1. INTRODUCTION

Atopic eczema is one of the most common chronic skin diseases. It affects infants and children, and persists into adulthood. Over the past few decades there has been a steady increase worldwide in the incidence of this disorder (Motala, 1998 : 14). Recently, in Japan, the incidence has been rising in the adult population (Itamura and Hosoya, 2003 : 108).

Atopic dermatitis is sometimes referred to as atopic eczema or infantile eczema and for the purpose of this dissertation the terms ‘dermatitis’ and ‘eczema’ are used synonymously to describe skin inflammation characterized by erythema and scaling, and sometimes accompanied by vesiculation and crusting. The characteristic feature histologically is epidermal intercellular oedema (spongiosis and spongiotic microvesiculation), and the eruption of atopic dermatitis is usually extremely itchy (Archer, 2000 : 25).

Atopic eczema should be viewed as a multidimensional phenomenon. It does not conform to an essential disease model, i.e. the disease is not an entity which ‘attacks’ patients, but rather a syndrome of related clinical features arising in response to a number of endogenous and exogenous factors (Williams, 2000 : 21,10).

Atopic eczema is an increasingly common problem which is part of the atopic syndrome, which includes bronchial asthma, allergic rhinitis and allergic conjunctivitis and has a genetic predisposition (Luger, *et al*. 2001 : 789). It is broadly accepted that atopic eczema results from an interaction between genetic and environmental influences (Archer, 2000 : 35).

Many observations have indicated that IgE-mediated mechanisms play a part in the pathogenesis of atopic eczema. Serum IgE levels are elevated in 80-85% of patients and specific IgE responses to a variety of foods and inhalant allergens are observed (Hishinuma, *et al*. 2001: 19). Environmental trigger factors include irritants (eg. detergents and house dust), and allergic factors (eg. Cow’s milk) (Archer, 2000 : 35).

Therapy is often symptomatic and patients are managed with steroid-based strategies (Jolles, *et al*. 2000: 551). Other therapies include antipruritics, coal tar preparations, UV light and food avoidance (Wachter and Lezdey, 1992: 407).

Therapy advances are needed, especially for those resistant to standard second-line therapies or suffering from unacceptable drug-related side effects (Jolles, *et al*. 2000 : 551).

Severe atopic eczema has been shown to have major impairment on the quality of life both in children and adults (Harper, *et al* . 2000 : 52).

1.1 Problem Statement

Atopic eczema has an overall prevalence of 2.3%. Significant morbidity may result with time off work or study, recurrent hospital admissions and disruption of personal and family life (Jolles, *et al*. 2000 : 551). Emotional stress, especially from stressful life events together with relapses and distressing itching, affect the psychological aspects of the individual (Itamura and Hosoya, 2003 : 108).

1.2 Purpose

It is the purpose of this randomised, double-blind, placebo-controlled study to evaluate the efficacy of a homoeopathic complex, (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH), in the treatment of atopic eczema in terms of clinical manifestations of the disease and its effect on the quality of life of the patient as measured by the Clinical evaluation index (Appendix C), the Patient's perception questionnaire (Appendix D) and the General well being schedule (Appendix E).

1.3 Assumptions

It has been assumed that patients took their medication as prescribed for the entire duration of the trial. It has also been assumed that patients did not resort to taking any other forms of treatment or medication during the trial.

2. REVIEW OF THE RELATED LITERATURE

Synonyms for atopic dermatitis are eczema, atopic eczema, infantile eczema, eczema constitutionnel, flexural eczema, Prurigo Besnier, allergic eczema, childhood eczema, Lichen Vidal, endogenous eczema, Sätexudativs Ekzematoid and neurodermatitis (Williams, 2000 : 10).

2.1 Classification of eczema

There are two major types of eczema – exogenous and endogenous. Exogenous eczemas can be cured or prevented by removal or avoidance of the cause. The endogenous group occurs in constitutionally predisposed individuals (Spence, 1993 : 255).

2.1.1 Exogenous eczema

There are three main groups of exogenous eczema. Firstly, there is irritant eczema where there is direct chemical damage to the skin (Spence, 1993 : 255). The skin is traumatized by rubbing with abrasives like sandpaper, by repeated washing and drying which remove its natural grease and by cold or wind. Dry skin increases the risk, so reactions become more common with age as the skin dries out, and tend to be worse in winter (Meredith, 1995 : 12).

Secondly, allergic contact eczema, which is a Type IV hypersensitivity reaction with a T-lymphocyte response, where it develops after a susceptible person becomes sensitized to an allergen. Substances which are involved include base metals, sticking plasters, cosmetics, rubber, glues and dyes (Meredith, 1995 : 13).

Lastly, photosensitive eczema appears in areas exposed to the sun (Spence, 1991: 75). The areas affected are the face, neck and arms. It is common in young women who sunbathe or use sunlamps. In older people it may be as a result of drugs and medicines which sensitise the skin

to light (Meredith, 1995 : 19). Relief should be obtained by avoidance of the photosensitizers (Spence, 1993 : 255).

2.1.2 Endogenous eczema

The endogenous group begins with atopic eczema, which results from a combination of inherited genetic susceptibility and exposure to environmental irritants (Landow, 1997 : 101).

In seborrhoeic dermatitis, the yeast *Pityrosporum*, plays a part in the irritation of the skin (Graham-Browne, 1997 : 110). It presents in newborn babies as 'cradle-cap'. On adults it may resemble dandruff (Meredith, 1995 : 16).

Bilaterally symmetric eruptions on the hands which appear as tiny clear vesicles have been given the term pompholyx as they resemble a 'bubble' under the skin. These vesicles may be preceded by itching or burning for several hours before appearing. (Landow, 1998 : 97).

Discoid eczema is also known as 'nummular eczema' and is characterized by red, itchy, weepy, coin-shaped patches. These patches readily become infected (Meredith, 1995 : 16).

Asteatotic eczema is the dry skin seen in elderly people especially those who are too ill to care for themselves properly or those in institutions. It occurs typically on the shins and lower legs in cold, windy weather. It stems from reduced sebum production and thinning skin due to old age (Meredith, 1995 : 16).

'Stasis' or gravitational eczema is also known as varicose eczema. Itchy, irritating patches form on the ankle near varicose veins or a previous thrombosis in leg veins (Meredith, 1995 : 19).

2.2 Aetiology

Although eczema is a common disease, little is known about its causes (Harris, *et al*. 2001 : 795). The role of genetic predisposition to the disease is well established (Schafer and Ring, 2000 : 155). However, a specific gene abnormality has not been determined (Archer, 2000 : 25).

2.2.1 Irritants

Excessive washing without appropriate skin lubrication is the most common irritant, as repeated exposure to water degrades the skins barrier to external irritants. Important topical irritants include wool, synthetic fabrics, mineral oils, solvents, sand and perspiration (Fitzpatrick and Aeling, 2001 : 51). A hot environment or excessive exercise sufficient to induce perspiration can worsen the condition (Landow, 1997 : 103).

2.2.2 Environmental allergens

Airborne particles such as tobacco, smoke, animal dander, molds and house dust mite exacerbate the disease in some (Fitzpatrick and Aeling, 2001: 51). The use of deodorants and soaps should be discouraged (Landow, 1997 : 103). Avoiding foods such as wheat, fish, nuts, yeast and citrus fruit may be beneficial (Westcott, 2000 : 22). Allergies to milk, eggs and soybean products have also been found to be causative agents (Fitzpatrick and Aeling, 2001 : 51).

2.2.3 Photosensitivity

This results due to exposure to sunlight or sunlamps. Chemicals in soaps and cleaners may also be light-sensitisers. Certain plants like parsnip, stinking mayweed and giant hogweed can also exacerbate the condition (Meredith, 1995 : 19).

2.2.4 Stress

Emotional crises such as job loss and domestic stress often exacerbate the disease. Anger, anxiety, depression and embarrassment can also be contributing factors (Landow, 1997 : 104).

2.2.5 Allergic contact

These include base metals such as nickel in jewellery and watch straps. Other causative agents are epoxy resin and chemical stabilisers in plastic and rubber. Dyes and inks can also bring about a reaction (Meredith, 1995 : 21).

2.3 Clinical Features

This inflammatory disease is characterized by a chronically relapsing course, a distinctive clinical appearance and severe pruritis (Johansson, *et al*. 2003 : 479). Research has shown that avoiding various trigger factors could help prevent the development of eczema (Westcott, 2000 : 21). The severity of eczema varies. In some people it may only have an occasional dry patch while in some, cases can be severely disabling and disruptive. Although any area of the body can be affected, it is commonly found on the head, face and neck, arms and behind the knees and toes (Westcott, 2000 : 22). In infants it manifests as a red, sometimes scaly, rash on the cheeks. Wrists, legs, arms and neck can also be involved. Older children and adults have a red, scaly eruption on flexural surfaces where repeated rubbing and scratching leads to lichenification (Archer, 2000 : 31-32). The predominant symptoms of atopic eczema are pruritis and resultant loss of sleep (Finlay, 1996 : 510). Eczema may be acute, sub-acute or chronic (Mackie, 1991 : 91).

2.3.1 Acute

Acute lesions of atopic eczema are itchy, red, oedematous papules and small vesicles that lead to weeping and crusting lesions (Zug and McKay, 1996 : 92). In infants lesions are itchy and scaly on the scalp, face and trunk (Mackie, 1991: 93). In addition, a rash may develop around the ears and this pattern changes around 18 months after which it appears on the neck, antecubital and popliteal fossae (Zug and McKay, 1996 : 1244).

2.3.2 Subacute

Redness is medically known as erythema and is caused by widening of blood vessels in the skin which increases blood flow to the affected areas. Skin inflammation appears as swelling on the skin's surface and in the underlying dermis. Dry, scaling skin is common (Mackie, 1991 : 930). Itching may be intense, persistent and unrelieved by scratching (Zug and McKay, 1996 : 1244).

2.3.3 Chronic

Flare-ups and remissions mark the chronic course of this disorder (Zug and McKay, 1996 : 1244). Chronic rubbing causes the leathery thickening known as lichenification (Westcott, 2000 : 23). Scratching promotes inflammation and secondary infection with the release of mediators that aggravate the itching problem (Riott and Delves, 1992 : 485). Secondary bacterial infections can be recognized as exudation and crusting (Archer, 2000 : 31). Sufferers will also be prone to other allergic skin complaints such as urticaria (Wescott, 2000 : 23).

2.4. Pathogenesis

The pathogenesis of atopic eczema remains elusive (Zug and McKay, 1996 : 1243). It is believed that when an individual with atopic eczema encounters an allergen, IgE triggers the immune system into setting off a complicated chemical chain which results in swelling, redness and itching (Westcott, 2000 : 20).

Although raised total and specific IgE levels and frequently abnormal skin tests occur in patients with atopic eczema, their precise role in the pathogenesis of atopic eczema is still far from clear (Williams, 2000 : 8). A possible pathogenic role for reaginic antibodies is seen by clinical association of atopic eczema with asthma and allergic rhinitis (Soter, 1984 : 137). Ishizaka and Ishizaka (1967) isolated IgE from the serum of allergic patients and demonstrated that it was the carrier of reaginic activity. IgE is found in serum and in secretions, and is bound to tissue mast cells and blood basophils. The higher the serum IgE level is, the more are bound to tissue cells. When tissue bound IgE molecules react with their specific antigens, pharmacologically active mediators, such as histamine are released (Fellner, 1980 : 92). When an antigen binds with the IgE antibodies attached to the mast cells or basophils, this causes an immediate change in cell membranes causing mast cells and basophils to rupture, others release their granules without rupturing. Other substances released are slow-reacting substances of anaphylaxis, eosinophil chemotactic substances, proteases, neutrophil chemotactic substances and heparin and platelet activating factors. These substances cause dilatation of local blood vessels and results in attraction of eosinophils and neutrophils to the reactive site. Local tissue damage by proteases, increased permeability of capillaries with loss of fluid into tissues and contraction of local smooth muscle cells (Guyton, 1991 : 21).

2.5 Clinical Diagnosis

The diagnosis of atopic eczema depends on the history and physical examination in conjunction with a personal and family history of atopy (Archer, 2000 : 31). Most patients with atopic eczema have elevated IgE positive skin prick tests reactions to a variety of allergens (Johansson, *et al.* 2003 : 479). Patch tests are usually conducted by putting potential allergens onto unaffected areas of the skin such as the arm or back. Each site is marked with a felt tip and covered with gauze and medical sticky tape for 24-48 hours. The skin is then examined a few days later. The test is positive when an eczematous reaction appears at the site (Meredith, 1995 : 45). A skin biopsy will confirm the diagnosis of eczema but is less reliable to differentiate the various forms from each other (Heyl and Swart, 1990 : 96).

For definitive diagnosis the patient must exhibit at least 3 of the major criteria and 3 of the minor criteria drawn up by Hanifin and Rajka (Archer, 2000 : 32).

Major Criteria

- Pruritis – itching
- Typical morphology and distribution (p.4).
- Flexural lichenification / linearity in adults. Facial and external involvement in infants and children.
- Chronic / chronically relapsing dermatitis
- Personal or family history of atopy (Asthma, allergic rhinitis, atopic eczema).

Minor criteria

- Xerosis – presence of generalized dry skin
- Ichthyosis – scaly, fish – like appearance on skin
- Immediate (type 1) skin test reactivity – Type I response to skin test
- Elevated serum IgE
- Early age of onset – in first five years
- Nipple eczema
- Chellitis – chronic desquamation of upper lip or both lips
- Recurrent conjunctivitis
- Dennie- Morgan infraorbital fold – may co-exist with allergic rhinitis. Lies under or on the floor of the orbit
- Keratoconus – a non-inflammatory, usually bilateral protrusion of the cornea, the apex being displaced downward and nasally
- Anterior subcapsular cataracts – bilateral cataracts in lens
- Orbital darkening
- Facial pallor / erythema
- Pityriasis alba – hypopigmentation in sun-exposed areas
- Anterior neck folds – horizontal creases
- Itch when sweating
- Intolerance to wool and lipid solvents
- Perifollicular accentuation – follicular papular appearance more common in black or oriental skin
- Food intolerance
- Course influenced by environmental / emotional factors
- White dermographism / delayed blanch – whitening of the skin due to pressure

(Williams, 2000 : 11)

2.6 Associated complications and disorders

The following are complications and disorders associated with eczema. Herpes Simplex lesions occur frequently on the skin. The lesions are monomorphic and in the presence of much scratching, one often does not see the vesicles. Colonization of lesions with *Staphylococcal* infection is a common complication (Archer, 2000 : 34). Hand and foot dermatitis are common, especially Juvenile plantar dermatosis, where the soles of the feet are shiny and tender with fissures (Mackie, 1991 : 95). Abdominal symptoms due to food allergies (such as milk and cheese) are frequent (Rook, *et al*. 1988 : 431).

The use of topical glucocortico-steroids have produced side-effects ranging from suppression of the hypothalamic-pituitary axis to cutaneous atrophy and striae (Griffiths, 2001 : 679). Other side-effects include thinning of the skin, burning, irritation and cataracts (Landow, 1997 : 107).

2.7 Natural history and prognosis

Atopic eczema can occur in any age group but it strikes most often in childhood (Westcott, 2000 : 22). A severe eczema sufferer is always likely to have sensitive skin (Meredith, 1995 : 10). There is a general tendency towards spontaneous improvement throughout childhood with some slight relapse during adolescence. It is difficult to assess the prognosis in individual cases and it is usually worse if both parents are affected (Rook, *et al*. 1988 : 432).

2.8 Implications

In terms of health care, atopic eczema deserves much attention since it is such a common and often debilitating problem (Archer, 2000 : 35). Ramifications are felt in financial and social terms where time off work or study is needed, recurrent hospital admissions and disruption of personal and family life occurs (Jolles, *et al.* 2000 : 551). Further costs arise from prescriptions of over-the counter preparations, travel to and from the General Practitioner and dermatologist, salary loss, clothing and laundry expenses. Patients with atopic eczema find that sleep, work and relationships are all affected by the condition (Herd, 2000 : 89).

Quality of life has been defined as the extent to which the hopes and ambitions are matched by experience and was initially promoted as a measure of outcome. It is intangible and should therefore rely on the statements of patients and compared at different time periods (Herd, 2000 : 91). Assessing quality of life issues in patients with atopic eczema is important as it assesses the impact that this condition has on their lives and acts as a baseline to record progress (Shum, *et al.* 2000 : 277). Heyl and Swart (1990) states that chronic eczema sufferers may become very despondent and sometimes hospitalization is required. Therefore, the main aim in the treatment of patients with atopic eczema is to provide an acceptable quality of life until remission occurs (McHenry, *et al.* 1995 : 847).

This study used the General well being schedule questionnaire (McDowell and Newell, 1996) which required the patients' own assessment to measure the efficacy of the homoeopathic complex (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH). The severity of the eczema and anxiety experienced by patients emphasizes the importance of addressing interpersonal issues as well as skin care in the treatment of atopic eczema (Linnet and Jemec, 1999 : 271).

2.9 Medical treatment

2.9.1 General treatment

In a study conducted in Singapore, by Tay *et al*. (2002) it was concluded that the most commonly used medication was antihistamines (23%), followed by moisturizers (15%), topical steroids (15%), antibiotics (9%) and systemic steroids (1.7%).

At present there are no effective treatments directed at the basic cause of eczema (Hishinuma, *et al.* 2001 : 19). Educating patients about stress management may be most helpful intervention (Landow, 1998 : 152).

2.9.2 Steroid therapy

Topical glucocorticosteroids as an effective treatment of atopic eczema was one of the major breakthroughs in dermatological therapy in the past 50 years (Griffiths, 2001 : 679). Corticosteroid creams are often used in acute flare-ups but ointments are preferred for chronic dermatitis (Zug and McKay, 1996 : 1248).
Extensive eczema requires systemic steroids like prednisone (Heyl and Swart, 1990 : 105).

2.9.3 Immunomodulatory therapy

Since atopic dermatitis is associated with a number of immunoregulatory abnormalities, therapy directed toward correction of the immune dysfunction offers an alternative, especially for patients unresponsive to conventional treatment. Cyclosporin A which is an immunosuppressant agent, has been reported to be effective in this regard. Unfortunately discontinuation of treatment results in relapse (Motala, 1998 : 18). Concern for progressive or irreversible nephrotoxicity with extended treatment has led to evaluation of topically

administered Cyclosporin A (Motala, 1998 : 18). Therapeutic advances are required especially for patients resistant to standard therapies, or suffering from unacceptable drug-related side-effects (Jolles, *et al*. 2000 : 551).

2.9.4 Antibiotics

Excessive dryness of the skin may cause little cracks which may predispose to infection. Treatment is usually with a systemic antibiotic such as tetracycline or erythromycin (Heyl and Swart, 1990 : 105).

2.9.5 Antipruritics

Oral antipruritics such as antihistamines, aspirin or paracetemol may be useful (Heyl and Swart, 1990 : 105). The therapeutic value of antihistamines seems to reside principally in their sedative properties (McHenry, 1995 : 845).

2.9.6 Tar-containing preparations

Tar containing compounds are older and messier than corticosteroid preparations and less effective (Landow, 1997 : 111).

2.9.7 Phototherapy

Doctors have found that sunlight does help some patients and in some cases light therapy may be recommended, usually as an outpatient at the local hospital (Meredith, 1995 : 53).

2.9.8 Side effects

Concern over the use of potent corticosteroids eg. Diprolene, is well founded in cases of atopic dermatitis. The skin in these patients tends to be of relatively normal thickness, thus allowing absorption of potentially dangerous amounts of potent agents. Possible side-effects of topical corticosteroids are atrophy, burning, contact dermatitis, hypopigmentation, irritation, itching, masking of cutaneous infections, perioral dermatitis, purpura, Rosaceaform dermatitis, striae, telangiectasia and thinning of the skin (Landow, 1997 : 107-108).

The use of antihistamine creams should be avoided as they provoke skin sensitivity and may worsen the condition. Antihistamines tend to cause drowsiness, headaches, a dry mouth and constipation (Meredith, 1995 : 50-51).

Other side-effects include adrenal suppression, cataracts, growth retardation, Iatrogenic Cushing's Syndrome and increased intraocular pressure (Landow, 1997 : 107-108).

At the end of the 20th century a 'steroid phobia' reigned, particularly amongst patients, parents of children with atopic eczema and general practitioners. As a consequence many patients were opting for the seemingly safer haven of alternative or herbal remedies (Griffiths, 2001 : 679).

2.10 Avoidance and control therapy

Although a genetic predisposition to allergy is unavoidable, environmental factors trigger off episodes of allergic reaction. It is important to avoid environmental trigger factors (Westcott, 2000 : 21).

Atopic skin has a poor tolerance for a wide range of environmental irritants. Even the most mundane exposure may precipitate a long lived flare of disease activity (Landow, 1997 : 102).

Eczema may be a manifestation of excessive sensitivity to detergents, soaps and chemicals (Memmler, *et al*. 1992 : 74). Use of various substances eg. deodorants, solvents and overuse of soap must be discouraged (Landow, 1997 : 103). Chronic inflammation of atopic eczema most likely involves a number of interdependent factors including repeated or persistent exposure to allergens such as foods, aeroallergens and microorganisms (Motala, 1998 : 16).

2.11 Homoeopathic treatment

Homoeopathy is a safe, gentle and effective system of medicine that powerfully stimulates the body's vital force to cure illness (Vithoulkas, 1981 : 15).
The homoeopathic system individualizes medicines according to the totality of the person's symptoms and uses medicines to stimulate the body's own defense mechanisms to initiate the healing process (Ullman, 1991: 3).

Homoeopathy is based on the fundamental principles of 'like cures like'.The most successful remedy will be that whose symptomatology presents the clearest and closest resemblance to the symptom-complex of the sick person (Boyd, 1989 : 2). The concept of the infinitesimally small dose is the second basic principle of homoeopathy. Apart from their therapeutic effectiveness, minute dosages render even the most toxic substances used in their preparation safe and free from unwanted side-effects (Gunavante, 1994 : 37).

Although classical homoeopaths keep time to homoeopathic principles in prescribing only single remedies, it has been found by clinical experience that remedies can be mixed together and administered successfully as a complex (Kayne, 1997 : 104). It is fair to record that many homeopathic practitioners favour the combination remedy and provide ample demonstrations of their effectiveness (Cook, 1989 : 73).

2.11.1 Homoeopathic research

In 1997 Opperman conducted a double-blind placebo-controlled trial using homoeopathic simillimum treatment in the management of atopic eczema. Thirty patients were selected for this study and were divided into two equal groups of fifteen, where group 1 received the placebo and group 2 received the homoeopathic simillimum treatment. Patients were given four treatments over a three month period. The parameters measured were the clinical manifestation of the disease and the patient's perception of the treatment. Statistical analysis of the results revealed a significant improvement in the treatment group and no significant improvement in the placebo group. Therefore, this study concluded that homoeopathic simillimum treatment was effective in the treatment of atopic eczema.

In 1991 Spence conducted a retrospective survey on the homoeopathic treatment of atopic eczema on 130 patients (40 adults and 90 children). According to this survey 85.5% of the sample group experienced a marked improvement in their eczema after receiving homoeopathic treatment. However, this was a retrospective survey so the treatment was not tested against a placebo. Also, the treatment period ranged from 3 months to 9 years and the sample group included adults and children.

Itamura and Hosoya conducted a study in 2003 to evaluate the efficacy of homoeopathic treatment in Japanese patients with atopic eczema. 17 patients were given individual homoeopathic treatment in addition to conventional dermatological therapy for a period of 6 months. The efficacy of the homoeopathic treatment was measured by objective assessment of the skin condition and the patient's own assessment using a 9 point scale similar to the Glasgow Homoeopathic Outcome Scale. Patients were evaluated every 3 months. Over 50% improvement was reported in the overall impression question. The results of this study suggest that homoeopathic treatment can be a useful strategy in addition to or instead of conventional dermatological treatment for atopic eczema.

In 2001, Botha conducted a randomised, double-blind study to evaluate the efficacy of a homoeopathic eczema complex (Herpin 2), (Arsenicum album D10, Bovista gigantea D6, Fluoricum acidum D6, Graphites D30, Hydrastis canadensis D8, Lycopodium clavatum D4, Sulphur D30 and Urtica urens D4), in the treatment of atopic eczema. Thirty patients were selected of which 15 received the homoeopathic complex and the remaining 15 received the placebo. The trial lasted 2 months. In this time patients were assessed every 4 weeks.
This trial measured and recorded the area affected by eczematous lesions, which formed the objective data, and recorded the patient's perception of the treatment via questionnaires, which formed the subjective data. This study found that there was no statistical difference between the treatment and the placebo groups. However, at the third (last) appointment, only the treatment group had a reduction in the total percentage body surface area affected by eczematous lesions. Botha found that the erythema in atopic eczema is often ill-defined, making accurate measurements difficult and this may have affected the overall results. Also, the complex (Herpin 2), had two remedies which were antidotal to each other. Hydrastis canadensis is antidoted by Sulphur, and Lycopodium clavatum is antidoted by Graphites (Boericke, 1995 : 333, 412). This may have compromised the therapeutic value of the complex (Herpin 2). Botha recommended that two appointments were sufficient to assess the change that occurred in both groups before and after the treatment. It was concluded that the homoeopathic complex (Herpin 2) does not necessarily improve the signs and symptoms of eczema.

The potency used in this study was 12CH for all the remedies in the complex. Low potencies which are, from mother tincture to 3CH, respond to local symptoms. Medium potencies which range from 3CH to 12CH are used for general symptoms. Higher potencies which are from 12CH to 30CH, work on the nervous or mental symptoms (Gunavante, 1994 : 86). A view commonly held is that high potencies such as 200CH and 1M are aimed at the mental level and very high potencies such as 50M and CM are aimed at the spiritual level (Cook, 1989 : 88). The most commonly used potencies include 9CH and 12CH (Gunavante, 1994 : 86).

2.12 Combination remedies

A combination or mixture of several different remedies given to the patient at the same time is known as polypharmacy (Cook, 1989 : 73). Complexes are a combination of medicines known to be effective in the treatment of a specific disease. The emphasis is placed on the disease and not on the symptoms of the patient. This form of treatment has been found to be useful in acute diseases when symptoms are vague. Complex prescribing is gaining popularity among large sections of the medical profession and the public who can buy them over-the counter (Ferley, *et al.*1989 : 329). According to Kayne (1997) complexes are used for three reasons. Firstly, when the homoeopath is unsure about the appropriate remedy and uses a complex to increase chance of a correct prescription. Secondly, when a patient is suffering from a condition, which has more than one symptom or the patient, has more than one complaint at one time. Finally, it is more convenient as it saves time and trouble.
Initial potencies should be low to medium range. Selecting 12CH makes a gentle starting point (Spence, 1993 : 257).

The homoeopathic combination used in this study consisted of the following remedies in the 12^{th} centesimal Hahnemanian potency : Arsenicum album, Graphites, Petroleum, Rhus toxicodendron, Sulphur and Urtica urens. The indications for these remedies are as follows:

ARSENICUM ALBUM : dry , scurfy eruption with white scales. Worse for cold or after scratching. Skin thickened or swollen. Urticaria from shellfish (Digby, 1996 : 19). Itching and burning of the skin; after rubbing itching is relieved but the burning remains. Relief is obtained by warmth and local heat, and this remedy is complementary to Rhus toxicodendron (Gibson, 1987 : 64).

GRAPHITES : scaly, chapped skin, thickens from scratching. Cracked skin with a moist, sticky exudate. Eruptions and cracking of skin in winter. Cracks of fingers and behind ears (Digby, 1996 : 19). Is a key remedy for skin complaints especially weeping eczema with a honey-like discharge that often occurs behind the ears and knees, on the palms of hands and on the nipples (Lockie and Geddes, 1995 : 56).

PETROLEUM : eczema where skin is dry with deep, bloody cracks especially on the hands and fingertips. Splitting of skin is worse for cold weather (Lockie and Geddes, 1995 : 139). Cracks and fissures also on palms (Boyd, 1989 : 129).

RHUS TOXICODENDRON : eruptions tend to itch and burn especially at night. Scratching is compulsive but affords little relief. Eruptions may be pustular, raw or weepy, sometimes covered with thick crusts. There are periodic exacerbations usually every Spring (Gibson, 1987 : 441). The skin is itchy, red, swollen and burning with a tendency to scaling (Lockie and Geddes, 1995 : 108). Is better for warm applications and dry weather (Boericke, 1995 : 555).

SULPHUR : eruptions red and itchy. Eruptions worse for heat of bath or bed. Sore and raw from perspiration. Water irritates the skin (Digby, 1996 : 19). This remedy is mainly used to treat skin conditions like eczema where, the skin looks dirty and is dry, scaly, itchy, hot and red, and is worse for scratching (Lockie and Geddes, 1995 : 76).

URTICA URENS : eczema especially when skin is itchy or blotchy. Burning and stinging skin complaints (Lockie and Geddes, 1995 : 111). Aggravated by cold compresses, baths or washing (Jouanny, 1984 : 433).

2.13 Placebo

In homoeopathic practice, a placebo is a non-medicated substance that is pharmacodynamically inert. It is used to contrast the effectiveness of non-medication in a controlled experiment against the use of medication in two comparable groups of patients (Gaier 1991 : 426). The effects of the placebo on the individual 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 (Dhawale, 1985 : 18).

Dodes (1997) states that some believe the placebo effect is psychological, due to a belief in the treatment or to a subjective feeling of improvement. A persons belief and hopes about a treatment, combined with their suggestibility, may have a significant biochemical effect.

The placebo effect is not a matter of mind over molecules, but of mind over behaviour. This effect may be a measurement of changed behaviour affected by a belief in the treatment. This includes change in attitude, in what one says about how one feels, and how one acts.

Another theory is that a process of treatment that involves showing attention, care and affection to the patient may itself trigger physical reactions in the body which promote healing. This process reduces stress by providing hope or reducing uncertainty about what treatment to take or what the outcome will be. This reduction in stress prevents or slows down further harmful physical changes from occurring (Dodes, 1997).

The results of this trial revealed that the placebo group showed even greater improvement than the treatment group and the above theories may lend some insight into why this occurred.

3. MATERIALS AND METHODS

3.1 The research methodology

3.1.1 Research design

This was a double-blind placebo-controlled trial using single variable design with 'before and after' measurements and a control group.

3.1.2 Patients

Patients were selected according to single random sampling as it allowed each element in the population an equal chance of being included in the sample and made the selection of every possible combination of the desired number of subjects equal (De Angelis, 1990 : 26).
Thirty patients were selected. Fifteen patients received placebo and fifteen patients received the complex treatment (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH).

3.1.3 Recruitment

Advertisements were placed in newspapers, health shops and clinics in the greater Durban area to recruit patients for the study.

3.1.4 Inclusion criteria

Patients :

- had to be between the ages of eighteen and sixty years.
- had to comply with the diagnostic criteria as in Appendix A (Hanifin and Rajka, 1980 : 45).
- participation was voluntary and each patient had to sign an Information letter (Appendix F) and a consent form (Appendix B).
- were on no other medication during the trial including medication for other conditions.

3.1.5 Exclusion criteria

Patients were excluded if they were suffering from a chronic infection or hypertension. Those receiving steroid therapy for three months or topical steroids for two weeks before commencement of the study were excluded (Wachter and Lezdey, 1992 : 408).

3.2 Experimental design and procedure

3.2.1 Initial consultation

- At the first consultation patients were selected according to the relevant inclusion and exclusion criteria (see 3.1.4 and 3.1.5).
- Patients were then assessed according to the Diagnostic criteria (Appendix A).

- Once these criteria were met, the patient was asked to read and sign the Information sheet (Appendix F) and patient consent form (Appendix B); after which they were accepted into the study.
- Patients then completed the Patients' perception questionnaire (Appendix D) and the General well being schedule (Appendix E) aided by the researcher.
- A full clinical case history (Appendix G) was then conducted.
- The researcher also performed a physical examination (Appendix H).

The prescription was dispensed by a member of staff at the Homoeopathic Day Clinic at the Durban Institute of Technology (D.I.T.).

3.2.2. Treatment

The medication or placebo was given in the form of pillules. These were dispensed at the first consultation and patients were told to take the medication twice daily for the duration of three months.

3.2.3 Randomisation

A randomisation sheet (Appendix I) was used to maintain the double-blind aspect of the study. The Co-Supervisor of this study prepared this sheet. Numbers one to thirty were written onto pieces of paper and placed in a hat. The first fifteen numbers drawn were placed into the Group A. The next fifteen numbers drawn were placed into Group B.

3.2.4 Medicine preparation

The complex used in this trial was prepared by Natura Laboratory (Pretoria, South Africa). The homoeopathic complex was prepared according to monographs in the French pharmacopoeia. Equal quantities of all ingredients were used to prepare the combination in the 12CH potency. The mixture was medicated using a 1% v/m in 96% alcohol. The placebo was not medicated. Both the complex and the placebo looked exactly the same and were placed into identical 20g amber bottles. The medicines were all in the form of white pillules. Bottles containing the treatment were labelled Group A. The placebo was placed in bottles labelled Group B.

3.2.5 Trial / Subsequent consultations

After the initial consultation, patients returned for their first follow-up consultation after three weeks after which subsequent consultations were conducted every two weeks. At every consultation patients filled in the Clinical evaluation index (Appendix C), the Patients perception questionnaire (Appendix D) and the General well being schedule (Appendix E).

3.3 Double-blind

This was a placebo-controlled, double-blind study. Neither the patients nor the researcher knew who received the treatment and who received the placebo.Thirty patients were divided into two groups of fifteen patients, using the randomisation sheet. Both groups underwent the same consultation (Appendix G) and examination procedures (Appendix H). They were also given the treatment or placebo in the same form and followed the directions as to the duration of the trial. Both the treatment and the placebo were indistinguishable from each other and were to be taken in the same manner.

3.4 Measurement

The Clinical evaluation index (Appendix C) was used to evaluate the changes that might occur in the clinical manifestations of atopic eczema (Opperman, 1997 : 23).

The Patients perception questionnaire (Appendix D) was used to evaluate the treatment in terms of the patients' perception in order to establish which aspects of homoeopathic treatment patients considered significant. The General well being schedule (Appendix E) indicates the subjective impact on psychological health and distress due to the experimental medicine (McDowell and Newell, 1996 : 206).

3.5 Statistical Analysis

Data was obtained from the questionnaires filled in by the patients. The answer blocks on the questionnaires were assigned numerical values. All numerical values were entered onto a spread sheet. The mean values for all the questionnaires were calculated and used to draw up bar charts.

P-values (probability values) were used to assess the degree of dissimilarity between two sets of measurements. The information needed for the calculation of P-values came from expressing a scientific hypothesis in probabilistic terms. In this study, the scientific hypothesis to be tested statistically was that a homoeopathic complex would be effective in the treatment of atopic eczema.

$P > 0.05$ is a null hypothesis, where there is no significant improvement.
$P < 0.05$ yields a statistically significant result (Bailar and Mosteller, 1992 : 15).

The null hypothesis (Ho) stated that there were no significant differences between the vaiables being compared i.e. $p > 0.05$

The alternative hypothesis (H1) stated that there were significant differences between the variables being compared i.e. $p < 0.05$

If the p value was > 0.05 the null hypothesis was accepted and the alternate hypothesis rejected.

If the p value was < 0.05 the null hypothesis was rejected and the alternate hypothesis was accepted.

Data obtained was analysed using the following non-parametric statistical tests.

- The Friedman Test was used to compare groups within themselves (Intra-group analysis). This test was used in procedures 1 and 3. Treatment and placebo groups were analysed independently of one another. If the Friedman test showed significant differences then the Wilcoxon Signed Ranks Test was conducted.
- The Wilcoxon Signed Ranks Test was used in each group to assess at which level significant changes occurred. This was done in procedure 2 and 4.
- The Mann-Whitney Unpaired Test was used to compare group 1 with group 2 (Inter-group analysis). This was procedure 5.

3.5.1 Procedure 1

Comparison within Group 1 (Treatment group)

The Friedman test was used to determine whether there were any significant differences between all the consultations in general.

3.5.2 Procedure 2

Comparison within Group 1 (Treatment group)

If the Friedman Test showed significant differences between the consultations overall, the Wilcoxon Signed Ranks Test was used to determine specifically between which consultations these occurred.

3.5.3 Procedure 3

Comparison within Group 2 (Placebo group)

The Friedman test was used to determine whether there were any significant differences between all the consultations in general.

3.5.4 Procedure 4

Comparison within Group 2 (Placebo group)

If the Friedman Test showed significant differences between the consultations overall, the Wilcoxon Signed Ranks Test was used to determine specifically between which consultations these differences occurred.

3.5.5 Procedure 5

Comparison between Group 1 and 2 (Inter-group analysis)

Using the Mann-Whitney Unpaired test, group 1 was compared to group 2, to determine any significant differences between the two groups at the relevant consultations.

4. RESULTS

4.1 Introduction

This is a presentation of results obtained after the data was statistically analysed. Data was collected from the questionnaires completed by the patients from the first consultation (baseline), until the last follow-up. There were 6 consultations.

Intra-group comparisons refer to comparisons made within a group, with both the treatment and placebo groups being analysed independently by the Friedmans Test. This was followed by the Wilcoxon Signed Ranks Test where applicable.

Inter-group comparisons refer to those made between the treatment and placebo group using the Mann-Whitney U test.

4.2 Abbreviations

$P < 0.05$ = significant difference
$P > 0.05$ = no significant difference
B = Baseline (first consultation)
F/UP = Follow-up

4.3 Criteria for admissibility of data

- Only data collected from the trial were accepted
- The only source of data were the questionnaires completed by patients in the presence of the researcher

4.4 Results of Treatment group (Group 1)

TABLE 4.4.1 Comparison of scores of the six consultations within the Treatment group using the Friedman Test for the Clinical evaluation index (Appendix C)

Questionnaire	Question number	p-value	conclusion
C	1	0.382	No difference
	2	0.131	No difference
	3	**0.014**	**Difference**
	4	0.152	No difference
	5	0.584	No difference
	6	0.388	No difference
	7	**0.000**	**Difference**
	8	**0.000**	**Difference**
	9	**0.000**	**Difference**
	10	**0.003**	**Difference**
	11	**0.001**	**Difference**
	12	**0.000**	**Difference**

The table above reveals that in the treatment group, a difference was seen in papules (question 3), dryness (question 7), crusts (question 8), scaling (question 9), bleeding (question 10), scratch marks (question 11), and itching (question 12). No differences were

seen in redness (question 1), swelling (question 2), pustules (question 4), erythematous macules (question 5), and weeping (question 6).

TABLE 4.4.2 Intra group comparison of scores for the Clinical evaluation index (Appendix C) using the Wilcoxon signed ranks test

QUESTION	B-F/UP 1	F/UP 2-F/UP 1	F/UP 3-F/UP 2	F/UP 4-F/UP 3	F/UP 5-F/UP 4	F/UP 5-B	F/UP 2-B
3	0.238	0.564	0.157	0.157	0.564	0.257	0.426
7	0.248	0.593	0.096	1.000	**0.014**	**0.002**	0.084
8	0.234	1.000	0.257	**0.014**	0.157	**0.006**	0.206
9	0.564	0.564	0.102	0.157	0.317	**0.004**	0.190
10	0.157	0.317	0.564	0.102	0.180	**0.004**	0.527
11	0.391	0.157	0.157	0.317	0.157	**0.010**	**0.047**
12	0.222	0.140	0.217	0.096	0.206	**0.001**	**0.017**
Total	0.084	0.277	0.230	**0.017**	**0.017**	**0.001**	**0.017**

This table reveals that a difference was seen in dryness (question 7), between the fourth and fifth follow-up and from baseline to the fifth follow-up. From follow-up three to four, and baseline to follow-up five, a change was seen in crusts (question 8). From baseline to follow-up five differences were seen in scaling (question 9) and bleeding (question 10). Scratch marks (question 11), show a difference from baseline to the fifth follow-up and from baseline to the second follow-up.The same results are seen for itching (question 12). The total scores show changes between the third and fourth follow-up, the fourth and fifth , and from baseline to the second and fifth follow-ups.

TABLE 4.4.3 Comparison of the total scores for Group 1 using the Wilcoxon Signed Ranks Test to assess the Clinical evaluation index (Appendix C)

Comparisons	p-value	conclusion
F/UP 1-B	0.084	No difference
F/UP 2-F/UP	0.277	No difference
F/UP 3-F/UP 2	0.230	No difference
F/UP 4-F/UP 3	**0.017**	**Difference**
F/UP 5-F/UP 4	**0.017**	**Difference**
F/UP 5-B	**0.001**	**Difference**
F/UP 2-B	**0.017**	**Difference**

The table above reflects the differences seen from the baseline (initial consultation), to the second and fifth follow-up consultations. Differences are seen between the third and fourth, and fourth and fifth follow-up consultations. Comparisons between the first to the third follow-up consultations show no differences.

TABLE 4.4.4 Comparison of scores of the six consultations within the Treatment group using the Friedman Test for the Patients' perception questionnaire (Appendix D)

Questionnaire	Question number	p-value	conclusion
D	**1**	**0.000**	**Difference**
	2a	0.072	No difference
	2b	**0.000**	**Difference**
	3	**0.000**	**Difference**
	4	**0.032**	**Difference**
	5	**0.000**	**Difference**
	6	**0.000**	**Difference**
	7	**0.000**	**Difference**
	8	**0.001**	**Difference**

This table reveals that there was no change in the eczema of the patient (question 2 a). There was a change in the severity of the eczema (question 1). A difference was seen as to whether the eczema was getting better or worse (question 2 b). There was also a difference in the skin surface texture (question 3), pain (question 4), bleeding (question 5), and in itching (question 6). Patients experienced a change from the usual disruption of sleep (question 7), and found a difference in the influence on their social life (question 8).

TABLE 4.4.5 Intra group comparison of scores for the Patients' perception questionnaire (Appendix D) using the Wilcoxon signed ranks test for group 1

QUESTION	B-F/UP 1	F/UP 2-F/UP 1	F/UP 3-F/UP 2	F/UP 4-F/UP 3	F/UP 5-F/UP 4	F/UP 5-B	F/UP 2-B
D1	0.248	**0.021**	0.317	**0.015**	**0.030**	**0.001**	**0.022**
2b	0.119	**0.011**	0.739	0.053	0.083	**0.001**	**0.017**
3	0.062	0.160	0.248	**0.013**	**0.011**	**0.001**	**0.020**
4	0.367	0.146	0.680	0.785	0.157	**0.004**	**0.020**
5	1.000	0.161	0.564	0.257	0.157	**0.002**	**0.014**
6	0.190	0.084	0.076	0.071	**0.047**	**0.001**	**0.046**
7	0.675	**0.050**	0.414	0.334	0.157	**0.003**	**0.024**
Total	0.069	**0.023**	0.098	**0.015**	**0.015**	**0.001**	**0.004**

Patients changed the rating of their eczema (question 1), between follow-up one and two, follow-up three to four, four to five, and from baseline to follow-up two and five. A change in the eczema (question 2 b), was seen from follow-up one to two, and from baseline to the second and fifth follow-up. Patients saw a change in the surface texture of their skin (question 3), between the third and fourth follow-up, the fourth and fifth follow-up and from baseline to the second and fifth follow-up. A difference in pain (question 4), and bleeding (question 5), was seen only from baseline to the second and fifth follow-up. Itching (question 6), changed between the fourth and fifth follow-up, and from baseline to the second and fifth follow-up. Patients also saw a change in the disruption of their sleep (question 7), and experienced this between the first and second follow-up, and from baseline to the second and fifth follow-up. The total scores reveal that differences occurred between the first and second follow-up, the third to fourth and between the fourth and fifth follow-up. These changes were also seen from baseline to the second and fifth follow-up.

TABLE 4.4.6 Comparison of the total scores for Group 1 using the Wilcoxon Signed Ranks Test to assess the Patients' perception questionnaire (Appendix D)

Comparisons	p-value	conclusion
F/UP 1-B	0.069	No difference
F/UP 2-F/UP 1	**0.023**	**Difference**
F/UP 3-F/UP 2	0.098	No difference
F/UP 4-F/UP 3	**0.015**	**Difference**
F/UP 5-F/UP 4	**0.015**	**Difference**
F/UP 5-B	**0.001**	**Difference**
F/UP 2-B	**0.004**	**Difference**

This table shows that there was no difference between the baseline to the first follow-up and from the second to the third follow-up. Differences were seen between the first and second follow-up, the third and fourth follow-up and between the fourth and fifth follow-up. Changes can also be seen from the baseline to the second and fifth follow-up.

TABLE 4.4.7 Comparison of the scores of the six consultations within the Treatment group using the Friedman Test for the General well being schedule (Appendix E)

Questionnaire	question number	p-value	conclusion
E	1	0.347	No difference
	2	0.118	No difference
	3	0.221	No difference
	4	0.223	No difference
	5	**0.012**	**Difference**
	6	**0.624**	**Difference**
	7	0.203	No difference
	8	0.097	No difference
	9	0.872	No difference
	10	0.065	No difference
	11	0.118	No difference
	12	0.083	No difference
	13	**0.026**	**Difference**
	14	0.068	No difference
	15	**0.000**	**Difference**
	16	**0.012**	**Difference**
	17	0.279	No difference
	18	**0.013**	**Difference**

The table above shows that patients felt a difference in stress they usually felt (question 5), and saw a change in their personal lives as well (question 6). Patients saw a difference with regards to emotional stability (question 13), and concern over their health (question 15). There was also a difference in how relaxed (question 16), and cheerful (question 18), patients felt.

TABLE 4.4.8 Intra group comparison of scores for the General well being schedule (Appendix E) using the Wilcoxon signed ranks test for group 1

QUESTION	B-F/UP 1	F/UP 2-F/UP 1	F/UP 3-F/UP 2	F/UP 4-F/UP 3	F/UP 5-F/UP 4	F/UP 5-B	F/UP 2-B
5	0.121	0.227	0.365	**0.041**	0.891	**0.041**	0.107
13	0.109	0.786	0.102	1.000	1.000	1.000	0.102
15	0.372	**0.002**	0.571	0.569	0.147	**0.002**	**0.009**
16	0.191	0.381	0.752	0.676	0.072	**0.010**	**0.033**
18	0.168	0.491	0.300	0.167	0.676	**0.037**	0.589

The table above reveals that patients felt a change in how stressed they felt (question 5), and this occurred between follow-up three and four, and from baseline to follow-up five. Question thirteen regarding emotional stability shows no difference. Concern over their health (question 15), changed between follow-up one and two, and from baseline to the second and fifth follow-up. Patients felt more relaxed (question 16), from baseline to the second and fifth follow-up. From baseline to the fifth follow-up there was a change in how cheerful or depressed patients felt (question 18).

TABLE 4.4.9 Comparison of the total scores for Group 1 using the Wilcoxon signed ranks test to assess the General well being schedule (Appendix E)

Comparisons	p-value	conclusion
F/UP 1-B	0.168	No difference
F/UP 2-F/UP 1	0.491	No difference
F/UP 3-F/UP 2	0.300	No difference
F/UP 4-F/UP 3	0.167	No difference
F/UP 5-F/UP 4	0.676	No difference
F/UP 5-B	**0.037**	**Difference**
F/UP 2-B	0.589	No difference

Differences were only seen between the baseline and the fifth follow-up.

4.5 Results of the placebo group (Group 2)

Table 4.5.1 Comparison of the scores of the six consultations within the placebo group using the Friedman Test for the Clinical evaluation index (Appendix C)

Questionnaire	Question number	p-value	conclusion
C	**1**	**0.012**	**Difference**
	2	**0.000**	**Difference**
	3	0.295	No difference
	4	0.416	No difference
	5	0.297	No difference
	6	0.089	No difference
	7	**0.000**	**Difference**
	8	**0.003**	**Difference**
	9	**0.000**	**Difference**
	10	0.072	No Difference
	11	**0.029**	**Difference**
	12	**0.000**	**Difference**

The placebo group shows that there was a difference in redness (question 1), and swelling (question 2). There were also changes in dryness (question 7), crusts (question 8), scaling (question 9), and scratch marks (question 11), and itching (question 12).

4.5.2 Intra group comparison of scores for the Clinical evaluation index (Appendix C) using the Wilcoxon signed ranks test for group 2

QUESTION	B-F/UP 1	F/UP 2-F/UP 1	F/UP 3-F/UP 2	F/UP 4-F/UP 3	F/UP 5-F/UP 4	F/UP 5-B	F/UP 2-B
1	**0.010**	0.317	1.000	0.564	0.317	**0.028**	**0.031**
2	**0.039**	0.317	1.000	1.000	1.000	**0.041**	**0.041**
7	**0.014**	0.527	0.096	0.206	0.257	**0.001**	**0.005**
8	**0.031**	0.655	0.705	0.257	1.000	**0.011**	0.059
9	0.084	0.763	0.058	0.102	0.317	**0.004**	0.084
11	0.380	0.257	0.317	1.000	0.157	**0.026**	0.084
12	**0.041**	0.102	0.271	**0.014**	0.180	**0.001**	**0.006**

In the placebo group differences in redness (question 1), swelling (question 2), and dryness (question 7), were seen from baseline to the first, second and fifth follow-up.
A change in crust formation (question 8), was seen between baseline to first and fifth follow-up. Scaling (question 9), and scratch marks (question 11), changed between the baseline and fifth follow-up. There was a difference in itching (question 12), which occurred between the baseline and the first, second and fifth follow-ups, and also between the third and fourth follow-up.

TABLE 4.5.3 Comparison of the total scores for Group 2 using the Wilcoxon Signed Ranks Test to assess the Clinical evaluation index (Appendix C)

Comparisons	p-value	conclusion
F/UP 1-B	**0.001**	**Difference**
F/UP 2-F/UP 1	0.531	No difference
F/UP 3-F/UP 2	**0.048**	**Difference**
F/UP 4-F/UP 3	0.129	No difference
F/UP 5-F/UP 4	0.090	No difference
F/UP 5-B	**0.001**	**Difference**
F/UP 2-B	**0.001**	**Difference**

Differences have been seen within the placebo group from the baseline (initial consultation), to the first, second and fifth follow-up. Changes were also seen between the second and third follow-up.

Table 4.5.4 Comparison of scores of the six consultations within the placebo group using the Friedman Test for the Patients' perception questionnaire (Appendix D)

Questionnaire	Question number	p-value	conclusion
D	**1**	**0.000**	**Difference**
	2a	**0.000**	**Difference**
	2b	**0.000**	**Difference**
	3	**0.000**	**Difference**
	4	**0.001**	**Difference**
	5	**0.013**	**Difference**
	6	**0.000**	**Difference**
	7	**0.003**	**Difference**
	8	**0.000**	**Difference**

The placebo group experienced differences in all eight questions in the Patients' perception questionnaire.

TABLE 4.5.5 Intra group comparison of scores for the Patients' perception questionnaire (Appendix D) using the Wilcoxon signed ranks test for group 2

QUESTION	B-F/UP 1	F/UP 2-F/UP 1	F/UP 3-F/UP 2	F/UP 4-F/UP 3	F/UP 5-F/UP 4	F/UP 5-B	F/UP 2-B
1	**0.003**	**0.011**	0.180	**0.019**	0.102	**0.001**	**0.001**
2a	**0.026**	0.102	0.655	0.317	0.317	**0.016**	**0.010**
2b	**0.004**	0.763	**0.035**	**0.025**	0.317	**0.001**	**0.006**
3	**0.007**	0.705	0.052	**0.008**	1.000	**0.001**	**0.003**
4	0.201	1.000	**0.038**	1.000	1.000	**0.027**	0.135
5	0.070	0.705	0.180	0.564	0.157	**0.016**	**0.046**
6	**0.019**	0.160	0.133	**0.034**	0.059	**0.001**	**0.003**
7	0.854	0.034	0.276	0.317	1.000	**0.012**	**0.020**
8	**0.014**	0.084	**0.038**	1.000	0.083	**0.004**	**0.009**

In the placebo group, the severity of eczema (question 1), changed between all of the combination of follow-ups measured except between follow-up two to three and four to five. The eczema changed (question 2a), between baseline to the first, second and fifth follow-ups. There was no change between the first and second and fourth and fifth follow-up with regards to whether the eczema was getting better or worse (question 2b). Changes were seen between the other follow-ups. Skin texture (question 3), was seen to have changed from baseline to the first, second and fifth follow-ups and between the third and fourth follow-up. From the second to the third consultation and from baseline to the fifth follow-up, patients saw a difference in pain (question 4). There was a difference in bleeding (question 5), only between baseline and the second and fifth follow-ups. A difference in itching (question 6) was noticed between the third and fourth follow-up and from baseline to the first, second and fifth follow-up. Disruption of sleep (question 7), changed between the first and second and from baseline to the second and fifth follow-up. The influence on social life (question 8), improved between the second and third follow-up, and from baseline to the first, second and fifth follow-up.

TABLE 4.5.6 Comparison of the total scores for Group 2 using the Wilcoxon Signed Ranks Test to assess the Patients' perception questionnaire (Appendix D)

Comparisons	p-value	conclusion
F/UP 1-B	**0.001**	**Difference**
F/UP 2-F/UP 1	**0.024**	**Difference**
F/UP 3-F/UP 2	**0.007**	**Difference**
F/UP 4-F/UP 3	**0.005**	**Difference**
F/UP 5-F/UP 4	**0.036**	**Difference**
F/UP 5-B	**0.001**	**Difference**
F/UP 2-B	**0.001**	**Difference**

These results reveal that differences were seen between all the follow-up combinations that were used in this test.

Table 4.5.7 Comparison of scores of the six consultations within the placebo group using the Friedman Test for the General well being schedule (Appendix E)

Questionnaire	Question number	p-value	conclusion
E	**1**	**0.002**	**Difference**
	2	0.146	No difference
	3	0.119	No difference
	4	0.001	No difference
	5	0.307	No difference
	6	0.705	No difference
	7	0.416	No difference
	8	**0.000**	**Difference**
	9	**0.000**	**Difference**
	10	**0.000**	**Difference**
	11	0.837	No difference
	12	**0.003**	**Difference**
	13	0.042	No difference
	14	**0.008**	**Difference**
	15	**0.000**	**Difference**
	16	**0.011**	**Difference**
	17	**0.042**	**Difference**
	18	**0.000**	**Difference**

In the placebo group, differences were seen with regards to how patients were feeling in general (question 1). There were also changes in how anxious patients felt (question 8), being able to wake up feeling rested (question 9), and fears about their health (question 10). Those who felt downhearted (question 12), experienced a difference. Feelings of tiredness (question 14), and their concerns about their health (question 15) also changed. Patients in this group also revealed that there was a difference with regards to how tense they felt (question 16), their energy levels (question 17), and whether they felt depressed or cheerful (question 18).

TABLE 4.5.8 Intra group comparison of scores for the General well being schedule (Appendix E) using the Wilcoxon signed ranks test for group 2

QUESTION	B-F/UP 1	F/UP 2-F/UP 1	F/UP 3-F/UP 2	F/UP 4-F/UP 3	F/UP 5-F/UP 4	F/UP 5-B	F/UP 2-B
1	**0.015**	0.629	0.380	1.000	1.000	**0.003**	**0.046**
4	**0.020**	1.000	0.564	0.317	0.317	**0.007**	**0.011**
8	**0.046**	0.347	0.414	0.157	0.317	**0.001**	**0.007**
9	**0.016**	0.334	0.131	0.317	1.000	**0.006**	**0.010**
10	**0.015**	0.852	0.271	**0.034**	1.000	**0.002**	**0.006**
12	0.135	0.518	0.157	0.102	0.317	**0.017**	**0.047**
13	0.102	0.157	0.157	1.000	1.000	0.102	0.414
14	0.159	0.831	0.161	**0.046**	0.083	**0.011**	0.132
15	**0.016**	1.000	**0.004**	**0.023**	0.174	**0.001**	**0.026**
16	0.236	0.409	0.101	0.131	0.285	**0.021**	0.477
17	0.569	0.560	0.157	0.206	0.166	**0.029**	0.915
18	0.277	0.643	0.070	0.458	0.832	**0.003**	0.068

In this group patients showed that they were feeling better (question 1), were not sad (question 4), or anxious (question 8), and were waking up fresh (question 9), and this was seen from the baseline to the first, second and fifth follow-up. Fears about their health (question 10), changed between the third and fourth follow-up, and from baseline to the first, second and fifth follow-up. Feelings of being downhearted (question 12), changed from baseline to the second and fifth follow-up. There were no differences in emotional stability (question 13), in the combination of follow-ups analysed. Question 14, which examined tiredness revealed changes between the third and fourth follow-up and from baseline to the fifth follow-up. There was no change in concern over their health (question 15), between the first and second follow-up, and between the fourth and fifth follow-up. Changes were seen in the other follow-ups that were analysed. The difference in how relaxed patients felt (question 16), their energy levels (question 17), and how cheerful they felt (question 18), can be seen between the baseline and fifth follow-up.

TABLE 4.5.9 Comparison of the total scores for Group 2 using the Wilcoxon Signed Ranks Test to assess the General well being schedule (Appendix E)

Comparisons	p-value	conclusion
F/UP 1-B	0.277	No difference
F/UP 2-F/UP 1	0.643	No difference
F/UP 3-F/UP 2	0.070	No difference
F/UP 4-F/UP 3	0.458	No difference
F/UP 5-F/UP 4	0.832	No difference
F/UP 5-B	**0.003**	**Difference**
F/UP 2-B	0.068	No difference

The above results reveal that differences were seen only between follow-up four and five. No other changes were seen.

4.6 Inter group analysis

TABLE 4.6.1 Results of the comparison between Group 1 and Group 2 of the total scores using the Mann-Whitney U-test for the Clinical evaluation index (Appendix C)

Questionnaire C	consultation	p-value	conclusion
	Baseline	0.917	No difference
	F/UP 1	0.037	No difference
	F/UP 2	0.219	No difference
	F/UP 3	0.259	No difference
	F/UP 4	0.218	No difference
	F/UP 5	0.124	No difference

The table above reveals that there were no differences of the total scores between group 1(treatment group) and group 2 (placebo group) for the Clinical evaluation index (Appendix C) as analysed by the Mann-Whitney U-test.

TABLE 4.6.2 Results of the comparison between Group 1 and Group 2 of the total scores using the Mann-Whitney U-test for the Patients' perception questionnaire (Appendix D)

Questionnaire D	consultation	p-value	Conclusion
	Baseline	0.662	No difference
	F/UP 1	0.077	No difference
	F/UP 2	0.227	No difference
	F/UP3	0.127	No difference
	F/UP 4	0.122	No difference
	F/UP 5	0.172	No difference

There were no differences between group 1(treatment group) and group 2 (placebo group) of the total scores for the Patients's perception questionnaire (Appendix D) when analysis was done using the Mann-Whitney U-test.

TABLE 4.6.3 Results of the comparison between Group 1 and Group 2 of the total scores using the Mann-Whitney U-test for the General well being schedule (Appendix E)

Questionnaire E	consultation	p-value	conclusion
	Baseline	0.863	No difference
	F/UP 1	0.826	No difference
	F/UP 2	1.000	No difference
	F/UP 3	0.137	No difference
	F/UP 4	0.275	No difference
	F/UP 5	0.476	No difference

There were no differences between group 1(treatment group) and group 2 (placebo group) of the total scores for the General well being schedule (Appendix E) when analysis was done using the Mann-Whitney U-test.

TABLE 4.6.4 Inter group comparison of scores at each consultation for the Clinical evaluation index (Appendix C) using the Mann-Whitney U-test

	B	**F/ UP 1**	**F/UP 2**	**F/UP 3**	**F/UP 4**	**F/UP 5**	
1	0.447	0.078	0.6220.	0.341	0.374	0.369	
2	0.298	0.148	0.073	0.073	0.317	1.000	
3	0.894	**0.015**	0.295	0.340	0.550	0.150	
4	0.498	0.317	1.000	1.000	1.000	1.000	
5	0.577	0.276	0.073	0.148	0.367	0.317	
6	0.613	0.944	0.944	0.630	0.630	0.550	
7	0.339	0.787	0.621	0.647	0.285	0.501	
8	0.502	0.555	0.873	0.333	1.000	0.609	
9	0.699	0.570	0.569	0.427	0.161	0.394	
10	0.340	0.128	0.122	**0.046**	0.671	1.000	
11	0.564	0.479	0.900	1.000	0.914	0.630	
12	0.171	0.148	0.324	0.571	0.300	0.231	

The inter group comparison reveals a difference seen for papules (question 3) at follow-up 1 and for bleeding (question 3), at the third follow-up.

TABLE 4.6.5 Inter group comparison of scores at each consultation for the Patients' perception questionnaire (Appendix D) using the Mann-Whitney U-test

	B	**F/ UP 1**	**F/UP 2**	**F/UP 3**	**F/UP 4**	**F/UP 5**	
1	0.843	0.063	0.182	0.355	0.354	0.454	
2a	0.291	0.614	0.326	1.000	0.317	0.962	
2b	0.369	0.267	0.695	0.531	0.222	0.699	
3	0.792	0.179	0.895	**0.013**	**0.040**	0.407	
4	0.126	0.106	0.546	**0.016**	**0.035**	**0.035**	
5	0.314	**0.047**	0.179	**0.046**	0.612	1.000	
6	0.210	0.088	0.152	0.246	0.328	**0.363**	
7	0.520	0.643	0.458	0.262	0.632	0.972	
8	0.714	0.738	0.352	0.257	0.466	0.301	

Differences in this comparison are change in surface texture of the skin (question 3), at the third and fourth follow-up. Question 4, which looks at pain associated with eczema shows differences at the third, fourth and fifth follow-up. With regards to bleeding (question 5), differences are seen at the first follow-up and at follow-up 3. At follow-up 5 there is a difference with regards to bleeding (question 6).

TABLE 4.6.6 Inter group comparison of scores at each consultation for the General well being schedule (Appendix E) using the Mann-Whitney U-test

	B	F/ UP 1	F/UP 2	F/UP 3	F/UP 4	F/UP 5	
1	0.155	0.369	0.512	0.465	0.602	0.352	
2	0.612	0.073	1.000	0.150	0.317	0.317	
3	0.962	0.150	0.150	1.000	1.000	1.000	
4	0.158	0.270	0.698	0.654	0.962	0.261	
5	0.863	0.559	0.623	0.780	0.737	0.670	
6	0.826	0.730	0.542	0.542	0.613	0.279	
7	1.000	0.150	0.317	1.000	0.317	1.000	
8	0.177	0.580	0.405	0.278	0.538	0.145	
9	0.137	0.734	0.647	0.408	0.632	0.632	
10	0.275	**0.008**	0.586	0.293	**0.033**	**0.025**	
11	0.476	0.650	0.782	0.774	0.589	0.541	
12	0.710	0.963	0.341	0.517	0.312	0.929	
13	0.073	0.073	0.543	1.000	1.000	1.000	
14	0.655	0.814	0.324	0.592	0.892	0.476	
15	0.720	**0.014**	1.000	0.209	0.107	0.166	
16	0.498	0.247	0.627	0.136	**0.034**	0.196	
17	0.752	0.406	0.816	0.594	0.255	0.440	
18	0.966	0.833	0.255	0.205	0.340	0.384	

This table shows differences at follow-up 1,4 and 5 for question 10, which looks at whether patients have been bothered by bodily pains. At follow-up 1, a difference is also seen regarding fears about health (question 15). The last difference is seen at follow-up 4, for question 16, which examines how tense or relaxed patients have felt.

4.7 Bar charts reflecting the comparison of means for group 1 and group 2 for the Clinical evaluation index (Appendix C)

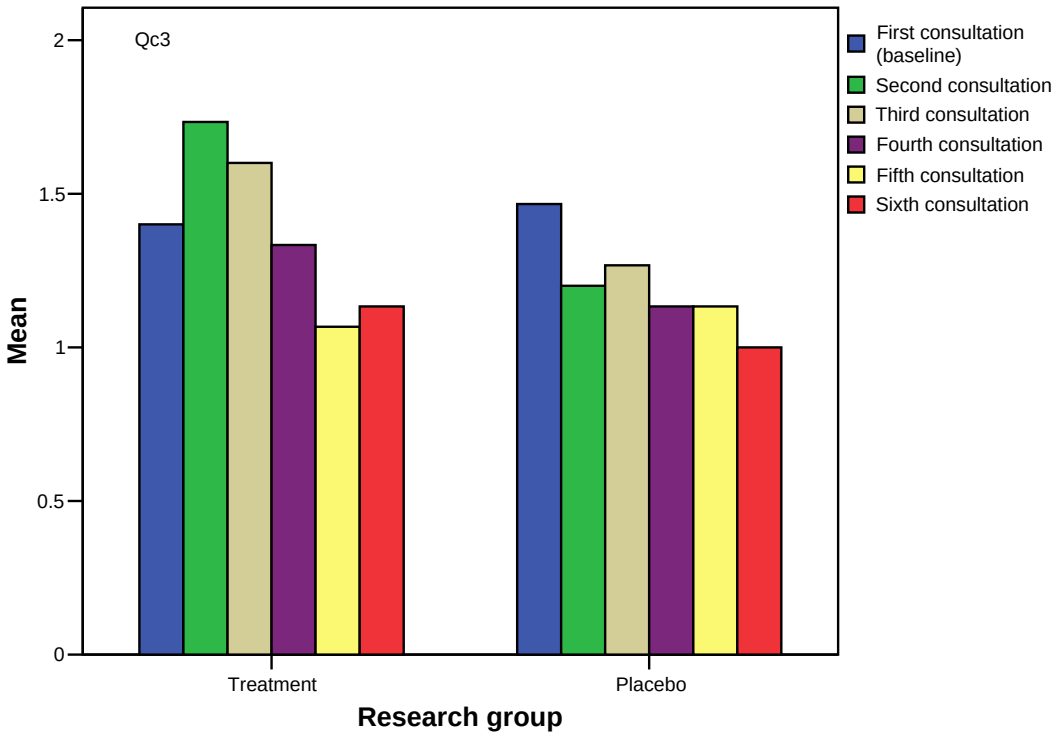

Figure 4.7.1. Comparison between group 1 and group 2 for **papules** (question 3)

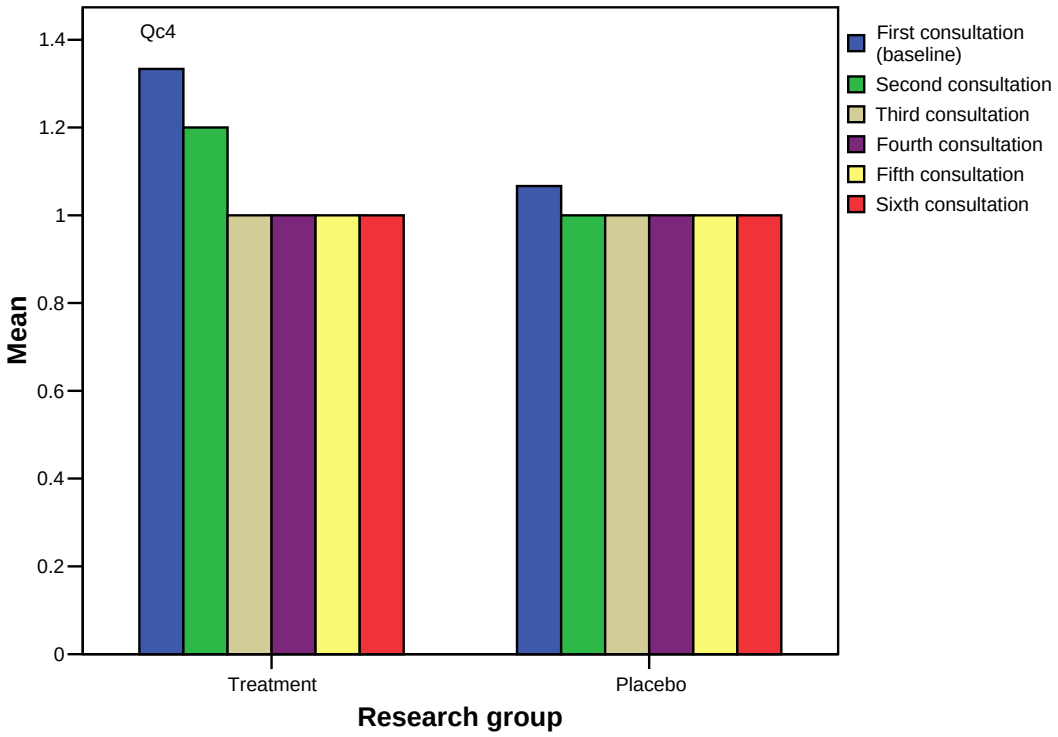

Figure 4.7.2. Comparison between group 1 and group 2 for **pustules** (question 4)

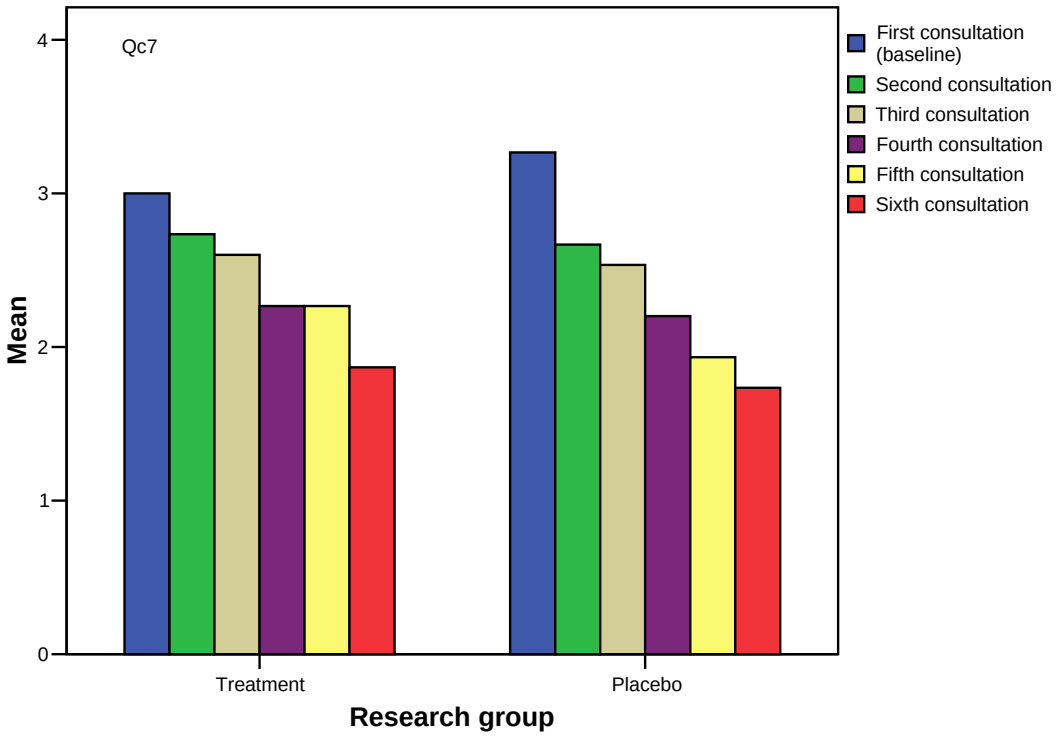

Figure 4.7.3. Comparison between group 1 and group 2 for **dryness** (question 7)

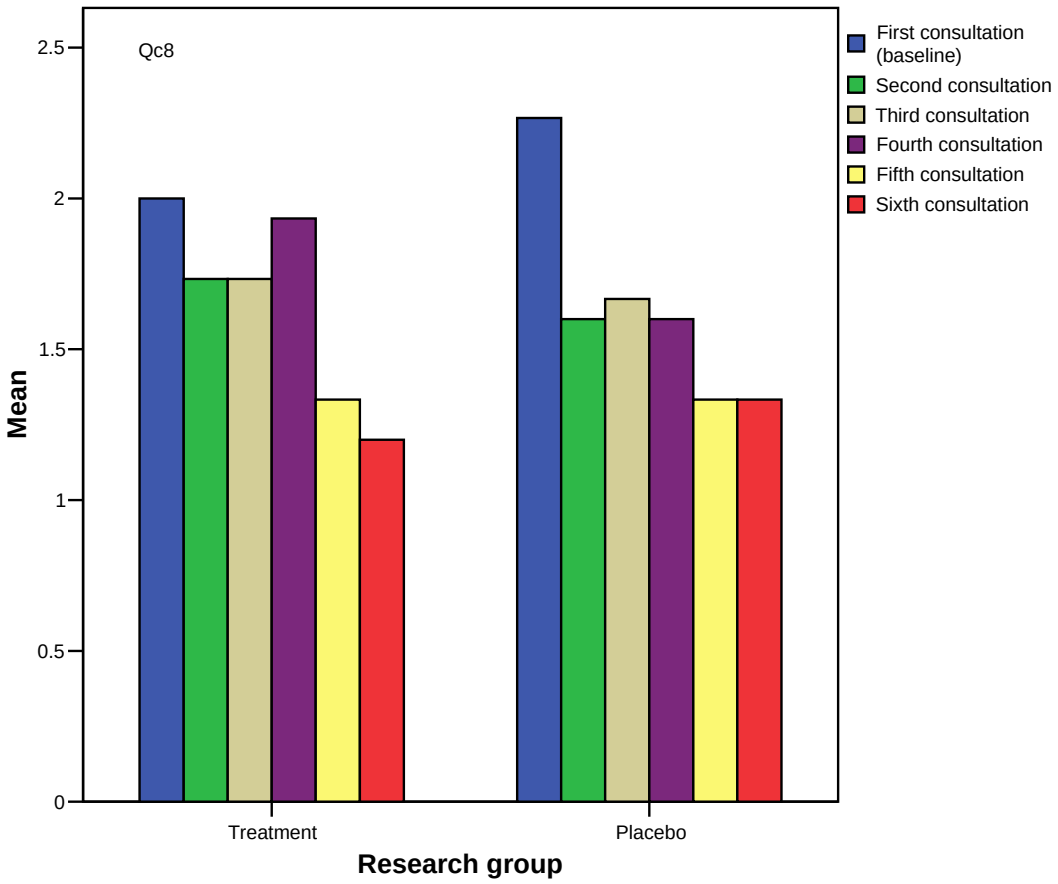

Figure 4.7.4. Comparison between group 1 and group 2 for **crusts** (question 8)

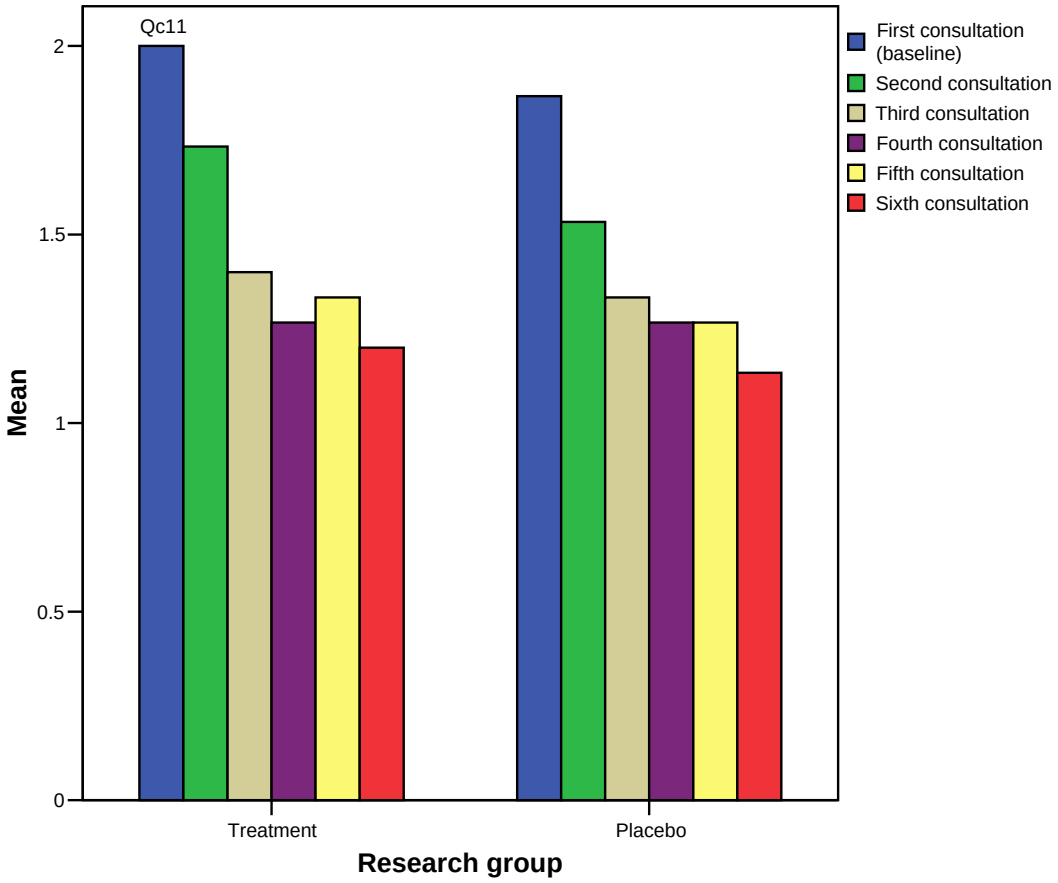

Figure 4.7.5. Comparison between group 1 and group 2 for **scratch marks** (question 11)

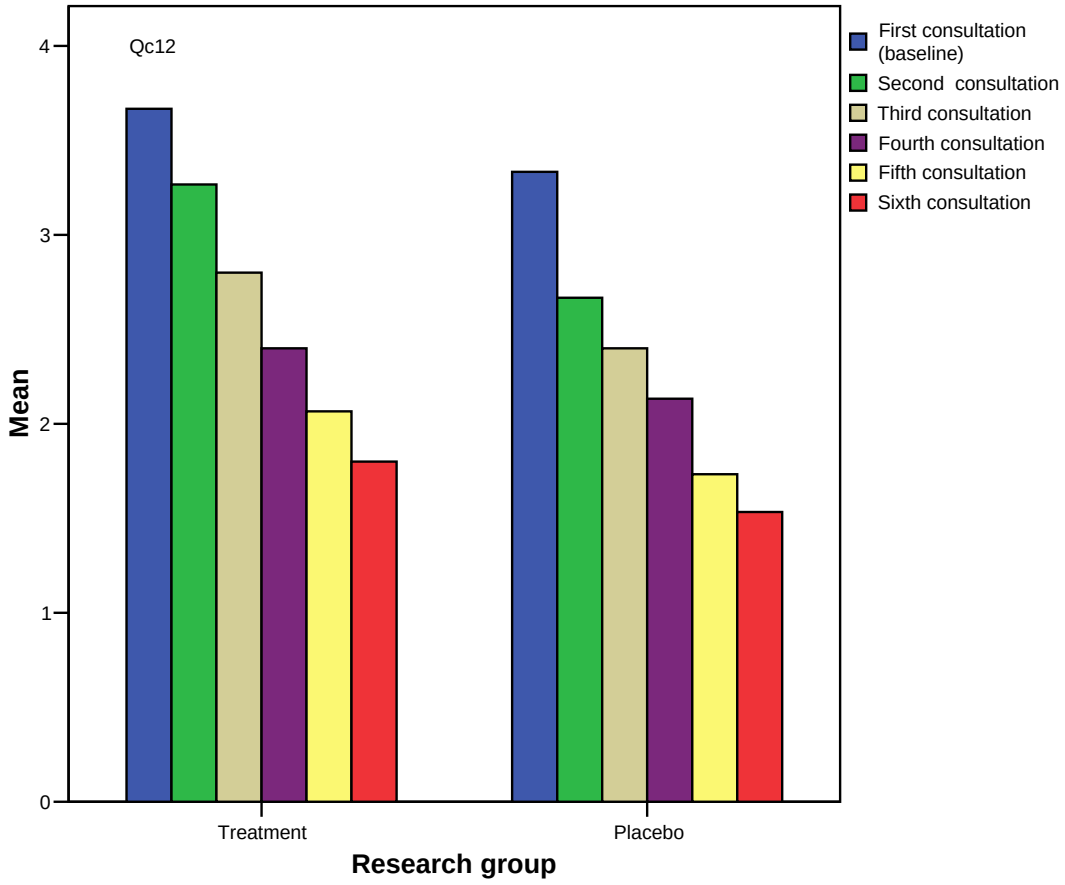

Figure 4.7.6. Comparison between group 1 and group 2 for **itching** (question 12)

4.8 Bar charts reflecting the comparison of means for group 1 and group 2 of the Patients' perception questionnaire (Appendix D)

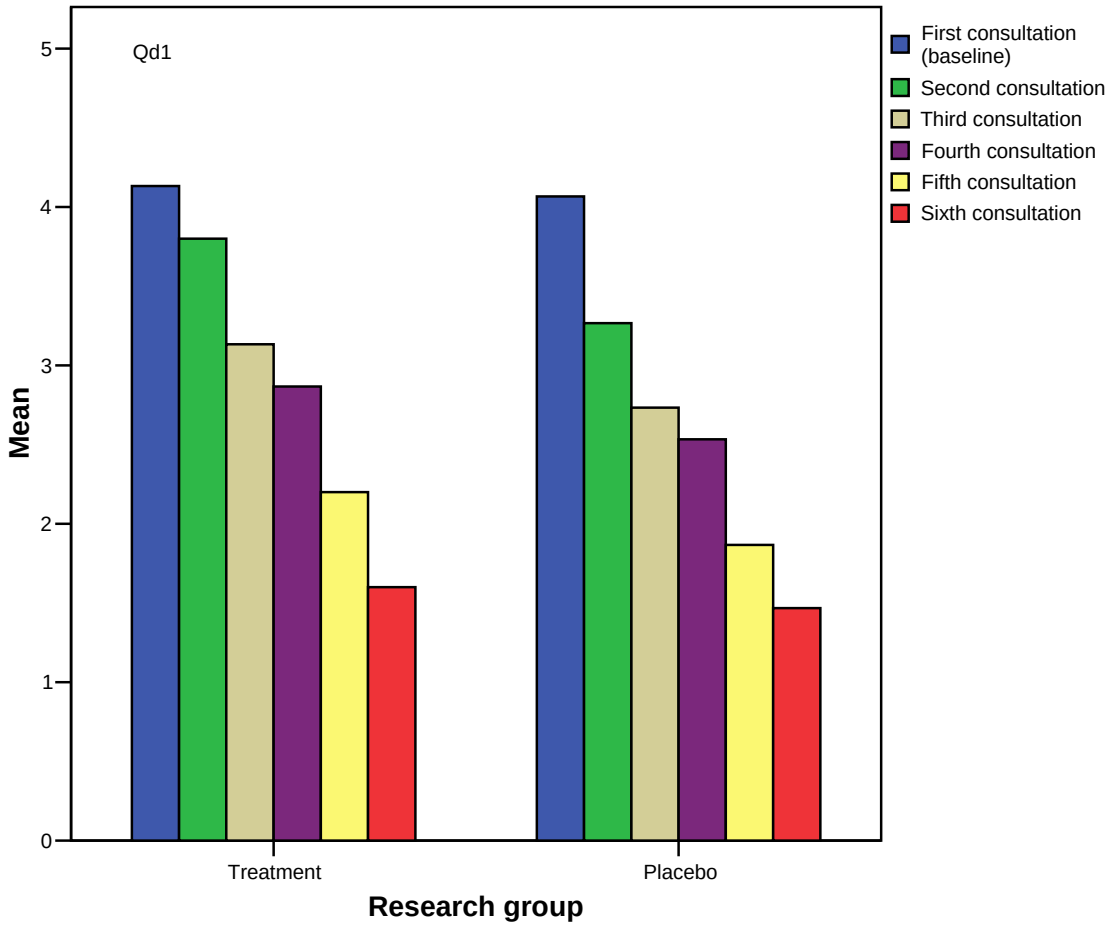

Figure 4.8.1. Comparison between group 1 and group 2 **rating severity of eczema** (question 1)

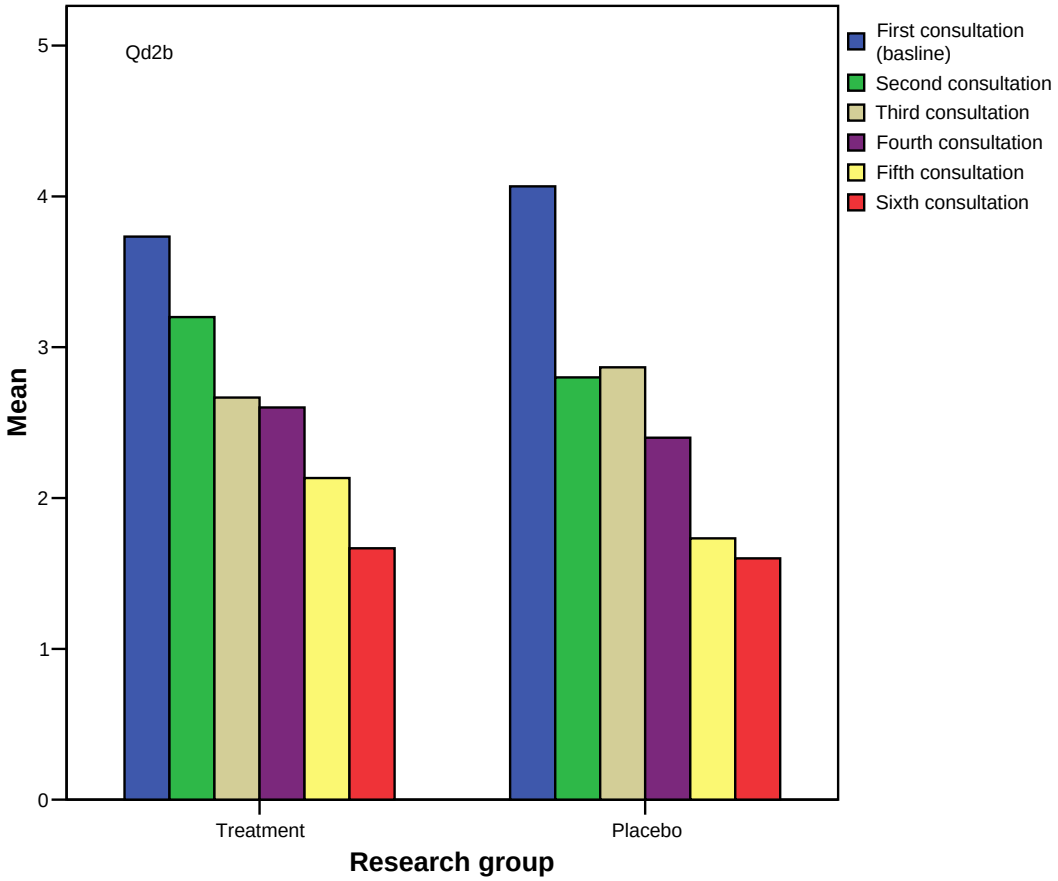

Figure 4.8.2 Comparison between group 1 and group 2 of **how eczema had changed** (question 2b)

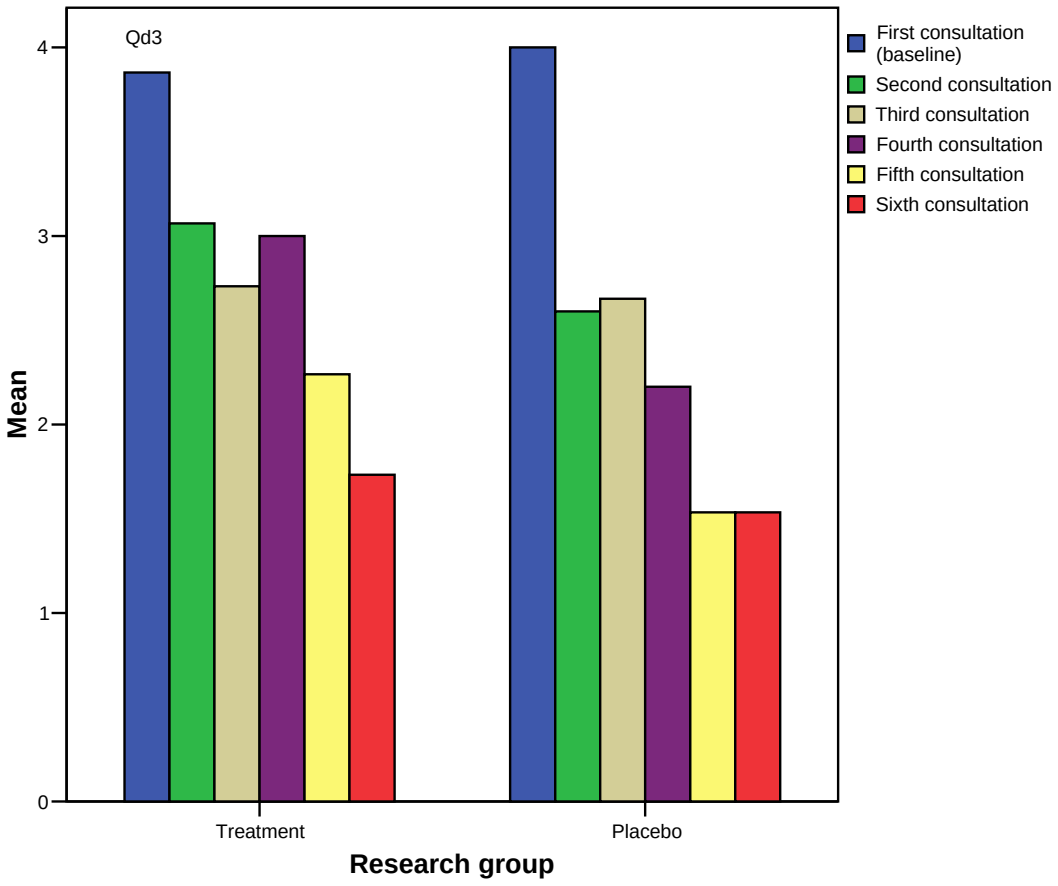

Figure 4.8.3 Comparison between group 1 and group 2 for **surface texture of the skin** (question 3)

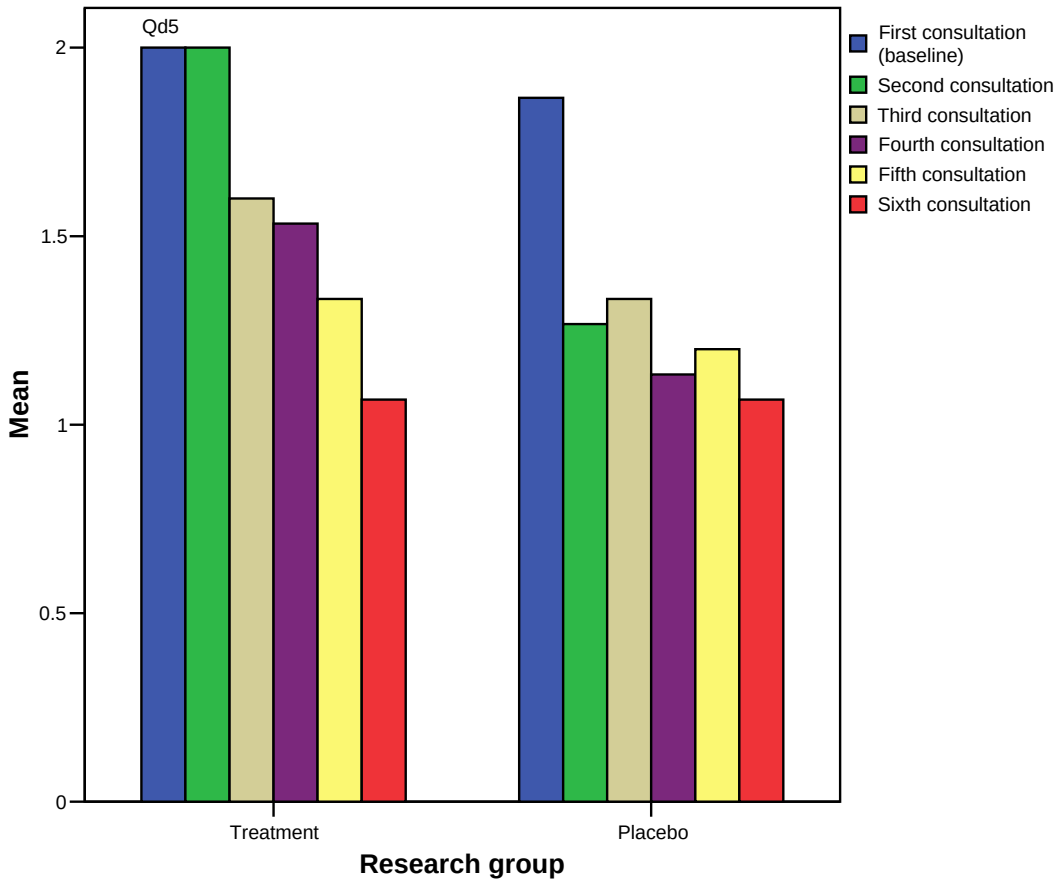

Figure 4.8.4 Comparison between group 1 and group 2 for **bleeding** (question 5)

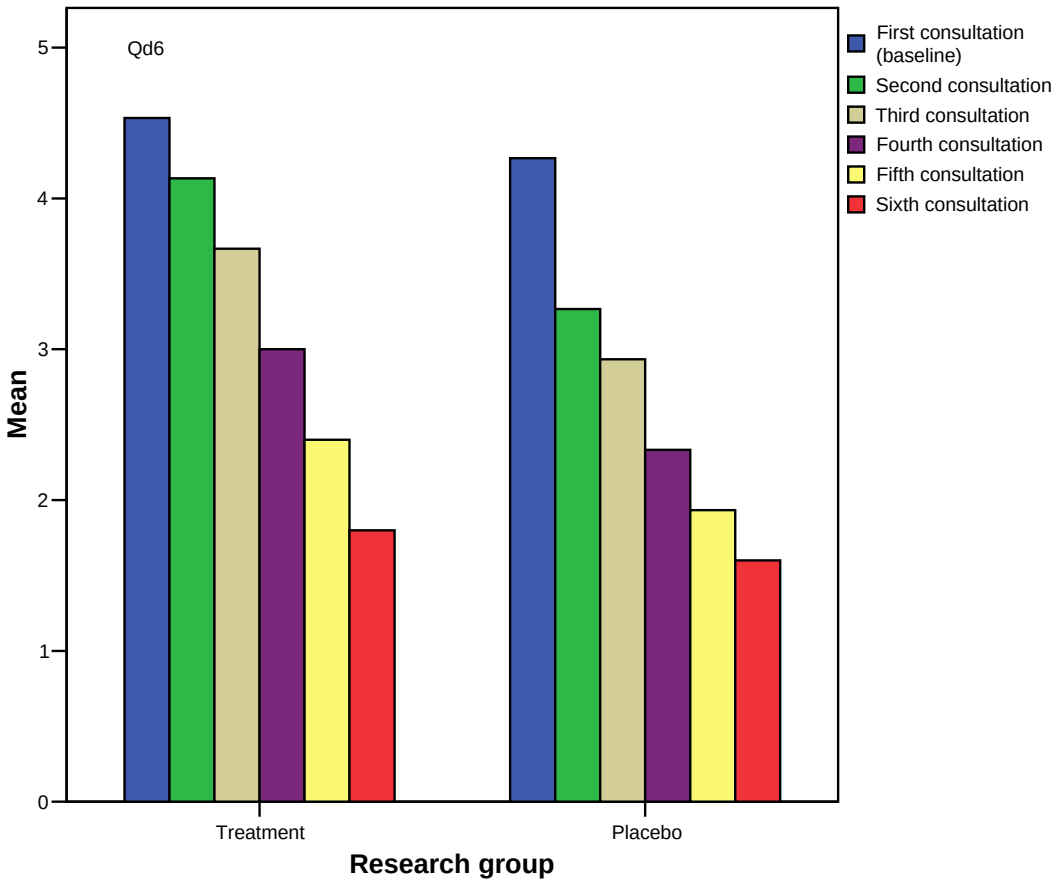

Figure 4.8.5 Comparison between group 1 and group 2 for **itching** (question 6)

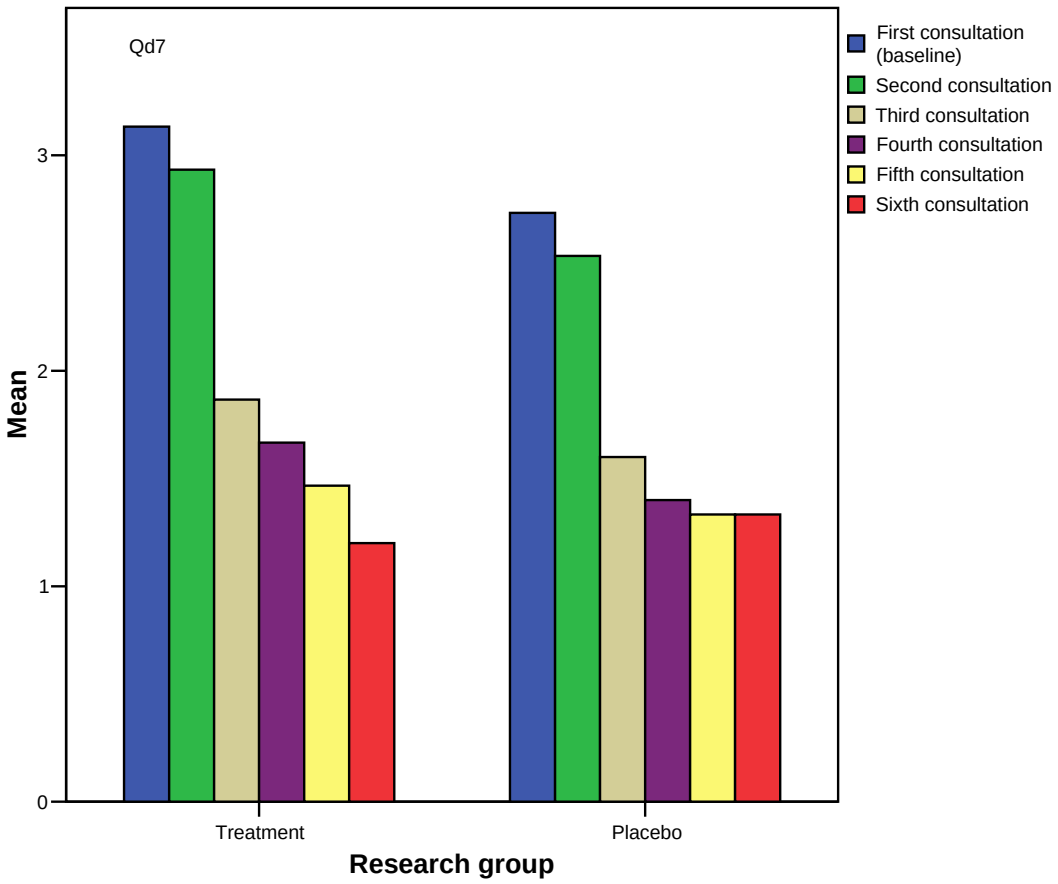

Figure 4.8.6. Comparison between group 1 and group 2 for **disruption of sleep** (question 7)

4.9 Bar charts reflecting the comparison of means for group 1 and group 2 for the General well being schedule (Appendix E)

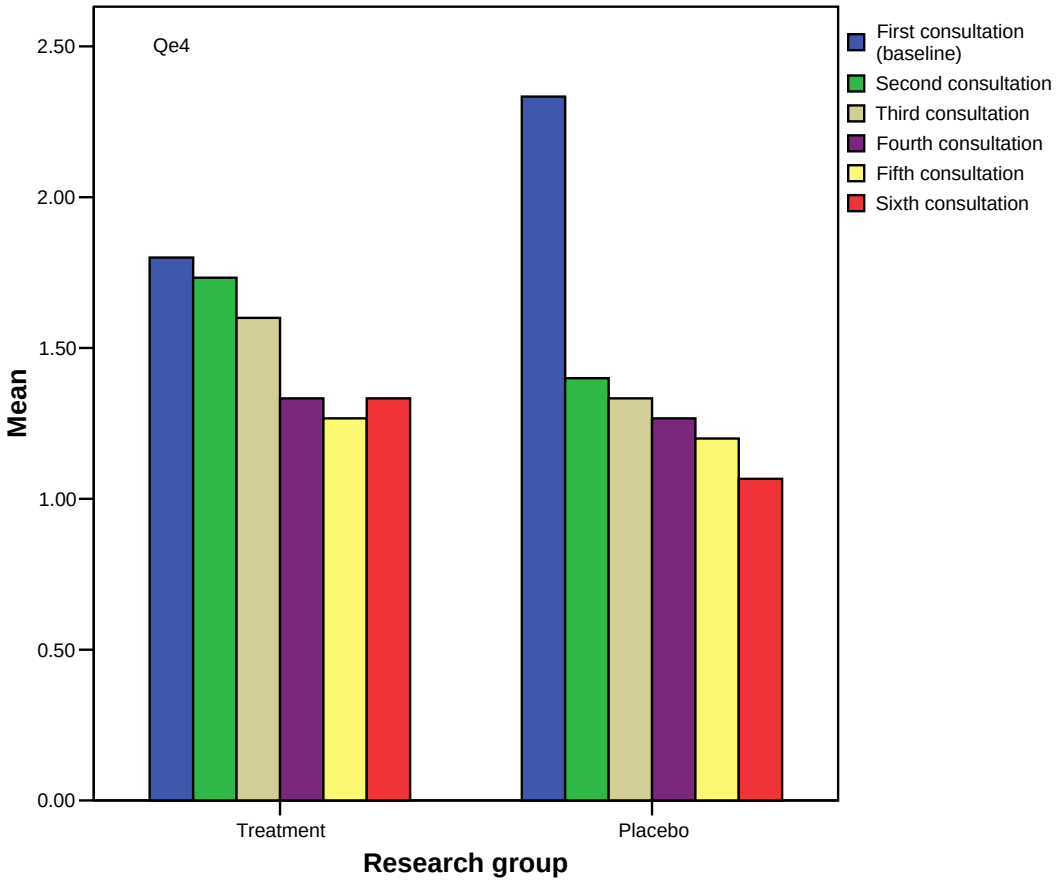

Figure 4.9.1 Comparison between group 1 and group 2 for **sadness** (question 4)

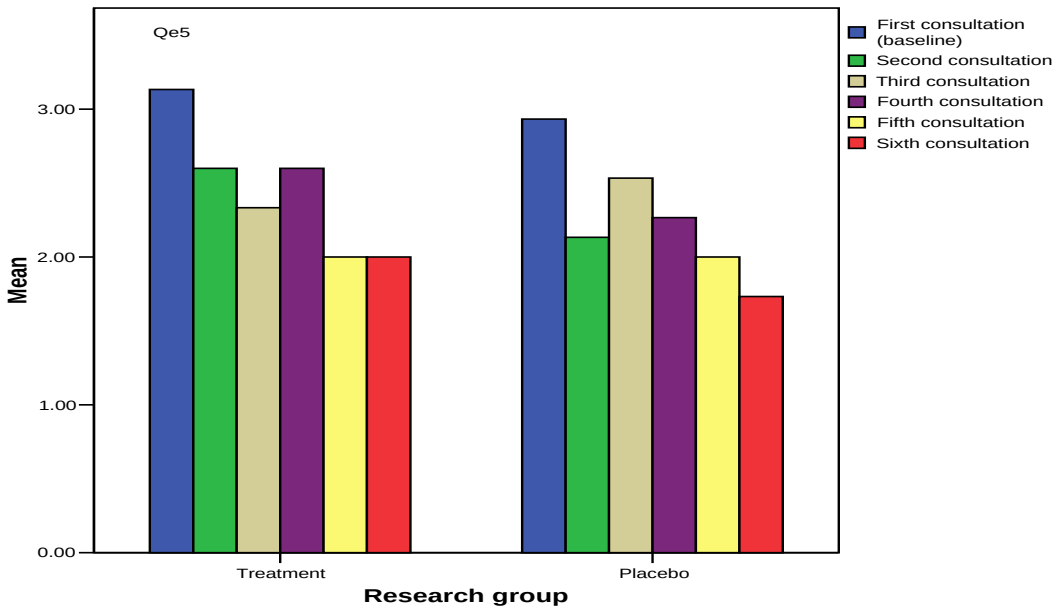

Figure 4.9.2 Comparison between group 1 and group 2 for **stress and pressure** (question 5)

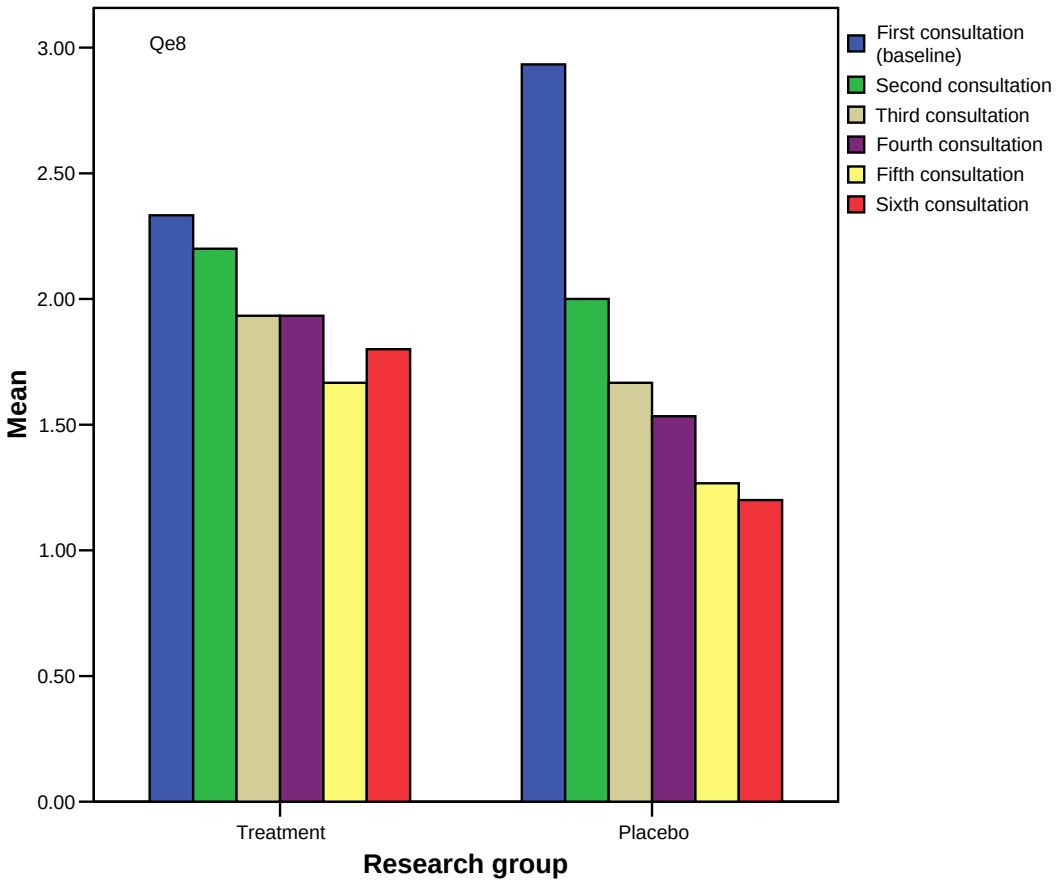

Figure 4.9.3 Comparison between group 1 and group 2 for **anxiety** (question 8)

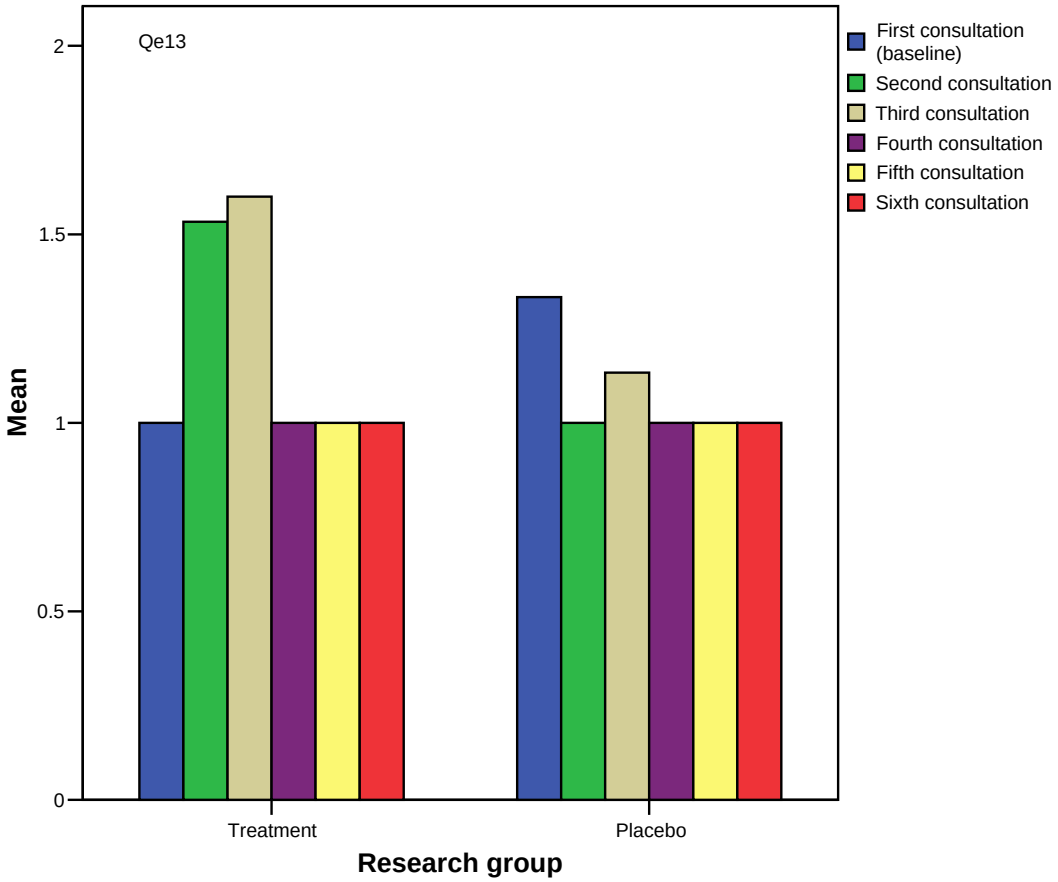

Figure 4.9.4 Comparison between group 1 and group 2 for **emotional stability** (question 13)

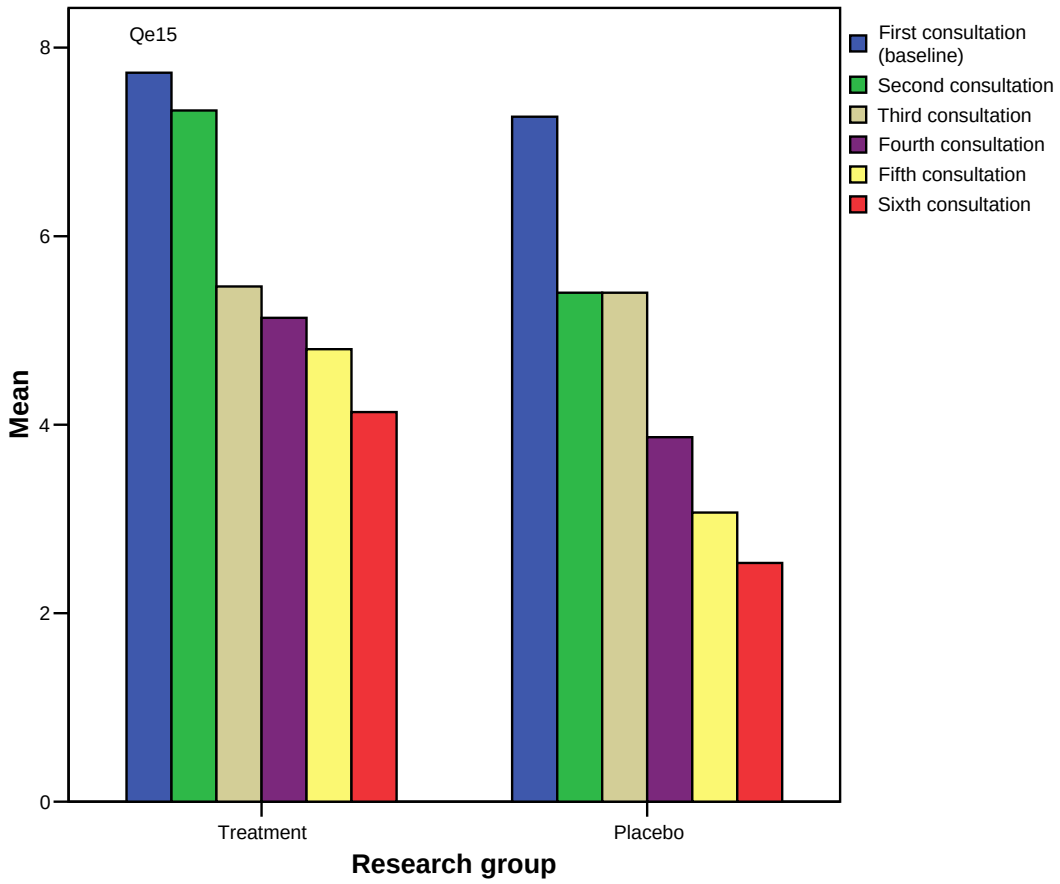

Figure 4.9.5 Comparison between group 1 and group 2 for **concern over their health** (question 15)

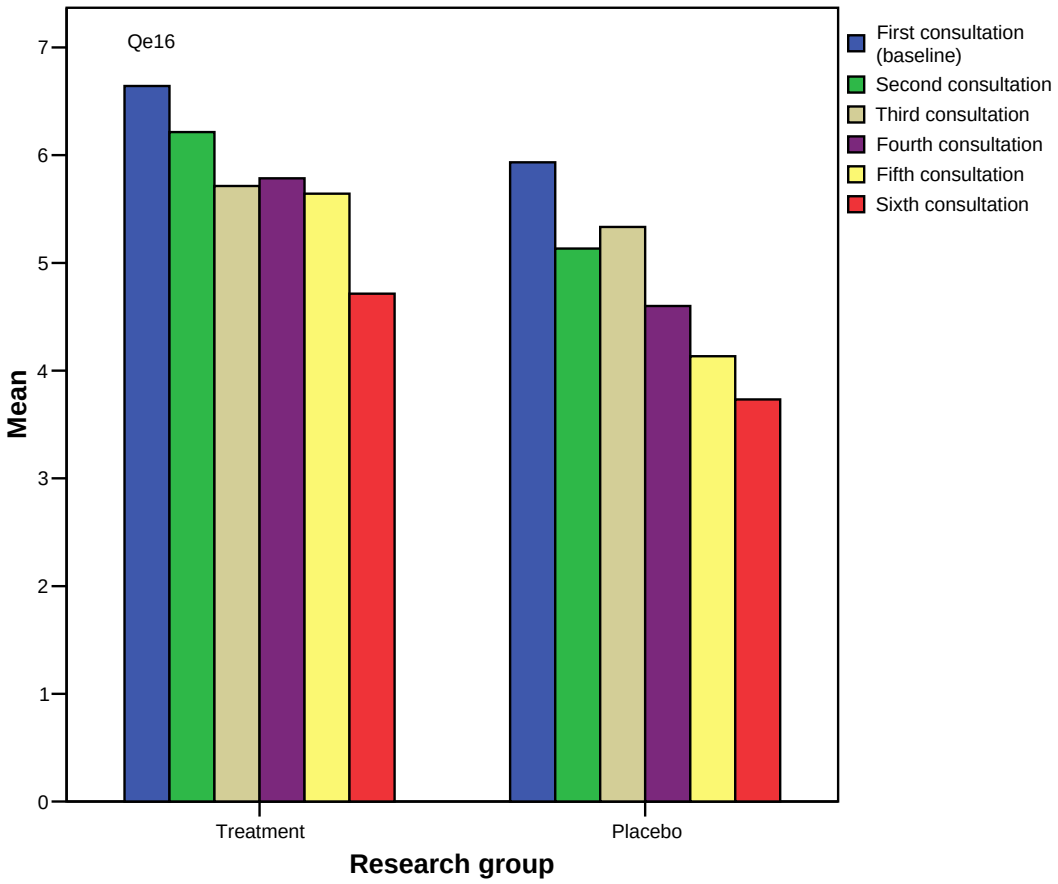

Figure 4.9.6 Comparison between group 1 and group 2 for **how tense or relaxed subjects felt** (question 16)

5. DISCUSSION

The results of this trial show that there was no statistical difference between the treatment group and the placebo group in the treatment of atopic eczema. The homoeopathic complex (Arsenicum album 12CH, Graphites 12CH, Petroleum 12 CH, Rhus toxicodendron 12CH, Sulphur 12 CH and Urtica urens 12 CH), was not effective in alleviating the symptoms of this condition.

With regards to the Clinical evaluation index (Appendix C), the intra-group comparisons show that within group 1 (treatment group), improvements occurred with regards to papules, dryness, crusts, scaling, bleeding and itching, by the fifth consultation (Table 4.4.1), i.e. in six out of the twelve variables. In the placebo group (group 2), by the fifth consultation, improvements were also found with regards to redness, swelling, dryness, crusts, scaling, scratch marks and itching (Table 4.5.1), i.e. in seven out twelve variables. Inter group analysis revealed that there was no significant difference between the two groups.

In the Patients' perception questionnaire (Appendix D), both groups rated their eczema as severe (Figure 4.8.1) at the baseline. By the last consultation both groups rated it as mild. The intra group analysis (Table 4.4.5), and (Table 4.5.5), show that both groups experienced improvements by the last consultation. The inter group analysis revealed that there was no statistically significant difference between the two groups (Table 4.6.5).

The intra group analysis of the General well being schedule revealed that both groups showed a high level of concern over their health at the baseline (initial consultation), (Figure 4.9.5). By the last consultation, both groups show an improvement (Table 4.5.8) and (Table 4.4.8). The intra group analysis of group 1, revealed that there were also improvements in how stressed patients felt (question 5), by the fourth and fifth consultations. Within this group, (group 1), improvements occurred from baseline to the second and fifth follow-up concerning how relaxed patients felt (question 16) and there was an improvement from baseline to the

fifth follow-up in how cheerful patients felt (question 18). In the placebo group (group 2), the intra group analysis revealed that there was no difference in emotional stability (question 13). By the last follow-up, patients felt better (question 1), were not sad (question 4), or anxious (question 8),and were waking up fresh and rested (question 9). Patients expressed less fears about their health (question 10), felt less downhearted (question 12), were less tired (question 14), and were more relaxed (question 16), had more energy (question 17) and felt more cheerful (question 18), (Table 4.5.8). Therefore, there were more improvements in the placebo group where ten out of the eighteen questions showed improvements, while in the treatment group only four out of the eighteen questions showed improvements. However, the inter group comparison revealed that by the last follow-up only the scores for question 10 (fears about health), were significantly different between the two groups (Table 4.6.6). There were no differences at baseline for the other questions. Thus, although improvement in various combinations of variables occurred within both groups, inter group analysis revealed that with the exception of question 10, there were no statistically significant differences between the two groups in terms of improvement at the various consultations.

The study conducted by Botha (2001), on the treatment of atopic eczema using the homoeopathic complex (Herpin 2), revealed that this complex had a limited role to play in alleviating the symptoms of atopic eczema. Botha found that by the third appointment there was no improvement in the subjective features of atopic eczema within the placebo and the treatment group. However, with regards to the objective manifestations of atopic eczema, improvement was seen within the treatment group by the third appointment. The placebo group showed no improvements in the objective manifestations.

In this study the subjective manifestations of atopic eczema were measured by the Patients' perception questionnaire (Appendix D), and the General well being schedule (Appendix E), By the last consultation both group 1 (Table 4.4.6) and group 2 (Table 4.5.6) showed an improvement with regards to the Patients's perception questionnaire (Appendix D). In the General well being schedule (Appendix E), group 1 (Table 4.4.9) and group 2 (Table 4.5.9) also showed an improvement by the last consultation. The objective manifestations of atopic eczema were measured in this study by the Clinical evaluation index (Appendix C). Group 1

(Table 4.4.3) and group 2 (Table 4.5.3) both showed an improvement. Therefore, in this study there was no difference between the subjective and objective manifestation of atopic eczema, whereas Botha (2001), shows an improvement in the objective manifestations only in the treatment group and no improvement in the subjective manifestations in both the treatment and placebo groups.

The results of this trial has shown that the use of a complex was no more effective than the use of a placebo in the treatment atopic eczema. Complexes can be indicated in conditions such as injuries. However, chronic conditions like eczema, require a holistic and comprehensive assessment of the case and treatment targeted at the fundamental level will lead to optimal results (Tomlinson 1999). Spence (1993), states that the accurate total simillimum produces the best clinical response in the treatment of eczema.

Expectations affect disease and its treatment, therefore, a patient's expectation of the effectiveness of a treatment can influence the outcome (Meredith, 1995 : 66).
Dodes (1997) states that whether the placebo effect is mainly psychological, misunderstood spontaneous healing, due to showing care and attention, or due to some combination of all three may not be known with complete confidence. The placebo effect played a significant role in this study as patients in the placebo group improved significantly in more variables in the Clinical evaluation index (Appendix C) and the General well being schedule (Appendix E), i.e. a profound placebo effect was thus noted.

Problems encountered in this study were that too many questionnaires were used to assess this condition. The Clinical evaluation index (Appendix C) and the Patients' perception questionnaire (Appendix D), were sufficient to assess the symptoms experienced by the patients. The General well being schedule (Appendix E), contained some questions which focused on the emotional impact of atopic eczema on patients, while the focus of this trial was on the physical impact of atopic eczema on patients. The complex prescribed (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH), contained remedies chosen for their similarities to the physical symptomatology of atopic eczema.

There were also too many follow-up consultations and patients found it difficult to make themselves available when required, thus this affected patient compliance which played a major role in the outcome of this study as some patients left the trial and had to be replaced.

The results of this study concluded that a homoeopathic complex (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH) was no more effective than the placebo in the treatment of atopic eczema.

6. CONCLUSIONS AND RECOMMENDATIONS

The results of this study concluded that a homoeopathic complex (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH), did not demonstrate clinical efficacy in the treatment of atopic eczema as it was no more effective than the placebo in the treatment of this condition.

Problems encountered were that the sample size was too small. A larger sample could impact more favourably on results in future studies.

The General well being schedule (Appendix E), although designed to assess psychological well being, was not specific enough to address the physical problems faced by eczema sufferers and the responses given by the patients were subjective. This is especially relevant when a complex is prescribed such as the one in this study, the ingredients of which were chosen based on their affinity for the physical symptomatology of atopic eczema. This questionnaire would be more applicable when conducting a study using simillimum treatment where psychological factors are considered in the case, and remedy choice. It is recommended that a questionnaire more suited to eczema be used instead of the General well being schedule (Appendix E) in order to clearly assess the emotional and psychological impact of eczema on individuals. The Clinical evaluation index (Appendix C) was valuable in assessing the signs and symptoms of atopic eczema. The General well being schedule (Appendix D) used in this study was helpful in assessing the impact of atopic eczema on the patients' quality of life.

Another problem was that there were possible antidoting effects between certain remedies. Arsenicum album and Graphites antidoted each other. Rhus toxicodendron and Arsenicum album antidoted Sulphur. Rhus toxicodendron was antidoted by Arsenicum album, Graphites and Sulphur (Boericke 1995 : 1082, 1096). This may have affected the outcome of this trial.

Future studies could also make use of more reliable objective measurements. The advent of a standardized measurement of the severity of atopic dermatitis, the Severity Scoring of Atopic dermatitis (SCORAD), has made it possible to document quantitative differentiation much better than before. Assistance by a qualified dermatologist could prove useful (Linnet and Jemec, 1999 : 269).

The number of consultations should be reduced to two where patients are assessed at the beginning of the trial and at the end. This would enable clearer comparison of the groups involved and ensure better patient compliance.

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8. APPENDICES

APPENDIX A

DIAGNOSTIC CRITERIA OF ATOPIC ECZEMA (Hanifin and Rajka 1980)

Must have 3 or more basic features :

YES / NO Pruritis

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 atophy (Asthma, allergic rhinitis, atopic eczema)

……..

Plus 3 or more minor features :

YES / NO Xerosis

YES / NO Ichthyosis

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 Chellitis

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 B

PATIENT CONSENT FORM

TECHNIKON NATAL HOMOEOPATHIC DAY CLINIC
CONFIDENTIAL PATIENT INFORMATION

TITLE: Dr/ Mr/ Mrs/ Ms/ Master (please circle)

FIRST NAME:……..SURNAME: ……..

DATE OF BIRTH:…….IDENTITY NO: ……

TEL. (HOME):……..(WORK):……..

CELL: ……...

RESIDENTIAL ADDRESS: ……..

PERSON to contact in an emergency:

NAME:…….

TEL NO:……...

PLEASE READ AND SIGN THE FOLLOWING:

AS A PATIENT AT THIS CLINIC, I UNDERSTAND THAT I AM ATTENDING A TEACHING INSTITUTE. I HEREBY GIVE PERMISSION TO ALLOW CLINICAL OBSERVATION AND DIAGNOSIS TO BE PERFORMED ON, AS WELL AS TREATMENT TO BE PRESCRIBED FOR MYSELF BY A RESEARCH STUDENT PRACTITIONER, SUPERVISED BY A QUALIFIED HOMOEOPATHIC CLINICIAN.

SIGNATURE:…….DATE:…….

APPENDIX C

CLINICAL EVALUATION INDEX

Every section must be answered. To be filled in by researcher (Opperman : 1997).

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 D

PATIENTS' PERCEPTION QUESTIONNAIRE (McDowell and Newell 1996)

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 understand the question. If there are any queries, please ask assistance from researcher.
4. 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 or disagree

4 = Disagree

5 = Totally disagree

STATE TO WHAT DEGREE YOU AGREE / DISAGREE WITH THE FOLLOWING STATEMENTS. PLEASE NOTE THAT THERE ARE NO INCORRECT OR CORRECT ANSWERS.

For example:

1. How severe would you rate your eczema?

Mild_____very severe

1 2 3 4 5

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

1. How severe would you rate your eczema?

   Mild _____very severe
   1 2 3 4 5

2. Has your eczema changed at all?
   Very much _____not at all
   1 2 3 4 5

If your eczema has changed, how has it changed?
Getting better _____getting worse
1 2 3 4 5

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

4. Are you experiencing any pain or tenderness with your eczema?
   No pain at all_____ much pain
   1 2 3 4 5

5. Has your eczema been bleeding?
   No bleeding at all _____very much bleeding
   1 2 3 4 5

6. How severe do you rate the itching of your eczema?
   None_____very severe
   1 2 3 4 5

7. How do you rate the severity in which your eczema disrupts your sleeping habits?
   None_____very restricting
   1 2 3 4 5

8. How severe does your eczema influence your social life?
   None_____very restricting
   1 2 3 4 5

APPENDIX E

GENERAL WELL BEING SCHEDULE (McDowell and Newell 1996)

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.

1. How have you been feeling in general? (During the past month).
    a. In excellent spirits
    b. In very good spirits
    c. In good spirits mostly
    d. I have been up and down in spirits a lot
    e. In low spirits mostly
    f. In very low spirits

2. Have you been bothered by nervousness or your 'nerves'? (During the past month)
    a. Extremely so-to the point where I could not work or take care of things
    b. Very much so
    c. Quite a bit
    d. Some-enough to bother me
    e. A little
    f. Not at all

3. Have you been in firm control of your behaviour, thoughts, emotions, or feelings? (During the past month)
    a. Yes, definitely so
    b. Yes, for the most part
    c. Generally so
    d. Not too well
    e. No, and I am somewhat disturbed
    f. No, and I am very disturbed

4. Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile? (During the past month
    a. Extremely so-to the point that I have just about given up
    b. Very much so
    c. Quite a bit
    d. Some-enough to bother me
    e. A little bit
    f. Not at all

5. Have you been under or felt you were under any strain, stress, or pressure? (During the past month)
    a. Yes-almost more than I could bear or stand
    b. Yes-quite a bit of pressure
    c. Yes-some more than usual
    d. Yes-some –but about usual
    e. Yes-a little
    f. Not at all

6. How happy, satisfied, or pleased have you been with your personal life? (During the past month)
    a. Extremely happy-could not have been more satisfied or pleased
    b. Very happy
    c. Fairly happy
    d. Satisfied-pleased
    e. Somewhat dissatisfied
    f. 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)
    a. Not at all
    b. Only a little
    c. Some-but not enough to be concerned or worried about
    d. Some and I have been a little concerned
    e. Some and I am quite concerned
    f. Yes, very much so and I am very concerned

8. Have you been anxious, worried, or upset? (During the past month)
    a. Extremely so-to the point of being sick or almost sick
    b. Very much so
    c. Quite a bit
    d. Some-enough to bother me
    e. A little bit
    f. Not at all

9. Have you been waking up fresh and rested? (During the past month)
    a. Every day
    b. Most every day
    c. Fairly often
    d. Less than half the time
    e. Rarely
    f. None of the time

10. Have you been bothered by any illness, bodily disorder, pains, or fears about your health? (During the past month)
    a. All the time
    b. Most of the time
    c. A good bit of the time
    d. Some of the time
    e. A little of the time
    f. None of the time

11. Has your daily life been full of things that were interesting to you? (During the past month)
    a. All the time
    b. Most of the time
    c. A good bit of the time
    d. Some of the time
    e. A little of the time
    f. None of the time

12. Have you felt downhearted and blue? (During the past month)
    a. All the time
    b. Most of the time
    c. A good bit of the time
    d. Some of the time
    e. A little of the time
    f. None of the time

13. Have you been feeling emotionally stable and sure of your self? (During the past month)
    a. All of the time
    b. Most of the time
    c. A good bit of the time
    d. Some of the time
    e. A little of the time
    f. None of the time

14. Have you felt, tired, worn out, used-up, or exhausted? (During the past month)
    a. All of the time
    b. Most of the time
    c. A good bit of the time
    d. Some of the time
    e. A little of the time
    f. None of the time

For each of the four scales below, note that the words at each end of the 0 to 10 scale describe opposite feelings. Circle any number along the bar which seems closest to how you have generally felt during the past month.

15. How concerned or worried about your health have you been?(During the past month)

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)

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)

0 1 2 3 4 5 6 7 8 9 10

_____

no energy at all very energetic dynamic

18. How depressed of cheerful have you been? (During the past month)

0 1 2 3 4 5 6 7 8 9 10

_____

very depressed very cheerful

APPENDIX F

INFORMATION LETTER

The efficacy of a homoeopathic complex (Arsenicum album 12CH, Graphites 12CH, Petroleum 12CH, Rhus toxicodendron 12CH, Sulphur 12CH and Urtica urens 12CH in the treatment of atopic eczema.

Name of student : Gavna A. Kalicharan

Project supervisor : Dr M. R. A. Moiloa

Project promoter : Dr C. M. Hall.

Co – promoter : Dr D. Naude

Patients Name : _____

Dear Patient

Thank you for agreeing to participate in this study. This project is a requirement of homoeopathic students as partial fulfillment of their masters degree in Technology: Homoeopathy. The aim of this study is to evaluate the efficacy of a homoeopathic complex in the treatment of atopic eczema. The trial period is 3 months and treatment is free of charge. These are the criteria which will enable you to be included in this study:

- Voluntary participation
- Both male and female subjects
- Subject's symptoms will have to comply with the diagnostic criteria as in Appendix A
- Subject should be on no other medication for atopic eczema during the trial
- Subjects will be excluded if they are suffering from chronic infection or hypertension. They must not be on steroid therapy for 3 months before starting the trial or on topical steroids for 2 weeks prior to inclusion in this study. You are entitled to withdraw from this trial if you so wish without any explaination. As this is a comparative study, a placebo (a non – medicated substance), will be used as a control. Therefore, there is a 50% chance that you may receive placebo treatment. At the end of the trial, those patients who received placebo will receive 3 months free supply of the appropriate treatment.

First consultation: Fill in the questionnaires A to E.

- Take a complete medical and homoeopathic case history
- Physical examination will be performed

Follow-up consultations : Patients are to return 3 weeks after initial consultation and are required to fill in the following questionnaires :

- Diagnostic criteria of atopic eczema
- Clinical evaluation index
- Patients' perception questionnaire
- General well being schedule

No treatment will be prescribed at the follow-up consultations. This process will be repeated every 2 weeks until the 3 months trial is over. All consultations are strictly confidential and no details will be disclosed to any unauthorized persons.

I_____ do hereby agree to abide by the delimitations and conditions set out in the above document.

_____

Patient's signature

Witness Name :_____ Signature : _____

Thank you for your participation

Gavna.A.Kalicharan.

APPENDIX G

CLINICAL CASE HISTORY (Compiled by researcher)

Patient's Name : _____ Date : _____

Marital status : _____ Age : _____

Allergies : _____ Sex : _____

Main Complaint:_____

_____

Current medication : _____

Treatment received : _____

Current Health Status : _____

Childhood illnesses : _____

Past medical history : Vaccinations, medications, hospitalization, operations, accidents and injuries, screening tests.

Psychiatric history : _____

Family history : history of Hypertension, Diabetes Mellitus, Tuberculosis, Cancer.

Health status of parents and siblings.

_____

Diet : cravings, aversions, thirst, preference for sweet or sour foods.

Sleep : position and dreams.

Fears : _____

Prefers consolation or to be left alone if upset : _____

Prefers the seaside or mountains : _____

Weather preference : hot, cold or rainy.

Home situation and significant others : _____

Important life experiences : _____

Religious beliefs : _____

Outlook on life : _____

Exercise and leisure activities : _____

Hobbies : _____

Environmental hazards : _____

Use of alcohol and tobacco : _____

SYSTEM REVIEW :

Generals : sudden weight loss or gain.

Skin : rashes, lumps, colour changes, status of hair and nails.

Head : headaches and injuries.

Eyes : vision, contact lenses, pain, cataracts.

Ears : hearing problems, tinnitus, earache, infection.

Nose and sinuses : colds, discharge and it’s colour, nose bleeds.

Mouth and throat : sore throat, hoarseness, tongue.

Neck : swollen glands, pain or stiffness.

Respiratory system : cough, sputum, wheezing, Asthma, Bronchitis.

Cardiac system : chest pain, dyspnoea, oedema, high blood pressure.

Gastrointestinal system : appetite, nausea and vomiting, constipation, diarrhoea, liver problems.

Urinary system : polyuria, nocturia, burning or pain on urination, incontinence.

Genitoreproductive system : hernias, menses, pregnancy and labour.

Peripheral vascular system : leg cramps, varicose veins, intermittent claudication.

Musculoskeletal sytem : joint pain or stiffness, arthritis, gout.

Neurologic system : fainting, seizures, numbness and tingling, involuntary movements.

Haematologic system : anaemia, easy bruising or bleeding.

Endocrine system : thyroid problems, excessive sweating.

Psychiatric : memory, depression, nervousness.

APPENDIX H

PHYSICAL EXAMINATION (Compiled by researcher)

VITAL SIGNS :

Temperature : _____ Pulse Rate : _____

Respiratory rate : _____ Blood pressure : _____

Height : _____ Weight : _____

GENERAL EXAMINATION :

Jaundice, Anaemia, cyanosis, clubbing, dehydration, oedema, lymphadenopathy, grooming and hygiene.

Eye examination : check for cataracts.

Ear examination : check for flaking and scaling.

Chest examination : _____

Inspection of skin at affected area : _____

APPENDIX I

RANDOMISATION SHEET

NO.	PATIENT NAME	GROUP A	GROUP B
1.	_____	X	
2.	_____	X	
3.	_____		X
4.	_____	X	
5.	_____		X
6.	_____		X
7.	_____	X	
8.	_____	X	
9.	_____		X
10.	_____		X
11.	_____		X
12.	_____	X	
13.	_____	X	
14.	_____	X	
15.	_____		X
16.	_____	X	
17.	_____		X
18.	_____	X	
19.	_____	X	
20.	_____		X
21.	_____		X
22.	_____	X	
23.	_____		X
24.	_____		X
25.	_____		X
26.	_____		X
27.	_____		X
28.	_____		X
29.	_____	X	
30.	_____	X	
31.	_____		X
32.	_____	X	