A Study comparing the effectiveness of miasmatic treatment as compared to homoeopathic simillimum in the treatment of Acne Vulgaris

by

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

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DEDICATION

I dedicate this dissertation to my parents, as an attempt to express my appreciation to them - for these years of study would not have been possible without the never-ending encouragement and support they lovingly showered me with.
God has steered me onto this path of Homoeopathy and I thank Him,

not just for guiding me through my years of study but also,
for blessing me

with strength and courage during trying times,
thus always granting me

a sense of inner peace by having the knowledge that I am never alone.
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ABSTRACT

The purpose of this double-blind study was to compare the effectiveness of miasmatic treatment as compared to homoeopathic simillimum in the treatment of Acne Vulgaris.

A final comparison was done with a concurrent study that was conducted on comparison of a herbal complex to homoeopathic simillimum in the treatment of Acne Vulgaris. This made it possible for miasmatic treatment to be compared to herbal complex. The ultimate purpose of this research study was to evaluate which treatment is the most effective in the treatment of this condition.

Thirty-four patients from the greater Durban area were selected from volunteers who met the diagnostic criteria as defined by Burke and Cunliffe (1984:83-92). Patients were of both sexes and were between the ages of 18 and 40. Patients had to discontinue any medication that they were on for four weeks before and during the trial period, for accuracy of the research study. Patients also had to be willing to not change their lifestyle and eating habits for the duration of the trial period.

Any patient who was pregnant, lactating, suffering from a chronic disease or undergoing any other form of treatment or medication was not accepted into the study.
Also, patients suffering from Acne fulminans, Acne rosacea or Acne conglobate were not accepted into the study.

Of the 34 patients recruited, 30 completed the study. These patients were divided into two groups according simple random sampling. Data was collected at the Homoeopathic Day Clinic at the Durban Institute of Technology, Steve Biko Campus.

15 patients received miasmatic treatment and 15 received homoeopathic simillimum. Patients were treated over a period of 9 weeks, with four consultations. The patients completed a Perception Questionnaire at each consultation. The questionnaire consists of 9 questions and each question is graded using a Semantic Differential Scale. Results were analysed statistically using the Mann-Whitney U-Test, Kruskall-Wallis H-Test, and the Friedman's T-Test and the Dunn Procedure.

The effect of homoeopathic treatment was measured in terms of reduction in the total number of lesions. The lesions were divided into 2 groups for analysis, namely non-inflamed and inflamed lesions. The Leeds Technique (Counting Technique) and grading as developed by Burke and Cunliffe (1984), was used to assess the acne vulgaris lesions.

The data was analysed in terms of an inter-group comparison firstly and secondly, an intra-group comparison was done.
The inter-group comparison using the Mann-Whitney U-Test, compared the miasmatic treatment group to the simillimum A treatment group, and then the miasmatic group to the herbal complex group. For both these tests the results showed that patients clinical manifestations of acne had decreased i.e. that patients showed improvement from all three methods of treatment. Statistically, it was found that all three methods proved effective but no particular group demonstrated superior efficacy over the others.

The second inter-group comparison used the Kruskall-Wallis H-Test to compare the 4 groups in combination i.e. 2 simillimum treatment groups, 1 miasmatic treatment group and 1 herbal complex treatment group. In terms of inflamed lesions, improvement was noted in all the groups and no statistically significant difference was seen between the groups.

Figure 2 (page 56) demonstrates the comparison of all 4 groups with regards to non-inflamed lesions. It is seen in this figure that the baseline measurement for the miasmatic treatment group was significantly lower than the other groups. A decrease in the number of lesions in all four groups was seen, however the decrease in the miasmatic treatment group was not as significant as the others. Therefore, although a statistical difference was evident, and it appears as if the miasmatic treatment group showed the least number of lesions at the end of the trial, this is not completely accurate since the initial measurements differed.
On comparison of the total number of lesions, there was only a significant
difference noted at baseline level, thereafter, no statistically significant difference
was noted.

Comparison of scores obtained from perception questionnaires indicated an
improvement in patients mental and emotional states but again no statistically
significant difference was seen between the groups.

Friedman's-T Test was used for the intra-group comparison. This compared
each consultation within each group. There was improvement seen in all groups
and no statistically significant difference was seen between the groups.

The Dunn Procedure made comparisons within each group comparing each
consultation to the succeeding consultations to ascertain in which consultations
improvements occurred. There were some consultations that showed
no improvement but for most of the calculations done an improvement was seen
from consultations 1 to 4. With regard to numbers of inflamed lesions, non-
inflamed lesions and total number of lesions and scores obtained from perception
questionnaires, Group B (Simillimum B treatment group) and the Herbal complex
group showed improvement in every category from consultations 1 to 4. No
improvement was noted in the perception questionnaire readings of both Group
A (Simillimum A treatment group) and the Miasmatic treatment group; also no
improvement was seen with regard to the numbers of non-inflamed lesions in
Group A. There was significant improvement seen in the other categories with
regard to these two groups. This confirms that there was significant improvement with all methods of treatment.

When the 4 questionnaires for each patient were compared, it was found that there was an improvement in the scores obtained, thus showing that the treatment had a positive effect on patient’s mental and emotional states.

The conclusions that can be drawn from this research study is that all three methods of treatment of acne vulgaris are effective but no group in particular demonstrated superior efficacy over the others.

Acne vulgaris is an extremely common condition with sometimes, severe psychological effects, therefore it is important and beneficial to find efficient methods of treating this almost inevitable condition. It would thus be beneficial if further trials are conducted with larger sample sizes and over a longer period of time.

Further studies should be conducted on comparison of:

1. simillimum treatment initially, followed by the herbal complex, and
2. miasmatic treatment initially, followed by the herbal complex
3. simillimum and miasmatic treatments, each compared to the topical application of the herbal complex

Studies could also be conducted on the individual herbal remedies to determine if any particular herb shows greater effectiveness in the treatment of acne vulgaris.
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DEFINITION OF TERMS

1) **Acne Vulgaris**: A common, inflammatory disease of the pilosebaceous glands characterized by comedones, papules, pustules, inflamed nodules, superficial pus-filled cysts, and in extreme cases, canalizing and deep inflamed, sometimes purulent sacs (Berkow and Beer, 1999:811).

2) **Simillimum**: (The superlative of simile: 'the most similar')
The remedy that most closely corresponds to the totality of symptoms. It is the most similar remedy corresponding to a case, the best covering the true totality of symptoms and when found, is always curative (or in incurable cases, it is the best possible palliative remedy) (Yasgur, 1998,187).

3) **Miasm**: A miasm is a predisposition towards chronic disease underlying the acute manifestation of illness,
   a) which is transmissible from generation to generation, and
   b) which may respond beneficially to the corresponding nosode prepared from either pathological tissue or from the appropriate drug or vaccine (Vithoulkas, 1980:130).
4) **Nosode**: A nosode is the potentised homoeopathic remedy prepared from diseased tissue or product of disease. It can be used to prevent or treat a miasm or the associated disease of the tissue or miasm (Yasgur, 1998:164)
CHAPTER 1 : INTRODUCTION

Acne Vulgaris is an inflammatory disorder of the sebaceous follicles that often lead to rupture of the follicles and scarring of the skin (Damjanov, 1996:2428).

One hundred percent of boys and 90% of girls will have some acne lesions during puberty. Acne can affect all ages from neonates to senior citizens. Nearly 85% of persons aged between 12 and 25 will have some acne lesions (Aeling, 2001:146).

1.1 Problem Statement
The purpose of this double-blind study was to compare the effectiveness of miasmatic treatment as compared to homoeopathic simillimum in the treatment of acne vulgaris, with regards to:

(1) patient perception, and
(2) objective clinical findings.

1.2 Statement of the objectives

1.2.1 The First Objective
The first objective was to evaluate the effectiveness of miasmatic treatment compared to homoeopathic simillimum in the management of Acne Vulgaris, in terms of patient perception.
1.2.2 The Second Objective

The second objective was to evaluate the effectiveness of miasmatic treatment compared to homoeopathic simillimum in the management of Acne Vulgaris, in terms of objective clinical findings.

1.2.3 The Third Objective

The third objective was to make a final comparison with a concurrent study that was conducted on a herbal complex compared to homoeopathic simillimum, in the treatment of acne vulgaris, thus making it possible for miasmatic treatment to be compared to the herbal complex.
CHAPTER 2 : REVIEW OF THE RELATED LITERATURE

2.1 ACNE VULGARIS

a) Definition

Acne vulgaris is common inflammatory disease of the pilosebaceous glands characterized by comedones, papules, pustules, inflamed nodules, superficial pus-filled cysts and in extreme cases, canalizing and deep, inflamed, sometimes purulent sacs (Berkow and Beer, 1999:811).

b) Incidence

The incidence peaks at 18 years of age but substantial numbers of men and women aged 20 to 40 are also affected (Brown and Shalita, 1998:1871).

One hundred percent of boys and 90 percent of girls have some acne lesions during puberty. Acne can affect all age groups from neonate to senior citizens. Nearly 85% of persons aged between 12 and 25 have some acne lesions (Aeling, 2001: 146).

In 1990, 4.5 million visits were made to dermatologists for acne-related skin problems. A recent study of clinical acne that examined 749 individuals reported a 3% prevalence in men and 12% in women ages 25 and over (Aeling, 2001:146).
c) **Signs and Symptoms**

Less common variants of acne:

- Conglobate acne – severe with cysts and intercommunicating sinuses and severe scarring


- Acne Rosacea – an inflammatory disorder usually beginning in middle age and characterized by telangiectasia, erythema, papules and pustules primarily in the central area of the face (Berkow and Beer, 1999:811).

i) **Comedones** include open comedones (blackheads) and closed comedones (whiteheads). Blackheads are formed when melanocytes, which are responsible for pigmentation, become compacted within the skin; they are NOT caused by poor hygiene (Cooley, *et al.* 1998:338).

ii) An **inflammatory papule** is an inflammatory reaction to sebum, fatty acids, and bacteria that occurs deep within the follicle and appears as a red "bump" under the skin surface (Cooley, *et al.* 1998:338).

iii) A pustule is an inflammation and exudates around a comedone; it occurs in the upper, more superficial portion of the dermis (Cooley, *et al.* 1998:338).
iv) A cyst consists of swollen, often tender, dilated follicles within the dermis (Cooley, et al. 1998:338).

Other features that may be present in addition to the typical lesions of acne include scarring and hyperpigmentation. Scarring is most commonly atrophic, leading to the formation of so-called ice-pick scars; it may also be hypertrophic or keloidal. Both scarring and hyperpigmentation may result in substantial disfigurement (Brown and Shalita, 1998:1872).

2.2 PATHOGENESIS

Many factors play a role in the pathogenesis of acne, including a hereditary predisposition (Aeling, 2001:147).

An interaction among hormones, keratin, sebum and bacteria determines the course and severity. Acne usually begins at puberty when an increase in androgens causes an increase in the size and activity of pilosebaceous glands. Intrafollicular hyperkeratosis leads to blockage of the pilosebaceous follicles and comedones form, composed of sebum, keratin, and micro-organisms particularly Propionobacterium acnes (Berkow and Beers, 1999:811).

Sebum, the lipid-rich secretion product of sebaceous glands, has a central role in the pathogenesis of acne and provides a growth medium for P.acnes. People with acne have higher rates of sebum production than unaffected individuals. Moreover, the severity of acne is generally proportional to the amount sebum production. Enlargements of the sebaceous glands and increased production of
sebum is stimulated by increase in production of adrenal and gonadal androgens that precedes the clinical onset of puberty (Brown and Shalita, 1998:811).

The earliest morphological change in the pilosebaceous unit in Acne Vulgaris is abnormal follicle epithelial differentiation. Desquamated cornified cells of the upper canal of the follicle become abnormally adherent; instead of undergoing the normal process of shedding and discharge through the follicular orifice, these cells form a retained, microscopic hyperkeratotic plug (the microcomedo) in the follicular canal. The mechanism of this process, also known as comedogenesis, is not known, but a follicular deficiency of linoleic acid may be involved.

Progressive enlargement of the microcomedones gives rise to clinically visible comedones, the non-inflammatory lesions of acne (Brown and Shalita, 1998:1871).

*P. acnes* is an anaerobic diptheroid that populates the androgen stimulated sebaceous follicle and is a normal constituent of the cutaneous flora. It is virtually absent from the skin before the onset of puberty. Sebaceous follicles containing microcomedones provide an anaerobic, lipid rich environment in which these bacteria flourish (Brown and Shalita, 1998:1871).

Acne is generally limited to the face, neck, chest, upper back and upper arms. Individual lesions are centered around the pilosebaceous follicles. The skin may have an oily texture appearance, showing increased sebum production. Closed comedones are known as whiteheads because they appear whitish. Open comedones (blackheads) appear as flat or slightly raised brown to black plugs
that distend the follicular orifices. The dark colour is due to oxidation of melanin pigment. There may be scarring and hyperpigmentation that may be present in addition to typical lesions of acne (Brown and Shalita, 1998:1872).

2.3 TREATMENT

2.3.1 ALLOPATHIC TREATMENT

Misconceptions about a relationship between acne and diet, physical exercise, or sex are common. Treatment depends on the severity of the lesions (Brown and Shalita, 1998:1873).

The treatment goal is to eliminate comedones, papules, cysts and nodules and to decrease the amount of hyperpigmented scarring (Cooley, et al. 1998:38).

2.3.1.1 Topical Treatment

Topical therapy is indicated for patients with non-inflammatory comedones or mild to moderate inflammatory acne.

Medications used in topical treatment may act against comedones (comedolytic agents) or inflammatory lesions (antibacterials and antibiotics) (Brown and Shalita, 1998:1872).

i) Benzoyl Peroxide bactericidal and keratolytic; it causes follicular desquamation (Cooley, et al. 1998:40).

Topical application results in a decrease in $P. acnes$ counts and an improvement in both non-inflammatory and inflammatory lesions. Irritation (redness, scaling) is a common but generally mild side effect. Contact
dermatitis occurs rarely and responds to withdrawal of the offending agent (Brown and Shalita, 1998:1873).

Benzoyl peroxide can result in bleaching of clothing, bed clothing and fabric (Cooley, et al. 1998:40).

ii) Topical antibiotics are effective in the treatment of inflammatory acne vulgaris; clindamycin and erythromycin are the most commonly used agents. These agents are bacteriostatic for *P.acnes*; topical application results in some reduction in *P.acnes* counts. Topical application of either antibiotic significantly reduces the number of papules and pustules in patients with inflammatory acne (Brown and Shalita, 1998:1873). One hundred and sixty-five subjects completed a 10-week, double blind controlled study where the purpose was to determine if a product containing both erythromycin and benzoyl peroxide is effective in the treatment of acne vulgaris. The study also compared this combination to erythromycin gel, benzoyl peroxide gel and the gel vehicle.

The benzoyl peroxide gel and the erythromycin gel were superior to the control gel; however, the combination product was more effective than any of the others. This was true for both pustular and papular lesions, but the most dramatic effect was on combined inflammatory lesions i.e. papules and pustules (Chalker, et al. 1983:933).

iii) Azelaic acid, also a topical treatment, has anti-microbial and anti-keratinizing properties. In clinical studies, a 20% cream was more
effective than placebo in resolving papules and pustules in patients with inflammatory acne, and was as effective as 0.05% tretinoin cream in resolving non-inflammatory lesions. Clinical experience with this agent, however, has been disappointing (Brown and Shalita, 1998:1872).

iv) Salicylic acid is effective against comedones and inflammatory lesions in Acne vulgaris. It may be useful, but less effective, option for patients who cannot tolerate tretinoin.

v) Topical tetracycline causes yellow staining of skin and clothing and fluorescence under ultraviolet lights, thus it may not be acceptable to patients. Various formulations of the topical antibiotics are available in gels, solutions, and lotions. There is concern, however, that these agents induce resistant strains of *P. acnes* (Brown and Shalita, 1998:1873).

vi) Nicotinamide, which has potent anti-inflammatory activity in vitro, is available in a gel that is used in the topical treatment of inflammatory acne. There are, however, few data supporting its efficacy (Brown and Shalita, 1998:1873).

vii) Adapalene is a synthetic derivative of naphthoic acid with retinoid-like activity. It has comedolytic and anti-inflammatory effects. In a random trial, adapalene 0.1% gel was more effective than tretinoin 0.025% gel against non-inflammatory lesions and as effective against inflammatory lesions in patients with mild to moderate acne, with a lower frequency of
local irritation. In clinical experience, however, adapalene has given more erratic results (Brown and Shalita, 1998:1872).

viii) Topical tretinoin is a retinoic acid, a vitamin A derivative, which inhibits the formation of microcomedones and increases cell turnover (Cooley, et al. 1998:40).

Tretinoin is the most effective available topical comedolytic agent. The drug reverses the process of abnormal follicle keratinisation, thereby reducing the microcomedo formation. Secondarily, the number of inflammatory lesions resulting from rupture of the microcomedones also decreases.

Topical tretinoin used during pregnancy may pose a risk to the fetus. Prospective human studies are lacking however oral rationing has been demonstrated to be teratogenic in rats (Aeling, 2001:386).

Side effects following topical use of tretinoin include red, edematous, crusted or blistered skin; hyperpigmentation or hypopigmentation, increased susceptibility to sunlight, erythema, pruritis, burning and dryness. Excessive application will cause redness, peeling or discomfort with no increase in results (Tretinoin, 2001).
2.3.1.2 Systemic Treatment

Systemic treatment for acne vulgaris includes oral antibiotics, isotreinoin, and hormonal agents but they have adverse side effects (Brown and Shalita, 1998:1873).

i) Oral antibiotics are used when inflammatory acne does not respond to topical treatment (Cooley, et al. 1998:40).

These antibiotics include tetracyclines (tetracyclines, doxycycline, minocycline), erythromycin and co-trimoxazole. These medications improve inflammatory acne by inhibiting the growth of P.acnes; and tetracyclines also have anti-inflammatory properties (Brown and Shalita, 1998:1873).

Tetracycline is the most cost-effective but minocycline is also considered because of its efficacy, lack of gastrointestinal side effects, and lack of photosensitization. Side effects include dizziness and pigmentation of the skin and mucus membranes.

The most common adverse effects of prolonged antibiotic use in women is candidal vaginitis. Long term use may also produce a pustular folliculitis around the nose and in the center of the face. This superinfection may be difficult to clear (Berkow and Beer, 1999:813).
Several adverse effects are associated with tetracycline therapy. It commonly produces gastrointestinal-upset (e.g. vomiting, diarrhea) and vaginal candidiasis through changes in the mucocutaneous bacterial flora. Benign intracranial hypertension is a rare but important adverse effect (Brown and Shalita, 1998:1873).

Erythromycin and co-trimoxazole are alternative treatments. Although erythromycin and tetracycline are equally effective in the treatment of inflammatory acne erythromycin is chosen in practice less frequently because of the emergence of resistant strains of P.acnes (the presence of which is often associated with treatment failure) and because it causes intolerable gastrointestinal side effects in many patients.

Co-trimoxazole effectively treats inflammatory acne, however the potential for serious, though rare, side effects include hypersensitivity reactions and bone marrow suppression generally limits its use to patients who have responded inadequately to the more commonly used oral antibiotics (Brown and Shalita, 1998:1874).

ii) Oral isotretinoin is the best treatment for patients in whom antibiotics are unsuccessful or in patients with very severe deep acne (Berkow and Beer, 1999:813). Trade names for the medication are Roaccutane and Oratane (Isotretinoin-information for patients, 2002). Representative brand names are Accutane and Amnesteem (Isotretinoin, 1999). Isotretinoin is the most effective known inhibitor of sebum production.
Since clinical improvement in acne vulgaris appears to correlate with a reduction of sebum production, this is believed to be the most important mechanism of action. Isotreinoin also markedly affects keratinization and probably exerts an effect on the cohesiveness of the follicular keratinocytes, thus reducing microcomedone formation. Less important actions include anti-inflammatory effects, antibacterial effects, and inhibition of microbial enzyme activity (Aeling, 2001:387).

The drug is teratogenic; its use during pregnancy is associated with a high rate of spontaneous abortions (Brown and Shalita, 1998:1874). Roaccutane causes foetal malformations. These foetal malformations have been documented and include hydrocephalus, microcephalus, abnormalities of external ear (micropinna, small or absent auditory canals), microphthalmia, cardiovascular abnormalities, facial dysmorphia, thymus gland abnormalities. Its use is therefore contra-indicated not only in women who are pregnant or who may become pregnant while undergoing treatment, but also in all women of childbearing potential unless using an effective contraceptive without any interruption for one month prior to therapy, the duration of therapy and for at least one month after discontinuation of therapy (Roaccutane, 2000).

Isotretinoin is classified as a pregnancy category X drug, which means that it is absolutely contra-indicated in patients who are pregnant. Between 1982 and 1989, the manufacturer received 151 reports of
patients who carried their fetuses to term and in 47% there were significant congenital malformations (Aeling, 2001:387).

With regard to psychiatric disorders, Accutane may cause depression and psychosis. In some cases, psychiatric illness is severe and there have been suicide attempts and suicides. It is important to note that depression itself is a major risk factor for suicidal behaviour. Thus, special attention is needed when prescribing drugs that may cause depression. An association with Accutane should be considered in patients with signs and symptoms of depression, even in the presence of other life stressors. Discontinuation of Accutane may be insufficient intervention and formal psychiatric evaluation is necessary (Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Acutane(isotretinoin), 2002).

Accutane has been associated with a number of cases of pseudomotor cerebri (benign intracranial hypertension), some of which involved concomitant use of tetracyclines. Early signs and symptoms of pseudomotor cerebri include papilledema, headaches, insomnia, lethargy, malaise, nervousness, paresthesias, seizures, stroke, syncope, and weakness (Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Acutane(isotretinoin), 2002).

More than 50 different acute and chronic adverse reactions of oral retinoid therapy have been documented (Aeling, 2001:387).
Several cases of clinical hepatitis have been noted which are considered to be possibly or probably related to Roaccutane® therapy. Additionally, mild to moderate elevations of liver enzymes have been observed in approximately 15% of individuals treated during clinical trials. Approximately 25% of patients receiving Roaccutane® experience an elevation in plasma triglycerides. Approximately 15% developed a decrease in high density lipoproteins and about 7% showed an increase in cholesterol levels. These effects on triglycerides, HDL and cholesterol were reversible upon cessation of Roaccutane® therapy (Roaccutane, 2003).

Diffuse interstitial skeletal hyperkeratosis ("DISH"), a normal and common ageing process may be accelerated in those taking excessive doses of isotretinoin for long periods. The result can be seen on X-rays of the affected bone and include spurs on the heel, knee and spine. DISH may result in aching discomfort, which does not necessarily resolve when isotretinoin is discontinued (Oakley, 2002).

The most frequently observed mucous membrane and skin manifestations are those associated with hypervitaminosis A, i.e. dryness of the mucosae; dryness of the nasal mucosae which can lead to epistaxis; dryness of the pharyngeal mucosae to hoarseness.
Dermatitis facialis, exanthema, pyogenic granuloma, paronychia, nail dystrophy, pruritis, sweating and increased formation of granulation tissue in the acne eruptions may occur (Roaccutane, 2003). More than 90% of patients receiving oral isotretinoin at therapeutic levels demonstrate cheilitis or xerosis to some degree (Aeling, 2001:387).

2.3.1.3 Antibiotic Resistance
According to Borglund (2001:3), antibiotics should not be used to treat severe acne. Borglund and her colleagues at the Karolinska Institute in Stockholm based their recommendations on the results of a study in which resistant P.acnes strains were recovered in 28% of 129 severe acne patients treated with antibiotics. They detected resistant strains in 6% of severe acne patients not treated with antibiotics. "While antibiotics have been used for the treatment of acne vulgaris for over 20 years and are still widely prescribed, our results suggest that it may be worthwhile to rethink this practice."

According to Moyer (2001:10), studies since the early 1980’s have suggested a clear association between the emergence of resistance to clindamycin and trimethoprim in P.acnes and the therapeutic use of these antibiotics.

2.3.1.4 Hormonal Treatment
Hormonal treatment improves acne decreasing androgen-induced sebum production. Side effects such as gynaecomastia, impotence, decreased libido and infertility generally preclude the use of these agents in men. Hormonal
treatment may be indicated for women with characteristics that suggest a
significant hormonal influence: inadequate response to other acne treatment;
acne that began or worsened adulthood; pre-menstrual flares of acne; excessive
facial oiliness; inflammatory acne limited to the area of male beard distribution;
and acne accompanied by mild to moderate hirsutism (Brown and Shalita,

Hormonal treatment in the form of a combined anti-androgen (cyproterone
acetate) / oestrogen pill, taken in courses as an oral contraceptive, may help
women with persistent acne resistant to treatment with antibiotics (Edwards, et

Oral contraceptives usually are helpful in acne treatment, because of their
oestrogen content. However, in some women, oral contraceptives can
exacerbate the condition (Stawiski, 1992:1006).

Spironolactone blocks androgen receptors and inhibits androgen synthesis and is
effective against lesions of inflammatory acne. Common side effects of therapy
include breast tenderness, menstrual irregularities and hyperkalaemia (Brown
2.3.1.5 Physical and Surgical Treatments

Physical or surgical treatments are sometimes a useful adjuvant to medical therapy. Comedo extraction, which is more easily accomplished after several weeks of tretinoin therapy, can be done to achieve a more rapid improvement than is possible with topical therapy alone. Tender nodules and cysts can be treated with intralesional injections of corticosteroids to reduce the size and inflammation of lesions quickly. Purulent nodules and cysts can be incised and drained.

Various methods, including dermabrasion, chemical peeling, laser resurfacing, punch grafts, collagen injection can be used to improve atrophic scarring (Brown and Shalita, 1998:1875).

2.3.2 PSYCHOLOGICAL EFFECT OF ACNE

A physician can determine the psychological effect of acne on a patient by understanding his perception of his condition.

The psychological effect of acne vulgaris is the major factor that brings patients to physicians for treatment. Acne patients frequently have feelings of inferiority, low self-esteem, anger, depression, frustration, and embarrassment. Recent studies have shown poor academic performance in students with severe acne. Another study has shown a significant difference in unemployment in patients with severe acne compared to age- and sex-matched controls; in a study of 625 patients, there was 16.2% unemployment in men with acne as compared to 9.2% in controls and 14.3% in women compared to 8.7% in controls (Aeling, 2001:147).
A study was undertaken by Chiu (2002) from Stanford University, California wherein the findings support anecdotal reports that emotional stress from external sources may exacerbate existing acne. Even after logistic regression that controlled for hours of sleep, quality of sleep, meals per day, and quality of diet, an increase in feelings of stress was positively correlated with a progressive increase in acne severity. Worsening of stress remained most highly associated with severe acne changes, while change in diet quality was the only other significant association (Brunk, 2002:54).

Exactly how stress may aggravate acne severity is not understood at this time. One theory holds that increased levels of stress can induce the release of a neuroactive substance in the body, which in turn can activate inflammatory processes or stimulate the sebaceous glands (Brunk, 2002:54).

Patients with long-standing and debilitating skin diseases may become depressed enough to commit suicide, as described in a paper by Cotterill and Cunliffe (1997:246-249) where it is described how 16 patients, 7 men and 9 women committed suicide after presenting with dermatological problems to two dermatologists. One of these patients was a 31-year-old woman, with gross acne-centered dysmorphophobia but absolutely minimal acne in reality, was desperate for treatment with istretinoin. Unfortunately, the drug was not available when she presented because of budgetary controls. She became so depressed about this situation that she killed herself.
The face is very important in body image and it is not surprising, therefore, that young men, particularly with severe acne scarring, become depressed and are at risk of suicide (Cotterill and Cunliffe, 1997:246-249).

Medical treatment does not really show much concern to the psychological impact of acne and this is where Homoeopathy differs.

With homoeopathic treatment the patient is assessed at all levels – physical, mental and emotional, thus recognizing the patients individuality, in the hope of a more successful management of acne (Chatterjee, 1993:1).

2.3.3 EFFECTS OF LIFESTYLE ON ACNE

According to Burke (1996:71), foods eaten can affect the skin in terms of acne but the susceptibility is quite particular for each person. As an example, some people are affected by nuts and others could be affected by a particular kind of nut such as peanuts or pistachios, or after eating a high fat foods. Very frequently dairy products can cause acne in certain people. Foods such as artichokes, spinach and shellfish have a high iodide content, which can cause acne even in individuals who ordinarily would not develop this condition. Also, some soft drinks contain brominated vegetable oils that can aggravate acne.

Although sun exposure may have an immediate drying effect on acne lesions, sun damages skin and is documented to cause more “cell-buildup” which can lead to or increase the chances of acne flare-ups (Lees, 2001:169).
According to Lees (2001:176), patients are constantly under the impression that acne is caused by lack of cleansing. Although keeping the skin as clean as possible is certainly important, acne is not caused by dirt. In fact, acne can be aggravated by too much cleaning. Repeated exposure to detergents, in facial cleansers for example, can aggravate acne if the patient is using the cleansers too often. Patients are advised to cleanse two to three times a day.

2.3.4 HOMEOPATHIC TREATMENT

2.3.4.1 Homoeopathic Simillimum

In Homoeopathy, the concepts of individual disease are not recognized. The vital force maintains harmony in human beings; thus the so-called disease state is disequilibrium of the vital force. Homoeopathy is based on the Law of Similars, therefore the simillimum is prescribed (Chatterjee, 1993:1-2).

Simillimum is the remedy that most closely corresponds to the totality of the symptoms. It is the most similar remedy corresponding to a case, and when found is always curative (or in incurable cases it is the best possible palliative remedy) (Yasgur, 1998:234).

To assess which remedy is to be prescribed, the patient is assessed on the mental, physical and emotional levels, thus recognizing the patient's individuality and the cause of the disease in the hope of a more successful management of the acne (Chatterjee, 1993:2).
Acne Vulgaris is one of the most common conditions that bring a patient to a homoeopath. The problem should never be tackled with superficial, local acting remedies. Instead deep acting constitutional remedies should be bombarded judiciously as soon as the totality is available (Master, 1993:354).

Any toxic substance such as birth control pills, antibiotics and recreational drugs taken on a regular basis produces iatrogenic (drug induced) symptoms. These symptoms, while being artificial elements in the case, also suppress other natural symptoms, which may have been important guiding features of the natural chronic case. This creates a serious obstacle to curative success (Wescott, 1994:30-31).

McDavid (1994) investigated the use of simillimum in the treatment of acne vulgaris where an experimental group of 15 patients received the simillimum and a group of 15 patients received placebo. The treatment period was 4 months with 5 consultations. A statistically significant improvement in the clinical manifestations of the acne vulgaris in those who received simillimum ($p = 0.006$) was demonstrated.

A clinical trial conducted by Van Niekerk (1999), compared the relative effectiveness of miasmatic treatment as opposed to simillimum treatment in terms of the objective clinical findings in patients with acne vulgaris. It was found that there was no statistically significant difference between the two treatments.
In 1997, Lee investigated the role of homoeopathic complex in the treatment of acne vulgaris. In the study, a control group of 16 patients received placebo and an experimental group of 18 received a homoeopathic acne complex of Silicea 30CH, Selenium 9CH, Hepar sulphuris 30CH, Kali bromatum 9CH, and Pulsatilla 30CH. The treatment period was 2 months with 5 consultations. There was no statistically significant improvement over the period of 5 consultations within or between the groups.

2.3.4.2 Miasmatic Treatment

The term 'miasm' comes from the Greek, meaning "pollution, taint". Hippocrates was the first to use it to express his concept of how infectious diseases could be carried by air, water and other sources. The doctors of Hahnemann's time used the term 'miasm' to indicate the unknown cause of disease which pollutes the whole system so as to produce a permanent disease state (De Schepper, 1999:355).

De Schepper (1999:355-356) states that Hahnemann, in treating patients with chronic disease, found that the well-chosen remedy would work for a while but then the patient would relapse. He found patterns of disease in the patients and in their family histories. He called these patterns miasms and declared that unless the underlying miasm was extinguished, a chronic disease could not be permanently cured with Homoeopathy, even with the well-chosen remedy.
Therefore Vithoulkas (1980:130) states that a miasm is a predisposition towards chronic disease underlying the acute manifestations of illness,

1) Which is transmissible from generation to generation, and

2) Which may respond beneficially to the corresponding nosode prepared from either pathological tissue or from the appropriate drug or vaccine.

From this definition, it is clear that there are a large number of miasms, and that the total number is constantly increasing with the advent of suppressive therapies.

Expanding on the definition of miasm by Vithoulkas (1980:130), with regards to acne, a hereditary predisposition has been observed as stated by Aeling (2001:147).

A miasm is characterized by the transmission from generation to generation, and by relief from the corresponding nosode (Vithoulkas, 1980:134).

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

This may be taken to imply that the way acne vulgaris keeps recurring in the patient is an indication for miasmatic treatment (Van Niekerk, 1999:6).

Vithoulkas (1980:134) states that chronic disease predisposition is the primary reason why some cases continue to relapse despite good therapy.
A nosode is the potentised homoeopathic remedy prepared from the diseased tissue or product of disease. It can be used to prevent or treat a miasm or the associated disease of the tissue or miasm (Yasgur, 1998:164).

The five major miasmatic nosodes are Psorinum, Medorrhinum, Syphillinum, Tuberculinum and Carcinosin (Watson, 1991:42).

According to Hahnemann, psora is the oldest miasm. Hahnemann believed that that psora had led to a bewildering variety of diseases because it had so many different original manifestations which had been suppressed (De Schepper, 1999:355).

Nosodes were originally introduced by Dr. Edward Bach in England and Dr. John Patterson in Glasgow, Scotland. (De Schepper, 1999:319).

Certain nosodes have a complete drug picture and these are based on provings, and featured fully in the materia medica. They may therefore be selected in the conventional manner (Cook, 1989:75).

De Schepper (1999:319) states that nosodes are relatively ineffective in the acute conditions they were derived from. Each nosode has a far wider range of applications than its own acute disease. It is probable that the acute sickness elicits such a specific reaction that other remedies are better indicated. Nosodes are more effective in acute cases as a prophylaxis in an epidemic and for the treatment of the lingering effects of disease.
As a chronic remedy, Kent, H.C Allen and other eminent homoeopaths have stressed the fact that nosodes should be prescribed on the symptoms and not for the disease of which the particular nosode is a product (De Schepper, 1999:319).

In Homoeopathy, the vital force, susceptibility and miasms are an intangible, inseparable, dynamic trio that compromises the living organisms. In order to select the correct remedy for a specific change of state in an individual, including alternations of states, classical homoeopaths apply the miasm principle. When viewing an individual's disease symptom pattern or image certain remedy actions express aspects of one or several miasmatic tendencies (Henriques, 1998:6).
CHAPTER 3: MATERIALS AND METHODS

3.1 STUDY DESIGN

3.1.1 Sample Group

The sample group consisted of 34 patients.

3.1.1.1 Recruitment

Subjects were recruited via advertisements and circulars which were placed at, and distributed at the Durban Institute of Technology, University of Natal, University of Durban Westville, Durban Girls High and various shopping centers in the Durban, Chatsworth, Amanzimtoti and Phoenix areas. The sample group was, therefore, obtained by means of convenience sampling i.e. those who responded to the advertisements.

Patients participation in the trial was voluntary, and each patient had to read and then sign the research information letter (Appendix A) and consent form (Appendix B).

34 patients who met the selection criteria (as outlined in section 3.1.1.2) were accepted into the trial and they were randomly divided into 2 groups; 17 patients received miasmatic treatment and 17 received simillimum treatment and this was recorded on a randomization list drawn up by an independent person who also dispensed the medication.
3.1.1.2 Selection Criteria

The patients were chosen for participation in the research, based on the following criteria:

3.1.1.2.1 INCLUSION CRITERIA:

a) Patients could be either male or female.

b) They had to be between the ages of 18 and 40.

c) They had to have defined acne vulgaris lesions as defined by Burke and Cunliffe (1984:83-92).

d) They had to be willing to not change their lifestyle and eating habits for the duration of the trial period.

e) They had to be literate to understand and fill in the questionnaires.

f) Patients had to be from the greater Durban area with easy access to the Durban Institute of Technology.

3.1.1.2.2 EXCLUSION CRITERIA:

a) Any patient who was pregnant, lactating, suffering from a chronic disease or undergoing any form of treatment or medication for acne vulgaris.

b) Any patient who was under the following treatment:

- Any dermatological therapy
- Antibiotic therapy
- Hormonal therapy
- Vitamin and mineral therapy
- Schussler tissue salts.
c) Patients who were suffering from Acne fulminans, Acne rosacea or Acne conglobate.

d) Patients who could not abstain from any form of chronic medication for the duration of the study.

e) Due to interaction of different drugs, if patients were on any form of medication and still wanted to participate in the trial, the researcher preferred, for the accuracy of the research study, that the patients discontinued their medication for four weeks before the trial and during the trial period. This included medication for acne. Thus, this established a baseline reading.

3.1.2 Materials

The homoeopathic miasmatic and simillimum medicines were made at the Durban Institute of Technology Steve Biko Campus Homoeopathic Day Clinic and dispensed in the form of powders. The medicines were made according to the German Homoeopathic Pharmacopaeia (Method number 10). Lactose powders were impregnated with approximately 10 to 12 granules of the appropriate remedy i.e. either the simillimum or the nosode. Powders were triple impregnated at a 1% v/v ratio in 96% ethanol base.

The placebos, which were used intercurrently in the treatment, were lactose powders to which lactose pills were added. Lactose pills were impregnated with 96% ethanol alone.
Patients were given a prescribed amount of medication per day and this dosage depended on the patient's individual case history. Either two or three powders and one powder per day was prescribed to be taken until the powders were finished. Patients were informed that:

1. Powders should be allowed to dissolve under their tongue,
2. Medicines should not be taken with water, and
3. Medicines should be taken half an hour before or one hour after meals.

The powders for the miasmatic treatment, the simillimum treatment and the intercurrent placebos were visually identical and the dosage was also identical so neither the patient nor the researcher had knowledge of which treatment the patient received.

3.1.3 Method

All patients recruited first read the information letter (Appendix A). The researcher assessed the patients according to the inclusion and exclusion criteria. If a patient was accepted into the study, the researcher continued with the initial consultation:

3.1.3.1 On initial consultation, the patients filled in the Perception Questionnaire (McDavid, 1994) (Appendix C). The score from this perception questionnaire at the initial consultation provided a baseline reading.
Perception questionnaires were also filled in at each follow-up. In total, 4 questionnaires were completed by each patient. They were handed back to the researcher for the required analysis and statistics. Then, at the initial consultation a complete medical and homoeopathic history was taken (Appendix F). A medical examination was also performed and during this the acne lesions were counted and measured using the Leeds Technique (Burke and Cunliffe, 1984):

**Leeds Technique for assessing acne – The Counting Technique (Burke and Cunliffe, 1984):**

Lesions are divided into inflammatory and non-inflammatory.

a) Non-inflamed lesions are open (blackheads) and closed (whiteheads) comedones.

Any intermediate lesions are counted according to their major component.

Prominent follicles, etc are excluded.

b) Inflammatory lesions are:

1) Superficial – papules, pustules; vary in size from 0.1 – 0.5cm in diameter.

2) Deep – nodules, cysts, and deep pustules which are 0.5cm or larger in diameter.

3) Macules – represent the resolving phase of either superficial or deep lesions and are either very large or very small.
A vernier caliper was used to measure the size of the lesions in order to classify them (Cunliffe et al. 1984;83).

Attention was paid to the following points to avoid errors in counting:

1) Patient must be comfortably seated for the observer to move around easily and count each area.
2) Good background lighting is needed.
3) Count the forehead, cheeks, midline and chin separately, then combine the counts, thus counting the whole face.
4) Palpation is necessary to distinguish macules from nodules, which are palpable but hardly visible.
5) Stretching of the skin will increase the visibility of the white- and blackheads (Barklie, 1999:26-27).

Then, in a double-blind manner, the patient received either the miasmatic treatment or the homoeopathic simillimum treatment, which were both dispensed in powder form.

The remedy to be prescribed was determined with the aid of materia medicas and a homoeopathic repertory, under the supervision of the supervisor and joint-supervisor of the trial. Potency selection was based on the individual case history.

A table of remedies prescribed and their potencies are in Appendix H.
The powders were made by the laboratory technician at the Durban Institute of Technology Steve Biko Campus Homoeopathic Day Clinic, who also served as the independent person who dispensed the medication.

The nosode and the simillimum are visually identical and the dosage was also identical therefore neither the patient nor the researcher was able which treatment the patient had received.

3.1.3.2 Patients were asked to take a prescribed amount of medication per day. This was dependant on the patients individual case history. Patients either received two or three powders, where one was to be taken per day until the powders were finished.

The treatment program lasted 9 weeks. The follow-ups were every 3 weeks; therefore patients were re-assessed after 3, 6 and 9 weeks. The patients condition was reviewed and recorded by the general medical examination, re-counting, re-grading and measuring.

3.1.3.3 At the first follow-up consultation, the patient again filled in the Perception Questionnaire (McDavid, 1994). Lesions were counted and measured again using the Leeds and Grading Techniques.

3.1.3.4 The researcher then filled out a prescription note but the independent person decided which treatment to administer according to the randomization list e.g. If at the initial consultation,
the patient was given similimum treatment he/she could not be
given a nosode at the second consultation.

3.1.3.5 The same procedure was followed at the third and fourth follow-ups.

3.1.5 Ethics

The trial was conducted according to the methodology approved by the
Faculty of Health Sciences Ethics Committee.

The nature of the study was explained to the patients who qualified for the
trial. If they agreed to participate, informed consent was obtained from the
patients by means of an Informed Consent Form (Appendix B).

Patient files were only accessible to the research supervisor and the
researcher, therefore patients confidentiality was maintained.

Contact numbers of the research supervisor were made available to patients
so that they could contact him in case of any emergency.

3.2 STATISTICAL ANALYSIS

Four subjects dropped out of the study, so statistical analysis was based on the
results of thirty patients i.e. 15 patients each in the similimum treatment group
and in the miasmatic treatment group.

All the questionnaires were screened and all the symptoms were assigned
numerical values, which were entered on spreadsheets. Statistical evaluation of
the data was conducted using the SPSS package version 9+.
3.2.1 Methods of Statistical Analysis

The lesions were counted in terms of inflamed and non-inflamed lesions and from this the total number of lesions was calculated. Patients also filled in a Perception Questionnaire (McDavid, 1994) at each of the four consultations. Thus, four variables of study were used: inflamed lesions, non-inflamed lesions, total number of lesions and scores from the perception questionnaire. Due to the sample sizes being small i.e. 15 patients in each group, the data was analysed in terms of non-parametric tests. The data was first analysed in terms of an inter-group comparison using the Mann-Whitney U-Test and the Kruskall-Wallis H-Test, and secondly in terms of an intra-group comparison. For the intra-group comparison, Friedman’s T-Test was employed. If the null hypothesis was rejected a multiple comparison procedure for use with Friedman’s T-Test (Dunn Procedure) was used to specify between which of the follow up consultations maximum improvement occurred.

All statistical tests were carried out at 5% significance level.

SUMMARY OF GROUPS USED IN STATISTICAL ANALYSIS

The treatment groups that are analysed are the two groups from this trial (Simillimum A treatment group and Miasmatic treatment group) and these groups are compared to the two groups from the research study that was conducted concurrently. These two groups are the Herbal Complex treatment group and simillimum B treatment group.
- Group A - Simillimum A Treatment Group
- Group B - Miasmatic Treatment Group
- Group C - Herbal Complex Treatment Group
- Group D - Simillimum B Treatment Group

3.2.1.1 INTER-GROUP COMPARISONS

3.2.1.1.1 Procedure 1

Comparison between group A and group B

Group A (Simillimum A) is the group that received homoeopathic simillimum treatment in this research study and the Simillimum B group is the group that received homoeopathic simillimum treatment in the study that was conducted concurrently; Govender, 2003.

The purpose was to determine if there was any difference between the two groups in terms of the four variables at each of the four consultations. Mann-Whitney U-Test was used to compare groups A and B with respect to each variable of interest.

(i) Hypothesis Testing

The null hypothesis Ho states that there is no difference between the two groups with respect to the variables of interest, at the $\alpha = 0.05$ level of significance. The alternative Ho states that there is a difference between the two groups.
Ho : there is no difference between the two groups

H1 : there is a difference between the two groups

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

(ii) Decision Rule

For a two-tailed test, the null hypothesis is rejected if $p < \alpha$ where $p$ is the observed significance level or P-value. Otherwise the null hypothesis is rejected at the same level.

Reject hypothesis if $p < \alpha = 0.05$

Accept hypothesis if $p \geq \alpha = 0.05$

3.2.1.1.2 Procedure 2

Comparison between Group B and Group C

Mann-Whitney U-Test was used to compare Group B to the herbal complex group with regard to each of the variables of interest. The purpose was to determine if there was any difference between the two groups with regard to each of the four variables at each of the four consultations.

Hypothesis testing and decision rule as for Procedure 1

3.2.1.1.3 Procedure 3

Comparison between Group A, Group B, Group C and Group D

The Kruskall-Wallis H-Test was used to compare the 4 groups in combination i.e. 2 simillimum treatment groups, 1 miasmatic treatment group and 1 herbal complex treatment group.
The purpose was to determine if there was any difference between the four groups with regard to each of the variables at each of the consultations.

(i) **Hypothesis Testing**

The null hypothesis $H_0$ states that there is no difference between the two groups with respect to the variables of interest, at the $\alpha = 0.05$ level of significance. The alternative $H_1$ states that there is a difference between the two groups.

$H_0 : $ there is no difference between the four groups  
$H_1 : $ there is a difference between the four groups  
$\alpha = 0.05 = $ level of significance of the test

(ii) **Decision Rule**

For a two-tailed test, the null hypothesis is rejected if $p < \alpha$ where $p$ is the observed significance level or P-value. Otherwise the null hypothesis is rejected at the same level.

Reject hypothesis if $p < \alpha = 0.05$
Accept hypothesis if $p \geq \alpha = 0.05$

**3.2.1.2 INTRA-GROUP COMPARISONS**

**3.2.1.2.1. Procedure 4**

**Comparison within Group A (simillimum A), Group B (miasmatic), herbal complex group and simillimum B group**

Friedman's T-Test was used for this intra-group comparison to determine whether there was any improvement between each of the consultations for each
of the variables of interest.

(i) **Hypothesis Testing**

The null hypothesis $H_0$ states that there is no improvement in the consultations with respect to the variables of interest, at the $\alpha = 0.05$ level of significance. The alternative $H_0$ states that there is a difference between the consultations.

$H_0 : \text{there is no improvement between the consultations}$

$H_1 : \text{there is an improvement between the consultations}$

$\alpha = 0.05 = \text{level of significance of the test}$

(iii) **Decision Rule**

For a two-tailed test, the null hypothesis is rejected if $p < \alpha$ where $p$ is the observed significance level or P-value. Otherwise the null hypothesis is rejected at the same level.

Reject hypothesis if $p < \alpha = 0.05$

Accept hypothesis if $p \geq \alpha = 0.05$ where $p = \text{reported p-value}$

3.2.1.2.2 Procedure 5

**Comparison within Group A, Group B, Group C and Group D**

If the null hypothesis for the Friedman's T-Test is rejected, a multiple comparison procedure using the Dunn Procedure was used to specify in which of the follow up consultations maximum improvement occurred.
Comparisons were made between consultations 1 and 2, 1 and 3, 1 and 4, 2 and 3, 2 and 4, and 3 and 4.

(ii) **Hypothesis Testing**

The equation for calculations using the Dunn Procedure is:

If $k = 4$, $b = 15$ and $Z = 2.409$,

then $|R_j - R_{j'}| \geq 2.409 \sqrt{b(k + 1)/6}$

$\geq 2.409 \sqrt{15 \times 4 \times 5/6}$

$\geq 17.03$

Let $R_j - R_{j'}$ be the two consultations where:

\[ j = 1,2,3,4 \quad \text{and} \]

\[ j' = 1,2,3,4 \quad \text{but} \quad j \neq j' \]

Therefore if $R_j - R_{j'} \geq 17.03$, then the hypothesis is accepted and,

$R_j - R_{j'} < 17.03$, then the hypothesis is rejected.

### 3.3 Procedure 6

A bar chart will be constructed to give a visual summary of the results obtained from the comparison between Simillimum A, Miasmatic, Herbal Complex and Simillimum B treatment groups at each consultation for each variable.
CHAPTER 4: RESULTS

4.1 INTRODUCTION

In this chapter, results obtained from statistical analysis of the data, is discussed.

4.2 CRITERIA FOR ADMISSIBILITY OF THE DATA

- The only data that was accepted for statistical analysis was that which was obtained from this trial and from the concurrent study that was conducted.

- The researcher performed all case histories and examinations.

4.3 ASSUMPTIONS

The researcher assumes that:

a) patients read and understood the patient information letter (Appendix A), and complied with the conditions stated therein, and

b) patients took their medication as prescribed.

4.4 TABLE 1: Comparison between Group A and Group B in terms of number of INFLAMED LESIONS in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.967</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.430</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.299</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.361</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: There was no difference in the number of inflamed lesions between the Simillimum A and Miasmatic treatment groups over the four consultations.
4.5 TABLE 2: Comparison of Group A and Group B in terms of number of NON-INFLAMED lesions in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.020</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.519</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.492</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.296</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: From the above table, it was concluded that there was no difference in the number of non-inflamed lesions from consultation 2 to 4 between Simillimum A and Miasmatic treatment groups. However, there was a significant difference in the number of non-inflamed lesions between the two groups at consultation 1.

4.6 TABLE 3 : Comparison of Group A and Group B in terms of TOTAL NUMBER OF LESIONS in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.085</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.619</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.983</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.967</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: The conclusion drawn was that there was no difference in the total number of lesions between the Simillimum A and Miasmatic treatment groups over the four consultations.
### 4.7 TABLE 4: Comparison of Group A and Group B in terms of scores obtained from the PERCEPTION QUESTIONNAIRE in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.308</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.917</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>1.000</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.309</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: There was no difference with regard to patient's perception between the Simillimum A and Miasmatic treatment groups over the four consultations.

### 4.8 TABLE 5: Comparison of Group B and Group C in terms of number of INFLAMED LESIONS in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.901</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.046</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.177</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.157</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: The conclusion drawn was that there was no difference with regard to inflamed lesions between the Miasmatic treatment group and the Herbal Complex group at the baseline measurement and at follow-ups 1, 3 and 4; but there was a difference at follow-up 1.
4.9 TABLE 6: Comparison of Group B and Group C in terms of number of NON-INFLAMED lesions in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.001</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.058</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.004</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.017</td>
<td>Difference</td>
</tr>
</tbody>
</table>

Conclusion: At consultations 1, 3 and 4, there was a difference with regard to non-inflamed lesions between the Miasmatic treatment group and the Herbal Complex group. As is seen in Figure 2 (page 56), the baseline measurements of non-inflamed lesions differed in that the miasmatic treatment group had a significantly lower number of lesions, therefore the difference seen at measurements 2 and 3 are not completely accurate since the initial measurements differed.
4.10 TABLE 7: Comparison of Group B and Group C in terms of TOTAL NUMBER OF LESIONS in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.034</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.494</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.561</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.618</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: A difference was evident at baseline measurement with regard to total number of lesions. At follow-ups 1, 2 and 3 there was no difference in the total number of lesions between the two groups.

4.11 TABLE 8: Comparison of Group B and Group C in terms of scores obtained from the PERCEPTION QUESTIONNAIRE in each group – using the Mann-Whitney U-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.560</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.124</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.819</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.096</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: There was no difference with regard to patient’s perception between the Miasmatic treatment group and Herbal Complex group over the four consultations.
4.12 TABLE 9: Comparison of Group A, Group B, Group C and Group D in terms of number of INFLAMED LESIONS in each group — using the Kruskall-Wallis H-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.992</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.124</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.570</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.336</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: There was no difference with regard to the number of inflamed lesions between the 4 treatment groups over the four consultations.
4.13 TABLE 10: Comparison of Group A, Group B, Group C and Group D in terms of number of NON-INFLAMED lesions in each group – using the Kruskall-Wallis H-Test

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.002</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.071</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.002</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.014</td>
<td>Difference</td>
</tr>
</tbody>
</table>

Conclusion: At baseline measurement and at follow-ups 2 and 3, there was a difference with regard to non-inflamed lesions between the 4 treatment groups.

Figure 2 (page 56) demonstrates the comparison of all 4 groups with regards to non-inflamed lesions. It is seen in this figure that the baseline measurement for the miasmatic treatment group was significantly lower than the other groups. A decrease in the number of lesions in all four groups was seen, however the decrease in the miasmatic treatment group was not as significant as the others. Therefore, although a statistical difference was evident, and it appears as if the miasmatic treatment group showed the least number of lesions at the end of the trial, this is not completely accurate since the initial measurements differed.
4.14 **TABLE 11: Comparison of Group A, Group B, Group C and Group D in terms of TOTAL NUMBER OF LESIONS in each group – using the Kruskall-Wallis H-Test**

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.021</td>
<td>Difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.619</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.538</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.797</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: There was no difference in the total number of lesions between the 4 treatment groups over follow-ups 1, 2, and 3; but there was a difference at the baseline measurement.

4.15 **TABLE 12: Comparison of Group A, Group B, Group C and Group D in terms of scores obtained from the PERCEPTION QUESTIONNAIRE in each group – using the Kruskall-Wallis H-Test**

<table>
<thead>
<tr>
<th>Consultation</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.459</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 1</td>
<td>0.328</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 2</td>
<td>0.866</td>
<td>No difference</td>
</tr>
<tr>
<td>Follow – up 3</td>
<td>0.246</td>
<td>No difference</td>
</tr>
</tbody>
</table>

Conclusion: The conclusion drawn was that there was no difference with regard to patient’s perception between the 4 treatment groups over the four consultations.
4.16 **TABLE 13**: Comparison of number of INFLAMED LESIONS within each group i.e. Group A, Group B, Group C and Group D – using the Friedman’s T-Test

Note: Each P- value represents calculations done from consultations 1 to 4

<table>
<thead>
<tr>
<th>Group</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simillimum A</td>
<td>0.001</td>
<td>Improvement</td>
</tr>
<tr>
<td>Miasmatic</td>
<td>0.004</td>
<td>Improvement</td>
</tr>
<tr>
<td>Herbal Complex</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Simillimum B</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
</tbody>
</table>

Conclusion: There was an improvement noted in the number of inflamed lesions in each group from consultation 1 to 4.

4.17 **TABLE 14**: Comparison of number of NON-INFLAMED LESIONS within each group i.e. Group A, Group B, Group and Group D – using the Friedman’s T-Test

<table>
<thead>
<tr>
<th>Group</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simillimum A</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Miasmatic</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Herbal Complex</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Simillimum B</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.15

Conclusion: There was an improvement in the number of non-inflamed lesions in each group from consultation 1 to 4.
4.18 TABLE 15: Comparison of TOTAL NUMBER OF LESIONS within each group i.e. Group A, Group B, Group D – using the Friedman’s T-Test

<table>
<thead>
<tr>
<th>Group</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simillimum A</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Miasmatic</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Herbal Complex</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
<tr>
<td>Simillimum B</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.16

Conclusion: There was an improvement in the total number of lesions in each group from consultation 1 to 4.

4.19 TABLE 16: Comparison of scores obtained from PERCEPTION QUESTIONNAIRES within each group i.e. Group A, Group B, Group C and Group D – using the Friedman’s T-Test

<table>
<thead>
<tr>
<th>Group</th>
<th>P – value</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simillimum A</td>
<td>0.033</td>
<td>Improvement</td>
</tr>
<tr>
<td>Miasmatic</td>
<td>0.007</td>
<td>Improvement</td>
</tr>
<tr>
<td>Herbal Complex</td>
<td>0.001</td>
<td>Improvement</td>
</tr>
<tr>
<td>Simillimum B</td>
<td>0.000 (&lt; 0.001)</td>
<td>Improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.15

Conclusion: There was an improvement in terms of patient perception in each group from consultation 1 to 4.
4.20 TABLE 17: Comparison of consultations within Group A with regard to INFLAMED LESIONS – using the Dunn Procedure

**NOTE:** \( R_j - R_{j'} \): the difference between 2 consultations

Is significant if \( R_j - R_{j'} > 17.03 \)

<table>
<thead>
<tr>
<th>( R_j - R_{j'} )</th>
<th>Simllimum A</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>0</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>17.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>23.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>17.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>23.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>6</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

**Conclusion:**

Improvement was seen between consultations 1 and 3, 1 and 4, 2 and 3 and 2 and 4.

4.21 TABLE 18: Comparison of consultations within Group A with regard to NON-INFLAMED LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>( R_j - R_{j'} )</th>
<th>Simllimum A</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>20.72</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>10.22</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>2.03</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>10.95</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>22.75</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>12.25</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

There was improvement between consultations 1 and 2 and 2 and 4.
### 4.22 TABLE 19: Comparison of consultations within Group A with regard to TOTAL NUMBER OF LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Simillimum A</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>14.55</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>24.45</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>39</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>9.9</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>24.45</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>14.55</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

Conclusion:

Improvement occurred between consultations 1 and 3, 1 and 4 and 2 and 4.

### 4.23 TABLE 20: Comparison of consultations within Group A with regard to scores obtained from PERCEPTION QUESTIONNAIRE – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Simillimum A</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>6.6</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>7.95</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>12.45</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>14.55</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>19.05</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>4.05</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

Conclusion:

There was improvement between consultations 2 and 4.
4.24 **TABLE 21**: Comparison of consultations within Group B with regard to **INFLAMED LESIONS** – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Miasmatic</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>6</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>17.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>23.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>11.1</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>17.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>6</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

There was improvement between consultations 1 and 3, 1 and 4 and 2 and 4.

4.25 **TABLE 22**: Comparison of consultations within Group B with regard to **NON-INFLAMED LESIONS** – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Miasmatic</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>9</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>21</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>28.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>12</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>19.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>7.5</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

Improvement occurred between consultations 1 and 3, 1 and 4 and 2 and 4.
4.26 **TABLE 23**: Comparison of consultations within Group B with regard to TOTAL NUMBER OF LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Miasmatic</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>6.9</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>21</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>33.9</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>14.1</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>27</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>12.9</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion**:

Improvement occurred between consultations 1 and 3, 1 and 4 and 2 and 4.

4.27 **TABLE 24**: Comparison of consultations within Group B, with regard to scores obtained from PERCEPTION QUESTIONNAIRE – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Miasmatic</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>6</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>22.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>15.45</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>16.5</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>9.45</td>
<td>No improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>7.05</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion**:

An improvement was only seen between consultations 1 and 3.
4.28 **TABLE 25**: Comparison of consultations within Group C with regard to INFLAMED LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Herbal Complex</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>15.45</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>18</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>34.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>2.55</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>19.05</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>16.5</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

Improvement was seen between consultations 1 and 3, 1 and 4 and 2 and 4.

4.29 **TABLE 26**: Comparison of consultations within Group C with regard to NON-INFLAMED LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Herbal Complex</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>14.4</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>24.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>34.95</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>10.05</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>20.55</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>10.5</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

Improvement was seen between consultations 1 and 3, 1 and 4 and 2 and 4.
### 4.30 TABLE 27: Comparison of consultations within Group C with regard to TOTAL NUMBER OF LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Herbal Complex</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>13.5</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>23.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>39.96</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>9.6</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>26.1</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>16.5</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

Conclusion:

Improvement was seen between consultations 1 and 3, 1 and 4 and 2 and 4.

### 4.31 TABLE 28: Comparison of consultations within Group C with regard to scores obtained from PERCEPTION QUESTIONNAIRE – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Miasmatic</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>7.95</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>14.4</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>27.45</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>6.45</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>19.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>13.05</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

Conclusion:

Improvement occurred between consultations 1 and 4 and 2 and 4.
4.32 **TABLE 29:** Comparison of consultations within Group D with regard to INFLAMED LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Simillimum B</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>12.9</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>17.4</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>31.5</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>4.5</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>18.6</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>14.1</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

Improvement was seen between consultations 1 and 3, 1 and 4 and 2 and 4.

4.33 **TABLE 30:** Comparison of consultations within Group D with regard to NON-INFLAMED LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Simillimum B</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 – R2</td>
<td>18</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R3</td>
<td>28.05</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 – R4</td>
<td>43.95</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 – R3</td>
<td>10.05</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 – R4</td>
<td>25.95</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 – R4</td>
<td>15.9</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

**Conclusion:**

Improvement occurred between consultations 1 and 2, 1 and 3, 1 and 4, and 2 and 4.
4.34  **TABLE 31**: Comparison of consultations within Group D with regard to TOTAL NUMBER OF LESIONS – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Simillimum B</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>16.5</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>26.4</td>
<td>Improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>42.9</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>9.9</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>26.4</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>16.5</td>
<td>No improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

Conclusion:

Improvement occurred between consultations 1 and 3, 1 and 4 and 2 and 4.

4.35  **TABLE 32**: Comparison of consultations within Group D with regard to scores obtained from PERCEPTION QUESTIONNAIRE – using the Dunn Procedure

<table>
<thead>
<tr>
<th>Rj - Rj'</th>
<th>Simillimum B</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 - R2</td>
<td>1.45</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R3</td>
<td>5.55</td>
<td>No improvement</td>
</tr>
<tr>
<td>R1 - R4</td>
<td>25.95</td>
<td>Improvement</td>
</tr>
<tr>
<td>R2 - R3</td>
<td>7.05</td>
<td>No improvement</td>
</tr>
<tr>
<td>R2 - R4</td>
<td>27.45</td>
<td>Improvement</td>
</tr>
<tr>
<td>R3 - R4</td>
<td>20.4</td>
<td>Improvement</td>
</tr>
</tbody>
</table>

Refer to note at 4.19

Conclusion:

Improvement occurred between consultations 1 and 4, 2 and 4 and 3 and 4.
4.36 Bar Charts

Figure 1:
Comparison of all 4 groups with regards to the means of INFLAMED LESIONS, for all 4 consultations

Conclusion for Figure 1:
The vertical axes in figures 1, 2 and 3 represent counts of the lesions. Improvement of the lesions is indicated by lower counts. Figure 1 demonstrated an overall decrease in inflamed lesions in all groups from the first to fourth consultations.
Figure 2:
Comparison of all 4 groups with regards to the means of NON-INFLAMED LESIONS, for all 4 consultations

Conclusion for Figure 2:
Again, an overall decrease in the number of non-inflamed lesions is displayed, however the miasmatic group showed no change from consultation 3 to 4. The simillimum B group showed the greatest overall improvement.
Figure 3:
Comparison of all 4 groups with regards to the means of TOTAL NUMBER OF LESIONS, for all 4 consultations

Conclusion for Figure 3:
All groups showed a significant decrease in the total number of lesions, however when comparing the miasmatic treatment group to the herbal complex group, it is displayed that the herbal complex group showed greater improvement.
Figure 4:
Comparison of all 4 groups with regards to the means of scores obtained from PERCEPTION QUESTIONNAIRES, for all 4 consultations

Conclusion for Figure 4:
The vertical axis in figure 4 represents the ratings used in the Perception Questionnaire (Appendix C). The questionnaire ranged from 0 to 5, with 0 being negative results and 5 being positive results.
Thus, if the rating gets higher, the improvement is greater.
Ratings improved in all groups, with each consultation having a higher rating than the previous one.
The miasmatic treatment group showed the most dramatic improvement, thus displaying that miasmatic treatment has a significant psychological effect.
CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

5.1 Interpretation

The purpose of this double-blind study was to compare the effectiveness of miasmatic treatment as compared to homoeopathic simillimum in the treatment of acne vulgaris, with regards to:

(1) patient perception, and

(2) objective clinical findings.

A final comparison was done with a concurrent study that was conducted on comparison of a herbal complex to homoeopathic simillimum in the treatment of acne vulgaris.

A clinical trial conducted by Van Niekerk (1999), compared the relative effectiveness of miasmatic treatment as opposed to simillimum treatment in terms of the objective clinical findings in patients with acne vulgaris. It was found that there was no statistically significant difference between the two treatments.

The ultimate purpose of this research study was to compare the miasmatic treatment to the herbal complex and thus to evaluate which treatment is the most effective in the treatment of acne vulgaris. Therefore, this research study can be seen as an extension of the study conducted by Van Niekerk (1999), thereby allowing for greater knowledge and understanding of the place and value of homoeopathic simillimum, miasmatic and herbal treatments of acne vulgaris.
Simillimum is the remedy that most closely corresponds to the totality of the symptoms. It is the most similar remedy corresponding to a case, and when found is always curative (or in incurable cases it is the best possible remedy) (Yasgur, 1998:234).

The inter-group comparison using the Mann-Whitney U-Test, compared the miasmatic treatment group to the simillimum A treatment group, and then the miasmatic group to the herbal complex group. For both these tests the results showed that patients clinical manifestations of acne had decreased i.e. that patients showed improvement from all three methods of treatment. Statistically, it was found that all three methods proved effective but no particular group demonstrated superior efficacy over the others.

The second inter-group comparison used the Kruskall-Wallis H-Test to compare the 4 groups in combination i.e. 2 simillimum treatment groups, 1 miasmatic treatment group and 1 herbal complex treatment group. In terms of inflamed lesions, improvement was noted in all the groups and no statistically significant difference was seen between the groups. On comparison of non-inflamed lesions, a statistically significant difference was seen in the baseline readings and statistically significant difference was seen at measurements 2 and 3. On comparison of the total number of lesions, there was only a significant difference noted at baseline level, thereafter no statistically significant difference was noted.
Comparison of scores obtained from perception questionnaires indicated an improvement in patients mental and emotional states but again no statistically significant difference was seen between the groups.

From the Friedman's T-Test, which compared each consultation within each group, it becomes evident that there was improvement seen in all groups and no statistically significant difference was seen between the groups.

Looking at the definition of simillimum and from the results that showed a decrease in the clinical manifestations of acne, it is confirmed that the simillimum treatment was effective.

When miasmatic and homoeopathic simillimum treatment groups were compared, it was found that the number of lesions had decreased in both groups thereby showing that there was no statistically significant difference between these two methods of treatment.

Vithoulkas (1980:134) states that chronic disease predisposition is the primary reason why some cases continue to relapse despite good therapy. Implicit in miasmatic treatment is the idea formulated by Hahnemann that it is impossible to fundamentally and permanently cure a chronic disease state unless treatment is directed towards the underlying miasm (Watson, 1991:41). Therefore, those patients who improved on miasmatic treatment suggest that treatment was successfully directed towards their underlying miasm.
5.2 Argument and Speculation

Chronic disease predispositions are the primary reason why some cases continue to relapse despite good therapy (Vithoulkas, 1980:134).

In the last analysis, the results of repertorisation must be forgotten while the homeopath’s full attention is placed upon a study of materia medicas. The goal, after all is to match the “essence” and totality of the patients symptoms with that of the remedy (Vithoulkas, 1980:201).

While the symptomatology for nosodes depends more on clinical experience than provings, in general, the clinical experience for most nosodes has accumulated for many years and has been checked by the experience of so many practitioners that it is considered trustworthy (De Schepper, 1999:317).

From lack of knowledge or understanding, however, nosodes have been mostly neglected. While it is true that nosodes are not as well proven as our well known poychrests, their indications are constantly becoming better known as they are more widely used (De Schepper, 1999:317).

This research study compared the homoeopathic simillimum to miasmatic treatment. Although it is not standard homoeopathic practice to randomly prescribe a simillimum or nosode, for the purpose of this research study, the random prescription of medication provided the opportunity to gain more knowledge and insight into the action of a nosode in a case where a simillimum may have been prescribed. Seeing that the simillimum remedies are more well known, as described by De Schepper (1999:317), it would be beneficial to learn more about the role of a nosode in a case where the role, or a
great part of the role of the simillimum can be assumed from previous experience.

Commenting on how Hahnemann’s theory of miasms was not well accepted and how it still remains controversial among homoeopaths even today, De Schepper (1999:357) says that he believes that the proof lies in its clinical effectiveness and that in his own practice he has found miasmatic prescribing to be a powerful and essential tool.

In this research study, the aim was to compare miasmatic treatment to simillimum treatment and the ultimate aim was to compare miasmatic treatment to the herbal complex. Both these comparisons allow for expansion of the previous knowledge of nosodes from the trial undertaken by Van Niekerk(1999).

Watson (1991:41) acknowledges that some homoeopaths consider the nosodes to be no different from other remedies and that there is no reason to prescribe them other than on symptom similarity. This confirms the findings of this research study with regard to there being no significant difference between simillimum and miasmatic treatments.

5.3 Recommendations

This research study together with the concurrent study that was performed, highlights three methods of treating acne vulgaris.

From statistical analyses, it is evident that all three methods of treatment proved effective in the treatment of acne vulgaris but no one group in particular demonstrated superior efficacy over the others, therefore it might be enlightening
if further studies are undertaken on comparing the prescribing of:

(1) simillimum treatment initially, followed by the herbal complex, and

(2) miasmatic treatment initially, followed by the herbal complex

to ascertain whether better results can be obtained in this manner i.e. using
homoeopathic and herbal remedies simultaneously.

Improvement seen in the miasmatic treatment group indicates that the treatment
was directed successfully towards the underlying miasm of the patient and in
terms of the simillimum treatment groups the remedy prescribed covered the
totality of symptoms of the patient.

From the miasmatic treatment, Carcinosin was the nosode that was the most
frequently prescribed. 10 patients from the total of 15 in the miasmatic treatment
group received Carcinosin, therefore further studies could be conducted on the
comparison of Carcinosin to the herbal complex and also Carcinosin to
simillimum treatment.

Many patients suffering from Acne Vulgaris or any other dermatological condition
or irritation generally seek comfort in having to make topical applications in an
attempt to relieve the condition. It is with this in mind that the researcher believes
it would be beneficial to conduct trials on simillimum and miasmatic treatments,
each compared to the topical application of the herbal complex.

Improvement in the herbal complex group indicates that the herbal remedies
used in the complex are effective, however it may be beneficial to conduct a
study on the individual herbal remedies to determine if any particular herb is more effective than any of the others.

For further studies larger sample sizes should be used for greater accuracy. Also, for achieving the goal of receiving more accurate results, studies such as this should be conducted over a longer period of time.
REFERENCES


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APPENDIX D: Grading Technique

APPENDIX E: Leeds Technique for assessing acne – The Counting Technique

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APPENDIX A1

Patient Consent Form and Information Letter
Patient Consent Form and Information Letter

Title of Research Project:
The relative effectiveness of miasmatic treatment compared to homoeopathic simillimum in the treatment of Acne Vulgaris.

Name of Supervisor:
Dr. A.H.A Ross  M.Tech(T.N) B.Mus(UCT)

Name of Research Student:
Olica Sewsunker

Patient Information:
Full name: ..................................................................................................................
Date of Birth: ..............................................................................................................
Age: .........................................................................................................................
Sex: ...........................................................................................................................

Dear Patient,

Thank you for considering to participate in this study. Students of Homoeopathy are required to complete a research project such as this as a partial fulfilment of their Master's Degree of Technology in Homoeopathy. The aim of this study is to evaluate the relative effectiveness of miasmatic treatment compared to homoeopathic simillimum in the management of Acne Vulgaris. A final comparison will be done with a concurrent study being conducted on comparing a herbal complex to homoeopathic simillimum in the treatment of Acne Vulgaris. This will be to evaluate which treatment is the most effective in the treatment of this condition.

Acne Vulgaris is a common skin disorder which starts at puberty but can extend into the fourth or fifth decade of life. Orthodox treatment and approach is variable and often results in complications or side-effects and this is disappointing not only for the patient, who may already be self-conscious but also for the physician. It is these reasons that justify the importance and relevance of this research study.
There have been research studies on Acne Vulgaris performed previously at Technikon Natal thus this research study can be seen as an extension of the preceding studies thereby allowing for a greater knowledge and understanding of the place and value of homoeopathic treatment of this common skin disorder. This research study will propose to determine the impact of homoeopathic treatment of this condition, and how effective it is in alleviating the signs and symptoms of Acne Vulgaris.

The demand for a safe and effective treatment for this condition is quite evident and growing. There are no known "side-effects" with homoeopathic treatment however a slight homoeopathic aggravation may occur in some patients. This means that your pimples might get worse and some of your old symptoms might come back, but this aggravation is short - lived, and is followed by amelioration.

Participation in this study is voluntary and you must be between the ages of 18 and 40 and you have to have visible acne. You must agree to discontinue any other form of medication you are on for 4 weeks before the trial starts and during the trial period. Your lifestyle and dietary habits must not be changed during the trial. You must be willing to take the prescribed amount of medication per day as directed and not expose the medication to any situation that might antidote it i.e. very high temperatures and aromatic substances such as peppermint and camphor.

You will not be included in this study if you are pregnant, breastfeeding, suffering from a chronic disease or undergoing any other form of treatment for acne or any other condition.

You will be free to withdraw from this study at any stage if necessary and no explanation will be required.

The trial period is 9 weeks with 4 consultations which are 3 weeks apart. After you have signed both the consent forms, the following procedure will take place at each visit:

- **Visit 1**
  a) Fill in questionnaire
  b) Consultation with medical and personal history
  c) Counting and grading of pimples
  d) Treatment will be prescribed.
• Visits 2, 3 and 4
  a) Fill in questionnaire
  b) General examination
  c) Re-counting and re-grading of pimples
  d) Treatment may be prescribed.

The direct benefit of this study is that the treatment may result in an improvement of your acne.
Your participation will increase our knowledge and understanding of the place and value of homoeopathic treatment for acne.

There will be strict patient-practitioner confidentiality. Your personal details will not be disclosed to any unauthorised persons.

The treatment is being supervised by a qualified homoeopath and is free of charge.

In case of any queries or problems arising during the research you may contact:

  Olica Sewusunker       Tel.: 031 – 204 204 1
                       (Clinic at Technikon Natal)

  Dr. Ashley Ross       Tel.: 031 – 204 204 1
                       (Clinic at Technikon Natal)

Please fill in the details on the next page.
I, ........................................................., DO HEREBY AGREE TO ABIDE BY THE DELIMITATIONS AND CONDITIONS SET OUT IN THE ABOVE DOCUMENT.

Date: ...........................................................................................................

Patient’s name: ...........................................................................................

Signature: ....................................................................................................

Witness: .......................................................................................................  

Signature: ....................................................................................................

Thank you.

Kind regards,

..........................................................  

Olica Sewsunker  
(Final year Homoeopathy student)
APPENDIX A2

Patient Consent Form and Information Letter (Zulu)
Incwadi Yokuzinikela kwesiguli

Ingiithi Yocwaningo:
Impumelelo ye miasmatic treatment ekulapheni isifo sezinduna iqathaniswa ne homeopathic similimum ekulapheni isifo sezinduna.

Igama lomhloli
Dr. A.H.A Ross  M.Tech (T.N)  B.Mus (UCT)

Igama lomfundisi owenza ucwaningo
Olica Sewsunker

Imininingwane yesigulu
Igama nesibongo
Usuku nokuslawa
Iminyaka vakho
Ubulili

Siguli Mzali

Siyabonga ngokuthi uzinikele kuloluucwaningo. Abafundi abafunda ihomoeopathy bafanaleke ukuba benze ucwaningo olujengalolu ukuze baphothule iziqu zabo eziphezulu kwezobulwepheshe kwezemilo ekulapheni Masters Degree of Technology in Homoeopathy.

Inhluso yaloluucwaningo ukuthola ukuthi i-miasmatic treatment iyasellapha kungcono yini isifo sezinduna uma siyiqathanisa ne homoeopathic similimum. Ukuqathanisa kokucencia kuzokwenziwa phakathi kwalezizindlela ezimbi i-herbal complex kanye ne homoeopathic similimum okumanje kwenziwa ucwaningo ngazo. Lokhu kuzokhombisa ukuthi iyiphi indlela engcono ekulapheni isifo sezinduna.

Izizinduna isifo sesikhunba esijwaveleke ukutholakala kubantu besilisa nabesifazane una sebengena ebungizweni nasebuntombini, kodwa kuyenzeka ukuthi umuntu akhule naso noma esedlulile ekuthombeni zimingi izindela zokuluwa nalesisifo kodwa akuzona zonke ezivimpelelo lokhu kudala ukukhathakzeka kophetwe vilesi isifo nodokoela abamhyanga yo, ingakho sibone kualulekile ukuba senze loolwanningo owphathelene nalesisifo.
Ucwani ngwesifo sezinduna Acne Vulgaris bese luke lwenziwe e Technikon Natal ngaphambilini ngakhoke Idlucwaningo lwe homoeopathic treatment luvangezelela olwazini nasekuqondeneni ukwelapha lesifo sesikhumba.

Inhloso yalolucwaningo ukuthola umthekela ngokwesibenzisa ingxube yamakhambi nokuhlola. Ukuthi iyimpumelelo engakanani ekushabalalaliseni izinduna kanye nezinkomba zazo.


• Uma uvakasha okokuqala:
  1) Uzogwalisa uhla lwemibuzo
  2) Uzohlolwa bese kutholakala umlando wempilo yakho
  3) Izinduna zizobalwa bese izinga lazo lihlwelwa ziyahlelwa
  4) Uzonikezwa imithi ozoyisebenzisa

• Uma usuvakasha okweibili, okwesithathu nokwesine:
  1) Uzogcwcalisa uhla lwemibuzo
  2) Uzohlolwa
  3) Inani lezinduna lizobalwa bese liyahlelwa futhi
  4) Uzomikezwa imithi ozoyisebenzisa

Wena uzohlomula ngalolucwaningo ngokuthi izinduna zakho zelapho. Ukuzimbhandakanya kwakho kulolucwaningho nokuqonda ukuthi indawo yehomoeopathic treatment ekulapheni izinduna.

Imininingwane avizikudawcwa noma vikubani ngaphandle kwenuume vesigulu. Ukuthathwa kwemihiti kuzobeka kuqaphelwe abahlengi kazi abaphesihle imithi imahala.

Uma umembuzo noma kuba nezinkinga ngesikhathi socwaningo ungathintana no:

Olica Sewsunker Tel.: 031 – 204 2041
(Eklinikhi ese Technikon Natal)

Dr. Ashley Ross Tel.: 031 – 204 2041
(Eklinikhi ese Technikon Natal)

Uyacelwa ukuthi ugwalise lenininingwane elandela yo.
Mina, ........................................... ngiyavuma ukulandela
nokwenza njengoba kubha liwe kulosomqo.

Usuku : ..............................................................

Igama lesiguli : ..............................................................

Isishicilelo : ..............................................................

Likafakazi : ..............................................................

Isishicilelo : ..............................................................

Siyabonga

Ube nosuku oluhle.

Olica Sewsunker
(Umfundi owenza ibanga lokuguna kwi homoeopathy
APPENDIX B1

Informed Consent Form
Informed Consent Form

Title of Research Project
The relative effectiveness of miasmatic treatment compared to homoeopathic simillimum in the treatment of Acne Vulgaris.

Name of Supervisor: Dr. A.H.A Ross
Name of Research Student: Olica Sewsunker

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?
   (a) at any time  Yes No
   (b) without having to give a reason for your withdrawing
   (c) without affecting your future health  Yes No
9. Do you agree to voluntarily participate in this study?  Yes No

If your answer is No to any of the above questions, please consult for further explanations before you sign.

Patient's Name : ......................................... Signature

Witness Name : ......................................... Signature: .................

Research Student : ......................................... Signature: .................

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APPENDIX B2

Informed Consent Form (Zulu)
**Incwadi Evunywe Ngokubonisana**

**Inqikithi Yocwaningo**
Impumelelo ye miasmatic treatment ekulapheni isifo sezinduna iqathaniswa ne homoeopathic simillimum ekulapheni isifo sezinduna.

**Igama Lomhloli :** Dr. A.H.A Ross  
**Igama lomfundi owenza ucwaningo :** Olica Sewusunker

**Usuku :** .................................................................

**FAKA ISIKOKELA EMPENDULWENI EFANELE**

1. Ngabe uyifundile iminingwabe ephepheni locwaningo ? Yebo Cha
2. Ngabe usitholile isikhathi sokubuza imibuzo emayelana nalesisifundo ? Yebo Cha
3. Ngabe uzitholile izimpendulo ezikwenelisayo zemibuzo yakho ? Yebo Cha
4. Ngabe ulitholile ithuba lokuxoxisa mayelana nalesisifundo ? Yebo Cha
5. Ngabe uthole incazelo eyanele mayelana nalesisifundo ? Yebo Cha
6. Ngabe ukhulume nobani ? ..............................................
7. Ngabe uyaqonda imiphumela yokuzibadakanya kwakho kulesisifundo ? Yebo Cha
8. Ngabe uyaqonda ukuthi ukkhululekile ukuhoa kulesisifundo
   (a) noma nini
   (b) ngaphandle kokunika izizathu zokuhoa, futhi
   (c) ngaphandle komthelela ekunakekelweni kweempilo yakho ? Yebo Cha
9. Uyavuma ukuzibandakanya ngaphandle kwenkokhelo ? Yebo Cha

**Uma uphendule ngo cha kunoma yimuphi umbuzo ngenhla, uyacelwa ukuba uthole iminingwane ngaphambili kokuba usayinde.**

**Igama lesiguli :** .................................................. Isishicilelo : ......................

**Igama likafakazi :** .................................................. Isishicilelo : ......................

**Igama lomfundi owenza ucwaningo :** .................................. Isishicilelo : ...............
APPENDIX C1

Perception Questionnaire
(McDavid, 1994)
Perception Questionnaire  
(McDavid 1994)

Questionnaire assessing patients perception to the treatment

Please note : This questionnaire is to be conducted personally by the researcher.

Date : ............................

Identifying data:
Name : ...........................................................................................................
Age : ..............................................................................................................
Date of Birth : ............................................................................................... 
Sex : ..............................................................................................................

Introduction
This research project aims to investigate the efficacy of homoeopathic treatment of Acne Vulgaris. The demand for some safe and effective treatment for this condition is quite evident and growing therefore the aim of this research project is to determine the impact of homoeopathic treatment on Acne and how effective it is in alleviating the signs and symptoms.

Your honest participation will contribute to our homoeopathic knowledge and will create an awareness of this safe and effective form of treatment.

This questionnaire is to assess any changes that occur after taking the prescribed medication. Thus the patients perception of the treatment is a significant consideration.

Instructions
Please answer this questionnaire with complete honesty. Each question is graded using a semantic differential scale. Place a cross over the number that best describes how you feel.
E.g. If a question asked how you felt about rainy days, and you love them, then a cross is placed over the number that resembles your closest feeling.

I hate them 1 2 3 4 5 I love them

Please note that the larger the number you choose, the more positive the response is.
Please complete the questionnaire.

Thank you.
Each question in this section is graded using a “Semantic Differential Scale” i.e. a scale consisting of 5 gradings, the highest (5) being the most positive.

1. Thus far how have you perceived the treatment to be?
   | Very good treatment | Not good at all |
   | 5 | 1 |

2. How severe would you rate your acne?
   | Mild | Very severe |
   | 5 | 1 |

3. Has your acne changed at all?
   | Very much | Not at all |
   | 5 | 1 |

   3.1 If your acne has changed, how has it changed?
   | Getting better | Getting worse |
   | 5 | 1 |

4. Has the surface texture of your skin changed?
   | Getting smoother | Becoming rougher |
   | 5 | 1 |

5. Are you experiencing any pain or tenderness with your acne?
   | No pain at all | Very much pain |
   | 5 | 1 |

6. Has your acne been bleeding?
   | No bleeding at all | Very much bleeding |
   | 5 | 1 |

7. How would you rate your acne now as compared with the period before the treatment started?
   | Very much better | No change at all |
   | 5 | 1 |

8. How has your attitude concerning your condition changed since taking the Homoeopathic medicine?
   | Very much better (+ve) | Deteriorated (-ve) |
   | 5 | 1 |

9. How do you feel people perceive your condition to be?
   | Mild | Severe |
   | 5 | 1 |
APPENDIX C2
Perception Questionnaire
(McDavid, 1994)
(Zulu)
Inhlolovo Ngokulidelekile

(McDavid 1994)

Inhlolovo ebuvekeza imiphumela iziguli eziyilindele ngokubamba ighaza kulesisisiyi

Qaphela: Loluhlha lwemibuzo luqokekelwe umcwaningi

Usuku:

Imininingwane
Igama : .............................................................
Iminyaka : ..........................................................
Usuku Lokuzalwa : ..............................................
Ubulili : .............................................................

Isingeniso
Inhlolo yalolocwancingo ukuhlola ukuthi kuyimpumelelo engakanani ukulwa nezinduna uma kusetshenziswa isu i homoeopathic treatment.
Kucacile ukuthi kunesidingo esikhulu sokuthola ikhambi lokwelapha isifo sezinduna, elingenabungozi.
Ukuzibhandakava kwakho ngokweqiniso kuzosiza ekwidiono nge homoeopathic treatment, ekwenye yezindlela ephepile futhi esebenzayo.

Lemibuzo izosisiza ekuboneni ukuthi kubhekho yini ushintsho emumva kokudla imithi ethize. Ngakhoke okushiwo yisiquli ngokusebenza kwemithi kubaluleke kakhulu.

Imigomo
Uyalelwaba uphendule lemibuzo ngokweqiniso impendulo yombuzo ngamunye ihlukaniswe amazinga amahlanu. Wena faka uphalwe phezu kwenonbolo elhaza kagono indlela oziszwa ngayo.
Isibonelo uma umbuzo ubuza uizwa kanjani ngezinsuku ezinemvula, ngabe uvazithanda na?
Kwimpendulo yakho uzofaka uphawu kwinombolo esedelese kakhulu nendlela oziszwa ngayo kanje:

\[
\text{Ngiyazizonda} \quad \frac{-}{-} \quad \frac{-}{-} \quad \frac{X}{-} \quad \text{Ngiyazithanda}
\]

Qaphela – ke uma ufaka uphalwe kwinombolo enkulule njenjesibonelwisa kusho ukuthi uyavumelana kakhulu nalesosimo.
Uvacelwa ukuthi uphendule lemibuzo elandelayo.
1. Kuze kube nanje uvizwa unjani ngokudla imithi?
   Kungeke kukusize
   Kuzokusiza
   1 2 3 4 5

2. Ucabanga ukuthi izinga lezinduna zakho libi kahle?
   Libi kakhulu
   Liphakathi nendawo
   1 2 3 4 5

3. Kugabe izinga lezinduna lishinthile na?
   Cha
   Yebo kakhulu
   1 2 3 4 5

3.1 Uma uthi izinga lezinduna lishinthile, ngaba lishinthile kanjani?
   Zibezinigi
   Ziyaphila
   1 2 3 4 5

4. Isikhumba sakho ngabe sishintshile na?
   Saba bulhadlahadla
   Saba bushelelezi
   1 2 3 4 5

5. Ngabe izinduna zakho zibuhlungu noma zintofono na?
   Zibuhlungu
   Azibuhlungu
   1 2 3 4 5

6. Ngabe izinduna zakho ziyophi na?
   Zophi kakulu
   Azophi kwakona
   1 2 3 4 5

7. Uma uqathisiza izinga lezinduna zakho nanje nangaphambi kokuba udle imithi unjani?
   Aziishintshile
   Zingcono kakhulu
   1 2 3 4 5

8. Ishintshe kanjani indlela ozizwa ngayo ngesimo okusona emva kokuqala ukudla imithi?
   Aselapheki siyaqubeka
   Siyalapheka
   1 2 3 4 5

9. Abantu bathi isimo sakho sesinjani?
   Sibi
   Sibanglono
   1 2 3 4 5
APPENDIX D

Grading Technique
(Burke and Cunliffe, 1984: 83 – 90)
Grading Technique

(1) A 0 - 10 visual – tactile grading system.

(2) Patient self assessment with the following categories – worse, no change, fair, good and excellent graded on a scale from 1 to 5 where 1 = worse, 2 = no change, 3 = fair, 4 = good, 5 = excellent.

(3) Severity of acne according to 0 – 4 scale with ½ points ratings where 0 = no acne, 1 = minimal acne, 2 = mild acne, 3 = moderate acne and 4 = severe acne
APPENDIX E

Leeds Technique for Assessing Acne –
The Counting Technique
Leeds Technique for assessing acne – The Counting Technique

Lesions are divided into inflammatory and non-inflammatory.

(a) Non-inflamed lesions are open (blackheads) and closed (whiteheads) comedones.
   Any intermediate lesions are counted according to their major component.
   Prominent follicles, etc. are excluded.

(b) Inflammatory lesions are:
   1) Superficial – papules, pustules; vary in size from 0.1 – 0.5 cm in diameter.
   2) Deep – nodules, cysts, and deep pustules which are 0.5 cm or larger in diameter.
   3) Macules – represent the resolving phase of either superficial or deep lesions and are either very large or very small.

A vernier calliper will be used to measure the size of the lesions in order to classify them (Cunliffe et al. 1984:83).

To avoid errors in lesion counting:

1) Patient must be comfortably seated for the observer to move around easily and count each area.

2) Good background lighting is needed.

3) Count the forehead, cheeks, midline and chin separately, then combine the counts, thus counting the whole face.

4) Palpation is necessary to distinguish macules from nodules which are palpable but hardly visible.

5) Stretching of the skin will increase the visibility of the white- and blackheads (Barklie, 1999: 26 – 27).
APPENDIX F

Standard Diagnostic Case History
(Chatterjee, 1993 : 10 – 14)
Standard Diagnostic Case History

Date of History: .................................................................

General Information:
Name: ..............................................................................
Age: ...................................................................................
Sex: .................................................................................
Address: ...........................................................................

Place of birth: ......................................................................
Marital status: .....................................................................
Occupation: .........................................................................

Source of referral: ..............................................................
Source of history: ...............................................................
5. What vaccinations / immunizations have you had previously or recently? (Tetanus, Pertussis, Diphtheria, Polio, Measles, Rubella, Mumps, Influenza, Hepatitis B, Haemophilus influenza type B)

6. Are you taking any medication? (Know: duration, dosage) (Pill, Vitamins, Minerals, etc.)

7. Do you smoke? (Onset, amount/day, Type)

8. Do you drink any form of alcohol? (Onset, amount/day, Type)

**Family History**

1. Are both your parents alive?
   1.1) Did / Do any of them have any medical problems?
   1.2) If any of them died, why? and When?

2. Do you have any siblings and are they still alive?
   2.1) If not, how did they die and when?
   2.2) Did your siblings have any medical problems?

3. Do you have any children and are they still alive?
   3.1) Do any of your children have any medical problems?

Possible family medical problems: Diabetes, Tuberculosis, Heart disease, Stroke, Kidney disease, Cancer, Arthritis, Anaemia, Headaches, Epilepsy, Mental illness.

**Social History**

1. Hobbies, exercise and leisure activities?
2. Any travelling (i.e. out of Durban)?
3. Any recent shocks or griefs?
4. Sleep patterns?
5. Diet?
Psychosocial History:
1. Home situation and significant others?
2. Daily life?
3. Important experiences?
4. Religious beliefs?
5. The patient's outlook?

SYSTEMS REVIEW:

1. GENERAL:
   (Usual weight, recent weight change, weakness, fatigue, fever)

2. SKIN:
   (Rashes, lumps, itching, dryness, colour change, hair and nail change)

3. HEAD:
   (Headaches, head injuries)

4. EYES:
   (Vision, glasses, contacts, pain, redness, double vision)

5. EARS:
   (Hearing problems, vertigo, tinnitus, earache, infection, discharge)

6. NOSE AND SINUSES:
   (Hayfever, nose bleeds, sinus troubles, frequency of colds)

7. MOUTH AND THROAT:
   (Frequency of sore throat, bleeding gums, sore tongue)

8. NECK:
   (Swollen glands, pain or stiffness in the neck)

9. RESPIRATORY SYSTEM:
   (Cough, sputum, haemoptysis, wheezing, asthma, bronchitis, emphysema, pneumonia, tuberculosis, pleurisy)

10. CARDIAC SYSTEM:
    (Heart trouble, high blood pressure, rheumatic fever, heart murmurs, chest pain or discomfort, palpitations, dyspnoea, orthopnoea, paroxysmal nocturnal dyspnoea, oedema, any heart tests)

11. GASTROINTESTINAL SYSTEM:
    (Any trouble swallowing, heartburn, anorexia, nausea, vomiting, regurgitation, vomiting of blood, indigestion, haemorrhoids, abdominal
pain, constipation, diarrhoea, food intolerance, excessive belching or passing of gas, jaundice, liver or gall bladder problem, hepatitis)

12. URINARY SYSTEM:
(Polyuria, nocturia, burning or pain on micturition, reduced force of stream, hesitancy, incontinence, urinary infection, stones)

13. GENITOREPRODUCTIVE SYSTEM:
(Discharge from or sores on the penis, hernias, testicular pain or masses, history of venereal disease)

14. PERIPHERAL VASCULAR SYSTEM:
(Intermittent claudication, leg cramps, varicose veins, thrombophlebitis)

15. MUSCULOSKELETAL SYSTEM:
(Muscular and joint pain, stiffness, arthritis, gout, backache)

16. NEUROLOGICAL SYSTEM:
(Fainting, blackouts, seizures, weakness, paralysis, numbness, tingling, tremor, or other involuntary movements)

17. HAEMATOLOGICAL SYSTEM:
(Anaemia, easy bruising or bleeding, past transfusions and possible reactions)

18. ENDOCRINE SYSTEM:
(Thyroid trouble, heat and cold intolerance, excessive sweating, diabetes, polyuria, excessive thirst or hunger)

19. PSYCHIATRIC:
(Nervousness, tension, depression, memory loss)
ON EXAMINATION:

VITAL SIGNS:
- Blood Pressure
- Pulse
- Respiration
- Temperature
- Weight and height

(Observe the state of health, stature, habits and sexual development, posture, motor activity, gait, dress, grooming and personal hygiene, odours of the body or breath, facial expression, reaction to persons and things in the environment.
Listen to the patient's speech, note state of awareness and level of consciousness)

GENERAL EXAMINATION:

1. POSITION THE PATIENT ON HIS BACK AT 45 DEGREES.

2. HANDS:
   (Note: Muscle condition, colour, nails [clubbing, spooned, splinter haemorrhages], sweat, temperature, circulation, any nodules, any lesions, joint pain)

3. FOREARM – ARM – SHOULDER:
   (Hair distribution, colour, temperature, muscle condition, skin lesions, any pain)

4. NECK:
   (Neck stiffness, thyroid gland, tracheal deviation, jugular venous pressure, glands, any pain)

5. FACE:
   (Twitches of facial muscles, drooping swelling lesions, inflammation, skin and hair distribution, colour, any pain)

6. EYES:
   (Ophthalmoscopic examination, visual acuity, pupil reaction to light, extraocular muscle movement, any pain)

7. NOSE:
   (Anosmia, epistaxis, runny nose, hayfever, lesions, any pain)
8. SINUSES:
   (Pain, headache, post-nasal drip)

9. LIPS:
   (Colour, lesions, pain)

10. MOUTH:
    (Bad breath, taste, lesions, pain)

11. TEETH:
    (Condition, pain, colour, caries, types of fillings)

12. GUMS:
    (Bleeding, colour)

13. TONGUE:
    (Indentations, colour, mapped, pain, lesions, taste)

14. THROAT:
    (Inflammation, pain, tonsils, deposits, voice)

15. EARS:
    (Hearing, lesions, pain, tympanic membrane, wax colour)

16. THORAX AND LUNGS:
    (Skin lesions, hair distribution, chest wall movement and shape,
     respiratory rate, depth, rhythm and effort, tender areas, tactile fremitus,
     percussion, auscultation)

17. HEART:
    (Rate, rhythm, amplitude, contour, bruits, thrills)

18. ABDOMEN:
    (Pain, tender areas, skin, spider naevi, distension, borborygmi, liver,
     kidneys, spleen, rebound tenderness, muscle guarding)

19. BACK:
    (Skin lesions, pain, contour of spine, moles, kidney pain)

20. PELVIS AND PERINEUM:
    (Only if indicated, glands, sexual development, lesions, skin, pain)
21. LOWER LIMB:
(Pain, skin, hair distribution, oedema, varicose veins, temperature, colour/filling, sensory)

22. FEET:
(Nails, temperature, colour, skin, pain, lesions, warts, athletes foot, odour)

ADDITIONAL HOMOEOPATHIC QUESTIONS:

MIND:
1. Fears
2. Sleep: (Position, Type, Dreams, On waking)
3. Confusion/Cloudiness
4. Excitement
5. Anxiety
6. Speech: (Hurried, Nasal, Lost/Difficult, Slow/Monotonous)
7. Imagination
8. Memory

EMOTIONS:
1. Depression
2. Melancholia
3. Mood

PHYSICAL:
1. Diet: (Cravings, aversions, add salt, drink in gulps or sips, hot or cold drinks,
   love eggs, etc.)
2. Best time of day
3. Coast or inland
4. Particular
5. Brittle hair
6. Modalities:
   a) Cold / warmth
   b) Movement / rest
   c) Touch
   d) Inside / outside
   e) Riding in a car
   f) Humidity / dryness
   g) Sitting still / changing position
   h) Time of day
      i) Thirsty / Not thirsty
      j) Itchy / not itchy
   k) Seaside / inland
      l) Consolation / no consolation
   m) Morning upon awakening
   n) After meals
   o) Winter / summer
   p) Strong pressure
   q) Dark
   r) Standing still
APPENDIX G1

How to take your Homoeopathic remedies
How to take your Homoeopathic Remedies

1. If you are taking powders – just open one end of the powder and tip it under your tongue, allow it to dissolve and DO NOT TAKE IT WITH WATER.

2. If you are taking pills or granules – DO NOT TOUCH THEM WITH YOUR FINGERS. The granules / pills are dispensed in a glass vial with a plastic lid. Take off the lid and put the desired number of pills / granules in the lid, place the pills / granules directly under the tongue and allow them to dissolve.

3. Take your remedies away from meals at least ½ hour before a meal or one hour after. Avoid eating MINT before or after taking medication.

4. The remedies must be stored away from camphor (e.g. Vicks products), light, heat, and electromagnetic radiation (TV’s, computers, etc.).

5. Try to avoid the intake of coffee during your treatment.

6. Always take the powders in numerical order or otherwise as directed by your student homoeopath.

FOR ANY QUERIES REGARDING YOUR MEDICATION, PLEASE DON’T HESITATE TO CALL RECEPTION ON : 204 2041 OR 204 2513
APPENDIX G2

How to take your Homoeopathic remedies
(Zulu)
Indlela yokuthatha imithi yakho ye homoeopathy

1. Uma uphuza okusampushana – vele uvule icala elilodwa lokusampushana bese ukubeka ngaphansi kolimi, kulinde kuze kuncibilike futhi UNGAKUPHUZI NAMANZI.

2. Uma uphuza amaphilisi nomu okusanhlamvane – UNGAKUTHINTI NGEMINWE YAKHO. Okusanhlamvana namaphilisi kufakwa ebhodleni eliwumtshumana elinesivalosepulasiti. Vula isivalo bese uthela inani elidinge kile lamaphilisi nomu okusanhlamvane esivalweni, beka amaphilisi nomu okusanhlamvane ngaphansi kolimi bese ukulinda kuze kuncibilike.


4. Imithi mayigcinwe kude nezinto ezinjenge Vicks, Camphor, Zambuck, ukukhanya, ukushisa futhi ungayibeki eduze kukamabonakude, iwayilense, ikhompuyutha kanye nokunye.

5. Zama ukugwema ukuphuza ikhofi ngesikhathi uselashwa.


Uma unemibuzo maqondana nemithi yakho, ungangabazi ukushayela kulenombolo : (031) 204 2041 nomu (031) 204 2513
APPENDIX H

Homoeopathic medicines used
<table>
<thead>
<tr>
<th>Remedies used in Simillimum Treatment</th>
<th>No. of patients</th>
<th>Potency prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenicum album</td>
<td>2</td>
<td>30CH/200CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200CH</td>
</tr>
<tr>
<td>Crotallus cascavella</td>
<td>1</td>
<td>200CH</td>
</tr>
<tr>
<td>Kali carbonicum</td>
<td>1</td>
<td>30CH/200CH</td>
</tr>
<tr>
<td>Lachesis muta</td>
<td>1</td>
<td>30CH/200CH</td>
</tr>
<tr>
<td>Mercurius solubilis</td>
<td>1</td>
<td>30CH/200CH</td>
</tr>
<tr>
<td>Natrum muriaticum</td>
<td>1</td>
<td>200CH / 1M</td>
</tr>
<tr>
<td>Nux Vomica</td>
<td>1</td>
<td>30CH/200CH</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>2</td>
<td>30CH/200CH/1M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30CH/200CH</td>
</tr>
<tr>
<td>Pulsatilla</td>
<td>1</td>
<td>200CH</td>
</tr>
<tr>
<td>Silicea terra</td>
<td>2</td>
<td>200CH</td>
</tr>
<tr>
<td>Sulphur</td>
<td>1</td>
<td>200CH/1M</td>
</tr>
<tr>
<td>Thuja</td>
<td>1</td>
<td>200CH</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>15</strong></td>
<td></td>
</tr>
<tr>
<td>Nosodes used in Miasmatic Treatment</td>
<td>No of patients</td>
<td>Potency prescribed</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>----------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Carcinosin</td>
<td>10</td>
<td>2 patients: 30CH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8 patients: 200CH</td>
</tr>
<tr>
<td>Medorrhinum</td>
<td>2</td>
<td>200CH</td>
</tr>
<tr>
<td>Psorinum</td>
<td>2</td>
<td>30CH</td>
</tr>
<tr>
<td>Tuberculinum bovinum</td>
<td>1</td>
<td>200CH</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>15</strong></td>
<td></td>
</tr>
</tbody>
</table>