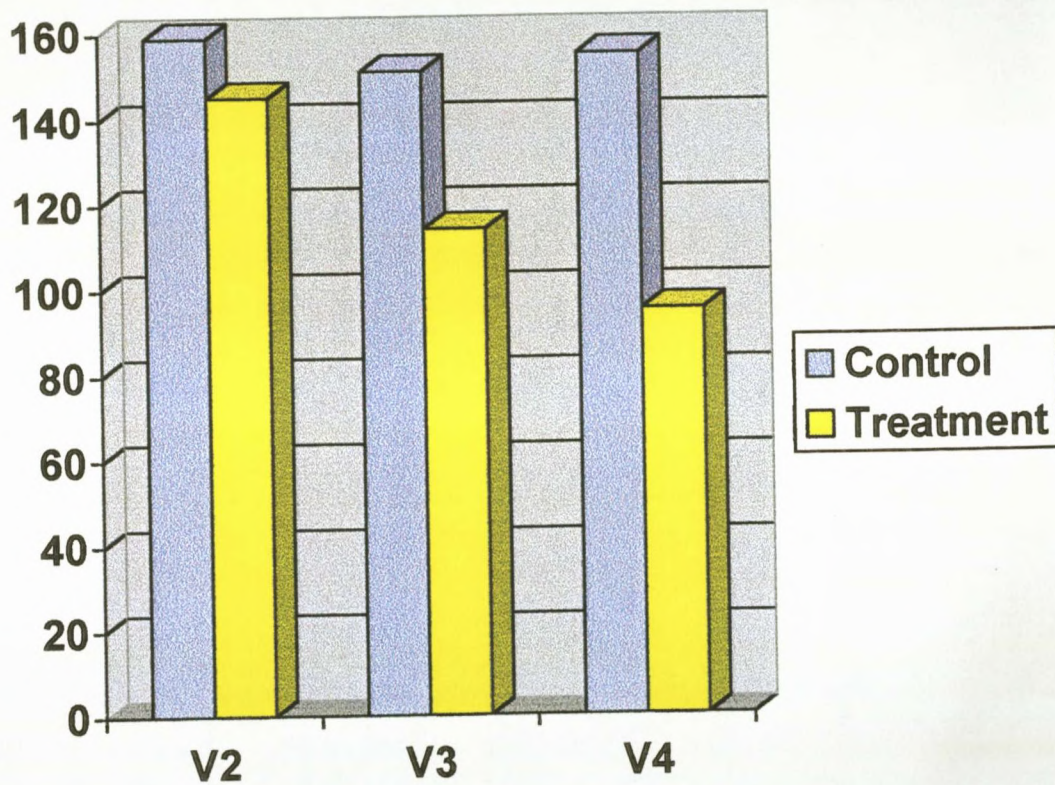
4.3.3.1 TABLE 4.10

The table that follows contains the data obtained from the synthesis of the clinical manifestations of the verrucae and the patient's perception to the treatment received. The values are the sum of each visit for both the surface areas of the warts and the corresponding value for the Patient Perception Questionnaire for both the *control* and *treatment groups*. It is important to note that for both the *treatment* and *control group* the first amount (V1) is absent in the patient's perception to the treatment received. The reason for this is that the patient's perception to the treatment questionnaire was only completed on the patients second visit (V2).

	WART SURFACE AREAS (cm ²)	PATIENT QUESTIONNAIRE TOTALS
CONTROL GROUP		
V1	7.1979	
V2	6.8635	159
V3	5.8924	151
V4	5.9752	155
TREATMENT GROUP		
V1	11.6230	
V2	10.3523	145
V3	6.7088	114
V4	6.4842	95

4.3.3.2 FIGURE 4.5

The graph represents the sum of the scores for the Patient Perception Questionnaire after each visit. It gives a graphical comparison between the **control group** and the **treatment group**.



x-axis = visit number

y-axis = sum of the Patient Perception Questionnaire totals

4.3.3.3 TABLE 4.11

This table displays the correlation, with respect to 4.1.4, between the clinical manifestations (x) of the verrucae (surface area) and the patient's perception to the treatment (y) for the entire period of the research.

Control group	Correlation	0.5370
	Probability	0.0390
Treatment group	Correlation	0.8010
	Probability	0.0000

The *correlation coefficient* in the **treatment group**, compared to that in the **control group**, shows a stronger, more linear relationship between the two variables x and y .

- The **control group**

The P-value was greater than 0.025. The null hypothesis must be accepted at the 5% level of significance. Thus it was concluded that there was no significant difference between Visit 2 and Visit 4 in the **control group** with respect to the correlation between the two variables.

- The **treatment group**

The P-value was less than 0.025. The null hypothesis must be rejected at the 5% level of significance. Thus it was concluded that there was a significant difference between Visit 2 and Visit 4 in the **treatment group** with respect to the correlation between the two variables.

CHAPTER 5

DISCUSSION

This study was designed to evaluate the efficacy of Homoeopathic Simillimum Treatment, so as to ascertain the role homoeopathy has to play in the treatment of verrucae, in terms of the clinical manifestations of verrucae and the patient's perception to the treatment received.

The results of the study showed that there was no overall improvement in patients, with common and flat verrucae, who received homoeopathic simillimum treatment compared to those patients who received placebo treatment.

The clinical manifestations of the verrucae, measured using photographs and computer software, was used as the objective criteria for this study. The measurements of the surface areas of the verrucae were statistically analysed using the Analysis of Variance (ANOVA) test.

Table 4.1 and Table 4.3 showed that there was no statistically significant improvement when the data before the treatment and after the treatment of both groups, *control* and *treatment group* respectively, were compared. A P-value of 0.7477 was calculated for the *control group* indicating that the initial and final wart surface areas were not significantly different. A P-value of 0.2872 was calculated for the *treatment group* indicating that the initial and final wart surface areas were not significantly different.

Bar graphs were constructed, **Figure 4.1** and **Figure 4.2**, using the initial (V1) and final (V4) consultation values in Appendix A and Appendix B respectively. This gives a visual illustration of the objective findings observed over the treatment period of four months. It is important to note in the bar charts that there was a 200% difference in complete remissions of the clinical manifestations of the verrucae in the **treatment group** as compared to that found in the **control group**.

Table 4.2 and **Table 4.4** are frequency tables displaying the rates of occurrence for both the **control** and **treatment groups** respectively. Considering the frequency of occurrence in the **control group**, 46.67% improved, 53.33% worsened and none stayed the same. The frequency of occurrence found in the **treatment group** showed that 60% improved, 40% worsened and none stayed the same.

Table 4.5 was used to compare the rate of change in clinical manifestations of the verrucae (surface areas) found within the **control** and **treatment groups**. There was no significant difference between the two, with the P-value calculated at **0.2840**.

The Patient Perception Questionnaire (Appendix E) provided the information concerning the patient's perception to the treatment. It was a subjective means of measurement.

Table 4.6 displays the inter-group comparisons made between the control and treatment groups for visits 1-3. Although there was no significant difference (< 0.025), in the comparison made between the **control** and **treatment groups**, the values recorded are exceptionally low. This is due, in part, to the small sample size. (Govender, 2000.)

Bar charts were constructed, **Figure 4.3** and **Figure 4.4**, using the initial (V2) and final (V4) consultation values in Appendix C and Appendix D respectively. This gives a visual illustration of the subjective measurements recorded over the treatment period of four months, for both the *control* and *treatment groups*, respectively. **Table 4.7** and **Table 4.8** are frequency tables displaying the rates of occurrence for both the *control* and *treatment groups* respectively. Considering the frequency of occurrence in the *control group*, 3% improved, 73.33% worsened and 6.67% stayed the same. The frequency of occurrence, found in the *treatment group*, showed that 73.33% improved, 26.67% worsened and none stayed the same.

The intra-group comparison, **Table 4.9**, revealed that there was indeed a significant difference between the *control* and *treatment groups*, especially when **Visit 2** was compared against **Visit 3** and **Visit 2** was compared against that of **Visit 4**, with values of **0.0150** and **0.0160** respectively.

The comparative analysis, **Table 4.11**, revealed that there was a poor correlation ($r = 0.5370$) between the clinical manifestations of the verrucae (surface area) and the patient's perception to the treatment in the *control group*. In the *treatment group*, however, there was a good correlation ($r = 0.8010$) between the clinical manifestations of the verrucae (surface area) and the patient's perception to the treatment.

According to the results of this clinical trial, it is demonstrated that homoeopathic simillimum treatment is not effective in the treatment of the clinical manifestations of verrucae, but is, however, effective in the treatment of verrucae in terms of patient's perception to the treatment received.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

This study proposed to determine the degree of proficiency of homoeopathy in the treatment of common and flat verrucae, with reference to the clinical manifestations of the verrucae and the patient's perception to the treatment, in order to determine the role of homoeopathy in the treatment of common and flat verrucae.

When the results for the clinical manifestations of the verrucae were compared it was found that there was no significant difference between the two variables, namely the **control** and **treatment groups**.

When the questionnaires for each patient was compared, using the Mann-Whitney U-test (inter-group comparison) and the Wilcoxon Signed Rank Test (intra-group comparison), it was found that the **placebo group** did not improve significantly. The **experimental group** however did improve significantly with regards to the patient's perception of the treatment received.

When the comparative analysis was done between the clinical manifestations of the verrucae and the patient's perception to the treatment, in both the **control** and **treatment groups**, there was a poor correlation between the two variables and no significant difference in the **control group**. The **treatment group**, on the other hand, showed a positive correlation and a significant difference between the two variables.

The results of this clinical trial demonstrated that homoeopathic simillimum treatment is not effective in the treatment of the clinical manifestations of verrucae, but is, however, effective in the treatment of verrucae in terms of patient's perception to the treatment received.

6.2 RECOMMENDATIONS

The study showed that there was no statistically significant difference between the **control** and **treatment groups** although the **treatment group** had a 200% difference in remissions as compared with that of the **control group**. A larger sample size should be used which would give the study more credibility and improve the range of results.

Further studies can place more emphasis on the psychology and the quality of life of wart sufferers. The importance of lifestyle changes and dietary advice, which were excluded from this study to keep the variables to a minimum, together with homoeopathy needs to be evaluated and studied further.

The economic viability of homoeopathy compared with that of allopathic treatment is also a recommendation for further studies.

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APPENDICES

APPENDIX A

Wart surface areas of the *Control group* for the duration of the research project.

Patient	V1	V2	V3	V4
1	0.32	0.2745	0.2832	0.2935
2	0.2114	0.2009	0.2126	0.1769
3	0.4172	0.338	0.4095	0.3538
4	0.4284	0.399	0.4566	0.5007
5	0.4788	0.5605	0.5244	0.5888
6	0.5353	0.5801	0.7491	0.7437
7	0.3592	0.3945	0.4026	0.4495
8	0.9521	0.8869	0.8806	0.8904
9	0.331	0.3075	0.3605	0.2959
10	0.0595	0.0641	0.0903	0.0773
11	0.265	0.3105	0.2796	0.2709
12	0.723	0.659	0.6996	0.7626
13	1.0227	0.9671	0	0
14	0.5662	0.3581	0	0
15	0.5281	0.5628	0.5438	0.5712

APPENDIX B

Wart surface areas of the **Treatment group** for the duration of the research project.

Patient	V1	V2	V3	V4
16	0.1582	0.2128	0	0
17	0.5514	0.5027	0	0
18	0.8644	0.994	1.0609	1.1067
19	1.6019	1.6755	1.6977	0.8124
20	2.7417	2.1636	0	0
21	1.4487	0.4698	0	0
22	0.2489	0.2825	0.2919	0.4538
23	0.1333	0.1506	0.137	0.1405
24	0.565	0.5596	0.4847	0.5376
25	0.8289	0.9355	0.9137	1.2311
26	0.3244	0.3379	0.3812	0.4316
27	0.306	0.2501	0	0
28	1.1584	1.1728	1.2222	1.2796
29	0.1668	0.1299	0	0
30	0.525	0.515	0.5197	0.4909

APPENDIX C

Patient Perception Questionnaire scores for the *Control group*.

Patient	V2	V3	V4
1	13	13	12
2	9	10	11
3	10	11	12
4	10	11	11
5	13	14	14
6	10	11	11
7	10	10	11
8	12	12	12
9	10	10	11
10	9	9	10
11	10	11	11
12	14	14	16
13	9	3	1
14	10	1	0
15	10	11	12

APPENDIX D

Patient Perception Questionnaire scores for the *Treatment Group*.

Patient	V2	V3	V4
16	8	1	0
17	10	10	2
18	10	11	12
19	10	7	5
20	9	5	3
21	6	0	0
22	8	8	7
23	10	11	11
24	9	8	7
25	8	8	7
26	15	15	16
27	8	6	0
28	15	14	16
29	9	1	0
30	10	9	9

APPENDIX E

QUESTIONNAIRE ON PATIENTS PERCEPTION TO THE TREATMENT OF COMMON AND FLAT VERRUCAE BY HOMOEOPATHIC SIMILLIMUM.

NAME:

ADDRESS:

TEL NO:

DATE OF BIRTH:

OCCUPATION:

This questionnaire has been designed especially so that you may give your perception of the treatment that you are receiving. It will also give you the opportunity to record any changes you have noticed while undergoing the treatment.

This questionnaire must be completed as honestly as possible. Your responses will be vital in evaluating whether this type of homoeopathic treatment is effective in the treatment of common and flat verrucae.

To indicate your response to the treatment, please select one of the numbers between 1 and 5, by circling the number.

1. Thus far how have you perceived the treatment to be ?

Excellent	0
Very good	1
Fair	2
Neutral, neither +ve or -ve	3
Not so good	4
Not good at all	5

2. Current number of warts: _____

3. Has the number of warts on your body changed ?

All the warts on my body have disappeared	0
There has been a definite decrease in number	1
There appears to be a slight decrease in number	2
There has been no change in number	3
There appears to be a slight increase in number	4
There has been a definite increase in number	5

4. Has the size of your warts changed ?

All the warts on my body have disappeared	0
Some or all of the warts have definitely decreased in size	1
Some or all of the warts appear to have decreased in size	2
There has been no change in size of any of the warts	3
Some or all of the warts appear to have increased in size	4
Some or all of the warts have definitely increased in size	5

5. Is there a sensation of pain in any of the warts and if so how has it changed ? NB answer this question only if pain exists.

All the warts on my body have disappeared	0
The sensation of pain has disappeared	1
The sensation of pain has decreased	2
There has been no change in the sensation of pain	3
The sensation of pain has increased	4
The sensation of pain has increased dramatically	5

APPENDIX F

Patient Consent Form

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

PATIENT/SUBJECT* Name _____
(in block letters)

Signature _____

PARENT/GUARDIAN* Name _____
(in block letters)

Signature _____

WITNESS Name _____
(in block letters)

Signature _____

RESEARCH STUDENT Name _____
(in block letters)

Signature _____

APPENDIX G

Remedies used in the *Treatment group*.

Patient	Remedies
16	Sepia
17	Thuja occidentalis
18	Sepia
19	Baryta carbonicum
20	Phosphorus
21	Phosphorus
22	Medorrhinum
23	Causticum
24	Calcarea carbonicum
25	Sulphur
26	Natrum muriaticum
27	Calcarea sulphuricum
28	Lac caninum
29	Lac caninum
30	Kalium carbonicum