

THE EFFECT OF HOMOEOPATHIC SIMILIMUM TREATMENT
ON ATOPIC ECZEMA

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This dissertation is dedicated to my parents, and my loving husband.

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ABSTRACT

The purpose of this placebo-controlled study was to evaluate the degree of proficiency of homoeopathic similimum treatment in atopic eczema, in terms of its clinical manifestations and patients perception of the treatment. It was hypothesized that the patients treated with homoeopathic similimum would respond favourably in terms of the presenting condition and that their perception of the treatment would be positive.

In this experimental study the single variable design was used for its 'before-and-after with control'. Thirty patients were selected from the greater Durban area, according to the diagnostic criteria of atopic eczema as identified by Hanifin and Rajka (1980) and divided into two groups according to simple random sampling. Data were collected at the Homoeopathic Day Clinic at Technikon Natal.

Group 1 received placebo and group 2 received homoeopathic similimum treatment. Patients received 4 treatments over a period of 3 months and data were obtained at the first and last consultation. The Patient's Perception Questionnaire and the General Well-Being Schedule were completed by the patients in the presence of the researcher. The Clinical Evaluation Index was completed by the researcher.

Results were statistically analysed using the Mann-Whitney U-test (inter-group comparison) and the Wilcoxon Signed Rank test (intra-group comparison). Bar charts were drawn using the mean values obtained from the questionnaires.

In all 3 questionnaires it was found that the placebo group did not improve significantly. The experimental group improved significantly with regards to patient perception and clinical manifestation. No improvement occurred in terms of the General Well-Being Schedule, which measured patients' psychological levels.

The results of this study demonstrated that homoeopathic similimum treatment is effective in the treatment of atopic eczema in terms of its clinical manifestation and patient perception.

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DEFINITIONS

Antibodies: An immunoglobulin molecule that reacts with a specific antigen that induced its synthesis and with similar molecules; classified according to mode of action (Dorland's Medical Dictionary 1988: 36).

Asteatosis: Any disease in which persistent dry scaling of the skin suggests scantiness or absence of sebum (Dorland's Medical Dictionary 1988: 65).

Atopy: [Gr. *atopos* out of place]

A genetic predisposition towards the development of immediate hypersensitivity reactions against common environmental antigens, occurring in 10% of the general population, 50% of those with one affected parent, and 75% of those with two affected parents. The most common clinical manifestation is allergic rhinitis, bronchial asthma, atopic dermatitis, and food allergy occurring less frequently. The form exhibited, may vary over time and may differ from that exhibited by the parents. (Dorland's Medical Dictionary 1988: 163.)

Eczema: [Gr. *ekzein* to boil over]

A pruritic papulovesicular dermatitis occurring as a reaction to many endogenous and exogenous agents, characterised in the acute stage by erythema, edema associated with a serous exudate between the cells of the epidermis (spongiosis) and an inflammatory infiltrate in the dermis, oozing and vesiculation, and crusting and scaling; and in the more chronic stages

by lichenification or thickening or both, signs of excoriations, and hyperpigmentation or hypopigmentation or both. (Dorland's Medical Dictionary 1988: 529.)

Immunoglobulin: A protein of animal origin with known antibody activity, synthesized by lymphocytes and plasma cells and found in serum and in other body fluids and tissues (Dorland's Medical Dictionary 1988: 301).

Langerhans cells: A modified macrophage circulating between the epidermis and the local lymph nodes whose prime function is presentation of antigen to T lymphocytes (Edwards and Bouchier 1991: 907).

Placebo: Any therapy or component of therapy that is deliberately used for its non-specific, psychological, or psycho-physiological effect, or that is used for its presumed specific effect, but is without specific activity for the condition being treated (Shapiro and Morris 1978: 369).

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

Simillimum: Similimum or the law of similars stipulates that there is a resemblance between the toxic and therapeutic actions of a same substance. The symptoms displayed by a sick individual are cured by the substance capable of giving the same symptoms in a healthy subject. (Horvilleur and Boyer 1990: 5.)

CHAPTER 1

INTRODUCTION

Atopic eczema is characterized by pruritis, asteatosis, lichenification and an erythematous, papulovesicular rash that may develop into weeping wounds and undergo periods of exacerbation and remission (Motala 1993: 66).

The estimated incidence of atopic eczema in the general population varies between 1 and 5%. Over the past few decades there has been a steady increase worldwide in the incidence of this disorder. (Motala 1993: 66.) Atopic dermatitis is a chronic and disabling condition that has a major impact on financial and social resources of the individual and the community, and no cure is available (Steinman and Potter 1994). In atopic eczema the patient is not only handicapped by his or her disease, but also the patient's normal life may be disturbed (Finley 1996).

Current therapy is mainly symptomatic, consisting of either oral or topical steroids, antipruritics, coal tar preparations, UV light and food avoidance. Steroids produce side effects that include skin atrophy, telangiectasia, purpura, striae and suppression of the hypothalamic-pituitary-adrenal axis when applied to large body

surface areas. (Wachter and Lezdey 1992.) Pharmacological treatment is only partially effective (Steinman and Potter 1994).

Homoeopathy is an approach that utilizes medicines that stimulate the body's own immune and defense systems to initiate the healing process. It is an approach that individualises medicines according to the totality of the person's physical, emotional and mental symptoms. (Ullman 1991: 3.)

According to Spence (1993), who did a retrospective survey of 130 cases of eczema using homoeopathic treatment, 85.5% of the sample group showed a marked improvement in their eczema as a result of homoeopathic medication. A literature survey has revealed that no clinical trial has been done on atopic eczema sufferers.

It was therefore the purpose of this placebo-controlled study to determine the effectiveness of homoeopathic similimum treatment in atopic eczema, in terms of its clinical manifestations and patients' perception of the treatment.

CHAPTER 2

REVIEW OF THE RELATED LITERATURE

2.1 ECZEMA IN PERSPECTIVE

Eczema is a collective term for many inflammatory skin conditions of the skin. It is defined differently in different countries. The term *dérmatitis* is often used synonymously with eczema, although in fact dermatitis means any inflammation of the skin. All eczemas are forms of dermatitis, but dermatitis is not always eczema. (Riott 1992: 484; Rorsman 1976: 46.)

This group of diseases may be classified as follows:

- Contact eczema: a) allergic b) irritant
- Atopic eczema
- ⊙ Lichen simplex
- ⊙ Seborrhoeic eczema
- Pityriasis alba / Follicular eczema
- Nummular eczema
- ⊙ Stasis eczema ("varicose eczema")

⊙ Exfoliated erythroderma.

(Rook et al. 1988: 419-426; Rorsman 1976: 46.)

Atopic dermatitis is also known as atopic eczema, constitutional eczema, endogenous eczema, allergic eczema, infantile eczema, flexural eczema, disseminated neurodermatitis, and Besnier's prurigo diathésique (Domonkos et al. 1982: 75).

The term atopy was introduced by Coca and Cooke in 1923. They had observed that certain disorders, such as asthma, eczema and urticaria run in families and that affected subjects show positive wheal and flare skin reactions to common inhalant antigens, but lack precipitating antibodies. (Riott 1992: 170.) This is a relapsing eczematous skin eruption that usually develops in patients with personal and family histories of atopic disease. In brief, atopic diseases are those respiratory, cutaneous, and gastrointestinal conditions that are associated with an inherited tendency to develop IgE antibody and clinical sensitivity to substances that are ordinarily innocuous. (Riott 1992: 484.)

Eczema and dermatitis are terms used to describe the symptoms of a certain kind of skin reaction that can have many possible causes. Sufferers range from newborn babies with an inherited tendency to angry outbursts of raw, itchy skin which may never be traceable to any external factor, to elderly workers whose skin is dry, cracked and tired after years of "abuse" from handling irritant substances. The two

outstanding features which the various forms have in common are that they can create profound psychological and physical distress for those afflicted and for their families, and they are often intensely resistant to treatment.

Eczema is one of the most irritating, distressing and often unsightly skin conditions, having far-reaching effects on a sufferer's health, happiness and lifestyle. As many as one in ten people may be affected at some time in their lives, often in childhood, but the disease can also strike in adulthood. (Meredith 1994: 3.)

Atopic eczema is a debilitating disease with extensive ramifications in both financial and social terms. The financial impact involves not only the family resources, but extends into the work environment, and finally to the whole community. A greater cost occurs in terms of social disruption, including days lost at school, family upheaval, and decline in school performance. Patients are known to attempt severe restrictive diets that may further compromise the child's health. Insufferable damage may be done to the self image in the older child with atopic dermatitis, particularly girls. (Steinman and Potter 1994.)

Sufferers from atopic eczema appear to pay a high price for their disease. Adults have to pay for prescriptions and are further punished by loss of salary and high clothing and laundry expenses. (Herd et al. 1996.) According to McHenry et al. (1995), patients with atopic eczema account for 10-20% of all referrals to dermatologist and about 30% of dermatological consultations in general practice.

2.2 AETIOLOGY

It is suggested that widespread environmental factors are operating in genetically susceptible persons, triggering the manifestation of the disease. Current studies indicate that contact of skin with environmental inhalant allergens or atopens mediate an allergen-specific immune-response via Langerhans cells expressing the high affinity for specific immunoglobulin E (IgE). (Kapp 1995.)

Atopic eczema typically runs a chronic course with exacerbations and remissions. A variety of 'trigger factors' may exacerbate eczema: irritants (e.g. soap, harsh chemicals), heat and humidity, stress and anxiety, certain foods (e.g. eggs, milk, wheat, soya protein and peanuts), inhalant allergens (e.g. house dust mites, pets, pollen and cut grass) and certain infections. (Motala 1994: 66.)

2.3 PATHOGENESIS

The exact pathogenesis of atopic dermatitis is unknown. Currently, it is believed that IgE-mediated reactions and cellular responses contribute to the chronic inflammation of this disorder. (Canizares 1982: 40.)

Atopics have a tendency to develop increased levels of reagenic antibodies (IgE) and peripheral eosinophilia, but the aetiologic significance of these findings is

unknown. This allergic tendency is genetically passed on from parent to child, and is characterised by the presence of large quantities of the type of antibodies called IgE antibodies. When an allergin (defined as an antigen that reacts specifically with a specific type of IgE reagin antibody) enters the body, an allergen-reagin reaction takes place, and a subsequent allergic reaction occurs. A special characteristic of the IgE antibodies is a strong propensity to attach to mast cells and basophils. Indeed, these cells can bind as many as half a million molecules of IgE antibodies. Then when an antigen binds with the IgE antibodies attached to the mast cells or basophils, this causes an immediate change in the membrane of the cells, causing many of the mast cells and basophils to rupture; others release their granules without rupturing and also secrete additional substances not already preformed in the granules. Some of the many different substances that are either released immediately or secreted shortly thereafter include *histamine*, *slow-reacting substance of anaphylaxis*, *eosinophil chemotactic substance*, *a proteases*, *a neutrophil chemotactic substance*, *heparin* and *platelet activating factors*. These substances cause phenomena such as dilatation of local blood vessels, attraction of eosinophils and neutrophils to the reactive site, damage to the local tissues by the protease, increased permeability of the capillaries with loss of fluid into the tissues, and contraction of local smooth muscle cells. (Guyton 1987: 212.)

Furthermore, IgE-bearing Langerhans cells are observed in lesional skin. This appears to occur by absorption of circulating IgE onto the high affinity receptor for IgE usually found on mast cells. The role of mast cells in that process is unclear at

present. However, besides their involvement in host responses to parasites, non-specific inflammation, angiogenesis, tissue-remodelling and wound healing there is no doubt that mast cells are of major importance in the propagation of IgE-dependent immediate hypersensitivity. (Kapp 1995.)

2.4 CLINICAL FEATURES

Atopic eczema is variable in its appearance, depending on whether it is acute, chronic or somewhere in between. In acute eczema primary lesions consist of redness, swelling, small papules, erythematous macules and discrete or coalescent vesicles. In secondary lesions minute excoriations, weeping or oozing of serous fluid and the development of crusts are common features. Chronic eczema consists of thickening and hyperpigmentation, with varying degrees of scaling, crusting, fissuring and lichenification (leathery thickening and aggregations of small, firm papules). (Isselbacher *et al.* 1992: 274; Riott 1992: 485.)

In atopic eczema it is often impossible to determine which lesions are primary and which follow itching and scratching. Lichenification is not peculiar to the atopic individual and not all patients with atopic dermatitis are capable of producing this epidermal thickening. (Rook *et al.* 1988: 426.)

Itching, which may be intense, is a common feature; accordingly, eczematous lesions are commonly excoriated. The most accepted explanation for atopic eczema

is that the itch threshold is lower than normal in some atopic patients. This may be explained by a hyperactivity of leucocyte phosphodiesterase that may be genetically determined. The itching leads to scratching, which promotes inflammation and secondary infection with the release of mediators that, in turn, aggravate the itching problem. (Riott 1992: 485.) Mechanical irritation of the skin (scratching) could result in the inflammatory response of the dermis (Kapp 1995). The skin of patients with atopic dermatitis tends to carry more staphylococci even without any clinical evidence of infection (Rook et al. 1988: 428). Although itching can be regarded as 'physiological', the resulting scratching can lead to further damage of the skin, thus increasing inflammation and pruritus. A vicious 'itch-scratch' circle is thus initiated. Intense itching is not only extremely distressing but can be as disabling as severe pain. It affects daily activities, sleeping patterns, and can result in school disruption for children. (Steinman and Potter 1994.)

Areas of atopic dermatitis itch more readily and more persistently with stimuli which normally elicit itching, e.g. histamine or proteolytic enzymes. These may also respond with the sensation of itch to stimuli which are usually only felt as touch. This accounts for much of the intolerance of atopic patients to wool. (Rook et al. 1988: 426.)

Many patients are aware that perspiration aggravates their condition. Disturbances of sweating due to poral occlusion may occur, and allergens ingested or derived from sweat may be excreted in the sweat. Atopic dermatitis is particularly prevalent

in temperate regions and seasonal exacerbations in spring and autumn are frequent. (Rook et al. 1988: 428.)

Psychological (e.g. anger, frustration and anxiety) and central nervous system factors also play a variable and often dominant role. The evidence for an atopic personality (outwardly calm, seething with suppressed anxieties and frustration, insecurity, aggression, egotism, above average intelligence) is conflicting. (Provost and Farmer 1985: 29-30; Rook et al. 1988: 428.)

The skin capillaries also react abnormally. Light firm pressure gives rise to a white line rather than the usual triple response, a change called white dermographia. (Sneddon and Church 1976: 41.)

The distribution of the rash typically varies with age. In infancy (3 months to 2 years) the cheeks, wrist and extensor aspect of the arms and legs are usually involved. The entire body may be affected but the nappy area is usually spared. In young children (2 years to 12 years) flexor surfaces, the neck, wrists and ankles are generally involved. In teenagers and young adults flexural surfaces, hands and feet are frequently involved. (Motala 1994: 66.)

2.5 CLINICAL DIAGNOSIS

In the late in 1980's, diagnostic guidelines were established for the first time to

delineate clinical populations that are subjects of investigative studies.

Based on the diagnostic criteria of Hanifin and Rajka (1980), atopic dermatitis is characterised by five major basic features. Firm diagnosis of atopic eczema would require the presence of at least 3 major basic features.

- Pruritus. The diagnosis of active atopic eczema cannot be made if there is no history of itching.

- Lichenification. This is a hallmark of the disease when seen in typical locations. Obviously other skin diseases may manifest lichenified skin e.g. lichen simplex chronicus without any evidence of atopic eczema.

- Chronically relapsing course. Atopic eczema is remarkable for its chronicity and for flares and relapses which may occur as often as weekly during active disease. At the other extreme, relapses appear many years after seemingly complete remissions.

- Atopic history.

- a. Personal. Manifestations of allergic respiratory disease are present in roughly 50% of patients.

- b. Family members. Approximately 70% of patients with atopic eczema are aware of other family members who have one or more manifestations of atopy.

Minor or less characteristic features:

In addition to having 3 of the basic features which are either less-specific or relatively rare, these characteristics might allow exclusion of, for example, a patient

with chronic allergic contact eczema who has pruritus, lichenification and family history of atopy.

- ◉ Xerosis. The presence of generalised dry skin is highly suggestive of atopic eczema. This feature tends to fluctuate with disease severity and, during remissions, it may not be detectable.
- ◉ Ichthyosis. This condition has been reported in 2-6% of patients with atopic eczema.
- ◉ Immediate (type I) skin test reactions. Hanifin and Rajka (1980) showed that approximately 80% of patients with atopic eczema manifested Type I responses to skin test antigens. The test is quite non-specific however, and its usefulness is highly dependent upon antigen quality, concentration and proper standardisation.
- ◉ Elevated serum IgE. This is a very non-specific feature seen in a number disease states. A high level may add considerable support to the diagnosis of atopic eczema but the serum concentration of IgE is normal in about 20% of patients.
- ◉ Early age of onset. Though obviously non-specific, this can be a very helpful clue for accepting or rejecting the diagnosis of atopic eczema. Ninety per cent of patients have an onset of their diseases in the first five years and adult onset will always raise suspicions as to the correctness of diagnosis.
- ◉ Cutaneous infections. Although the majority of patients with atopic eczema have no problems with infections, recurrent, poorly controlled eruptions of Herpes simplex or warts may support the diagnosis. In addition, superficial staphylococcal oozing or pustular lesions are seen in many patients.
- ◉ Non-specific hand eczema. Hand eczema occurred in 70% of patients and the

disease begins on the hands in one-third of cases. The presence of dry, scaling inflammations, especially on the dorsal hands and wrists, may be indicative of atopic eczema.

- ◉ Nipple eczema. Although not common, the presence of chronic lichenified, fissured or weeping eczema over one or both nipples is quite specific for atopic eczema.

- ◉ Cheilitis. Chronic desquamation of the upper lip is perhaps most specific for atopic eczema but patients commonly may have involvement of both lips.

- ◉ Recurrent conjunctivitis. This problem commonly coexist with allergic rhinitis and may be indicative of strong reaginic reactivity.

- ◉ Anterior subcapsular cataracts. These spontaneously developing, bilateral cataracts in the anterior lens are quite specific for atopic eczema.

- ◉ Orbital darkening. The so-called 'allergic shiners' are seen in various atopic disorders and are present in the majority of patients.

- ◉ Facial pallor and facial erythema. These somewhat paradoxical features may be present simultaneously and both are frequently overlooked as features of atopic eczema.

- ◉ Pityriasis alba. This mild post-inflammatory hypopigmentation occurs most in sun-exposed areas of patients with no evidence of atopy but the presence of pityriasis alba may be a clue to the disease in some patients.

- ◉ Anterior neck folds. These horizontal creases are certainly not specific but are present in the majority of patients.

- ◉ Itch when sweating. This is an almost universal symptom among patients with

atopic eczema. It may be precipitated by exertion, thermal or emotional sweating and occlusion from non-porous clothing or ointments.

- Intolerance to wool and lipid solvents. This probably reflects the decreased itch threshold to irritants on atopic skin and is a very common feature.

- Food intolerance. Cutaneous reactions to food are seen in a considerable number of children with atopic eczema.

- Course influenced by environmental and emotional factors. Perhaps no other dermatological conditions are so prominently associated with stresses and environmental changes, and the majority of patients are highly cognisant of these associations.

- White dermatographism and delayed blanching.

(Fitzpatrick et al. 1987: 1401; Hanifin and Rajka 1980; Kapp 1995.)

Williams et al. (1996) proposed a new and simple list of diagnostic criteria in Britain.

In order to qualify as a case, subjects are required to have a history of an itchy skin condition plus three or more of the following:

- a history of a rash in the skin creases (folds of elbows, behind the knees, fronts of ankles or around the neck).

- A personal history of asthma or hay fever.

- A history of a generally dry skin in the last year.

- onset under the age of 2

- visible flexural dermatitis as defined by a photographic protocol.

(McHenry et al. 1995; Williams et al. 1996.)

2.6 ASSOCIATED DISORDERS AND COMPLICATIONS

Allergic rhinitis and asthma occur in 30-50% of cases of infantile eczema.

Drug reactions of the anaphylactic type are more common in atopic persons because of their increased liability to produce reagins after natural exposure to antigens. Abdominal symptoms due to food allergy are more frequent in patients with atopic disorders but are not restricted to them. Alopecia areata is statistically associated with atopy. Patients with atopic dermatitis, both active and quiescent, are liable to develop generalized infections with the viruses of herpes simplex and vaccinia. (Rook *et al.* 1988: 431.)

2.7 NATURAL HISTORY AND PROGNOSIS

The age of onset is under the age of 6 months in 75% of cases. There is a general tendency towards spontaneous improvement throughout childhood, with often some slight relapse during adolescence. It is difficult to assess the prognosis in individual cases. It is worse if both parents are affected. The personality of the child and its parents, and environmental factors are equally important. Follow-up studies have demonstrated persistence of dermatitis into adult life in approximately 60% of those with an onset of disease during the first 5 years of life. (Rook *et al.* 1988: 432.)

2.8 MEDICAL TREATMENT

2.8.1 General management

Treatment has to be directed against all the known factors, but the basic principle is to prevent scratching. Reassurance, explanation and encouragement for child and parents are perhaps more important for this than any other chronic diseases. Factors known to aggravate atopic dermatitis must be reduced, e.g. soap, wool, and extremes of climates. (Rook et al. 1988: 432-433.)

2.8.2 Drug therapy

Modern medicine can be very effective in relieving symptoms of eczema but it cannot offer a cure. For many sufferers this means a life overshadowed by episodes of unsightly, irritating and even painful skin. It may mean years of being dependent on skin creams or drugs to keep the skin manageable, or severe restrictions on the occupations, hobbies and social activities that can be pursued. (Meredith 1994: 1-2.)

Current therapy is mainly symptomatic, consisting of either oral or topical steroids, antipruritics, coal tar preparations, UV light and certain food avoidance. Steroids produce side effects that include skin atrophy, telangiectasia, purpura, striae and suppression of the hypothalamic-pituitary-adrenal axis when applied to large body surface areas. (Wachter and Lezdey 1992.)

Drugs are administered mainly for their sedative or antipruritic effect. In practice many patients find that Chlorpheniramine or Promethazine provides useful help. Trimeprazine can usefully be given at night time, in the form of syrups for children. Oral Sodium Cromoglycate has proved rather disappointing in the treatment of this disease. (Rook et al. 1988: 434.)

It is too early to assess the reported benefit from ingestion of Evening Primrose Oil. Corticosteroids administered systemically have little place in the management of these patients. They can be given for a few weeks to help the patient over an acute crises. Systemic antibiotics are necessary when there is extensive, clinically obvious infection, sometimes even when there is no infection. (Rook et al. 1988: 434.)

The aim of topical therapy is to protect the skin from further scratching, from environmental factors, and to suppress inflammatory changes and secondary infections if present. Acute exudative lesions, especially localized, are best treated with a topical steroid cream, to which an antibiotic may be added if there is clinical evidence of infection. (Rook et al. 1988: 434.) Their use on the face in severe atopic eczema is relatively common. These steroid preparations applied to the face can pose a real threat to the patient's vision. It is important that patients on facial steroids be reminded regularly of the risk of glaucoma and advised to use their treatment sparingly. (Aggarwal et al. 1993.)

In a survey of members of the National Eczema Society, over half of respondents

said that their eczema interfered with their life and two thirds said that their expectations of their initial consultation with their general practitioner or hospital consultant had been only partly met (McHenry et al. 1995). Atopic dermatitis is one of the most difficult therapeutic challenges for physicians. Patients become frustrated and hostile and tend to press for quick 'cures'. (Provost and Farmer 1985: 31.)

2.9 HOMOEOPATHIC TREATMENT

Sir William Osler, considered to be the father of modern medicine, acknowledged the homoeopaths' serious interest in scientific medicine. Speaking to a group of conventional physicians in 1905, Osler stated: "It is not as if our homoeopathic brothers are asleep: far from it. They are awake - many of them at any rate - to the importance of the scientific study of disease." (Osler 1987.)

People generally turn to natural medicine after years of conventional treatment, and many find relief where conventional methods have failed. There are safe and effective treatments for eczema which offer a prospect of real improvement for more than 80% of patients, and almost everyone can expect to find something to lessen the frequency and severity of attacks. (Meredith 1994: 1-2.)

2.9.1 Homoeopathic simillimum treatment

Simillimum treatment is when the symptom-complex presented by the patient is

compared with the symptom-complexes produced by "drugs". In many cases there will be a resemblance, often extraordinarily close, between the patient's symptom picture and the picture of the effects of some "drugs" on healthy persons. The basis of homoeopathy is that the most successful remedy for any given occasion will be that one of whose symptomatology presents the clearest and closest resemblance to the symptom-complex of the sick person in question. That is: "Let like be treated by like". (Boyd 1989: 2.) Homoeopaths understand eczema as an internal disorder, so they need to choose a remedy individually based on a full evaluation of the patient's physical, emotional and mental characteristics as well as his or her genetic endowment (Ullman 1991: 99).

Eczema has a notoriously slow rate of progress under homoeopathic treatment, and patients should be forewarned about this. The homoeopath should never predict that a single dose or one remedy will resolve the problem, especially in a chronic condition. He will only lose credibility if the remedy must be changed or when an intercurrent remedy is required. It is helpful if the patient is repeatedly reminded that the goal is to strengthen the system as a whole. (Neustaedter 1991: 254-255.)

According to Spence (1993), endogenous eczema occurs in constitutionally predisposed individuals, and thus endogenous eczema is classified as being constitutional. This means that these patients often have a family history of atopic diseases. Constitutional eczema includes patients who suffered from eczema as babies which lasted for quite some time and then gave way to other related

syndromes: asthma, spasmodic coryza, migraine, etc. This is what is known as an atopic terrain. Homoeopathic physicians recognise this chronic reactional mode as the psoric terrain. (Spence 1993.)

The homoeopathic treatment of eczema therefore requires three primary investigations:

- A search for the symptomatic remedy, i.e. the remedy whose base substance may create a cutaneous lesion similar to that of the patient.
- A search for the basic remedy depending on the chronic diseases suggested by the reactional mode of the patient in relation to time and space. This is the first etiological factor.
- A search for a possible allergen which would justify isopathy. This is the second etiological factor. (Jouanny 1984: 223-224.)

2.9.2 Hering's Law of Cure

"If cure is in progress, symptoms will manifest at levels which are progressively of less crucial importance to the freedom of the individual to express fullness and creativity of life" (Vithoulkas 1981: 231).

- Healing moves from the deepest part of the organism (the mental and emotional states as well as the vital organs) to the more superficial parts (the skin, muscles, ligaments and extremities).
- Healing flows from the upper part of the body to the lower parts.
- Healing progresses in reverse chronological order of the appearance of

symptoms. (Ullman 1981: 66-77.)

Patients often note that the eczema returns, sometimes worse than before, when cortisone treatment is stopped. For the fortunate ones, the eczema may not come back; however, from a homoeopathic point of view, this may be either a good or a bad sign. It may mean that the patient has finally grown out of the condition, or it may mean that the internal condition has been driven deeper into the body, ultimately to manifest itself in a more serious disease. (Ullman 1991: 99.)

The action of corticosteroids is suppressive rather than curative (Lessof 1981: 199). Most commonly, homoeopaths see the suppression of skin symptoms later resulting in a lung condition, usually asthma. Since the skin does much breathing for the body and acts as a 'third lung', it is predictable that disease would attack the superficial lung first. Then, as the condition is either ineffectively treated or suppressed, it attacks the two primary sources of life's breath. (Ullman 1991: 99.)

The suppression of a disease usually leads to a more deep-seated illness surfacing. For example, many children whose eczema has been 'successfully' treated with steroids may suffer from asthma at a later date. These two events are seen by the orthodox medical profession as having only a casual connection, whereas the homoeopath believes that the suppression of the eczema has caused the asthma. Successful homoeopathic treatment involves the eczema reappearing at the same point. (Castro 1995: 15.)

Conventional physicians commonly note that eczema and asthma are linked, although they, unlike homoeopaths, generally treat them as separate illnesses and prescribe different medications for them (Ullman 1991: 99).

Homoeopaths assume that whenever treatment simply controls or suppresses, true cure will remain elusive, and disease is likely to penetrate deeper into the person. Hering's Law of Cure affirms the homoeopathic view that skin symptoms generally are the least threatening to the survival of the organism. (Ullman 1991: 99, 147.)

2.10 THE PLACEBO EFFECT

Placebo is an agent employed in medical practice with the primary aim of gratifying the patient. The agent employed is usually pharmacologically inert, at least in the dosage and form employed, and leads to certain effects on the individual. These effects are not determined by the known pharmacological properties of the substance; it is the psychological state of the individual at the time of its administration that determines the effects produced by the placebo. (Dawle 1985: 18.) The placebo effect is a very controversial topic, and much has been written on it in the past decade. Vernick (1995) states that many modern scientific studies have been able to verify the effectiveness of such treatments, showing that about a third of patients improve when given a placebo.

Sugar of milk, cane sugar globules, tablets or cones and alcohol are some of the

forms in which placebo is employed in homoeopathic practice (Dawle 1985: 419).

2.11 MEASURING INSTRUMENTS

The very heart of the homoeopathic approach is a medical case history and physical examination (Bates 1991: 5-70). Only by utilizing these can the all-important detail of the particular illness, and the individual characteristics of the patient be determined. This is essential for the selection of the suitable remedy which will be similar to the symptoms. A careful physical examination must always be carried out after history-taking. The full facilities of modern diagnostic techniques should be utilised, when these are relevant and in the genuine interests of the patient. (Boyd 1989: 19.)

The Patient's Perception Questionnaire which was constructed by the researcher, was used to determine the change that might occur in the patient's perception. The purpose of the General Well-Being Schedule was to offer a brief but broad-ranging indicator of subjective feelings of psychological well-being and distress for use in community surveys (MacDowell and Newell 1996: 206-213). In the present study, the purpose of the Clinical Evaluation Index, which was constructed by the researcher, was to determine the change that might occur in the clinical manifestations of the atopic eczema.

2.12 SUMMARY

Atopic eczema is one of the most irritating, distressing and often unsightly skin conditions, that has a profound effect on the patient's social and financial well-being (Meredith 1994: 3). One to five percent of the general population will suffer at one time in their lifetime of atopic eczema (Motala 1994: 66).

It is defined as an acute or chronic inflammatory condition of the skin, typically erythematous, edematous, papular, vesicular, and crusting; followed often by lichenification and scaling and occasionally by duskiness of the erythema and infrequently, hyperpigmentation. It is often accompanied by sensations of itching and burning and the vesicles form by intraepidermal spongiosis. (Dorland's Medical Dictionary 1988: 529.)

It has also been observed that asthma, urticaria, allergic rhinitis, and food allergies are present in the family history of atopic eczema sufferers. Aetiology is mainly unknown, but certain trigger factors and aggravating conditions have been identified. (Kapp 1995.)

The exact pathogenesis is unknown, and currently it is believed that IgE-mediated reactions and cellular responses contribute to the chronic inflammation of this disorder (Canizares 1982: 40). Conventional medical treatment of this condition is again a poor example of symptom suppression. Homoeopaths understand that skin

diseases are not simply skin problems but are the result of an underlying internal disorder. (Meredith 1994: 3.)

Using cortisone or other strong steroidal medicines suppresses the natural defensive effort of the body. Although they are sometimes highly effective in suppressing symptoms, they do not treat the internal disease. (Meredith 1994: 3.)

The aim of this placebo-controlled study was to evaluate the effectiveness of homoeopathic similimum treatment in atopic eczema sufferers, in relation to clinical manifestation and patients' perception of the treatment.

CHAPTER 3

MATERIALS AND METHODS

3.1 STUDY DESIGN

The objectives of this study were to evaluate the effect of homoeopathic similimum treatment with regards to clinical manifestations and general wellness in each participating patient. In this experimental study the single variable design was used for its 'before-and-after with control'. Thirty patients were selected, and 15 patients were allocated to the treatment group, and 15 to the placebo group.

Simple random sampling was used, which gives each element in a population an equal chance of being included in the sample and makes the selection of every possible combination of the desired number of subjects equally likely. The sample subjects were selected by using the roll of a dice (Appendix A - DeAngelis 1990: 26.)

3.2. SUBJECTS

Prior to taking part in the study, patients were carefully selected and certain entry criteria were used to minimize variations:

- A minimum of thirty patients were included in the study.
- Only patients between the age of sixteen and fifty five years were included in the study (Omenaas *et al.* 1994).
- Patients who were able to read and write English were included.
- The diagnosis was done clinically, and the patient's symptoms had to comply with the Diagnostic Criteria (Appendix B - Hanifin and Rajka 1980).
- Patient participation in this study was voluntary, and each had to sign the required Patient Consent Form (Appendix C).
- The patients were not permitted to take any other treatment or medication for their eczema.

Patients were excluded if they were pregnant or suffered from diabetes, cardiac disease, chronic infection or hypertension. Patients who had received systemic steroid therapy for 3 months or topical steroids for 2 weeks before commencement of this study were excluded. (Wachter and Lezdey 1992.)

3.3. ETHICS

The nature of the study was explained to the patients. If they agreed to participate, a consent form was signed (Appendix C).

3.4. INTERVENTIONS

There were two groups, i.e. Group 1 and Group 2. Group 1 received the placebo medication, but were otherwise treated exactly the same as group 2. Group 2 received homoeopathic similimum treatment, prepared according to the Homoeopathic Pharmacopoeia and prepared by a homoeopathic pharmacist. The homoeopathic pharmacist was a neutral member in the study and randomly divided the sample of thirty into two groups according to the simple random sampling. He then allocated valid homoeopathic medication to fifteen members of the treatment group and placebo medication to the other fifteen members. (Neither the researcher nor the patients knew who received homoeopathic or placebo medicine, thus making this a double blind study.)

The remedies were prescribed on an individualistic manner. Thus each patient received a different remedy and potency according to the individual's condition. A wide range of remedies and potencies were used; the basic principle of homoeopathic similimum treatment.

3.5 MEASUREMENTS

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

1. Advertisements in the newspapers, shopping mall bulletins, health shops and health clubs/gyms in the greater Durban area. Also on the notice boards at Technikon Natal and the University of Natal.
2. Assessing whether the patients that responded to the advertisements were suitable for the study i.e. criteria. (see 3.2)
3. On the first visit the researcher gave the patient the Information Sheet (Appendix D). The researcher then conducted a complete medical and homoeopathic case history, performed a full physical examination (Appendix E - Bates 1991: 5-70) and completed the Clinical Evaluation Index (Appendix F - compiled by researcher).
4. If he/she were accepted into the study, they completed the following documentation on the first visit: Patient Consent Form (Appendix C), a Patient Perception Questionnaire (Appendix H - compiled by researcher) and General Well-Being Schedule (Appendix I - MacDowell and Newell 1996: 206-213). Each patient had to complete the questionnaires under the researcher's supervision so as to ascertain a baseline of their symptoms.
5. Each case was repertorized and checked by a qualified homoeopath.
6. Following that, the prescriptions were submitted to a homoeopathic pharmacist.
7. This person prepared and handed the medication to the patients.
8. A period of one month was allowed to pass during which the patients took their medication.

9. On the follow-up consultation each patient's case history and physical examination were reviewed to assess whether they should continue with their current medication or whether their script should be altered to suit their present clinical manifestation. (Should the medication for a patient change, the prescription was handed to the homoeopathic pharmacist and the necessary changes were made, according to whether the patient was in the placebo or treatment group.)

10. Step 8 and 9 were repeated twice, allowing the experimental phase of the study to run over a period of three months.

11. On the last consultation all three questionnaires mentioned in step 3 were filled in again under the researcher's supervision.

The Patient Perception Questionnaire (Appendix H) was used to compare the treatment of atopic eczema in terms of the patients' perception in order to establish what aspects of homoeopathic treatment patients considered significant. The General Well-Being Schedule (Appendix I) offers a broad-ranging indicator of subjective feelings of psychological well-being and distress. It reflects the way the individual feels about his 'inner personal state'. (McDowell & Newell 1990: 206-213.) Love et al. (1989) noted that it is necessary to include psychological evaluation when using subjective measurements. The Clinical Evaluation Index (Appendix F) was used to evaluate the data concerning the clinical manifestations of atopic eczema before and after the introduction of homoeopathic treatment.

Within all three questionnaires the Likert scale was used: the higher the number the more negative the response, the lower the number the more positive the response (Huysamen 1990: 106).

3.6 STATISTICAL ANALYSES

All the questionnaires were screened. The answer blocks on the questionnaires were assigned numerical values. The scores were added up and converted to percentage values. The mean values for all the questionnaires were calculated, and bar charts were drawn from these results. All the data were then statistically analysed.

Statistical evaluation of the data was conducted by using Statgraphics Plus by Manugistics Inc. (2115 East Jefferson Street, Rockville, Maryland, USA). Analyses were performed using the Mann-Whitney U-test (inter-group comparisons) and the Wilcoxon Signed Rank test (intra-group comparisons). The Wilcoxon Signed Rank test and the Mann-Whitney U-test are both non-parametric tests, which allows them to be better suited to small sample groups such as those participating in this study. (Daniel 1978: 31, 82.) The level of significance (α) was set at 5% or 0.05 (Daniel 1987: 31-37).

P values were used to assess the degree of dissimilarity between two or more sets of measurements or between one set of measurements and a standard. A *P* value

is a probability. The information needed for the calculation of the P value comes from expressing a scientific hypothesis in probalistic terms. In this study the scientific hypothesis to be tested statistically was that homoeopathic similimum treatment would be effective in the treatment of atopic eczema. Such a hypothesis is called a null hypothesis, and when the hypothesis is accepted ($P > 0.05$), it is concluded that there has been no significant improvement. When the P value is between 0.05 and 0.01, the result is called 'statistically significant'. (Bailar and Mosteller 1992: 15, 183-185.) The results of the study are presented in the next chapter.

CHAPTER 4

RESULTS

4.1 INTRODUCTION

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

- Clinical Evaluation Index (Appendix F)
- Patient Perception Questionnaire (Appendix H)
- General Well-Being Schedule (Appendix I)

Comparisons were done within the two groups, using the Mann-Whitney U-test. Then comparisons were done between the two groups using the Wilcoxon Signed Rank test. The use of these non-parametric tests showed whether there was a significant difference between the two groups. For each questionnaire the averages were tabulated from the above tests. Bar charts were drawn using the percentage values obtained from the mean of numerical values on the questionnaires (Appendix J).

4.2 CRITERIA FOR THE ADMISSIBILITY OF THE DATA

- Only data collected from the trial were accepted.
- All interviews and external examinations were conducted by the researcher.
- All questionnaires were completed in the researcher's presence.
- Only information concerning changes in the clinical manifestations of atopic eczema, collected from patients who had taken homoeopathic medication (made according to those principles set out in the Homoeopathic pharmacopoeia) or placebo treatment, was accepted into this study.

All the questionnaires were completed by the patients participating in the study, and the data were processed under the supervision of the researcher.

4.3 RESULTS

4.3.1 PATIENT PERCEPTION QUESTIONNAIRE

4.3.1.1 TABLE 4.1

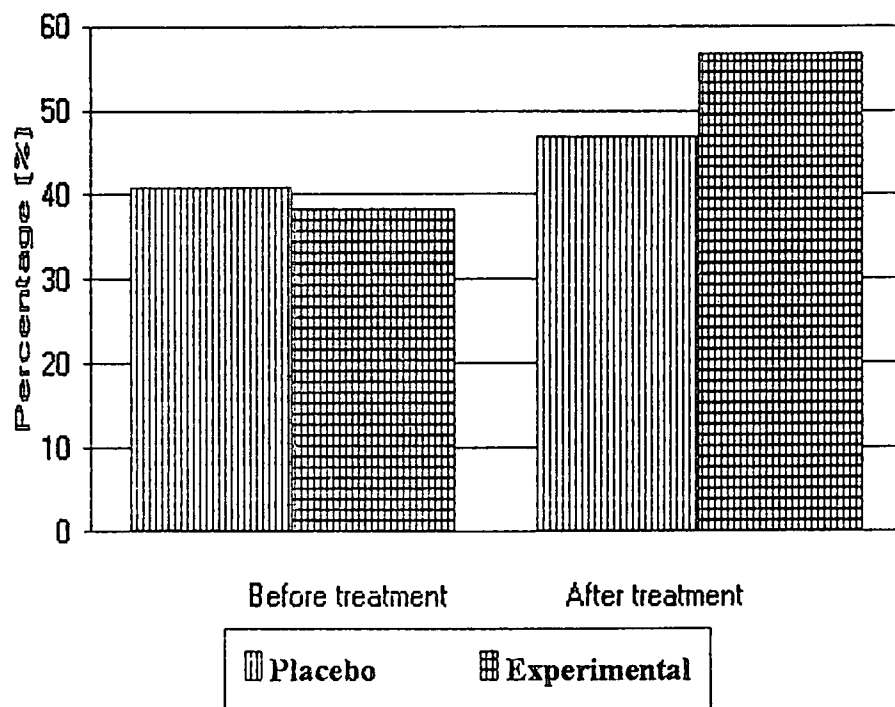
The mean values of the results of the Mann-Whitney U-test were calculated and are tabulated below.

Placebo vs Experimental	Two-tailed Z-value	Probability Value (P)
Before treatment	0.3025	0.1495833
After treatment	0.3142	0.1567

The P value is greater than 0.05. Thus the null hypothesis was accepted for both groups. It was concluded that there was no significant difference between the two groups before and after treatment.

4.3.1.2 FIGURE 4.1

**Comparison of before and after treatments between the two groups
with reference to the Patient Perception Questionnaire.**



The before treatment for both groups were similar. The after treatment for both groups showed improved, but the experimental group showed a marked improved.

4.3.1.3 TABLE 4.2

The mean values of the results of the Wilcoxon signed rank test were calculated and are tabulated below.

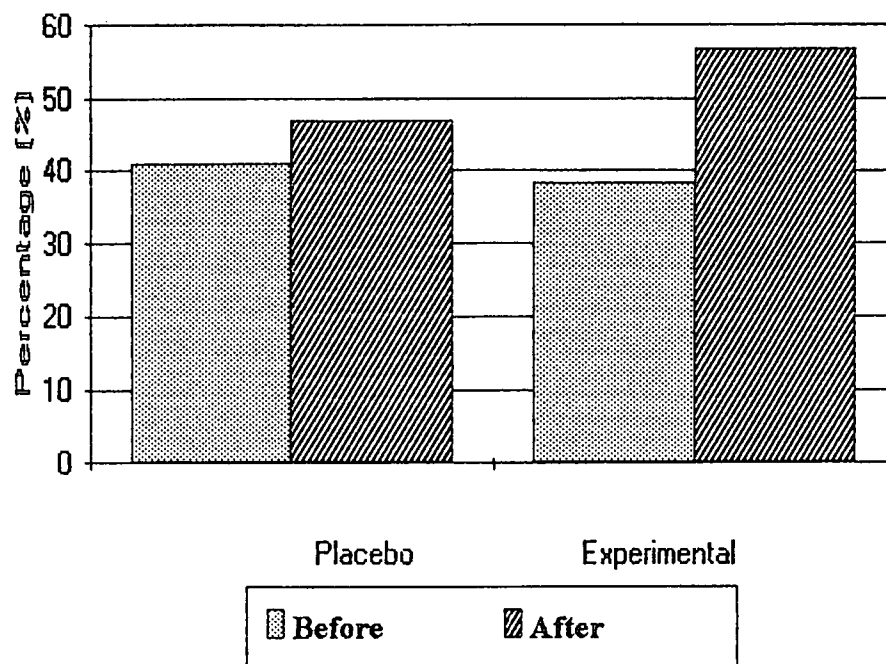
Before vs after treatment	Two-tailed Z-value	Probability Value
Placebo	0.50225	0.2502916
Experimental	0.0736166	0.0365583

The P value for the placebo group is greater than 0.05. Thus the null hypothesis was accepted. It was concluded that there was no significant difference in the placebo group.

The P value for the experimental group is less than 0.05. Thus the null hypothesis was rejected. It was concluded that there was a significant difference in the experimental group before and after treatment.

4.3.1.4 FIGURE 4.2

**Comparison of before and after treatment within each group
with reference to the Patient Perception Questionnaire.**



Both groups showed improvement, but the experimental group showed a marked improvement.

4.3.2 GENERAL WELL-BEING SCHEDULE

4.3.2.1 TABLE 4.3

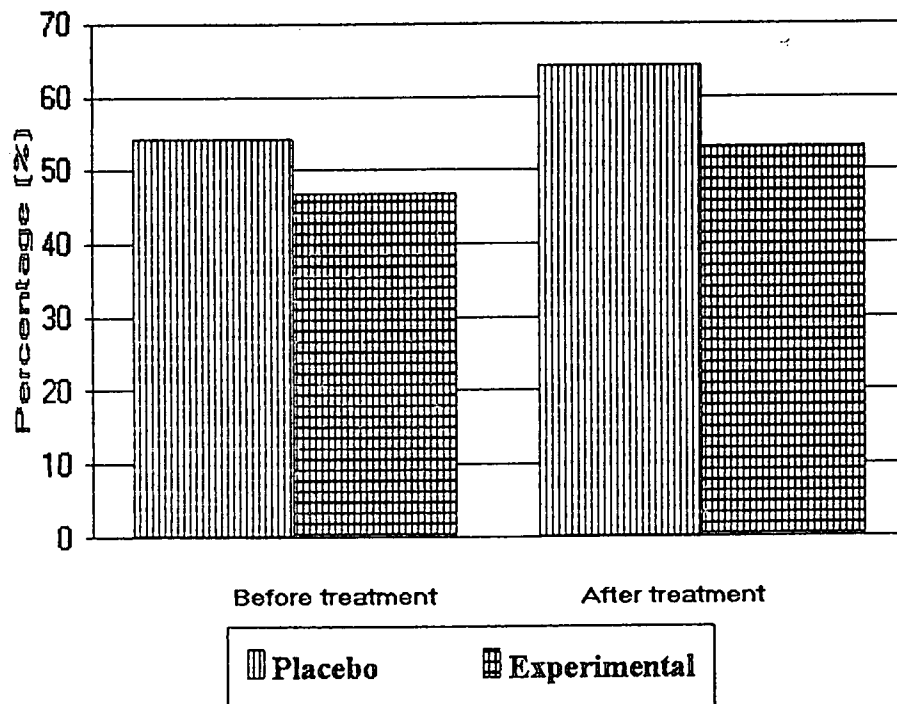
The mean values of the results of the Mann-Whitney U-test were calculated and are tabulated below.

Placebo vs Experimental	Two-tailed Z-value	Probability Value (P)
Before treatment	0.4387777	0.2185555
After treatment	0.2637555	0.13185

The P value is greater than 0.05. Thus the null hypothesis was accepted for both groups. It was concluded that there was no significant difference between the two groups before and after treatment.

4.3.2.2 FIGURE 4.3

**Comparison of before and after treatment between the two groups
with reference to the General Well-Being Schedule.**



The placebo group showed a better psychological well-being than the experimental group before and after the treatment.

4.3.2.3 TABLE 4.4

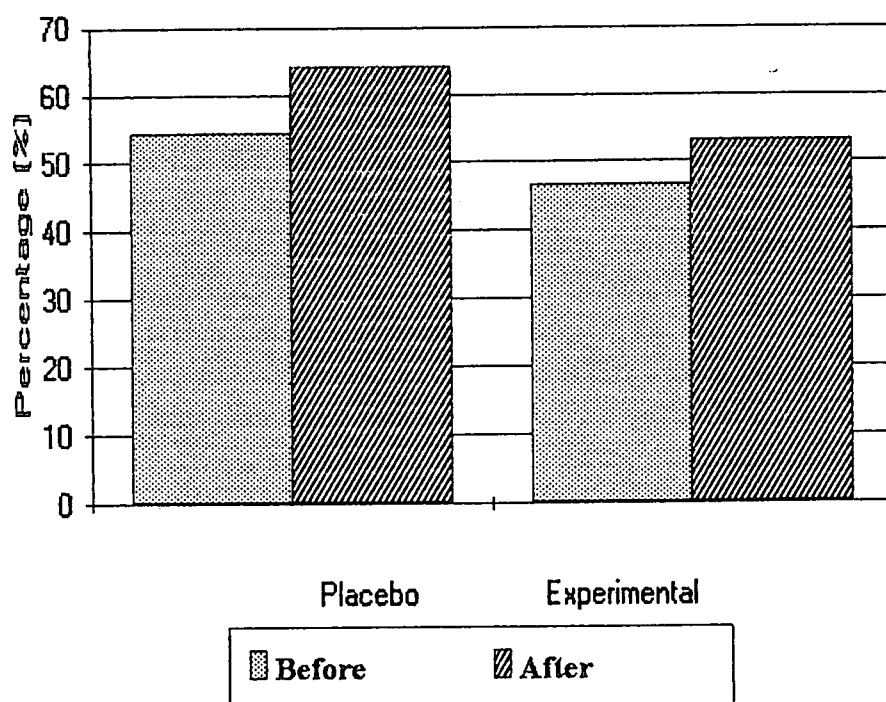
The mean values of the results of the Wilcoxon signed rank test were calculated and are tabulated below.

Before vs after treatment	Two-tailed Z-value	Probability Value (P)
Placebo	0.385777	0.1920555
Experimental	0.4309444	0.2141666

The P value is greater than 0.05 for both groups. Thus the null hypothesis was accepted. It was concluded that there was no significant difference between the two groups before and after treatment with reference to the General Well-Being Schedule.

4.3.2.4 FIGURE 4.4

Comparison of before and after treatment within each group
with reference to the General Well-Being Schedule.



Both groups showed an improved psychological well-being after the treatment.

4.3.3 CLINICAL EVALUATION INDEX

4.3.3.1 TABLE 4.5

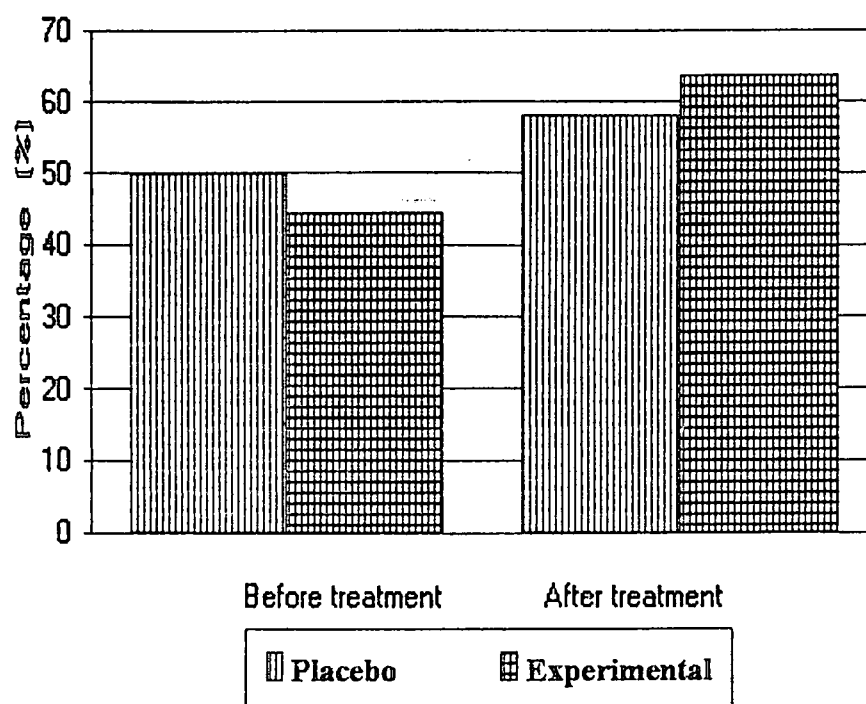
The mean values of the results of the Mann-Whitney U-test were calculated and are tabulated below.

Placebo vs Experimental	Two-tailed Z-value	Probability Value
Before treatment	0.5125	0.2554166
After treatment	0.456666	0.2233333

The P value is greater than 0.05. Thus the null hypothesis was accepted for both groups. It was concluded that there was no significant difference between the two groups before and after treatment.

4.3.3.2 FIGURE 4.5

**Comparison of before and after treatment between the two groups
with reference to the Clinical Evaluation Index.**



The placebo group had better clinical conditions before the treatment than the experimental group. After the treatment both groups showed an improvement, but the experimental group showed a marked improvement in their clinical condition.

4.3.3.3 TABLE 4.6

The mean values of the results of the Wilcoxon signed rank test were calculated and are tabulated below.

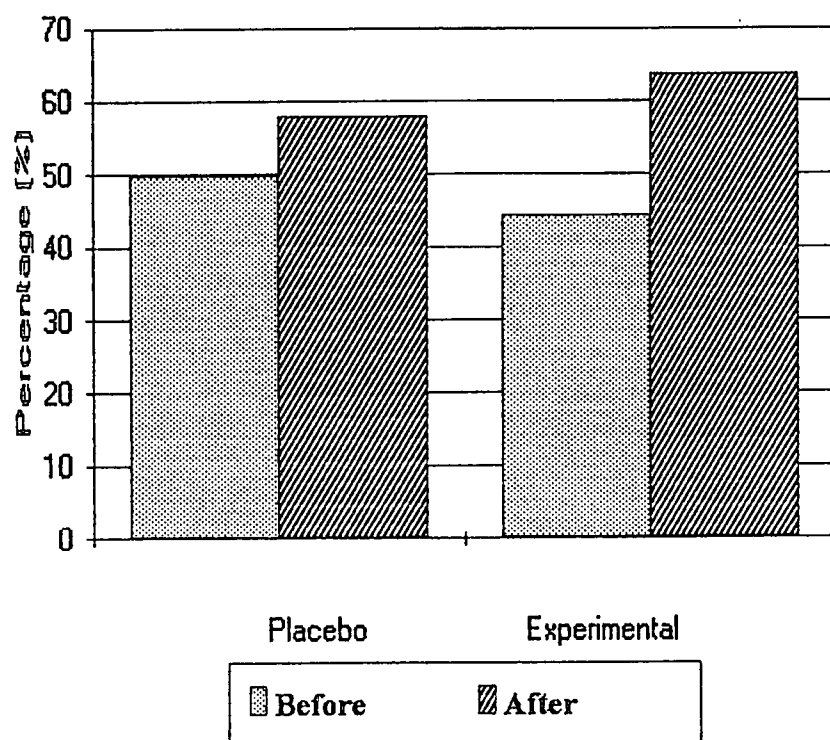
Before vs after treatment	Two-tailed Z-value	Probability Value (P)
Placebo	0.43525	0.2170833
Experimental	0.0467333	0.0212416

The P value for the placebo group is greater than 0.05. Thus the null hypothesis was accepted. It was concluded that there was no significant difference in the placebo group before and after the treatment.

The P value for the experimental group is lesser than 0.05. Thus the null hypothesis was rejected. It was concluded that there was a significant difference in this group before and after treatment with reference to the Clinical Evaluation Index.

4.3.3.4 FIGURE 4.6

Comparison of before and after treatment within each group
with reference to the Clinical Evaluation Index.



Both groups showed improvement, but the experimental group showed a marked improvement.

CHAPTER 5

DISCUSSION

The results of this study showed that there was an overall improvement in patients with atopic eczema who received homoeopathic similimum treatment compared to the patients who received placebo.

In the Patient Perception Questionnaire (Appendix G) there was no statistically significant improvement when the data before the treatment and after the treatment of both groups were compared (Table 4.1). The mean scores of the questionnaires were used to construct bar charts which are presented as a visual illustration of the findings. In Figure 4.1 the inter-group relationship shows that before the treatment the two groups demonstrated similar results and that after the treatment both groups had improved.

Table 4.2 showed that there was a statistically significant improvement in the experimental group, indicating that the perception of the patients to homoeopathy and towards their clinical manifestation was more positive. Figure 4.2 illustrates this improvement graphically. Once again the placebo group also showed some

improvement. Patients respond to placebos in a variable manner. In approximately 35% of patients a placebo effect occurs in response to almost any procedure (Lewith and Aldridge 1993: 40).

The General Well-Being Schedule (Appendix H) which measured the patients' psychological well-being showed no statistically significant improvement when the before and after the treatment were compared (Table 4.3). In the bar chart (Figure 4.3) that follows, the placebo group illustrated a tendency of a better psychological well-being before the treatment than the experimental group, and this even improved more after the treatment. The reason for the improvement of the placebo group was not clear. However Love *et al.* (1989) suggests, that some patients could have attempted to please the therapist by reporting more favourable results.

The experimental group only had a slight improvement after the treatment. In Table 4.4 the Inter-group comparison showed no statistically significant improvement. Figure 4.4 shows that both groups had a very slight improvement.

The Clinical Evaluation Index (Appendix D) showed no statistically significant difference when the data before and after the treatments were compared (Table 4.5). Figure 4.5 shows a slight improvement in the placebo group, and a marked improvement in the experimental group. Table 4.6 shows that there was no statistically significant difference in the placebo group before and after the treatment. However, the data obtained from the Patient Perception Index after the 3 month trial period showed a significant difference in the experimental group

(Table 4.6). Figure 4.6 illustrates a slight improvement in the placebo group, and a marked improvement in the experimental group.

This study supports the hypothesis that homoeopathic simillimum treatment is effective in the treatment of atopic eczema in terms of patient perception and clinical manifestation.

The results are not directly comparable to other studies due to different sample sizes, treatments and the study period. But in a retrospective survey done by Spence (1991), the majority of patients improved (85.5%) substantially as a result of homoeopathic medication.

Problems that were encountered were that this study was very subjective. Objectivity can be achieved by using photographs or using observers that have no part in the study to monitor the progress of the patient. Also according to Pocock (1993) most trial reports in medical journals rely heavily on significant tests and pay inadequate attention to estimating the potential magnitude of treatment differences. Small trials require huge observed differences to be statistically significant. (Lewith and Aldridge 1993: 21.) It is therefore recommended that future studies involve a larger sample size when this issue is investigated.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

This study demonstrates that homoeopathic similimum treatment is effective in the treatment of atopic eczema in terms of patient perception and clinical manifestation. The placebo group showed no statistically significant improvement in all three the questionnaires. The experimental group showed statistically significant improvement in the Patient Perception Questionnaire and Clinical Evaluation Index. However the General Well-Being Schedule showed no significant improvement for this group.

Since homoeopathy's effectiveness in atopic eczema has been demonstrated, further studies can place more emphasis on the psychology and quality of life of atopic eczema sufferers, as the findings may guide the practitioners to treat atopic eczema more effectively. The importance of life style changes and dietary advice (which were excluded from this study to keep the variables to a minimum) together with homoeopathy, needs to be evaluated and studied further. The economic viability of homoeopathy compared with allopathic treatment is also a recommendation for further studies as many of the patients claimed that they had previously spent large sums of money in an effort to find a cure for their illness.

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APPENDICES

APPENDIX A

Simple RANDOM SAMPLING of patients into EXPERIMENTAL or PLACEBO groups:

Nine throws of a dice will give the group allocation to the patients, numbered from 1-34, the order in which they are accepted into the study.

RESULT OF DICE THROW ORDER OF ALLOCATION

1	EECC
2	CCEE
3	ECCE
4	CEEC
5	ECEC
6	CECE

Where E represents Experimental group and C represents the Placebo group.

THROW #	RESULT OF THROW	PATIENT #	PATIENT NAME
e.g. 3	E	1.	
	C	2.	
	C	3.	
	E	4.	
	5.	
	6.	
	7.	
	8.	
	9.	
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	31.	
	32.	
	33.	
	34.	

APPENDIX B

DIAGNOSTIC CRITERIA OF ATOPIC ECZEMA (Hanifin and Rajka 1980)

Must have 3 or more basic features:

YES / NO	Pruritus
YES / NO	Typical morphology and distribution:
YES / NO	Flexural lichenification of linearity in adults
YES / NO	Facial and extensor involvement in infants and children
YES / NO	Chronic or chronically-relapsing eczema
YES / NO	Personal or family history of atopy (asthma, allergic rhinitis, atopic eczema)

Plus 3 or more minor features:

YES / NO	Xerosis
YES / NO	Ichtyosis
YES / NO	Immediate (type 1) skin test reactivity
YES / NO	Elevated serum IgE
YES / NO	Early age of onset
YES / NO	Tendency toward cutaneous infections
YES / NO	Tendency toward non-specific hand or foot eczema
YES / NO	Nipple eczema
YES / NO	Cheilitis
YES / NO	Recurrent conjunctivitis
YES / NO	Anterior subcapsular cataracts
YES / NO	Orbital darkening
YES / NO	Facial pallor/facial erythema
YES / NO	Pityriasis alba
YES / NO	Anterior neck folds
YES / NO	Itch when sweating
YES / NO	Intolerance to wool and lipid solvents
YES / NO	Food intolerance
YES / NO	Course influenced by environmental/emotional factors
YES / NO	White dermographism/delayed blanch

APPENDIX C

PATIENT CONSENT FORM

AN INVESTIGATION INTO THE EFFECT OF
HOMOEOPATHIC SIMILIMUM TREATMENT ON ATOPIC ECZEMA

SUPERVISOR: Dr. E.C. Poolman

RESEARCHER: Celia Opperman

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 with the researcher? | YES/NO |
| 5. Have you received enough information about this study? | YES/NO |
| 6. Do you understand the implications of your
involvement in this study? | YES/NO |
| 7. 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. | |
| 8. Do you agree to voluntarily participate in this study? | YES/NO |

PATIENT Name _____
(in block letters)

Signature _____

PARENT Name _____
(in block letters)

Signature _____

WITNESS Name _____
(in block letters)

Signature _____

RESEARCHER _____
(in block letters)

Signature _____

APPENDIX D

INFORMATION SHEETS

TAKING HOMOEOPATHIC MEDICINE

* This document offers a short explanation of how to take Homoeopathic medicine, where to store medicine, when to take medicine and an explanation as to why all the pills look the same.

* The three most common ways of receiving Homoeopathic medicines, are liquid, pillules and granules. Pillules and granules should be put directly into one's mouth (don't use your hands to achieve this process) place under the tongue and allow to dissolve (they should not be chewed or swallowed). Liquids can be taken directly into the mouth or mixed with a little water. In both cases the medicine should be held in the mouth for about fifteen seconds.

* Homoeopathic medicines must not be stored in direct sunlight and away from strong smelling substances such as camphor, hand creams and perfumes.

* Homoeopathic medicines should be taken as directed on the container, but one should always bear in mind that the medicine should be taken about fifteen minutes before meals or an hour after meals. If you have just brushed your teeth, rinse your mouth with warm water before taking your medication.

* If one receives more than one bottle of pillules or granules, the medication in both containers appears to be identical! The white pillules or granules are made from sac lac (milk sugar) and serve as a vehicle for the Homoeopathic medicine i.e. The Homoeopathic medicine originally in liquid form is distributed over the pillules or granules and allowed to be absorbed.

HOMOEOPATHY THE WORLD OVER, KEEPING PEOPLE HEALTHY!

WHAT TO EXPECT WHEN YOU SEE A NATURAL THERAPIST

- * Consultation usually take much longer (at least an hour)
- * You are likely to be asked a wide range of questions about yourself, your emotions, your job, family, relationships and social life, what you eat and drink, your sleeping and relaxation habits.
- * Therapy is likely to involve advice about your lifestyle (diet, exercise, sleep, emotions and so on) as well as any specific treatments like pills or massage.
- * Therapy will not necessarily be directed only at the problem you came with, but may encompass any aspects the therapist feels are out of balance.
- * Treatment may take longer to work because they attempt to get to the roots of a problem rather than offering rapid symptom relief.
- * They thus often require more patience, time and effort, and a greater commitment to change. You will generally be expected to take responsibility for your own health and to be actively involved in the healing process.
- * Sometimes treatment results in a period of temporarily aggravation of symptoms. This need not to happen, but if it does the patient should not be alarmed. If there are any queries phone your practitioner and confirm with him or her.

THE PRINCIPLE OF NATURAL MEDICINE

Homoeopaths:

- * operate 'holistically', which means they take account of the 'whole person' -their mind, body and spirit - as well as their surroundings, lifestyle and relationships.

- * believe good health stems from emotional, mental and physical balance, and that imbalance and disharmony create dis-ease and illness. Often these principles are refined from those of oriental philosophy with its view of a life energy or force and opposing but balanced forces operating both within the body and throughout the universe.

- * believe the body has a natural ability to heal itself, and the function of treatment is to assist the body's own healing powers.

- * view symptoms as the body's own attempts to fight disease, and believe that rather than suppressing symptoms treatment should aim to tackle the root cause of the problem.

- * the emotions, personality, reactions and circumstances of an individual - is seen as important, in determining therapy.

- * Therefore two people with the same condition will not necessarily receive the same treatment.

APPENDIX E

STANDARD DIAGNOSTICS CASE HISTORY AND PHYSICAL EXAMINATION

(Bates 1991: 5-70)

Date of History:

Identifying Data

Name: _____

Age: _____

Sex: _____

Race: _____

Place of birth: _____

Marital Status: _____

Occupation: _____

Religion: _____

Source of referral:

Source of History:

Reliability:

Past Surgical History:

Any operations since you were born?

Past Medical History:

1. Have you ever had any serious medical problems?

(Rheumatic fever, Pneumonia, Tuberculosis, Jaundice, High Blood Pressure)

2. Can you remember your childhood illnesses?

(Mumps, Measles, Chickenpox, German measles, Tuberculosis)

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, Diphtheria, Polio, Measles, Rubella, Mumps, Influenza, Hepatitis B, Haemophilus influenza type B)

6. Are you taking any medications ?

(Know: onset, duration, dosage)(Pill, Vit's, Homoeopathic medicine, Minerals Herbs)

7. Do you smoke ?

(Onset, Amount/day, Type)

(Onset, Amount/day, Type)

Family History:

Possible family medical problems: Diabetes, Tuberculosis, Heart diseases, High blood pressure, Stroke, Kidney diseases, Cancer, Arthritis, Anaemia, Headaches, Epilepsy, Mental illness.

Main Complaint: What seems to be the problem today ?

History of Main Complaint:

(Onset, Location, Aetiology, Duration, Character, Modalities, Concomitant, Radiation,
Patient's response to Symptoms & incapacity's)

Social History:

1. Hobbies, exercise and leisure activities ?
2. Any travelling (i.e. out of Durban) ?
3. Any recent shocks or griefs ?
4. Diet ?

Psychosocial History:

1. Home situation and significant others ?
2. Daily life ?
3. Important experiences ?
4. Religious beliefs ?
5. The patient's outlook ?

Systems review:

1. General:

(Usual weight, Recent weight change, Weakness, fatigue, Fever)

2. Skin:

(Rashes, Lumps, Sores, Itching, Dryness, Colour change, Change in hair and nails)

3. Head:

(Headaches, Head injuries)

4. Eyes:

(Vision, Glasses, Contact lenses, Pain, Extensive tearing, Redness, Double vision, Cataracts)

5. Ears:

(Hearing problems, Tinnitus, Vertigo, Earache, Infection, Discharge)

6. Nose and Sinuses:

(Frequency of colds, Nasal stuffiness, Discharge or itching, Hayfever, Nose bleeds, Sinus

trouble)

7. Mouth and Throat:

(Bleeding gums, Sore tongue, Frequency of sore throat, Hoarseness)

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, Loss of appetite, Nausea, Vomiting, Regurgitation, Vomiting of blood, Indigestion, Haemorrhoids, Constipation, Diarrhoea, Abd pain, Food intolerance, Excessive belching or passing of gas, Jaundice, Liver or gallbladder trouble, Hepatitis)

12. Urinary:

(Polyuria, nocturia, Burning or pain on urination, Haematuria, Urgency, Reduced calibre or force of urinary stream, Hesitancy, Incontinence, Urinary infection, Stones)

13. Genitoreproductive system:

(Hernias, Discharge from or sore on the penis, Testicular pain or masses, History of venereal disease, Sexual interest)

14. Peripheral Vascular:

(Intermittent claudication, Leg cramps, Varicose veins, Thrombophlebitis)

15. Musculoskeletal:

(Muscular and joint pains, Stiffness, Arthritis, Gout, Backache)

16 Neurologic:

(Fainting, Blackouts, Seizures, Weakness, Paralysis, Numbness, Tingling, Tremor or other involuntary movements)

17. Haematologic:

(Anaemia, Easy bruising or bleeding, Past transfusions & possible reactions)

18. Endocrine:

(Thyroid trouble, Heat or cold intolerance, Excessive sweating, Diabetes, Excessive thirst or hunger. Polyuria)

19. Psychiatric:

(Nervousness, Tension, Depression, Memory loss)

ON EXAMINATION:

Vital Signs:

Pulse:

Resp:

BP:

T °C:

Weight:

Height:

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

General inspection:

General examination:

1. Position the patient on their backs at 45°.

2. Hands:

(Note: Muscle condition, colour, nails (clubbing, spooned, splinter haemorrhage), 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, JVP, Glands, any Pain)

5. Face:

(Twitches of facial muscles, Drooping, swellings, lesions, inflammation, skin, hair distribution, colour, any pain)

6. Eyes:

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

7. Nose:

(Anosmia, any pain, epistaxis, runny nose, hayfever, lesions)

8. Sinuses:

(Pain, headaches, post nasal drips)

9. Lips:

(colour, lesions, pains)

10. Mouth:

(Bad breath, taste, lesions, pain)

11. Teeth:

(Condition, pain, colour, caries, types of fillings)

12. Gums:

(bleeding, colour)

13. Tongue:

(Indentation, colour, mapped, pain, lesion 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 effort, tender areas, tactile fremitus, percussion, auscultation)

17. Heart:

(Rate, rhythm, amplitude, contour, bruits, thrills)

18. Abdomen:

(Pain, tender areas, skin, spider naevi, distention, borborigmy, 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 limbs:

(Pain, skin, hair distribution, oedema, varicose veins, temperature, colour, sensory)

22. Feet:

(Nails, temperature, colour, skin, pain, lesions, warts, athletes foot, odour)

Additional Homoeopathic Questions

Mind:

1. Fears:

2. Sleep:

(Position, type, dreams, on waking)

3. Confusion / cloudiness:

4. Excitement:

5. Anxiety:

6. Speech:

(Hurried, nasal, lost/difficult, slow/monotonous)

7. Imagination:

8. Memory:

Emotions:

1. Depression:

2. Melancholia:

3. Mood:

Physical:

1. Diet:

(Cravings, aversions, salt, drink in gulps or sips, hot or cold drinks, love eggs)

2. Best time of the day:

3. Coast or inland:

4. Particular:

5. Brittle hair:

6. Modalities: (< = worse; > = improved)

a. Cold:

b. Warmth:

c. Movement:

d. Touch:

e. Rest:

f. Riding in car:

g. Humidity:

h. > for being seated, bending forward:

i. < at night & between sundown and sunrise:

j. > in mountains:

k. < between 4 pm & 8 pm, the height occurring at 5pm:

l. > for lying on stomach:

m. seaside

n. Night:

o. Consoled:

p. Morning on awakening:

q. After meals:

r. < by anger & intellectual effort:

s. Winter and summer:

t. Strong pressure:

u. > by being outside & moving around:

v. > slow motion, by changing position:

w. < going up or down stairs:

x. Dark:

y. Standing still:

z. < for heat of bed and water:

z1. < for wine and stimulants:

Differential Diagnosis

APPENDIX F

CLINICAL EVALUATION INDEX (compiled by researcher)

Every section must be answered. To be filled in by researcher.

1 = None

2 = Mild

3 = Moderate

4 = Severe

	1	2	3	4
REDNESS				
SWELLING				
PAPULES				
PUSTULES				
ERYTHEMATOUS MACULES				
WEEPING				
DRY				
CRUSTS				
SCALING				
BLEEDING				
SCRATCH MARKS				
ITCHING				

APPENDIX G
COVER LETTER

AN INVESTIGATION INTO THE EFFECT OF
HOMOEOPATHIC SIMILIMUM TREATMENT ON ATOPIC ECZEMA

Thank you for considering to be part of this study. The fifth year students of homoeopathy are required to complete a dissertation as partial fulfilment of their Masters Diploma in Homoeopathy. The dissertation is undertaken with the purpose of adding to the homoeopathic pool of knowledge and promoting homoeopathy.

It is important that this research, is conducted because atopic eczema on publicly visible parts of the body causes a certain amount of psychological stress to individuals that are sensitive to their appearance. Not much scientific research has been accomplished in the homoeopathic treatment of atopic eczema. There are many different methods of treating Atopic Eczema homoeopathically. It is therefore necessary to analyze which method works best and why, and whether in fact homoeopathy has a place for treating atopic eczema.

By carrying out this research project certain benefits will be afforded; namely by adding to the current knowledge of eczema treatment in homoeopathy, and by doing this homoeopathy will receive more respect in the scientific community.

Celia Opperman (Researcher)

APPENDIX H

PATIENT'S PERCEPTION QUESTIONNAIRE (compiled by reseacher)

VISIT NO: _____

NAME: _____

DATE: _____

INSTRUCTIONS:

1. The answers to this questionnaire is strictly confidential, and used for research purposes only.
2. Please answer as objectively as possible.
3. Please make sure you have answered all questions.
4. Please read each question carefully, and make sure you understand the question. If there are any queries, please ask assistance from researcher.
5. Please answer the questionnaire honestly ! It is designed to assess your opinion of the treatment you are going to receive.

1 = Totally agree

2 = Agree

3 = Neither agree nor Disagree

4 = Disagree

5 = Totally Disagree

State to what degree you agree/disagree with the following statements.
Please note that there are no wrong or correct answers.

For example

1. How severe would you rate your eczema:

Mild X Very severe
 1 2 3 4 5

Mark at number 5 if you think your eczema is very bad.

1. How do you perceived the treatment to be thus far.

Very good Not good at all
 1 2 3 4 5

2. How severe would you rate your eczema

Mild Very severe
 1 2 3 4 5

3. Has your eczema changed at all?

Very much Not at all
 1 2 3 4 5

3.1. If your eczema has changed, how has it changed?

Getting better Getting worse
 1 2 3 4 5

4. Has the surface texture of your skin changed?

Getting smoother Becoming rougher
 1 2 3 4 5

5. Are you experiencing any pain or tenderness with your eczema?

No pain at all Very much pain
1 2 3 4 5

6. Has your eczema been bleeding?

No bleeding at all Very much bleeding
1 2 3 4 5

7. How would you rate your eczema now as compared with the period before the homoeopathic treatment started ?

Very much better No change at all
1 2 3 4 5

8. How has your attitude concerning your condition changed since taking homoeopathic medicine?

Much better(+ve) Deteriorated(-ve)
1 2 3 4 5

9. How severe do you rate the itching of your eczema?

None Very severe
1 2 3 4 5

10. How do you rate the severity in which your eczema disrupt your sleeping habits?

None Very severe
1 2 3 4 5

11. How severe does your eczema influence your social life?

None Very restricting
1 2 3 4 5

APPENDIX I

GENERAL WELL-BEING SCHEDULE (MacDowell and Newell 1996: 206-219)

READ - This section of the examination contains questions about how you feel and how things have been going with you. For each question, mark (X) the answer which best applies to you.

<p>1. How have you been feeling in general? (DURING THE PAST MONTH)</p>	<p>1. (001) 1 <input type="checkbox"/> In excellent spirits 2 <input type="checkbox"/> In very good spirits 3 <input type="checkbox"/> In good spirits mostly 4 <input type="checkbox"/> I have been up and down in spirits a lot 5 <input type="checkbox"/> In low spirits mostly 6 <input type="checkbox"/> In very low spirits</p>
<p>2. Have you been bothered by nervousness or your "nerves"? (DURING THE PAST MONTH)</p>	<p>2. (002) 1 <input type="checkbox"/> Extremely so -- to the point where I could not work or take care of things 2 <input type="checkbox"/> Very much so 3 <input type="checkbox"/> Quite a bit 4 <input type="checkbox"/> Some -- enough to bother me 5 <input type="checkbox"/> A little 6 <input type="checkbox"/> Not at all</p>
<p>3. Have you been in firm control of your behavior, thoughts, emotions OR feelings? (DURING THE PAST MONTH)</p>	<p>3. (003) 1 <input type="checkbox"/> Yes, definitely so 2 <input type="checkbox"/> Yes, for the most part 3 <input type="checkbox"/> Generally so 4 <input type="checkbox"/> Not too well 5 <input type="checkbox"/> No, and I am somewhat disturbed 6 <input type="checkbox"/> No, and I am very disturbed</p>
<p>4. Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile? (DURING THE PAST MONTH)</p>	<p>4. (004) 1 <input type="checkbox"/> Extremely so -- to the point that I have just about given up 2 <input type="checkbox"/> Very much so 3 <input type="checkbox"/> Quite a bit 4 <input type="checkbox"/> Some -- enough to bother me 5 <input type="checkbox"/> A little bit 6 <input type="checkbox"/> Not at all</p>
<p>5. Have you been under or felt you were under any strain, stress, or pressure? (DURING THE PAST MONTH)</p>	<p>5. (005) 1 <input type="checkbox"/> Yes -- almost more than I could bear or stand 2 <input type="checkbox"/> Yes -- quite a bit of pressure 3 <input type="checkbox"/> Yes -- some - more than usual 4 <input type="checkbox"/> Yes -- some - but about usual 5 <input type="checkbox"/> Yes - a little 6 <input type="checkbox"/> Not at all</p>

6. How happy, satisfied, or pleased have you been with your personal life? (DURING THE PAST MONTH)

6.

- (006)
- 1 ☐ Extremely happy -- could not have been more satisfied or pleased
 - 2 ☐ Very happy
 - 3 ☐ Fairly happy
 - 4 ☐ Satisfied -- pleased
 - 5 ☐ Somewhat dissatisfied
 - 6 ☐ Very dissatisfied

7. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel, or of your memory? (DURING THE PAST MONTH)

7.

- (007)
- 1 ☐ Not at all
 - 2 ☐ Only a little
 - 3 ☐ Some -- but not enough to be concerned or worried about
 - 4 ☐ Some and I have been a little concerned
 - 5 ☐ Some and I am quite concerned
 - 6 ☐ Yes, very much so and I am very concerned

8. Have you been anxious, worried, or upset? (DURING THE PAST MONTH)

8.

- (008)
- 1 ☐ Extremely so -- to the point of being sick or almost sick
 - 2 ☐ Very much so
 - 3 ☐ Quite a bit
 - 4 ☐ Some -- enough to bother me
 - 5 ☐ A little bit
 - 6 ☐ Not at all

9. Have you been waking up fresh and rested? (DURING THE PAST MONTH)

9.

- (009)
- 1 ☐ Every day
 - 2 ☐ Most every day
 - 3 ☐ Fairly often
 - 4 ☐ Less than half the time
 - 5 ☐ Rarely
 - 6 ☐ None of the time

10. Have you been bothered by any illness, bodily disorder, pains, or fears about your health? (DURING THE PAST MONTH)

10.

- (010)
- 1 ☐ All the time
 - 2 ☐ Most of the time
 - 3 ☐ A good bit of the time
 - 4 ☐ Some of the time
 - 5 ☐ A little of the time
 - 6 ☐ None of the time

11. Has your daily life been full of things that were interesting to you? (DURING THE PAST MONTH)

11.

- (011)
- 1 ☐ All the time
 - 2 ☐ Most of the time
 - 3 ☐ A good bit of the time
 - 4 ☐ Some of the time
 - 5 ☐ A little of the time
 - 6 ☐ None of the time

12. Have you felt down-hearted and blue? (DURING THE PAST MONTH)

12.

- (012)
- 1 ☐ All of the time
 - 2 ☐ Most of the time
 - 3 ☐ A good bit of the time
 - 4 ☐ Some of the time
 - 5 ☐ A little of the time
 - 6 ☐ None of the time

13. Have you been feeling emotionally stable and sure of yourself? (DURING THE PAST MONTH)

13.

- (013) 1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

14. Have you felt tired, worn out, used-up, or exhausted? (DURING THE PAST MONTH)

14.

- (014) 1 ☐ All of the time
2 ☐ Most of the time
3 ☐ A good bit of the time
4 ☐ Some of the time
5 ☐ A little of the time
6 ☐ None of the time

15. How concerned or worried about your HEALTH have you been? (DURING THE PAST MONTH)

15.

- (015) 0 1 2 3 4 5 6 7 8 9 10
Not concerned at all Very concerned

16. How RELAXED or TENSE have you been? (DURING THE PAST MONTH)

16.

- (016) 0 1 2 3 4 5 6 7 8 9 10
Very relaxed Very tense

17. How much ENERGY, PEP, VITALITY have you felt? (DURING THE PAST MONTH)

17.

- (017) 0 1 2 3 4 5 6 7 8 9 10
No energy AT ALL, listless Very ENERGETIC, dynamic

18. How DEPRESSED or CHEERFUL have you been? (DURING THE PAST MONTH)

18.

- (018) 0 1 2 3 4 5 6 7 8 9 10
Very depressed Very cheerful

APPENDIX J

PERCENTAGE VALUES OF FIGURES

The mean of the questionnaires were calculated as a percentage, and are tabulated below.

Groups	Patient Perception Questionnaire	General Well-Being Schedule	Clinical Evaluation Index
Placebo before treatment	40.78%	54.41	49.86
Placebo after treatment	47.00	64.25	57.92
Experimental before treatment	38.33	46.72	44.44
Experimental after treatment	56.78	53.23	63.61