# A study comparing the effectiveness of a herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea* and *Taraxacum officinale*) as compared to homoeopathic simillimum in the treatment of Acne vulgaris.

**By**

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology : Homoeopathy, in the Faculty of Health Sciences at the Durban Institute of Technology.

I, Nervashnee Govender, do hereby declare that this dissertation represents my own work both in conception and execution.

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# ***Dedication***

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# ABSTRACT

The purpose of this study was to compare the effectiveness of a herbal-complex consisting of (*Arctium lappa, Berberis aquifolium, Echinacea purpurea and Taraxacum officinale*), as compared to homoeopathic simillimum in terms of the clinical manifestations and the patients' perception of response to the treatment.

This study was a double blind, randomised study. Convenience sampling was employed to draw 30 patients, of both sexes, between 18-40 years of age, from the greater Durban area. Only patients, diagnosed by the researcher as suffering from Acne vulgaris, and those who were screened according to the selection criteria (see section 3.4), were accepted into this study. Those suffering from acne fulminans, acne rosacea or conglobate acne were excluded. Upon selection, they were allowed to sign the consent form after reading, understanding and completing the information letter (all in English and Zulu). An independent person, using a simple sampling method, randomly allocated the patients into the respective groups. Of the selected 30 patients, 15 received the herbal-complex (Group 1) and the remaining 15 received the homoeopathic simillimum (Group 2). It was hypothesized that the homoeopathic simillimum would result in a similar or greater response when compared to the herbal-complex.

The treatment protocol consisted of a course of 4 consultations, 3 weeks apart, over a treatment period of 9 weeks. Subjective and objective measurements were taken at each of the 4 consultations, at The Durban Institute of Technology Steve-Biko Campus, Homoeopathic Day Clinic. An extensive case history was performed on each patient at the first consultation, in order to assess their mental, emotional and physical status, following which the patients were seen at regular 3-week intervals, thereafter. The patients' lesions (number and type) were graded and tabulated at the

first and subsequent consultations. At each consultation, the patient completed a perception questionnaire, regarding the response to the treatment administered.

Based on the case history and physical examination, the homoeopathic simillimum was prescribed, according to the Law of Similars, and the herbal-complex was also prescribed on the same prescription, and the independent person allocated and dispensed the appropriate medication according to the randomisation list. Both the herbal-complex and homoeopathic simillimum were dispensed at the Durban Institute of Technology Steve-Biko Campus, Homoeopathic Day Clinic Laboratory, and the base substances were provided by Parceval and Natura (Pty) Ltd laboratories respectively. The herbal complex was administered 10 drops twice daily for the duration of the study and the homoeopathic simillimum was administered, in powder form, once daily over a period of 3 days. The herbal-complex was dispensed in two 50ml amber glass bottles and the simillimum was dispensed as 3 powders at the first and third consultations only.

The effectiveness of the herbal-complex and homoeopathic simillimum was measured firstly, in terms of the patients' perception of the response to the treatment, using a perception questionnaire, in English and Zulu (subjective measure), and secondly the reduction in the tabulation of the total number and type of lesions (i.e. acne severity, inflamed and non-inflamed lesions and total lesion count), using the visual-tactile grading and Leeds Counting Technique respectively, for assessing Acne vulgaris (objective measure).

Upon collection of data, the statistical package SPSS ©, was used to record and analyse the data. Due to the sample size being below 60, non-parametric tests were used. Inter-group comparisons were made using Mann-Whitney U-test. The results showed that there was no statistically significant difference, for the perception

questionnaire, inflamed lesions, non-inflamed lesions and total lesion count, between the two groups, i.e. both showed a similar reduction. The similarity in p values indicates that the perception by the patients to the treatment, and other variables of interest i.e. lesions of both groups were similarly influenced. Intra-group comparisons were made using the Friedman T-test for K-related samples. A Dunn procedure (a multiple comparison test) was then performed for significant findings to determine at which stage significant improvement occurred. Both treatment groups showed a statistically significant improvement, throughout the study from consultation 1 to 4. It was noted that for both groups, for all the variables of interest, the results were statistically insignificant, between consultations 2 and 3.

It can be concluded that the herbal-complex work as effectively as the homoeopathic simillimum, by significantly affecting the clinical appearance of Acne vulgaris in the patients examined and with regard to their perception of response to the treatment.

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# DEFINITION OF TERMS

**Acne vulgaris:** is an inflammatory disease of the pilosebaceous glands characterized by comedones, papules, pustules, inflamed nodules, pustular cysts and deep inflamed purulent sacs (Berkow, 1999:811). A papular eruption, due to inflammation, with accumulation of secretions of the sebaceous or oil producing glands (Yasgur, 1998:3).

**Abscess:** a localised collection of pus buried in tissues, organs or confined spaces, formed by the process of suppuration and disintegration of tissue (Saunders, 1994:5; Yasgur, 1998:1).

**Adrenarche:** augmentation of adrenal cortical secretion, involving especially androgens, a physiologic change that occurs at approximately the age of 8 years in both sexes (Saunders, 1994:31).

**Alkaloid:** any of the various physiologically active nitrogen containing organic bases derived usually from plants eg. nicotine, berberine etc. They are generally better in taste, alkaline, and unite with acids to form salts, and their common names end in –ine (Yasgur, 1998:9).

**Allopathy:** treatment whose action has no direct relationship to, (is other than) the effects of the illness, the symptoms. The effects of the drug or treatment method bear no relationship to the symptoms or other effects of the illness (Swayne, 2000:8). A term applied to that system of therapeutics (mainly orthodox medicine), in which diseases are treated by producing a condition, incompatible with, or antagonistic to the condition to be cured or alleviated (Saunders, 1994:48).

**Alterative:** a medicine, which alters the course of disease, modifying the nutritive processes, while promoting waste, and thus indirectly curing some chronic diseases. An alterative acts to correct disordered metabolism and promote repair (Yasgur, 1998:10).

**Anaesthesia:** loss of ability to feel pain, caused by administration of a drug or by other medical intervention (Saunders, 1994:74).

**Androgen:** any substance that promotes masculinization (Saunders, 1994:71).

**Antibacterial:** destroying or suppressing the growth or reproduction of bacteria, or a substance that destroys bacteria or suppresses their growth or reproduction (Saunders, 1994:92).

**Anti-inflammatory:** counteracting or suppressing inflammation or an agent that counteracts or suppressed the inflammatory processes (Saunders, 1994:97).

**Antimicrobial:** killing microorganisms, or suppressing their multiplication or growth; or an agent that kills microorganisms or suppresses their multiplication or growth (Saunders, 1994:98).

**Antiseptic:** tending to inhibit the growth and or reproduction of microorganisms, especially pathogenic ones, also an agent used to inhibit that growth (Yasgur, 1998:18).

**Atrophy:** a shrivelling or wasting of the tissues of a part or of the entire body (Yasgur, 1998:23)

**Bactericidal:** destructive to bacteria (Saunders, 1994:173).

**Bacteriostatic:** inhibiting the growth or multiplication of bacteria or an agent that inhibits the growth or multiplication of bacteria (Saunders, 1994:173).

**Comedo:** (comedones) a blackhead, a collection of sebaceous (oily) material and dead cells retained in the hair follicle and excretory duct of the sebaceous gland, the surface covered with a dark crust. It is the primary lesion of acne vulgaris (Yasgur, 1998:54). A non-inflammatory lesion of acne vulgaris, consisting of a plug of keratin and sebum within the dilated orifice of a hair follicle containing the bacteria *Propionibacterium acnes* (Saunders, 1994:358).

**Comedogenic (genesis):** a process of producing comedones (Saunders, 1994:358).

**Cyst:** an abnormal sac containing gas, fluid or semisolid material (Yasgur, 1998:62).

**Dermabrasion:** planning of the skin done by mechanical means, as by fine sandpaper or wire brushes (Saunders, 1994:446).

**Follicular hyperkeratosis:** of, or pertaining to a follicle/s, with hypertrophy of the corneous layer of the skin or any disease characterized by it (Saunders, 1994:647,795).

**Hyperpigmentation:** abnormally increased pigmentation (Saunders, 1994:798).

**Hypertrophy:** the enlargement or overgrowth of an organ or part due to an increase insize of its constituent cells (Saunders, 1994:802).

**Keloid:** a sharply elevated irregularly-shaped, progressively enlarging scar due to the formation of excessive amounts of collagen in the corium during connective tissue repair (Saunders, 1994:877).

**Keratolytic:** pertaining to, characterized by, or producing keratolysis; or an agent that promotes keratolysis (Saunders, 1994:879).

**Law of Similars:** (Similia Similibus Curantur) the homoeopathic formula expressing the Law of Similars, or the doctrine that any drug which is capable of producing morbid symptoms in the healthy, will remove similar symptoms occurring as an expression of disease (Yasgur, 1998:317).

**Macule:** (a macula) a small discoloured patch or spot on the skin, not elevated above the general surface, 1 cm or less in diameter (Yasgur, 1998:141).

**Microorganism:** a microscopic organism, those of medical interest includes bacteria, viruses, fungi and protozoa (Saunders, 1994:1039).

**Nodule:** a lump deeply set in the skin less than or equal to 1cm in diameter (Yasgur, 1998:164).

**Papule:** a small, circumscribed solid elevation of the skin, varying in size from a pinpoint to a split pea (Yasgur, 1998:176).

**Phytotherapy:** is an empirical system of medicine that uses plant remedies only destined to support the healing life-force, in disease treatment (Gaier, 1991:423).

**Pilosebaceous:** pertaining to the hair follicles and sebaceous glands (Saunders, 1994:1294).

**Polypharmacy:** multiple drug therapy, or the practice of preparing or prescribing medicines containing more than one medicinal substance, or of administering several different medicines at the same time or concurrently (Swayne, 2000:164).

**Pustule:** a small, circumscribed elevation on the skin, containing pus and less than 1cm in diameter. A pus-filled vesicle, bulla or tiny abscess in the skin, that can vary in colour (white, yellow etc.), depending somewhat on the infecting organism eg. acne pimples and boils (Yasgur, 1998:206).

**Pyogenic granuloma:** pus-producing, small nodular, delimited aggregation of mononuclear inflammatory cells (Saunders, 1994:716,1394).

**Rebound:** a reversed response on the withdrawal of a stimulus (Saunders, 1994:1430).

**Sebaceous glands:** glands, which secrete sebum, a whitish waxy fat (Yasgur, 1998:229).

**Simillimum:** the drug picture most like the clinical picture in the patient, the most accurate match between clinical characteristics of the patient and the Materia Medica; the basis of accurate and effective prescribing in homoeopathy (Swayne, 2000, 194). It is the remedy that most closely corresponds to the totality of the symptoms; 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).

**Stratum corneum (epidermidis):** horny layer of the epidermis; the outermost layer of the epidermis, consisting of cells that are dead and desquamating (Saunders, 1994:1586).

**Suppression:** the palliative treatment of a symptom or condition, so that it is relieved but is not resolved. It may remain dormant or become manifest in some other, possibly more serious or deep-seated disorder (Swayne, 2000:202-3).

**Totality of Symptoms:** the complete clinical picture of the patient during the illness; comprises all the mental symptoms, general symptoms and local (particular) symptoms and signs, test findings if appropriate, the complete symptom pattern from which the simillimum must be found (Swayne, 2000:215-6).

# CHAPTER ONE

## 1.1 INTRODUCTION

The skin functions to protect the body from injury, light, chemicals, extreme temperature and from invasion of micro-organisms and is responsible for the maintenance of a stable and harmonious internal environment and has the closest connection between the inner being and the outside world. The skin will often be an outer reflection of internal problems and must be treated as such. Orthodox medicine classes the different skin disease according to histological changes occurring in the skin tissue. This approach ignores to a large extent the idea that skin problems can be manifestations of internal problems and should be treated as such and not as local phenomena. Most of the chronic skin conditions that affect humanity are the result of internal processes and causes. As our skin is our interface with the world, it is often the site to manifest disharmony in one's life (Hoffman, 1997:78-79).

Skin eruptions are nature's way of quieting an internal disease, which threatens vital organs, by developing an external malady. The homoeopathic remedy brings out the reappearance of skin eruptions, and many forms of suppression. It is important to allow internal disorders to be discharged through the skin, rather than suppressing them with treatments directed at the skin. In addition to purely mechanical protection, the skin also seems to have a specific biological function, designed to protect the internal organs from disease agents. By virtue of its chemical composition, the skin may possess the function of removing toxic substances introduced into the body (Ghegas, 1994:A139; Watson, 1991:91).

The skin consists of a superficial layer, the epidermis (stratum corneum) and a deep connective tissue layer, the dermis. The fascia, lying deep to the skin consists of the superficial and deep fascia. The superficial fascia, extending between the dermis and underlying deep fascia, contains fat, sweat glands, blood and lymphatic vessels and nerves, whereas the deep fascia is thin and is loosely attached to the superficial fascia and adherent to the underlying muscles, hence the periosteum of bone. The above structures are essential to hold the other structures or parts together and protect against infection by providing a barrier (Moore, 1992:33).

The normal pilosebaceous unit is made up of sebaceous glands, a rudimentary hair, and a wide piliary duct lined with stratified squamous epithelial cells (Cooley *et al.*, 1998:38). The pilosebaceous unit is composed of a hair follicle, the sebaceous glands and the products of these structures: hair and sebum. The sebaceous glands and follicular epithelia are responsive to circulating androgens and direct androgen stimulation with resultant sebaceous gland enlargement (Lassus, 1996:341).

According to McBride & Simpson (2000:8), 95% and 83% of 16 year-old boys and girls respectively are affected, and the increasing numbers of patients in the over-20 age group are being referred for specialist opinion. Significant lesions are also present in 1% of men and 5% of women at the age of 40 years. The prevalence of acne is similar to those 20 years ago; however it is milder in teenagers and is involving an older population who has high expectations of treatment. Brown & Shalita (1998:1871), agree that acne is a disease of adolescence (between 15-19 years). The incidence peaks at 18 years and improving around 20 years. Some have acne between 24-29 years, sometimes continuing into the 3$^{rd}$ and 4$^{th}$ decades. While acne can't be regarded as life

threatening, affected individuals experience diminished self-esteem, depression, frustration, social withdrawal, embarrassment and physical scarring.

Acne, is the common condition of spots with recurrent often itchy, round and red thickened areas of the skin, which may become infected and chronic. It is common on the face, but may also occur on the chest and back or in any greasy areas of the skin. The condition is harmless and although the cause is still not clear, it is thought to be related to hormonal changes, or to a diet that is too high in sugar. It is a distressing condition, as people are preoccupied with their appearance, especially their hair and skin. Any form of spot or blemish may become a source of teasing or shame, embarrassment or awkwardness (Smith, 1994:6). Acne vulgaris is an inflammatory condition of the hair follicle and its' sebaceous gland is characterized by comedones, erythematous papules, pustules, nodules and cysts (Kaminer & Gilchrest, 1995:S7). Some dermatologists consider acne to be one disease, whereas it constitutes a spectrum, in its severity, in the type of lesions present and the site involved (Cunliffe, 1989:6).

There are many microorganisms involved in the pathogenesis i.e. *Propionibacterium acnes*, *Staphylococcus epidermidis* and *Malassezia furfur* but *Propionibacterium acnes* (*P. acnes)* is the most important one, thus many therapies have been designed to reduce the amount and function of this organism (Sommer *et al.*, 1997:211).

There are many forms of orthodox treatment for Acne vulgaris, which often results in many side effects and resistance to therapy, but no cure is offered thus there is an obvious need for alternative forms of treatment to be investigated i.e. Homoeopathy

(Barklie, 1999:4). With Homoeopathic treatment, the patient is assessed at all levels i.e. physical, mental and emotional, thus recognising the patients individuality, in the hope of a more successful management of acne (Chatterjee,1993:1). Herbal remedies have been used for many years in the treatment of Acne vulgaris but they have only recently been clinically tested (Barklie,1999:2) and can be an effective adjunct to homoeopathic simillimum treatment.

One needs to bear in mind the patients health and allopathic medicines' side-effects (which are numerous and troublesome and the result of many failures in treatment) since these need to be treated first before treating acne itself (McDavid, 1994:32). Master (1993:354), states that acne vulgaris is one of the problems for which patients seek alternative treatment and often consult with the homoeopath.

Several studies have been conducted on acne vulgaris. McDavid (1994) investigated the effectiveness of homoeopathic simillimum in the treatment of acne vulgaris and had found that there was a statistically significant improvement in the clinical manifestations of acne vulgaris ($p = 0.006$). The frequently indicated remedies were *Sulphur iodatum* and *Kalium bromatum*.

Lee (1997) investigated the role of a homoeopathic complex (*Silicea 30CH, Selenium 9CH, Hepar sulphuris 30CH, Kalium bromatum 9CH, Arctium lappa 3CH and Pulsatilla 30CH*) in the treatment of acne vulgaris. The results showed no significant improvement over the period of 5 consultations within and between both groups. The effects of *Kalium bromatum*, used by McDavid (1994), were further elaborated upon in the above research.

In another clinical trial, van Niekerk (1999) investigated the effectiveness of miasmatic treatment as compared to homoeopathic simillimum in terms of the objective clinical findings in patients with acne vulgaris. There was no statistically significant difference between the 2 treatments but both were significant in reducing the clinical manifestations. The above research was an extension of McDavid's (1994) research and further elaborated on the effect and importance of homoeopathic simillimum.

Barklie (1999) investigated the effectiveness of a homoeopathic complex (*Silica terra 30CH, Natrum muriaticum 15CH, Sulphur iodatum 15CH, Kalium bromatum 9CH, & Selenium 9CH*) as compared to a herbal complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) in the treatment of acne vulgaris in terms of its clinical manifestations. It was found that there was no significant difference between the herbal and homoeopathic group hence both were effective. In the homoeopathic complex used, the 2 commonly used remedies in McDavid's research (1994) was used and elaborated on and the knowledge of these remedies was further investigated. In the herbal-complex the remedy *Arctium lappa* was used by Lee (1997), thus further being an extension of the previous 3 studies.

Although this herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) has been used for acne treatment prior to this, it has not been compared to homoeopathic simillimum before, and Barklie (1999) recommends that this complex be compared to homoeopathic simillimum for acne vulgaris treatment.

The above treatments have all been useful and successful in the treatment of Acne vulgaris. This research incorporates the findings of the above 4 trials, mostly

complementing Barklie's research (1999), as the same herbal-complex was used, in order to further investigate its role in the treatment of Acne vulgaris. This study also further investigated and extended the role of homoeopathic simillimum as investigated by McDavid (1994) and van Niekerk (1999).

A concurrent study on Acne vulgaris was done by Sewsunker (2003), at the Durban Institute of Technology- Steve Biko Campus Homoeopathic Day Clinic, which compared the effect of homoeopathic simillimum to miasmatic treatment in the treatment of Acne vulgaris. Miasmatic treatment in homoeopathy is based on the assumption that there exists in virtually everyone an inherited or acquired energy blockage or disturbance producing a predisposition towards a particular and recognizable pattern of illness (Watson, 1991:41). In patients with a chronic disease like acne vulgaris, it would mean that there is an inherited or acquired tendency to develop this disease and this predisposition must be treated in order to cure the patient. The prescription is either nosodes made from disease products or miasmatic remedies. Sewsunker's study will be an extension of and further reinstates van Niekerk's research but, that trial will further use the data from this research to ascertain and compare which treatment is the most effective in Acne vulgaris treatment i.e. homoeopathic simillimum, herbal-complex or miasmatic treatment.

A search of the indexes of Medline (1993-2002) and British Homoeopathic Journal (1982-2002), LINKS (1987-2002) revealed no comparison being done on homoeopathic simillimum and a herbal complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea* and *Taraxacum officinale)* in the treatment of acne vulgaris thus stressing the need to compare the effectiveness of a herbal-complex (*Arctium lappa, Berberis*

*aquifolium, Echinacea purpurea* and *Taraxacum officinale)* to homoeopathic simillimum. This study was aimed at acne vulgaris specifically, between the ages of 18 and 40, as a chronic condition and other types of acne were excluded.

## 1.2 THE TREATMENT OF THE SUB-PROBLEMS

### 1.2.1 OBJECTIVES / PROBLEM STATEMENT

The purpose of this double-blind, randomized clinical trial was to compare the effectiveness of a herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) as compared to homeopathic simillimum, by measuring the reduction in the number of acne lesions on the patients' faces and in terms of the patient's perception of response to treatment, in the treatment of Acne vulgaris.

#### 1.2.1.1 Subproblem 1:

To investigate the effectiveness of a herbal-complex on the signs and symptoms of Acne vulgaris in terms of subjective and objective clinical findings, to establish the value of a herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) in the treatment of Acne vulgaris.

#### 1.2.1.2 Subproblem 2:

To investigate the effectiveness of homoeopathic simillimum on the signs and symptoms of Acne vulgaris in terms of subjective and objective clinical findings, to establish the value of homoeopathic simillimum in the treatment of Acne vulgaris.

# CHAPTER TWO

## REVIEW OF THE RELATED LITERATURE

### 2.1 DEFINITION & INCIDENCE

Acne is a disorder of the sebaceous follicle. The word is derived from the Greek word *acme*, which means “prime of life” (Cooley *et al*., 1998:38). Acne vulgaris is an inflammatory disease of the pilosebaceous glands characterized by comedones, papules, pustules, inflamed nodules, pustular cysts and deep inflamed purulent sacs (Berkow, 1999:811).

According to Lehmann *et al.* (2002:231), an estimated 45 million people in the United States have acne vulgaris. According to Heyl & Swart (1990:149), in Southern Africa, acne is usually noted to be a problem of the adolescent, with the onset shortly before puberty but usually begins after puberty and is at its worst between the ages of 14 and 18 years. However it has been noticed, that acne is not only a problem of the teenager but is also seen in young people in their early twenties and sometimes begins at a later age. Clinical evidence in South Africa, suggests that in men the condition tends to be worse and clears by the age of 25 and only a small percentage will suffer into middle age, and the onset after 25 is rare. In women there is a large percentage with active acne between the age group 24-29, with many developing acne after 34 years of age and some after 40 years of age, as menopause approaches (Presbury, 1993:2).

It is estimated that facial acne affects between 67% and 100% of teenagers and remains a health problem for many into early adulthood (Martin *et al.*, 2001:380). According to Fitzpatrick & Aeling (2001:146), 100% of boys and 90% of girls have some acne lesions during puberty but acne can affect any age group including neonates.

Nearly 85% of persons aged between 12 & 25 have some acne lesions. Tan *et al.* (2000:439), in accordance agrees that 91% of male and 79% of female adolescents, and 3% of male and 12% of female adults. The success of acne therapy, both prescribed and over-the-counter, makes study of the incidence of acne and its natural evolution impossible. The peak incidence of acne is 14-17 years in girls with 40% of all females affected and 5% of women continue to have acne up to the age of 40 however there's no figures for the percentage of women who suffer from acne in their perimenopausal and menopausal years (Callan, 1997:23).

Onset is often at puberty, with boys more frequently affected than girls. Some studies suggest that the prevalence of acne vulgaris in teenage boys approaches 100% by age 16 years. Acne may occur before puberty and more commonly in females. It has been reported that 3% of female patients have clinical acne before the onset of other obvious features of puberty (Tan *et al.*, 2000:439). Some girls experience their first acne vulgaris lesions more than 1 year before menarche, at the time of increased adrenal gland activity, referred to as adrenarche. After peaking in the teenage years, the prevalence of the disease decreases. In adults 25 to 34 years of age, approximately 8% have acne, whereas it occurs in approximately 3% of adults 35 to 44 years old (Kaminer & Gilchrest, 1995:S8). The shift in the incidence of acne away from schoolchildren to an older age group has produced a much more demanding and articulate group of patients with high expectations for improvement (Healy & Simpson, 1994:831). According to Callan (1997:22), that while the clinical appearance of acne and the severity is the same in both sexes, 70% of females with acne experience worsening during the premenstrual week. Exacerbations may also be seen at times of hormonal change i.e. pregnancy and

lactation. Comedonal acne has a peak incidence at 12 years, papular acne at 16 years, pustular acne and nodular acne between 16 and 20 years (Cunliffe, 1989:3).

## 2.2 AETIOLOGY

The aetiology is complex and includes a combination of hormonal, bacteriologic and genetic influences. According to Tan *et al.* (2000:440-2), the tendency to severe acne may be inherited and to a lesser extent, diet, poor skin hygiene and infection may be implicated, with stress, anxiety, dirt, heat, humidity, cosmetics, exercise, sweating, hormones and menses being aggravating factors.

### 2.2.1 Androgens

Acne is usually associated with a high rate of sebum secretion. Androgens are known stimulants of sebum secretion and oestrogen reduces sebum excretion. This is most obvious during puberty when profound body changes are inaugurated by various hormonal triggers. A sudden onset of severe acne associated with hirsuitism and/or menstrual abnormalities may be indicative of an endocrine disorder in female patients (Stawiski, 1992:1006). According to Douglass (1995:352), castrated men and oophorectomized women do not develop acne and the importance of androgenic factors in women is underscored by the regular presence of rather severe acne in patients with polycystic ovarian disease and in those with sterol hydroxylase defiencies. Woman with moderate to severe acne, hirsuitism, and irregular menses should be evaluated for polycystic ovarian syndrome (PCOS). Severe disease is more prevalent in males than females (Kaminer & Gilchrest, 1995:S8). According to Guttman (2000:S5), polycystic ovarian syndrome (PCOS) is a hyperandrogenic state with symptoms like acne,

oligomenorrhea or amenorrhea, anovulation, infertility, and hirsuitism and it could very often be misdiagnosed for acne vulgaris.

Approximately 70% of women frequently experience a deterioration or flare of their acne 2 to 7 days before the onset of menses, the lesions remaining more prominent for the next 7-10 days, with a gradual improvement at the beginning of the next menstrual cycle. Conversely, acne vulgaris may improve during pregnancy, but exacerbations can also develop (Kaminer & Gilchrest, 1995:S8). According to Wurward (2001:60,75), menstruation predisposes the skin to acne because of the abnormal hormonal balance i.e. excess then decreases in the production of folliculin, and an increase of androgens. Menstruation is accompanied by a hypersecretion of the sebaceous glands, which is why women are more susceptible to oiliness and breakouts.

According to Ramsay *et al.* (1995:308), androgens like testosterone, 11-deoxycortisol and androstenedione are increased in men with acne. Sources of androgens are adrenals, extra glandular sites, testes (males), and ovaries (females). The hyperactive sebaceous glands could be as a result of excessive androgen production. In men, acne vulgaris seems to be related to a disordered androgen metabolism also.

### 2.2.2 Mechanical factors

Mechanical factors, such as rubbing, friction pressure, and stretching of the skin, can trigger acne. Among the more common mechanical causes are football helmets, surgical tape, shirt, collars, and wrestling (Stawiski, 1992:1006). Friction and trauma (i.e. from helmets, chin straps and headbands) may rupture preexisting microcomedones and elicit inflammatory acne (Isselbacher *et al.*, 1996:278). Cunliffe (1989:8), states

acne is more common and severe in industrial and mining areas than in the countryside. Increased hydration of the stratum corneum can precipitate acne, which explains why in subjects in hot and humid environments i.e. kitchens, laundries etc. have severe acne.

### 2.2.3 Medication and cosmetics

Medications can also precipitate the onset of acne. Chronic oral corticosteroids used for treatment for other conditions, (e.g. systemic lupus erythematosus) can trigger superficial pustules over the face, chest and back. Oral contraceptives are usually helpful in acne treatment, due to oestrogen content, but in some women, oral contraceptives can exacerbate the condition. Other drugs known to aggravate or precipitate acne are bromides, iodides, phenobarbital, phenytoin and lithium. Industrial workers may be exposed to chlorinated hydrocarbons, which are acnegenic (Stawiski, 1992:1006). Glucocorticoids, applied topically or administered systemically, may elicit acne (Isselbacher *et al.*, 1996:278). According to Van der Pijl *et al.* (1996:622), acne is common after organ transplantation and steroids are usually blamed, but recently cyclosporin has been associated with severe acne. According to Wurward (2001:60), birth control pills affects the skin by causing hyperpigmentation and changes the amount of acne breakouts, which is especially interesting when someone who has never experienced acne as a teenager, sees frequent breakouts after discontinuing an oestrogen or androgene pill. Steroids like cortisone can cause a certain type of ‘acne’, which is in fact due to inflammation of the follicles. Bromides and diodides can cause acne breakouts and barbiturates and high doses of vitamin B12 can cause acne-type lesions (Isselbacher *et al.*, 1996:278).

Topical agents in cosmetics or hair preparations such as lanolin and oleic acid, and

chronic topical exposure to certain industrial compounds that contain insoluble cutting oils (impure paraffin mixtures), halogenated hydrocarbons, and coal tar and its derivatives may predispose to comedone formation (Isselbacher *et al.*, 1996:278). Acne in women between 20 and 40 is frequently caused by comedo-producing oil-based cosmetics and moisturizers (Kaminer & Gilchrest, 1995:S8).

As many as 15% of patients with acne vulgaris experience a flare after sweating, with ductal hydration postulated as a responsible factor (Kaminer & Gilchrest, 1995:S8). Hot, humid conditions that promote sweating appear to worsen acne, by increasing hydration around the blocked sebaceous ducts (Callan, 1997:23). Acne may be induced or exacerbated by drugs, occupational contactants, friction, cosmetics, premenstrual flare and sweating (Cotran *et al.,* 1999:1206).

### 2.2.4 Diet

The dietary cause is related to the state of the body's ability to metabolise carbohydrates and fats. If there is a metabolic problem or a preponderance of such food in the diet, acne may be aggravated (Douglass, 1995:352). According to Cunliffe (1989:6), in the 1970s patients were advised to avoid pork fat, chocolate, nuts etc. with chocolate being the most aggravating. It has been later found that large amounts of chocolate ingested, doesn't exacerbate acne. Iodides and fluorides have also been blamed for acne especially cystic acne and scarring. Dietary manipulation can modify sebaceous gland function i.e. a low-calorie diet can decrease sebum excretion rate.

### 2.2.5 Genetics & Racial studies

Acne vulgaris appears to be familial, according to Cunliffe, (1989:6). Additional evidence

for a genetic link is the high concordance between monozygotic twins, in which the severity of acne and the sebum excretion rate are nearly identical (Kaminer & Gilchrest, 1995:S8; Cunliffe, 1989:6).

According to Kaminer & Gilchrest (1995:S8), and Cunliffe (1989:6), severe acne vulgaris has also been associated with the XYY genotype. Patients with severe nodulocystic acne have the abnormal XYY chromosome complement, but did not possess the other classical features of the syndrome i.e. increased height and mental deficiency (Apert's syndrome).

Racial studies provide useful information, in terms of genetic predisposition to acne, and the role of environmental factors i.e. diet and ultraviolet light. Racial studies indicate that acne vulgaris is more prevalent in white than in black Americans. In addition, white Americans often have more severe lesions than do Japanese ancestry (Kaminer & Gilchrest, 1995:S8; Cunliffe, 1989:6).

### 2.2.6 Stress

College students with acne, experience worsening of the disease when under stress before taking examinations. It has been found that emotional stress from external sources may exacerbate existing acne. In one study, it was noted that the participants experienced a higher Leeds acne score during exam periods than during non-exam periods. 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 acne change, while change in diet quality was the only other

significant association. One theory holds for how exactly stress aggravates acne severity, that increased levels of stress can induce the release of neuro-active substance in the body, which in turn can activate inflammatory processes or stimulate the sebaceous glands (Brunk, 2002:54). According to Wurward (2001:60), acne is influenced and aggravated by stress, often minor stresses. When stress occurs, the hypothalamus stimulates the pituitary gland to produce more hormones i.e. androgens which stimulates the sebaceous glands of the skin, causing them to produce more oil. Stress also affects the adrenal gland by producing adrenaline, cortisone and testosterone, thus producing acne breakouts.

According to Douglass (1995:355), acne from a homoeopathic standpoint is known to be caused by various causative factors, e.g. menstruation and pregnancy, masturbation, food habits and allergies and emotions. According to Schroyens (1997:1636), remedies like *Selenium* and *Staphysagria*, are most commonly associated with ill effects of masturbation i.e. the rubric “ailments from masturbation”. Most of the remedies used as simillimum, in this research, are also included in that rubric. In *Selenium*, Phatak (1995:471-2), states, there are ill effects of debauchery, masturbation, loss of fluids, sexual excesses and has greasy skin with acne too and in S*taphysagria*, Phatak (1995:492), states it produces both physical and moral sexual disturbances, with a tendency to masturbation, and sexual excesses and the physical state corresponding to the effects of that habit, i.e. acne. In *Staphysagria* symptoms are also aggravated by masturbation. Fitzpatrick & Aeling (2001:6), believes that masturbation does not cause acne however they have made reference to and contradicted Dr. R.V. Pierce’s book, *The People’s Common Sense Medical Adviser*, that masturbation causes acne, blindness etc.

Other causes observed are during stressful situations especially amongst teenagers, after abuse of various cosmetics and occupational i.e. exposure to various organic and inorganic chemicals (Douglass, 1995:355).

### 2.2.7 Weather

Sunlight ultraviolet radiation (UVR) has been used in the treatment of acne for its effect of camouflage i.e. hiding or making lesions inconspicuous, produced by the erythema initially and the subsequent pigmentation is of marked help psychologically. UVR also influences the surface bacteria and penetrate lower epidermis and upper dermis therefore having an effect on bacteria located deeper in the sebaceous glands. Sunlight also has a scaling effect, which enhances the removal of follicular corneocytes but excess scaling may even potentiate ductal obstruction. Ultraviolet B (UVB) radiation enhances the 'comedogenic' potential of squalene (Cunliffe, 1989:8).

## 2.3 MYTHS

### 2.3.1 Diet

It is helpful to discuss the myths about the causes of acne vulgaris with patients to alleviate fears and unnecessary behavioural modifications. Folklore has blamed the eating of chocolates and foods rich in fat and oils, but there is no scientific evidence to support these claims (Kaminer & Gilchrest, 1995:S8).

### 2.3.2 Cleansing & Hygiene

Many physicians have observed the patient with acne who has been told over and over by well-meaning family and friends that acne is caused by "dirty skin." These unfortunate patients spend hours cleaning and "sterilising" their skin. In fact, many of these

therapies, including alcohol washes and intensive scrubbing, only serve to impair the skin's natural barrier function, precipitate an apparent worsening of the disease, and limit tolerance for effective therapies (Kaminer & Gilchrest, 1995:S8). According to Smith (1994:14), and Barry (1983), many 'work' at their acne, rubbing, cleansing and applying endless creams and lotions which aggravate the condition, because a moist environment is created for bacteria in addition to the high skin sugar levels to multiply hence the skin should be left alone when acne presents and the affected area kept clean with a cleansing cream rather than soap which blocks the pores. To prevent the risk of secondary infection, rubbing or endless touching of the skin should be avoided. There is no scientific evidence that frequent washing helps acne or that lack of bathing worsens the condition. The most frenetic cleansing only removes surface lipids, a process which is virtually complete within half a minute. The water does not reach the deep recesses of the hair follicle where the acne organism *Propionibacterium acnes* or *Corynebacterium acnes*, multiplies. Repeated washing with bactericidal soaps may reduce surface aerobic flora, but scrubbing has no effect on the real culprit, which proliferates in its follicular sanctuary.

### 2.3.3 Stress

According to Kaminer & Gilchrest (1995;S9), stress is commonly blamed for acne flares. Although it is not possible to state categorically that there is an association between stress and acne, many patients believe that this is the case. Some of these patients are experiencing stress about the appearance of their skin, or there may be an independent source of stress in their lives. Many patients resort to picking at their acne lesions when stressed, and this in turn might be responsible for the perceived flare.

### 2.3.4 Ultraviolet light

Many patients believe that sunlight improves their acne lesions and go to great lengths to find ultraviolet light sources. Although the beneficial effects on inflammatory or comedonal lesions are dubious and undocumented, there is likely to be a significant effect on the patient's perception on how they look. A tan makes them feel good, and in turn they think their acne has improved. Although there is nothing inherently wrong with improving the patient's self image, ultraviolet therapy incurs the risk of skin cancer and photoaging in the future. PUVA (psoralen and UVA) exposure can cause acne (Kaminer & Gilchrest, 1995:S9). Callan (1997:23), agrees that ultraviolet exposure has been accepted by patients as improving acne by increasing exfoliation and via the camouflage effect, i.e. covering or obscuring acne.

Another myth is that acne primarily affects teenagers not adults that is untrue, as it is now seen more prevalent in adults (Fitzpatrick & Aeling, 2001:146).

## 2.4 VARIANTS AND SPECTRUM OF ACNE

1. Acne related to intrinsic causes
    - Acne vulgaris
    - Perioral dermatitis
    - Acne conglobata
    - Hidradenitis suppurativa
    - Acne fulminans
    - Pyoderma Faciale

2. Acne related to extrinsic causes

- Acne excoriee des jeunes filles
- Acne mechanica (Immobility acne, frictional acne etc.)
- Acne tropicalis
- Acne aestivalis
- Favre-Racouchot syndrome
- Drug-induced acne (hormones, antiepileptic, lithium etc.)
- Acne cosmetica
- Pomade acne
- Occupational acne
- Chloracne

3. Childhood acne
    - Neonatal acne
    - Infantile acne

4. Acneiform eruptions
    - Rosacea
    - Acne keloidalis nuchae
    - Gram-negative folliculitis
    - Steroid acne

## 2.5 DIFFERENTIAL DIAGNOSIS

- Acne agminata
- Acne varioliformis
- Acneiform eruption of Behçets syndrome

- Adenoma sebaceum
- Apert's syndrome
- Boils
- Cushings syndrome
- Dental sinus
- Familial comedones
- HIV infections
- Hyperalimentation "acne"
- Micropapular perioral 'sarcoid'
- Milia
- Molluscum contagiosum
- Perioral dermatitis
- Pityrosporum folliculitis
- Perioral eruption caused by Candida albicans
- Plane warts
- Seborrhoeic eczema
- Senile (solar) comedones
- Stein-Leventhal syndrome
- Sycosis barbae

## 2.6 PATHOGENESIS

The pathogenesis of acne is multifactorial, involving androgenic stimulation, sebaceous hypersecretion, follicular obstruction, *Propionibacterium acnes (P. acnes)*, and inflammatory mediators (Tan *et al.*, 2001:42).

### 2.6.1 Increased sebum production

According to Callan (1997:22), and Brown & Shalita (1998:1871), sebum, the lipid-rich secretion product of sebaceous glands and provides a growth medium for *P. acnes*. There is a higher rate of sebum production in people with acne than unaffected individuals. At adrenarche, which can be as early as 8 or 9 years in females and marks the commencement of increased secretion of androgens by the adrenal glands, ovaries and other extraglandular sites, results in increased sebum production from androgen-stimulated sebaceous glands, which in turn enlarge and increase in activity. With the onset of puberty and menarche, androgen production starts in the ovaries. Increasing androgen production (prepubertal) increases pilosebaceous glandular activity and sebum production. Acne does not occur until the sebaceous glands have been stimulated by androgens to adult levels of function. The severity of acne is proportional to the amount of sebum production. Patients with complete androgen insensitivity have undetectable sebum production and do not have acne.

### 2.6.2 Blockage of pilosebaceous ducts (Ductal hypercornification)

Abnormal follicular-epithelial differentiation occurs forming a hyperkeratotic plug in the follicular canal leading to follicular and pilosebaceous duct blockage, in androgen-sensitive areas (i.e. face, chest and back). Ductal hypercornification (an increase in keratin within the follicular duct of the pilosebaceous unit) takes place and desquamated cornified cells of the follicle become adherent. There is hyperproliferation of corneocytes and retention of horny cell material (retention hyperkeratosis). Instead of undergoing shedding, emptying and discharging through the follicular orifice, these cells form a retained, microscopic hyperkeratotic plug (microcomedo) in the follicular canal (intra-follicular hyperkeratosis). Progressive enlargement of microcomedones gives rise to

visible comedones composed of sebum, keratin and microorganisms by comedogenesis (Berkow, 1999:811; Brown & Shalita, 1998:1871; McBride & Simpson, 2000:10).

### 2.6.3 Proliferation of bacteria

Normal skin is usually colonized with a variety of bacteria. Human skin is covered by a relatively dry and impermeable outer layer of keratinocytes, which are shed daily with attached colonies of bacteria. The low pH (5.5) skin and the presence of fatty acids inhibit microbial growth, but wet skin is permeable to microorganisms, and heat and humidity aggravates existing conditions like acne (Kumar *et al.*, 1992:265). According to Brown & Shalita (1998:1871), acne is not infectious. *Propionibacterium acnes*, *Staphylococcus epidermidis* and *Malassezia furfur* are microflora isolated from the skin. These proliferate beneath the sebaceous blockage and produce mediators, which diffuse from the follicle into the surrounding dermis. The pilosebaceous glands secrete sebum allowing for *Propionibacterium acnes* (*P. acnes*) growth. *P. acnes* is an anaerobic diphtheroid that populates the androgen-stimulated sebaceous follicle and is a normal constituent of cutaneous flora. It is absent from the skin before the onset of puberty. Higher counts of *P. acnes* are seen in individuals with acne than those without. There is no relation between the number of bacteria and severity of acne, but a reduction in bacterial numbers with antibiotics use, causes a decrease in acne severity. Sebaceous follicles with microcomedones provide an anaerobic, lipid-rich environment in which these bacteria flourish (Brown & Shalita 1998:1871; McBride & Simpson, 2000:10; Callan, 1997:22).

### 2.6.4 Inflammatory changes

Closed comedones have microscopically detectable openings on the skin surface, and

are liable to cause breaks in the follicular wall. Sebaceous follicles provide a favourable environment in which *P.acnes* proliferates producing extracellular lipases that hydrolyse triglycerides to glycerol and free fatty acids, which are proinflammatory and comedogenic, which then provoke follicular hyperkeratosis, comedone formation, and rupture of the follicle. *P. acnes* produces exoenzymes, prostaglandin-like mediators and a chemotactic factor. These attract neutrophils to the follicular lumen, which result in leucocyte hydrolytic enzyme release, finally causing damage to and rupture of the follicular wall. Follicular leakage and rupture excites inflammation. Ductal corneocytes produce interleukins and tumour necrosis factor (potent promoters of inflammation). There is also a release of proteases (hydrolytic enzymes), an activation of complement pathways and a type III/IV host response to *P. acnes*. The premenstrual acne flare is thought to be caused by inflammatory effects of progesterone and oestrogen (McBride & Simpson, 2000:10; Brown & Shalita, 1998:1871; Callan, 1997:22; Lassus, 1996:341).

Closed comedones rupture before they become visible and the contents are spread into the surrounding tissue. The end result is an inflammatory reaction with acne lesion development. Follicular rupture and extension of the inflammatory process to the dermis, results in the formation of inflammatory acne vulgaris lesions i.e. papules, pustules, and nodules. If the rupture is superficial, a pustule develops and if the rupture is massive and occurs in the deeper dermis, nodules, abscesses and cysts form. Depending on the degree of inflammation and whether or not there is sebaceous gland involvement, lesions vary from small papules to large cysts with possible scarring (McBride & Simpson, 2000:10; Brown & Shalita, 1998:1871; Callan, 1997:22; Lassus, 1996:341).

## 2.7 CLINICAL FEATURES

### 2.7.1 CLASSIFICATION OF LESIONS

The direct approach is to first define the predominant lesion type as comedo, papulopustule, or cyst then the number of lesions can be counted and the degree of severity established. Comedones, papulopustules and cysts respond differently to treatment thus it is imperative that the lesion subtype is precisely defined. Acne can be separated into nine types i.e. comedonal, papulopustular, and cystic, then further into mild, moderate or severe (Kaminer & Gilchrest, 1995:S7).

#### 2.7.1.1 Comedones:

The acne lesion begins as a sebaceous blockage, developing into a visible or invisible microcomedone, closed comedone (whitehead) or open comedone (blackhead). Non-inflammatory lesions are open and closed comedones (Brown & Shalita, 1998:1871-2; Cotran *et al.*, 1999:1206-7).

Closed comedones are pilosebaceous ducts distended with inspissated ductal material whose orifice is barely visible to the naked eye and appear as skin coloured papules with a closed overlying surface whose contents are not easily expressible. It is a small, palpable lesion 0.1-3.0 mm in diameter. 75% of closed comedones develop into inflamed lesions and 25% resolve within 3-4 days. The larger ones last many weeks or months and are potentially proinflammatory (Brown & Shalita, 1998:1871-2; Cotran *et al.*, 1999:1206-7; Callan, 1997:22-23; Cunliffe, 1989:14).

Open comedones (blackheads, due to melanin oxidation) are raised, dilated pores that plugs and distend follicular orifices and are easily expressible. In the blackheads, the sebaceous secretion mixes with keratinous debris accumulated in the blocked

sebaceous pore and becomes oxidized on the surface, giving rise to the typical appearance and are not caused by poor hygiene. The open comedone is 0.1-3.0 mm in diameter and takes several weeks to develop. The larger ones extrude a worm-like grey-white greasy material. Blackheads are considered as the hallmark of acne but their absence does not negate the diagnosis. Comedonal rupture results in inflamed lesions i.e. papules, pustules or nodules (Brown & Shalita, 1998:1871-2; Cotran *et al.*, 1999:1206-7; Callan, 1997:22-23; Cunliffe, 1989:14).

**2.7.1.2 Papules:**

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.*, 1998:38). According to Cunliffe (1989:14-20), they are palpable inflamed lesions, varying in size, firmness, and redness. Papules can develop from normal looking skin (which was the site of a microcomedone), whitehead or blackhead. There are active and less active papules. Less active papules are less red, smaller than active lesions (4mm) and last longer and resolve directly via a macule, or develop into an active papule or pustule. The early papule has an erythematous flare around the developing lesion, lasting 1-3 hours, which is slightly uncomfortable with minimal tenderness. The active papule resolves directly to a macule or indirectly via a less active papule).

**2.7.1.3 Pustules:**

A pustule is an inflammatory exudate around a comedone and occurs in the upper, most superficial part of the dermis (Cooley *et al.*, 1998:38). According to Cunliffe (1989:20), superficial pustules are either active or less active. The less active lesions are smaller,

less indurated and of a shorter duration than the active lesions. Pustules are less frequently seen than papules but resolve via the macular phase like papules. Unmodified pustules last 5 days (shorter than papules) because pustules contain polymorphonucleocytes whose lysosomal enzymes resolve the inflammation more effectively than the lymphocytes do, which are a feature of papules. Deep pustules are less common and are seen in severe acne. They arise from a preexisting inflammatory papule or nodule and may persist in the pustular phase for 7 days or more. Deep pustules are tender. Resolution passes through a papular phase and takes 2-6 weeks. Pustular rupture produces cysts, abscesses or nodules (Brown & Shalita, 1998:1871-2; Cotran *et al.*, 1999:1206-7). Combination acne is an acne condition in which there is a mixture of comedones, papules and pustules present in one patient and often in one area according to Cooley *et al.*, (1998:38).

**2.7.1.4 Nodules:**

Nodules are deep-seated structures that tend to remain for as long as 8 weeks before finally resolving but some may not resolve completely hence resulting in scarring. Resolution is via the papular phase (Cunliffe, 1989:20).

**2.7.1.5 Cysts:**

A cyst consists of swollen, often tender, dilated follicles within the dermis (Cooley *et al.*, 1998:38). According to Cunliffe (1989:20), they are uncommon but when they do occur they may reach several centimetres in diameter and are widespread. Cysts are unilocular or multilocular and drain a little, thick, viscid, creamy yellow material when aspirated. The lesions coalesce, producing boggy areas associated with sinuses, necrosis and granulomatous inflammation, a condition called acne conglobata. In the

most severe form of acne, multiple draining sinuses result from the fusion of cysts and nodules. Cysts are more severe than papules or pustules, which are more severe than comedones. The end result is scarring.

**2.7.1.6 Macules :**

They are the end result of most inflamed lesions and may last for up to 3 weeks. The average life span of a macule is 7 days (Cunliffe, 1989:20).

**2.7.1.7 Postinflammatory pigmentation:**

According to Cunliffe (1989:20), it is a nonspecific inflammatory feature especially in coloured skins but contributes considerably to the patient's disfigurement and early treatment needs to be instituted to minimize this. This pigmentation takes up to 8 months to fade.

**2.7.1.8 Pyogenic granulomas:**

They are usually seen in severe acne patients and in patients receiving isotretinoin but is generally rarely seen in other less severe acne patients (Cunliffe, 1989:20).

**2.7.1.9 Scars:**

Scarring is atrophic, hypertrophic or keloidal (Brown & Shalita, 1998:1872). According to Callan (1997:23), and Cunliffe (1989:20), scarring is often seen resulting from severe inflammatory nodulocystic lesions occurring deep in the dermis however in some patients, who have not had nodulocystic acne, can develop scarring from more superficial inflamed lesions. There are 2 types of tissue responses in acne scarring i.e. increased tissue formation and loss of tissue. Increased tissue formation includes

hypertrophic and keloid scars. Loss of tissue type of scarring includes ice-pick scars, depressed fibrotic scars, superficial and deep soft scars, atrophic macules, and follicular macular atrophy. Acne cysts may result in either keloid (hypertrophic) or depressed (atrophic) scars. Severe nodular and papular acne results in depressed 'ice pick' scarring. The degree of the scarring depends on the depth of inflammation and the degree to which sebaceous glands are involved in the inflammatory process, which then determines whether there is a loss of tissue in the dermis. Scarring is variable in different subjects with similar inflammatory lesions, with some prone to scarring and other not. Picking, squeezing and excoriation exaggerate scarring. A rare complication of scarring is calcification to produce an osteoma cutis but there is usually no palpable or visible evidence of calcification except as pigmented palpable nodules or on X-ray.

### 2.7.2 SEVERITY OF ACNE

According to Lehmann *et al.* (2002:237), identifying acne severity is the most important patient characteristic especially to determine treatment options. The method of categorizing is varied and includes lesion counting on all or part of the face, comparison of patients to a photographic standard and comparison of patients to a text description. The terminology often used is mild, moderate, or severe while others use numerical scores e.g. 1-4, 0-10, etc. Healy & Simpson (1994:831), and McBride & Simpson (2000:11), grade the severity of acne for therapeutics according to the Leeds grading scale, but agree in the general treatment of acne vulgaris most doctors would divide the condition into mild, moderate, and severe. Mild disease consists of open and closed comedones and some papules and pustules, while moderate acne encompasses more frequent papules and pustules with mild scarring. Severe disease contains all of the above plus nodular abscesses and leads to more extensive scarring, which may be

keloidal. The severity of acne increases gradually reaching a peak 3-5 years after the onset but sometimes a lot earlier.

### 2.7.3 DISTRIBUTION OF LESIONS

The earliest lesions, mainly comedones (mildly inflamed or non-inflammatory) are usually located on the forehead. The inflammatory lesions appear on the cheeks, nose and chin. The most common location for acne is the face but the chest and back maybe involved (Isselbacher *et al.,* 1996:278).

According to Callan (1997:26), adolescent acne and acne in young women is of non-inflammatory comedonal type in the alar and chin creases. Mature-age acne (i.e. acne over 25 years) is of papular and/or nodular variety on the lower half of face (lower cheeks, jaw-line, chin and neck). Perimenopausal acne has various forms, usually of the persistent, extremely tender and indolent type, mainly around the chin and jaw-line.

## 2.8 PSYCHOLOGICAL ASPECTS

According to Brown & Shalita (1998:1871), the importance of acne should not be underestimated because the disease has important negative psychological consequences on the individual i.e. diminished self-esteem, social withdrawal due to embarrassment, depression and unemployment. There are many measures available for assessing changes in acne severity e.g. Acne lesion counting and Acne grading, but the patient's perception of changes includes factors other than lesion size and number according to Martin *et al.*, (2001:380,383). As facial acne is clearly visible and with it comes a degree of social negativity, even mild acne can decrease a person's self-confidence, body image, willingness to be seen in public and social interactions. Most

Quality of Life questionnaires (QoL) correlate more strongly with patient-reported severity than with physician-reported severity thus suggesting that the patients' perception of their disease is an important consideration in the evaluation and treatment of acne. The aspects, which prompt patients to seek care, are very often related to their psychosocial wellbeing. Acne-QoL (a disease-specific questionnaire) covers acne severity of the face and trunk and a broad age group, and is useful in assessing the impact of facial acne on health related quality of life and to evaluate therapeutic change. It also covers 4 domains (self-perception, role-social, role-emotional, acne symptoms. According to Girman *et al.* (1996:481,487-9), the primary motivation for young adult acne patients to seek treatment is the associated negative impact on psychosocial and social wellbeing. Acne is associated with psychosocial distress, including anxiety, depression, self-consciousness, embarrassment, lowered self-concept, lack of self-confidence and perceived social rejection. There is also resultant lower academic performance and higher unemployment.

Other symptoms noted are feelings of unattractiveness and dissatisfaction, emotional distress, changes in social assertiveness, worry and concern about perceptions and opinions of others or in social interactions (social inhibition or phobia), and feelings of anger, frustration and aggravation. Due to the proximity of breakouts with stressful periods in the lives of acne patients, it has been suggested that stress and anger exacerbate the condition. Some patients express concerns about interviewing for a job or a perceived reduction in opportunities due to acne. The preoccupation with acne and the concern about bodily functions are psychologically disabling symptoms of acne. Frustration about recurrence of lesions, annoyance about the time needed to cleanse

and treat the face and worries about that the treatment will not work fast enough is particularly distressing (Girman *et al.*, 1996:487-9).

According to Cotterhill & Cunliffe (1997:246,249,230), there is a popular view of dermatologists that their patients never die but they fail to realize that some patients with 'skin failure' become so disturbed that they commit suicide successfully. Skin disease, or perceived skin failure is now added to the list of mental disorders central to suicide. Patients with long-standing and debilitating skin disease may become depressed enough to commit suicide. There is a risk of suicide in patients with established psychiatric problems, referred to dermatologists with concurrent skin disorders i.e. acne. It is important that dermatologists recognize how mental disease can present in their patients. In acne, the face is very important in body image and it is not surprising, that young men with severe facial acne scarring, can become depressed and are at risk of suicide but women, concerned with facial complaints are more at risk of becoming depressed and attempting suicide, the only signs are when they are obsessed with facials and acne camouflage or cover-up. A simple psychological screening of acne patients, before being seen, can help identify severe depressive features. It is necessary to note the importance of skin/mind relationships and the importance of recognizing mental disease i.e. depression in patients. It serves to emphasize the need for the early treatment intervention to lessen acne scarring. Most dermatologists should be in a position to help patients with severe depression associated with skin problems and should appreciate that minor imperfections in major body image areas i.e. face, hands, scalp etc. may cause major distress.

In contrast, it has been suggested that patients with facial acne may be less self-

conscious than those with acne on their back or chest as they adjust to its constant visibility. It has also been noticed in some studies that students with severe acne are more extroverted than the ones with milder acne. Patients with the same clinical criteria differ dramatically in terms of their clinical assessment of emotional wellbeing. Patients rate themselves more severely than the dermatologist and the psychological aspects of acne are more related to self-perception than to acne grading or lesion counts. These symptoms and aspects were not expressed before, possibly because the patients were not asked about them. Unstructured interviews allow patients to more freely discuss the impact of acne on their social and psychological wellbeing (Girman *et al.*, 1996:481, 487-9). According to Oakley (1996:39), patients whose lives are significantly affected, by their disease, even if mild, may be keen to bare with the inconvenience of oral retinoids hence benefit psychosocially, whereas those who are emotionally well adjusted to clinically severe disease, may fail to comply with potentially toxic or troublesome treatment. In order to rapidly assess the disability caused by acne, a questionnaire covering emotions, attitudes, daily activities, disabilities, financial considerations is necessary at the initial consultation and repeated often to assess whether the treatment has been beneficial (Oakley, 1996:39).

## 2.9 COURSE & PROGNOSIS

Many persons experience complete resolution of their lesions without any residual signs of the disease, whereas others have to deal with persistent acne vulgaris to the residual effects, including scarring and keloids. There appears to be a subset of young women in whom lesions persist well beyond their teenage years, and a second subset of women who do not have their initial acne vulgaris episode until their late twenties or early thirties (Kaminer & Gilchrest, 1995:S8). Cunliffe (1989:3), states there is little information on the

age at which spontaneous resolution of acne occurs but is usually possible in the late teens or early twenties. Berkow (1999:811) agrees that acne usually spontaneously remits but the time of remittance cannot be predicted. Douglass (1995:351), in accordance agrees, the peak activity of acne is in the mid or late teen years with a steady improvement starting around age 20 but the disease activity may continue into the 4$^{th}$ decade. Women seem to be prone to this long lasting form of acne. Hormonal factors play a major role in the course of the disease. Acne seems to be more severe in men. Cystic lesions, which are common in men, are only rarely found in women. In women a monthly peak of acne activity often occurs during the week prior to their menses. Acne tends to improve during the 3$^{rd}$ to 9$^{th}$ month of pregnancy but rebound worsening sometimes occurs following parturition and cessation of lactation. It is difficult to predict the future severity of acne at the time a young patient is first seen. The presence of cysts and a family history of scarring acne are, however, bad prognostic signs. Callan (1997:23), in accordance agrees that there is no reliable guidelines for prognosis because in the majority of women, acne improves and disappears by the mid twenties, however some develop acne for the first time over the age of 20 and in a small percentage acne persists (modified in appearance) into the late twenties and thirties and some develop acne for the first time during pregnancy and around menopause.

When acne is untreated, individual small papules and pustules resolve spontaneously in 7 to 10 days. Resolution of these lesions does not result in scarring even when some degree of picking is carried out. Large papules and cysts require several weeks to resolve and even then post-inflammatory colour changes may persist for months. Scarring is usually found at the site of deep-seated papules and is almost invariably present following resolution of fluctuant cysts. (Douglass, 1995:351).

## 2.10 TREATMENT

The aims of treatment are to prevent scarring, limit disease duration, reduce psychological stresses, decrease sebum output, control bacterial proliferation, and reduce/prevent comedones. Treatment should start early to prevent scarring because established scars are difficult to treat (Berkow, 1999:812). Callan (1997:28), agrees that the treatment of acne aims to inhibit androgen stimulation of sebaceous glands, reduce sebaceous blockages, decrease bacterial activity and suppress inflammation. Treatment should suite the individual patients' needs and preference i.e. some are opposed to long-term antibiotic therapy in severe acne whereas some with minimal acne demand more potent therapy. The other goal of treatment is to eliminate comedones, papules, pustules, cysts and nodules and to decrease the amount of hyperpigmented scarring (Cooley *et al.*, 1998:38). Healy & Simpson (1994:831) agrees that treatment should prevent scarring, limit disease duration, and reduce the impact of psychological stress, and that treatment should be administered early to prevent scarring since established scars have little improvement. According to Sommer *et al.* (1997:211), treatment measures include colony counts of *P. acnes* and micrococcaceae, measurements of skin surface lipid free fatty acids and sebum excretion rate.

According to Cunliffe (1989:253), the patient should be told that acne is caused by his type of skin and by hormonal changes occurring in adolescence. These alterations are not due to abnormalities of sex hormones but to an overreaction of the sebaceous unit to normal levels. It is also necessary to explain to the patients that there are different sorts of acne, not just differences in severity and the types of acne lesions, and treatment is given is based upon the type of acne, its severity and location. For effective

improvement, treatment needs to be for at least 6 months and compliance is important. The side-effects need to be discussed with patients as well.

### 2.10.1 ALLOPATHIC TREATMENT

According to Lehmann *et al.* (2002:237), the first-line therapy includes a cleanser, keratolytic, antibacterial (topical), and combinations. Second-line therapy includes retinoid (topical), antibacterial (oral) and combinations. Treatment prescribed at referrals i.e. for more severe acne, includes retinoid (oral) and antiandrogen treatment.

#### 2.10.1.1 Topical therapy:

Used for mild to moderate acne, and are comedolytic and antimicrobial in action.

***a) Benzoyl peroxide***: is bactericidal for *P. acnes* but causes irritation and contact dermatitis. It is a potent oxidizing agent with bacteriostatic, comedolytic and keratolytic properties, causes follicular desquamation, and reduces inflammatory and non-inflammatory lesions. Topical usage decreases *P. acnes* counts. It needs long-term usage, but does not alter the bacterial resistance pattern of antibiotic resistance and prevents resistance when used together with erythromycin. The adverse effects include bleaching of clothes and hair, skin irritation (redness and scaling) and allergic dermatitis (McBride & Simpson, 2000:11; Brown & Shalita, 1998:1872). Benzoyl peroxide, according to Cooley *et al.*, (1998:40), eliminates bacteria at the skin surface but do not penetrate deep into the follicular orifice. It is beneficial when, a wide distribution of lesions, are present and when adherence to treatment is problematic. Eady *et al.* (1994:334), agrees it is a broad spectrum antibacterial, which produces death via the interaction of oxidized intermediates with constituents of microbial cells, and bacterial resistance is unlikely to occur despite widespread usage.

***b) Salicylic acid***: is a peeling agent, and is useful against comedones and inflammatory lesions in acne. It is useful but less effective in patients who cannot tolerate tretinoin (Brown & Shalita, 1988:1872).

***c) Azelaic acid***: is antikeratinizing, antibacterial (against *P. acnes* and *Staphylococcus epidermidis*), comedolytic, keratolytic, antiproliferative and inhibits melanin production in proliferating melanocytes. It is a dicarboxylic acid that is suitable for both non-inflammatory and inflammatory acne and is less irritant than benzoyl peroxide. It is useful in lightening postinflammatory hyperpigmentation (Brown & Shalita, 1998:1872; Callan,1997:28).

***d) Silicol gel***: according to Lassus (1996:343), has an effect on papulopustular acne on facial skin by means of a peeling effect, decreased sebum production, and an increase in the water content in the stratum corneum.

***e) Adapalene***: it is agreed by Shalita *et al.* (1996:482-483), Brown & Shalita (1998:1872), and McBride & Simpson (2000:11), that adapalene is a napthoic acid derivative with retinoid-like properties but more tolerable than other retinoids. It is a potent modulator of cellular differentiation, keratinization, is comedolytic and anti-inflammatory in action, thus indicated for acne vulgaris treatment of the face, chest and back where comedones, pustules and papules predominate. It can be used alone or in combination with benzoyl peroxide and other preparations. It is non-photosensitizing and is more potent than tretinoin in reducing non-inflammatory and total acne lesion counts and has a milder irritant effect i.e. skin discomfort, erythema, skin dryness, and acne flare.

***f) Fusidic acid***: is useful in facial acne. It causes gradual reduction in lesion count especially inflamed lesions, and reduces micrococcaceae and has some reductions in acne grade and lesion count, but does not reduce *P. acnes* counts, surface free fatty acids or sebum excretion rate. Fusidic acid has been used for the treatment of boils and impetigo in the past and also suppresses *P. acnes in vitro* therefore suggesting its use in acne treatment (Sommer *et al.*, 1997:211,213).

***g) Nicotinamide***: is a potent anti-inflammatory agent for cutaneous disorders, topically and systemically. It is an active form of niacin and a source of vitamin B3. It serves as a precursor in the synthesis of coenzymes. There is similar efficacy to topical clindamycin in acne treatment, but unlike clindamycin, it doesn't cause pseudomembranous colitis or resistance of microrganisms. Nicotinamide, by means of it anti-inflammatory effect, have the ability to contribute to the resolution and prevention of inflammatory acne lesions (Shalita *et al.*, 1995:434,436).

***h) Tretinoin***: are vitamin A derivatives that reverses abnormal follicular keratinization, reduces micro-comedo formation (keratolytic), decreases sebaceous gland functioning and decreases inflammatory lesions, that results from microcomedone rupture, but is contraindicated in pregnancy, and causes local skin irritation (erythema, peeling and burning) and photoirritation i.e. ultraviolet light sensitivity. It lightens postinflammatory hyperpigmentation in black patients. The required time for improvement is 3-4 months (Brown & Shalita, 1998:1872; McBride & Simpson, 2000:11)

***i) Topical isotretinoin***: Brown & Shalita (1998:1872), Callan (1997:28), and McBride & Simpson (2000:11), agrees that this produces superficial peeling of the skin that

unblocks follicles, is keratolytic, reduces comedogenesis and reduces both non-inflammatory and inflammatory lesions by affecting abnormal follicular keratinization, It causes skin irritation, sensitivity to ultraviolet light, hyper- or hypopigmentation, are teratogenic in early pregnancy and is contraindicated during lactation. It is a safer alternative to oral isotretinoin without the side-effects but does not affect sebum production.

***j) Topical antibiotics***: for example clindamycin, and erythromycin and are bacteriostatic for *P. acnes,* reducing *P. acnes* counts and number of inflammatory lesions i.e. papules and pustules by altering the metabolic pathways of *P acnes*. Topical antibiotics are tolerated better than the systemic ones due to less severe side-effects. They offer an alternative treatment for patients who are allergic to benzoyl peroxide (Cooley *et al.*, 1998:40; Brown & Shalita, 1998:1872-3).

***i) Clindamycin***: treats mild acne and is useful for pregnant women who are unable to tolerate oral tetracycline usage. It causes mild exfoliation (Callan, 1997:28).

***ii) Erythromycin***: is useful in pregnancy but contraindicated during lactation. There are mild adverse effects thus very safe to use. The combination of erythromycin and benzoyl peroxide topically is more effective than erythromycin alone. They work synergistically together by reducing inflammatory lesions i.e. papules and pustules and have a slight effect on comedones. They act by means of an antibacterial-keratolytic effect. There is also a greater degree of penetration by erythromycin due to ‘loosening’ of stratum corneum by benzoyl peroxide and also there is reduction and prevention of

erythromycin-resistant strains of *P. acnes* developing with benzoyl peroxide (Eady *et al.*, 1994:331, 334-336).

**2.10.1.2 Systemic treatment:**

Used for moderate to severe acne and penetrates sebaceous follicles more readily with serious adverse effects. Systemic treatment, include oral antibiotics, isotretinoin and hormonal agents (Brown & Shalita, 1998:1873).

**2.10.1.2.1 Oral antibiotics**

**2.10.1.2.1.i) Mechanism of action of antibiotics**

They are anti-inflammatory and suppress the number of *P. acnes* and reduce surface free fatty acids. They help acne by reducing chemotaxis to *P. acnes* and by modifying the complement pathways and are also potent scavengers of the superoxide radical (Cunliffe, 1989:263).

They are used when topical antibiotics fail or are intolerable in inflammatory and pustular acne, when there is shoulder, back or chest involvement (where patient finds it difficult to apply topical antibiotics), and when there are scarring and pigmentary possibilities. Oral antibiotics include tetracyclines (tetracycline, doxycycline, minocycline), erythromycin and co-trimoxazole. They inhibit growth of *P. acnes* thus improving inflammatory acne. Tetracyclines and erythromycin are anti-inflammatory, by reducing leucocyte chemotaxis and antibacterial by inhibiting bacteria associated with acne (Brown & Shalita, 1998:1873). Treatment with antibiotics is suppressive, that aims to minimize the signs and symptoms of acne and very often it requires topical therapy to work effectively. Broad-spectrum antibiotics increase the risk of vaginal thrush (Callan,

1997:30). McBride & Simpson (2000:11), states oral antibiotic courses should continue for a minimum of 3 months before accepting failure. Unwanted effects of systemic antibiotics include diarrhoea, dyspepsia, candidiasis and folliculitis.

***a) Tetracycline***: is a commonly prescribed oral antibiotic but causes gastrointestinal upset (vomiting, diarrhea), sun sensitivity, vaginal candidosis and benign intracranial hypertension. Its absorption is impaired by food, milk etc. thus it needs to be taken before meals. Contraindicated in pregnancy, during lactation and children (Brown & Shalita, 1998:1873). It is inexpensive and relatively free from side effects according to, Cooley *et al.* (1998:40). Women on the oral contraceptive pill for contraception (i.e. birth control) should be advised that tetracyclines may decrease the effectiveness of the pill and that additional barrier contraception should be used. As tetracycline is contraindicated in pregnancy, topical clindamycin hydrochloride, benzoyl peroxide, or erythromycin are safer alternatives. Tetracycline causes fixed drug eruptions, headaches due to benign intracranial hypertension, phototoxicity, photo-onycholysis, oesophageal ulceration and Gram-negative folliculitis. Tetracycline therapy interferes with blood levels of lithium and causes idiosyncratic liver toxicity (Callan, 1997:30-4).

***b) Doxycycline***: is better absorbed from the gastrointestinal tract and reduces inflammatory acne lesions (Brown & Shalita, 1998:1874)

***c) Minocycline***: is the antimicrobial of choice due to its efficacy, has a lack of dietary restrictions, gastrointestinal problems and photosensitization (Berkow, 1999:812), and rapid reduction in *P. acnes* counts and inflammatory lesions. Side effects are reversible vestibular disturbances (e.g. dizziness, vertigo, ataxia), headaches, blue-grey

discolouration or pigmentation of mucosa and inflamed or scarred or sun-exposed skin, hepatitis, systemic lupus erythematosus-like syndrome, liver disease and serum sickness etc. It is often used when patients are resistant to tetracycline and erythromycin (McBride & Simpson, 2000:11; Brown & Shalita, 1998:1874). According to Guttman (2000:S5), the lupus occurs over long-term exposure and resolves upon minocycline discontinuation and the bluish discoloration of soft tissues resolve with vitamin C usage. According to Sitbon *et al.* (1994:1633-9), minocycline, being a semisynthetic tetracycline derivative, causes vasculitis, reversible minocycline pneumonitis and eosinophilia. There have been evidence of pulmonary infiltrates, hypoxaemia and blood eosinophilia in patients treated with minocycline. In the study none of the patients had a history of lung or systemic disease, exposure to aerocontaminants, pneumotoxic drugs, radiation, or oxygen therapy. With the removal of the drug, patients recovered but severe cases needed steroid therapy. Adverse effects include respiratory symptoms, nausea, dyspnoea, fever, blood eosinophilia, transient vestibular symptoms, photosensitivity, hyperpigmentation, and skin rashes. As it induces teeth discoloration in the fetus, it is contraindicated in pregnancy. Minocycline, according to Beneton *et al.* (1997:1252), induces a hypersensitivity syndrome which is a severe adverse drug reaction characterized by a drug eruption, visceral involvement (cardiac, kidney, lung or liver) and eosinophilia or atypical lymphocytosis. Although these reactions are rare, given the number of times it has been prescribed, minocycline should not be used as a first-line antibiotic in acne vulgaris, as the reactions are severe.

***d) Lymecycline***: is a second-generation tetracycline and has no dietary restriction. It has reduced gastrointestinal side effects and no effect on skin pigmentation (McBride & Simpson, 2000:11).

***e) Erythromycin***: is equally effective in the treatment of inflammatory acne but is used less frequently due to the emergence of resistant strains of *P. acnes* and intolerable gastrointestinal side-effects. It has been replaced by trimethoprim due to erythromycin having high bacterial resistance (Brown & Shalita, 1998:1874; McBride & Simpson, 2000:11). It is often used if tetracyclines are contraindicated i.e. children under 12 years of age. It is safe to use in pregnancy (Callan, 1997:30).

***f) Sulphonamides***: can be used in resistant cases, but produce more side-effects with long-term use (Callan, 1997:30).

***g) Co-trimoxazole***: treats inflammatory acne but causes hypersensitivity reactions (i.e. toxic epidermal necrolysis), rash and bone marrow suppression. If is often used in patients who did not respond well to other oral antibiotics (Brown & Shalita, 1998:1874).

***h) Trimethoprim***: it is as effective as tetracycline and co-trimoxazole (Cunliffe, 1989:263).

***i) Clindamycin***: improves inflammatory acne but causes pseudomembranous colitis (Brown & Shalita, 1998:1874).

**2.10.1.2.2 Isotretinoin** (Accutane®/Roaccutane®)

It is used for nodular and severe acne and reduces sebaceous gland size and activity by inhibiting sebocyte differentiation, decreasing sebum production, suppressing *P. acnes* proliferation and inhibiting comedogenesis and is anti-inflammatory. It is the only treatment that affects all major aetiological factors involved in acne. It is teratogenic and

use during pregnancy causes spontaneous abortions and life-threatening congenital malformations. Females need to use 2 methods of contraception for 1 month before taking, while taking and at least 1 month after discontinuing the drug and must have a negative pregnancy test prior to therapy (Berkow, 1999:813; Brown & Shalita, 1998:1874).

According to Callan (1997:34), women of childbearing age must be adequately protected against pregnancy with oral contraceptives, unless hysterectomy or tubal ligation has been done. Contraindications include patients with pseudotumor cerebri, inflammatory bowel disease, hyperlipidemia, hepatitis, children and pregnant females (Fitzpatrick & Aeling, 2001:152). Due to the potential severe adverse effects, it is reserved for severe nodulocystic acne, severe, inflammatory acne that is resistant to conventional therapy, late-onset acne (as this is often resistant to oral antibiotics) and have a potential for physical scarring or serious emotional consequences. It is often used when less severe acne is resistant to other conventional systemic treatments (Brown & Shalita, 1998:1874-5). Side effects include mucocutaneous effects (i.e. dryness or irritation of skin and mucous membranes, cheilitis, xerosis, blepharitis, blurred vision, nose bleeds, conjunctivitis, epistaxis), musculoskeletal pain and stiffness, eczema, hyperostosis, pruritis, photosensitivity, alopecia, anaemia, leukopenia, hypertriglyceridaemia, hypercholesterolaemia, hepatic dysfunction and acute pancreatitis etc. Benign intracranial hypertension is a side effect common to isotretinoin and tetracyclines, therefore concomitant use of both drugs is contraindicated (Brown & Shalita, 1998:1874-5; McBride & Simpson, 2000:12; Callan, 1997:34).

Blood lipids, liver enzymes, and blood counts monitored initially and once each month while the patient is taking isotretinoin, and 1 month after therapy has been stopped. Pretreatment investigations i.e. liver function and cholesterol tests (to exclude hypercholesterolaemia) are necessary, and need to be repeated during treatment. Frequently seen are transient rises in plasma, lipids, and liver enzymes during treatment (Cooley *et al.*, 1998:40; Callan, 1997:34).

According to Girman *et al*. (1996:487-489) and Martin *et al*. (2001:383), possible early intervention and medical attention, and the use of isotretinoin, decreases the severity of acne and decreases the risk of possible suicides, as it causes rapid reduction of the acne lesions thus improving self-confidence, decreasing embarrassment and frustration. Many are able to cope with the adverse effects of isotretinoin as their main concern is that the acne is permanently eradicated. To them the disadvantages of isotretinoin treatment do not outweigh the massive advantages gained.

**2.10.1.2.3 Hormonal treatment**

Hormonal treatment improves acne by blocking androgen receptors, inhibiting androgen synthesis and decreasing androgen-induced sebum secretion. Side-effects are gynaecomastia, impotence, decreased libido, infertility, menstrual irregularities etc. It is useful when other therapies fail, acne began/worsened in adulthood, acne with premenstrual-flare, excessive facial oiliness, inflammatory lesions localised to the beard area and hirsuitism (Berkow, 1999:813; Brown & Shalita, 1998:1875). Birth control pills may affect the skin by causing hyperpigmentation and may change the amount of acne breakouts. It is important to note when someone who never experienced acne as a teenager, but has noticed frequent breakouts after discontinuing a pill high in oestrogen,

or starting a pill high in androgen (Wurward, 2001:6). Spironolactone, oestrogen and cyproterone acetate are used (Brown & Shalita, 1998:1875).

**a) Antiandrogens**

***i) Spironolactone***: blocks androgen receptors and inhibits androgen synthesis and is effective against inflammatory acne lesions. Side-effects include breast tenderness, menstrual irregularities and hyperkalaemia (Brown & Shalita, 1998:1875).

Callan (1997:32), suggests its usage when the oral contraceptive is contraindicated or when the patient wishes not to use this type of hormone preparation, spironolactone can be used. It causes polymenorrhoea as a side effect. Due to the risk of hyperkalaemia and hyponatraemia, regular serum electrolyte monitoring and regular blood pressure check-ups are necessary and potassium supplements avoided. Antiandrogen therapy used alone or in conjunction with antibiotics, can cause breast soreness, weight gain and bleeding.

**b) Oral contraceptives**

***i) Oestrogens***: decrease serum concentrations of free androgens, by suppressing ovarian hormonal production and increasing concentration of sex-hormone binding globulin. Oestrogen and progestagen combination in oral contraceptives are useful in acne therapy (Brown & Shalita, 1998:1875). According to Callan (1997:32), in women with premenstrual flares of acne, who do not respond adequately to antibiotics plus topical therapy, oestrogen (a nonandrogenic oral contraceptive) may help.

***ii) Cyproterone acetate***: is a potent androgen-receptor blocker and progestagen (Brown & Shalita, 1998:1875). According to Callan (1997:32), it is a combined oral contraceptive, which should be avoided until pubertal development is complete as it may affect longitudinal bone growth. In women who have had a hysterectomy or peri- and postmenopausal women, this preparation without oestrogen can be given. Although Diane-35 is a useful contraceptive, when used in conjunction with oral antibiotics, precautions should be taken. Oral contraceptives containing norethisterone or levonorgestrel may aggravate acne, according to McBride & Simpson (2000:11). According to Callan (1997:32), oral contraceptive therapy should not be given to females before completing puberty or before reaching their full growth potential as these preparations can accelerate epiphyseal closure hence the 'safe' age to start hormone therapy depends on the individuals physical development and sexual maturity but a good guide is menarche.

#### 2.10.1.2.4 Oral steroids

Corticosteroids are used to suppress adrenal and ovarian androgens. They are indicated when other hormonal therapies fail (Brown & Shalita, 1998:1875). According to McBride & Simpson (2000:11), oral steroids are used in very inflammatory severe acne e.g. acne fulminans, in which patients develop an immune complex reaction to *P. acnes*. It is more usual as a side effect of steroid use, either for therapeutic purposes (i.e. transplant patients) or with the abuse of anabolic steroids, then treated in terms of its severity.

### 2.10.1.3 Treatment of cysts and scars

Comedone extraction is effective after tretinoin therapy. For macrocomedones (large

whiteheads) hyfrecation of fine cold point cautery with local anaesthesia is useful (Healy & Simpson, 1994:832).

Acne surgery, dermabrasion, chemical peeling, laser resurfacing, bovine collagen injections, punch grafts and ultraviolet light are helpful adjuvant for improving atrophic acne scars (Brown & Shalita, 1998:1875; Berkow, 1999:813). According to McBride & Simpson (2000:12), dermabrasion is useful in patients with extensive but superficial scarring and is performed when the disease is inactive but is less popular because of the risk of blood-borne infection in the operating theatre. Early keloid formation can be reduced by triamcinolone injections or excision.

Cysts may be aspirated and injected with triamcinolone acetonide (intralesional corticosteroid injections) to reduce lesion (nodules and cysts) size and inflammation quickly but this results in deep scarring. They can be frozen with liquid nitrogen with resultant minimal scarring and to reduce inflammation. Local excision of cysts may be indicated in some patients (Brown & Shalita, 1998:1875; Berkow, 1999:813; McBride & Simpson, 2000:12).

Radiation therapy i.e. X-ray therapy and ultraviolet radiation, are useful to reduce size of sebaceous glands and sebum output (Cunliffe, 1989:279). X-ray usually inhibits sebaceous gland activity. This has been noted after dental x-rays, whereby, a marked decrease in the amount of oil production and breakouts of the skin have been noticed according to Wurward, (2001, 5:60).

#### 2.10.1.4 Investigations

None are usually necessary though swabs may be needed to exclude a pyogenic infection, anaerobic infection or Gram-negative folliculitis. A full endocrinological assessment is necessary to investigate acne associated with virilisation to exclude an androgen-secreting tumour or non-classical 21-hydroxylase deficiency (Edwards *et al.*, 1996:955). According to Wurward (2001:60), those predisposed to acne, should screen their vitamins for kelp, seaweed or straight iodine (potassium iodine) and eliminate these from their intake.

#### 2.10.1.5 Treatment failure

Many acne therapies aim to reduce the numbers and functions of *P. acnes*, the most important organism involved in the aetiology of inflammatory acne. Not all patients respond to the therapies available and there are many clinical failures. Poor compliance is cited as one of the reasons (Sommer *et al.*, 1997:211). Compliance with acne treatments decreases after the initial 3 months due to decreased enthusiasm and a false sense of security once improvement is noticed agrees Cooley *et al.*, (1998:38). Another reason is the variability in the duct penetration and concentration of topically applied treatments due to the wash-out effect of a high sebum excretion rate, which reduces the success of effective therapy, according to Sommer *et al.*, (1997:211,214). The other very important reason, according to Sommer *et al.* (1997:211,214) is increased *P. acnes* resistance to oral and topical antibiotics and there is recent evidence that oral and topical anti-microbials work less well than previously due to poor compliance and *P. acnes* resistance. According to Moyer (2001:10), Dr. Nord states that dermatologists will need to rethink their management of acne with the emergence of strains of antibiotic-resistant *P. acne vulgaris*. It is recommended that dermatologists restrict topical and

systemic antibiotic treatment and patients on these therapies should be frequently monitored. Antibiotics should not be used to treat severe acne, rather use other agents to treat severe acne i.e. isotretinoin and nonantibiotic local agents (benzoyl peroxide) should be used. Until the late 1970s, propionibacteria e.g. *P. acnes* were susceptible to and its cutaneous effects were inhibited, by antibiotics and since the 1980s there has been the emergence of resistance to clindamycin, tetracycline, erythromycin and trimethoprim. There is a relationship between a patient's carriage of resistant strains and failure to respond to antibiotic therapy. The antibiotic resistance problem is relevant to the treatment of acne. Another concern is that this resistance may spread to other bacteria. According to Shalita *et al.* (1995:434), it is agreed systemic and topical antimicrobial agents have been widely prescribed for the past 30 years, for the treatment of inflammatory acne vulgaris and although they continue to be effective, their use has been associated with the emergence of resistant strains of *Staphylococci* and *Propionibacterium*, thus being the cause of antimicrobial therapeutic failure. Guidelines were thus proposed to restrict the use of antimicrobials for acne treatment.

According to Healy & Simpson (1994:832), rapid induction of antibiotic resistance in *P. acnes* accompanied by relapse of acne is noticed in topical erythromycin and clindamycin and systemic tetracycline, erythromycin, and doxycycline. Eady *et al.* (1993:555-6), agrees that the failure to respond to treatment with antibiotics (i.e. erythromycin, clindamycin, doxycycline and tetracycline) except Minocycline is due to carriage of resistant bacterial strains (i.e. *P. acnes*). The advantages of Minocycline (simpler dosage regime, absence of resistance in *P. acnes*, and efficacy in tetracycline-recalcitrant acne) support its use in acne therapy but it should not be used in patients with liver disease or lupus erythematosus. Antibiotics and resistant bacteria are spread,

by touching. Siblings and close contacts of patients on long-term antibiotic treatment carry antibiotic-resistant strains of staphylococci on their skins. High prevalence of resistance highlights the need for policies to restrict usage of antibiotics to limit the spread of resistant strains thus preserving antibiotic effectiveness in treating acne.

To achieve this:

- don't prescribe antibiotics unless absolutely necessary
- keep treatment courses short
- use benzoyl peroxide as an antibacterial to control person-to-person transfer of antibiotic-resistant bacteria
- avoid concomitant oral and topical treatment with dissimilar antibiotics
- good compliance is necessary
- re-educate patients not to expect an endless supply of alternative medications (Eady *et al.,* 1993:555-6, Dawson, 1998:422).

Benzoyl peroxide together with antibiotics controls transfer of resistant bacteria and prevents the induction of antibiotic resistance but this is only shown to be effective against *Staphylococcus epidermis* (Healy & Simpson, 1994:832).

According to Guttman (2000:S5), Dr. Lebwohl suggests that, dermatologists should be observant for drug, interactions, antibiotic resistance, and other co-morbid conditions as causes of treatment failure in acne patients, and to keep in mind that medical management and not treatment discontinuation are appropriate interventions for acne drug-induced adverse effects. Dr. Lebwohl devised a mnemonic PIMPLES (Phenytoin, Isoniazid or Iodides, Moisturizers, Phenobarbitol, Lithium, Ethionamide, Steroids) to

represent some of the acnegenic medication used, as well as lithium-tetracycline interaction, whereby tetracycline increases the serum lithium concentration, which exacerbates acne-inducing potential. In addition it was stated that *P. acnes* was increasingly resistant to tetracycline, but more susceptible to doxycycline and more especially minocycline. This highlights the need for alternative antimicrobial treatments. The presence of acne imitators i.e. adenoma sebaceum, pseudofolliculitis etc., are important to consider in the evaluation of patients who fail isotretinoin treatment. Polycystic ovarian syndrome is a common cause of refractoriness to isotretinoin.

If the severity of acne assessed by the clinician is at odds with the patient's perception/opinion, it may lead to dissatisfaction with treatment (Oakley, 1996:38).

Although there is enough literature on the basic science, clinical features, psychosocial impact, and treatment of acne, there's a lack of information on the knowledge and understanding of acne patients about their condition. This information can lead to awareness development and educational programs to increase patient understanding of their condition, enhance patient adaptation, coping mechanisms and compliance with treatment (Tan *et al.*, 2000:440).

#### 2.10.1.6 Therapeutically difficult patients

- The patient who is difficult because of the doctor's inappropriate management or lack of interest.
- The patient who may genuinely fail to respond to adequate therapy despite maximum compliance.
- The patient who may develop one or more problematic side-effects.

- The patient who has severe acne or a severe variant of acne.
- The patient who has many cysts.
- A miscellaneous group of problem patients i.e. unemployed acne patients, Acne excoriee, the dysmorphobic patient, the professional patient, the over-expectant patient, hyperpigmentation, localized acne, and the wrong diagnosis.
- The scarred patient (Cunliffe, 1989:325-336).

### 2.10.2 HOMOEOPATHIC TREATMENT:

The aims of conventional treatment are to decrease androgen uptake and keratogenesis of the cells of the pilosebaceous glands. Homoeopathic treatment has the same effect, but is longer-lasting and non-toxic. Patients may be impatient to get results, hence a local treatment to be prescribed at the same time as homeopathic treatment, is often requested. The substances used must be gentle to the skin. As acne can affect and cause strain on a person's social and personal life, homoeopathic treatment often includes a remedy acting on the emotional sphere. Therapies should always include symptomatic and constitutional remedies (Jouanny, 1994:274). According to Douglass (1995:354), acne vulgaris is one of the common diagnoses brought forward by the patient to a homoeopath. The problem should never be tackled with superficial, local acting remedies, instead, deep acting constitutional remedies should be given as soon as the complete totality of the symptoms is available.

#### 2.10.2.1 The Law of Similars

In homoeopathy, the concept of individual diseases is not often recognized and is not seen as the most important, when compared to individuality. The life giving principle or force (which Hahnemann called the vital force) maintains harmony in human beings,

thus the disease state is disequilibria of the vital force. Homoeopathy is based on the Law of Similars therefore the simillimum, which is similar to the person's totality of symptoms is prescribed (Chatterjee, 1993:1-2). According to Watson (1991:92), the homoeopathic tenet that cure is through "similars", means that the remedy for any disease or illness is the substance, which when administered to a healthy person yields precisely the symptom-pattern of a given case.

#### 2.10.2.2 Suppression and Rebound

According to Ghegas (1994:A139, A140), "suppression" means symptoms may disappear while the pathological process continues. But when the suppressive medication is stopped the symptoms recur in a more intense and violent manner than prior to the therapy i.e. "rebound". "Suppression" in homoeopathy means the suppression of the organism's own self-healing effort and "rebound" means the desperate attempt of the body's healing power to assert itself against both the "disease" and the improper suppressive medicine. Suppression of skin disorders with steroid ointments etc. can have serious consequences for patient i.e. the disease is "pushed" inside. The best method to deal with this problem is by taking the complete history, and finding a constitutional remedy, the problem can be solved, or there can be a general amelioration of the patient without amelioration of the acne.

#### 2.10.2.3 Totality of symptoms

The totality of symptoms insisted on by Hahnemann does not refer only their numerical sum, but to their relative importance. This method involves prescribing a remedy because the symptoms of the patient are similar to symptoms found within the remedy-picture. Hahnemann wrote " so that each individual case of disease is most surely,

radically, rapidly and permanently annihilated and removed only by a medicine capable of producing (in the human system) in the most similar and complete manner the totality of its symptoms, which at the same time are stronger than the disease" (Watson, 1991:89). According to Watson (1991:90-3), the totality of symptoms (i.e. all of them) must be taken down, but only a portion of those symptoms may then be selected and utilized for finding the simillimum i.e. a selected partiality of the given totality of symptoms. This provides a more reliable guide to the curative remedy than the totality itself. The symptom similarity includes characteristic, keynote, complete, strange, rare and peculiar, and three-legged stool symptoms. Characteristic symptoms serves to indicate character, distinguish, a distinct peculiarity or quality. Keynotes provide differentiation between several remedies, which appear to be well indicated on other grounds. Symptoms only become strange or rare or peculiar in the context of the individual in whom they are found. These are easy to locate provided the prescriber is familiar with the signs and symptoms common to disease. The emphasis is not "what is present in this illness?" but rather "what is strange in this individual?"

According to Watson (1991:92), Boenninghausen had the idea that every symptom is a manifestation of the disorder in the whole person, and if each symptom is coming from the same source then each could be used to lead back to that source i.e. concomitant, location, aetiology, modality, and sensation.

#### 2.10.2.4 The Simillimum

The 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). According to Chatterjee (1993:1-2), to assess the simillimum that needs 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, with the hope of successful management of the acne. Homoeopathic medication is given in a minimum dosage just sufficient to restore the vital force to its original state of dynamic equilibrium.

Hahnemann advocated the single remedy on practical and theoretical grounds. He thought that the use of medical mixtures led to over-drugging of the patient, and realized the impossibility of predicting the synergistic effect of several drugs administered simultaneously. The homoeopathic provings are all of single substances and chemical compounds never as medicinal mixtures (Watson, 1991:92). Those symptoms or conditions which never appeared in the provings, but which have been repeatedly cured by the remedy, in practice, when prescribed on other symptoms present, can be used as simillimum prescribing (Watson, 1991:92). According to Watson (1991:92), while pathology is not altogether ignored, by homoeopaths, they rely on the symptoms for selecting the remedy. The remedies have been proven for their sense-perceptible symptoms alone, and these are necessary for the physician's guide to treatment. Homoeopaths claim that when the patient receives the one single remedy whose symptomatology most perfectly matches his own symptoms, the whole disease is entirely removed. The physician must be guided by the symptoms, and if he chooses a wrong remedy, it will usually have no effect.

**2.10.2.5 Simillimum remedies dispensed:**

The homoeopathic simillimum was obtained by matching it to the patient's totality of symptoms. There were many indicated remedies but the remedy most similar was

selected. The frequency of remedies prescribed and dispensed appears in Table 3 in Chapter 4. The homoeopathic indications of the simillimum remedies listed below were obtained from various Materia Medicas.

***a) Arsenicum album***: is used in skin disorders which are burning and itching and which are ameliorated by warmth (Ghegas, 1994:A138).

Affects head, face, nose and neck areas. Skins dry, cold and bluish with inflamed spots. Conical pimples (whitish or reddish) with burning and itching. Eruption of small red pimples, painful black pimples, itchy pimples small and tickling. Pustules filled with blood and pus (Clarke, 1999:186).

***b) Carcarea carbonica***: flaccidity of the skin, burning, smarting, itching. Eruption of lenticular red and raised spots with great heat, much thirst. Skin hot and dry during motion. Skin of the body rough, dry and as if covered with a kind of miliary eruption. Skin unhealthy, every injury tends to ulcerate. Encysted tumours (Clarke, 1999:350).

***c) Carcinosinum***: acne leaving keloid scars. Café au lait compexion. Moles numerous (Vermeulen, 1999:447)

***d) Causticum Hahnemannii***: acne affects the nose area. Warts on nose. Violent itching in the back. Burning itching of body at night and suppressed by mercury and sulphur. Skin injuries which heal and become sore again (Clarke, 1999: vol 1, 440).

***e) Ignatia amara***: itching easily better for scratching, disappears with sweat. Skin painful

> pressure. Itching from becoming heated in open air and sensitive to drafts (Vermeulen, 1997:880; Clarke, 1999: vol 2, 14).

***f) Lachesis muta***: little tumours in the skin with dark or blue spots between them on the face. The face is very red or bluish. Old scars show a blue colour. Except for the discoloration the skin remains intact (Ghegas, 1994:A142).

Papules raised and red. Skin very hard to heal, masses of blood pass through the pores. Ulcers surrounded by pimples. Papulae, warts, hard swellings. Eruptions of vesicles of a yellow or of a bluish-black colour (Clarke, 1999: vol2, 226).

Capillaries dilated, small wounds bleed much and sore places gangrenous. Pustular eruptions become black. Intense itching at night. Least touch or pressure produces black and blue spots. Confluent smooth, round, white pustules of size of a mustard seed, they contain a white fluid and itch intolerably (Vermeulen, 1997:1001-2).

***g) Medorrhinum***: yellowness of skin. Intense and incessant itching < night. Copper-coloured spots remain after eruption. Small pedunculated warts (Clarke, 1999: vol2, 418). Sycotic red nodes and skin cold. Red spots itching when scratched (Vermeulen, 1997:1098).

***h) Natrum muriaticum***: it is the principal remedy in the treatment of acne vulgaris. The acne located on the face and back, do not have a very characteristic appearance but the patient's appearance is notable. The skin on the face is hyperseborrheic, oily and dirty. The hairline of the scalp is marked by the coexistence of acne and scaly inflammatory lesions and the hair is greasy. The lips are dry, cracked and there's a medial fissure on the lower lip and the tongue is mapped. Palmo-plantar hyperhydrosis and hangnails are

common. The upper part of the body is thin, despite a good appetite. There is a tendency to depression and introversion (Jouanny, 1994:277).

Alopecia. Affects edge of scalp. Chronic comedonal acne. Greasy, oily esp. on oily parts. Dry eruptions on margin of scalp. Skin harsh, unhealthy or yellow. Painful scars and redness of old scars. Red spots preceded by sensation of heat in face. Comedones (Vermeulen, 1997:1182).

Itching and pricking in skin. Pain and redness of an old cicatrix (Clarke, 1999: vol2, 561).

***i) Phosphorus***: desquamation of skin and burning in the skin. Red spots and pale skin. Wounds bleed much, heal and break out again. Thin, foul, bloody pus. Anaesthesia of skin and burning or formication. Red streaks after scratching (Clarke, 1999: vol3, 792; Vermeulen, 1997:1293).

***j) Pulsatilla praetensis***: acne lesions have a cyanotic aspect, and are aggravated by foods rich in fat. Venous disorders and affections of the ear-nose-throat are seen and frequent menstrual disorders are experienced (Jouanny, 1994:276).

Symptoms are variable, the acne intermittent, worse from a high intake of either sweet or hot foods, such as chocolate, also aggravated by heat (Smith, 1994:15).

Menstrual disorders and acute ear-nose-throat complaints with acne. Chronic acne. Acne at puberty. Skin itches on being heated. Biting, itching < evening in bed and not > scratching (Vermeulen, 1997:1358).

Pale skin. Itching, burning and pricking. Frequent redness when parts cold. Pus copious and yellow (Clarke, 1999: vol3, 924-5).

***k) Staphysagria***: tingling sensation. Unhealthy skin, easily suppurating. Itching eruptions (Clarke, 1999: vol3, 1262).

Thick scabs, dry and itch violently. Itching changes location on scratching. Pedunculated figwarts. Skin symptoms alternating with joint pains. Itching eruptions, burning after scratching. Skin unhealthy, doesn't heal (Vermeulen, 1997:1519).

**2.10.2.6 Homoeopathic indications of Herbal remedies used in the complex**

These homoeopathic indications were also obtained from various Materia Medicas.

***a) Arctium lappa***: "Inveterate acne > touch; pimples; dry scaly skin; pustular yellow scabs; eruptions sticky on face, head and neck" (Vermeulen, 1997:1012).

***b) Berberis aquifolium***: The acne eruptions come in blotches. The rest of the skin is dry and scaly. Pimples extend from face towards the neck. It is an age-old remedy to clear the complexion of the face (Master, 1995:356). Acne; blotches and pimples; pimply, dry, rough, scaly skin; clears complexion" (Vermeulen, 1997:288).

***c) Echinacea purpurea***: "Small, red pimples on neck and face; recurring boils; carbuncles" (Vermeulen, 1997:703-4).

***d) Taraxacum officinale***: "Purulent pimples on face, cheeks, alae-nasi, corners of mouth; pustules; unhealthy sycotic skins" (Vermeulen, 1997:1575-6).

**2.10.3 Polypharmacy**

Polypharmacy covers any prescribing technique in which two or more remedies are prescribed simultaneously, either in alternation with each other or as a combined

formula (complex). The two methods of prescribing are according to individualization or diseased-based. Individualization prescribing is when several remedies are given concurrently or alternately according to each patient's individual case. Diseased-based prescribing is whereby multiple remedies are prescribed on the basis that they all have a degree of similarity to a particular disease process without regard for individual peculiarities. Low potencies are more frequently employed, ranging from tincture to 6c, and the prescription is repeated on daily (Watson, 1991:71).

Hahnemann was not averse to prescribing several remedies simultaneously or in alternation with one another, on the contrary. By combining several remedies together bearing much similarity to a specific disease/condition, i.e. acne, and prescribing them for that specific disease, the practitioner is able to avoid the necessity to individualize each case and is thus able to give every patient with acne, the same prescription. The assumption is that whichever remedy in the combination is most similar to the acne of the person being treated, will act or the other, non-indicated remedies will do nothing, or that a group of remedies known to bear similarity to the typical symptoms of acne will, collectively, bring about a curative response (Watson, 1991:73).

According to Watson (1991:75-6), the main arguments against polypharmacy, is firstly that the remedies were proven singly, thus they ought only to be given singly, as no-one can predict how several remedies will act on an individual when given simultaneously. The worse that can happen after a combined prescription is that the patient didn't get better which can also happen when a single remedy is administered. Secondly the practitioner will be uncertain as to which remedy worked, assuming a curative response takes place at all. Most patients couldn't be bothered whether one remedy or six were

prescribed, as long as they got better. Only the practitioners seem to be bothered and frustrated. Polypharmacy is best suited to serious case, where disease is presenting in several different ways simultaneously, and to cases in which palliation is more desirable or more likely than cure. Polypharmacy will in certain cases, achieve the desired result in a shorter period of time than would have been the case using single remedies.

### 2.10.4 Other complementary medicines used in treating Acne vulgaris

According to Gardiner *et al.* (2001:104), although acne treatments are effective and can often be purchased inexpensively without a physician's consultation or prescription, some patients prefer a more "natural" approach. Most of them are interested in lifestyle matters with the hoped to remove acne symptoms (cleansers, diet, exercise), others who recognize the relationship between stress and more severe outbreaks want to pursue stress management techniques and others are interested in herbal remedies. There has been an increased demand for botanical medicine due to the movement towards non-toxic healthcare. To understand and know the properties of plant substances and how to use them clinically is important (Hoffman, 1997:76).

There have been various studies conducted at the Durban Institute of Technology, using herbal remedies or complexes. Barklie (1999) used the same herbal complex as the one used in this study, and compared it to a homoeopathic complex, in the treatment of Acne vulgaris. Dhanraj (2001) investigated the efficacy of *Echinacea angustifolia* as an antimicrobial. Ramlachan (2002) investigated the efficacy of certain *Compositae* species (*Arctium lappa, Calendula officinalis* and *Echinacea purpurea*) herbal extracts by comparing them to Nystatin®. This was an *in vitro* study to assess the inhibitory effects

of the remedies on *Candida albicans* growth. The above studies are just a few of the many herbal studies conducted at the Durban Institute of Technology.

Many studies using complexes or polypharmacy, were also conducted at the Durban Institute of Technology i.e. Barklie (1999) compared two complexes (homoeopathic complex vs. herbal complex) in the treatment of Acne vulgaris, and Lee (1997) investigated the effects of a different homoeopathic complex on Acne vulgaris.

#### 2.10.4.1 Phytotherapy

Phytotherapy is an empirical system of medicine that uses plant remedies only destined to support the healing life-force, in disease treatment, thus complementary to homoeopathy (Gaier, 1991:423).

If herbs are looked at as sources of valuable chemicals, their healing power is limited, for beyond the physical level, they work on the level of the life force also. The herbs are used not so much to treat named diseases but to implement a shift in underlying physiological processes so the body can heal itself. Herbs were traditionally used to affect organic physiological responses throughout the body thus reinforcing the body's own curative powers. For many herbs the therapeutic reaction may be more in the relationship of the various constituents found in the formulations of multiple herbs, rather than on any particular biochemical agent. These complementary actions or their combined action may have different effects depending on the condition and constitution of the individual. By treating not only the manifestations of disease but also its underlying cause, we can achieve true and lasting effects from herbal therapy (Hoffman, 1997:16; Tierra, 1999:11(1), 6-7). The relationship between clinical observation and the

knowledge of plant properties must be coherently integrated to achieve clinical outcomes consistent with botanical medicine (Kenner, 1998:188).

All the symptom-pictures of remedies fitting the types of acne patients should be combined to form a synergistic remedy complex that cures the signs and symptoms of Acne vulgaris. A herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea and Taraxacum officinale)* was used by Barklie (1999) and was compared to a homoeopathic compex. There were no statistically significant differences with respect to the 3 variables of interest i.e. non-inflamed, inflamed and total lesions, between the herbal and homoeopathic complexes. Both the complexes proved to be equally effective in reducing the acne lesions.

**2.10.4.2 Herbal Remedies used in the Herbal-complex**

***2.10.4.2.a) Arctium lappa:*** (Burdock: *Compositae* family) acts as an alterative, antiseptic, anti-tumour, diaphoretic, antipyretic, diuretic, depurative, hypoglycemic and, thus useful for skin afflictions e.g. acne, dry scaly eruptions, abscesses, etc. (Hoffman, 1997:76-9). According to Wood (1997:137-151), it cleans the liver and kidney and corrects a “polluted” bloodstream, ridding the system of toxic waste products thus restoring functions of the skin. It has a cooling and drying effect on the skin as well heals dry, scaly skin and poor healing wounds. Skin diseases depending upon a deprave state of the cutaneous tissue and less upon the state of the blood itself are conditions in which Burdock is used. According to Boericke it is very important in skin therapies. It is a strong plant with a slow, steady, and hardy influence, rejuvenating old chronic conditions by acting primarily on the liver, kidneys and skin. Hoffman (1997:76-9), states that Burdock will move the body to a state of integration and health, removing

such indicators of system imbalance as skin problems. Externally it may be used as a compress or poultice to speed up healing Burdock seeds (which are non-toxic) influences sebaceous glands thus useful in adult acne. The oily seeds are said to restore the smoothness of healthy skin. The local use of seedling roots is effective in acne. Combine with *Echinacea* for skin complaints.

Ramlachan (2002) found that *Arctium lappa* was an effective antifungal (*in vitro*) in reducing or inhibiting the growth of Candida albicans, when compared to 62% ethanol, over 18-36 hours. However there were no differences noted between the groups i.e. p= 0.050 and 1.000. When compared to Nystatin®, *Arctium lappa* showed a milder antifungal effect i.e. p= 0.000, in reducing the growth, over 18-36 hours. *Arctium lappa* and *Echinacea purpurea* showed similar inhibitory effects on Candida albicans growth, over 18-36 hours i.e. p =.0.884 and 1.000, thus *Arctium lappa* ia antifungal.

***2.10.4.2.b) Berberis aquifolium*:** (Mountain-Oregon grape: *Berberidaceae* family) acts as an alterative, anti-infective, anticonvulsant, carminative, antibiotic, and immune-stimulator and has antipyretic and anticancer effects and is non-toxic. Combine with A*rctium lappa* for chronic skin conditions e.g. acne (Murray, 1995:165; Hoffman, 1997:186). The effects of some alkaloids (berberine – an alkaloid of *Berberis aquifolium*) and flavonoids, which are major ingredients in some Japanese Kampoh drugs (Japanese –Chinese traditional herbal medicines) i.e. Seijo-bofu-to and Keigai-rengyo-to, are experientially known to be efficacious by internal use for the treatment of acne vulgaris, mediated by the inhibition of lipogenesis in the sebaceous glands of the hamster ear, an excellent animal model of human sebaceous glands. In the study, by Seki & Morohashi (1993), it was found that there was a 54-64% inhibition of sebaceous

lipogenesis by berberine. Berberine one of the main ingredients of *Coptidis rhizoma*, which has been used as a folk medicine and belongs to the isoquinoline alkaloids, possesses antibacterial and anti-inflammatory activity. Both preparations of Japanese Kampoh drugs mentioned above, contain *Coptidis rhizoma,* which is rich in berberine (Seki & Morohashi, 1993:56-60). Hoffman (1997:186), states that, alteratives, like *Berberis aquifolium*, gradually alter and correct a "polluted" condition of the blood stream and restore a healthier functioning. It is most often used in the context of skin conditions, the roots of which lie deep within the metabolism of the individual.

According to Murray (1995:165-6), Berberine exhibits a broad spectrum of antibiotic-activity. Its action against pathogens is actually stronger than that of antibiotics commonly used in the treatment of diseases caused by these pathogens. It also activates macrophages, which are responsible for engulfing and destroying bacteria, viruses etc. hence purifying the blood.

***2.10.4.2.c) Echinacea purpurea:*** (*Compositae* family*)* acts as an antimicrobial, antiseptic, alterative, anti-inflammatory, anaesthetic, blood purifier, immune-stimulator and has anti-cancer effects as well as used in wound healing (Hoffman, 1997:196-7). *Echinacea purpurea* has a potent antibody enhancing ability and indicates no immunosuppression with long-term use (Bodinet & Freudenstein, 1999:59). It is a remedy, according to Wood (1997:244-6), for autoinfection and where the bloodstream becomes slowly infected, elimination is imperfect, the body tissues become altered and there is septic action within the fluids and tissues, resulting in inflammatory and septicaemic processes. It's used for abscesses, boils, poor wound healing, sloughing skin, pimples and dry, dirty skin, and clears eruptions. Echinacea, according to Murray (1995:95-103), promotes tissue regeneration, reduces inflammation and maintains the

structure and integrity of the connective tissues and ground substance. It's used internally for infections (mostly bacterial infections) and externally for burns, abscesses, and other inflammatory skin conditions. It is possible that it possesses some anti-infective properties that prevent bacterial adherence. It is non-toxic if used at recommended doses and parenteral administration is contraindicated in pregnancy and those with allergic tendencies especially to Asteraceae family.

Ramlachan (2002) found that *Echinacea purpurea* was an effective antifungal (*in vitro*) in reducing or inhibiting the growth of Candida albicans, when compared to 62% ethanol, over 18-36 hours. However there were no differences noted between the groups i.e. p= 0.120 and 1.000. When compared to Nystatin®, *Echinacea purpurea* showed a milder antifungal effect i.e. p= 0.000, in reducing the growth, over 18-36 hours. Dhanraj (2001) stated that *Echinacea angustifolia*, another herb of the *Echinacea* species, in 62% ethanol reduced the growth of *Staphylococcus epidermidis* (one of the microrganisms found in Acne vulgaris) and is able to influence bacterial growth, whereas the tincture in 30% ethanol is totally ineffective. It was noticed that the diameter of the inhibitory zones were increased and that *Staphylococcus epidermidis* (the normal commensal of skin) is sensitive to *Echinacea angustifolia* in 62% ethanol, thus *Echinacea angustifolia* is an effective antimicrobial.

***2.10.4.2.d) Taraxacum officinale:*** (Dandelion: *Compositae family)* acts as an alterative, stimulant, bactericidal, intoxicant, and depurative thus useful for inflammation, abscesses, eczema, and is non-toxic (Hoffman, 1997:216). Its primary pharmacological activities relate to the liver function, digestion and diuresis (Murray, 1995:88). While influencing the liver, dandelion purifies the blood thus assisting in acne (Wood,

1997:466). Vukovic (1999:146), agrees that dandelion root improves liver and digestive function. Like burdock root, it has gentle laxative and diuretic properties to flush toxins out of your system. Dandelion and burdock are rich in minerals, like potassium and magnesium, making them ideal not only for cleansing but strengthening too (Vukovic, 1999:146).

Hoffman (1997:79), suggests the use of the above herbs for Acne treatment.

## 2.11 SUMMARY

Acne is an androgen-dependent inflammatory disease of the sebaceous glands, affecting women from adolescence to menopause with psychosocial implications due to cosmetic disfigurement, therefore and counselling should be tailored to the requirements of individual women (Callan, 1997:36). According to McBride & Simpson (2000:12), acne is a source of distress with considerable psychological and social impact. As a result of increased understanding of the disease, effective treatment options and referral, there has been significant reduction in the morbidity of the disease. If there is early and effective treatment with regular review and referral, the cosmetic effect and psychological effect of this common and disfiguring disease of acne is reduced thus ensuring long-term benefits for the patient.

According to Tan *et al*. (2001:443), the delay in seeking medical attention for acne is very often an obstacle to cure and it is imperative that there is early intervention to prevent the risk of scarring and other consequences. Accessible, accurate, community-based education on the natural history of acne, pathogenesis, risk of sequelae, the effectiveness and expected duration of treatment, and the importance of prompt medical

attention, is necessary for a complete understanding and removal of the disease. Due to the inadequacy of information by current, there are increasing misconceptions on the causality and perceptions of patients. By incorporating information on treatment preferences (in terms of severity and gender), patient input on treatment selection can be facilitated, understanding of treatment options enhanced and patient compliance.

The present allopathic treatment of acne, brings with it severe side-effects, frequent relapses, and resultant frustration, thus causing patients to seek alternative forms of treatment. With dietary modifications, there has been significant improvement as well as with Ayurvedic medications. Homoeopathic simillimum, homoeopathic complexes and herbal complexes (i.e. McDavid (1994), Van Niekerk (1999), Lee (1997), and Barklie (1999) as mentioned earlier) have all shown to be effective in acne treatment, but there has not been a comparison done on homoeopathic simillimum and a herbal complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea* and *Taraxacum officinale*) for acne, to assess which was more effective, thus there is a need to compare them to assess their relative efficacy.

The general health of the patient is to be considered in the treatment of Acne vulgaris, in terms of therapeutic measures. One cannot treat acne as a disease only, as it is only a manifestation of some internal disturbance which must be corrected, eventually resulting in the disappearance of acne, thus further emphasizing the need for alternative treatment i.e. homoeopathy (McDavid, 1994:32).

A search of the indexes of Medline (1993-2003) and British Homoeopathic Journal (1982-2003) reveals no comparison being done on homoeopathic simillimum and a

herbal complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea* and *Taraxacum officinale)* in the treatment of acne vulgaris thus stressing the need to compare the effectiveness of a herbal complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea* and *Taraxacum officinale)* to homoeopathic simillimum.

# CHAPTER THREE

# MATERIALS AND METHODS

## 3.1 STUDY DESIGN

### 3.1.1 Recruitment & Patient selection

Subjects of both sexes, between 18 and 40 years, were recruited via advertisements, distribution of pamphlets and circulars, posters, referrals and verbal communication, by convenience sampling from the greater Durban area. Posters containing details on the research, to invite participants to join the trial, were placed on notice boards at technikons, universities, health shops, pharmacies and shopping centres in the Durban and surrounding areas.

### 3.1.2 Establishing a baseline reading

Only persons who had not received any treatment for acne vulgaris in the preceding 1 month were included in this research. Ideally patients should be off any treatment for at least 3 months before starting research but in practice this is normally impossible. Burke & Cunliffe (1984:83) recommend a minimum of 3 months wash-out period before a clinical trial in order to establish an adequate baseline.

The baseline reading in this proposed study was established at the first consultation, when the patients completed the perception questionnaire, prior to case taking, and also the grading and counting of the various lesions at the first consultation. This was used to assess the acne before the treatment was administered, then the acne was compared to the baseline readings at subsequent consultations

### 3.1.3 Subjects selection

An independent person handled the double-blind randomized allocation of subjects into 2 equal groups of 15 i.e. herbal-complex (Group 1) or homoeopathic simillimum (Group 2) thus each patient had an equal chance of being selected for each group, and their corresponding medicines. As patients entered the research project, they were allocated to their appropriate groups (i.e. herbal-complex or homoeopathic simillimum), according to the randomization list kept by the independent person. All patients recruited first read and understood all that was required in the information letter (Appendix A), and the researcher elaborated where necessary. If they met the selection criteria and were willing to participate in the study, then only did they sign the information letter and consent form (Appendix A & B).

## 3.2 SAMPLE SIZE

Due to the fact that Acne vulgaris is a very common disorder it is possible to make use of a large sample group. Although there is a high incidence/prevalence of acne, the sample size was restricted to 30, due to firstly, the viability within the clinic situation not having a high patient turnover, and secondly, limited space due to internship and research patients using these facilities, hence the clinic situation could not facilitate a larger sample size. A minimum sample of 30 patients was required for statistical analysis, however 34 participants (between 18 and 40 years of age) were recruited and randomly divided into 2 equal groups of 17 each (i.e. herbal-complex group and homoeopathic simillimum group), which allowed for two potential dropouts per group.

## 3.3 SELECTION CRITERIA

### 3.3.1 Inclusion criteria:

a. Subjects could be male or female.
b. Subjects had to be between the ages of 18 and 40 years of age.
c. Patients had to have Acne vulgaris lesions as defined by Burke & Cunliffe (1984:83-90), with a minimum of 10 non-inflamed and/or inflamed lesions.
d. Due to the interaction of different drugs, if the patients were on any form of medication and still wanted to participate in the trial, it was discussed with the patients and was preferred, by the researchers, for the accuracy of this research study, to discontinue any other form of medication that they were on, 4 weeks before the trial started and during the trial.
e. They had to be willing not to change their lifestyle or dietary habits for the duration of the trial.
f. Subjects had to be literate to be able to understand and complete the consent forms and questionnaires.
g. Patients had to be from the greater Durban area with easy access to The Durban Institute of Technology – Steve Biko Campus.
h. Patients participated in this study voluntarily.

### 3.3.2 Exclusion criteria:

a. Any patient who was pregnant, lactating, suffering from a chronic disease or undergoing any other form of prescribed treatment or medication for Acne vulgaris.
b. Any patient who was undergoing any dermatological, antibiotic, hormonal or vitamin and mineral therapies or taking Schussler tissue salts.

c. Patients who suffered from acne fulminans, acne rosacea, or conglobate acne.
d. Patients who could not abstain from any form of chronic medication (e.g. Antihypertensives) for the duration of the study.

## 3.4 MEANS OF COLLECTION AND TREATMENT OF THE DATA

All the data required was obtained from the participating patients at the Durban Institute of Technology- Steve Biko Campus Homoeopathic Day Clinic. The researcher carried out the data collection. The patients in both groups were required to complete the perception questionnaire (Appendix C), after meeting the selection criteria and signing the information letter and consent form (Appendix A & B), at the commencement of the study and one at each follow-up i.e. 4 consultations, thus a total of 4 questionnaires were completed for each patient. Screening of the completed perception questionnaires was done, to determine whether all questions were filled out correctly and whether all respondents met the selection criteria. The questionnaires were handed back to the researcher for the required analysis and statistics. The questionnaires assessed the patient's perception to the treatment in the form of a semantic differential scale, which provided values for each question, which was then stored onto a spreadsheet and a total and percentage calculated for each questionnaire.

The data concerning the clinical manifestations was reported by means of a standard diagnostic questionnaire incorporated into the case history (Appendix F). Each patient's acne was graded and the number and types of lesions were tabulated on the face using the visual-tactile grading and Leeds Technique for counting. These were done at each of the 4 consultations, thus having 4 readings in total for each patient. Each patient's case was repertorised and the homoeopathic simillimum was found, whether the patient

was on the herbal-complex group or homoeopathic simillimum group. The data was interpreted by non-parametric statistical tests. From the case histories and physical examinations, data about the patient's health and habits were used to, help the researcher decide on an appropriate homoeopathic medicine, diagnose the case and diagnose any concomitant diseases. The data was transferred onto spreadsheets, the values of which were used to test the hypothesis.

## 3.5 ETHICS

The Faculty of Health Sciences, Research and Ethics Committee of the Durban Institute of Technology, before the commencement of the clinical trial, approved this research. The Durban Institute of Technology Research Ethics Policy and Guidelines were strictly adhered to. All the patients that were recruited first read and understood all that was required of them in the information letter (Appendix A), and the researcher elaborated and carefully explained to the patients the procedures of the trial. If they met the selection criteria and were willing to participate in the study, then only did they sign the information letter and consent form (Appendix A & B). An informed consent form was obtained from each patient. The patients were reassured that the research data and their details would be handled and treated with strict confidentiality.

## 3.6 INTERVENTIONS

The herbal-complex consisted of mother tinctures of *Arctium lappa*, *Berberis aquifolium*, *Echinacea purpurea* and *Taraxacum officinale* (62% alcohol each). The individual herbal remedies in the complex were provided and prepared (according to the German Homoeopathic Pharmacopoeia) by Parceval and Natura (Pty) Ltd laboratories and combined in equal parts at the Durban Institute of Technology-Steve Biko Campus

Homoeopathic laboratory. The complex was made up in 62% alcohol and dispensed in 50ml amber glass dropper bottles by the independent person.

For the simillimum treatment, the Durban Institute of Technology- Steve-Biko Campus Homoeopathic Laboratory provided the medication/remedies. These remedies were dispensed in powder packets (a minimum of 3 lactose powders for each prescription). Powders impregnated with X number, i.e. approximately 10-12, granules of the respective remedy, which were triple impregnated at a 1% v/v in the Durban Institute of Technology- Steve-Biko Campus Homoeopathic Laboratory. These were prepared (according to the German Homoeopathic Pharmacopoeia) and dispensed by the independent person.

## 3.7 TREATMENT AND MEASUREMENT

All the patients who satisfied the requirements and selection criteria underwent treatment. The researcher interviewed each patient and a complete homoeopathic and medical case history was taken (Appendix F), a general examination was performed and the acne lesions were measured using a vernier calliper (borrowed from the Department of Homoeopathy, Durban Institute of Technology). Both the Grading Technique (visual-tactile) and the Leeds Counting Technique (Burke & Cunliffe, 1984:83-92) (Appendix D & E) were performed. For lesion measurement and counting, the researcher was assisted by an independent person (mainly 5$^{th}$ year students) to prevent bias and subjectivity on the part of the researcher. Photographs taken before, during and after, as done by McDavid (1994), would have shown how effective the treatment proved to be, thus proving to be a very useful objective tool. The visible results in the photographs would show proof and visually explain the results obtained from the grading and lesion

counting, thus being a 3-dimensional approach for acne assessment. In this research, photography, together with grading and lesion counting, would have accurately assessed the patients' acne, but photography was not available for assessment of acne in this research, hence there were no visual results to correlate with the results obtained from the grading and lesion counting. This entire procedure took between 1-2 hours then a prescription note was completed and the medication was dispensed, according to the randomization list.

The treatment program lasted 9 weeks with 4 consultations 3 weeks apart. The patients' conditions were assessed at each consultation. The treatment period was shortened, to reduce the discomfort index and some psychological implications of the disease, as patients want quick and effective results. For the purposes of a research study, 9 weeks has proven to be adequate to obtain a reaction. If necessary and desired, after the 9 weeks, the patients could seek further treatment at the Homoeopathic Day Clinic.

For each patient a simillimum had to be selected, prescribed and displayed together with the herbal-complex, on the prescription note, then forwarded to the independent person, who dispensed the appropriate medication and dosage according to the randomization list. Simillimum selection/prescription was based on homoeopathic principles, i.e. the Law of Similars and a qualified homoeopath, oversaw the selection of the homoeopathic simillimum by the researcher. All prescriptions were authorized and signed by the clinician/qualified homoeopath. The totality of the symptoms as presented by the patient and those symptoms, which were elicited by careful and extensive case taking by the researcher, were necessary for the homoeopathic simillimum selection. The symptoms were repertorised to find what a homoeopath would call a constitutional remedy for the

patient. The symptom picture of the patient was matched with the symptom picture of a remedy, selected from the Materia Medica, in order to prescribe the most indicated remedy. The researcher individually decided upon the potency and dose, i.e. usually 3 powders but many more powders e.g. 25 powders could be prescribed depending on the patient's symptoms. The dosage could vary in that one potency e.g. 30ch, or ascending potencies e.g. 30ch, 200ch, M or L.M. potencies could be used. In this study mainly ascending potencies were used and 3 powders were given to each patient. The rationale for using high homoeopathic potencies rather than low potencies, was that acne is a chronic disease and most of the patients had quite longstanding acne with scarring, and to effectively move towards cure, accurate prescription of the simillimum, of high potencies were decided upon and used.

Patients on the herbal-complex were allocated two 50ml bottles of the herbal-complex at the initial consultation. The two 50ml bottles were to last 9 weeks. They were instructed to take 10 drops of the herbal-complex in a little water twice a day, 30 minutes before meals. Those patients on homoeopathic simillimum, according to the Law of Similars, each received 3 medicated-powders on the first and third consultations respectively and were instructed to take a powder each day for 3 days, 30 minutes before meals. Patients were required to take the prescribed amount of medication per day as directed and not to expose the medication to any situation that might antidote it (Appendix G).

The independent person, who dispensed the medicine to the patients, provided the relevant instructions as how to take their medicine. The herbal tinctures in the complex were in liquid form and had a distinct colour, and the powders could not be impregnated with the complex. In order for impregnation to take place the tinctures would have to be

diluted, then potentized, then finally impregnated. These procedures would affect the biochemistry and structure of the complex, whose effects then would be unpredictable as the effects of the resultant complex have not been proven or used as yet, thus the difficulty in trying to make the 2 medicines visually indistinguishable. Although the 2 types of medication were visually distinguishable, patients were instructed not to reveal any information in this regard to the researcher or other participants. Neither the researcher nor the patient knew who was issued the herbal-complex or homoeopathic simillimum and the patients were instructed not to disclose the form or dosage of treatment that was taken, to the researcher.

At the **first follow-up consultation** the patient completed the perception questionnaire (Appendix C), lesions were measured and counted again and a general examination performed. The researcher noted whether the patient's symptoms worsened (i.e. initial aggravation) and whether the patient had improved, deteriorated, or remained unchanged during the treatment, then it was decided whether to change, stop or continue treatment. The researcher could repeat the homoeopathic simillimum remedy, or increase the potency, etc. as seen fit, however the treatment regimen of patients in the herbal-complex could not be altered, as a supply was only given at the first consultation, to last for the duration of the study. At the end of the first follow-up, although the researcher filled out a prescription note, no treatment was given for either group. It was necessary not to prescribe, for the patients on the homoeopathic simillimum group as it allowed time for the remedy to act effectively. It was decided upon prior to the study, that no medication would be prescribed for either group, at the first follow-up. On observation, and with the researcher being totally unaware of which group the patients in concern were in, all the patients in both groups continued to improve at

the first follow-up, thus it was necessary not to prescribe any medication at this follow-up. At this follow-up the simillimum remedy could be repeated, or the potency decreased or increased, or placebo powders given, but the researcher opted not to prescribe anything for either group.

At the **second follow-up consultation**, the patient again completed the perception questionnaire (Appendix C), lesions were measured and counted again and a general examination performed again. The researcher also noted whether the patient's symptoms worsened and whether the patient had improved, deteriorated, or remained unchanged during the treatment, then it was decided whether to change, stop or continue treatment. On the second follow-up consultation, the patients in the homoeopathic simillimum group received a second set of powders, either the same remedy but of either a higher or lower potency or a different remedy selected based on symptoms presented at the second follow-up consultation. At this follow-up consultation, 3 or more powders could be prescribed but the researcher selected only 3 powders for all the patients on the homoeopathic simillimum treatment. The patients on the herbal-complex treatment did not receive any more medication as they had received a supply at the first consultation, and this supply was to last for the entire duration of the study.

The **third follow-up consultation** followed the same procedure as the 1$^{st}$ follow-up consultation. At the third follow-up consultation, the patient completed the final perception questionnaire (Appendix C), lesions were measured and counted again and a general examination performed again. The researcher also noted whether the patient's symptoms worsened and whether the patient had improved, deteriorated, or remained unchanged during the course of treatment. At the end of the third follow-up, although the

researcher filled out a prescription note, no treatment was given for either group. For the homoeopathic simillimum group it was necessary not to prescribe as it allowed time for the remedy (given at the second follow-up consultation) to act effectively as the patients still continued to improve at the third follow-up. At this follow-up the simillimum remedy could be repeated, or the potency decreased or increased, or placebo powders given, but the researcher opted not to prescribe anything for either group.

## 3.8 ASSESSMENT

The effectiveness of the Herbal-complex and the homoeopathic simillimum were measured using subjective and objective data, at all 4 treatment sessions. At each of the visits, each of the patients had to complete a perception questionnaire. The questionnaires were available in both English and Zulu and the counting (objective) measures were done too.

At the first consultation each patient was assessed and interviewed and the lesions were graded, and the number and type of lesions (i.e. inflamed and non-inflamed lesions) tabulated. Acne vulgaris lesions on the face were only counted. The patients were required to participate in the trial for 9 weeks. Each patient attended 3 follow-up consultations, 3 weeks apart, at which time; the researcher observed the patient's lesions and any changes in number, type or grading were noted. Patients were observed by the same researcher, under the same lighting conditions (i.e. overhead fluorescent light), at each visit. Clinical manifestations of acne vulgaris in the patients were measured using the visual-tactile Grading Technique and Leeds Counting Technique (Burke & Cunliffe, 1984:83-92) (Appendix D & E).

## 3.9 CLASSIFICATIONS AND GRADING OF OBJECTIVE DATA

There are two methods for classifying and grading acne i.e. firstly an overall assessment of the acne severity in a particular area i.e. the face (grade between 0 to 10), is accurate, rapid, and useful in the clinic situation, and secondly for use in detailed therapeutic trials, the use of a counting system is needed to distinguish between active and less active acne lesions. These techniques are simple and reproducible when carried out with attention to detail (Cunliffe *et al.*, 1991). Both these methods were used in the trial.

### 3.9.1 THE GRADING TECHNIQUE

The acne grading system includes assessment of the size and density of lesions, the intensity of lesional inflammation and formation of scars. This morphological classification seems feasible and reliable however quantification of severity is difficult. It is possible to count, define and describe each lesion but this is not feasible in daily practice. The sites usually graded are the face, chest, and back and are graded on a scale of mild, moderate or severe. Acne grading uses a pattern diagnosis system i.e. a global/total evaluation of lesions and their complications e.g. drainage, haemorrhage and pain, and taking into account the total impact of the disease influenced by the disfigurement it causes (Cunliffe *et al.*, 1991:495-9). Guidelines for grading acne are:

1) A **0-10** visual-tactile grading system.
2) A careful count of the following lesions - papules, pustules (active and less active), deep pustules, nodules, cysts and macules.
3) 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.

4) Severity of acne according to a **0- 4** scale with half point ratings where, **0** = no acne, **1** = minimal acne, **2** = mild acne, **3** = moderate acne and **4** = severe acne (Cunliffe *et al.*, 1991:495-9).

### 3.9.2 LEEDS TECHNIQUE FOR ASSESSING ACNE - THE COUNTING TECHNIQUE

The lesions were divided into inflamed and non-inflamed lesions as follows:

**a) Non-inflamed lesions** are blackheads and whiteheads and each type is assessed. Any intermediate lesions are counted according to their major component. Prominent follicles, milia or trichostasis spinulosa are common and should not be counted as acne lesions as they affect the results. Non-inflamed lesions consist of open and closed comedones. Acne manifested only by non-inflammatory lesions can rarely be characterized as severe, unless the number, size and extent of such lesions are so overwhelming so as to be considered severe (Cunliffe, 1989:115-6).

**b) Inflamed lesions** are either superficial (papules and pustules), or deep (deep pustules, nodules and cysts). Lesion severity is graded as mild, moderate or severe.

I) Superficial papules and pustules vary in size from 0.1cm (with minimal erythema) to 0.5cm (with marked flare). The smaller less inflammatory lesions are referred to as ‘less active papules or pustules’, and the larger erythematous lesions as ‘active papules or pustules’. There are some intermediate lesions, which fall between these two types and are defined in practice according to their major component.

II) Deep lesions are mainly nodules which are 0.5cm or larger. Some deep lesions have a pustular component and are referred to as deep pustules. Palpation is

essential as some nodules are invisible but easily palpable. Suppurative nodular lesions are referred to as cysts.

III) **Macules** represent the resolving phase of either superficial or deep lesions and may be either large or small. They should be included in acne assessment as they contribute to the overall degree of inflammation. As they evolve, they become brown and much less distinct thus making counting of individual macules very difficult (Cunliffe, 1989:115-6)

A vernier caliper (which was borrowed from Durban Institute of Technology - Steve Biko Campus Homoeopathic Department) was used to measure the size of the lesions in order to classify them (Burke and Cunliffe, 1984:83).

The clinical diagnosis of severe acne should be based on the presence of any of the following aspects: persistent or recurrent inflammatory nodules, extensive papulopustular disease, scarring, persistent purulent drainage from lesions or presence of sinus tracks. Apart from the examination of the skin, other factors from the patient's standpoint i.e. psychosocial aspects, occupational consequences of the disease, inadequate therapeutic responsiveness etc. is necessary to determine the severity of acne. These factors should be taken into account as they influence the choice of remedy chosen (McDavid, 1994:19).

Inflammatory acne lesions are usually located on one or more of the following sites: face, neck, back and chest (McDavid, 1994:19). According to Cunliffe (1989:116), since acne spots are liable to spread to all acne-prone areas of the face, it is necessary to grade the whole face, even in cases where lesions are not widespread. This area

includes the chin and anterior part of neck. Shoulders are included in both chest and back assessment excluding the arms. Because the back and chest are hard to define, counts for clinical trials are usually confined to the face.

Cunliffe (1989:115), suggests two doctors should examine the patients, to confirm the reproducibility of the method. Patients have to be counted at every consultation to compare reproducibility by the same doctor and a comparison between doctors to be made on the same day of consultation.

The techniques of grading and counting are not perfect, but they are reproducible. There has not been much improvement in the technique nor have there been any further pitfalls noticed (Burke & Cunliffe, 1984:87-8). Assessment should be by individual lesion counting, although this is time-consuming and probably needs greater practice than grading and on a day-to-day management of patients an overall grading assessment is required (Cunliffe, 1989:121).

Lesion counting is not easy and perfection takes time. To avoid errors, attention to the following points, according to Burke & Cunliffe, (1984:87-8), is helpful:

1) The patient must be seated comfortably for the observer to move around him easily to count each area.
2) Good background fluorescent lighting is needed. A Brighton 1001 lamp with a cold fluorescent light, which can be moved easily to illuminate both sides of the patient during examination, is recommended, but this facility was not available, thus normal lighting was used.

3) When counting, the face is divided into right and left sides and both sides are counted. In some patients the lesions are clustered around the midline, making a right-left division difficult, thus the forehead, the cheeks and chin are counted separately and the counts combined. Some observers may count lesions from one area only. As acne affects several sites and may improve at one site or deteriorate at another, it is preferable to count the whole face.

4) Palpation is necessary, as some macules may look like nodules, but on palpation show no depth. Conversely, a nodule may be hardly visible but can be felt to lie deep to the skin.

5) Stretching of the skin increases the visibility of the number of whiteheads and blackheads, but as the extent or degree of stretching may vary, this is not permitted. For similar reasons, it is recommended that no lens be used. If a lesion is impalpable and not obvious with good lighting, then such a lesion is best ignored.

All the above recommendations except the lighting recommendation, were adhered to and performed for each patient at each consultation.

**c) Pitfalls for the unwary** (Cunliffe, 1989:117)

*1) Prominent follicles*. Around the nose and on the chin, there is often a confusion of non-inflamed lesions with prominent follicles, thus in therapeutic trials, it is recommended that non-inflamed lesions are not to be counted either on the nose or around the edge of the nose.

*2) Sandpaper acne*. This is present in 2% of youngsters. ‘Sandpaper’ acne is seen commonly on the forehead of patients and are characterized by many (usually 100

or more) very superficial lesions, which are impossible to classify correctly, thus such patients should be excluded from clinical trials.

*3) Hair styles.* Long, uncut hair and certain modern hairstyles, may mask non-inflamed lesions, therefore non-inflamed lesions should be counted around the hairline. However inflamed lesions are easily recognizable in this area.

*4) Shaving*. Patients may grow a beard or moustache during the trial. This should be dissuaded as it complicates the results. Patients may develop a low-grade folliculitis on the chin and neck due to shaving trauma, however the papules and pustules associated with folliculitis are less easily felt than acne lesions. Patients should shave daily at a constant time preferably, as stubble can affect the interpretation of all lesions.

*5) Cosmetics*. Despite being advised not to use make-up, some females will still use make-up. Any make-up must be removed and the patient is observed 30 minutes later, when the erythema caused by washing has settled.

*6) Ultraviolet radiation*. This camouflages the non-inflamed lesions and makes the inflamed lesions look less inflamed thus trials should not be performed in summer.

*7) Other dermatoses*. Sycosis barbae may occur in association with acne and low-grade seborrhoeic eczema may stimulate a primary irritant dermatitis seen with treatments like benzoyl peroxide.

**d) Other methods for assessing acne**

The grading technique, Leeds Counting technique and palpation were done on each of the patients in this study, to assess the severity and extent of their acne. The following techniques or methods for assessing acne, especially photography, which is a very useful and effective tool, was not utilized in this research. As the grading technique has

a limited range and can detect only relatively large differences, Cook *et al.*, improved on this by using photography to grade acne on a 0-8 scale. This technique is considered to be useful, reliable and sensitive to small changes but it has many criticisms (Cunliffe, 1989:117).

Firstly, there are technical problems, i.e. there has to be constant lighting, constant distance between the patient and camera and constant standardized developing procedures are essential and difficult to maintain accurately. It is also not a very economical procedure to utilize.

Secondly, photographs will never adequately detect the small non-inflamed lesions, which are important aetiologically.

Thirdly, photography is two-dimensional and there is a lack of palpation and depth perception, which is essential in acne grading. Distinguishing deep lesions from active superficial lesions or macules is not possible (McDavid, 1994:22-3; Cunliffe, 1989:121). According to Cunliffe (1989:121), an experienced photographer with excellent equipment is a valuable means of assessing acne grade, but not all dermatologists and observers, have these advantages.

According to Cunliffe (1989:118), Allen and Smith extended the photographic technique by comparing their patients with the photographs and adding an important palpation criterion. The grading scale was also modified to a more acceptable 0-8 scale. An intradoctor correlation of their acne severity grade and lesion count was performed too. McDavid (1994:24) did a clinical trial on acne using photography and suggests a combination of acne grading and lesion counting together with photography needs to be

utilised in order to obtain optimum effectiveness. In this research, photography, together with grading and lesion counting, would have accurately assessed the patients' acne, but photography was not available for assessment of acne in this research, hence there were no visual results to correlate with the results obtained from the grading and lesion counting.

In contrast, Oakley (1996:37), states that lesion counts and photographs may be used to assess the extent and severity of acne, but are rarely applied in clinical practice and the quality of the patient's life or the functional or cosmetic disability is not routinely assessed.

## 3.10 METHODS OF STATISTICAL ANALYSIS OF DATA

The proposed study aimed to demonstrate which treatment (herbal-complex or homoeopathic simillimum) was most effective in the treatment of Acne vulgaris.

Two types of data were analysed for the duration of the study i.e. subjective and objective data. The perception questionnaires, completed before each of the 4 consultations during the 9 weeks treatment period, constituted the subjective data. These questionnaires, completed by the patients were screened to ensure that they had been completed correctly. These questionnaires were to assess how the patients perceived the treatment to be throughout the trial period.

For the objective data, the number and type of acne vulgaris lesions (clinical manifestations) were tabulated, analysed, graded (by visual tactile grading) and counted by means of the Leeds Technique, in order for statistical analysis to be made. These

were conducted on each patient, at each consultation i.e. a total of 4 consultations over 9 weeks. An independent person was present during the tabulation i.e. grading and counting, of the type and number of lesions, to prevent bias on the part of the researcher.

The subjective and objective data were statistically analysed with the level of significance ($\alpha$) set at 5 % or 0.05.

### 3.10.1 STATISTICAL PROCEDURES

Mr. K. Thomas, the Durban Institute of Technology research statistician, was consulted with regards to the manner in which data from the research study was to be analysed. In this study, Group 1 contained 15 patients, who made up the herbal-complex group, and Group 2 contained the remaining 15 patients, which made up the homoeopathic simillimum group. Since the sample size per group was small i.e. n = 30 (15 patients per group), non-parametric tests were used for data analysis. Four variables of study were used: perception questionnaire totals (subjective data), number of inflamed lesions, number of non-inflamed lesions and the total number of lesions (objective data). There were 4 readings taken for each treatment group (i.e. 4 consultations) for each of the 4 variables of study. Data was transferred onto a spreadsheet in the SPSS© 9.0 software package (2001-2002) for statistical analysis (SPSS Inc., 1999).

The data was analysed in terms of an inter-group comparison firstly (i.e. Mann-Whitney U-test), and secondly an intra-group comparison (i.e. Friedman T-test). The Mann-Whitney U-test was used for inter-group analysis of the subjective and objective data, which compared both the herbal-complex and homoeopathic simillimum treatment

groups. For the intra-group comparison, Friedman T-test for repeated measures i.e. each consultation's readings, were employed for both the subjective and objective data, on the total sample. If the null hypothesis were rejected, a multiple comparison procedure for use with Friedman T-test (Dunn procedure) would be used to specify in which of the consultations maximum improvement occurred.

All statistical tests were carried out at a 5% significance level ($\alpha$ = 0.05). The results all had shown to be statistically significant, therefore further post-hoc testing was done (Dunn procedure). The mean, standard deviation and p-values of the herbal-complex group and homoeopathic simillimum group were used as descriptive statistics and bar charts (using SPSS© 9.0) were constructed to illustrate significant results of the tests. Appropriate p-values were used for decision purposes, which will be referred to later. The p-value (probability value) is a probability, with a value ranging from zero to 1 (Daniel, 1978:31,82; Instat, 2002). SPSS© 9.0 software package was the statistical package used.

GROUPS ANALYSED

Group 1 constitutes the herbal-complex group

Group 2 constitutes the homoeopathic simillimum group

#### 3.10.1.1 Mann-Whitney U-Test

*Comparison of Group 1 and Group 2:*

The Mann-Whitney U-test is a non-parametric, unpaired two-tailed test, used to compare the data obtained from two independent groups i.e. Groups 1 and 2, with respect to each variable of interest. The purpose of this test was to determine whether

there was any significant difference between the two treatment groups, with respect to the variables of interest i.e. Perception Questionnaire, Inflamed Lesions (number of lesions), Non-inflamed Lesions (number of lesions) and Total Lesion Count (inflamed and non-inflamed lesions counted together), at the $\alpha = 0.05$ level of significance.

**Hypothesis testing**

*Alternative hypothesis*

It was hypothesized that the homoeopathic simillimum would be more effective than the herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) in the treatment of Acne vulgaris in terms of subjective and objective clinical findings.

*Null hypothesis*

It was hypothesized that both the homoeopathic simillimum and herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) would be equally effective in the treatment of Acne vulgaris in terms of subjective and objective clinical findings

The null hypothesis $H_o$ states that there was no difference between the two groups with respect to the variable of interest. The alternative hypothesis $H_1$ states that there was a difference between the two groups with respect to the variable interest.

$H_o: \mu_1 = \mu_2$ (There was no difference between the groups)

$H_1: \mu_1 \neq \mu_2$ (There was a difference between the groups)

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

**Decision rule**

For a two-tailed test:

Reject $H_o$ at $\alpha = 0.05$ level of significance if $p < \alpha/2$

Accept $H_o$ at $\alpha = 0.05$ level of significance if $p \geq \alpha/2$

p was the observed significance level of the test (McClave *et al.,* 1997:722).

### 3.10.1.2 The Friedman T-Test for K-Related Samples

The Friedman T-test is a non-parametric test that compares three or more paired groups (Instat, 2002) If the p-value is small, one can conclude that at least one of the treatments differ from the rest, it is therefore necessary to look at post-hoc tests to determine which group/treatment differs from which other group/treatment (Instat, 2002). In this study the post-hoc test used was a multiple comparison procedure called the Dunn Procedure (Daniel, 1978:31,82). The Friedman's T-test was used within the herbal-complex group and the homoeopathic simillimum group, to determine if there was any significant difference according to the variables of interest i.e. Perception Questionnaire, Inflamed Lesions (number of lesions), Non-inflamed Lesions (number of lesions) and Total Lesion Count (inflamed and non-inflamed lesions counted together), between the first, second, third and fourth consultations.

**Hypothesis testing**

The null hypothesis $H_o$ states that there was no difference between consultations with respect to the variable of interest. The alternative hypothesis $H_1$ states that there was a difference between consultations with respect to the variable of interest.

$H_o$: $\mu 1 = \mu 2$ (There was no difference between the groups)

H1: $\mu 1 \neq \mu 2$ (There was a difference between the groups)

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

**Decision rule**

For a two-tailed test:

Reject Ho at $\alpha$ = 0.05 level of significance if $p < \alpha/2$

Accept Ho at $\alpha$ = 0.05 level of significance if $p \geq \alpha/2$

p was the observed significance level of the test (McClave *et al.,* 1997:722).

**3.10.1.3 The Dunn Procedure**

If the null hypothesis Ho was rejected for the Friedman T-test, then this multiple comparison procedure had to be applied to determine which of the consultations were significantly different and to specify in which of the consultations maximum improvement occurred (Daniel, 1978,31, 82). Refer to 4.4.3 for the procedure.

## 3.11 INTERPRETATION OF DATA

For each patient, the total values for each questionnaire were compared with themselves over a period of time (9 weeks). Once all 30 patients completed 4 questionnaires each, a statistical test (Mann-Whitney U-test) was used to compare all the questionnaires to determine if there are any trends and if these trends correlate with the data obtained from counting and grading of lesions. Data was interpreted by studying the values of the readings of each patient i.e. the general condition of the acne, enabling the researcher to highlight any trends in the treatment of acne, when comparing all the patients together and when assessing the individual's acne. The data from the spreadsheets were used to test the hypothesis. All statistical analyses were

performed with the necessary guidance of a statistician. All the data was kept confidential. Each patient's information was stored in their respective files after the consultations.

# CHAPTER FOUR

# RESULTS

## 4.1 INTRODUCTION

This chapter contains firstly, the demographic data of all the patients included in the study, secondly, the frequency of remedies used and thirdly the statistical analysis of the subjective and objective data obtained from the patients over the treatment period. The data for statistical analysis was measurement using a perception questionnaire (Appendix C), and lesion tabulation via grading (visual tactile) and counting using the Leeds Technique (Appendix D & E) for 4 consultations, over 9 weeks. There were 15 patients in Group 1 and 15 in Group 2. Group 1 received the herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) and Group 2 received the homoeopathic simillimum.

## 4.2 CRITERIA GOVERNING THE ADMISSIBILITY OF THE DATA

Only data collected from the trial was accepted. Information was obtained by the researcher, from the case histories, examinations, perception questionnaires, grading and counting of lesions using the Leeds Technique. All questionnaires were explained to the patient, who then completed the questionnaires in the presence of the researcher. The questionnaires were then checked to see if they were completed correctly. All diagnostic case histories (Appendix F), physical examinations and repertorisations were performed by the researcher. The grading and counting of lesions were performed by the researcher and observed by an independent person to prevent bias on the part of the researcher. All procedures and data collection was performed at the Durban Institute of Technology - Steve Biko campus Homoeopathic Day Clinic.

- The data required for testing the hypothesis for the subjective findings in both groups were obtained from each patient's response to the perception questionnaire at each consultation i.e. a total of 4 questionnaires completed for each patient. All the data was obtained from specific questions asked in the perception questionnaire (Appendix C), assessing the patient's perception to the treatment. The questionnaire was given to the patients on their first visit, and every consultation thereafter. A letter of introduction, explaining the nature of the research was handed with the first questionnaire. The questionnaires were completed by the patient supervised by the researcher at the beginning of each consultation.
- The data required for testing the objective findings in both groups were obtained from the grading and counting of the inflamed and non-inflamed lesions on the face, by means of the Leeds Technique at each consultation. Using the visual-tactile grading technique and physically grading and counting the lesions, lesions were assessed according to size, number, and type. This data was transferred onto a spreadsheet. The data concerning the specific remedies to be given, may be found in Materia Medicas and repertories.

The null hypothesis $H_o$ stated that there was no difference between consultations with respect to the variables of interest. The alternative hypothesis $H_1$ stated that there was a difference between consultations with respect to the variables of interest. The level of significance ($\alpha$) was set at 0.05.

## 4.3 DEMOGRAPHIC DATA

**Table 1 Gender distribution**

| GENDER DISTRIBUTION | | | |
|---|---|---|---|
| **Gender** | **Group 1** | **Group 2** | **Total** |
| **Females** | 14 | 11 | 25 (83.3%) |
| **Males** | 1 | 4 | 5 (16.7%) |

The male to female ratio is approximately 1:5. According to Tan *et al*. (2000:443), male patients tend to have more severe grades of acne in adolescence with an increase in prevalence exceeding females, between the ages of 13 and 18 years. This reverses in adulthood where women are more frequently and severely affected. Male patients, despite having severe acne, seem to be underrepresented in trials and in the referral population.

**Table 2 Age distribution**

| AGE DISTRIBUTION | | | |
|---|---|---|---|
| **Age intervals** | **Group 1** | **Group 2** | **Total** |
| **18-20** | 3 | 5 | 8 (26.7%) |
| **21-25** | 7 | 8 | 15 (50%) |
| **26-30** | 3 | 1 | 4 (13.3%) |
| **31-35** | 1 | 1 | 2 (6.7%) |
| **36-40** | 1 | 0 | 1 (3.3%) |

- The mean age for Group 1 was approximately 24 years.
- The mean age for Group 2 was approximately 23 years.
- The mean age for the sample was 23 years.
- The age range was 18 - 40 years.

**Table 3.1 Severity Grading**

| SEVERITY GRADING AT BASELINE READING | | | |
|---|---|---|---|
| **Severity** | **Group 1** | **Group 2** | **Total** |
| **Severe (4)** | 0 | 1 | 1 |
| **Moderate(3)** | 11 | 4 | 15 |
| **Mild (2)** | 4 | 9 | 13 |
| **Minimal (1)** | 0 | 1 | 1 |

**Table 3.2 Frequency of Remedies indicated**

| Remedy Name | Potency | Frequency prescribed | Frequency dispensed |
|---|---|---|---|
| *Arsenicum album* | 30ch, 200ch, M | 2 | 2 |
| *Carcinosinum* | 30ch, 200ch | 2 | 1 |
| *Calcarea carbonica* | 30ch, 200ch | 1 | 1 |
| *Causticum Hahnemannii* | 30ch, 200ch, M | 1 | 1 |
| *Ignatia amara* | 30ch, 200ch | 1 | 1 |
| *Lachesis muta* | 30ch, 200ch | 1 | 1 |
| *Medorrhinum* | 30ch, 200ch | 2 | 2 |
| *Natrum carbonicum* | *30ch, 200ch* | 1 | 0 |
| *Natrum mutiaticum* | *30ch, 200ch, M* | 4 | 2 |
| *Phosphorus* | *30ch, 200ch, M* | 3 | 1 |
| *Pulsatilla praetensis* | *30ch, 200ch, M* | 5 | 2 |
| *Sepia officinalis* | *30ch, 200ch, M* | 5 | 0 |
| *Silica terra* | *30ch, 200ch* | 1 | 0 |
| *Staphysagria* | *30ch, 200ch, M* | 1 | 1 |

## 4.4 ANALYSED DATA

### 4.4.1 THE INTER-GROUP ANALYSIS USING THE MANN-WHITNEY U-TEST

#### 4.4.1.1 Mann-Whitney U-test - Perception Questionnaire

**Table 4 Comparison between Group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Mann-Whitney U-test for Perception Questionnaire (Appendix C).**

| Perception Questionnaire | | | | |
|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | |
| | **Mean** | **S.D.** | **P-value** | **Conclusion** |
| **Tx1** | 65.33 | 20.63 | 0.279 | No Difference |
| **Tx2** | 73.47 | 10.29 | 0.661 | No Difference |
| **Tx3** | 77.80 | 10.67 | 0.491 | No Difference |
| **Tx4** | 86.07 | 8.69 | 0.559 | No Difference |

Tx1 = Consultation 1 (Baseline reading)  Tx3 = Consultation 3

Tx2 = Consultation 2  Tx4 = Consultation 4

$\alpha = 0.05$ = level of significance

$P < \alpha/2$ : herbal-complex and homoeopathic simillimum groups are different.

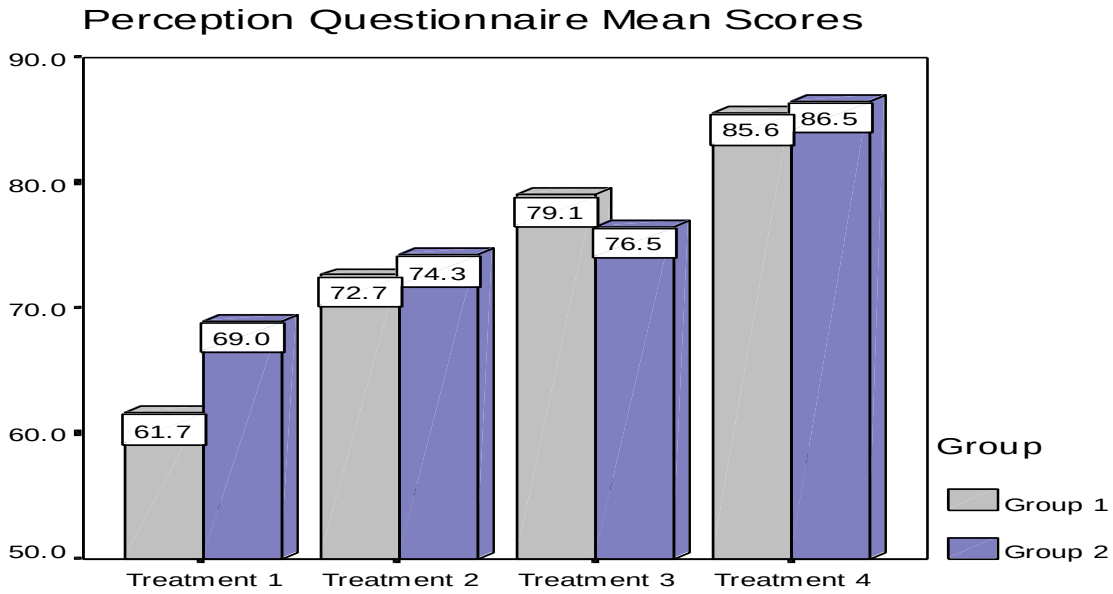
$P \geq \alpha/2$ : herbal-complex and homoeopathic simillimum groups are not different.

**Conclusion**: From the p-values, it can be concluded that there is no difference between group 1 and 2 for the Perception Questionnaire. The null hypothesis is thus accepted for the Perception Questionnaire, indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference between the groups over the 4 consultations.

♦ S.D. = Standard Deviation

♦ The p-value that is indicated above is the reported p-value/2.

**FIGURE 1 - PERCEPTION QUESTIONNAIRE**




Treatment 1= Consultation 1 (Baseline reading) Treatment 3 = Consultation 3

Treatment 2= Consultation 2 Treatment 4 = Consultation 4

↑score or mean = improvement ↓score or mean = deterioration

**4.4.1.2 Mann-Whitney U-test- Inflamed Lesions**

**Table 5 Comparison between Group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Mann-Whitney U-test for the Inflamed Lesions (Appendix D & E)**

| Inflamed Lesions | | | | |
|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | |
| | **Mean** | **S.D.** | **P-value** | **Conclusion** |
| **Tx1** | 24.97 | 20.52 | 0.868 | No Difference |
| **Tx2** | 13.10 | 8.15 | 0.755 | No Difference |
| **Tx3** | 13.43 | 11.90 | 0.852 | No Difference |
| **Tx4** | 7.90 | 6.24 | 0.738 | No Difference |

Tx1 = Consultation 1(Baseline reading) Tx3 = Consultation 3

Tx2 = Consultation 2 Tx4 = Consultation 4

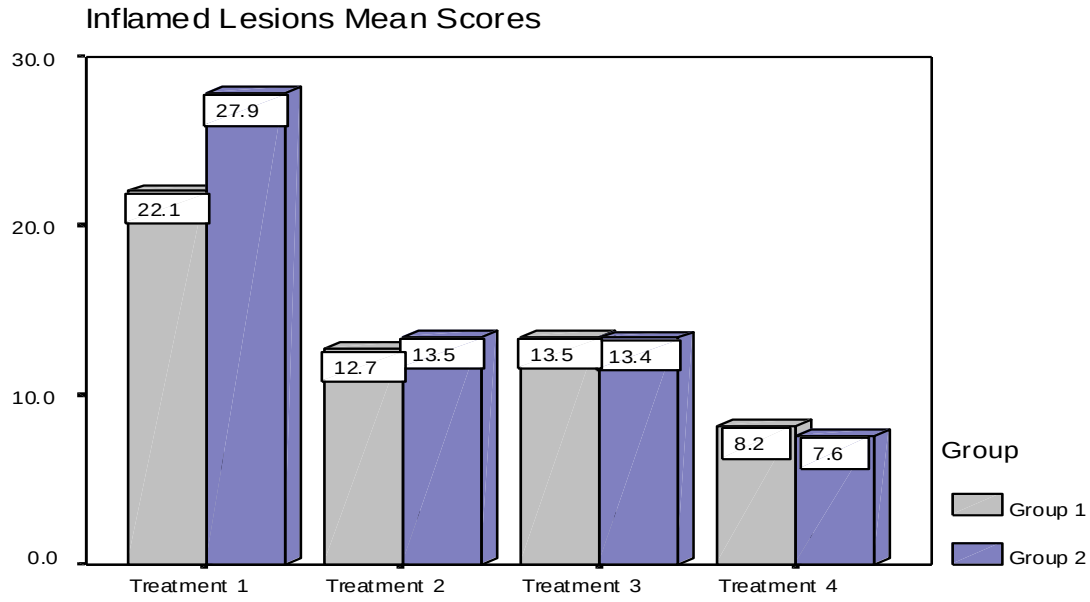
$\alpha$ = 0.05 = level of significance

P < $\alpha$/2 : herbal-complex and homoeopathic simillimum groups are different.

P $\geq$ $\alpha$/2 : herbal-complex and homoeopathic simillimum groups are not different.

**Conclusion**: From the p-values, it can be concluded that there is no difference between group 1 and 2 for the Inflamed Lesions. The null hypothesis is thus accepted for the Inflamed Lesions, indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups over the 4 consultations.

**FIGURE 2 – INFLAMED LESIONS**




Treatment 1= Consultation 1(Baseline reading) Treatment 3 = Consultation 3

Treatment 2= Consultation 2 Treatment 4 = Consultation 4

↑ mean = increased lesion counts ↓ mean = decreased lesion counts

#### 4.4.1.3 Mann-Whitney U-test - Non-inflamed Lesions

**Table 6 Comparison between group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Mann-Whitney U-test for the Non-inflamed Lesions (Appendix D & E)**

| Non-Inflamed Lesions | | | | |
|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | |
| | **Mean** | **S.D.** | **P-value** | **Conclusion** |
| **Tx1** | 39.57 | 17.93 | 0.361 | No difference |
| **Tx2** | 21.90 | 12.91 | 0.176 | No difference |
| **Tx3** | 15.73 | 8.34 | 0.404 | No difference |
| **Tx4** | 10.50 | 4.72 | 0.503 | No difference |

Tx1 = Consultation 1 (Baseline reading)

Tx2 = Consultation 2

Tx3 = Consultation 3

Tx4 = Consultation 4

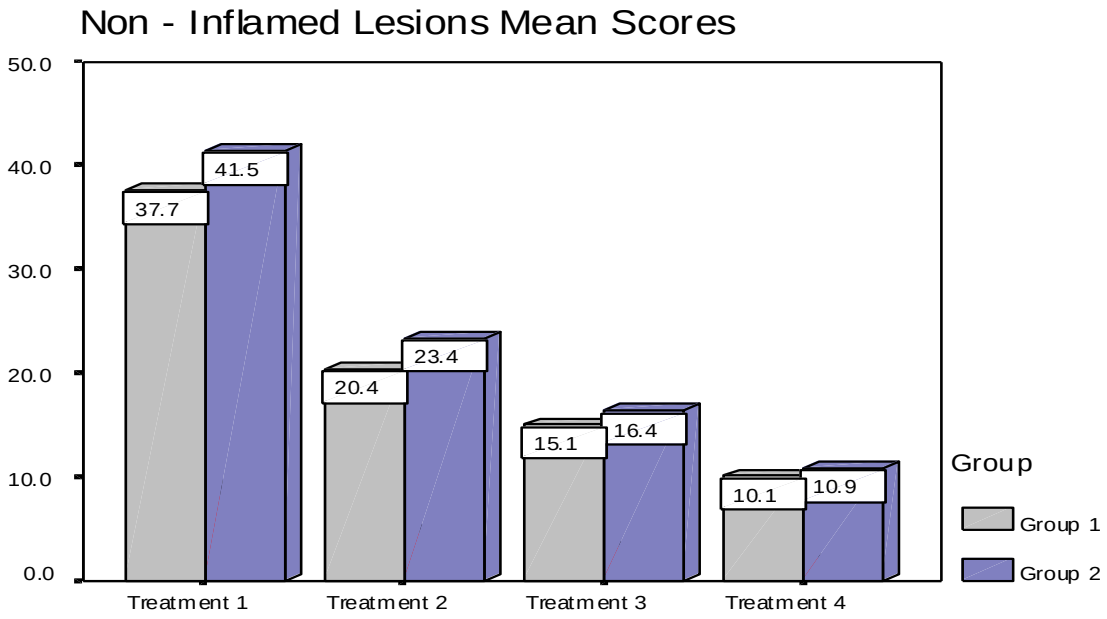
$\alpha = 0.05$ = level of significance

$P < \alpha/2$ : herbal-complex and homoeopathic simillimum groups are different.

$P \geq \alpha/2$ : herbal-complex and homoeopathic simillimum groups are not different.

**Conclusion**: From the p-values, it can be concluded that there is no difference between group 1 and 2 for the Non-inflamed Lesions. The null hypothesis is thus accepted for the Non-inflamed Lesions, indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference between the groups over the 4 consultations.

**FIGURE 3 – NON-INFLAMED LESIONS**




Treatment 1= Consultation 1(Baseline reading)

Treatment 2= Consultation 2

Treatment 3 = Consultation 3

Treatment 4 = Consultation 4

↑ mean = increased lesion counts

↓ mean = decreased lesion counts

**4.4.1.4 Mann-Whitney U-test - Total Lesion Count**

**Table 7 Comparison between group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Mann-Whitney U-test for the Total Lesion Count (Appendix D & E)**

| Total Lesion Count | | | | |
|---|---|---|---|---|
| **Herbal vs. Homoeopathic** | | | | |
| | **Mean** | **S.D.** | **P- value** | **Conclusion** |
| **Tx1** | 64.53 | 23.46 | 0.271 | No difference |
| **Tx2** | 35.00 | 17.23 | 0.237 | No difference |
| **Tx3** | 29.17 | 17.19 | 0.361 | No difference |
| **Tx4** | 18.40 | 7.75 | 0.819 | No difference |

Tx1 = Consultation 1 (Baseline reading)

Tx2 = Consultation 2

Tx3 = Consultation 3

Tx4 = Consultation 4

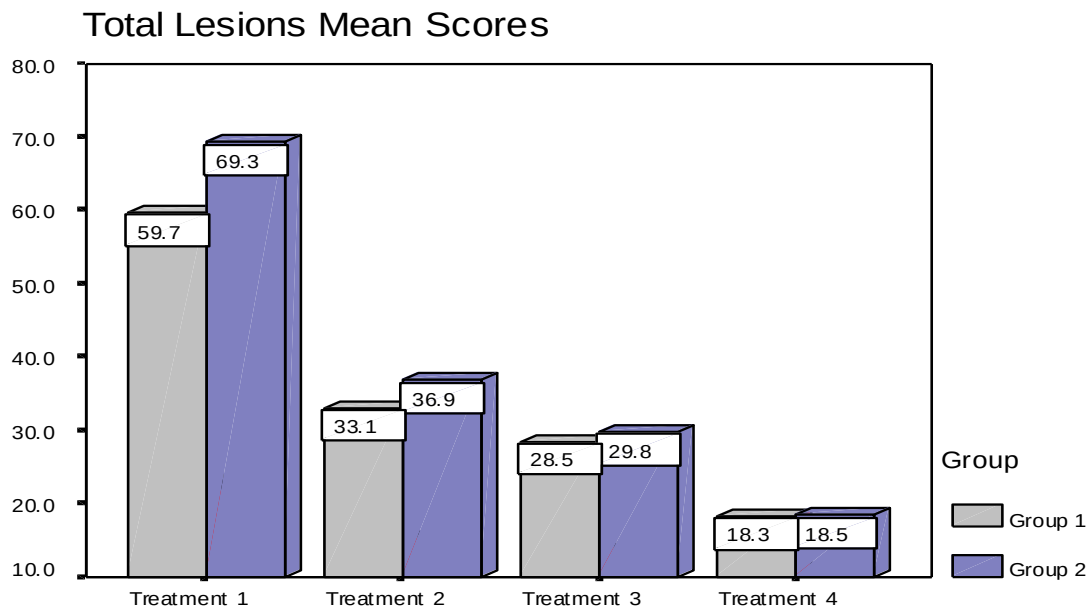
$\alpha = 0.05$ = level of significance

$P < \alpha/2$ : herbal-complex and homoeopathic simillimum groups are different.

$P \geq \alpha/2$ : herbal-complex and homoeopathic simillimum groups are not different.

**Conclusion**: From the p-values, it can be concluded that there is no difference between group 1 and 2 for the Total Lesion Count. The null hypothesis is thus accepted for the Total Lesion Count, indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference between the groups over the 4 consultations.

**FIGURE 4 – TOTAL LESION COUNT**




Treatment 1= Consultation 1 (Baseline reading) Treatment 3 = Consultation 3

Treatment 2= Consultation 2 Treatment 4 = Consultation 4

↑ mean = increased lesion counts ↓ mean = decreased lesion counts

### 4.4.2 THE INTRA-GROUP ANALYSIS USING THE FRIEDMAN T-TEST

#### 4.4.2.1 Friedman T-test - Perception Questionnaire

**Table 8 Comparison between group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Friedman T-test for Perception Questionnaire for 4 treatments (Appendix C).**

| Perception questionnaire | | | | | | | |
|---|---|---|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | | | | |
| **Group 1** | **Mean** | **S.D.** | **P-value** | **Group 2** | **Mean** | **S.D.** | **P-value** |
| **Tx 1** | 61.67 | 21.10 | **0.001 p<0.025** | **Tx 1** | 69.00 | 20.20 | **0.000 p<0.025** |
| **Tx 2** | 72.67 | 11.20 | | **Tx 2** | 74.27 | 9.62 | |
| **Tx 3** | 79.07 | 11.39 | | **Tx 3** | 76.53 | 10.13 | |
| **Tx 4** | 85.60 | 8.53 | | **Tx 4** | 86.53 | 9.12 | |

Tx1 = Consultation 1 (Baseline reading) Tx3 = Consultation 3

Tx2 = Consultation 2 Tx4 = Consultation 4

For both groups 1 & 2 (p = 0.001 and p = 0.000 respectively), the null hypothesis Ho is rejected for the Perception Questionnaire (i.e. $p < 0.025$), indicating that at the $\alpha = 0.05$ level of significance, there was a statistically significant difference between consultations (i.e. $p < 0.025$). In terms of the mean values, Group 2 showed a better improvement comparatively between consultations, except for treatment 3, for the Perception Questionnaire.

#### 4.4.2.2 Friedman T-test - Inflamed Lesions

**Table 9 Comparison between group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Friedman T-test for Inflamed Lesions for 4 treatments (Appendix D & E)**

| Inflamed Lesions | | | | | | | |
|---|---|---|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | | | | |
| **Group 1** | **Mean** | **S.D.** | **P-Value** | **Group 2** | **Mean** | **S.D.** | **P-value** |
| **Tx 1** | 22.07 | 12.24 | **0.000 p<0.025** | **Tx 1** | 27.87 | 26.55 | **0.000 p<0.025** |
| **Tx 2** | 12.73 | 8.14 | | **Tx 2** | 13.47 | 8.43 | |
| **Tx 3** | 13.47 | 12.43 | | **Tx 3** | 13.40 | 11.79 | |
| **Tx 4** | 8.20 | 6.67 | | **Tx 4** | 7.60 | 6.01 | |

Tx1 = Consultation 1(Baseline reading) Tx3 = Consultation 3

Tx2 = Consultation 2 Tx4 = Consultation 4

For both groups 1 & 2 (p = 0.000 for each group), the null hypothesis $H_O$ is rejected for the Inflamed Lesions (p < 0.025), indicating that at the $\alpha$ = 0.05 level of significance, there was a statistically significant difference between consultations (i.e. p < 0.025). In terms of the mean values, Group 2 showed a better reduction comparatively between consultations, except for treatments 3 and 4, for the Inflamed Lesions.

#### 4.4.2.3 Friedman T-test - Non-inflamed Lesions

**Table 10 Comparison between group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Friedman T-test for Non-inflamed Lesions for 4 treatments (Appendix D & E).**

| Non-inflamed Lesions | | | | | | | |
|---|---|---|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | | | | |
| **Group 1** | **Mean** | **S.D.** | **P-value** | **Group 2** | **Mean** | **S.D.** | **P-value** |
| **Tx 1** | 37.67 | 20.12 | **0.000 p<0.025** | **Tx 1** | 41.47 | 15.93 | **0.000 p<0.025** |
| **Tx 2** | 20.40 | 15.18 | | **Tx 2** | 23.40 | 10.47 | |
| **Tx 3** | 15.07 | 9.69 | | **Tx 3** | 16.40 | 7.01 | |
| **Tx 4** | 10.13 | 5.04 | | **Tx 4** | 10.87 | 4.52 | |

Tx1 = Consultation 1 (Baseline reading) Tx3 = Consultation 3

Tx2 = Consultation 2 Tx4 = Consultation 4

For both groups 1 & 2 (p = 0.000 for each group), the null hypothesis $H_O$ is rejected for the Non-inflamed Lesions (i.e. p < 0.025), indicating that at the $\alpha$ = 0.05 level of significance, there was a statistically significant difference between consultations (i.e. p

< 0.025). In terms of the mean values, Group 2 showed a better reduction comparatively between consultations, for the Non-inflamed Lesions.

#### 4.4.2.4 Friedman T-test - Total Lesion Count

**Table 11 Comparison between group 1 (herbal-complex) and 2 (homoeopathic simillimum) using the Friedman T-test for Total Lesion Count for 4 treatments (Appendix D & E).**

| Total Lesion Count | | | | | | | |
|---|---|---|---|---|---|---|---|
| Herbal vs. Homoeopathic | | | | | | | |
| **Group 1** | **Mean** | **S.D** | **P-value** | **Group 2** | **Mean** | **S.D.** | **P-value** |
| **Tx 1** | 59.73 | 22.57 | **0.000 p<0.025** | **Tx 1** | 69.33 | 24.12 | **0.000 p<0.025** |
| **Tx 2** | 33.13 | 20.11 | | **Tx 2** | 36.87 | 14.25 | |
| **Tx 3** | 28.53 | 20.85 | | **Tx 3** | 29.80 | 13.29 | |
| **Tx 4** | 18.33 | 8.90 | | **Tx 4** | 18.47 | 6.72 | |

Tx1 = Consultation 1 (Baseline reading) Tx3 = Consultation 3

Tx2 = Consultation 2 Tx4 = Consultation 4

For both groups 1 & 2 ($p = 0.000$ for each group), the null hypothesis $H_o$ is rejected for the Total Lesion Count (i.e. $p \leq 0.025$), indicating that at the $\alpha = 0.05$ level of significance, there was a statistically significant difference between consultations (i.e. $p < 0.025$). In terms of the mean values, Group 2 showed a better reduction comparatively between consultations, for the Total Lesion Count.

### 4.4.3 THE DUNN PROCEDURE (MULTIPLE COMPARISON TEST)

If the null hypothesis Ho is rejected for the Friedman T-test, then this multiple comparison procedure will have to be applied to determine which of the treatments are significantly different (Daniel, 1978).

The null hypothesis was rejected for all the objective and subjective findings in both the groups, thus it was necessary to apply the Dunn procedure (described below) to the perception questionnaires, inflamed and non-inflamed lesions and total lesion count readings, to determine which of the treatments were significantly different.

Let *Rj* and *Rj'* be the *jth* and the *j'th* treatment rank totals.

Let $\alpha$ be the experiment-wise error rate. Usually $\alpha = 0.10$.

**Decision Rule :**

$$|Rj - Rj'| \geq z\sqrt{bk(k+1)/6}$$

In the above formula :

*b* = the number of blocks/sample size

*k* = the number of treatments

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

In order to compute the treatment rank totals, the values in each block were ranked, the sum of the ranks, and average rank for each treatment was computed.

Rank totals = Average rank $*$ 30 (*b* = 30)

In this case, $k = 4$, $z = 2.409$, $\alpha = 0.10$, $b = 30$.

$$|Rj - Rj'| \geq z\sqrt{bk(k+1)/6}$$

$$\geq 2.409\sqrt{30*4*5/6}$$

$$\geq 2.409\sqrt{100}$$

$$\geq 2.409 * 10$$

$$\geq 24.09$$

The value 24.09 will be used for comparison purposes, i.e. if the absolute values between consultations are greater than or equal to 24.09, then the result is declared statistically significant, otherwise the result is insignificant. $|Rj - Rj'|$ is significant if $|Rj - Rj'| \geq 24.09$.

#### 4.4.3.1 Applying The Dunn Procedure for The Perception Questionnaire

**Table 12 Mean Rank and Rank totals for Perception Questionnaire**

| Perception Questionnaire (Rank Totals) | | | | | |
|---|---|---|---|---|---|
| **Group 1** | **Mean Rank** | **Rank totals** | **Group 2** | **Mean Rank** | **Rank Totals** |
| **Tx 1** | 1.67 | 50.1 | **Tx 1** | 2.00 | 60 |
| **Tx 2** | 2.20 | 66 | **Tx 2** | 1.90 | 57 |
| **Tx 3** | 2.63 | 78.9 | **Tx 3** | 2.37 | 71.1 |
| **Tx 4** | 3.50 | 105 | **Tx 4** | 3.73 | 111.9 |

**Table 13 Dunn Procedure for Perception Questionnaire**

| Groups | *Rj - Rj'* | Absolute values | Conclusion |
|---|---|---|---|
| **Group 1** | ***R1 - R2*** | **15.9** | **No difference** |
| | ***R1 - R3*** | 28.8 | Statistically significant |
| | ***R1 - R4*** | 54.9 | Statistically significant |
| | ***R2 - R3*** | **12.9** | **No difference** |
| | ***R2 - R4*** | 39 | Statistically significant |
| | ***R3 - R4*** | 26.1 | Statistically significant |
| **Group 2** | ***R1 - R2*** | **3** | **No difference** |
| | ***R1 - R3*** | **11.1** | **No difference** |
| | ***R1 - R4*** | 51.9 | Statistically significant |
| | ***R2 - R3*** | **14.1** | **No difference** |
| | ***R2 - R4*** | 54.9 | Statistically significant |
| | ***R3 - R4*** | 40.8 | Statistically significant |

For Group1, between *R1-R2, R2-R3*, and for Group 2, between *R1-R2, R1-R3, R2-R3* for the Perception Questionnaire, the result is declared statistically **insignificant**. For Group1, between *R1-R3, R1-R4, R2-R4, R3-R4*, and for Group 2, between *R1-R4, R2-R4, R3-R4,* for the Perception Questionnaire, the result is declared **significant**.

#### 4.4.3.2 Applying The Dunn Procedure For Inflamed Lesions

**Table 14 Mean Rank and Rank totals for Inflamed Lesions**

| Inflamed Lesions (Rank Totals) | | | | | |
|---|---|---|---|---|---|
| **Group 1** | **Mean Rank** | **Rank totals** | **Group 2** | **Mean Rank** | **Rank totals** |
| **Tx 1** | 3.63 | 108.9 | **Tx 1** | 3.53 | 105.9 |
| **Tx 2** | 2.60 | 78 | **Tx 2** | 2.67 | 80.1 |
| **Tx 3** | 2.43 | 72.9 | **Tx 3** | 2.37 | 71.1 |
| **Tx 4** | 1.33 | 39.9 | **Tx 4** | 1.43 | 42.9 |

**Table 15 Dunn procedure for the Inflamed Lesions**

| Groups | *Rj – Rj'* | Absolute Values | Conclusion |
|---|---|---|---|
| **Group 1** | ***R1 - R2*** | 30.9 | Statistically significant |
| | ***R1 - R3*** | 36 | Statistically significant |
| | ***R1 - R4*** | 69 | Statistically significant |
| | ***R2 - R3*** | **5.1** | **No difference** |
| | ***R2 - R4*** | 38.1 | Statistically significant |
| | ***R3 - R4*** | 33 | Statistically significant |
| **Group 2** | ***R1 - R2*** | 25.8 | Statistically significant |
| | ***R1 - R3*** | 34.8 | Statistically significant |
| | ***R1 - R4*** | 63 | Statistically significant |
| | ***R2 - R3*** | **9** | **No difference** |
| | ***R2 - R4*** | 37.2 | Statistically significant |
| | ***R3 - R4*** | 28.2 | Statistically significant |

For Group1, between *R2-R3*, and for Group 2, between *R2-R3* for the Inflamed Lesions, the result is declared statistically **insignificant**. For Group1, between *R1-R2, R1-R3, R1-R4, R2-R4, R3-R4*, and for Group 2, between *R1-R2, R1-R3, R1-R4, R2-R4, R3-R4,* for the Inflamed Lesions, the result is declared **significant**.

#### 4.4.3.3 Applying The Dunn procedure for the Non-inflamed Lesions

**Table 16 Mean Rank and Rank totals for Non-Inflamed Lesions**

| Non-Inflamed Lesions (Rank Totals) | | | | | |
|---|---|---|---|---|---|
| **Group 1** | **Mean Rank** | **Rank totals** | **Group 2** | **Mean Rank** | **Rank totals** |
| **Tx 1** | 3.73 | 111.9 | **Tx 1** | 4.00 | 120 |
| **Tx 2** | 2.77 | 83.1 | **Tx 2** | 2.80 | 84 |
| **Tx 3** | 2.10 | 63 | **Tx 3** | 2.13 | 63.9 |
| **Tx 4** | 1.40 | 42 | **Tx 4** | 1.07 | 32.1 |

**Table 17 Dunn procedure for the Non-inflamed Lesions**

| Groups | *Rj – Rj'* | Absolute Values | Conclusion |
|---|---|---|---|
| **Group 1** | ***R1 - R2*** | 28.8 | Statistically significant |
| | ***R1 - R3*** | 48.9 | Statistically significant |
| | ***R1 - R4*** | 69.9 | Statistically significant |
| | ***R2 - R3*** | **20.1** | **No difference** |
| | ***R2 - R4*** | 41.1 | Statistically significant |
| | ***R3 - R4*** | **21** | **No difference** |
| **Group 2** | ***R1 - R2*** | 36 | Statistically significant |
| | ***R1 - R3*** | 56.1 | Statistically significant |
| | ***R1 - R4*** | 87.9 | Statistically significant |
| | ***R2 - R3*** | **20** | **No difference** |
| | ***R2 - R4*** | 51.9 | Statistically significant |
| | ***R3 - R4*** | 31.8 | Statistically significant |

For Group1, between *R2-R3*, *R3-R4* and for Group 2, between *R2-R3* for the Non-inflamed Lesions, the result is declared statistically **insignificant**. For Group1, between *R1-R2, R1-R3, R1-R4, R2-R4,* and for Group 2, between *R1-R2, R1-R3, R1-R4, R2-R4, R3-R4,* for the Non-inflamed Lesions, the result is declared **significant**.

#### 4.4.3.4 Applying The Dunn procedure for the Total Lesion Count

**Table 18 Mean Rank and Rank totals for Total Lesion Count**

| Total Lesion Count | | | | | |
|---|---|---|---|---|---|
| Ranks | | | | | |
| **Group 1** | **Mean Rank** | **Rank totals** | **Group 2** | **Mean Rank** | **Rank totals** |
| **Tx 1** | 3.77 | 113.1 | **Tx 1** | 3.93 | 117.9 |
| **Tx 2** | 2.87 | 86.1 | **Tx 2** | 2.83 | 84.9 |
| **Tx 3** | 2.23 | 66.9 | **Tx 3** | 2.17 | 65.1 |
| **Tx 4** | 1.13 | 33.9 | **Tx 4** | 1.07 | 32.1 |

**Table 19 Dunn procedure for the Total Lesion Count**

| Groups | *Rj – Rj'* | Absolute Values | Conclusion |
|---|---|---|---|
| **Group 1** | ***R1 - R2*** | 27 | Statistically significant |
| | ***R1 - R3*** | 46.2 | Statistically significant |
| | ***R1 - R4*** | 79.2 | Statistically significant |
| | ***R2 - R3*** | **19.2** | **No difference** |
| | ***R2 - R4*** | 52.2 | Statistically significant |
| | ***R3 - R4*** | 33 | Statistically significant |
| **Group 2** | ***R1 - R2*** | 33 | Statistically significant |
| | ***R1 - R3*** | 52.8 | Statistically significant |
| | ***R1 - R4*** | 85.8 | Statistically significant |
| | ***R2 - R3*** | **11.8** | **No difference** |
| | ***R2 - R4*** | 52.8 | Statistically significant |
| | ***R3 - R4*** | 33 | Statistically significant |

For Group1, between *R2-R3*, and for Group 2, between *R2-R3* for the Total Lesion Count, the result is declared statistically **insignificant**. For Group1, between *R1-R2, R1-R3, R1-R4, R3-R4, R2-R4,* and for Group 2, between *R1-R2, R1-R3, R1-R4, R2-R4, R3-R4,* for the Total Lesion Count, the result is declared **significant**.

## 4.5 COMPARISON WITH THE CONCURRENT STUDY ON ACNE VULGARIS

Sewsunker (2003), in her trial found that the 2 groups i.e. miasmatic treatment and homoeopathic simillimum groups, showed statistically significant improvement for all the variables of interest. The miasmatic treatment for patients with acne vulgaris was found to be equally effective as the homoeopathic simillimum treatment. It was found that both treatment groups reduced the clinical manifestations of acne and the patients' perception of treatment improved throughout the trial. Comparisons were also made with the 2 treatment groups used in this research i.e. herbal-complex and homoeopathic simillimum groups. The results from the tests done in Sewsunker's research are only discussed in this research but the data, tests and results (tables and graphs) are all reflected, further elaborated on and discussed in Sewsunker's research. It was discussed and decided upon between the 2 researchers i.e. Sewsunker and myself, that the results will only be discussed and explained in both research studies, but the graphs and tables will only be reflected in Sewsunker's research, thus preventing duplication.

### 4.5.1 MANN-WHITNEY U-TEST

#### 4.5.1.1 Perception Questionnaire

It was noted that there were no significant differences between the miasmatic treatment and homoeopathic simillimum groups, for consultations 1 to 4 for the Perception Questionnaire i.e. $p = 0.308$ (consultation 1), $p = 0.917$ (consultation 2), $p = 1.000$ (consultation 3), and $p = 0.309$ (consultation 4), although all the patients' perceptions improved during the trial. The null hypothesis is thus accepted for the Perception Questionnaire (miasmatic vs. simillimum), indicating that at the $\alpha = 0.05$ level of significance there was no statistically significant difference between the groups over the 4 consultations.

For the comparison between the miasmatic treatment and herbal-complex, there were no significant differences noted for consultations 1 to 4 for the Perception Questionnaire also, i.e. p = 0.560 (consultation 1), p = 0.124 (consultation 2), p = 0.819 (consultation 3), and p = 0.096 (consultation 4). The null hypothesis is thus accepted for the Perception Questionnaire (miasmatic vs. herbal-complex), indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups over the 4 consultations.

#### 4.5.1.2 Inflamed Lesions

It was noted that there were no significant differences between the miasmatic treatment and homoeopathic simillimum groups, for consultations 1 to 4 for the Inflamed Lesions i.e. p = 0.967 (consultation 1), p = 0.430 (consultation 2), p = 0.299 (consultation 3), and p = 0.361 (consultation 4) although the lesions decreased or improved during the trial. The null hypothesis is thus accepted for the Inflamed Lesions (miasmatic vs. simillimum), indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups over the 4 consultations.

For the comparison between the miasmatic treatment and herbal-complex, there were no significant differences noted for consultations 1, 3, 4 for the Inflamed Lesions i.e. p = 0.901 (consultation 1), p = 0.177 (consultation 3), and p = 0.157 (consultation 4). The null hypothesis is thus accepted for the Inflamed Lesions (miasmatic vs. herbal-complex) for consultations 1, 3, and 4, indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups for those 3 consultations. The null hypothesis was rejected for consultation 2, where there was a significant difference noted between the miasmatic treatment and herbal-complex. The p

value is 0.046, thus indicating that at the $\alpha$ = 0.05 level of significance there was a statistically significant difference between the groups for consultation 2.

#### 4.5.1.3 Non-inflamed Lesions

It was noted that there were no significant differences between the miasmatic treatment and homoeopathic simillimum groups, for consultations 2 to 4 for the Non-inflamed Lesions i.e. p = 0.519 (consultation 2), p = 0.492 (consultation 3), and p = 0.296 (consultation 4), although the lesions decreased or improved during the trial. The null hypothesis is thus accepted for the Inflamed Lesions (miasmatic vs. simillimum), for consultations 2 to 4 indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups for consultations 2 to 4. For consultation 1, p = 0.020, thus the null hypothesis is rejected indicating that at the $\alpha$ = 0.05 level of significance there was a statistically significant difference between the groups.

For the comparison between the miasmatic treatment and herbal-complex, there were significant differences noted for consultations 1, 3, 4 for the Non-inflamed Lesions i.e. p = 0.001 (consultation 1), p = 0.004 (consultation 3), and p = 0.017 (consultation 4). The null hypothesis is thus rejected for the Non-inflamed Lesions (miasmatic vs. herbal-complex) for consultations 1, 3, and 4, indicating that at the $\alpha$ = 0.05 level of significance there were statistically significant differences between the groups for those 3 consultations. The null hypothesis was accepted for consultation 2, where there was no significant difference noted between the miasmatic treatment and herbal-complex. The p value is 0.058, thus indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups for consultation 2.

#### 4.5.1.4 Total Lesion Count

It was noted that there were no significant differences between the miasmatic treatment and homoeopathic simillimum groups, for consultations 1 to 4 for the Total Lesion Count i.e. p = 0.085 (consultation 1), p = 0.619 (consultation 2), p = 0.983 (consultation 3), and p = 0.961 (consultation 4), although the lesions reduced or improved during the trial. The null hypothesis is thus accepted for the Total Lesion Count (miasmatic vs. simillimum), indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups over the 4 consultations.

For the comparison between the miasmatic treatment and herbal-complex, there were no significant differences noted for consultations 2 to 4 for the Total Lesion Count, i.e. p = 0.494 (consultation 2), p = 0.561 (consultation 3), p = 0.618 (consultation 4). The null hypothesis is thus accepted for the Total Lesion Count (miasmatic vs. herbal-complex), indicating that at the $\alpha$ = 0.05 level of significance there was no statistically significant difference between the groups for those 3 consultations. The null hypothesis was rejected for consultation 1, where there was a significant difference noted between the miasmatic treatment and herbal-complex. The p value is 0.001, thus indicating that at the $\alpha$ = 0.05 level of significance there was a statistically significant difference between the groups for consultation 1.

### 4.5.2 FRIEDMAN T-TEST FOR K-RELATED SAMPLES

#### 4.5.2.1 Perception Questionnaire

For all the groups i.e. herbal-complex, simillimum B (the simillimum group of this research), miasmatic treatment and simillimum A (the simillimum group of Sewsunker's research) (p = 0.001, p = 0.000, p = 0.007 and p = 0.033 respectively), the null

hypothesis $H_O$ is rejected for the Perception Questionnaire, indicating that at the $\alpha$ = 0.05 level of significance, there was a statistically significant difference between consultations for all 4 groups (i.e. $p < 0.05$). In terms of the varying p values, simillimum B group was highly significant and showed a greater improvement ($p = 0.000$) comparatively between consultations for the Perception Questionnaire. This could possibly be due to the variation in case taking done by the individual researchers together with how the patients' perceived the treatment to be.

#### 4.5.2.2 Inflamed Lesions

For all the groups i.e. herbal-complex, simillimum B, miasmatic treatment and simillimum A ($p = 0.000$, $p = 0.000$, $p = 0.004$ and $p = 0.001$ respectively), the null hypothesis $H_O$ is rejected for the Inflamed Lesions, indicating that at the $\alpha$ = 0.05 level of significance, there was a statistically significant difference between consultations for all 4 groups (i.e. $p < 0.05$). In terms of the varying p values, the herbal-complex and simillimum B groups were highly significant and showed greater improvement ($p = 0.000$ each) comparatively between consultations for the Inflamed Lesions. This could possibly be due to the variation in case taking done by the individual researchers.

#### 4.5.2.3 Non-inflamed Lesions

For all the groups i.e. herbal-complex, simillimum B, miasmatic treatment and simillimum A ($p = 0.000$ for each group), the null hypothesis $H_O$ is rejected for the Non-inflamed Lesions (i.e. $p < 0.05$), indicating that at the $\alpha$ = 0.05 level of significance, there was a statistically significant difference between consultations for all 4 treatment groups equally. The Non-inflamed Lesions were considerably decreased for all 4 forms of treatment, thus each treatment group was highly significant in acne vulgaris treatment.

#### 4.5.2.4 Total Lesion Count

For all the groups i.e. herbal-complex, simillimum B (the simillimum group of this research), miasmatic treatment and simillimum A (the simillimum group of Sewsunker's research) ($p = 0.000$ for each group), the null hypothesis $H_o$ is rejected for the Total Lesion Count (i.e. $p < 0.05$), indicating that at the $\alpha = 0.05$ level of significance, there was a statistically significant difference between consultations for each of the 4 treatment groups. The Total Lesion Count also decreased considerably during the trial for all 4 treatment groups, and all groups were highly significant in acne vulgaris treatment.

### 4.5.3 KRUSKALL WALLIS H-TEST

This test is an intergroup comparison which combines all 4 treatment groups, i.e. miasmatic treatment, herbal-complex, simillimum A and B, a combination of both researchers studies, for each of the variables of interest, i.e. perception questionnaire, inflamed and non-inflamed lesions, and total lesion count, for each consultation. This test compares each treatment group with one another, and assesses which treatment group had the most improvement, and also at which stage of the treatment period, each of the treatment groups were most effective. All the data was collated and compared, from both this research and Sewsunker's research, together by both researchers, and it was then given to Sewsunker, who performed this test, and all the results are reflected and explained further in Sewsunker's research. To prevent duplication, the results and comparisons are only explained in this research, as it was not necessary for both researchers to conduct the same test on the same results.

#### 4.5.3.1 Perception Questionnaire

For the Perception Questionnaire, the null hypothesis was accepted for all 4 treatment groups for all 4 consultations, (i.e. $p = 0.459$, $p = 0.328$, $p = 0.866$ and $p = 0.246$ respectively) as $p > 0.05$. This indicates that there was no significant difference noted between the 4 different treatment groups, stating thus that they all were equally effective in terms of the patients' perception of the treatment administered for their acne. They were all effective in improving the patients' perception to the treatment administered.

#### 4.5.3.2 Inflamed Lesions

For the Inflamed Lesions the null hypothesis was accepted for all 4 treatment groups for all 4 consultations, (i.e. $p = 0.992$, $p = 0.124$, $p = 0.570$ and $p = 0.336$ respectively) as $p > 0.05$. This indicates that there was no significant difference noted between the 4 different treatment groups, for all 4 consultations, stating thus that they all were equally effective in reducing the number of inflamed lesions.

#### 4.5.3.3 Non-inflamed Lesions

For the Non-inflamed Lesions the null hypothesis was rejected for all 4 treatment groups for consultations 1, 3 and 4, (i.e. $p = 0.002$, $p = 0.002$, and $p = 0.014$ respectively) as $p < 0.05$. This indicates that there were significant differences noted between the 4 different treatment groups, for those 3 consultations, stating thus that they caused variable reduction in the number of non-inflamed lesions, thus the Dunn procedure was done to note which treatment was most effective and between which consultations the reduction of lesions was most effective. The null hypothesis was accepted for consultation 2 (i.e. $p = 0.071$), as $p > 0.05$, indicating that there was no significant difference noted between

the 4 different treatment groups, stating thus that they all were equally effective in reducing the number of inflamed lesions.

#### 4.5.3.4 Total Lesion Count

For the Total Lesion Count, the null hypothesis was accepted for all 4 treatment groups for consultations 2 to 4, (i.e. $p = 0.619$, $p = 0.538$, and $p = 0.797$ respectively) as $p > 0.05$. This indicates that there were no significant differences noted between the 4 different treatment groups, for those 3 consultations, stating thus that they were equally effective in reducing the total number of lesions. The null hypothesis was rejected for consultation 1 (i.e. $p = 0.021$), as $p < 0.05$, indicating that there was a significant difference noted between the 4 different treatment groups, stating thus that they caused variable reduction in the total number of lesions, thus the Dunn procedure was done to note which treatment was most effective and between which consultations the reduction of lesions was most effective

### 4.5.4 DUNN PROCEDURE

A similar trend has also been noticed in Sewsunker's research, in that between consultation 2 and 3, the result has been declared statistically insignificant. For the Perception Questionnaire, Non-inflamed Lesions, and Total Lesion Count, for all 4 groups i.e. herbal-complex, simillimum A and B and miasmatic treatment, between consultations 2 and 3, there has been no difference or the result is statistically insignificant. For the Inflamed Lesions, only the herbal-complex, miasmatic treatment and simillimum B groups showed the above trend. The possibility of a cyclic change occurring in the remedies' duration of action and effectiveness, and aggravations to the remedies, are possible reasons, for between consultation 2 and 3, that the result is

statistically insignificant. There have also been variable results as well, with respect to the other in-between consultations, but those results are reflected, elaborated on and discussed further in Sewsunker's research.

# CHAPTER FIVE

# DISCUSSION

## 5.1 DISCUSSION OF THE RESULTS

This study was aimed at observing and monitoring the management of patients with acne, by treating them either with the herbal-complex or homoeopathic simillimum. Patients were screened according to the selection criteria (Appendix A). Thirty-four patients were initially accepted into the study and allocated to one of two groups according to a randomization list, formulated by an independent person. Of the 34 patients, 2 dropped out. The study sample was then changed to 30 for statistical analysis.

This chapter discusses the subjective and objective data presented in Chapter 4. The subjective data was obtained from the Perception Questionnaire and the objective data was obtained from the grading and tabulation of lesions i.e. Inflamed Lesions, Non-inflamed Lesions and Total Lesion Count. Data was obtained at each of the 4 consultations. The demographic data, obtained from the case history that is presented in Chapter 4 will be discussed too.

## 5.2 DISCUSSION OF THE DEMOGRAPHIC DATA

Twenty-five (83.3%) of the patients in this study were female and five (16.7%) were male, a ratio of 5:1 (Table 1). According to Table 2, the highest percentage of patients were distributed in the age category 18-30 years, with 26,7% of the total patients in this study being between 18-20 years old, 50% being 21-25 years old, 13.3% being 26-30 years old, 6.7% being 31-35 yeas old and 3.3% being 36-40 years old. The age range being 18-40 and the mean age for the sample was 23 years. It seems that the condition

is apparently more prevalent in females than in males and in early to middle adulthood i.e. 18-30 years.

## 5.3 DISCUSSION OF THE SUBJECTIVE AND OBJECTIVE DATA

The outcome of this clinical trial showed that there was an improvement in both the herbal-complex and homoeopathic simillimum treatment groups for the treatment and management of Acne vulgaris in all patients.

### 5.3.1 Inter-group Analysis

The data from all 4 consultations from both groups was assessed to determine if there was any difference between the 2 groups and which treatment protocol was more effective, in terms of the patients perception of treatment and clinical manifestations of the presenting condition. The 4 variables studied in this investigation were the perception questionnaires, the number of inflamed lesions, non-inflamed lesions and the total lesion count. It can be seen in Table 4, 5, 6 and 7 that there was no statistically significant difference with respect to any of the 4 variables between the herbal-complex group (Group 1) and the homoeopathic simillimum group (Group 2). It was found that both treatment groups reduced the clinical manifestations of acne and the patients' perception of treatment improved throughout the trial, thus showing that no difference could be found when comparing the effectiveness of a herbal-complex to homoeopathic simillimum in the treatment of Acne vulgaris. The treatment period of 9 weeks was long enough to observe the effect of either the herbal-complex or the homoeopathic simillimum, on the patient's perception of treatment and the signs and symptoms of acne vulgaris.

#### 5.3.1.1 The Perception Questionnaire

The inter-group relationships (Table 4) between Group 1 (herbal-complex) and Group 2 (homoeopathic simillimum) for the Perception Questionnaire (Appendix C) disclose that there was no statistical significant difference in the results between the 2 groups for all 4 consultations. This would indicate that the perception by the patient to the treatment was influenced similarly by both the herbal-complex and the homoeopathic simillimum. The mean values of the Perception Questionnaire for 4 consultations, during the trial, were used to present a visual illustration for the findings with bar charts (Figure 1). Both groups from the graph, showed a trend towards improvement. This graph incorporated data for both the herbal-complex and homoeopathic simillimum, allowing a comparison to be made between the 2 groups. In Figure 1 the inter-group relationship showed that Group 2 exhibited a slightly higher mean score than Group 1, except for consultation 3, where Group 1, had a slightly higher mean value than Group 2, thus indicating a greater improvement in the patients' perception of treatment. However, both groups showed similar significant improvement in terms of the perception to treatment, thus the null hypothesis, which states that there is no statistical significant difference between the groups, was accepted and the alternative hypothesis rejected.

#### 5.3.1.2 The Inflamed Lesions

The inter-group relationships (Table 5) between Group 1 and Group 2 for the tabulation of the Inflamed Lesions (Appendix D & E) disclose that there was no statistical significant difference in the results between the 2 groups for all 4 consultations. The mean values of the Inflamed Lesions for 4 consultations, during the trial, were used to present a visual illustration for the findings with bar charts (Figure 2). Both groups from the graph, showed a trend towards improvement. This graph incorporated data for both

the herbal-complex and homoeopathic simillimum, allowing a comparison to be made between the 2 groups. The inflamed lesions were sensitive and responded well to and improved on both forms of treatment. There was a marked and gradual reduction in inflamed lesions between the first and 4th consultations. In figure 2, Group 2 showed a much better reduction, when compared to Group 1, in the number of inflamed lesions, in terms of the mean scores, in consultations 1 & 2, but Group 1 had a greater reduction in consultations 3 & 4. Both treatment groups are statistically significant in reducing the number of inflamed lesions, thus the null hypothesis is accepted and the alternative hypothesis is rejected. It can be concluded that the whole group showed a significant improvement over the observation period for inflamed lesions.

#### 5.3.1.3 The Non-inflamed Lesions

The inter-group relationship (Table 6), between the herbal-complex group and homoeopathic simillimum group for the tabulation of the Non-inflamed Lesions (Appendix D & E), revealed that there was no significant difference between the first and 4th consultations. The means scores for both groups, reflected on a barchart (Figure 3), reveals that there was a distinct trend towards a reduction of non-inflamed lesions, but Group 2 proved to have a slightly better reduction in non-inflamed lesions, in all consultations, when compared to Group 1. The non-inflamed lesions responded equally well to both treatments, and showed statistically significant reduction in number, thus the null hypothesis is accepted and the alternative hypothesis was rejected. It was evident that both treatment groups were effective and statistically significant in reducing the non-inflamed lesions. The overall reduction in the non-inflamed lesions in both groups was statistically significant, with no marked statistical difference between the 2 treatment groups.

#### 5.3.1.4 Total Lesion Count

The inter-group comparison (Table 7), between Group 1 and Group 2, for the Total Lesion Count (Appendix D & E), revealed that there was no significant difference between the first and 4$^{th}$ consultations, when the 2 groups were compared. The mean values of the Total Lesion Count for 4 consultations, during the trial, were used to present a visual illustration for the findings with bar charts (Figure 4). As both the Non-inflamed and Inflamed Lesions, showed marked and gradual reduction during the trial, with both Group 1 & 2 showing similar reduction in the number of both lesions, thus the Total Lesions Count should show a similar reduction, as both the Inflamed and Non-inflamed lesions are added to give a Total Lesion Count. The results obtained show that there was a significant reduction in the total lesions for both the groups, thus there was not significant difference between the groups. The means scores for the Total Lesion Count (Figure 4) reveal that Group 2 was slightly better in terms of the reduction of the lesions, for all 4 treatments, although both groups showed a similar trend towards reduction, towards the end of trial. It was evident, both treatment protocols were effective in reducing the total lesions, therefore the null hypothesis, which states that there is no statistical significant difference between the groups, was accepted, and the alternative hypothesis, which states that there was a difference between groups, was rejected. It can be concluded that the whole group showed a statistically significant improvement over the observation period for all the lesions.

### 5.3.2 Intra-group Analysis

The evaluation of the subjective and objective data obtained from the initial, second, third and final consultations represent the time response of the treatment. The analysis of the intra-group data between consultation 1 & 2, 1 & 3, 2 & 3 represents the initial

relative effectiveness of the treatment protocol. The comparison of the data between consultations 1 & 4, 2 & 4, 3 & 4, represent the overall relative effectiveness of the treatment protocol, i.e. herbal-complex vs. homoeopathic simillimum, as a whole.

#### 5.3.2.1 The Perception Questionnaire

An analysis of the results at consultations 1, 2, 3, and 4, revealed a statistically significant difference in both groups ($p = 0.001$ and $p = 0.000$ for groups 1 and 2 respectively), indicating that there was an improvement in the perception of treatment by patients in both groups. The results for Groups 1 and 2 were highly significant ($p < 0.025$), hence the Dunn procedure (a multiple comparison procedure) was carried out to determine at which stage maximum improvement occurred. The intra-group relationship (Table 8) within both groups for Perception Questionnaire, shows varying degrees of improvement over the trial period thus it is necessary to carry out the Dunn procedure. Within Group 1, the results from this procedure showed that between consultation 1 and 2, and consultation 2 and 3, there was no statistical significant improvement, but between consultation 1 and 3, 1 and 4, 2 and 4, and, 3 and 4 there was a statistically significant improvement. Within Group 2, the results from this procedure showed that between consultation 1 and 2, 1and 3, and, 2 and 3, there was no statistical significant improvement, whereas between consultation 1 and 4, 2 and 4, and 3 and 4, there was a statistically significant improvement. The possibility of a cyclic change occurring in the remedies' duration of action and effectiveness is possibly the reason, for between consultation 2 and 3, that the result is statistically insignificant. An analysis of the data from the first to the final consultation showed an overall improvement in the patients' perception of treatment, which was statistically significant, thus indicating that both the treatments were effective. The Perception Questionnaire monitored the patients'

perception of the treatment over the trial period. The Dunn procedure showed that the initial relative effectiveness of the treatment protocol of both the groups, especially Group 2, was not statistically significant, but as a whole, the relative effectiveness of the treatment, was statistically significant, thus the perception questionnaire is an effective tool to assess the effectiveness of the treatment administered.

#### 5.3.2.2 The Inflamed Lesions

An analysis of the results at consultations 1, 2, 3, and 4, revealed a statistically significant difference in both groups ($p = 0.000$ for both groups i.e. $p < 0.025$), indicating that there was a marked reduction in the number of inflamed lesions (according to the Leeds Counting Technique, Appendix D and E), in patients in both groups. The results for Group 1 and 2 were highly significant ($p = 0.000$ i.e. $p < 0.025$), hence the Dunn procedure (a multiple comparison procedure) was carried out to determine at which stage maximum improvement occurred. The intra-group relationship (Table 9) within both groups for Inflamed Lesions, shows varying degrees of reduction over the trial period thus it is necessary to carry out the Dunn procedure. Within Group 1, the results from this procedure showed that between consultation 2 and 3, there was no statistical significant improvement, but between consultation 1 and 2, 1 and 3, 1 and 4, 2 and 4, and, 3 and 4 there was a statistically significant improvement. Within Group 2, the results from this procedure also showed that between consultation 2 and 3, there was also no statistical significant improvement, whereas between consultation 1 and 2, 1 and 3, 1 and 4, 2 and 4, and 3 and 4, there was a statistically significant improvement. The possibility of a cyclic change occurring in the remedies' duration of action and effectiveness is possibly the reason, for between consultation 2 and 3, that the result is statistically insignificant. An analysis of the data from the first to the final consultation

showed an overall reduction in the number of inflamed lesions, in the patients, which was statistically significant. The comparison of the data showed a statistically significant improvement in both groups, indicating that both the treatments administered were as effective in the treatment of Acne vulgaris.

#### 5.3.2.3 The Non-inflamed Lesions

An analysis of the results at consultation 1, 2, 3, and 4, revealed a statistically significant difference in both groups ($p = 0.000$ for both groups, i.e. $p<0.025$), indicating that there was a marked reduction in the number of non-inflamed lesions (according to the Leeds Counting Technique, Appendix D and E), in patients in both groups. The results for Group 1 and 2 were highly significant ($p = 0.000$, i.e. $p<0.025$), hence the Dunn procedure (a multiple comparison procedure) was carried out to determine at which stage maximum improvement occurred. The intra-group relationship (Table 10) within both groups for Non-inflamed Lesions, shows varying degrees of reduction over the trial period. Within Group 1, the results from this procedure showed that between consultation 2 and 3 and 3 and 4, there was no statistical significant improvement, but between consultation 1 and 2, 1 and 3, 1 and 4, and 2 and 4, there was a statistically significant improvement. Within Group 2, the results from this procedure also showed that between consultation 2 and 3, there was also no statistical significant improvement, whereas between consultation 1 and 2, 1 and 3, 1 and 4, 2 and 4, and 3 and 4, there was a statistically significant improvement. The possibility of a cyclic change occurring in the remedies' duration of action and effectiveness is possibly the reason, for between consultation 2 and 3, that the result is statistically insignificant. An analysis of the data from the first to the final consultation showed an overall reduction in the number of non-inflamed lesions in the patients, which was statistically significant. The comparison of

the data showed a statistically significant improvement in both groups, indicating the treatment protocol administered to the patients, in both groups was effective in the treatment and management of Acne vulgaris.

#### 5.3.2.4 The Total Lesion Count

An analysis of the results at consultation 1, 2, 3, and 4, revealed a statistically significant difference in both groups ($p = 0.000$ for both groups i.e. $p<0.025$), indicating that there was a marked reduction in both the number of inflamed and non-inflamed lesions (according to the Leeds Counting Technique, Appendix D and E), in patients in both groups. The results for Group 1 and 2 were highly significant ($p = 0.000$ i.e. $p<0.025$), hence the Dunn procedure (a multiple comparison procedure) was carried out to determine at which stage maximum improvement occurred. It is necessary to carry out the Dunn procedure as the intra-group relationship (Table 11) within both groups for the Total Lesion Count, shows varying degrees of reduction over the trial period. Within both Group 1 and 2, the results from this procedure showed that between consultation 2 and 3, there was no statistical significant improvement, but between consultation 1 and 2, 1 and 3, 1 and 4, 2 and 4, and 3 and 4 for both groups, there was a statistically significant improvement. The possibility of a cyclic change occurring in the remedies' duration of action and effectiveness is possibly the reason, for between consultation 2 and 3, that the result is statistically insignificant. An analysis and comparison of the data from the first to the final consultation showed an overall reduction in the number of total lesions in the patients which was statistically significant, thus indicating that both the treatments administered were effective in the treatment and management of Acne vulgaris. The Dunn procedure showed that as a whole, the relative effectiveness of the treatment protocol of both the groups was statistically significant.

## 5.4 INTER-GROUP HYPOTHESIS

It was hypothesized that there would be a statistically significant difference between the two groups with respect to the objective and subjective clinical findings, showing that the homoeopathic simillimum would be more effective than the herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*), in the treatment of Acne vulgaris. Although the homoeopathic simillimum proved to be better (when comparing the mean values), than the herbal-complex, both treatment groups resulted in statistically significant improvement with regard to the patients' perception of the treatment and the reduction of the specific lesions, however, there were no statistically significant differences between the two groups (Figures 1-4).

## 5.5 INTRA-GROUP HYPOTHESIS

It was hypothesized that there would be a difference between consultations with regards to the variables of interest i.e. perception questionnaire, inflamed and non-inflamed lesions and total lesion count, in both groups, showing that the homoeopathic simillimum is more effective than the herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) in the treatment of Acne vulgaris. According to patients' perception of treatment and the reduction of lesions, there was (according to the Dunn procedure), differences between consultations for both groups. Improvement was statistically insignificant, between consultations 2 and 3, for both groups with regard to all the variables of interest. The possibility of a cyclic change (i.e. the remedy reaches its duration of action, then slows down its activity for some time, then starts working again, thus at the second follow-up not much occurred) occurring in the remedies' duration of action and effectiveness is possibly the reason for this. Although the p-values for the perception questionnaire, were different i.e. p=0.001 and p

= 0.001, respectively, both groups were statistically significant, as p< 0.025. This is equally true for the other variables of interest, i.e. inflamed and non-inflamed lesions and total lesion count. An overall analysis of the data from the first to the 4th consultations showed an overall improvement in both groups.

## 5.6 CONCLUSIONS

It can thus be seen that both the herbal-complex and homoeopathic simillimum, improved and reduced the inflamed, non-inflamed and total lesions and the patients' perception of response to treatment improved over time, between the 1st and 4th consultations. In each treatment group, when the clinical manifestations of the individual's acne improved, so their perception to the treatment showed a similar improvement. It would seem with all the variables of interest that there was initially a large improvement, which made statistically significant difference, but after the third consultation it was not as significant an improvement between consultations, as between consultations 1 and 2. All the results showed that the herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*) was just as effective as the homoeopathic simillimum, in the treatment of Acne vulgaris, and that 9 weeks was adequate enough to obtain a positive response.

# CHAPTER SIX

## CONCLUSIONS AND RECOMMENDATIONS

### 6.1 CONCLUSIONS

In this study the researcher compared the effectiveness of a herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea & Taraxacum officinale*), to homoeopathic simillimum in the treatment of acne vulgaris, in terms of the of clinical manifestations and patients perception of treatment. It was found that the herbal-complex showed a similar significant reduction in the number of lesions as the homoeopathic simillimum. This supports the findings of McDavid (1994) and van Niekerk (1999) that homoeopathic simillimum treatment significantly affects the clinical manifestations of Acne vulgaris ($p = 0.006$ and $p = 0.0001$ respectively), as well supports findings of Barklie (1999) that the herbal complex is also as effective in reducing or improving the clinical manifestations i.e. the lesions, of Acne vulgaris. In this study (herbal-complex vs. homoeopathic simillimum) both the inflamed lesions and the non-inflamed lesions were significantly reduced and the patients' perception of both the treatments proved to be favourable over the duration of the trial.

The grading technique and Leeds Counting Technique plays a vital role in monitoring progress in acne patients and is a useful tool in the homoeopathic practice as recognised by previous researchers, McDavid (1994), Lee (1997), van Niekerk (1999) and Barklie (1999), as it provides an objective measurement of the changes in the clinical manifestations of Acne vulgaris. The above objective tools would prove to be more effective, however, if photography (i.e. before, during and after the trial) was also utilized as a further measurement of acne severity, as the results would achieve more objectivity and be more conclusive.

Acne vulgaris is an extremely common and distressing condition but is also a self-limiting, preventable disease with a good prognosis. While acne cannot be regarded as a life-threatening disease, it can severely disrupt the lives of sufferers, socially and psychologically, both young and old. The condition is as bad as the patient's perception of it and needs to be dealt with at that level (Presbury, 1993:1-2; McBride & Simpson, 2000:12; Tan *et al*., 2001:443).

The universality of acne has resulted in significant efforts to treat this disease, with particular interest in the understanding of the pathogenesis for the disease and the development of therapeutic strategies, but with a variable success rate, thus necessitating further improvements for treating the disease. While acne cannot be prevented, adequate and prompt treatment will prevent or minimize scarring (Callan, 1997:36). Treatment should be tailored around severity, age and sex of the sufferer, individualizing symptoms, and the psychosocial impact on the sufferer, with severity being one of the most powerful determinants. By matching the currently available treatment to the patient's individual needs, one can almost ensure control, and that patients no longer need to suffer from active acne (Presbury, 1993:1-6).

Time alone, without special medical treatment, is sufficient to bring about a cure, in most cases. The majority of patients prefer a quicker cure, and that is very often the reason for consulting a physician. The cure of acne involves the removal of the existing eruption, prevention of relapses, or frequent outbreaks of eruptions. The success will be due to the accuracy with which the practitioner unravels, removes or ameliorates the aetiological factors, thus removing the whole disease (Douglass, 1995:427).

A concurrent study, by Sewsunker (2003) compared homoeopathic simillimum to miasmatic treatment in the treatment of Acne vulgaris, the result of which was further compared to this study to assess which treatment i.e. homoeopathic simillimum, miasmatic treatment or herbal-complex, was most effective in the treating Acne vulgaris. It was concluded that all 4 treatment groups were effective in treating acne vulgaris. Each treatment group showed improvement in different aspects i.e. some were more effective in reducing particular types of lesion or in terms of the perception questionnaire, improvement in perception to the treatment administered.

From this study, it can be safe to state that as far as the perceptions of the patients and the clinical manifestations are concerned, homoeopathy and phytotherapy play both an observably notable and statistically significant role, in the treatment and management of Acne vulgaris.

### 6.1.1 Limitations, drawbacks and arguments of this proposed study

The first limitation of the study was the sample size being too small. A larger sample size could have affected the conclusions derived from this study considerably. As acne is a common condition and affects a wide variety of people, with a large sample size a greater perspective of the disease, its control, treatment and prognosis would be obtained.

The use of non-parametric statistical tests, due to the fact that a small sample size was used (less than 60), can prove to be unreliable hence unreliable results could be obtained (Barklie, 1999:45, Govender, 2002).

The perception questionnaire should cover more of the psychological aspects experienced by the patients, thus new questionnaires need to be formulation to effectively measure these psychological aspects thus resulting in a more thorough measurement tool. The format and content of the questionnaires utilized in this research were informative and targeted many key factors but unfortunately didn't cover much of the psychological aspects experienced by the patients. The questionnaires were most effective in assessing the patients' perception of the treatment administered. The psychological aspects were however clearly expressed while taking case histories during consultations.

Various factors could have influenced the patients' perception to treatment, but due to this study being a double-blind study, one could not ascertain which factors were influencing the acne evolution and hence the perception towards the treatment.

The fact that the researcher performed the lesion counting and grading, does introduce some bias in the study, although there was an independent person observing the procedure it is possible that a human error may have occurred when taking the readings. Grading and counting of individual lesions is a tedious and time consuming procedure, and requires much precision and accuracy on the part of the researcher. The results can only be documented and reflected but the visible effects cannot be verified and referenced later. Photographs, another measurement for assessing acne severity, would have been a more accurate assessment together with lesion counting and grading. This procedure i.e. photography, would have removed any form bias on the part of the researcher as it would have been visible to see the effects produced by the treatment administered, thus proving to be an effective objective measuring tool.

Photography provides a ‘hard copy’ of the results obtained through treatment, but all three measuring tools (i.e. lesion counting and grading, and photography) are necessary for acne assessment, as they provide a 3-dimensional approach to assess acne severity.

Homoeopathy is based on the Law of Similars, and should thus be the aim of practitioners when prescribing a remedy to make sure that the remedy or remedies match the patient’s symptoms. Herbal medicines can possibly work in the same way as homoeopathic simillimum remedies, if different herbs can be prescribed for the same pathology in different people, according to their individual symptoms i.e. matching the herbal effects with the patients individual symptoms. The individual herbal tinctures effects need to be clearly understood before matching them to patient’s totality of symptoms. The herbal complex used in this study did not exactly match the individual symptoms of the patient. Although the patients showed improvement, it would not be long lasting if the complex did not contain the individual’s remedy or remedies.

In the homoeopathic practice, the practitioner could be faced with the difficulty of deciding whether to repeat the simillimum, wait or should it be followed with another well selected remedy. Each case according to homoeopathic principles must consider the patients’ individual merits and after proper case taking and repertorisation is carried out, should one decide on a remedy repeat or change. In this study the possibility of the wrong remedy being given to the patients, was reduced due to the fact that a qualified homoeopath approved the prescriptions before dispensing the medication.

Due to the lack of a placebo arm to the study, the results are somewhat impartial, especially if stress was an important aetiological factor. Although placebo-controlled studies are considered unethical, the placebo effect would have provided more insight into the study, as well as, would have affected the results considerably. In homoeopathy the interest in the patients condition is priority, and if stress were a trigger for the acne, there would have been marked improvement in the patients condition.

For more accuracy in data collection, stricter controls should be administered i.e. independent persons to dispense medication, and observe counting of lesions at each consultation, full case histories to be performed and more accurate measures to be administered to decide on the remedy, and sample sizes should be larger for parametric statistical tests to be performed for data analysis, hence ensuring reliability.

## 6.2 RECOMMENDATIONS

According to Tan *et al.* (2001:439, 442-3), accessible, accurate, community-based education on the natural history of acne, pathogenesis, risk of sequelae, effectiveness and duration of treatment and the importance of prompt medical attention, is needed for the control and cure of Acne vulgaris. As many patients believe that information from all sources are inadequate, it is necessary that the mass media and practitioners alike, provide adequate information on acne, highlighting sources of both accurate information and persisting misconceptions. By incorporating information on treatment preferences, patient input into therapeutic selection is facilitated, understanding of treatment options is enhanced, and patient compliance is thus enhanced.

Research is necessary to determine what the sequence of acne therapy (first-line,

second-line and referral) needs to be. Attention should be focused on therapeutic strategy, not just drug efficacy. The optimal duration of acne therapy needs to be considered, as treatment that works more quickly is more desirable than one that is equally effective but takes a bit longer to achieve the desired effect. A variety of therapies are effective, but research is needed to define which patients are expected to benefit the most from specific types of treatments (Lehmann *et al*., 2002:239-240).

Controlled clinical studies in homoeopathy are difficult, as one must take note of homoeopathic characteristics, especially the individualising principle, together with strict scientific study procedures. It would be ideal in Group 1 (herbal-complex group), once a washout period has occurred, that the homoeopathic simillimum, which was determined for each patient early in the trial, be administered and the results recorded. Thus a comparative study could have been done between the herbal-complex and homoeopathic simillimum, on the same person.

**6.2.1 Further studies should**:

- compare the effectiveness of one of the herbal tinctures in the herbal-complex to the homoeopathic simillimum in the treatment of Acne vulgaris
- concentrate on the relative effectiveness of the homoeopathic and 'herbal' simillimum in the treatment of Acne vulgaris
- qualitative studies rather than quantitative studies should be the focus of future studies.
- investigate the use of the Acne Disability Index and Health Related Quality of Life Questionnaires as useful subjective (qualitative) tools in clinical trials and

Homoeopathic practice to gain a better outlook of the disease (Acne vulgaris) process and its social and psychological effects on the person.

- investigate the use and incorporation of photography of various skins and other grading and counting techniques, as useful objective tools in clinical trials and Homoeopathic practice to effectively assess and tabulate the lesions of the disease (Acne vulgaris) and its process.
- placebo-controlled studies, although not being very ethical, should also be investigated, especially if stress is an important aetiological factor in acne vulgaris, thus also allowing for the introduction and investigation of stress-control mechanisms to control or treat acne due to stress.

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# APPENDICES

**APPENDIX A – (A1 AND A2)** INFORMATION LETTER – ENGLISH AND ZULU

**APPENDIX B – (B1 AND B2)** INFORMED CONSENT FORM – ENGLISH AND ZULU

**APPENDIX C** – **(C1 AND C2)** PERCEPTION QUESTIONNAIRE – ENGLISH AND ZULU

**APPENDIX D** – GRADING TECHNIQUE

**APPENDIX E** – LEEDS COUNTING TECHNIQUE

**APPENDIX F** – STANDARD DIAGNOSTICS CASE HISTORY

**APPENDIX G** – **(G1 AND G2)** HOW TO TAKE HOMOEOPATHIC REMEDIES? – ENGLISH AND ZULU

**APPENDIX A 1**

**INFORMATION LETTER**

Title of Research Project : A study comparing the effectiveness of a herbal-complex (*Arctium lappa, Berberis aquifolium, Echinacea purpurea and Taraxacum officinale)* as compared to homoeopathic simillimum in the treatment of Acne vulgaris.

Name of Supervisor : Dr. A.H.A. Ross M.Tech (Hom)(TN), B.Mus (UCT)

Name of Research student : Nervashnee Govender

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 fulfillment of their Master's Degree in Technology : Homoeopathy.

The aim of this study is to evaluate the efficacy of a herbal-complex as compared to homoeopathic simillimum in the management of Acne vulgaris. A final comparison will be done with a concurrent study (i.e. homoeopathic simillimum vs. miasmatic treatment), being conducted for the treatment of Acne vulgaris. This is to evaluate which treatment is most effective.

Acne vulgaris is a common skin disorder which starts at puberty but can extend into the 3$^{rd}$ and 4$^{th}$ 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 any 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 4 research studies of Acne vulgaris performed previously at Durban Institute of Technology-Steve Biko Campus 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 Acne vulgaris and how effective it is in alleviating the signs and symptoms of this condition.

The demand for 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 old symptoms might come

back but this is short-lived and is followed by amelioration.

In order to ensure that this study complies with the scientific method, only certain persons may be accepted into the study.

**To be in this study you:**

- have to enter the study voluntarily
- have to be between the ages of 18 & 40 years
- have to have visible acne
- must agree to discontinue any other form of medication you are on, 4 weeks before the trial starts and during the trial
- must not change your lifestyle or dietary habits during the trial
- must be willing to take a prescribed amount of medication per day, as directed and not to expose the medicines to any situation that might antidote it, such as very high temperatures and aromatic substances eg. peppermint and camphor.

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

The duration of this study is 9 weeks however you will be free to withdraw from this study, at any stage, if necessary and no explanation will be required.

After you have signed both the Information letter and consent form, the following procedure, for each visit, will take place.

**Visit 1:**
a) fill in perception questionnaire
b) consultation with medical and personal history taking
c) general examination will be performed
d) counting and grading of pimples
e) treatment will be prescribed

**Visit 2, 3, 4**:
a) fill in questionnaire
b) general examination will be performed
c) recounting and re-grading of pimples will be done
d) treatment may be prescribed depending on the response to treatment

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 homoeopathy for acne treatment. There will be strict patient-practitioner confidentiality. Your personal details will not be disclosed. All data will only be accessible to the researcher and

supervisor concerned. A qualified homoeopath is supervising the treatment and the treatment is free of charge.

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

Nervashnee Govender Tel : 2042041 (Homoeopathic Clinic at Durban Institute of Technology-Steve Biko Campus)

Dr. Ashley Ross (MTech (Hom) (TN)) Tel : 2042542 (Homoeopathic Clinic at Durban Institute of Technology-Steve Biko Campus)

Thank you.

Kind regards

Nervashnee Govender
(Final year Homoeopathic student)

---

*Please complete, sign, detach and return to secretary.*

Patient Information

Full name :……..
Date of Birth :……..
Age :……..
Sex :……..

I, _____HAVE READ AND UNDERSTAND THE INFORMATION LETTER AND DO HEREBY AGREE TO ABIDE BY THE DELIMITATIONS AND CONDITIONS SET OUT IN THE ABOVE DOCUMENT.

Patients Name :_____
Signature _____

Witness Name :_____
Signature :_____

_____ Date:_____
Nervashnee Govender
(Final year Homoeopathic student)

**APPENDIX A2**

**INCWADI YOKUZINIKELA KWESIGULI**

Inghithi yocwaningo: Impumelelo ye igxube yamakhambi (*Arctium lappa, Berberis aquifolium, Echinacea purpurea ne Taraxacum officinale)* ekulapheni isifo sezinduna iqathaniswa ne homoeopathic simillimum ekulapheni isifo sezinduna.

Igama lomhloli: UDokotela A.H.A Ross M.Tech (Hom)(TN) B.Mus (UCT)

Igama lomfundi owenza ucwaningo: Nervashnee Govender

Siguli

Siyabonga ngokuthi uzinikele kulolucwaningo. Abafundi abafunda ihomoeopathy bafanaleke ukuba benze ucwaningo olujengalolu ukuze baphothule iziqu zabo eziphezulu kwezobulhwepheshe kwezepilo ekulapheni, Master's Degree of Technology in Homoeopathy.

Inhloso yalolucwaningo ukuthola ukuthi igxube yamakhambi iyaselapha kanglono yini isifo sezinduna uma siyiqathanisa ne homoeopathic simillimum. Ukuqathanisa kokugcina kuzokwenziwa phakathi kwalezizindlela ezimbili ihomoeopathic simillimum kanye ne imiasmatic treatment okumanje ucwaningo ngazo. Lokhu kuzokhombisa ukuthi iyiphi indlela engcono ekulapheni isifo sezinduna.

Izinduna isifo sesikhumba esijwayeleke ukutholakala kubantu besilisa nabesifazane uma sebengena ebunsizweni nasebuntombini, kodwa kuyenzeka ukuthi umuntu akhule naso noma esedlulile ekuthombeni. Zimingi izindlela zokulwa nalesisifo kodwa akuzona zonke eziyimpumelelo. Lokhu kudala ukukhathakzeka kophethwe vilesisifo kanye nodokotela abamnyanga yo, ingakho sibone kubalulekile ukuba sense lolulwaningo owphathelene nalesisifo.

Ucwaningo isifo sezinduna bese luke lwenziwe eDurban Institute of Technology-Steve Biko Campus ngaphambilini ngakhoke lolucwaningo lwe ihomoeopathic treatment luvangezelela olwazini nasekuqondeni ukwelapha lesifo sesikhumba.

Inhloso yalolucwaningo ukuthola umthekela ngokusebenzisa ihomoeopathic treatment nokuhlola. Ukuthi iyimpumelelo engakanani ekushabalaliseni izinduna kanye nezinkomba zazo.

Kuyabonakala ukuthi kunesidingo esikhulu kakhulu sekhambi elingenbungozi elisebenziseni ihomoeopathic treatment. Kodwa ke ezinye zeziguli zingathola

ukuhlukumezeka uma zisebenzisa ihomoeopathic treatment, lokhu kosho. Abukho ubungozi obaziwayo ekusebenziseni ihomoeopathic treatment, kodwa ke ezinye zeziguli zingathola ukuhlukumezeka. Uma zisebenzisa ihomoeopathic treatment, lokhu kusho ukuthi izinga lezinduna lingaqhubekala noma kuvuke izinduna ezikade seziphelile kuhlukumezeka kungaba okwesikhashana bese kulandelwa ukusha kwezinduna.

Awuzukukhokhelwa mali ngokuzibandakanya kwakho kuloluhlelo. Kuzothathwa abantu abaneminyaka ephakathi kuka 18 no 40, kuphela futhi abanezinduna ezibonakalayo. Kufanele uzimisele ukuyeka ukudla nanamo yimuthi imithi okade uyidla amasonto amane ngaphambi koyiyinyo nangesikhathi soyiyinyo. Indlela ophila ngayo nokudla obukade ukudla nendlela odla ngayo ungakushintshi ngesikhathi soyiyinyo. Ngesikhathi soyiyinyo ungayishinthi inendlela ophila ngayo nokudla obukade ukudla. Kuzodingeka  ukuba uzimisele ukudla imithi ozoyinikezwa eklinikhi uyidle uyiqede futhi uqaphele ukuthi imithi awuyibeki endaweni khona ukonakala njengase ndaweni eshisavo kakhulu, indawo enephunga lika peppermint kanye camphor.

Umuntu okhulelwe, umuntu oncelisayo umuntu ogulayo onesifo esidinga ukwelashwa isikhathi eside chronic condition, umuntu odla imithi yinoma yimuphi. Umuthi wanoma yisiphi isifo abavumelekile ukuzimbandakanya kulolucwaningo.

Unghoxa nanoma yinini uma ucwaningo seluqalile, futhi awuphoqelekile. Ukuthi unikeze isizathu sokhuhoxa kwakho. Isiyiyinyo sizoba amaviki awu 9, kuzodingeka ukuba uhambele eklinikhi ka 4, udlulise amasonto awu 3 koku vakashela eklinikhi.

Uma ususayinile womabili amafomu okuzinikela nantu uhlelo ozolulandela uma njalo uvakashele eklinikhi :

**Uma uvakasha okokuqala:**

1) Uzogwalisa uhla lwemibuzo
2) Uzohlolwa bese kutholakala umlando wempilo yakho
3) Izinduna zizobalwa bese izinga lazo ziyahlelwa
4) Uzonikezwa imithi ozoyisebenzisa

**Uma usuvakasha okweibili, okwesithathu nokwesine :**

1) Uzogwalisa uhla lwemibuzo
2) Uzohlolwa
3) Inani lezinduna lizobalwa bese liyahlelwa futhi
4) Uzonikezwa imithi ozoyisebenzisa

Wena uzohlomula ngaloluchwaningo ngothuki izinduna zakho zelapheke.

Ukuzimbhandakanya kwakho kulolucwaningo nokuqonda ukuthi indawo yehomoeopathic treatment ekulapheni izinduna.

Imininingwane avizikudacwa noma yikubani ngaphandle kwenvume vesigulu. Ukuthathwa kwemithi kuzobe kuqaphelwe abahlengi kazi abaqeqeshiwe imithi imahala.

Uma unombuzo noma kuba nezinkinga ngesikhathi socwaningo ungathintana no:

Nervashnee Govender Tel.: 031 – 204 2041
(Eklinikhi ese Durban Institute of Technology-Steve Biko Campus)

UDokotela Ashley Ross (MTech (Hom)(TN)) Tel.: 031 – 204 2542
(Eklinikhi ese Durban Institute of Technology-Steve Biko Campus)

Siyabonga.

Ube nosuku oluhle.

Nervashnee Govender
(Umfundi owenza ibanga lokuguna kwi-homoeopathy)

---

Imininingwane yesigulu

Igama nesibongo: ……..
Usuku lokuzalwa: ……..
Iminyaka yakho: ……..
Ubulili: ……..

**Mina,……..ngiyavuma ukulandela nokwenza njengoba kubha liwe kulosomqu**.

Igama lesiguli:……
Isishicilelo :……

Likafakazi :……
Isishicilelo :……

_____
Nervashnee Govender Usuku:_____
(Umfundi owenza ibanga lokuguna kwi-homoeopathy)

---



**APPENDIX C1:**

**PERCEPTION QUESTIONNAIRE : Assessing patients perception to treatment**

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

Date :……

**IDENTIFYING DATA:**

Name :……..
Age :……..
Sex :……..
Date of birth :……..

INTRODUCTION

This research project aims to investigate the efficacy of homeopathic treatment of Acne vulgaris. The demand for some successful, non-harming treatment for this condition is quite evident and growing therefore the aim of this research project is to determine the impact of homoeopathic treatment of Acne and how effective it is at alleviating the signs and symptoms. Your honest participation will contribute to the homoeopathic knowledge and will create an awareness of this safe and effective form of treatment for acne. 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.

If it is necessary, the researcher will give the patient a brief definition and explanation of homoeopathy.

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 placed over the number that resembles your closest feeling.

I hate them --- --- --- --- -**x**-I love them
**1 2 3 4 5**

Please note that the larger the number you choose the more positive the response is. Complete all the questions. Thank you.

**QUESTIONNAIRE**

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?
   Not good at all --- --- --- --- --- Very good treatment
   **1 2 3 4 5**

2. How severe would you rate your acne?
   Very severe --- --- --- --- --- Mild
   **1 2 3 4 5**

3. Has your acne changed at all?
   Not at all --- --- --- --- --- Very much
   **1 2 3 4 5**

3.1. If your acne has changed, how has it changed?
   Getting worse --- --- --- --- --- Getting better
   **1 2 3 4 5**

4. Has the surface texture of your skin changed?
   Becoming rougher --- --- --- --- --- Getting smoother
   **1 2 3 4 5**

5. Are you experiencing any pain or tenderness with your acne?
   Very much pain --- --- --- --- --- No pain at all
   **1 2 3 4 5**

6. Has your acne been bleeding?
   Very much bleeding --- --- --- --- --- No bleeding at all
   **1 2 3 4 5**

7. How would you rate your acne now as compared with the period before the treatment started?
   No change at all --- --- --- --- --- Very much better
   **1 2 3 4 5**

8. How has your attitude concerning your condition changed since taking the Homoeopathic medicine?
   Deteriorated (-ve) --- --- --- --- --- Very much better (+ve)
   **1 2 3 4 5**

9. How do you feel people perceive your condition to be?
   Severe --- --- --- --- --- Mild
   **1 2 3 4 5**

**APPENDIX C2**

**INHLOLOVO NGOKULIDELEKILE**

Inhlolovo ebuyekeza imiphumela iziguli eziyilindele ngokubamba iqhaza kulesisiyivinyo.

Qaphela : Loluhla lwemibuzo luqokekelwe

Usuku :……

**Imininqwane :**

Igama :……
Iminyaka :……
Usuku lokuzalwa :……
Ubulili :……

**ISINGENISO**

Inhloso yalolucwaningo ukuhlola ukuthi kuyimpumelelo engakanani ukulwa ne zinduna uma kusetshenziswa isu iHomoeopathic treatment. Kucacile ukuthi kunesidingo esikhulu sokuthola ikhambi lokwelapha isifo sezinduna, elingenabungozi.

Ukuzibhandakaya kwakho ngokweqiniso kuzosiza ekwandiseni ulwazi nge iHomoeopathic treatment. Ekwenye yezindlela ephephile futhi esebenzayo.

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

**IMIGOMO**

Uyalelwa ukuba uphendule lemibuzo ngokweqiniso impendulo yombuzo ngamunye ihlukaniswe amazinga amahlanu. Wena faka uphawu phezu kwenombolo echaza kagcono indlela ozizwa ngayo.
Isibonelo uma umbuzo ubuza ukuthi uzizwa kanjani ngezinsuku ezinemvula, ngabe uyazithanda na?
Kwimpendulo yakho uzofaka uphawu kwinombolo esodelene kakhulu nendlela ozizwa ngayo. Kanje :

Ngiyazizonda --- --- --- --- -**x**- Ngiyazithanda.
**1 2 3 4 5**

Qaphela-ke uma ufaka uphawu kwinombholo enkulu njengesibonelo esingenhla kusho ukuthi uyavumelana kakhulu nalesosimo. Uyalelwa ukuthi uphendule lemibuzo elandelayo.

1. Kuze kube manje uzizwa unjani ngokudla imithi?
   Kungeke kukusize --- --- --- --- --- Kuzokusiza
   **1 2 3 4 5**

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

3. Kungabe izinga lezinduna lishintshile na?
   Cha --- --- --- --- --- Yebo kakhulu
   **1 2 3 4 5**

3.1. Uma uthi izinga lezinduna lishintshile, ngabe lishintshile kanjani?
   Zibeziningi --- --- --- --- --- Ziyaphela
   **1 2 3 4 5**

4. Isikhumba sakho ngabe sishintshile na ?
   saba buhadlahadla --- --- --- --- --- Saba bushelelezi
   **1 2 3 4 5**

5. Ngabe izinduna zakho zibuhlungu noma zintofontofo na?
   Zibuhlungu --- --- --- --- --- Azibuhlungu
   **1 2 3 4 5**

6. Ngabe izinduna zakho ziyopha na?
   Zopha kakhulu --- --- --- --- --- Azophi kwakona
   **1 2 3 4 5**

7. Uma uqhathanisa izinga lezinduna zakho manje nangaphambi kokuba udle imithi linjani?
   Azishintshile --- --- --- --- --- 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 G1

## 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. If you are taking drops (liquid potencies) add 10 drops in a little water and swallow after circulating in the mouth for a few seconds.

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 a **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 homeopath.

**FOR ANY QUERIES REGARDING YOUR MEDICATION, PLEASE DON'T HESITATE TO CALL RECEPTION ON: 204 2041 OR 2042513.**

**APPENDIX G2**

**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 noma okusanhlamvana – **UNGAKUTHINTI NGEMINWE YAKHO**. Okusanhlamvana namaphilisi kufakwa ebhodleni eliwumtshumana elinesivalo sepulasitiki. Vula isivalo bese uthela inani elidingekile lamaphilisi noma okusanhlamvana esivalweni, beka amaphilisi noma okusanhlamvana ngaphansi kolimi bese ukulinda kuze kuncibilike.

3. Phuza imithi yakho kusasele isigamu sehora ngaphambi kokudla noma uyiphuze sekuphele ihora elilodwa udlile. Gwema ukudla into ene Peppermint ngaphambi noma ngemuva kokuphuza imithi.

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

5. Zama ukugwema ukuphuza ikhofi ngesikhathi uselashwa.

6. Njalo phuza okusampushana ngenani elibekiwe noma ngendlela oyalelwe gayo udokotela wakho.

**UMA UNEMIBUZO MAQONDANA NEMITHI YAKHO, UNGANGABAZI UKUSHAYELA KULENOMBOLO: (031) 204 2041 NOMA (031) 204 2513**

**APPENDIX F**

**STANDARD DIAGNOSTICS CASE HISTORY**
(Chatterjee, 1993:10-14)

Date of History:

General Information:

Name:

Age:

Sex:

Address:

Place of birth:

Marital status:

Occupation:

Source of referral:

Source of history:

Main complaint: What seems to be the problem?

History of main complaint: (Onset, Aetiology, Location, Duration, Character, Modalities, Concomitants, Radiation, Patients response to symptoms).

Past Surgical History:
Any operations since you were born?

Past Medical History:
(Rheumatic fever, Pneumonia, Tuberculosis, Jaundice, High Blood Pressure)

1. Have you ever had any serious medical problems?
   (HIV AIDS, Cancer,Tuberculosis etc.)

2. Can you remember your childhood illnesses?
   (Mumps, Measles, Chicken Pox, German Measles)

3. Have you ever been in hospital for anything?

4. Do you have any allergies?

5. What vaccinations / immunizations have you had recently or previously? (Tetanus, Pertussis, Diphteria, 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, cause and time of death?

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 all alive?
3.1) Do any of your children have any medical probems?

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?
2) Any traveling (ie. Out of Durban) ?
3) Any recent shock or grief?
4) Sleep patterns?
5) Diet ?

**PSYCHOSOCIAL HISTORY**

1) Home situation and significant others?
2) Daily life?
3) Important experiences?
4) Religious beliefs?
5) The patients outlook?

**SYSTEMS REVIEW :**

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

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

3) HEAD:
(Headaches, head injuries)

4) EYES:
(Vision, glasses, contact lenses, pain, redness, double vision, cataract)

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 gallbladder problems, hepatitis)

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

13) REPRODUCTIVE SYSTEM:
(Discharge from or sores on the penis, hearnias, testicular pain or masses, history of venereal diseases)

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 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, odors of the body or

breath. Facial expression, reaction to person and things in the environment. Listen to the patients 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: (Opthalmoscopic 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, Athlete's 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 the 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 car :
    f. humidity/dryness :
    g. sitting still/changing position :
    h. time of day :
    i. thirsty/not thirst:
    j. itchy/not itching :
    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 D**

**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 a **0 to 4** scale with half 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 (Burke & Cunliffe (1984))

Lesions are divided into non-inflamed and inflamed as follows:

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) Inflamed lesions are:

   1) superficial lesions (papules and pustules) –vary in size from 0,1 to 0,5cm in diameter
   2) deep lesions (nodules, cysts, deep pustules) which are 0,5 cm in diameter or larger
   3) macules represent the resolving phase of either superficial or deep lesions and are either large or small.

A vernier caliper (which will be borrowed from Dept. of Homoeopathy, Durban Institute of Technology-Steve Biko campus) will be used to measure the size of the lesions in order to classify them. (Burke & Cunliffe, 1984:83)

**To avoid errors in lesion counting:**

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

2) Good background fluorescent 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 whiteheads and blackheads (Burke & Cunliffe, 1984:87-88).

**APPENDIX B1**

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

**TITLE OF RESEARCH PROJECT** : A study comparing the effectiveness of a herbal-complex (*Arctium lappa, Berberis Aquifolium, Echinacea purpurea and Taraxacum officinale)* as compared to homoeopathic simillimum in the treatment of Acne vulgaris.

**NAME OF SUPERVISOR** : Dr. A.H.A. Ross MTech (Hom) (TN)

**NAME OF RESEARCH STUDENT** : Nervashnee Govender

**DATE :**

**PLEASE CIRCLE THE APPROPRIATE ANSWER**

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

**IF YOUR ANSWER IS 'NO' TO ANY OF THE ABOVE QUESTIONS, PLEASE ASK FOR FURTHER EXPLANATIONS BEFORE YOU PUT YOUR SIGNATURE.**

PATIENT/SUBJECT*Name_____Signature_____
(in block letters)

WITNESS Name_____Signature_____
(in block letters)

RESEARCH STUDENT Name:_____Signature_____
(in block letters)

**APPENDIX B2**

**INCWADI EVUNYWE NGOKUBONISANA**
(kumele igcwaliswe isiguli* ifomu iphindaphinwe kabili)
*Cisha lokho ongahambisani nakho.

**Inqikithi yocwaningo** : Impumelelo ye igxube yamakhambi (*Arctium lappa, Berberis aquilfolium, Echinacea purpurea ne Taraxacum officinale)* ekulapheni isifo sezinduna iqathaniswa ne homoeopathic simillimum ekulapheni isifo sezinduna.

**Igama lomhloli :** Dr. A.H.A. Ross MTech (Hom)(TN)
**Igama lomfundi owenza ucwaningo:** Nervashnee Govender

**Usuku:**

**Faka isikokela empendulweni efanele**

1. Ngabe uyifundile imininingwane 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 ulithlile ithuba lokuxoxisa mayelana nalesisifundo? Yebo Cha
5. Ngabe uthole incazelo eyanele mayelana nalesisfundo? Yebo Cha
6. Ngabe ukhulume nobani?_____ Yebo Cha
7. Ngabe uyaqonda imiphumela yokuzimbadakanya kwakho kulesisifundo? Yebo Cha
8. Ngabe uyaqonda ukuthi ukhulukile ukuhoxa kulesisifundo Yebo Cha
    a) noma nini
    b) ngaphandle kokunika izizathu zokuhoxa, futhi
    c) ngaphandle komthelela ekunakekelweni kwempilo yakho?
9. Uyavuma ukuzibandakanya ngaphandle kwenkokhelo? Yebo Cha

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

**Uyacelwa ukuba ubhale ngamagama amakhulu :**

Igama lesiguli_____Isishicilelo_____

Igama likafakazi_____Isishicilelo_____

Igama lomfundi
owenza ucwaningo_____Isishicilelo_____

**APPENDICES:**

1) **A (1 & 2)** - INFORMATION LETTER
2) **B (1 & 2)** - INFORMED CONSENT FORM
3) **C (1 & 2)** - PERCEPTION QUESTIONNAIRE
4) **D** - GRADING TECHNIQUE
5) **E** - LEEDS COUNTING TECHNIQUE
6) **F** - STANDARD DIAGNOSTICS CASE HISTORY
7) **G (1 & 2)** - HOW TO TAKE HOMOEOPATHIC REMEDIES?
8) **H** - QUOTATION FROM DURBAN INSTITUTE OF TECHNOLOGY-STEVE BIKO CAMPUS HOMOEOPATHIC LABORATORY
9) **I** - QUOTATION FROM PARCEVAL PHARMACEUTICAL COMPANY