

***The Efficacy of a Homoeopathic Eczema Complex
(Herpin 2[®]) in the Treatment of
Atopic Eczema***

by

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology in the Department of Homoeopathy at Technikon Natal.

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This dissertation is dedicated to my parents for their love and support

ACKNOWLEDGEMENTS

I would like to express my gratitude to everyone involved in making this dissertation possible.

In particular I would like to thank:

Dr R. Steele – For his valuable advice and guidance as a supervisor.

Dr R. Mostert – For her assistance as a co-supervisor.

Mr K. Thomas – For his assistance as a statistician.

Mary Green and other staff at Natura Homoeopathic Laboratory involved in the preparation of the remedies.

The staff at Technikon Natal Homoeopathic Day Clinic for their assistance in booking patients and dispensing medication.

Costa Jacovides and the staff at Atlas Pharmacy for their assistance and the use of the facilities.

All the patients who took part in the study for their participation.

ABSTRACT

The aim of this study was to determine what role a homoeopathic eczema complex (Herpin 2[®]) has to play in the management of atopic eczema. A sample of thirty patients was obtained by means of convenience sampling from the greater Durban area. From this sample fifteen were treated with the homoeopathic eczema complex and the remaining fifteen received placebo treatment. The double blind protocol was used to conduct this study with all medications being dispensed by a neutral party. Every four weeks for the duration of the two-month trial, the percentage body surface area affected by eczematous lesions was measured and recorded and questionnaires regarding the patients' perception of the treatment were completed.

The subjective data obtained from the questionnaires, and the objective data obtained from the measurement of the percentage body surface area were statistically analysed by means of the Mann-Whitney U-test and the Wilcoxon's signed ranks test. In each case α was set at 0.05 specified level of significance. The null hypothesis, with respect to the Mann-Whitney U-test, was accepted if $p \geq \alpha$ and it was rejected if $p < \alpha$. For the Wilcoxon's signed ranks test, the null hypothesis was accepted if $p/2 \geq \alpha$ and it was rejected if $p/2 < \alpha$. (p= reported p-value)

The results of the study indicate that there is no statistical difference between the placebo and treatment groups with regards to the subjective and objective

manifestations of atopic eczema at the end of the eight-week treatment period. Both the placebo and treatment groups showed a significant improvement in the subjective manifestations of atopic eczema, while there was an improvement in the objective manifestations of atopic eczema in the treatment group only. However, statistically there is no difference between the two groups, and it is therefore concluded that the homoeopathic eczema complex (Herpin 2[®]) does not necessarily improve the signs and symptoms of atopic eczema.

TABLE OF CONTENTS

Dedication	i
Acknowledgements	ii
Abstract	iii
Table of contents	v
List of tables	viii
List of figures	ix
Definition of terms	x
CHAPTER ONE Introduction	1
CHAPTER TWO Review of the related literature	3
2.1 Definition and classification	3
2.2 Incidence and psychosocial effect	4
2.3 Aetiology	5
2.4 Pathogenesis	7
2.5 Clinical features	8
2.6 Diagnosis	11
2.7 Associated disorders and complications	13
2.8 Prognosis	16
2.9 Medical treatment	16
2.10 Homoeopathic treatment	18
2.10.1 Herpin 2 [®] : Materia Medica and potencies	21
2.11 The Placebo effect	24

CHAPTER THREE	Materials and Methods	25
3.1	Sampling method	25
3.2	Sample size	25
3.3	The subjects	25
3.4	Methodology	26
3.5	Treatment	27
3.6	Data analysis	29
CHAPTER FOUR	Results	32
4.1	The criteria governing the admissibility of the data	32
4.2	Comparison between the placebo and treatment groups	32
	4.2.1 Subjective data	32
	4.2.2 Objective data	36
4.3	Comparison within the placebo and treatment groups	38
	4.3.1 Comparison within the placebo and treatment groups between visit one and two	38
	4.3.2 Comparison within the placebo and treatment groups between visit one and three	39
CHAPTER FIVE	Discussion	45
CHAPTER SIX	Conclusions and recommendations	48

REFERENCES

50

LIST OF APPENDICES

- A. Simple random sampling of treatments into experimental or control groups
- B. Diagnostic criteria of atopic eczema
- C. Eczema study – Information sheet
- D. Patient consent form
- E. Patient's perception questionnaire
- F. Percentage body surface area involvement
- G. Standard medical case history format

LIST OF TABLES

Comparison between the placebo and treatment groups

Table 4-1: Subjective data 32

Table 4-2: Objective data 36

Comparison within the placebo and treatment groups between appointment one and two

Table 4-3: Subjective data 38

Table 4-4: Objective data 39

Comparison within the placebo and treatment groups between appointment one and three

Table 4-5: Subjective data 40

Table 4-6: Objective data 44

LIST OF FIGURES

Comparison between the placebo and treatment groups

Figure 4-1: The subjective mean totals of both groups	34
Figure 4-2: The subjective means of both groups	35
Figure 4-3: The objective means of both groups	37

Comparison within the placebo and treatment groups between appointment one and three

Figure 4-4: The subjective means of the placebo group between the first and third appointment	42
Figure 4-5: The subjective means of the treatment group between the first and third appointment	43

DEFINITION OF TERMS

Allergen: An antigenic substance capable of producing immediate-type hypersensitivity (allergy) (Dorland's Illustrated Medical Dictionary 1994: 47).

Antigen: Any substance which is capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response, that is, with specific antibody or specifically sensitised T-lymphocytes, or both (Dorland's Illustrated Medical Dictionary 1994: 95).

Atopy: A genetic predisposition to form excessive IgE antibodies to inhaled, injected or ingested antigens and to develop one or more of a group of diseases which include asthma, hay fever, urticaria, food and other allergies and atopic eczema (Edwards et al. 1995: 945-946).

Autosome: Any ordinary paired chromosome alike in males and females, as distinguished from sex chromosomes (Dorland's Illustrated Medical Dictionary 1994: 164).

Dizygotic: Pertaining to or derived from two separate zygotes (Dorland's Illustrated Medical Dictionary 1994: 500). (See zygote.)

Eczema: A pruritic papulovesicular dermatitis occurring as a reaction to many endogenous and exogenous agents, characterised in the acute stage by erythema, edema associated with a serous exudate between the cells of the epidermis (spongiosis) and an inflammatory infiltrate in the dermis, oozing and vesiculation, and crusting and scaling; and in the more chronic stages by lichenification or thickening or both, signs of excoriations, and hyperpigmentation or hypopigmentation or both (Dorland's Illustrated Medical Dictionary 1994: 528).

Erythema: An increase in blood flow in an inflamed area caused by products released from the tissues (Guyton 1992: 576).

Excoriation: A scratch or abrasion of the skin (Dorland's Illustrated Medical Dictionary 1994: 590).

Langerhans Cells: Modified macrophages that circulate between the epidermis and the local lymph nodes, whose prime function is presentation of antigen to T lymphocytes (Edwards et al. 1995: 943).

Lichenification: A dry leathery thickening with increased skin markings, secondary to rubbing and scratching (Edwards et al. 1995: 945).

Monozygotic: Pertaining to or derived from one zygote (Dorland's Illustrated Medical Dictionary 1994: 1056).

Papule: A small circumscribed, superficial, solid elevation of the skin less than 1cm. in diameter (Dorland's Illustrated Medical Dictionary 1994: 1224).

Papulovesicular: Characterised by the presence of papules and vesicles (Dorland's Illustrated Medical Dictionary 1994: 1224).

Placebo: A dummy treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished (On-line Medical Dictionary).

Similimum: The remedy which best matches your symptoms (Ullman and Reichenberg-Ullman 1995: 13).

Vesicle: A small circumscribed epidermal elevation, less than 5mm. in circumference, usually containing a clear fluid (Dorland's Illustrated Medical Dictionary 1994: 1820).

Xerosis: Abnormal dryness, as of the eye, skin, or mouth (Dorland's Illustrated Medical Dictionary 1994: 1850).

Zygote: The fertilised ovum; the cell resulting from union a male and a female gamete (sperm and ovum) (Dorland's Illustrated Medical Dictionary 1994: 1859).

CHAPTER ONE: INTRODUCTION

Atopic eczema is an intensely pruritic, chronically relapsing skin disorder (Arndt 1980: 51). It is characterised primarily by pruritus (itching) and a red, papulovesicular eruption and by the development of secondary features such as lichenification, scaling and fissures (Pillsbury and Heaton 1980: 155). There is evidence suggesting a substantial increase in the prevalence of the disease over the past thirty years (McHenry et al. 1995: 843). Atopic eczema often occurs during the most critical stages of life: in infancy it interferes with a healthy mother-child relationship; in adolescence it causes disfigurement during a critical formative period. This may have a particularly devastating effect on the mental and emotional development of patients. (Arndt 1980: 51.)

The conventional treatment of atopic eczema tends to be symptomatic rather than curative. Acute episodes can be controlled by the use of topical or systemic medications but exacerbations cannot be prevented. (Schuler and Fritsch 1992: 269.)

Homoeopathy is a therapeutic system that utilises the Law of Similars in order to restore health gently and permanently by the removal of the disease "in its whole extent, in the shortest, most reliable and most harmless way." (Hahnemann 1997: 92).

A retrospective survey was conducted by Spence (1991) on 130 cases of eczema treated with homoeopathy. According to this survey 85,5% of the sample group experienced a marked improvement in their eczema after

homoeopathic treatment. Opperman (1997) investigated the effect of homoeopathic similimum treatment on atopic eczema. Statistical analysis of the results revealed a significant improvement in the experimental group and no significant improvement in the control group. The type of treatment used in the study by Opperman requires a consultation with (and a prescription by) a qualified homoeopathic practitioner and is therefore not available to the general public over the counter.

The homoeopathic eczema complex that was used in this study is available over the counter in most health shops and pharmacies. This complex is called Herpin 2[®] and is manufactured by Natura Homoeopathic Laboratory (Pretoria, South Africa). According to Green (2000) no clinical trials have previously been conducted on this complex as to its efficacy in the management of atopic eczema.

It was therefore the purpose of this study to evaluate the efficacy of Herpin 2[®] in the treatment of atopic eczema in terms of the patients' perception of the treatment and the percentage body surface area involved in order to determine what role the complex can possibly play in the management of atopic eczema.

CHAPTER TWO: REVIEW OF THE RELATED LITERATURE

2.1 Definition and Classification

According to Gianotti and Brogelli (1992: 103) there is no clear definition for the word eczema. It is derived from a Greek word that literally means "boiling out" (Clark-Huff and Weston 1978: 86). Eczema is a collective term that embraces a number of clinically and pathogenetically different entities. These are all characterised in the acute stage by red, papulovesicular, oozing and crusted lesions; and in the chronic stage by the development of raised, scaling plaques. (Kumar et al. 1997: 669.)

The disease is classified as follows:

- Exogenous eczema
 - Irritant contact eczema
 - Allergic contact eczema
- Endogenous eczema
 - Atopic eczema
 - Seborrhoeic eczema
 - Discoid eczema
 - Asteatotic eczema
 - Gravitational eczema
 - Neurodermatitis

Pompholyx

(Edwards et al. 1995: 945.)

Atopic eczema is associated with features of atopic disease. Atopy is an inherited tendency to form excessive immunoglobulin E (IgE) antibodies in response to inhaled, injected and ingested antigens and to develop one or more of a group of diseases including asthma, hay fever, urticaria, food and other allergies and atopic eczema (Ewards et al. 1995: 945-946). Atopic eczema is a chronic, recurrent pruritic dermatitis occurring in individuals with a constitutional predisposition to atopy (Clark-Huff and Weston 1978: 87). This is the type of eczema that will be addressed in the remainder of this dissertation.

2.2 Incidence and psychosocial effect

Atopic eczema affects 5-15% of schoolchildren and 2-10% of adults. Patients suffering from atopic eczema account for 10-20% of all referrals to dermatologists and approximately 30% of dermatological consultations in general practice. Furthermore, there is evidence suggesting a substantial increase in the prevalence of the disease over the past thirty years. (McHenry et al. 1995: 843.)

Atopic eczema causes much physical suffering, disability and anguish for the patient and his/her family (Solomon 1975: 258). It can have a particularly devastating effect on the mental and emotional development of patients. This is because it occurs during the most critical stages of life: in infancy it

interferes with a healthy mother-child relationship; in adolescence and early adulthood it causes disfigurement during a critical formative period. (Arndt 1978: 51.) Atopic eczema not only affects the enjoyment of childhood but may also cause tremendous stress during adolescence. Most affected teenagers become increasingly depressed and frustrated and a sense of hopelessness can descend on the whole family. Atopic eczema in adolescence is associated with an increased tendency to the development of hand (and feet) eczema in later life. This can lead to difficulties in choosing a suitable occupation. (Graham-Brown and Ebling 1968: 2883.) The itching associated with the eczema is intensely distressing and can be as disabling as severe pain. It affects daily activities, sleeping patterns and can result in school disruption for children. (Marks 1997: 16.)

2.3 Aetiology

No direct cause can be ascribed to atopic eczema (Schering 1975: 6). Several factors appear to play a role in the manifestation of the disease.

2.3.1 Genetics

Studies have demonstrated that approximately 70% of patients with atopic eczema have a family history of atopic eczema, asthma or hay fever (Solomon 1975: 258). However, the inheritance of atopic eczema is controversial. The disorder is concordant in 86% monozygotic twins but only in 21% dizygotic ones. Autosomal dominant, recessive and polygenic modes of inheritance have been suggested by different workers. (Edwards et al. 1995: 946.) The difficulty in determining a clear mode of inheritance may be

ascribed to the fact that what is inherited is not a skin lesion but a tendency to pruritus, which manifests itself on exposure of the skin to a stressful internal or external environment (Solomon 1975: 259).

2.3.2 Environmental factors

According to Clark-Huff and Weston (1978) several environmental factors may be responsible for the exacerbations and the distribution of the dermatitis on the body surface. Eczema can often be linked to some external substance acting as an antigen. These are commonly substances such as wool, feathers, pollens, egg white, wheat, milk and oranges. (Schering 1975: 6.) Sudden changes and extremes of temperature and humidity often aggravate the condition. This results in more intense itching during the dry winter and humid summer months. Other activities that result in a sudden reduction in skin temperature (such as undressing or leaving a bath) frequently lead to itching. Patients with atopic eczema also tend to tolerate exercise poorly because their cutaneous vessels cannot adapt quickly to the changes in skin temperature induced by sweating. A bout of intense pruritus may be precipitated in some patients by direct contact with detergents, primary irritant chemicals, perfumes and colognes. (Solomon 1975: 262.)

2.3.3 Emotional stress

According to Schering (1975) emotional stress is a major precipitating factor to eczema outbursts in adolescents and adults. The eczema itself may induce feelings of inadequacy which in turn lead to anxiety, depression and as a result an aggravation of the need to scratch (Solomon 1975: 262.)

2.4 Pathogenesis

The exact pathogenesis of atopic eczema remains unclear. Multiple biological mechanisms could be involved as an atopic-like dermatitis can be associated with a number of distinct inborn errors of metabolism. (Clark-Huff and Weston 1978: 97.) The itching, which induces scratching, seems to be the common factor through which allergic, irritant and other factors contribute to the development of the disorder. Pruritus is said to be an essential ingredient in the pathogenesis of the skin inflammation. In fact, "atopic dermatitis is not a rash that itches, but rather an itch that rashes." (Jacobs and Goldsobel 1988: 385).

Disordered immune function leading to a host-environment interaction is considered a fundamental part of the pathogenesis of atopic eczema (Graham-Brown 1998: 8). Studies have shown that serum IgE is raised in most patients with atopic eczema. On the other hand there are 10-20% of patients with typical atopic eczema who do not have demonstrable hyperimmunoglobulinaemia E. However, there is usually some correlation between specific IgE levels and disease activity in any one patient tested at various times. (Ewan et al. 1992: 101.)

In addition to elevated IgE levels, the majority of patients with atopic eczema also show prick test positivity to a wide range of allergens. However, the immunohistologic features found in atopic eczema are more in keeping with those of a type IV hypersensitivity reaction (cell-mediated) than a type I reaction (mediated by IgE). (Graham-Brown 1998: 8.)

Studies of clinically involved skin in atopic eczema have revealed that epidermal Langerhans cells in atopic skin are able to bind IgE, and that IgE is also present on the surface of antigen-presenting cells in the dermal infiltrate. This has led to the following hypothesis: percutaneously absorbed antigen might bind to allergen-specific IgE on the surface of epidermal Langerhans cells and thereby induce T-lymphocyte activation and an eczematous hypersensitivity response. Nevertheless, much remains unclear and other factors may also play fundamental roles in the pathogenesis of atopic eczema. (Graham-Brown 1998: 8-9.)

2.5 Clinical features

Atopic eczema is a chronic fluctuating disease, with an age of onset between 2-6 months in the majority of cases. Onset before the age of 2 months is exceptional, but the disease may start at any age later in life, even over the age of 50 years. (Champion and Parish 1992: 602.)

The disorder typically follows a chronic fluctuating clinical course, marked by periods of remissions and exacerbations, although it may have a chronic persistent course in some cases. (Clark-Huff and Weston 1978: 89.)

Itching is the predominant symptom. It may be extremely violent, driving the patient to a frenzy of scratching. This accounts for the excoriation commonly observed in eczematous lesions (Schering 1975: 6).

The morphology of the skin lesions of atopic eczema depend on the different age groups in which it occurs and whether the eczema is acute, sub-acute or

chronic (Heyl and Swart 1990: 95; Clark-Huff and Weston 1978: 87). In acute eczema the lesions are erythematous, papulovesicular with oozing, crusting and oedema. Sub-acute eczema is typically less erythematous and vesiculation is replaced by scaling, fissuring and lichenification. The chronic stage of eczema is characterised predominantly by dry skin with scaling and lichenification. These features may all be present at any one time (and may occur together) in the different age groups in which atopic eczema occurs. (Clark-Huff and Weston 1978: 87.)

2.5.1 Infantile phase

In the infant, atopic eczema most frequently involves the face and often also occurs on the head, neck, trunk and extremities (Heyl and Swart 1990: 95). The napkin area is usually spared. Once the child begins to crawl, the exposed surfaces, particularly the extensor aspects of the knees, are most involved. (Champion and Parish 1992: 602.)

In infancy, atopic eczema is characterised by erythematous papulovesicular lesions that are often oozing and crusted. These lesions are intensely itchy and scratching leads to excoriations, which may become secondarily infected. (Heyl and Swart 1990: 95.) In some infants the skin is also very dry, and this predisposes them to more itching and recurrent inflammation (Arndt 1980: 52). The eczema usually interferes with sleep and causes irritability in the affected infant (Heyl and Swart 1990: 95). It clears up by the age of 18 months in less than 50% of cases (Champion and Parish 1992: 602). In a large number of these cases the disease recurs in late childhood,

adolescence, or even early adulthood (Solomon 1975: 259). The cases that do not clear up gradually change into the pattern characteristic of the childhood phase (Champion and Parish 1992: 602).

2.5.2 Childhood phase

The childhood phase is characterised by a flexural distribution of lesions, particularly in the large skin folds such as the flexural surfaces of the elbows and knees, the neck, eyelids, wrists and ankles. The genitals and gluteal folds may also be involved. The lesions tend to be dry and lichenified, rather than erythematous and oozing. Scratch papules and excoriations are common. (Heyl and Swart 1990: 95.) In the childhood phase, involvement of the hands, usually with exudative lesions, is often present (Champion and Parish 1992: 602).

2.5.3 Adolescent and adult phase

The late stage of atopic eczema is seen in adolescents and adults and is similar to the childhood phase, with lichenification, excoriations and scratch papules (Champion and Parish 1992: 603). Involvement of the wrists and hands is characteristic, although flexural involvement of the knees and elbows, the eyelids, neck, groin and inner aspects of the thighs is also common (Heyl and Swart 1990: 95). Other patterns are often present. In adolescent and young women, the nipples may be involved. The lips and adjacent skin of the face is commonly involved. Photosensitivity is often present in the late stage.

2.6 Diagnosis

According to Graham-Brown (1998) atopic eczema can be the easiest as well as the most difficult entity to diagnose. There is no specific pathologic test for atopic eczema (Graham-Brown 1998: 3). A skin biopsy will confirm the diagnosis of an eczematous dermatitis, but there are no specific features to facilitate the differentiation of the various forms (Heyl and Swart 1990: 96). Other tests, including eosinophil counts, IgE levels and skin prick testing only confirm the presence of an atopic diathesis, which can usually be established from the history (Graham-Brown 1998: 3, 5). The diagnosis therefore remains clinical.

A list of diagnostic criteria proposed by Hanifin and Rajka are used for the clinical diagnosis of atopic eczema, particularly in research and clinical studies where the study group has to be clearly defined (Graham-Brown 1998: 5).

According to the diagnostic criteria of Hanifin and Rajka cases are required to have at least 4 major features and at least 3 minor features for a diagnosis of atopic eczema to be made (Hanifin 1992: 77).

Major features

1. Pruritus
2. Early age of onset
3. Typical morphology and distribution:
 - Flexural lichenification and linearity in adults

- Facial and extensor involvement during infancy and childhood
- 4. Chronic or chronically relapsing dermatitis
- 5. Personal or family history of atopy (asthma, allergic rhinoconjunctivitis, atopic dermatitis)

Minor features

1. Xerosis
2. Ichthyosis / palmar hyperlinearity / keratosis pilaris
3. Immediate, type I skin test response
4. Hand / foot dermatitis
5. Cheilitis
6. Nipple eczema
7. Susceptibility to cutaneous infections (especially *Staphylococcus aureus* and *Herpes simplex*)
8. Perifollicular accentuation

Recently a simpler checklist was developed by a British dermato-epidemiologist by the name of Hywel Williams for the diagnosis of atopic eczema in the clinical setting. The diagnostic features of atopic eczema as proposed by Williams follow:

Must have:

An itchy skin condition (or report of scratching or rubbing in a child).

Plus 3 or more of the following:

1. History of involvement of the skin creases such as folds of the elbows, behind the knees, fronts of the ankles, or around the neck (or the cheeks in children younger than 4 years).
2. A personal history of asthma or hay fever (or history of atopic disease in a first degree relative, in children younger than 4 years).
3. A history of general dry skin in the last year.
4. Visible flexural eczema (or eczema involving the cheeks/forehead and outer limbs in children younger than 4 years).
5. Onset in the first 2 years of life (not applicable for children younger than 4 years).

(Graham-Brown 1998: 6.)

2.7 Associated disorders and complications

2.7.1 Other manifestations of atopy

As a result of the inheritance of atopy, other atopic manifestations, particularly asthma and allergic rhinitis are often found in association with atopic eczema. These disorders occur in 30-50% of cases of atopic eczema and may begin at different ages and may follow independent clinical courses. (Champion and Parish 1992: 604; Clark-Huff and Weston 1978: 88.)

2.7.2 Drug sensitivity

Anaphylactic reactions to certain drugs occur more commonly in patients with atopic eczema. This may be due to the increased liability of atopic persons to

produce IgE after natural exposure to antigens. Anaphylactic reactions even to topically applied drugs have also been recorded. (Champion and Parish 1992: 604.)

2.7.3 Food allergy

Patients with atopic disorders are more likely to develop abdominal symptoms as a result of food allergy, although these reactions are not restricted to atopic patients (Champion and Parish 1992: 604).

2.7.4 Urticaria

Cases of allergy-related urticaria are found more frequently in atopic individuals. Contact urticaria occurs more commonly in atopic eczema and may present as an acute exacerbation of the atopic eczema. (Champion and Parish 1992: 604.)

2.7.5 Infections

Secondary bacterial infection with *Staphylococci* or *Streptococci* is very common in atopic eczema and contributes to many exacerbations of the disease, even without any visible purulent exudate. Patients with atopic eczema are predisposed to the development of acute generalised infections with the viruses of *Herpes simplex* (eczema herpeticum) and *Vaccinia* (eczema vaccinatum). This may result in a severe systemic illness with pyrexia and a generalised eruption, or may be completely localised to areas of pre-existing atopic eczema. (Champion and Parish 1992: 604-605.)

2.7.6 Ocular complications

Keratoconus, or conical cornea, may be associated with atopic eczema. It occurs as a result of degeneration of the cornea, due to raised intra-ocular pressure and gives rise to visual disturbances (Champion and Parish 1992: 606).

Cataract is an uncommon complication which occurs in up to 10% of the more severe adolescent and adult cases. It is almost always bilateral. Progression may be slow or alarmingly rapid and may coincide with an exacerbation of the skin disease. (Champion and Parish 1992: 606.)

2.7.7 Exfoliative erythroderma

Exfoliative erythroderma is a rare complication of atopic eczema. It may present as an acute or chronic generalised exfoliative dermatitis in adolescents with asthma and extensive atopic eczema. Metabolic consequences such as excessive protein loss, hypoproteinaemia, faulty temperature regulation and high-output cardiac failure may develop. Hair and nails may be lost. This is a serious complication of atopic eczema and should be recognised and treated as early as possible. (Clark-Huff and Weston 1978: 96.)

2.8 *Prognosis*

The prognosis is often difficult to assess. It is worse if both parents are affected. Other factors such as the personality of the child and its parents and

factors in the environment are equally important. The presence of a pronounced epidermal component affects the prognosis badly, as ocular complications are more likely to occur in these cases. There is a general tendency towards spontaneous improvement throughout childhood, although relapses do occur. 30-50% of infantile eczema cases develop asthma or hay fever later in life. (Champion and Parish 1992: 607.)

2.9 *Medical treatment*

2.9.1 General management

According to Hanifin (1992: 93) the most important factor in the management of atopic eczema is patient education regarding the realities of their disease. Orthodox medicine can offer no cure for atopic eczema. Its course can only be moderated by the avoidance of trigger factors and by drug therapy. The avoidance of trigger factors prevents itching, scratching and further inflammation. (Hanifin 1992: 93.)

2.9.2 Specific therapeutic modalities

The medical treatment of atopic eczema tends to be symptomatic rather than curative. Therapy consists of the use of topical preparations such as emollients, topical corticosteroid creams and coal tar preparations; and the administration of systemic agents such as antibiotics, antihistamines and corticosteroids. (Champion and Parish 1992: 609.)

Topical therapy has an important place in the medical treatment of atopic eczema. It serves to protect the skin from further scratching and

environmental factors, and to suppress inflammatory changes and secondary infection. Emollients may be added to the bath or applied directly to the skin. Topical corticosteroid creams remain the cornerstone of treatment for both the acute exudative and chronic lichenified lesions. (Champion and Parish 1992: 609.) This is due to its immunosuppressive and anti-inflammatory effect. However, the prolonged use of topical steroids can result in a number of serious side effects. (Eckman and Stiller 1995: 4.) These include severe skin atrophy, secondary Cushing's syndrome and bone disease. Furthermore, there is an increase in the occurrence of contact sensitivity to medicaments, including topical steroids. (Graham-Brown 1998: 12.)

According to Champion and Parish (1992: 609) the liberal use of the strongest topical steroids for a short period of time has almost eliminated the need for systemic corticosteroids. In fact, the administration of systemic corticosteroids have little place in the management of atopic eczema. Antibiotics are administered when extensive, clinically obvious infection is present. Antihistamines are administered mainly for their sedative and antipruritic effect. (Champion and Parish 1992: 609.) Recent evidence suggests however, that these agents have an insignificant antipruritic effect and affords relief mainly by virtue of their central sedative action (Graham-Brown 1998: 13-14; Champion and Parish 1992: 609).

The use of evening primrose oil for a period of 2-3 months can be beneficial in some cases of atopic eczema. However, the precise indications are unclear

since it cannot be predicted which patients will respond. (Champion and Parish 1992: 609-610.)

Recently studies were conducted on the effect of traditional Chinese herbal therapy on atopic eczema. The results revealed a highly significant improvement in the severity of dermatitis with few side effects after prolonged use. This reflects the growing interest in (and the possible benefits of) complementary medicine as a treatment modality for atopic eczema. Orthodox medicine usually fails to provide a cure for atopic eczema and patients often turn to complementary medicine for relief. (Graham-Brown 1998: 20-21.)

In a recent survey of members of the National Eczema Society (Great Britain) over 50% of respondents confirmed that their eczema interfered with their life and roughly two-thirds said that their expectations of the initial consultation with their general practitioner or hospital consultant had only been partly met (McHenry et al. 1995: 843). This explains why the treatment of atopic eczema is one of the greatest challenges for physicians today.

2.10 Homoeopathic treatment

Homoeopathy is a very individualised form of therapy. The basis for selection of the appropriate homoeopathic remedy is a careful assessment of each patient's unique reaction to the disease (Cook 1989: 33). The aim of homoeopathic treatment is to galvanise the body's intrinsic self-healing

system into action by the administration of substances that increase the symptoms slightly (Lockie and Geddes 1995: 14-15).

Polypharmacy is a form of Homoeopathic therapeutics where a number of different remedies are administered to the patient at the same time in the form of a complex. These remedies, usually employed in low potencies, have similar pathological actions and are aimed to match the totality of symptoms of a clinical condition. In other words, the complex will cover the various symptoms and clinical manifestations of a disease. This gives the complex a wide spectrum of action so that it may be used by most people suffering from that disease. (Cook 1989: 73.)

Drainage, or Detoxication, may also explain the mechanism of action of homoeopathic complexes. Drainage remedies are employed in low potencies and are chosen because of their selective action on the "particular tissue or organ whose functioning is disturbed, and owing to this disturbance, prevents the free elimination of organic by-products and toxins." (Maury 1965: 42.)

Two randomised double-blind placebo-controlled trials were conducted by Ramgolam *et al.* (2000) on the effect of Zemaphyte, a decoction of 10 Chinese herbs, on atopic eczema. The results proved Zemaphyte to be efficacious in the treatment of atopic eczema in adults and children. However, there are concerns of possible toxicity of these herbs with prolonged use. There is no danger of toxicity associated with the use of homoeopathic medicines, since these medicines are highly diluted.

Despite research of relevant databases, there is surprisingly little research on the effect of homoeopathic treatment on atopic eczema.

A retrospective survey was conducted by Spence (1991) on 130 cases (90 children and 40 adults) of eczema treated with homoeopathy. According to this survey 85.5% of the sample group experienced a marked improvement in their eczema after homoeopathic treatment. However, as this was only a retrospective survey, the treatment was not tested against a placebo. There were also multiple variables, such as the treatment period which varied from 3 months to 9 years, and the sample group which included adults and children.

Opperman (1997) conducted a placebo-controlled study to evaluate the effect of homoeopathic similimum treatment on atopic eczema. Thirty patients were selected for the study and were randomly divided into two groups of fifteen patients each. Group one received placebo treatment and group two received homoeopathic similimum treatment. Patients were given four treatments over a three-month period. The parameters measured were the patients' perception of the treatment (subjective data) and the clinical manifestations of atopic eczema (objective data). Statistical analysis of the results revealed a significant improvement in the experimental group and no significant improvement in the control group. However, Opperman's results may not be very reliable because of possible subjectivity in interpreting clinical signs. The objective measure that was used in Opperman's research was a clinical evaluation index, which involved the assessment of the objective features of atopic eczema, such as redness, swelling, excoriation and lichenification. Her

lack of experience in interpreting objective features (the research having taken place during her internship) may have rendered the results less reliable.

Homoeopathic similimum treatment requires a comprehensive evaluation of the patient's totality of symptoms, or the "expressions of the disturbed physiologic (*sic*) functioning", by a qualified homoeopathic practitioner. This "symptom picture" is then compared to a similar picture of a specific remedy, which is then given to the patient to effect a cure (Whitmont 1991: 5). This type of treatment is only possible with a one-on-one consultation in a day clinic or private practice set-up.

In Polypharmacy no individualisation of the case is required, as the remedies in the complex are selected to cover all the different expressions of a specific disease (Cook 1989: 73). This is the rationale behind the sale of over the counter homoeopathic complexes.

Natura Homoeopathic Laboratory (Pretoria, South Africa) has combined a number of different remedies capable of producing (and therefore curing) the signs and symptoms of atopic eczema in their complex, Herpin 2[®]. According to Green (2000) no studies have previously been done on this complex.

2.10.1 Herpin 2[®]: *Materia medica* and potencies

2.10.1.1 Arsenicum iodatum D10:

Dry, itchy, scaly skin with marked exfoliation in large scales, leaving a raw exuding surface beneath. Eczema that is watery and oozing and worse after

washing. Induration and hardening of the skin with vesicles, which turn into pustules and form scabs.

2.10.1.2 *Bovista gigantea D6:*

Eczema and herpetic eruptions. Red, dry, burning eczema with the formation of thick crusts. Moist vesicular eruptions with itching which is worse from warmth and hot weather. Itching that disturbs sleep and is not relieved by scratching.

2.10.1.3 *Fluoricum acidum D6:*

Destruction of the tissues of the skin such as occurs in bedsores, ulcerations and varicose ulcers. Atony of the capillary and venous system. Inflammation of the skin and of scar tissue with the formation of vesicles and pustules. Dry, harsh itching or cracked skin with burning pains.

2.10.1.4 *Graphites D30:*

Formation of cracks, dry, crusty eruptions, scabs and profuse serous, sticky, honey-like exudations. The folds of the skin (flexor surfaces) are mainly affected. All discharges are offensive. Severe itching with increased discharge after scratching. The itching is worse in the evening and at night, from cold and when at rest.

2.10.1.5 *Hydrastis canadensis D8:*

General tendency to unhealthy skin and profuse perspiration. Moist eruptions with offensive discharges, itching and burning. Yellowish-looking vesicles with

oozing after washing. The itching is aggravated on coming from the cold into a warm room.

2.10.1.6 Lycopodium clavatum D4:

Chronic cases of eczema associated with urinary, gastric and hepatic disorders. There is easy bleeding after scratching and a thick, malodorous discharge. Humid, suppurating eruptions with thick crusts. Symptoms are aggravated by heat and in wet, stormy weather. Eczema due to fear, fright, remorse, anxiety and vexation.

2.10.1.7 Sulphur D30:

The skin is rough and course, with much soreness in the folds of the skin and a tendency to pustular eruptions. Eruptions may be humid and offensive with an acrid discharge; or dry and offensive with cracks, easy bleeding, and burning pains. Eruptions are intensely itching and there is soreness after scratching. The itching is worse from warmth, at night, from bathing and wool.

2.10.1.8 Urtica urens D4:

Urticarial eruptions with violent itching, burning and stinging. Erythema and itching blotches. Symptoms are worse after bathing, exercise and from warmth. Rubbing the affected parts affords local amelioration.

(Boericke 1997, Clarke 1991, Douglass 1995, Morrison 1993, Schroyens 1997, Tyler 1992, van Wyk 1999, Vermeulen 1997.)

2.11 *The placebo effect*

A placebo is a dummy treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effect of the experimental treatment can be distinguished (On-line Medical Dictionary). The placebo effect may be attributed to a person's beliefs and hopes about a treatment, combined with their suggestibility (Carrol 2000). Patients who have a positive attitude to treatment tend to respond more favourably to placebos than patients with a negative attitude. However, the relevance of the suggestibility and attitudes of patients does not negate the value of placebos in clinical trials. The treatment under study must perform significantly better than the placebo for the treatment to be regarded as effective. (On-line Medical Dictionary.)

CHAPTER THREE: MATERIALS AND METHODS

3.1 Sampling method

The population of this study included males and females from the greater Durban area who suffer from atopic eczema. The sample group was obtained by means of convenience sampling, i.e., those responding to advertisements and who met the selection criteria. Advertisements were placed in the local newspapers and on notice boards in Technikon Natal, University of Natal (Durban), M.L. Sultan Technikon, health shops, pharmacies and health and sports clubs in the greater Durban area.

3.2 Sample size

The sample group consisted of thirty-four patients, although only data obtained from thirty patients were needed for the final results. This larger number was to allow for dropouts. The sample group was randomly divided into two groups: the placebo group and the treatment group, consisting of seventeen patients each.

3.3 The subjects

Participation in this study was voluntary, and respondents had to meet the following selection criteria:

- 3.3.1 Participants had to comply with the diagnostic criteria outlined by Hanifin (1992) (Appendix B).

- 3.3.2 Participants had to be between the age of 15 and 55 years.
- 3.3.3 Only patients with a history of at least one outburst during the previous year and with the most recent lesion being present for at least one week were included in the study.
- 3.3.4 Participants were not permitted to undergo corticosteroid treatment for any other condition during the study.
- 3.3.5 Patients that were on topical and/or inhaled corticosteroid treatment for any reason had to discontinue the treatment for one week before being accepted into the study (Boguniewicz et al. 1998: 637-642).
- 3.3.6 Patients who had not had any systemic corticosteroid treatment for a period of six weeks were permitted to participate in the study (Boguniewicz et al. 1998: 637-642).
- 3.3.7 Participants were not permitted to take any other form of medication (topical and oral) for their eczema from the commencement of the study.

3.4 Methodology

The duration of this study was two months. There was one follow-up appointment after four weeks and a final follow-up appointment at eight weeks. This amounted to three appointments per patient.

At the first appointment the patients were asked to sign the Patient Consent Form (Appendix D). At each appointment:

3.4.1 The researcher conducted a full medical case history and physical examination (see Appendix G for a standard form).

3.4.2 The researcher measured and recorded the percentage body surface area affected by eczematous lesions. This was accomplished by using the method commonly used to measure surface area involvement, namely the rule of nines (Muir et al. 1987). This method is frequently used by eczema researchers (Mills et al. 2000: 687-689). In this method the total body surface area comprises 9% for the head and neck, each arm, the front and back of each leg and the four trunk quadrants, with 1% for the genitalia. The surface area covered by the patient's hand equals 1%, which is used for the measurement of smaller areas. (Charman et al. 1999: 109.) (Appendix F.) Smaller individual lesions were measured with a ruler and converted to a percentage value by comparing it to the size of the patient's hand (also measured with a ruler).

3.4.3 The patient completed a Patient Perception Questionnaire (Appendix E).

3.5 Treatment

The homoeopathic complex and the placebo were made up by Natura Homoeopathic Laboratory (Pretoria, South Africa). The homoeopathic complex were manufactured according to method 5a of the German Homoeopathic Pharmacopoeia (German Homoeopathic Pharmacopoeia 1993: 35-36) in 25 millilitres of 20% alcohol. The placebo treatment consisted

of 25 millilitres of 20% alcohol only, and was also made up by Natura Homoeopathic Laboratory (Pretoria).

Each dropper bottle had a label stating "Eczema Study" and a number from one to thirty-four. The homoeophaerapist at Natura Homoeopathic Laboratory randomly assigned these numbers to the treatment and placebo groups according to the roll of a dice (see Appendix A for explanation of the method). The coded information was sent from Natura Homoeopathic Laboratory to the researcher in a sealed envelope. This envelope was lodged with an outside party (the Head of the Department of Homoeopathy, Technikon Natal) for the duration of the study and was only opened when the results were ready to be analysed. Patients entering the study received the treatment bottle whose number corresponded to the chronological number of their entrance into the study. Neither the researcher nor the patients knew which patient was receiving which treatment during the course of the study.

Each patient was given two bottles for use during the two-month treatment period. Patients were instructed to take ten drops of the treatment on the tongue, three times per day at least fifteen minutes before or after food, drink, tooth brushing or smoking. This protocol was followed every day by each patient for the duration of the eight-week treatment period.

At the end of the study the patients who received the placebo treatment were given the homoeopathic eczema complex. Those who wished to continue with specific homoeopathic treatment were given the opportunity to do so,

although this was as regular paying patients at the Technikon Homoeopathic Day Clinic.

3.6 Data analysis

Non-parametric statistical methods for data analysis were used in this study. The reason for this being the small sample size per group ($n_1=15$, $n_2=15$). Data entry and analysis was performed using the computer package *SPSS version 9+*.

3.6.1 Subjective data

The subjective data was obtained from the Patient Perception Questionnaires. Each question in the questionnaire had a possible maximum score of 4 and a possible minimum score of 0. The data was integrated and interpreted by means of the Mann-Whitney U-test for inter-group comparisons (Daniel 1978: 31, 82). The results were tabulated to show whether there were differences between the two groups for each appointment. The Wilcoxon's signed ranks test was used to determine whether there were any improvements within the two groups between the first and third appointments.

3.6.2 Objective data

The objective data obtained from the measurement of the percentage of the total body surface area was integrated and interpreted by means of the Mann-Whitney U-test for inter-group comparisons. The results were tabulated to show whether there were differences between the two groups for each appointment. The Wilcoxon's signed ranks test was used to determine

whether there were any improvements within the two groups between the first and third appointments.

3.6.3 The Mann-Whitney U-Test

The Mann-Whitney U-test was used to compare the placebo and treatment groups, with respect to each variable. The two groups were treated as being independent of one another (unpaired). The purpose of this test was to determine whether there was any difference between the two groups.

Hypothesis testing:

H_0 : There is no difference between the two groups.

H_1 : There is a difference between the two groups.

In each case α was set at 0.05 (specified level of significance).

Decision rule:

H_0 was rejected if $p < \alpha$ and accepted if $p \geq \alpha$. P is the observed significance level of the test. That is: $P =$ (two-tailed z-value). (SPSS package version 9+.)

3.6.4 Wilcoxon's signed ranks test

The Wilcoxon's signed ranks test was used to test for improvements within the two independent groups for each appointment.

Hypothesis testing:

H_0 : There is no difference between the appointments.

H_1 : There is a difference between the appointments.

Again in each case α was set at 0.05 (specified level of significance).

Decision rule:

H_0 was rejected if $p/2 < \alpha$ and accepted if $p/2 \geq \alpha$. P is the observed significance level of the test. Reported p-value $\div 2$. (SPSS package version 9+.)

3.6.5 Tables and summary statistics

The p-values of the Mann-Whitney unpaired test and the Wilcoxon's signed ranks test were calculated and demonstrated in the form of tables. Summary statistics (mean, mode, median, standard error, the coefficient of variation) are provided.

3.6.6 Figures

Visual summaries of the results are given in the form barcharts.

3.6.7 Statistical package

The statistical package, Statistical Package for Social Sciences (SPSS) version 9+ was used for data entry and analysis.

CHAPTER FOUR: RESULTS

4.1 The criteria governing the admissibility of the data

Only data obtained from the trial was used. All appointments were conducted personally by the researcher. Only the data obtained from participants who had taken their medication according to the directions was utilised.

4.2 Comparison between the placebo and treatment groups

4.2.1 Subjective data

4.2.1.1 Table 4-1

The p-values of the Mann-Whitney U-test were calculated and are tabulated below:

Question	Appointment number	p-value	H ₀ decision
1	1	0.745	Accept
	2	0.691	Accept
	3	0.045	Reject
2	1	0.387	Accept
	2	0.220	Accept
	3	0.576	Accept
3	1	0.864	Accept
	2	0.574	Accept
	3	0.862	Accept
4	1	0.966	Accept
	2	0.678	Accept
	3	0.689	Accept
5	1	0.222	Accept
	2	0.346	Accept
	3	0.172	Accept
6	1	0.221	Accept
	2	0.360	Accept
	3	0.389	Accept
7	1	0.068	Accept
	2	0.023	Reject

	3	0.598	Accept
8	1	0.696	Accept
	2	0.339	Accept
	3	0.622	Accept
9	1	0.553	Accept
	2	0.647	Accept
	3	0.602	Accept
10	1	0.675	Accept
	2	0.351	Accept
	3	1.000	Accept
Total	1	0.308	Accept
	2	0.329	Accept
	3	0.662	Accept

With respect to the subjective totals for each appointment, the p-value is greater than 0.05. The null hypothesis is thus accepted and it is concluded that there was no difference in the subjective manifestations of atopic eczema at each appointment.

The p-value of both question one and seven for appointment three and two respectively is less than 0.05. The null hypothesis is thus rejected with respect to these two questions. It is thus concluded that there is a significant difference with respect to question one and seven in appointment three and two respectively.

4.2.1.2 *Figure 4-1 and Figure 4-2 (see p.34 and p.35)*

FIGURE 4-1

Comparison between the placebo and treatment groups with regards to the mean totals of the questionnaires for consultations 1, 2 and 3

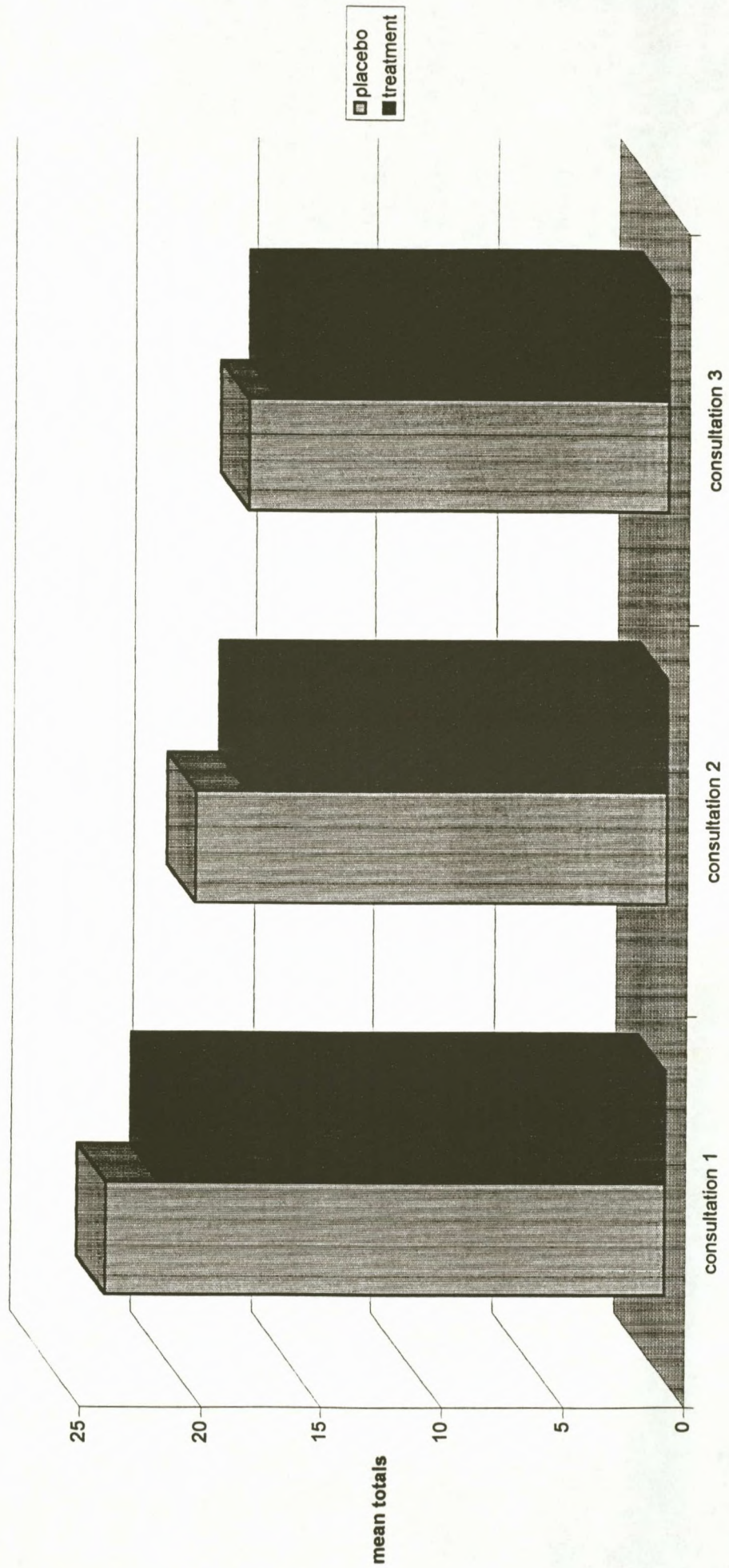


FIGURE 4-2

Comparison between the placebo and treatment groups with regards to the means of the 10 questions for consultation 3 (end of treatment)

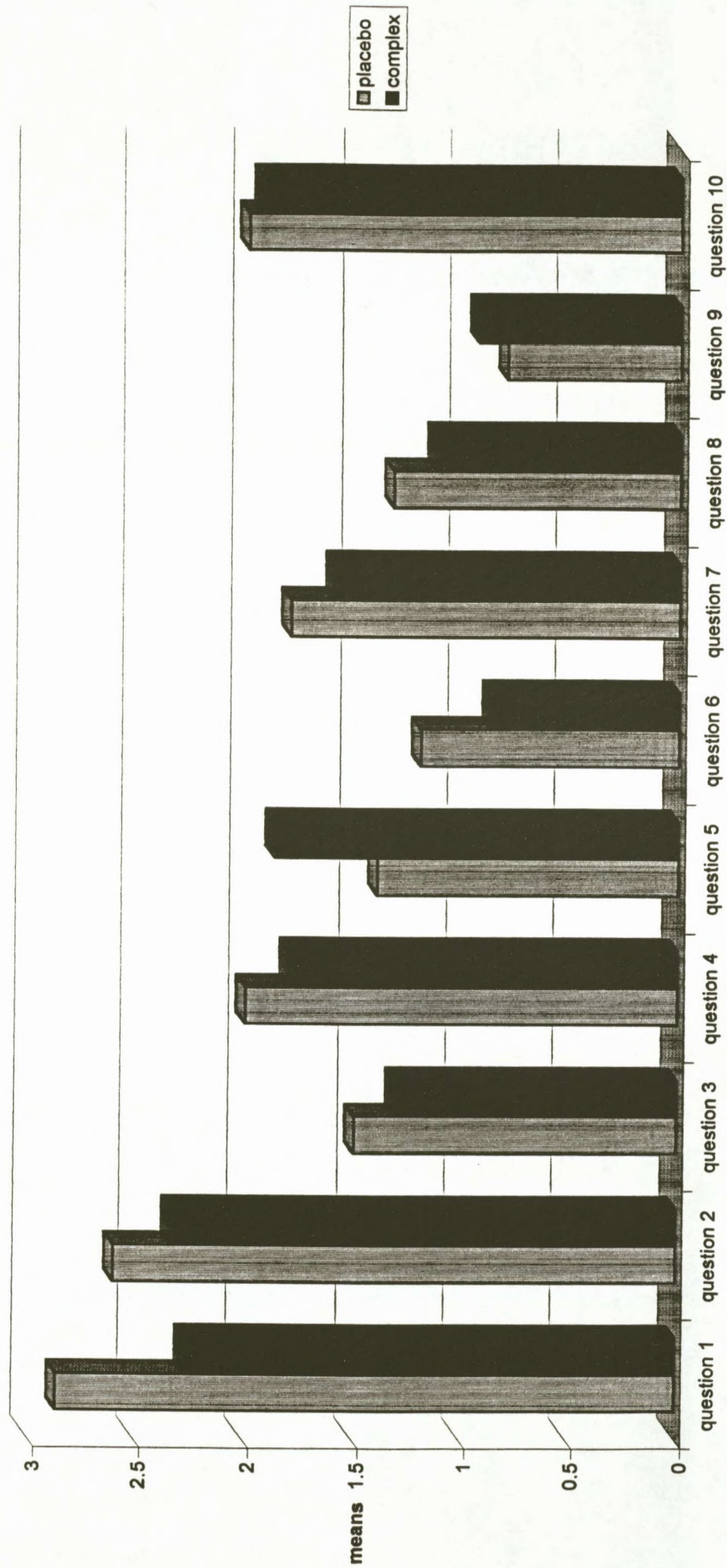


Figure 4-1 is a graphic demonstration of the subjective mean totals of the placebo and treatment groups over the eight-week period. The means of the treatment group with respect to the subjective totals are less than those of the placebo group.

Figure 4-2 is a graphic demonstration of the subjective means of the placebo and treatment groups for the third appointment. The means of all the questions, except question five and nine, are less than those of the placebo group.

4.2.2 Objective data

4.2.2.1 Table 4-2

The p-values of the Mann-Whitney U-test were calculated and are tabulated below:

Variable	Appointment number	p-value	H ₀ decision
% Total body surface area affected	1	0.772	Accept
	2	0.787	Accept
	3	0.418	Accept

In each case the p-value is greater than 0.05. The null hypothesis is thus accepted and it is concluded that there was no difference in the percentage of the total body surface area affected by eczematous lesions at each appointment.

4.2.2.2 Figure 4-3 (see p.37)

FIGURE 4-3

Comparison between the placebo and treatment groups with regards to the objective mean measurements of affected skin in consultations 1, 2 and 3

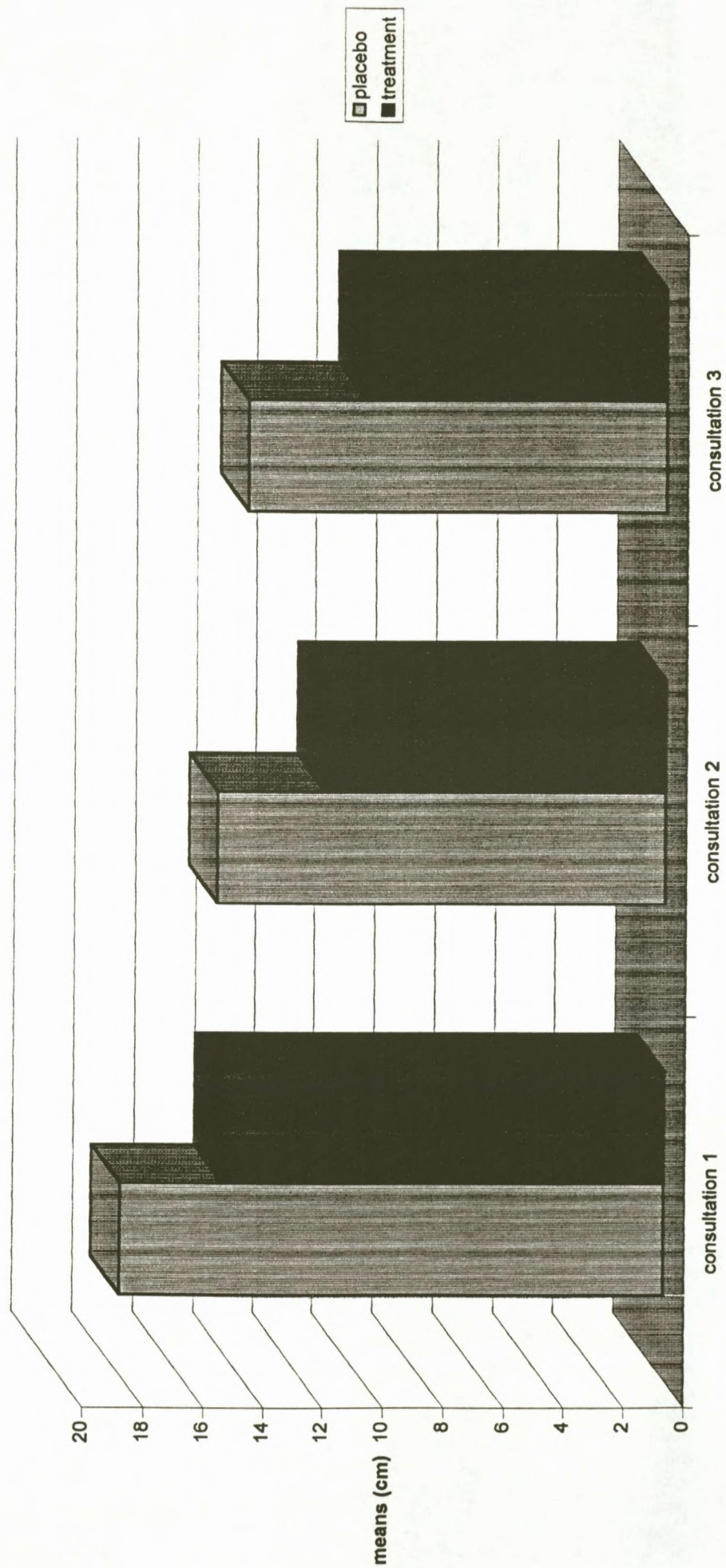


Figure 4-3 is a graphic demonstration of the objective means of the placebo and treatment groups over the eight-week period. The graph shows that the means of the treatment group with respect to each appointment are less than those of the placebo group.

4.3 Comparison within the placebo and treatment groups

4.3.1 Comparison within the placebo and treatment groups between appointment one and two

4.3.1.1 Table 4-3 Subjective data

The p-values of the Wilcoxon's signed ranks test were calculated and are tabulated below:

Variable	Group	p-value	H ₀ decision
Subjective totals	Placebo	0.480	Accept
	Treatment	0.007	Reject

(The p-values in the above table are reported $p\text{-value} \div 2$ as stated in the decision rule.)

The p-value of the placebo group is greater than 0.05. The null hypothesis is thus accepted and it is concluded that there is no improvement in the subjective manifestations of atopic eczema within the placebo group between the first and second appointment. The p-value of the treatment group is less than 0.05. The null hypothesis is thus rejected and it is concluded that there is a significant improvement in the subjective features of atopic eczema within the treatment group between the first and second appointment.

4.3.1.2 *Table 4-4 Objective data*

The p-values of the Wilcoxon's signed ranks test were calculated and are tabulated below:

Variable	Group	p-value	H ₀ decision
% Total body surface area affected	Placebo	0.388	Accept
	Treatment	0.035	Reject

(The p-values in the above table are reported $p\text{-value} \div 2$ as stated in the decision rule.)

The p-value of the placebo group is greater than 0.05. The null hypothesis is thus accepted and it is concluded that there was no improvement in the objective features of atopic eczema within the placebo group between the first and second appointment.

The p-value of the treatment group is less than 0.05. The null hypothesis is thus rejected and it is concluded that there was a significant improvement in the objective features of atopic eczema within the treatment group between the first and second appointment.

4.3.2 Comparison within the placebo and treatment groups between appointment one and three

4.3.2.1 *Subjective data*

4.3.2.1.1 Table 4-5

The p-values of the Wilcoxon's signed ranks test were calculated and are tabulated below:

Question	Group	p-value	H ₀ decision
1	Placebo	0.052	Accept
	Treatment	0.002	Reject
2	Placebo	0.020	Reject
	Treatment	0.008	Reject
3	Placebo	0.340	Accept
	Treatment	0.042	Reject
4	Placebo	0.072	Accept
	Treatment	0.009	Reject
5	Placebo	0.004	Reject
	Treatment	0.159	Accept
6	Placebo	0.012	Reject
	Treatment	0.167	Accept
7	Placebo	0.095	Accept
	Treatment	0.500	Accept
8	Placebo	0.005	Reject
	Treatment	0.014	Reject
9	Placebo	0.207	Accept
	Treatment	0.282	Accept
10	Placebo	0.015	Reject
	Treatment	0.003	Reject
Total	Placebo	0.003	Reject
	Treatment	0.003	Reject

(The p-values in the above table are reported p-value \div 2 as stated in the decision rule.)

With respect to the subjective totals of the placebo and treatment groups, the p-value is less than 0.05. The null hypothesis is thus rejected and it is concluded that there was a significant improvement in the subjective manifestations of atopic eczema in both groups at the third appointment.

The p-values of the placebo group with respect to questions two, five, six, eight and ten are less than 0.05. The null hypothesis is thus rejected with respect to these questions. It is concluded that there was a significant improvement in the subjective features of atopic eczema, with respect to these questions, within the placebo group at the third appointment.

The p-values of the treatment group with respect to questions one, two, three, four, eight and ten are less than 0.05. The null hypothesis is thus rejected with respect to these questions. It is concluded that there was a significant improvement in the subjective features of atopic eczema, with respect to these questions, within the treatment group at the third appointment.

The p-values of both groups with respect to the remaining questions are greater than 0.05. The null hypothesis is thus accepted and we can conclude that there was no improvement in the subjective features of atopic eczema, with respect to these questions, within the placebo and treatment groups at the third appointment.

4.3.2.1.2 Figure 4-4 and Figure 4-5 (see p.42 and p.43)

Figure 4-4 is a graphic demonstration of the subjective means of the placebo group between the first and third appointment. The graph shows that the means of the third appointment are less than those of the first appointment.

Figure 4-5 is a graphic demonstration of the subjective means of the treatment group between the first and third appointment. The graph shows that the means of the third appointment are less than those of the first appointment.

FIGURE 4-4

Comparison between consultation 1 and 3 with regards to the means of the 10 questions for the placebo group

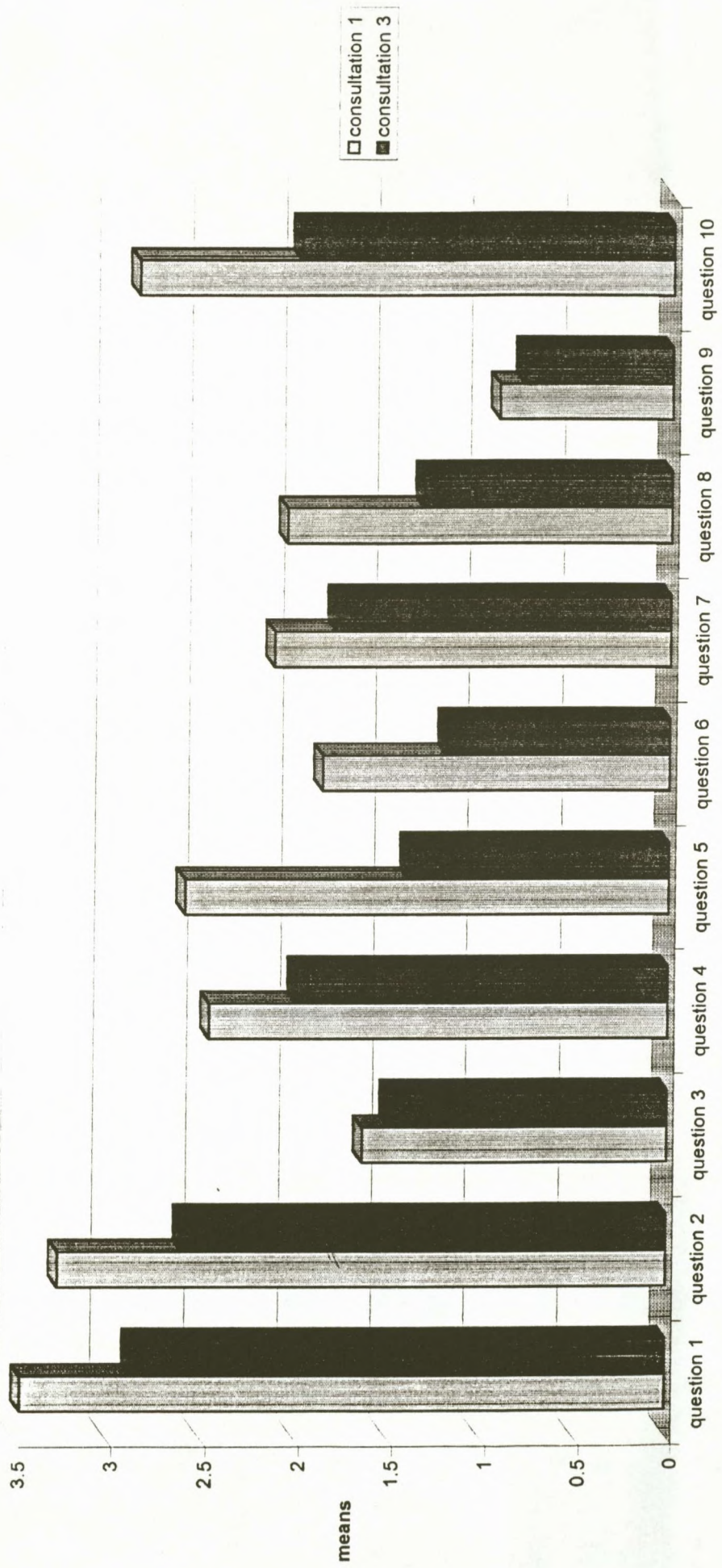
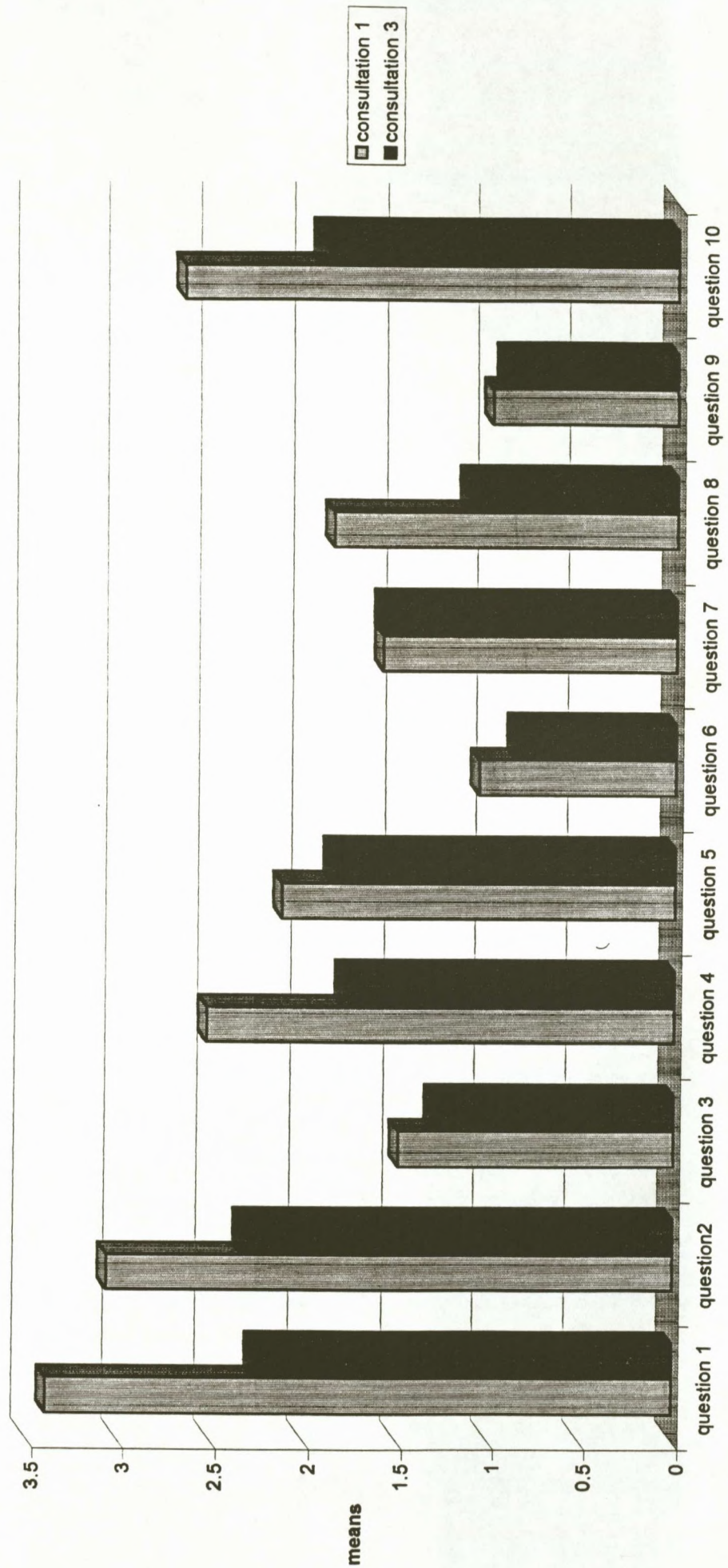


FIGURE 4-5

Comparison between consultation 1 and 3 with regards to the means of the 10 questions for the treatment group



4.3.2.2 Table 4-6 Objective data

The p-values of the Wilcoxon's signed ranks test were calculated and are tabulated below:

Variable	Group	p-value	H ₀ decision
% Total body surface area affected	Placebo	0.101	Accept
	Treatment	0.031	Reject

(The p-values in the above table are reported $p\text{-value} \div 2$ as stated in the decision rule.)

The p-value of the placebo group is greater than 0.05. The null hypothesis is thus accepted and it is concluded that there was no improvement in the objective manifestations of atopic eczema within the placebo group at the third appointment.

The p-value of the treatment group is less than 0.05. The null hypothesis is thus rejected and it is concluded that there was a significant improvement in the objective manifestations atopic eczema within the treatment group at the third appointment.

CHAPTER FIVE: DISCUSSION

The results of this investigation indicate that the homoeopathic eczema complex (Herpin 2[®]) does not improve the subjective manifestations of atopic eczema more than a placebo, although it improves the objective manifestation of atopic eczema (measured as the percentage body surface area involved) more than a placebo.

With regards to the second appointment, only the treatment group experienced a significant improvement in the subjective and objective features measured. However, at the third appointment a significant improvement in the subjective manifestations of atopic eczema occurred in both the placebo and treatment groups, whilst only the treatment group had a significant reduction in the total percentage body surface area affected by eczematous lesions.

Difficulties in assessing surface area involvement may have influenced the overall results. According to Charman *et al.* (1999) the measurement of surface area involvement is an unreliable method of assessing disease severity objectively, due to observer error. The erythema in atopic eczema is often ill-defined, making accurate measurements difficult. Improvement can also occur in one objective feature, such as dryness and scaling, without affecting the total surface area involvement. More reliable objective data may have been obtained if the severity of all the objective features were assessed by means of a severity scoring index, such as the SCORAD severity score (Isolauri *et al.* 2000: 1604-1610) with the assistance of an experienced dermatologist.

The use of complexes in homoeopathy is a contentious issue. One can understand that more than one remedy can be indicated in conditions such as injuries, where a violent external influence is directly responsible for the state of the patient. However, for a chronic condition such as atopic eczema, which has its origins at a genetic and fundamental level, only a holistic and comprehensive assessment of the case and treatment targeted at the fundamental level will lead to optimal results. (Tomlinson 1999.)

Another difficulty is that with complex treatment the focus is on the pathology, rather than the patient. A medicine is therefore selected based the condition that a patient is suffering from, rather than the individual expressions of the person's suffering. The problem is that conventional medical categories and principles are used to classify and select a homoeopathic treatment, instead of using homoeopathic categories and principles to select such a treatment. (Tomlinson 1999.)

Furthermore, two of the remedies in the complex are antidotal. *Hydrastis canadensis* is antidoted by Sulphur, and *Lycopodium clavatum* is antidoted by Graphites (Vermeulen 1997: 851, 1055). The impact this would have on the therapeutic value of the complex is unclear and entirely speculative.

Nevertheless, there is a place for over-the-counter complexes for members of the public to self-treat common, acute conditions. For many patients, these complexes are their first contact with homoeopathy, and they may go on to consult qualified homoeopaths afterwards. However, for the treatment of

chronic, deep seated conditions such as atopic eczema, the deep nature of the patient has to be considered in context to the patient's pathology.

(Tomlinson 1999.)

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

On the basis of the results of this study it can be concluded that Herpin 2[®] has a limited role, if any, to play in the management of atopic eczema.

Recommendations for further studies:

1. A larger sample size should be used.
2. There should only be 2 appointments: one at the beginning of the study and one at the end of the study. Data obtained from an intervening appointment is superfluous since what is assessed is the change which occurred in both groups before and after the treatment.
3. The efficacy of Herpin 2[®] in the treatment of other types of eczema, such as allergic contact dermatitis.
4. An evaluation of the relative efficacy of a homoeopathic similimum treatment and Herpin 2[®] in the management of atopic eczema.
5. The effect of Herpin 2[®] on atopic eczema and the other manifestations of atopy (such as allergic rhinitis and asthma) in one study.

6. An evaluation of the effect of the plant substances in Herpin 2[®], namely *Hydrastis Canadensis* and *Urtica urens*, as herbal tinctures on atopic eczema. This will increase the body of research on the effect of herbal treatment on atopic eczema.

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LIST OF APPENDICES

- A. Simple random sampling of treatments into experimental or control groups
- B. Diagnostic criteria of atopic eczema
- C. Eczema study – Information sheet
- D. Patient consent form
- E. Patient's perception questionnaire
- F. Percentage body surface area involvement
- G. Standard medical case history format

APPENDIX A

SIMPLE RANDOM SAMPLING OF TREATMENTS INTO EXPERIMENTAL OR CONTROL GROUPS (Adapted from Opperman 1997.)

Nine throws of a dice will give the group allocation to the bottles, numbered from 1-34.

RESULT OF DICE THROW	ORDER OF ALLOCATION
1 _____	EECC
2 _____	CCEE
3 _____	ECCE
4 _____	CEEC
5 _____	ECEC
6 _____	CECE

Where E represents Experimental group and C represents Control group.

BOTTLE #	THROW #	ALLOCATION ORDER
e.g.: 1.		E
2.		C
3.		C
4.		E
1.	_____	_____
2.		_____
3.		_____
4.		_____
5.	_____	_____
6.		_____
7.		_____
8.		_____

9.	—	—
10.		—
11.		—
12.		—
13.	—	—
14.		—
15.		—
16.		—
17.	—	—
18.		—
19.		—
20.		—
21.	—	—
22.		—
23.		—
24.		—
25.	—	—
26.		—
27.		—
28.		—
29.	—	—
30.		—
31.		—
32.		—
33.	—	—
34.		—

APPENDIX B

DIAGNOSTIC CRITERIA OF ATOPIC ECZEMA (Hanifin 1992)

NAME: _____

DATE: _____

MAJOR FEATURES – Must have 4 or more:

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

MINOR FEATURES - Must have 3 or more:

- | | |
|----------|--|
| YES / NO | Xerosis |
| YES / NO | Ichyosis / Parmar hyperlinearity / keratosis pilaris |
| YES / NO | Immediate (type 1) skin test reactivity |
| YES / NO | Susceptibility to cutaneous infections |

YES / NO Tendency toward non-specific hand or foot eczema

YES / NO Nipple eczema

YES / NO Cheilitis

YES / NO Perifollicular accentuation

ACCEPTED INTO STUDY YES / NO

ENTRY NUMBER: _____

APPENDIX C

ECZEMA STUDY – INFORMATION SHEET

Atopic eczema is a disabling and distressing condition for which, despite the expertise of medical technology, a satisfactory cure is yet to be found.

The incidence of atopic eczema is increasing, and so is the demand for some successful, non-harmful treatment. Homoeopathic treatment is gentle, effective and has no side effects. It aims to stimulate the body's own defence mechanisms to initiate the healing process. Treatment with homoeopathic complexes is an extension of homoeopathic philosophy that employs a number of specific remedies for the treatment of every case of a specific disease. Many of these complexes are sold over-the-counter at pharmacies and health-shops.

This research project intends to determine the impact of such an over-the-counter homoeopathic eczema complex on the signs and symptoms of atopic eczema.

There will be two groups of treatment, one will be the active treatment group and the other will be the placebo treatment group (placebo: a medically inactive substance used in controlled studies for comparison with presumed active drugs). If you were in the placebo treatment group, you will receive the active treatment at the end of the study.

By completing the following questionnaire you will enable us to evaluate the effectiveness of the eczema complex in the treatment of atopic eczema and to determine what role the complex can possibly play in the management of the disorder.

Thank you for the courtesy of your assistance.

Okker Botha

APPENDIX D

PATIENT CONSENT FORM

Date: _____

Title of research project: The efficacy of a Homoeopathic Eczema Complex (Herpin 2®) in the Treatment of Atopic Eczema.

Name of supervisor: Dr R. Steele.

Name of research student: Okker Botha.

PLEASE CIRCLE THE APPROPRIATE ANSWER YES / NO

1. Have you read the research information sheet? YES / NO

2. Have you had an opportunity to ask questions regarding this study? YES / NO

3. Have you received satisfactory answers to your questions? YES / NO

4. Have you had an opportunity to discuss this study? YES / NO

5. Have you received enough information about this study? YES / NO

6. Who have you spoken to? _____

7. Do you understand the implications of your involvement in this study? YES / NO

8. Do you understand that you are free to withdraw from
this study?

- a) at any time YES / NO
- b) without having to give a reason for withdrawing, and YES / NO
- c) without affecting your future health care. YES / NO

8. Do you agree to voluntarily participate in this study? YES / NO

**If you have answered no to any of the above, please obtain the
necessary information before signing**

PATIENT Name: _____ Signature: _____
(in block letters)

PARENT / GUARDIAN Name: _____ Signature: _____
(if patient is under 18 years age) (in block letters)

WITNESS Name: _____ Signature: _____
(in block letters)

RESEARCHER Name: _____ Signature: _____
(in block letters)

APPENDIX E

PATIENT'S PERCEPTION QUESTIONNAIRE (Adapted from Finlay and Khan 1994)

NAME: _____

ENTRY NO.: _____

VISIT NO.: _____

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 that you have answered all questions.
 4. Please read each question carefully and make sure that you understand the question. If there are any queries, please ask for assistance from the researcher.
 5. Please answer the questionnaire honestly. It is designed to assess your opinion of the treatment that you are going to receive.
-

DERMATOLOGY LIFE QUALITY INDEX

The aim of this questionnaire is to measure how much your eczema has affected your life OVER THE LAST FOUR WEEKS. Please tick \surd one box for each question.

Please note that there are no correct / incorrect answers.

1. Over the last four weeks, how **itchy, sore, painful** or **stinging** has your skin been?
- Very much
A lot
A little
Not at all
2. Over the last four weeks, how **embarrassed** or **self conscious** have you been because of your eczema?
- Very much
A lot
A little
Not at all
3. Over the last four weeks, how much has your eczema interfered with you going **shopping** or looking after your **home** or **garden**?
- Very much
A lot
A little
Not at all
Not relevant
4. Over the last four weeks, how much has your eczema influenced the **clothes** you wear?
- Very much
A lot
A little
Not at all
Not relevant

5. Over the last four weeks, how much has your eczema affected any **social** or **leisure** activities?

Very much
A lot
A little
Not at all
Not relevant

6. Over the last four weeks, how much has your eczema made it difficult for you to do any **sport**?

Very much
A lot
A little
Not at all
Not relevant

7. Over the last four weeks, has your eczema prevented you from **working** or **studying**?

Yes
No

If "No", over the last four weeks how much has your eczema been a problem at **work** or **studying**?

A lot
A little
Not at all

8. Over the last four weeks, how much has your eczema created problems with your **partner** or any of your **close friends** or **relatives**?

Very much
A lot
A little
Not at all
Not relevant

9. Over the last four weeks, how much has your eczema caused any **sexual difficulties**?

Very much

A lot

A little

Not at all

Not relevant

10. Over the last four weeks, how much has your eczema interfered with your **sleep**?

Very much

A lot

A little

Not at all

APPENDIX F

PERCENTAGE BODY SURFACE AREA INVOLVEMENT

(Adapted from Charman et al. 1999)

To be filled in by researcher.

NAME: _____

ENTRY NO.: _____

VISIT NO.: _____

DATE: _____

HAND MEASUREMENT: _____

REGION	%	PERCENTAGE INVOLVEMENT
HEAD AND NECK	9%	
ANTERIOR TRUNK	18%	
POSTERIOR TRUNK	18%	
RIGHT ARM	9%	
LEFT ARM	9%	
GENITALIA	1%	
RIGHT LEG	18%	
LEFT LEG	18%	
TOTAL % BODY SURFACE AREA		

APPENDIX G

STANDARD MEDICAL CASE HISTORY FORMAT (Bates 1995)

Date: _____

Identifying Data:

Name:

Age:

Sex:

Race:

Date of birth:

Place of birth:

Marital status:

Occupation:

Religion:

Chief Complaint(s):

(a) location, (b) quality / sensation, (c) severity, (d) onset, (e) duration,
(f) frequency, (g) precipitating / aggravating factors, (h) relieving
factors, (i) associated manifestations, (j) alternations.

Past Medical History:

(a) childhood illnesses, (b) vaccinations, (c) adult illnesses, (d) accidents /
injuries, (e) hospitalisations, (f) operations.

Current Health Status:

(a) current medications, (b) diet, (c) exercise and leisure, (d) sleeping patterns, (e) environmental hazards, (f) allergies, (g) tobacco, (h) alcohol and drugs.

Family History:

(a) allergies, (b) skin, (c) stroke, (d) heart disease, (e) hypertension, (f) TB, (g) RA, (h) cancer, (i) diabetes.

Father; Mother; Aunts/Uncles; Siblings; Grandparents; Children

Systems Review:

1. GENERAL:

(a) usual weight, (b) recent change in weight, (c) weakness, (d) fatigue, (e) fever.

2. SKIN:

(a) rashes, (b) lumps, (c) itching, (d) dryness, (e) colour change, (f) nail and hair change.

3. HEAD:

(a) headaches, (b) head injuries.

4. EYES:

(a) vision, (b) glasses / contact lenses, (c) pain, (d) redness, (e) double vision, (f) cataracts.

5. EARS:

(a) hearing, (b) tinnitus, (c) earache, (d) infection, (e) discharge, (f) vertigo.

6. NOSE AND SINUSES:

(a) colds, (b) nasal stuffiness, (c) discharge, (d) itching, (e) hayfever, (f) nosebleeds, (g) sinus problems.

7. MOUTH AND THROAT:

(a) sore throats, (b) hoarseness, (c) bleeding gums, (d) sore tongue.

8. NECK:

(a) pain or stiffness, (b) swollen glands.

9. RESPIRATORY SYSTEM:

(a) cough, (b) sputum, (c) haemoptysis, (d) wheezing, (e) asthma, (f) bronchitis, (g) emphysema, (h) pneumonia, (i) TB, (j) pleurisy.

10. CARDIAC SYSTEM:

(a) chest pain, (b) blood pressure, (c) palpitation, (d) dyspnoea, (e) oedema.

11. GASTROINTESTINAL:

(a) dysphagia, (b) heartburn, (c) nausea, (d) vomiting, (e) appetite, (f) haematemesis, (g) bowel movements, (h) gas and bloating.

12. URINARY SYSTEM:

(a) polyuria, (b) dysuria, (c) nocturia, (d) haematuria, (e) urgency, (f) hesitancy, (g) dribbling, (h) incontinence, (i) infections, (j) stones.

13. REPRODUCTIVE SYSTEM:

(a) discharge, (b) pain, (c) STD, (d) menarche, (e) duration and frequency of periods, (f) bleeding, (g) dysmenorrhoea, (h) menopausal symptoms, (i) pregnancy, (j) contraception.

14. PERIPHERAL VASCULAR SYSTEM:

(a) intermittent claudication, (b) leg cramps, (c) varicose veins, (d) clots in the veins.

15. MUSCULOSKELETAL SYSTEM:

(a) joint and muscle pain, (b) stiffness, (c) arthritis, (d) gout, (e) backache.

16. NEUROLOGICAL SYSTEM:

(a) fainting, (b) blackouts, (c) seizures, (d) paralysis, (e) numbness and tingling, (f) tremor and other involuntary movements.

17. HAEMATOLOGICAL SYSTEM:

(a) anemia, (b) easy bruising or bleeding.

18. ENDOCRINE SYSTEM:

(a) heat / cold intolerance, (b) hyperhydrosis, (c) polyuria, (d) excessive hunger or thirst.

Psychosocial History:

(a) home situation and significant others, (b) any major trauma or upsets in the past, (c) daily life, (d) important experiences, (e) fears / anxieties, (f) hopes / dreams, (g) anger / impatience / frustration, (g) depression, (h) concentration / confusion / loss of memory, (i) religious beliefs, (j) outlook on life.

PHYSICAL EXAMINATION:

Vital signs:

Pulse; respiratory rate; blood pressure; temperature; weight and height.

General examination:

Jaundice; pallor; cyanosis; clubbing; oedema; lymphadenopathy; hydration; perspiration palms.

Heart and lungs:

Inspection; palpation; percussion; chest expansion; vocal fremitus; auscultation (heart and lungs); breast exam.

Abdomen: Inspection; abdominal reflex; auscultation; palpation (liver, kidneys, spleen); percussion (shifting dullness).

Pelvis and Perineum:

(Only if indicated.) Sexual development; lesions; pain; lymphadenopathy.

Lower Limbs:

Inspection; palpation; neurological (sensation, reflexes); muscular strength / tone; range of movement; coordination.

Back:

Inspection; percussion; palpation; auscultation.

Neck:

Trachea; thyroid; lymph nodes.

Upper Limbs:

Inspection; palpation; neurological (sensation, reflexes); muscular strength / tone; range of movement; Grip test; Allen's test; Phalen's test; Tinnel's sign; coordination.

Neurological:

Gait; Pronator drift; Romberg test.

Cranial Nerves:

CN I – XII

Ear, Nose, Mouth and Throat:

Inspection; palpation.